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9 *Attorneys for Defendant Cordis Corporation*

10
11 UNITED STATES DISTRICT COURT
12 NORTHERN DISTRICT OF CALIFORNIA
13 OAKLAND DIVISION

14
15 DAVID RESOVSKY, GEORGE TODD,
DAVID BROWN, GWEN KRAMER;

16 Plaintiffs,

17 v.

18 CORDIS CORPORATION, a corporation, and
19 DOES 1 through 100, inclusive;

20 Defendants.

Case No. _____

**NOTICE OF REMOVAL OF
ACTION PURSUANT TO 28 U.S.C.
§§ 1332, 1441, 1446 and 1453 BY
DEFENDANT CORDIS
CORPORATION**

1 TO THE HONORABLE UNITED STATES DISTRICT JUDGE:

2 Please take notice that defendant Cordis Corporation (“Cordis”) hereby removes this
3 action to federal court pursuant to 28 U.S.C. §§ 1332, 1441, 1446 and 1453 with full reservation
4 of any and all defenses and objections.

5 In support of this notice, Cordis respectfully submits as follows:

- 6 1. On April 20, 2016, plaintiffs Jerry Dunson, Joseph Gieber, Cheryl Grech, Robert
7 Flanagan and Carol Flanagan filed a complaint (“Compl.”) against Cordis Corporation
8 and Does 1 through 100 in the Superior Court of the State of California for the County
9 of Alameda, Civil Action No. RG16812476 (“*Dunson*”).
- 10 2. On May 3, 2016, plaintiffs Heather Quinn, Brian Quinn, Kathryn Kirby, Allison
11 Brauer, Edward Brown, Patricia Brown, Michael Hickson, William Schenk, and
12 Christina Jones filed a complaint against Cordis Corporation; Johnson & Johnson; and
13 Does 1 through 50 in the Superior Court of the State of California for the County of
14 Alameda, Civil Action No. RG16814166 (“*Quinn*”).
- 15 3. On May 13, 2016, plaintiffs in *Quinn* filed a First Amended Complaint (“FAC”),
16 adding as plaintiffs Nancy Folz, Edward Chizek and Andrew Chapman. Plaintiffs’
17 FAC does not assert claims against Johnson & Johnson.
- 18 4. On May 5, 2016, plaintiffs Walter Herbert, Russell Anderson, Martha Graham, Frank
19 Graham, Tamarra Grayson, Timothy Howard, Ted Michael Martinez, Cynthia
20 Martinez, Judy Shaffer and John Shaffer, Jr. filed a complaint against Cordis
21 Corporation; Johnson & Johnson; and Does 1 through 50 in the Superior Court of the
22 State of California for the County of Alameda, Civil Action No. RG16814569
23 (“*Herbert*”).
- 24 5. On May 13, 2016, plaintiffs in *Herbert* filed a FAC, adding as plaintiffs Clarice Stepp
25 and Allison Fisher. Plaintiffs’ FAC does not assert claims against Johnson & Johnson.
- 26 6. On May 6, 2016, plaintiffs Geanice Grant, Violet Elaine Kern, Russell Hopkins,
27 Anthony Burbine, Courtney Comer, William Gouge, Rhonda Gail Schenk, Jennifer
28 Allison, Bobby Fuller, Robert Edward Becker, Terry Ann Fountain, Marguerite

1 Norton, James Franklin Williams, Sr., Betty Reed, Clint Hurtado, Mark Wehmeier,
 2 Jennifer Schock, and Jordan Deed filed a complaint against Cordis Corporation;
 3 Johnson & Johnson; and Does 1 through 50, in the Superior Court of the State of
 4 California for the County of Alameda, Civil Action No. RG16814688 (“*Grant*”).

5 7. On May 13, 2016, plaintiffs in *Grant* filed a FAC, adding as plaintiffs Michelle Young
 6 and Victor Blair. Plaintiffs’ FAC does not assert claims against Johnson & Johnson.

7 8. On May 6, 2016, plaintiffs David Resovsky, George Todd, David Brown and Gwen
 8 Kramer filed a complaint against Cordis Corporation and Does 1 through 100 in the
 9 Superior Court of the State of California for the County of Alameda, Civil Action No.
 10 RG16814745 (“*Resovsky*”).

11 9. On May 20, 2016, plaintiffs Michael Barber, Andrew Clos, Jacquelyn Hanson, Donald
 12 Hernandez, Sr., Rhonda Hernandez, James Lewis, Connie Patterson, Carolyn
 13 Simmons, Walter Simmons, Michael Donlin, David Hamilton, Stephen Vandall,
 14 Heather Vandall, Dorothy Mills, Lakisha Hooks, Deborah Jarvis, Caroline Carr,
 15 Geraldine Clark, Robert Spishak, Barbara Spishak, Reina Jones, Venesia Johnson,
 16 Darnell Kilgore, Joseph Hershberger, Russell Zukrigil and Brian Zukrigil filed a
 17 complaint against Cordis Corporation; Johnson & Johnson; Cardinal Health, Inc.; and
 18 Does 1 through 50 in the Superior Court of the State of California for the County of
 19 Alameda, Civil Action No. RG16816487 (“*Barber*”).

20 10. On May 20, 2016, plaintiffs Lisa Oehring, Luther Leatham, Sonji Hutchinson, Sandra
 21 Sutter, Lynda Smith, Alan Goldberg, Benito Brown, Lupe Brown, Patricia Bunker,
 22 Carmen Burgess, Travis Burkhart, Kimberly Burkhart, Philip Faciana, Louise Hill,
 23 Keith Hunter, Ellen Juvera-Saiz, Brandi Kirk, Lisa Kumbier, Jessica Larimore,
 24 Herman Malone, Dorothy May, Dustin Merritt, Cindy Seymore, Freddie Wilson,
 25 Donald Holland, James McCord, Billy Richard, Melanie Richard, John Rogers, Sean
 26 Maguire, Laura Maguire, Gilda Southerland, Vincent Southerland, and Chad
 27 Southerland filed a complaint against Cordis Corporation; Johnson & Johnson;
 28 Cardinal Health, Inc.; and Does 1 through 50 in the Superior Court of the State of

California for the County of Alameda, Civil Action No. RG16816490 (“*Oehring*”).

11. On May 20, 2016, plaintiffs Wanda Holden, Tambda Shifflet, Lanora Barrett, Marcello Coogan, Willie P. Cook, John Dawson, Fredderick Hall, Thomas Husted, Sabrina Jackson, Juan Nelle Jeanes, Steven Johnson, Kendall McCoy, Michelle Montoya, Karen Neal, Debra Porter, Tommy Porter, Carl Rexing, Hazel Webb, Cheryl Wright, Evelyn Wright, and Thomas Yaudas filed a complaint against Cordis Corporation; Confluent Medical Technologies, Inc.; and Does 1 through 100 in the Superior Court of the State of California for the County of Alameda, Civil Action No. RG16816600 (“*Holden*”).

12. Thereafter, on May 27, 2016, plaintiffs in *Quinn* filed a notice of motion and motion for consolidation of cases pursuant to California Code of Civil Procedure § 1048(a), seeking to consolidate the actions of *Dunson*, *Quinn*, *Herbert*, *Grant*, *Resovsky*, *Barber*, *Oehring*, and *Holden*, as well as “any similar actions filed with this court or that may be filed with this court in the future.” *See Quinn* Notice of Motion and Motion for Consolidation of Cases (“Motion for Consolidation” or “Mot.”) at 3-4 (attached hereto as Ex. A). The motion defines these eight and future-filed matters as the “Related Actions.” *Id.* at 4 (Ex. A). The motion seeks consolidation of these Related Actions “for all pretrial purposes, including discovery and other proceedings, and the institution of a bellwether-trial process” to address common questions plaintiffs identify regarding alleged product failure and defendants’ knowledge thereof. *Id.* at 4, 7 (Ex. A). Plaintiffs assert that this process would serve “to avoid the risk of inconsistent adjudications.” *Id.* at 1 (Ex. A).

13. The Memorandum of Points and Authorities in Support of the *Quinn* Motion for Consolidation (“Mem.”) represents that “[a]ll of the plaintiffs in the Related Actions, and their respective attorneys and counsel of record, support the consolidation sought in this motion.” Mem. at 1, 6 (Ex. A).

14. Plaintiffs initiated service of the *Quinn* Motion for Consolidation on May 27, 2016. Mot., Certificate of Service (Ex. A). Cordis received service of the Motion for

Consolidation on June 1, 2016. (Ex. A).

15. Removal is timely pursuant to 28 U.S.C. § 1446(b) because this Notice of Removal is being filed within thirty (30) days after receipt by Cordis of the *Quinn* Motion for Consolidation, “from which it may first be ascertained that the case is one which is or has become removable.” 28 U.S.C. § 1446(b)(3).

16. In accordance with 28 U.S.C. § 1446(a), copies of all process, pleadings and orders served upon Cordis in this matter are attached as Exhibits A and B.

17. The Superior Court of the State of California for the County of Alameda is located within the Oakland Division of the United States District Court for the Northern District of California.

18. As shown below, this Court has jurisdiction pursuant to the Class Action Fairness Act of 2005, 28 U.S.C. § 1332(d), in that this is a mass action in which monetary relief claims of more than 100 persons are proposed to be tried jointly on the ground that the plaintiffs’ claims involve common questions of law or facts; the parties are of at least minimally diverse citizenship; the aggregate amount in controversy exceeds \$5,000,000; and at least one plaintiff puts more than \$75,000 in controversy, exclusive of interest and costs.

19. By removing this mass action to this Court, Cordis does not admit any of the facts alleged in the complaint (or those in the Related Actions), or waive any defenses, objections, or motions available to it under state or federal law. Cordis reserves the right to challenge the adequacy and viability of the complaint (and those in the Related Actions) in all respects. *See* 5 Charles Alan Wright & Arthur R. Miller, *Federal Practice and Procedure* § 1395 (3d ed. 1998) (“A party who removes an action from a state to a federal court does not thereby waive any of his or her Federal Rule 12(b) defenses or objections.”).

**THE COURT HAS JURISDICTION UNDER
THE CLASS ACTION FAIRNESS ACT OF 2005**

20. This action involves product liability claims arising from the alleged implantation of

Inferior Vena Cava filters (“IVC filters” or “filters”)—the TrapEase[®] Permanent Vena Cava Filter and the OptEase[®] Vena Cava Filter—into various individuals. Mem. at 1 (Ex. A). An IVC filter is a medical device that is placed surgically into the inferior vena cava in the heart “to catch blood clots and stop them from traveling to the heart or lungs.” *Id.* Plaintiffs allege injuries arising from purported failure or defect of these IVC filters.

21. Removal of this action is authorized under the Class Action Fairness Act of 2005, 28 U.S.C. §§ 1332, *et seq.* (“CAFA”). 28 U.S.C. §§ 1332(d) and 1453.

22. Under CAFA, a federal court has jurisdiction over a “mass action,” defined as “any civil action . . . in which monetary relief claims of 100 or more persons are proposed to be tried jointly on the ground that the plaintiffs’ claims involve common questions of law or fact,” 28 U.S.C. § 1332(d)(11)(B)(i); where there is minimal diversity between the parties, *id.* § 1332(d)(2); where the amount in controversy exceeds an aggregate amount of \$5 million, exclusive of interest and costs, *id.*; and where at least one plaintiff satisfies the \$75,000 amount in controversy element, *see id.* § 1332(d)(11)(B)(i); *Freitas v. McKesson Corp.*, No. 12-5948 SC, 2013 WL 685200, at *2 (N.D. Cal. Feb. 25, 2013).

23. While a presumption against removal may pertain in some settings, it does not pertain to CAFA removal. The United States Supreme Court has resolved that “no antiremoval presumption attends cases invoking CAFA, which Congress enacted to facilitate adjudication of certain class actions in federal court.” *Dart Cherokee Basin Operating Co. v. Owens*, 135 S. Ct. 547, 554 (2014).

A. This Is A Mass Action For CAFA Purposes

24. CAFA’s mass action removal provision is triggered when plaintiffs have “proposed to [] tr[y] jointly” the claims of 100 or more persons “on the ground that the plaintiffs’ claims involve common questions of law or fact.” 28 U.S.C. § 1332(d)(11)(B)(i).

25. Here, plaintiffs’ so-called “Related Actions” consist of eight cases with approximately 140 plaintiffs, of which “approximately 120 are personal injury plaintiffs,

approximately 17 are loss of consortium plaintiffs, and three are wrongful death plaintiffs (for the same decedent).” Mem at 6 (Ex. A). Accordingly, the numeric element of CAFA’s mass action rule is satisfied.

26. The *Quinn* Motion for Consolidation asserts that the so-called “Related Actions” present common questions of law and fact. See Mem. at 6-8 (Ex. A). This element of CAFA removal is thus satisfied.

27. Plaintiffs also “propose” a “joint trial” as CAFA requires. For CAFA removal purposes, the jurisdictional focus is on the “substance” of what plaintiffs propose. See *Corber v. Xanodyne Pharms., Inc.*, 771 F.3d 1218, 1225 (9th Cir. 2014) (*en banc*). Thus the request for a joint trial may be either explicit or implicit. See *id.*; *Allen v. Wilson*, No. CV 14-9686-JGB (AGRX), 2015 WL 846792, at *4 (C.D. Cal. Feb. 26, 2015).

28. Seeking consolidation pursuant to Section 1048(a)—as plaintiffs do here—can itself be probative of a “proposal” for “joint trial.” As compared to a motion for coordination, “[a] motion to consolidate pursuant to Section 1048 would certainly be even stronger evidence of a plaintiff’s intent to propose a joint trial.” *Allen*, 2015 WL 846792, at *2. The substance of plaintiffs’ motion and supporting memorandum corroborates this. On its face, plaintiffs’ motion seeks more than consolidation “solely for pretrial proceedings.” See 28 U.S.C. 1332(d)(11)(B)(ii)(IV) (excluding from definition of mass action a civil action where “the claims have been consolidated or coordinated solely for pretrial proceedings”).

29. Specifically, the *Quinn* Motion for Consolidation seeks consolidation of the so-called Related Actions “for all pretrial purposes, including discovery and other proceedings, and the institution of a bellwether-trial process.” Mot. at 4 (Ex. A).

30. Further still, plaintiffs propose that this “bellwether-trial process should be crafted and instated” to address common questions they identify regarding alleged product failures and defendants’ knowledge thereof. Mem. at 9 (Ex. A).

31. Plaintiffs assert that a “bellwether-trial process” is desirable, *inter alia*, “to avoid the

1 risk of inconsistent adjudications.” *Id.* at 1 (Ex. A). Plaintiffs state this goal
 2 repeatedly. *Id.* at 2, 7-8. Courts have found consolidation proposals seeking to avoid
 3 the risk of inconsistency as tantamount to seeking a “joint trial” for CAFA removal
 4 purposes. *See, e.g., Corber*, 771 F.3d at 1223-24; *Allen*, 2015 WL 846792, at *3; *see*
 5 *also Atwell v. Boston Sci. Corp.*, 740 F.3d 1160, 1164-65 (8th Cir. 2013); *In re Abbott*
 6 *Labs., Inc.*, 698 F.3d 568, 573 (7th Cir. 2012).

7 32. While plaintiffs suggest that they “are not requesting a consolidation of Related
 8 Actions for purposes of a single trial to determine the outcome for all plaintiffs,”
 9 Mem. at 7, this rhetoric rings hollow given what in fact they propose. Plaintiffs do not
 10 limit their consolidation request to pretrial proceedings. They do not limit their
 11 request to achieving efficiency goals. And they propose not merely a bellwether trial,
 12 but an entire “process” and “protocol” for bellwether trials. In like circumstances,
 13 courts look beyond rhetoric, focus on the substance of the request, and find the joint
 14 trial element satisfied. *Corber*, 771 F.3d at 1225; *Allen*, 2015 WL 846792, at *4; *see*
 15 *also Atwell*, 740 F.3d at 1166; *In re Abbott Labs.*, 698 F.3d at 573.¹

16 33. With their consolidation motion and brief, plaintiffs have proposed to try jointly the
 17 monetary relief claims of 100 or more persons, satisfying CAFA’s mass action
 18 requirement.

19 **B. The Parties Are Minimally Diverse**

20 34. There is minimal diversity between Cordis and plaintiffs insofar as “at least one
 21 plaintiff is diverse in citizenship from any defendant.” *Ibarra v. Manheim Invs., Inc.*,
 22 775 F.3d 1193, 1195 (9th Cir. 2015).

23 35. Defendant is informed and believes that plaintiff Kathryn Kirby, a plaintiff in this
 24 mass action who is part of the *Quinn* action “at all times relevant to this action was
 25 and is a citizen and resident of the state of South Carolina.” *Quinn* FAC ¶ 10.

26 ¹ Seeking bellwether trials is not inconsistent with a proposal to try cases jointly. “[A] joint trial
 27 can take different forms so long as the plaintiffs’ claims are being determined jointly.” *In re*
 28 *Abbott Labs*, 698 F.3d at 573.

36. Defendant Cordis is now, and was at the time plaintiff filed the complaint, and at all intervening times, a corporation organized and existing under the laws of the State of Florida, with its principal place of business in Ohio.²

37. As such, for the purposes of diversity jurisdiction, Cordis is a citizen and resident of the states of Florida and Ohio.

38. Accordingly, there is a minimal diversity between Cordis and at least one plaintiff in this mass action, Kathryn Kirby. *See* 28 U.S.C. § 1332(d)(2)(A) (the diversity requirement of CAFA is satisfied when “any member of a class of plaintiffs is a citizen of a State different from any defendant”).

C. The Amount In Controversy Requirement Is Met

39. “[T]he general federal rule has long been to decide what the amount in controversy is from the complaint itself.” *Horton v. Liberty Mut. Ins. Co.*, 367 U.S. 348, 353 (1961).

40. When measuring the amount in controversy, a court assumes that the complaint’s allegations are true and that a jury would return a verdict for plaintiff on all claims made in the complaint. *Korn v. Polo Ralph Lauren Corp.*, 536 F. Supp. 2d 1199, 1205 (E.D. Cal. 2008). If the complaint seeks both actual and punitive damages, each must be considered “to the extent claimed” to determine the jurisdictional amount for diversity jurisdiction. *Campbell v. Bridgestone/Firestone, Inc.*, No.

CIVF051499FVSDLB, 2006 WL 707291, at *1 (E.D. Cal. Mar. 17, 2006) (quoting *Bell v. Preferred Life Assur. Soc. of Montgomery, Ala.*, 320 U.S. 238, 240 (1943)).

The “ultimate inquiry” is not what a defendant may actually owe, but what amount the plaintiff’s complaint puts “in controversy.” *Korn*, 536 F. Supp. 2d at 1205.

² The complaints in the *Dunson*, *Quinn*, *Herbert*, *Grant*, *Resovsky*, *Barber*, *Oehring*, and *Holden* actions, as well as the *Quinn* Motion to Consolidate, erroneously allege that Cordis’ principal place of business is in California. *See Dunson* Compl. ¶ 7; *Quinn* FAC ¶¶ 28, 29; *Herbert* FAC ¶¶ 20, 21; *Grant* FAC ¶¶ 28, 29; *Resovsky* Compl. ¶ 6; *Barber* Compl. ¶¶ 34, 35; *Oehring* Compl. ¶¶ 41, 42; *Holden* Compl. ¶ 23; Mem. at 2-3 (Ex. A). In any event, there are plaintiffs in this mass action, including Plaintiff Kirby, who are citizens of states other than California, preserving minimal diversity. Further, under CAFA, “the case may be removed even if one or more defendants are citizens of the state in which the action was brought.” *Ibarra*, 775 F.3d at 1195.

41. Under CAFA, “a defendant’s notice of removal need include only a plausible allegation that the amount in controversy exceeds the jurisdictional threshold.” *Dart Cherokee*, 135 S. Ct. at 554; *id.* at 553 (noting that, by design, § 1446(a) tracks general pleading requirements of Federal Rule of Civil Procedure 8(a)).
42. Here, it is apparent from the complaints in the Related Actions that plaintiffs seek an amount in controversy that exceeds \$5 million in the aggregate, exclusive of costs and interest, and that at least one plaintiff’s claim exceeds \$75,000.
43. More than 130 plaintiffs seek to recover an array of damages, including general, special, and punitive damages, in strict products liability, negligence and fraud. Under CAFA, this Court considers whether the value of these claims in the aggregate exceeds \$5 million. *See* 28 U.S.C. § 1332(d)(6), (d)(11) (“In any [m]ass action, the claims of the individual [] members shall be aggregated to determine whether the matter in controversy exceeds the sum or value of \$5,000,000, exclusive of interests and costs.”). Further, removal under CAFA is proper for “mass action” suits if at least one plaintiff’s claim exceeds \$75,000. *See* 28 U.S.C. § 1332(d)(11)(B)(i); *Freitas*, 2013 WL 685200, at *2.
44. This mass action asserts the claims of more than 115 IVC filter recipients who seek to recover for extreme “pain and suffering” and other injuries, 15 claims for loss of consortium, and 1 claim for wrongful death.
45. More than one hundred and fifteen plaintiffs allege that following implantation of their TrapEase® or OptEase® IVC filters, they may suffer or have suffered harm, such as “life-threatening injuries and damages[,] and require[d] extensive medical care and treatment,” or that they were subject to “significant medical expenses, extreme pain and suffering, loss of enjoyment of life, [and] disability,” among other injuries. *See, e.g., Quinn Am. Compl.* ¶¶ 10-11; *Dunson Compl.* ¶¶ 1-2; *Grant Am. Compl.* ¶¶ 10-11; *Oehring Compl.* ¶¶ 16-17; *Holden Compl.* ¶¶ 1-2; *Herbert Am. Compl.* ¶¶ 8-9; *Barber Compl.* ¶¶ 9-10; *Resovsky Compl.* ¶¶ 1-2. They contend that their injuries have caused or will cause them to “continue to suffer significant medical expenses,”

1 “pain and suffering,” and other damages. *See e.g., id.* The representatives of a
2 deceased individual implanted with an IVC filter similarly allege that the deceased
3 suffered “fatal injuries, damages, and untimely death.” *Oehring* Compl. ¶ 40. As a
4 result, plaintiffs each seek to recover substantial damages, including general, special,
5 and punitive damages.

6 46. Courts in comparable settings have found that claims and assertions like those
7 plaintiffs allege here, including those of extreme or severe pain and past and future
8 medical expenses, set forth an amount in controversy exceeding \$75,000 for each
9 plaintiff, exclusive of interest and costs. *See, e.g., Campbell*, 2006 WL 707291, at *2
10 (apparent from the complaint that amount in controversy exceeded \$75,000 where
11 plaintiffs (1) asserted strict products liability, negligence, and breach of warranty
12 claims against multiple defendants for “severe” injuries and (2) sought compensatory
13 damages for wage loss, hospital and medical expenses, general damages, and loss of
14 earning capacity) (emphasis added)); *Bryant v. Apotex, Inc.*, No. 1:12-CV-01377-LJO-
15 JLT, 2012 WL 5933042, at *4 (E.D. Cal. Nov. 27, 2012) (finding amount in
16 controversy was satisfied where plaintiff sought compensatory damages for injuries
17 and “severe pain” lasting six months, *severe* emotional distress, and punitive damages
18 arising out of administration of certain drugs in “crushed form”) (emphasis added));
19 *McCoy by Webb v. Gen. Motors Corp.*, 226 F. Supp. 2d 939, 941 (N.D. Ill. 2002)
20 (“courts have routinely held that when plaintiffs allege serious, permanent injuries and
21 significant medical expenses, it is obvious from the face of the complaint that the
22 plaintiffs’ damages exceeded the jurisdictional amount”); *Purdiman v. Organon*
23 *Pharms. USA, Inc.*, No. 2:08-CV-0006-RWS, 2008 WL 686996, at *2 (N.D. Ga. Mar.
24 12, 2008) (concluding that the “amount of damages at issue in this action, including
25 past medical bills, the cost of future medical treatment, pain and suffering, and lost
26 wages, more likely than not exceed[ed] \$75,000” where plaintiff alleged that she
27 sustained “permanent and debilitating” injuries as a result of using defendants’ birth
28 control medical device, including “intense pain” and future medical testing, treatment,

and monitoring for pulmonary embolisms).

47. Each of the IVC filter recipients here asserts an amount in controversy that exceeds \$75,000, satisfying the requirement that at least one plaintiff's claim exceeds \$75,000. As such, plaintiffs cumulatively seek well more than the requisite \$5 million.

48. Beyond the damages alleged by supposed device recipients, an additional 15 plaintiffs in this mass action seek to recover loss of consortium damages—thereby enhancing the damages pleaded and underscoring that the claims here exceed the \$5 million aggregate threshold. *See, e.g., General Motors Corp. v. Doupnik*, 1 F.3d 862, 864-65 (9th Cir. 1993) (assessing applicability of comparative fault to \$1.6 million jury award for loss of consortium for a single plaintiff).

49. Plaintiffs' prayers for punitive damages make all the more undeniable plaintiffs' pleading of more than \$5 million in controversy. *See Bell*, 320 U.S. at 240 (both actual and punitive damages are included in calculating the amount in controversy).

50. Although Cordis denies any liability to plaintiffs, their allegations of economic and non-economic loss, extreme pain and suffering, loss of consortium, and wrongful death plainly place more than \$5 million in controversy, exclusive of interest and costs.

D. All Other Prerequisites To Removal Are Met

51. Pursuant to 28 U.S.C. § 1446(d), a copy of this notice is being served on plaintiffs, and filed with the clerk of court for this Court and with the clerk of the court for the Superior Court of the State of California for the County of Alameda.

52. Cordis reserves the right to amend or supplement this Notice of Removal.

E. This Mass Action Is Properly Removed To This Court

53. Because this is a mass action in which plaintiffs propose to try monetary relief claims of 100 or more persons jointly, there is minimal diversity of citizenship, the aggregate amount in controversy exceeds \$5 million and at least one plaintiff's claim exceeds \$75,000, this Court has original subject matter jurisdiction over this putative class action.

1 54. Because subject matter jurisdiction exists under 28 U.S.C. § 1332(d), this action is
2 removable pursuant to 28 U.S.C. § 1453.

3 WHEREFORE, Cordis hereby respectfully gives notice that the above action, formerly
4 pending in the Superior Court of the State of California for the County of Alameda, is removed to
5 the United States District Court for the Northern District of California.

6
7 June 6, 2016

CROWELL & MORING LLP

8
9 By: /s/ Kevin C. Mayer

10 Attorneys for Defendant Cordis Corporation
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PROOF OF SERVICE

I, Jennifer S. Tai, state:

My business address is 515 South Flower St., 40th Floor, Los Angeles, CA 90071. I am over the age of eighteen years and not a party to this action.

On the date set forth below, I served the foregoing document(s) described as:

Notice of Removal of Action Pursuant to 28 U.S.C. §§ 1332, 1441, 1446 and 1453 By Defendant Cordis Corporation

on the following person(s) in this action:

**Troy A. Brenes
BRENES LAW GROUP
16 A Journey, Suite 200
Aliso Viejo, CA 92656
Telephone: 949.397.9360
Facsimile: 949.607.4192**

Attorneys for Plaintiffs

- ☒ **BY FIRST CLASS MAIL:** I am employed in the City and County of Los Angeles where the mailing occurred. I enclosed the document(s) identified above in a sealed envelope or package addressed to the person(s) listed above, with postage fully paid. I placed the envelope or package for collection and mailing, following our ordinary business practice. I am readily familiar with this firm's practice for collecting and processing correspondence for mailing. On the same day that correspondence is placed for collection and mailing, it is deposited in the ordinary course of business with the United States Postal Service.
- ☐ **BY MESSENGER SERVICE:** I served the document(s) identified above by placing them in an envelope or package addressed to the person(s) listed above and providing them to a professional messenger service for service. A declaration of personal service by the messenger is attached.
- ☐ **BY OVERNIGHT DELIVERY:** I enclosed the document(s) identified above in a sealed envelope or package addressed to the person(s) listed above, in an envelope or package designated by the overnight delivery carrier with delivery fees paid or provided for. I placed the envelope or package for collection and overnight delivery at an office or a regularly utilized drop box of the overnight delivery carrier, or by delivering to a courier or driver authorized by the overnight delivery carrier to receive documents.
- ☐ **BY FACSIMILE:** Based on an agreement of the parties to accept service by facsimile transmission, I faxed the document(s) identified above to the person(s) at the fax number(s) listed above. The transmission was reported complete and without error. I have attached a copy of the transmission report that was issued by the facsimile machine.
- ☐ **BY ELECTRONIC MAIL:** Based on a court order or an agreement of the parties to accept service by electronic mail, I caused the document(s) identified above to be transmitted electronically to the person(s) at the e-mail address(es) listed above. I did not receive, within a reasonable time after the transmission, any electronic message or other indication that the transmission was unsuccessful.

1 I declare under penalty of perjury under the laws of the United States and the State of
2 California that the foregoing is true and correct.

3 Executed on June 6, 2016, at Los Angeles, California.


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5 _____
6 Jennifer S. Tai
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EXHIBIT A Part 1


**Service of Process
Transmittal**

06/01/2016

CT Log Number 529257439

TO: Magdalene Riley
Cardinal Health, Inc.
7000 Cardinal Pl
Dublin, OH 43017-1091

RE: Process Served in Ohio

FOR: Cardinal Health, Inc. (Domestic State: OH)

ENCLOSED ARE COPIES OF LEGAL PROCESS RECEIVED BY THE STATUTORY AGENT OF THE ABOVE COMPANY AS FOLLOWS:

TITLE OF ACTION: JERRY DUNSON, et al., Pltfs. vs. CORDIS CORPORATION, etc., et al., Dfts. // To: Cardinal Health, Inc.

DOCUMENT(S) SERVED: Notice(s), Proof(s) of Service, Service List(s), Memorandum, Declaration, Complaint(s), First Amended Complaint(s), Attachment(s), Order

COURT/AGENCY: Alameda County Superior Court, CA
Case # RG16812476

NATURE OF ACTION: Product Liability Litigation - Breach of Warranty - TrapEase and OptEase filters

ON WHOM PROCESS WAS SERVED: C T Corporation System, Cleveland, OH

DATE AND HOUR OF SERVICE: By Priority Mail on 06/01/2016 postmarked: "Not Post Marked"

JURISDICTION SERVED : Ohio

APPEARANCE OR ANSWER DUE: June 28, 2016 at 3:00 p.m.

ATTORNEY(S) / SENDER(S): Ramon Rossi Lopez
LOPEZ McHUGH LLP
100 Bayview Circle, Suite 5600
Newport Beach, CA 92660
(949) 737-1501

REMARKS: See documents for additional cases numbers listed

ACTION ITEMS: CT has retained the current log, Retain Date: 06/02/2016, Expected Purge Date: 06/07/2016

Image SOP

Email Notification, Laura Garza laura.garza@cardinalhealth.com

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**Service of Process
Transmittal**

06/01/2016

CT Log Number 529257439

TO: Magdalene Riley
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7000 Cardinal Pl
Dublin, OH 43017-1091

RE: Process Served in Ohio

FOR: Cardinal Health, Inc. (Domestic State: OH)

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Email Notification, Joshua Stine joshua.stine@cardinalhealth.com

SIGNED:
ADDRESS:

C T Corporation System
1300 East 9th Street
Suite 1010
Cleveland, OH 44114
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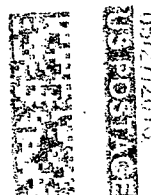
CARDINAL HEALTH, INC.
C/O CT CORPORATION
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CLEVELAND OH 44114-1501

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Attorneys for Plaintiffs

**SUPERIOR COURT OF THE STATE OF CALIFORNIA
 FOR THE COUNTY OF ALAMEDA**

JERRY DUNSON, *et al.*;

Plaintiffs,

vs.

CORDIS CORPORATION, a corporation, and
 DOES 1 through 100, inclusive,

Defendants.

Case No.: RG16812476

**NOTICE OF MOTION AND MOTION FOR
 CONSOLIDATION OF CASES**

Date: June 28, 2016
 Time: 3:00 p.m.
 Dept.: 30
 Reservation No.: R-1743489

Judge: Hon. Brad Seligman

Trial Date: None
 Action Filed: April 20, 2016

*(Filed concurrently with Memorandum of Points
 and Authorities In Support of Motion; Declaration
 of Matthew R. Lopez; and [Proposed] Order)*

HEATHER QUINN, *et al.*;

Plaintiffs,

vs.

CORDIS CORPORATION; JOHNSON &
 JOHNSON; and DOES 1 through 50;

Case No. RG16814166

Judge: Hon. Brad Seligman

Trial Date: None
 Action Filed: May 3, 2016

Defendants.

WALTER HERBERT, *et al.*;

Plaintiffs,

vs.

CORDIS CORPORATION; JOHNSON &
JOHNSON; and DOES 1 through 50;

Defendants.

Case No.: RG16814569

Judge: Hon. Brad Seligman

Trial Date: None

Action Filed: May 5, 2016

GEANICE GRANT, *et al.*;

Plaintiffs,

vs.

CORDIS CORPORATION; JOHNSON &
JOHNSON; and DOES 1 through 50;

Defendants.

Case No.: RG16814688

Judge: Hon. Brad Seligman

Trial Date: None

Action Filed: May 6, 2016

DAVID RESOVSKY, *et al.*;

Plaintiffs,

vs.

CORDIS CORPORATION, a corporation, and
DOES 1 through 100, inclusive,

Defendants.

Case No.: RG16814745

Judge: Hon. Brad Seligman

Trial Date: None

Action Filed: May 6, 2016

MICHAEL BARBER, *et al.*;

Plaintiffs,

vs.

CORDIS CORPORATION, a corporation;
JOHNSON & JOHNSON, a corporation;
CARDINAL HEALTH, INC., a corporation;
and DOES 1 through 50;

Case No.: RG16816487

Judge: Hon. Brad Seligman

Trial Date: None

Action Filed: May 20, 2016

Defendants.

LISA OEHRING, *et al.*;

Plaintiffs,

vs.

CORDIS CORPORATION, a corporation;
JOHNSON & JOHNSON, a corporation;
CARDINAL HEALTH, INC., a corporation;
and DOES 1 through 50;

Defendants.

Case No.: RG16816490

Judge: Hon. Brad Seligman

Trial Date: None

Action Filed: May 20, 2016

WANDA HOLDEN, *et al.*;

Plaintiffs,

vs.

CORDIS CORPORATION, a corporation,
CONFLUENT MEDICAL TECHNOLOGIES,
INC., a corporation; and DOES 1 through 100,
inclusive,

Defendants.

Case No.: RG16816600

Judge: Hon. Brad Seligman

Trial Date: None

Action Filed: May 20, 2016

TO ALL INTERESTED PARTIES IN EACH CASE CAPTIONED ABOVE AND THEIR
ATTORNEYS OF RECORD:

PLEASE TAKE NOTICE that on June 28, 2016 at 3:00 p.m., or as soon after that as the matter
can be heard, in Dept. 30 of the above-entitled Court located at 1225 Fallon St., Oakland, California,
94612, Plaintiffs in *Heather Quinn, et al. vs. Cordis Corporation, et al.*, Case No. RG16814166 will
move the Court to order pursuant to *Code of Civil Procedure* § 1048(a) to consolidate Case No.
RG16812476, *Jerry Dunson, et al. vs. Cordis Corporation, et al.*; Case No. RG16814166, *Heather
Quinn, et al. vs. Cordis Corporation, et al.*; Case No. RG16814569, *Walter Herbert, et al. vs. Cordis
Corporation, et al.*; Case No. RG16814688, *Geanice Grant, et al. vs. Cordis Corporation, et al.*; Case
No. RG16814745, *David Resovsky, et al. vs. Cordis Corporation, et al.*; Case No. RG16816487,

1 *Michael Barber, et al. vs. Cordis Corporation, et al.*; Case No. RG16816490, *Lisa Oehring, et al. vs.*
 2 *Cordis Corporation, et al.*; Case No. RG16816600, *Wanda Holden, et al. vs. Cordis Corporation, et al.*
 3 and any similar actions filed with this court or that may be filed with this court in the future (hereinafter,
 4 collectively referred as “Related Actions”), for all pretrial purposes, including discovery and other
 5 proceedings, and the institution of a bellwether-trial process. All of the plaintiffs in the Related Actions,
 6 and their respective attorneys and counsel of record, as set forth below, are in support of this motion.

7 The parties named in *Jerry Dunson, et al. vs. Cordis Corporation, et al.*, Case No. RG16812476
 8 are Plaintiffs Jerry Dunson, Joseph Gieber, Cheryl Grech, Robert Flanagan, and Carol Flanagan.¹
 9 Defendants are Cordis Corporation and Doe Defendants 1 through 100. Plaintiffs are represented by
 10 Troy A. Brenes of Brenes Law Group. None of the defendants have, yet, appeared in the action. Based
 11 on information and belief, however, Defendant Cordis Corporation is represented by Kevin Mayer,
 12 Andrew D. Kaplan and Rebecca B. Chaney of Crowell & Moring LLP.

13 The parties named in *Heather Quinn, et al. vs. Cordis Corporation, et al.*, Case No.
 14 RG16814166 are Plaintiffs Heather Quinn, Brian Quinn, Kathryn Kirby, Allison Brauer, Edward
 15 Brown, Patricia Brown, Michael Hickson, William Schenk, and Christina Jones.² Defendants are Cordis
 16 Corporation, Johnson & Johnson, and Doe Defendants 1 through 50. Plaintiffs are represented by
 17 Ramon Rossi Lopez, Matthew R. Lopez and Amorina P. Lopez of Lopez McHugh LLP.³ None of the
 18 defendants have, yet, appeared in the action. Based on information and belief, however, Defendant
 19 Cordis Corporation is represented by Kevin Mayer, Andrew D. Kaplan and Rebecca B. Chaney of
 20 Crowell & Moring LLP.

21 The parties named in *Walter Herbert, et al. vs. Cordis Corporation, et al.*, Case No.
 22 RG16814569 are Plaintiffs Walter Herbert, Russell Anderson, Martha Graham, Frank Graham, Tamarra
 23

24 ¹ Plaintiffs filed a First Amended Complaint (“FAC”) on May 24, 2016. Among other things, the FAC
 25 includes three additional plaintiffs—Mary Eldeb, Dayna Currie, and Harlowe Currie—and added
 Defendant Confluent Medical Technologies, Inc.

26 ² Plaintiffs filed a First Amended Complaint (“FAC”) on May 13, 2016. Among other things, the FAC
 27 includes three additional plaintiffs—Nancy Folz, Edward Chizek, and Andrew Chapman—and removed
 Defendant Johnson & Johnson.

28 ³ Thomas P. Cartmell and David C. DeGreeff of Wagstaff & Cartmell, LLP are out-of-state attorneys for
 whom Plaintiffs will be filing applications with the Court to be admitted *pro hac vice*.

Grayson, Timothy Howard, Ted Michael Martinez, Cynthia Martinez, Judy Shaffer, and John Shaffer.⁴ Defendants are Cordis Corporation, Johnson & Johnson, and Doe Defendants 1 through 50. Plaintiffs are represented by Ramon Rossi Lopez, Matthew R. Lopez and Amorina P. Lopez of Lopez McHugh LLP and Gregory D. Rueb of Rueb & Motta, PLC.⁵ None of the defendants have, yet, appeared in the action. Based on information and belief, however, Defendant Cordis Corporation is represented by Kevin Mayer, Andrew D. Kaplan and Rebecca B. Chaney of Crowell & Moring LLP.

The parties named in *Geanice Grant, et al. vs. Cordis Corporation, et al.*, Case No. RG16814688 are Plaintiffs Geanice Grant, Violet Elaine Kern, Russell Hopkins, Anthony Burbine, Courtney Comer, William Gouge, Rhonda Gail Schenk, Jennifer Allison, Bobby Fuller, Robert Edward Becker, Terry Ann Fountain, Marguerite Norton, James Franklin Williams, Sr., Betty Reed, Clint Hurtado, Mark Wehmeier, Jennifer Schock, and Jordan Deed.⁶ Defendants are Cordis Corporation, Johnson & Johnson, and Doe Defendants 1 through 50. Plaintiffs are represented by Ramon Rossi Lopez, Matthew R. Lopez and Amorina P. Lopez of Lopez McHugh LLP and Laura J. Baughman of Baron & Budd, P.C. None of the defendants have, yet, appeared in the action. Based on information and belief, however, Defendant Cordis Corporation is represented by Kevin Mayer, Andrew D. Kaplan and Rebecca B. Chaney of Crowell & Moring LLP.

The parties named in *David Resovsky, et al. vs. Cordis Corporation, et al.*, Case No. RG16814745 are Plaintiffs David Resovsky, George Todd, David Brown, and Gwen Kramer.⁷ Defendants are Cordis Corporation and Doe Defendants 1 through 100. Plaintiffs are represented by Troy A. Brenes of Brenes Law Group. None of the defendants have, yet, appeared in the action. Based

⁴ Plaintiffs filed a First Amended Complaint ("FAC") on May 13, 2016. Among other things, the FAC includes two additional plaintiffs—Clarice Stepp and Allison Fisher—and removed Defendant Johnson & Johnson.

⁵ Howard Nations of The Nations Law Firm is an out-of-state attorney for whom Plaintiffs will be filing an application with the Court to be admitted *pro hac vice*.

⁶ Plaintiffs filed a First Amended Complaint ("FAC") on May 13, 2016. Among other things, the FAC includes two additional plaintiffs—Michelle Young and Victor Blair—and removed Defendant Johnson & Johnson.

⁷ Plaintiffs filed a First Amended Complaint ("FAC") on May 24, 2016. Among other things, the FAC includes three additional plaintiffs—Richard Longston, Ronald Mareski, and Linda Mareski—and added Defendant Confluent Medical Technologies, Inc.

on information and belief, however, Defendant Cordis Corporation is represented by Kevin Mayer, Andrew D. Kaplan and Rebecca B. Chaney of Crowell & Moring LLP.

The parties named in *Michael Barber, et al. vs. Cordis Corporation, et al.*, Case No. RG16816487 are Plaintiffs Michael Barber, Andrew Clos, Jacquelyn Hanson, Donald Hernandez, Sr., Rhonda Hernandez, James Lewis, Connie Patterson, Carolyn Simmons, Walter Simmons, Michael Donlin, David Hamilton, Stephen Vandall, Heather Vandall, Dorothy Mills, Lakisha Hooks, Deborah Jarvis, Caroline Carr, Geraldine Clark, Robert Spishak, Barbara Spishak, Reina Jones, Vanesia Johnson, Darnell Kilgore, Joseph Hershberger, Russell Zukrigil, and Brian Zukrigil. Defendants are Cordis Corporation, Johnson & Johnson, Cardinal Health, Inc., and Doe Defendants 1 through 50. Plaintiffs are represented by Ramon Rossi Lopez, Matthew R. Lopez and Amorina P. Lopez of Lopez McHugh LLP.⁸ None of the defendants have, yet, appeared in the action. Based on information and belief, however, Defendant Cordis Corporation is represented by Kevin Mayer, Andrew D. Kaplan and Rebecca B. Chaney of Crowell & Moring LLP.

The parties named in *Lisa Oehring, et al. vs. Cordis Corporation, et al.*, Case No. RG16816490 are Plaintiffs Lisa Oehring, Luther Leathem, Sonji Hutchinson, Sandra Sutter, Lynda Smith, Alan Goldberg, Benito Brown, Lupe Brown, Patricia Bunker, Carmen Burgess, Travis Burkhardt, Kimberly Burkhardt, Philip Faciana, Louise Hill, Keith Hunter, Ellen Juvera-Saiz, Brandi Kirk, Lisa Kumbier, Jessica Larimore, Herman Malone, Dorothy May, Dustin Merritt, Cindy Seymore, Freddie Wilson, Donald Holland, James McCord, Billy Richard, Melanie Richard, John Rogers, Sean Maguire, Laura Maguire, Gilda Southerland, Vincent Southerland, and Chad Southerland. Defendants are Cordis Corporation, Johnson & Johnson, Cardinal Health, Inc., and Doe Defendants 1 through 50. Plaintiffs are represented by Ramon Rossi Lopez, Matthew R. Lopez and Amorina P. Lopez of Lopez McHugh LLP.⁹ None of the defendants have, yet, appeared in the action. Based on information and belief, however,

⁸ Turner W. Branch, Margaret M. Branch and Adam T. Funk of Branch Law Firm are out-of-state attorneys for whom Plaintiffs will be filing applications with the Court to be admitted *pro hac vice*.

⁹ David P. Matthews of Matthews & Associates and Richard A. Freese and Tim K. Goss of Freese & Goss, PLLC are out-of-state attorneys for whom Plaintiffs will be filing applications with the Court to be admitted *pro hac vice*.

1 Defendant Cordis Corporation is represented by Kevin Mayer, Andrew D. Kaplan and Rebecca B.
2 Chaney of Crowell & Moring LLP.

3 The parties named in *Wanda Holden, et al. vs. Cordis Corporation, et al.*, Case No.
4 RG16816600 are Plaintiffs Wanda Holden, Tandra Shifflet, Lanora Barrett, Marcello Coogan, Willie P.
5 Cook, John Dawson, Frederick Hall, Thomas Husted, Sabrina Jackson, Juan Nelle Jeanes, Steven
6 Johnson, Kendall McCoy, Michelle Montoya, Karen Neal, Debra Porter, Tommy Porter, Carl Rexing,
7 Hazel Webb, Cheryl Wright, Evelyn Wright, and Plaintiff Thomas Yaudas, Sr. Defendants are Cordis
8 Corporation, Confluent Medical Technologies, Inc., and Doe Defendants 1 through 100. Plaintiffs are
9 represented by Troy A. Brenes of Brenes Law Group. None of the defendants have, yet, appeared in the
10 action. Based on information and belief, however, Defendant Cordis Corporation is represented by
11 Kevin Mayer, Andrew D. Kaplan and Rebecca B. Chaney of Crowell & Moring LLP.

12 The motion should be granted on the grounds that all of the Related Actions arise out of the same
13 set of operative facts; specifically, all Plaintiffs (or Decedent) were implanted with Defendants' Inferior
14 Vena Cava ("IVC") filter medical devices— the TrapEase™ Permanent Vena Cava Filter or the
15 OptEase™ Vena Cava Filter—and suffered injury and/or death due to a malfunction of the Defendants'
16 IVC filter. Both devices are nearly identical in manufacture, design, warnings provided, and marketing
17 claims made. Moreover, the Related Actions each contain common issues such that the oral and written
18 discovery sought from Defendants in each Related Action will be the same; the majority of the expert
19 discovery in each Related Action will also be the same. Consolidation of all of the Related Actions for
20 purposes of pretrial discovery proceedings and creation of a bellwether-trial process will avoid
21 unnecessary duplication of evidence and procedures, avoid the risk of inconsistent adjudications, and
22 avoid many of the same witnesses testifying on common issues in all actions, as well as promote judicial
23 economy and convenience.

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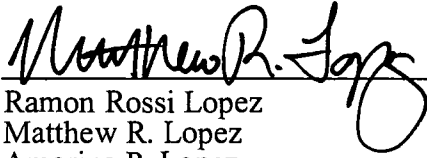
28 ///

1 The motion will be based on this notice, the attached memorandum of points and authorities, the
2 attached Declaration of Matthew R. Lopez and Exhibits attached thereto, the records and files of this
3 action, and the oral and documentary evidence which may be introduced at the hearing.
4

5 Dated: May 27, 2016

Respectfully submitted,

LOPEZ McHUGH LLP

6
7
8 By: 
9 Ramon Rossi Lopez
Matthew R. Lopez
10 Amorina P. Lopez

11 Attorneys for Plaintiffs
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PROOF OF SERVICE
STATE OF CALIFORNIA, COUNTY OF ORANGE

I am a resident of the county aforesaid: I am over the age of eighteen years and not a party to the within entitled action: my business address is 100 Bayview Circle, Suite 5600, Newport Beach, California 92660.

On May 27, 2016 I served the within **NOTICE OF MOTION AND MOTION FOR CONSOLIDATION OF CASES** on interested parties in said action, by placing a true copy thereof enclosed in a sealed envelope with postage thereon fully prepaid, in the United States mail in Newport Beach, California addressed as follows: SEE ATTACHED SERVICE LIST

 X **BY REGULAR MAIL:** I am readily familiar with the firm's practice of collection and processing correspondence for mailing. Under that practice it would be deposited with US Postal Service on that same day with postage thereon fully prepaid at Newport Beach, California in the ordinary course of business. I am aware that on motion of the party served, service is presumed invalid if postal cancellation date or postage meter date is more than one day after date of deposit for mailing in affidavit.

 BY FEDERAL EXPRESS/UPS OVERNIGHT DELIVERY SERVICE: Said documents were delivered to an authorized courier or driver authorized by the express service carrier to receive documents with delivery fees paid or provided for.

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 BY PERSONAL SERVICE: Said documents were personally delivered by:

- ☐ leaving copies at the attorney's office, in an envelope or package clearly labeled to identify the attorney being served;
- ☐ with a receptionist or, with a person having charge thereof;
- ☐ in a conspicuous place in the office between the hours of 9 a.m. and 5 p.m.
- ☐ by leaving copies at the individual's residence with some person of not less than 18 years of age;
- ☐ in a conspicuous place in between the hours of 8 in the morning and 6 p.m.

I declare, under penalty of perjury under the laws of the State of California that the foregoing is true and correct. Executed on **May 27, 2016** at Newport Beach, California.


Brooke Meyers

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1 1300 East Ninth Street
2 Cleveland, OH 44111

3 Confluent Medical Technologies
4 CT Corporation
5 818 West Seventh Street, Suite 930
6 Los Angeles, CA 90017

6 ***DEFENDANTS***

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Attorneys for Plaintiffs

**SUPERIOR COURT OF THE STATE OF CALIFORNIA
 FOR THE COUNTY OF ALAMEDA**

JERRY DUNSON, *et al.*;

Plaintiffs,

vs.

CORDIS CORPORATION, a corporation, and
 DOES 1 through 100, inclusive,

Defendants.

Case No.: RG16812476

**MEMORANDUM OF POINTS AND
 AUTHORITIES IN SUPPORT OF MOTION
 FOR CONSOLIDATION OF CASES**

Date: June 28, 2016

Time: 3:00 p.m.

Dept.: 30

Reservation No.: R-1743489

Judge: Hon. Brad Seligman

Trial Date: None

Action Filed: April 20, 2016

*(Filed concurrently with Notice of Motion;
 Declaration of Matthew R. Lopez; and [Proposed]
 Order)*

HEATHER QUINN, *et al.*;

Plaintiffs,

vs.

CORDIS CORPORATION; JOHNSON &
 JOHNSON; and DOES 1 through 50;

Case No.: RG16814166

Judge: Hon. Brad Seligman

Trial Date: None

Action Filed: May 3, 2016

Defendants.

WALTER HERBERT, *et al.*;

Case No.: RG16814569

Plaintiffs,

Judge: Hon. Brad Seligman

vs.

Trial Date: None

CORDIS CORPORATION; JOHNSON &
JOHNSON; and DOES 1 through 50;

Action Filed: May 5, 2016

Defendants.

GEANICE GRANT, *et al.*;

Case No.: RG16814688

Plaintiffs,

Judge: Hon. Brad Seligman

vs.

Trial Date: None

CORDIS CORPORATION; JOHNSON &
JOHNSON; and DOES 1 through 50;

Action Filed: May 6, 2016

Defendants.

DAVID RESOVSKY, *et al.*;

Case No.: RG16814745

Plaintiffs,

Judge: Hon. Brad Seligman

vs.

Trial Date: None

CORDIS CORPORATION, a corporation, and
DOES 1 through 100, inclusive,

Action Filed: May 6, 2016

Defendants.

MICHAEL BARBER, *et al.*;

Case No.: RG16816487

Plaintiffs,

Judge: Hon. Brad Seligman

vs.

Trial Date: None

CORDIS CORPORATION, a corporation;
JOHNSON & JOHNSON, a corporation;
CARDINAL HEALTH, INC., a corporation;
and DOES 1 through 50;

Action Filed: May 20, 2016

Defendants.

LISA OEHRING, *et al.*;

Plaintiffs,

vs.

CORDIS CORPORATION, a corporation;
JOHNSON & JOHNSON, a corporation;
CARDINAL HEALTH, INC., a corporation;
and DOES 1 through 50;

Defendants.

Case No.: RG16816490

Judge: Hon. Brad Seligman

Trial Date: None

Action Filed: May 20, 2016

WANDA HOLDEN, *et al.*;

Plaintiffs,

vs.

CORDIS CORPORATION, a corporation,
CONFLUENT MEDICAL TECHNOLOGIES,
INC., a corporation, and DOES 1 through 100,
inclusive,

Defendants.

Case No.: RG16816600

Judge: Hon. Brad Seligman

Trial Date: None

Action Filed: May 20, 2016

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A. The Court Has the Statutory Authority to Order that All of the Related Actions be Consolidated Pursuant to *Code of Civil Procedure* § 1048(a) on the Grounds that They All Involve the Same Common Operative Facts and Contain Common Issues. 6

B. The Moving Plaintiffs Have Met Their Burden of Showing That Consolidation of the Related Actions is Proper in That They Have Shown That the Issues in Each Case Are the Same and that Economy and Convenience Would Be Served. 8

C. No Party to The Related Actions Will Be Prejudiced By Consolidation. 9

D. The Court Should Exercise Its Broad Discretion and Grant This Motion for Consolidation..... 10

VI. CONCLUSION 10

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I.

INTRODUCTION

The Related Actions are product liability cases being asserted against Cordis Corporation, as the primary Defendant¹, alleging defective Inferior Vena Cava filters (hereinafter “IVC filters” or “filters”). All of the Related Actions involve two IVC filters—the TrapEase™ Permanent Vena Cava Filter and the OptEase™ Vena Cava Filter—that are nearly identical in manufacture, design, warnings provided, and marketing claims made. IVC filters are medical devices placed in the inferior vena cava, ostensibly to catch blood clots and stop them from traveling to the heart or lungs. Recent studies, however, have shown that the filters have no efficacy. In fact, the filters have been shown to double the risk of pulmonary embolism, the very condition which they are intended to prevent. The filed cases generally allege defective design, misrepresentation in marketing, and failure to warn doctors and patients adequately about the risks of the devices and for refusing to warn that the filters were not effective—in other words, that they did not work—and that they increased the risk that the patients receiving their filters would be more likely to develop a pulmonary embolus than if there were no filter implanted at all.

There are approximately 140 plaintiffs with filed cases in this Court. All of the plaintiffs in the Related Actions, and their respective attorneys and counsel of record, support the consolidation sought in this motion.

Consolidation of these Related Actions for purposes of pretrial discovery and proceedings, along with the formation of a bellwether-trial process, will avoid unnecessary duplication of evidence and procedures in all of the actions, avoid the risk of inconsistent adjudications, and avoid many of the same witnesses testifying on common issues in all actions, as well as promote judicial economy and convenience.

The declaration of Matthew R. Lopez and Exhibits attached thereto clearly show that consolidation of all of the above-listed actions will avoid repetitive law and motion of the same common

¹ Some actions have named Johnson & Johnson, the parent company of Cordis Corporation, Cardinal Health, Inc., the corporation that recently acquired Cordis Corporation from Johnson & Johnson in October 2015, and Confluent Medical Technologies, Inc., the maker and supplier of Nitinol for Cordis IVC filters and affiliate of Cordis Corporation involved in the design of Defendants’ IVC filters.

1 issues, avoid unnecessary costs and delays to the Court and to all of the parties, and eliminate the risk of
2 inconsistent adjudications.

3 Moving Plaintiffs in *Heather Quinn, et al. vs. Cordis Corporation, et al.*, Case No. RG16814166
4 have attempted in good faith to comply with *California Rule of Court* 3.350 in that all named parties in
5 each case have been listed; the names of those who have appeared, and the names of their respective
6 attorneys of record have been listed; the captions of all the cases represented by counsel of record for
7 Moving Plaintiffs sought to be consolidated have been listed, with the lowest numbered case listed first;
8 and Moving Plaintiffs have filed all moving papers into the lowest numbered case, *Jerry Dunson, et al.*
9 *vs. Cordis Corporation, et al.*, Case No. RG16812476, and served an entire copy of this motion and
10 notice of motion, including the memorandum of points and authorities, and supporting declarations and
11 Exhibits, on all attorneys of record and all non-represented parties in all of the cases sought to be
12 consolidated, and a proof of service has been filed as a part of the motion; and a notice of the motion to
13 consolidate has been filed in each Related Action sought to be consolidated.

14 II.

15 JURISDICTION AND VENUE IS PROPER FOR CONSOLIDATION

16 Defendant Cordis Corporation (“Cordis”) is a multi-national corporation which is incorporated
17 under the laws of Florida with its principal place of business located at 6500 Paseo Padre Pkwy.,
18 Fremont, California, 94555, which is within Alameda County. Defendant Cordis Corporation was a
19 wholly-owned subsidiary of Defendant Johnson & Johnson’s (“J&J”) and part of the J&J family of
20 companies until October 2015. On October 4, 2015, Defendant Cardinal Health (“Cardinal”) publicly
21 announced that it acquired J&J’s Cordis business. Cardinal is a corporation or business entity organized
22 and existing under the laws of Ohio with its headquarters in Dublin, Ohio.

23 Defendants are “at home” in the State of California. Cordis maintains campuses and facilities in
24 Fremont and Oakland, California, in Alameda County, and has its headquarters here. Cordis’ website
25 lists its address as 6500 Paseo Padre Parkway, Fremont, CA 94555 (*see* <https://www.cordis.com/> (last
26 visited May 27, 2016). A Cordis-affiliate website represents that Cordis’ “North American operations
27 are based out of the San Francisco Bay Area” and also lists the 6500 Paseo Padre Parkway, Fremont, CA
28 94555 address [*see* <http://www.cardinalhealth.com/en/cmp/ext/cor/cordis.html>] (last visited May 27,

2016)]. Thus, Cordis affirmatively represents to the public that its headquarters and principal place of business are in California.

Further, based on information and belief, the maker and supplier of the Nitinol used in Cordis IVC filters, is called Cordis Nitinol and/or Nitinol Devices & Components, Inc. and/or Confluent Medical Technologies, Inc., as successor-in-interest to each other, and is also located in Fremont, CA. It is an affiliate of Defendants directly involved in the design of the IVC filters at issue. All of the foregoing consequently establishes, upon information and belief, that the State of California is the “nerve center” for Cordis. See *Hertz Corp. v. Friend*, 559 U.S. 77 (2010).

III.

SUMMARY OF THE CASES AND THE ALLEGATIONS OF PRODUCT DEFECT

IVC filters are implanted medical devices marketed as preventing blood clots (called “thrombi”) from traveling from the lower portions of the body to the heart and lungs. IVC filters are designed to be implanted, either temporarily or permanently, within the vena cava. The vena cava is a large vein that returns blood to the heart. The superior vena cava returns blood to the heart from the upper portion of the body, such as the head and arms. The inferior vena cava returns blood to the heart from the lower portion of the body. In certain people, and for various reasons, thrombi travel from vessels in the legs and pelvis, through the vena cava into the lungs. Often these thrombi develop in the deep leg veins. The thrombi are called “deep vein thromboses” or DVT. Once a thrombus reaches the lungs it is considered a “pulmonary embolus,” or PE.

The Defendants have designed, manufactured, marketed and sold two (2) versions of its IVC filter at issue in the Related Actions. The first Cordis filter was its TrapEase™ Permanent Vena Cava Filter (“TrapEase filter”), which was and remains a permanent filter, meaning it was intended to be implanted into the body for the life of the patient. Cordis then created its second IVC filter—the OptEase™ Retrievable Vena Cava Filter (“OptEase filter”), which was initially cleared by the FDA only as a permanent device, but later received clearance for use as an optional or retrievable filter. (Collectively, the TrapEase filters and the OptEase filters are hereinafter referred as “Defendants’ IVC filters” or “Cordis IVC filters”). Both of the Cordis filters are represented by Defendants to be capable

1 of being left in the body permanently, but the OptEase filter can be removed from the patient after
2 placement.

3 The TrapEase filter is made with Nitinol – a nickel titanium alloy. The filter utilizes a design
4 known as a double basket or double filter for the capture of blood clots and/or emboli. This design
5 consists of a basket made of six diamond-shaped struts proximally and six diamond-shaped struts
6 distally, forming proximal and distal baskets, which are connected by six straight struts to create a single
7 symmetric filter. The filter has proximal and distal anchoring barbs located on each connecting strut for
8 fixation of the filter to the vena cava wall to prevent movement after placement.

9 In September 2002, Defendants sought clearance through the 510(k) process to market the
10 OptEase Vena Cava Filter for the same indicated uses as the TrapEase filter. Defendants represented
11 that the OptEase filter contained the same fundamental technology and was substantially equivalent in
12 terms of safety and efficacy as the predicate devices already available on the market. Unlike the
13 TrapEase filter, which has proximal and distal anchoring barbs located on each connecting strut for
14 fixation of the filter to the vena cava wall, the OptEase filter has anchoring barbs for fixation of the filter
15 only on the superior end of each of the six straight struts and has a hook at the inferior end of the basket
16 to allow retrieval with a snare. The OptEase filters demonstrated a propensity to fracture, tilt, perforate
17 and migrate as did its predicate device, the TrapEase filter. The Cordis IVC filters continue to share
18 several of the same design defects and complications.

19 Defendants sought Food and Drug Administration (“FDA”) clearance to market each of its IVC
20 filters under the notification provisions of Section 510(k) of the Medical Device Amendments of 1976 to
21 the federal Food, Drug and Cosmetic Act (“Act”). Under Section 510(k) of the Act (21 U.S.C. 321 *et*
22 *seq.*), an entity engaged in the design, manufacture, distribution or marketing of a device intended for
23 human use may notify the FDA 90 days before it intends to market the device, and may sell the new
24 device based upon a showing that the device is substantially equivalent to a legally marketed predicate
25 device. *See* 21 C.F.R. §§ 807.81, 807.92(a)(3). “Substantial equivalence” means that the new device
26 has the same intended use and technological characteristics as the predicate device. This clearance
27 process allows a manufacturer to bypass the rigorous safety scrutiny required by the pre-market approval
28 process.

1 On or about January 10, 2001, Defendants obtained Food and Drug Administration (“FDA”) 2 clearance to market the TrapEase filter device as a permanent IVC filter under Section 510(k) of the 3 Medical Device Amendments. Defendants’ notification of intent to market asserted that the TrapEase 4 filter was substantially equivalent to the IVC filters already on market, or the “predicate device”. In or 5 around September 2002, Defendants sought clearance through the 510(k) process to market the OptEase 6 Vena Cava Filter for the same indicated uses as the TrapEase filter. In 2003, the FDA cleared the 7 OptEase filter for the additional intended use of *optional retrieval*.

8 The Cordis IVC filters quickly proved to be problematic for the Defendants in that they 9 presented an increased risk of fracturing, titling within the inferior vena cava, perforating the wall of the 10 inferior vena cava (frequently penetrating into other organs and tissues such as the aorta and duodenum), 11 and migrating through the body. The Cordis IVC filters employ the same basic design and are 12 constructed of the same materials. The TrapEase filters and the OptEase filters have demonstrated the 13 same problems—namely, they migrate, fracture, perforate, and tilt, and, in addition, studies show that 14 they lack efficacy and, indeed, actually increase the risk of PE.

15 Plaintiffs all allege that Defendants’ IVC filters were widely advertised and promoted by them as 16 a safe and effective treatment for prevention of recurrent pulmonary embolism via placement in the vena 17 cava when, in fact, Defendants knew or should have known their IVC filters were defective due to, *inter* 18 *alia*, the filters’ inability to withstand normal and expected anatomical and physiological loading cycles 19 exerted *in vivo*.

20 Defendants knew or should have known that their IVC filters were likely to fracture, tilt, 21 perforate the vena cava wall and/or migrate, be prothrombotic, and, thus, cause injury. Despite their 22 knowledge, Defendants failed to disclose to physicians, patients or to the Plaintiffs that their IVC filters 23 were subject to fracture, tilt, perforation, migration, and causing thrombi and occlusion of the IVC. 24 Defendants then continued to promote their IVC filters as safe and effective, despite the absence of 25 adequate clinical trials to support long- or short-term efficacy and even after studies have shown them to 26 lack such efficacy.

27 Plaintiffs all allege that the Defendants concealed the known risks and failed to warn of known 28 or scientifically knowable dangers and risks associated with their IVC filters, as aforesaid. The failure

1 modes of Defendants' IVC filters are attributable, in part, to the fact that they all suffer from a design
 2 defect causing them to be unable to withstand the normal anatomical and physiological loading cycles
 3 exerted *in vivo*. Plaintiffs allege that Defendants failed to provide sufficient warnings and instructions
 4 that would have put Plaintiffs, their physicians, and the general public on notice of the dangers and
 5 adverse consequences caused by implantation of Defendants' IVC filters, including, but not limited to
 6 the design's failure to withstand the normal anatomical and physiological loading cycles exerted *in vivo*.

7 Plaintiffs in the Related Actions further allege that Defendants' IVC filters were designed,
 8 manufactured, distributed, sold and/or supplied by the Defendants, and were marketed while defective
 9 due to the inadequate warnings, instructions, labeling, and/or inadequate testing in light of Defendants'
 10 knowledge of their filters' defects and the serious adverse events resulting therefrom.

11 IV.

12 PENDING ACTIONS

13 As of the date this motion is filed, Movants' counsel is aware of approximately 140 plaintiffs
 14 with filed cases in this Court. Of the 140 plaintiffs, approximately 120 are personal injury plaintiffs,
 15 approximately 17 are loss of consortium plaintiffs, and three are wrongful death plaintiffs (for the same
 16 decedent). Based on information and belief, there are no other similarly-related actions filed in any
 17 other court in the State of California. It is anticipated that other Plaintiffs will file additional California
 18 state actions in Alameda County against the Defendants based on the same or similar legal theories.
 19 Counsel for the plaintiffs listed herein collectively have well over one hundred or more similar cases to
 20 prosecute, at this time. All of the plaintiffs in the Related Actions, and their respective attorneys and
 21 counsel of record, support the consolidation sought in this motion.

22 V.

23 LEGAL ARGUMENT

24 **A. The Court Has the Statutory Authority to Order that All of the Related Actions be** 25 **Consolidated Pursuant to *Code of Civil Procedure* § 1048(a) on the Grounds that** 26 **They All Involve the Same Common Operative Facts and Contain Common Issues.**

27 *Code of Civil Procedure* § 1048(a) states that, "when the actions involving a common question
 28 of law or fact are pending before the court, it may order a joint hearing or trial of any or all the matters
 in issue in the actions; it may order all the actions consolidated and it may make such orders concerning

proceedings therein as may tend to avoid unnecessary costs or delay.” The purpose of consolidation is to enhance trial court efficiency (i.e. to avoid unnecessary duplication of evidence and procedures); and to avoid the substantial danger of inconsistent adjudications (i.e. different results because tried before different judge and jury, etc.). See *Todd-Stenberg v. Dalkon Shield Claimants Trust* (1996) 48 CA4th 976, 978-79.

To be clear, Moving Plaintiffs are not requesting a consolidation of Related Actions for purposes of a single trial to determine the outcome for all plaintiffs, but rather a single judge to oversee and coordinate common discovery and pretrial proceedings. Moving Plaintiffs contend that consolidation of the Related Actions for purposes of pretrial proceedings and the formation of a bellwether-trial process is proper on the grounds that all of the Actions arise out of the same set of operative facts and contain common issues. Indeed, with more filings to come, consolidating these 140 pending actions before the Court for pretrial proceedings will further CCP § 1048(a)’s goals of promoting and ensuring the just and efficient conduct of the actions and avoiding inconsistent or conflicting substantive and procedural determinations.

The general liability (product defect) written discovery will be the same in each of the Related Actions. In other words, the design, safety, marketing, and performance of the allegedly defective products will be at issue in each of the Related Actions and discovery on those issues will be virtually identical for all the cases.

The electronically-stored information (ESI) issues will be the same in each of the Related Actions.

The general liability witnesses on behalf of Defendants will be the same in each of the Related Actions. In other words, the deposition of corporate employees related to certain categories, such as, the design, testing, marketing, post-market evaluation, and performance of Defendants’ IVC filters, will be the same in each of the Related Action.

While fact-specific information relative to each Plaintiff will vary, a complex court with consolidated actions could easily establish Plaintiff Fact Sheet categories that are identical for all Plaintiffs. In other words, the general categories of plaintiff-specific information will be the same for each case, even as some of the plaintiff-specific information will certainly vary. In sum, much of the

1 common case needs will be the same in every case and consolidation would reduce waste and
2 duplication.

3 To date, there have been several experts retained by Plaintiffs' counsel to testify as to general
4 liability and causation. Many of these experts have provided hours of expert testimony in litigation
5 related to another IVC filter manufacturer. Many of the same Plaintiffs' counsel in the pending Related
6 Actions have dedicated countless hours to the same experts, writing reports and developing the science
7 in other IVC filter litigations. Consolidation would avoid the need for these experts, as well as the
8 defendants' experts, to provide general causation testimony and written reports in each individual action.

9 Without the efforts of a centralized court with authority to monitor and guide the discovery
10 process for an already high number of Related Actions, the aggregate discovery efforts that would have
11 to be undertaken by both Plaintiffs and Defendants in each individual action would be massive.
12 Moreover, the necessity of both parties to file pretrial motion for rulings before different or the same
13 judges in the same court, but at different times, would bring forth many individual similar motions and
14 countless interrogatories and requests for production relating to the same information. Indeed, motions
15 for summary judgment may be filed in any or all of the cases, before different judges, or the same
16 judges, but at different times, and could result in different and sometimes conflicting rulings on the same
17 generic issues.

18 Additionally, consolidation of the Related Actions may create the opportunity for settlement of
19 cases. Bellwether trials would likely prove to be an effective tool to resolution of the Cordis IVC filter
20 cases. Plaintiffs' counsel is aware of over fifty additional unfiled cases that will be filed in the near
21 future, and it is likely there will be hundreds more to come.

22 Consolidation of the Related Actions for purposes of pretrial discovery and proceedings, and the
23 formation of a bellwether-trial process will avoid unnecessary duplication of evidence and procedures in
24 all of the actions; avoid the risk of inconsistent adjudications and avoid many of the same witnesses
25 testifying on common issues in all actions, as well as promote judicial economy and convenience.

26 **B. The Moving Plaintiffs Have Met Their Burden of Showing That Consolidation of**
27 **the Related Actions is Proper in That They Have Shown That the Issues in Each**
28 **Case Are the Same and that Economy and Convenience Would Be Served.**

1 Moving Plaintiffs contend that they have met their burden of showing that consolidation of the
2 Related Actions for purposes of pretrial discovery and the formation of a bellwether-trial process is
3 proper in that they have shown that the issues in each case are the same and that economy and
4 convenience would be served by a consolidation of the Related Actions for pretrial proceedings and the
5 implementation of a bellwether-trial process. The primary defendant, Cordis Corporation, is the same in
6 each Related Action. Ultimately, the defendants in each Related Action will be the same, after
7 Plaintiffs' counsel have reached a consensus, based on information and belief, or have had the benefit of
8 conducting preliminary discovery on the matter.

9 In this litigation, injuries are alleged to have occurred from product failure (filter fracture, tilt,
10 perforation and/or migration) and the plaintiffs all allege that the defendants knew or should have known
11 that the product would fail in such a manner. Such questions merit centralization for purposes of
12 consolidating discovery to reduce judicial waste. For the same reasons, as well as to encourage
13 settlement of all the Related Actions, a bellwether-trial process should be crafted and instated.

14 Moreover, the causes of action asserted in each of the Related Actions could have been joined by
15 all the plaintiffs in one complaint, requiring only the addition of case-specific factual allegations for
16 each individual plaintiff. Here, 140 plaintiffs, thus far, have filed actions with this Court that arise out of
17 allegations that Cordis IVC filters are defective and that their marketing and manufacture were
18 negligent. All cases focus on health hazards resulting from failure of the Defendants' IVC filters and
19 allegations of failure to warn doctors and consumers.

20 The moving plaintiffs have complied with *California Rule of Court* 3.350 in that all named
21 parties in each case have been listed; the names of those who have appeared, and the names of their
22 respective attorneys of record have been listed; the captions of all the cases represented by counsel of
23 record for Moving Plaintiffs sought to be consolidated have been listed, with the lowest numbered case
24 listed first; and Moving Plaintiffs have served an entire copy of this motion and notice of motion,
25 including the memorandum of points and authorities, and supporting declarations and Exhibits, on all
26 attorneys of record and all non-represented parties in all of the cases sought to be consolidated, and a
27 proof of service has been filed as a part of the motion.

28 **C. No Party to The Related Actions Will Be Prejudiced By Consolidation.**

1 An order by the Court to consolidate all of the Related Actions for purposes of pretrial
2 proceedings, including discovery, and the formation of a bellwether-trial process will not prejudice any
3 parties involved, for the reasons stated above. Case-specific discovery will be conducted on a case-by-
4 case basis, but establishing a consolidated proceeding will result in a process that will minimize the
5 burden on both the parties and the Court. Beyond well-crafted case-specific written discovery,
6 depositions of plaintiffs, health care providers and third parties can be reserved for only those cases
7 within a bellwether pool and the Case Management Order that will adopt a bellwether trials protocol and
8 scheduling order.

9 **D. The Court Should Exercise Its Broad Discretion and Grant This Motion for**
10 **Consolidation.**

11 A trial court has broad discretion in ruling on a motion to consolidate. The granting or denial of
12 the motion to consolidate rests in the sound discretion of the trial court, and will not be reversed except
13 upon a clear showing of abuse of discretion. See *Fellner vs. Steinbaum* (1955) 132 Cal.App. 2d 509,
14 511.

15 **VI.**

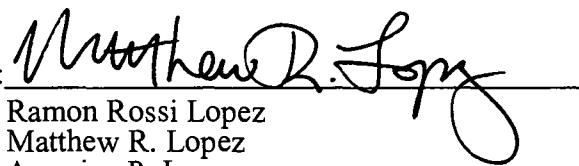
16 **CONCLUSION**

17 Based on the above, it is respectfully requested that the Court order that all of the Related
18 Actions be consolidated as requested in this motion.

19
20 Dated: May 27, 2016

Respectfully submitted,

21 LOPEZ McHUGH LLP

22
23 By: 
24 Ramon Rossi Lopez
25 Matthew R. Lopez
26 Amorina P. Lopez

27 Attorneys for Plaintiffs
28

PROOF OF SERVICE
STATE OF CALIFORNIA, COUNTY OF ORANGE

I am a resident of the county aforesaid: I am over the age of eighteen years and not a party to the within entitled action: my business address is 100 Bayview Circle, Suite 5600, Newport Beach, California 92660.

On May 27, 2016 I served the within **MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF MOTION FOR COSOLIDATION OF CASES** on interested parties in said action, by placing a true copy thereof enclosed in a sealed envelope with postage thereon fully prepaid, in the United States mail in Newport Beach, California addressed as follows: SEE ATTACHED SERVICE LIST

 X **BY REGULAR MAIL:** I am readily familiar with the firm's practice of collection and processing correspondence for mailing. Under that practice it would be deposited with US Postal Service on that same day with postage thereon fully prepaid at Newport Beach, California in the ordinary course of business. I am aware that on motion of the party served, service is presumed invalid if postal cancellation date or postage meter date is more than one day after date of deposit for mailing in affidavit.

 BY FEDERAL EXPRESS/UPS OVERNIGHT DELIVERY SERVICE: Said documents were delivered to an authorized courier or driver authorized by the express service carrier to receive documents with delivery fees paid or provided for.

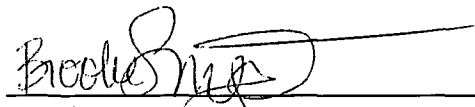
 BY FACSIMILE: Said documents were transmitted by facsimile transmission and the transmission was reported as complete and without error.

 BY E-MAIL: Said documents were transmitted by electronic mail transmission and the transmission was reported as complete and without error.

 BY PERSONAL SERVICE: Said documents were personally delivered by:

- ☐ leaving copies at the attorney's office, in an envelope or package clearly labeled to identify the attorney being served;
- ☐ with a receptionist or, with a person having charge thereof;
- ☐ in a conspicuous place in the office between the hours of 9 a.m. and 5 p.m.
- ☐ by leaving copies at the individual's residence with some person of not less than 18 years of age;
- ☐ in a conspicuous place in between the hours of 8 in the morning and 6 p.m.

I declare, under penalty of perjury under the laws of the State of California that the foregoing is true and correct. Executed on **May 27, 2016** at Newport Beach, California.



 Brooke Meyers

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12 Attorneys for Plaintiffs

13
 14 **SUPERIOR COURT OF THE STATE OF CALIFORNIA**
 15 **FOR THE COUNTY OF ALAMEDA**

16 JERRY DUNSON, *et al.*;

17 Plaintiffs,

18 vs.

19 CORDIS CORPORATION, a corporation, and
 20 DOES 1 through 100, inclusive,

21 Defendants.

Case No.: RG16812476

**DECLARATION OF MATTHEW R. LOPEZ
 IN SUPPORT OF MOTION FOR
 CONSOLIDATION OF CASES**

Date: June 28, 2016

Time: 3:00 p.m.

Dept.: 30

Reservation No.: R-1743489

Judge: Hon. Brad Seligman

Trial Date: None

Action Filed: April 20, 2016

*(Filed concurrently with Notice of Motion;
 Memorandum of Points and Authorities In Support
 of Motion; and [Proposed] Order)*

22 HEATHER QUINN, *et al.*;

23 Plaintiffs,

24 vs.

25 CORDIS CORPORATION; JOHNSON &
 26 JOHNSON; and DOES 1 through 50;

Case No.: RG16814166

Judge: Hon. Brad Seligman

Trial Date: None

Action Filed: May 3, 2016

1
2 Defendants.

3 WALTER HERBERT, *et al.*;

Case No.: RG16814569

4 Plaintiffs,

Judge: Hon. Brad Seligman

5 vs.

Trial Date: None

6 CORDIS CORPORATION; JOHNSON &
7 JOHNSON; and DOES 1 through 50;

Action Filed: May 5, 2016

8 Defendants.

9
10 GEANICE GRANT, *et al.*;

Case No.: RG16814688

11 Plaintiffs,

Judge: Hon. Brad Seligman

12 vs.

Trial Date: None

13 CORDIS CORPORATION; JOHNSON &
14 JOHNSON; and DOES 1 through 50;

Action Filed: May 6, 2016

15 Defendants.

16
17 DAVID RESOVSKY, *et al.*;

Case No.: RG16814745

18 Plaintiffs,

Judge: Hon. Brad Seligman

19 vs.

Trial Date: None

20 CORDIS CORPORATION, a corporation, and
21 DOES 1 through 100, inclusive,

Action Filed: May 6, 2016

22 Defendants.

23 MICHAEL BARBER, *et al.*;

Case No.: RG16816487

24 Plaintiffs,

Judge: Hon. Brad Seligman

25 vs.

Trial Date: None

26 CORDIS CORPORATION, a corporation;
27 JOHNSON & JOHNSON, a corporation;
28 CARDINAL HEALTH, INC., a corporation;
and DOES 1 through 50;

Action Filed: May 20, 2016

Defendants.

LISA OEHRING, *et al.*;

Case No.: RG16816490

Plaintiffs,

Judge: Hon. Brad Seligman

vs.

Trial Date: None

CORDIS CORPORATION, a corporation;
JOHNSON & JOHNSON, a corporation;
CARDINAL HEALTH, INC., a corporation;
and DOES 1 through 50;

Action Filed: May 20, 2016

Defendants.

WANDA HOLDEN, *et al.*;

Case No.: RG16816600

Plaintiffs,

Judge: Hon. Brad Seligman

vs.

Trial Date: None

CORDIS CORPORATION, a corporation,
CONFLUENT MEDICAL TECHNOLOGIES,
INC., a corporation; and DOES 1 through 100,
inclusive,

Action Filed: May 20, 2016

Defendants.

I, Matthew R. Lopez, declare as follows.

1. I am an attorney at law duly licensed to practice before all courts in the State of California. I am an attorney of record for over 100 plaintiffs in five of the above-entitled proceedings, including the moving plaintiffs in *Heather Quinn, et al. vs. Cordis Corporation, et al.*, Case No. RG16814166, and, as such, I have knowledge of the matters contained herein and they are true and correct of my own personal knowledge, except for those matters stated upon information and belief, as to those matters, I believe them to be true and correct. If called and sworn as a witness, I could and would testify competently thereto.

2. I make this declaration in support of the foregoing motion for consolidation of all of the Related Actions for purposes of pretrial proceedings, including discovery, and the formation of a

1 bellwether-trial process, as set forth in the Notice of Motion and Motion for Consolidation of Cases, on
2 the grounds that all of the Related Actions arise out of the same set of operative facts and contain
3 common issues, as evidenced in the complaints filed with this Court for each Related Action. True and
4 correct copies of the filed complaints, including First Amended Complaints where applicable, pertaining
5 to the Related Actions are attached to this declaration as follows:

6 i. Complaint filed on April 20, 2016 in *Jerry Dunson, et al. vs. Cordis Corporation,*
7 *et al.*, Case No. RG16812476 is attached as Exhibit 1.

8 1. First Amended Complaint filed on May 24, 2016 in *Jerry Dunson, et al.*
9 *vs. Cordis Corporation, et al.*, Case No. RG16812476 is attached as
10 Exhibit 2.

11 ii. Complaint filed on May 3, 2016 in *Heather Quinn, et al. vs. Cordis Corporation,*
12 *et al.*, Case No. RG16814166 is attached as Exhibit 3.

13 1. First Amended Complaint filed on May 13, 2016 in *Heather Quinn, et al.*
14 *vs. Cordis Corporation, et al.*, Case No. RG16814166 is attached as
15 Exhibit 4.

16 iii. Complaint filed on May 5, 2016 in *Walter Herbert, et al. vs. Cordis Corporation,*
17 *et al.*, Case No. RG16814569 is attached as Exhibit 5.

18 1. First Amended Complaint filed on May 13, 2016 in *Walter Herbert, et al.*
19 *vs. Cordis Corporation, et al.*, Case No. RG16814569 is attached as
20 Exhibit 6.

21 iv. Complaint filed on May 6, 2016 in *Geanice Grant, et al. vs. Cordis Corporation,*
22 *et al.*, Case No. RG16814688 is attached as Exhibit 7.

23 1. First Amended Complaint filed on May 13, 2016 in *Geanice Grant, et al.*
24 *vs. Cordis Corporation, et al.*, Case No. RG16814688 is attached as
25 Exhibit 8.

26 v. Complaint filed on May 6, 2016 in *David Resovsky, et al. vs. Cordis Corporation,*
27 *et al.*, Case No. RG16814745 is attached as Exhibit 9.

1. First Amended Complaint filed on May 24, 2016 in *David Resovsky, et al. vs. Cordis Corporation, et al.*, Case No. RG16814745 is attached as Exhibit 10.

vi. Complaint filed on May 20, 2016 in *Michael Barber, et al. vs. Cordis Corporation, et al.*, Case No. RG16816487 is attached as Exhibit 11.

vii. Complaint filed on May 20, 2016 in *Lisa Oehring, et al. vs. Cordis Corporation, et al.*, Case No. RG16816490 is attached as Exhibit 12.

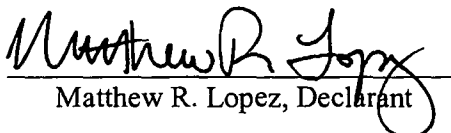
viii. Complaint filed on May 20, 2016 in *Wanda Holden, et al. vs. Cordis Corporation, et al.*, Case No. RG16816600 is attached as Exhibit 13.

3. Counsel for Moving Plaintiffs intend to file an Amended Notice of Related Actions in each case for which Moving Plaintiffs seek to consolidate for pretrial proceedings and a bellwether-trial process to advise the Court as to the number of Related Actions before the Court, prior to the hearing the Motion to Consolidate on June 28, 2016. A true and correct copy of the Amended Notice of Related Actions filed on May 24, 2016 in *Heather Quinn, et al. vs. Cordis Corporation, et al.*, Case No. RG16814166 is attached to this declaration as Exhibit 14.

4. All of the plaintiffs in the Related Actions and their respective representatives and counsel of record support this Motion to Consolidate.

5. Consolidation of all of the Related Actions for all pretrial purposes, including discovery and other pretrial proceedings, and the application of a bellwether-trial process, will avoid unnecessary duplication of evidence and procedures in all of the actions, avoid the risk of inconsistent adjudications and avoid many of the same witnesses testifying on common issues in all actions, as well as promote judicial economy and convenience, and encourage resolution of all the actions.

I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct and that this Declaration is executed on May 27, 2016 in Newport Beach, California.


Matthew R. Lopez, Declarant



ORIGINAL

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 ALAMEDA COUNTY

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9 SUPERIOR COURT OF CALIFORNIA, COUNTY OF ALAMEDA
 10 RENE C. DAVIDSON ALAMEDA COUNTY COURTHOUSE

9 JERRY DUNSON, JOSEPH GIEBER, CHERYL)
 10 GRECH, ROBERT FLANAGAN and CAROL)
 11 FLANAGAN,)

11 Plaintiff(s),)

12 vs.)

13 CORDIS CORPORATION, a corporation,)
 14 and DOES 1 through 100, inclusive,)
 15)

15 Defendant(s).)
 16)
 17)

Case No.:

RG16812476

COMPLAINT FOR DAMAGES

DEMAND FOR JURY TRIAL

18 Plaintiffs JERRY DUNSON, JOSEPH GIEBER, CHERYL GRECH, ROBERT
 19 FLANAGAN and CAROL FLANAGAN hereby sue defendants CORDIS CORPORATION and
 20 DOES 1 through 100 and allege as follows:

21 **PARTIES**

22 1. Plaintiff Jerry Dunson underwent placement of a TrapEase™ Permanent Vena Cava
 23 Filter (referred to as "TrapEase filter," "device" or "product" hereinafter) at Saddleback Memorial
 24 Medical Center located in Laguna Hills, California. The device subsequently malfunctioned and
 25 caused, *inter alia*, thrombosis of the inferior vena cava. As a result of the malfunction, Mr. Dunson
 26 has suffered life-threatening injuries and damages and required extensive medical care and
 27
 28

1 treatment. Plaintiff has suffered and will continue to suffer significant medical expenses, extreme
2 pain and suffering, loss of enjoyment of life, disability, and other losses.

3 2. Plaintiff Joseph Gieber underwent placement of a TrapEase filter which
4 subsequently malfunctioned. The device, *inter alia*, fractured, perforated his vena cava, and caused
5 thrombosis of the vena cava and filter. As a result of these malfunctions, he suffered life-threatening
6 injuries and damages and required extensive medical care and treatment, including multiple medical
7 procedures. Plaintiff has suffered and will continue to suffer significant medical expenses, extreme
8 pain and suffering, loss of enjoyment of life, disability, and other losses.

9 3. Plaintiff Cheryl Grech underwent placement of a TrapEase filter which
10 malfunctioned after placement. The device, *inter alia*, fractured, tilted and migrated. As result of
11 these malfunctions, she has suffered and will continue to suffer significant medical expenses, pain
12 and suffering, loss of enjoyment of life, disability, and other losses.

13 4. Robert Flanagan underwent placement of a TrapEase filter, which subsequently
14 malfunctioned. The device, *inter alia*, caused thrombosis of the vena cava and filter. As a result of
15 these malfunctions, he suffered life-threatening injuries and damages and required extensive
16 medical care and treatment, including multiple medical procedures. Plaintiff has suffered and will
17 continue to suffer significant medical expenses, extreme pain and suffering, loss of enjoyment of
18 life, disability, and other losses.

19 5. All of the above plaintiffs underwent placement in and were residents of the United
20 States at the time these devices were implanted and when the devices subsequently failed and
21 caused injury.

22 6. Prior to the device being implanted in Robert Flanagan and to the present, Robert
23 Flanagan and Plaintiff Carol Flanagan have been and continue to be legally married. Although not
24 implanted with the device, Ms. Flanagan has suffered loss of consortium damages (economic and
25 non-economic) as a direct result of Mr. Flanagan's use of the device.

26 7. Defendant Cordis Corporation ("Cordis") is a corporation organized under the laws of
27 the State of Florida, with its principal place of business at 6500 Paseo Padre Pkwy, Fremont,
28

1 California, 94555. Cordis at all times relevant to this action, designed, set specifications for,
2 manufactured, prepared, compounded, assembled, processed, marketed, distributed, and sold the
3 TrapEase™ Permanent Vena Cava Filter ("TrapEase filter") and OptEase™ Permanent Vena Cava
4 Filter ("OptEase filter") to be implanted in patients throughout the United States, including
5 California. Cordis may be served with process by serving its registered agent, CT Corporation
6 System, at 818 West Seventh Street Suite 930, Los Angeles, California 90017.

7 8. The true names and/or capacities, whether individual, corporate, partnership,
8 associate, governmental, or otherwise, of Defendant DOES 1 through 100, inclusive, are unknown
9 to Plaintiffs at this time, who therefore sue said Defendants by such fictitious names. Plaintiffs are
10 informed and believe, and thereon allege, that each Defendant designated herein as a DOE caused
11 injuries and damages proximately thereby to Plaintiffs as is hereinafter alleged, and that each DOE
12 defendant is liable to Plaintiffs for the acts and omissions alleged herein below and the injuries and
13 damages resulting therefrom. Plaintiffs seek leave to amend this Complaint to allege the true names
14 and capacities of said DOE defendants when the same are ascertained.

15 9. Plaintiffs are informed and believe, and thereon allege, that at all times herein
16 mentioned, the Defendant and each of the DOE defendants were the agent, servant, employee
17 and/or joint venturer of the other co-defendants, and each of them, and at all said times each
18 Defendant, including DOE defendants, were acting in the full course, scope, and authority of said
19 agency, service, employment and/or joint venture.

20 10. Plaintiffs are informed and believe, and thereon allege, that at all times mentioned
21 herein, Defendant and DOES 1 through 100, and each of them, were also known as, formerly
22 known as, and/or were the successors and/or predecessors in interest/business/product line/or a
23 portion thereof, assigns, a parent, a subsidiary (wholly or partially owned by, or the whole or partial
24 owner), affiliate, partner, co-venturer, merged company, alter egos, agents, equitable trustees and/or
25 fiduciaries of and/or were members in an entity or entities engaged in the funding, researching,
26 studying, manufacturing, fabricating, designing, developing, labeling, assembling, distributing,
27 supplying, leasing, buying, offering for sale, selling, inspecting, servicing, contracting others for
28 marketing, warranting, rebranding, manufacturing for others, packaging, and advertising the device.

1 11. Defendant and DOES 1 through 100, and each of them, are liable for the acts,
2 omissions and tortious conduct of its successors and/or predecessors in interest/business/product
3 line/or a portion thereof, assigns, parent, subsidiary, affiliate, partner, co-venturer, merged
4 company, alter ego, agent, equitable trustee, fiduciary and/or its alternate entities in that Defendant
5 and DOES 1 through 100, and each of them, enjoy the goodwill originally attached to each such
6 alternate entity, acquired the assets or product line (or a portion thereof), and in that there has been a
7 virtual destruction of Plaintiffs' remedy against each such alternate entity, and that each such
8 Defendant has the ability to assume the risk-spreading role of each such alternate entity.

9 12. Plaintiffs are informed and believe, and thereon allege that, at all times herein
10 mentioned, DOES 1 through 100, and each of them, were and are corporations organized and
11 existing under the laws of the State of California or the laws of some state or foreign jurisdiction;
12 that each of the said DOE defendants were and are authorized to do and are doing business in the
13 State of California and regularly conducted business in the State of California.

14 13. Upon information and belief, at all relevant times, DOES 1 through 100, and each of
15 them, were engaged in the business of researching, developing, designing, licensing, manufacturing,
16 distributing, selling, marketing, and/or introducing into interstate commerce and into the State of
17 California, either directly or indirectly through third parties or related entities, its products,
18 including the TrapEase and OptEase inferior vena cava filters.

19 14. At all relevant times, DOES 1 through 100, and each of them, conducted regular and
20 sustained business and engaged in substantial commerce and business activity in the State of
21 California, which included but was not limited to researching, developing, selling, marketing, and
22 distributing their products, including the TrapEase and OptEase inferior vena cava filters, in the
23 State of California.

24 15. Upon information and belief, at all relevant times, DOES 1 through 100, and each of
25 them, expected or should have expected that their acts would have consequences within the United
26 States including in the State of California, and said Defendants derived and continue to derive
27 substantial revenue therefrom.

28

17. This Court has jurisdiction over all causes of action alleged in this Complaint pursuant to the California Constitution, Article VI, § 10.

INFERIOR VENA CAVA FILTERS GENERALLY

22. People at risk for DVT/PE can undergo medical treatment to manage the risk. For example, a doctor may prescribe medications like Heparin, Warfarin, or Lovenox to regulate the clotting factor of the blood. In some people who are at high risk for DVT/PE, or who cannot

1 manage their conditions with medications, physicians may recommend surgically implanting an
2 IVC filter to prevent thromboembolic events.

3 23. As stated above, IVC filters have been on the market for decades. All IVC filters are
4 only cleared for use by the FDA for prevention of recurrent pulmonary embolism in patients at risk
5 for pulmonary embolism and where anticoagulation has failed or is contraindicated. In 2003,
6 however, an explosion in off-label use began with the introduction of IVC filters that were cleared
7 for both permanent placement and optional removal. Most of this market expansion came from
8 uses such as prophylactic prevention of pulmonary embolism without a prior history of pulmonary
9 embolism.

10 24. Indeed, from 2000 through 2003 there was a race between manufactures to bring the
11 first IVC filter to market with the added indication of optional retrieval. In 2003, the FDA cleared
12 the first three (3) IVC filters for a retrieval indication. These were the OptEase filter (Cordis &
13 J&J), the Recovery Filter (C.R. Bard, Inc.) and the Gunther Tulip Filter (Cook Medical).

14 25. Upon information and belief, Plaintiffs allege that this market expansion and off-
15 label use was driven by baseless marketing campaigns made by Defendants targeting bariatric,
16 trauma, orthopedic and cancer patient populations.

17 26. The medical community has just recently begun to awaken to the fact that despite
18 marketing claims by Defendants, there is no reliable evidence that any IVC filter offers a benefit
19 and that these products expose patients to substantial safety hazards. For example, an October 2015
20 article published in the Annals of Surgery concerning trauma patients inserted with IVC filters
21 concluded that IVC filters were not effective in preventing pulmonary emboli, and instead actually
22 caused thrombi to occur.

23 27. Comparing the results of over 30,000 trauma patients who had not received IVC
24 filters with those who had received them, the Annals of Surgery study published its alarming
25 results:

- 26 a. Almost twice the percentage of patients with IVC filters in the study died compared
27 to those that had not received them.
- 28 b. Over five times the relative number of patients with IVC filters developed DVTs.

c. Over four times the relative percentage of patients with filters developed thromboemboli.

28. Over twice the percentage of patients developed a pulmonary embolus – the very condition Defendants represented to the FDA, physicians, and the public that its IVC filters would prevent.

29. Other studies have also revealed that these devices suffer common failure modes such as migration, perforation, thrombosis, fracture all of which can cause serious injury or death. For example, recent studies for Defendants IVC Filters have revealed fracture rates as high as 50% and recommend medical monitoring and/or removal.

30. These studies, including the *Annals of Surgery* study, have now shown that not only is there no reliable evidence establishing that IVC filters are efficacious but that they also pose substantial health hazards.

THE TRAPEASE™ AND OPTEASE™ IVC FILTERS

31. On January 10, 2001, Defendants bypassed the more onerous Food and Drug Administration's ("FDA's") approval process for new devices and obtained "clearance" under Section 510(k) of the Medical Device Amendments to the Food, Drug, and Cosmetic Act to market the Trap Ease™ Permanent Vena Cava Filter and Introduction Kit ("TrapEase filter") as a permanent filter by claiming it was substantially equivalent in respect to safety, efficacy, design, and materials as the then already available IVC filters.

32. Section 510(k) permits the marketing of medical devices if the device is substantially equivalent to other legally marketed predicate devices without formal review for the safety or efficacy of the device. The FDA explained the difference between the 510(k) process and the more rigorous "premarket approval" ("PMA") process in its amicus brief filed with the Third Circuit in *Horn v. Thoratec Corp.*, which the court quoted from:

A manufacture can obtain an FDA findings of 'substantial equivalence' by submitting a premarket notification to the agency in accordance with section 510(k) of the [Food Drug and Cosmetic Act.] 21 U.S.C. § 360(k). A device found to be 'substantially equivalent' to a predicate device is said to be 'cleared' by the FDA (as opposed to "approved" by the agency under a PMA.

1 376 F.3d 163, 167 (3d. Cir. 2004). A pre-market notification submitted under 510(k) is thus
2 entirely different from a PMA, which must include data sufficient to demonstrate that the produce
3 involved is safe and effective.

4 33. In *Medtronic, Inc. v. Lohr*, the U.S. Supreme Court similarly described the 510(k)
5 process, observing:

6 If the FDA concludes on the basis of the [manufacturer's] § 510(k) notification
7 that the device is 'substantially equivalent' to a pre-existing device, it can be
8 marketed without further regulatory analysis.... The § 510(k) notification process
9 is by no means comparable to the PMA process; in contrast to the 1,200 hours
10 necessary to complete a PMA review, the § 510(k) review is completed in average
11 of 20 hours As on commentator noted: "The attraction of substantial
12 equivalence to manufacturers is clear. Section 510(k) notification required little
13 information, rarely elicits a negative response form the FDA, and gets processed
14 quickly.

15 518 U.S. 470, 478-79 (1996).

16 34. Pursuant to *Wyeth v. Levine*, 555 U.S. 555 (2009), once a product is cleared "the
17 manufacturer remains under an obligation to investigate and report any adverse associated with the
18 drug...and must periodically submit any new information that may affect the FDA's previous
19 conclusions about the safety, effectiveness, or labeling" This obligation extends to post-market
20 monitoring of adverse events/complaints.

21 35. On July 7, 2000, Defendants obtained clearance through this 510(k) process to begin
22 marketing the Trap Ease filter as a permanent filter.

23 36. The TrapEase filter is made of NITINOL (a nickel titanium alloy whose full name is
24 Nickel Titanium Naval Ordinance Laboratory) and has a symmetrical double-basket design with six
25 straight struts connecting the proximal and distal baskets. The device has proximal and distal
26 anchoring barbs located on each connecting strut for fixation of the filter to the vena cava wall to
27 prevent movement after placement.

28 37. On September 18, 2002, Defendants sought clearance through the 510(k) process to
market the Cordis OptEase™ Permanent Vena Cava Filter ("OptEase filter") for the same indicated
uses as the TrapEase Filter. Defendants represented that the OptEase filter had the same basic
fundamental technology and was substantially equivalent in respect to safety and efficacy as the

1 predicate devices (TrapEase Filter, Gunther Tulip filter, and the Vena Tech LGM Vena Cava
2 Filter).

3 38. Defendants have further represented that the OptEase filter has the same design as
4 TrapEase filter except that unlike the TrapEase filter, which has proximal and distal anchoring barbs
5 located on each connecting strut for fixation of the filter to the vena cava wall, the OptEase filter
6 has anchoring barbs for fixation of the filter only on the superior end of each of the six straight
7 struts and has a hook at the inferior end of the basket to allow retrieval with a snare.

8 39. Both designs suffer similar design flaws rendering them defective and unreasonably
9 dangerous. Defendants filters are designed in such way that when exposed to expected and
10 reasonably foreseeable *in-vivo* conditions the devices will fracture, migrate, tilt, perforate internal
11 organs and vasculature, and lead to the formation of thromboembolism and pulmonary embolism.

12 40. For instance, Defendants chose not to electropolish their filters. The manufacturing
13 process used to manufacture NITINOL medical devices leads to surface blemishes, draw marking,
14 pitting, gouges and cracks, which can act as stress concentrators leading to fatigue failure.
15 Electropolishing removes these conditions, which substantially increase fatigue and corrosion
16 resistance. Electropolishing has been industry standard for implanted NITINOL medical devices
17 since at least the 1990's.

18 41. The anchoring mechanism of Defendants' filters is also insufficient to prevent tilting
19 and migration post-placement.

20 42. The configuration of Defendants' filters also renders them prothrombotic. This
21 means that these filters actually lead to the formation of blood clots and pulmonary embolism – the
22 exact condition that devices are meant to prevent.

23 43. That Defendants allowed these devices to proceed to market indicates that they failed
24 to establish and maintain an appropriate Quality System in respect to design and risk analysis.

25 44. At a minimum, a manufacturer must undertake sufficient research and testing to
26 understand the anatomy of where a medical device will be implanted so as to understand what
27 forces the device may be exposed to once implanted in the human body. This design input must
28 then be used to determine the minimum safety requirements or attributes the device must have to

1 meet user needs. In the case of an IVC filter, user needs include: a device that will capture DVTs of
2 sufficient size to cause harmful consequences and that will not fracture, migrate, tilt, perforate the
3 vena cava or be prothrombotic.

4 45. Prior to bringing a product to market, a manufacturer must also conduct sufficient
5 testing under real world or simulated use conditions to ensure that the device will meet user needs
6 even when exposed to reasonably foreseeable worst case conditions.

7 46. Defendants failed to adequately establish and maintain such policies and procedures
8 in respect to their IVC filter devices.

9 47. Once brought to market, Defendants' post-market surveillance system should have
10 revealed that the TrapEase and OptEase filters were unreasonably dangerous and substantially more
11 prone to failing and causing injury than other available treatment options.

12 48. For instance soon after market release, Defendants began receiving large numbers of
13 adverse event reports ("AERs") from health care providers reporting that the TrapEase and OptEase
14 filters were fracturing post-implantation and that fractured pieces and/or the entire device was
15 migrating throughout the human body, including the heart and lungs. Defendants also received
16 large numbers of AERs reporting that the TrapEase and OptEase filters were found to have
17 excessively tilted, perforated the inferior vena cava, or caused thrombosis or stenosis of the vena
18 cava post-implantation. These device malfunctions were often associated with reports of inability to
19 retrieve the device and/or severe patient injuries such as:

- 20 a. Death;
- 21 b. Hemorrhage;
- 22 c. Cardiac/pericardial tamponade;
- 23 d. Cardiac arrhythmia and other symptoms similar to myocardial infarction;
- 24 e. Severe and persistent pain;
- 25 f. Perforation of tissue, vessels and organs;
- 26 g. compartment syndrome.

27 49. Recent medical studies have confirmed what Defendants have known or should have
28 known since shortly after the release of each of these filters - not only do TrapEase and OptEase

1 filters fail at alarming rates, but they also fail at rates substantially higher than other available IVC
2 Filters. For instance, a recent large medical study found that OptEase and TrapEase filters suffer
3 fracture rates of 37.5% and 23.1%, respectively, when left implanted a minimum of 46 months.
4 Another recent study found that the TrapEase filter had a 64% fracture rate when left in more than
5 four (4) years. Another study found a statistically significant increased rate of caval thrombosis with
6 the OptEase filter compared to Gunther Tulip and Recovery Filters.

7 50. As a minimum safety requirement, manufacturers must establish and maintain post-
8 market procedures to timely identify the cause of device failures and other quality problems and to
9 take adequate corrective action to prevent the recurrence of these problems.

10 51. Defendants, however, failed to take timely and adequate action to correct known
11 design and manufacturing defects with the OptEase and TrapEase filters.

12 52. Defendants also misrepresented and concealed the risks and benefits of the TrapEase
13 and OptEase filters in labeling and marketing distributed to the FDA, physicians and the public.

14 53. For instance, Defendants represented that these devices were safe and effective. As
15 discussed above, however, there is no reliable evidence establishing that these devices actually
16 improve patient outcomes.

17 54. Defendants also represented that the design of these devices would eliminate the risk
18 that pieces of the devices could perforate the vena cava, that the devices could tilt, or that fractures
19 could occur and migrate throughout the body. The medical literature and AERS have proven these
20 claims to be false.

21 55. Defendants also represented that these devices were more effective and safer than
22 other available IVC filters. As discussed above, there is no reliable basis for such claims and the
23 evidence indicates otherwise.

24 56. Defendants also marketed the OptEase filter as being "easy" to remove. However,
25 the OptEase filter is one of the most difficult filters to remove after implantation and quite often
26 cannot be removed at all. As Dr. William T. Kuo, one of the leading authors on IVC filters, recently
27 explained in the *Journal of Vascular Interventional Radiology*:

28 "...we thought the OPTEASE and TRAPEASE filter types were subjectively
among the most difficult to remove in our study, often requiring aggressive blunt

1 dissection force in addition to laser tissue ablation to achieve removal. A possible
2 explanation is the relatively large amount of contact these filters make with the
3 underlying vena cava and the possible induction of greater reactive tissue
4 formation.”

5 57. This is particularly concerning because having an IVC filter for a prolonged period
6 of time increases the risk of developing chronic deep venous thrombosis, PE, IVC occlusion, post-
7 thrombotic syndrome, filter fracture, and caval perforation with pain and organ injury. Many
8 patients with IVC filters are now routinely managed with lifelong anticoagulation solely to reduce
9 the risk of having the filter in place, subjecting patients to the risks and inconvenience of
10 anticoagulation.

11 58. Defendants also failed to adequately disclose the risks of these filters, such as
12 migration, fracture, perforation, tilt, thrombosis, the prothrombotic nature of the devices, that the
13 devices may not be retrievable, or that these failures were known to be causing severe injuries and
14 death or the rate at which these events were occurring.

15 59. Defendants labeling was additionally defective in that it directed physicians to
16 implant the OptEase filter upside down. When the OptEase was placed as directed by the labeling,
17 the hooks designed to ensure stability were facing in the wrong direction, rendering an already
18 inadequate anchoring system even further defective. As Defendants’ now explain in their labeling,
19 implanting the device in this fashion “can result in life threatening or serious injury including, but
20 not limited to dissection, vessel perforation, migration of the filter with secondary damage to
21 cardiac structures, ineffective pulmonary embolism prevention or death.”

22 60. Defendants began a series of recalls on March 29, 2013 relating to its labeling, which
23 instructed physicians to implant the devices upside down. These recalls were not timely, nor did
24 they fully correct the defects in Defendants’ labeling. Further, Defendants downplayed the danger
25 patients were exposed to and failed to take adequate steps to ensure patients actually received notice
26 of the recall.

27 61. The FDA classified the initial recall as a Class I recall, which are the most serious
28 type of recall and involve situations in which the FDA has determined there is a reasonable
29 probability that use of these products will cause serious adverse health consequences or death.

1 62. Defendants have admitted that any patients implanted with one of these recalled
2 units should receive medical monitoring. Specifically, these patients should undergo imaging to
3 ascertain whether or not the device was properly deployed and, if not, be assessed for removal.

4 63. Given the unreasonably high failure and injury rates associated with Defendants
5 filters when left implanted long-term, Defendants should be required to pay for medical monitoring
6 to assess the condition of these devices and whether or not retrieval should be undertaken.

7 **ESTOPPEL FROM PLEADING STATUTES OF LIMITATIONS OR REPOSE**

8 64. Plaintiffs incorporate by reference all prior allegations.

9 65. Plaintiffs are within the applicable statute of limitations for their claims because
10 Plaintiffs (and their healthcare professionals) did not discover, and could not reasonably discover,
11 the defects and unreasonably dangerous condition of Defendants' IVC filters.

12 66. Plaintiffs' ignorance of the defective and unreasonably dangers nature of
13 Defendants' IVC filters, and the causal connection between these defects and Plaintiffs' injuries and
14 damages, is due in large part to Defendants' acts and omissions in fraudulently concealing
15 information from the public and misrepresenting and/or downplaying the serious threat to public
16 safety its products present.

17 67. In addition, Defendants are estopped from relying on any statutes of limitation or
18 repose by virtue of its unclean hands, acts of fraudulent concealment, affirmative misrepresentations
19 and omissions.

20 68. Such conduct includes intentional concealment from Plaintiffs, Plaintiffs' prescribing
21 health care professionals, the general consuming public and the FDA of material information that
22 Defendants' filters had not been demonstrated to be safe or effective, and carried with them the
23 risks and dangerous defects described above.

24 69. Defendants had a duty to disclose the fact that Defendants' filters are not safe or
25 effective, not as safe as other filters on the market, defective, and unreasonably dangerous, and that
26 their implantation and use carried the above described risks.

27

28

COUNT I:
STRICT PRODUCTS LIABILITY- DESIGN DEFECT
By all Plaintiffs

70. Plaintiffs re-allege and incorporate by reference each and every allegation contained in the foregoing paragraphs as though fully set forth herein.

71. At all times relevant to this action, Defendants developed, tested, designed, manufactured, inspected, labeled, promoted, distributed and sold into the stream of commerce the TrapEase and OptEase filters, including the devices implanted in Plaintiffs.

72. The devices implanted in plaintiffs were in a condition unreasonably dangerous at the time they left Defendants' control.

73. The devices implanted in Plaintiffs were expected to, and did, reach their intended consumers without substantial change in the condition in which they were in when they left Defendants' possession. In the alternative, any changes that were made to the devices implanted in Plaintiffs were reasonably foreseeable to Defendants.

74. The TrapEase and OptEase filters, including the devices implanted in Plaintiffs, were defective in design and unreasonably dangerous at the time they left Defendants' possession because they failed to perform as safely as an ordinary consumer would expect when used as intended or in a manner reasonably foreseeable by the Defendants, and because the foreseeable risks of these devices exceeded the alleged benefits associated with their use.

75. At the time Defendants placed their TrapEase and OptEase filters, including the device implanted in Plaintiffs, into the stream of commerce, safer alternative designs were commercially, technologically, and scientifically attainable and feasible.

76. Plaintiffs and their health care providers used the devices in a manner that was reasonably foreseeable to Defendants.

1 77. Neither Plaintiffs, nor their health care providers, could have by the exercise of
2 reasonable care discovered the defective condition or perceived the unreasonable dangers with these
3 devices prior to Plaintiffs' implantation with the devices.

4 78. As a direct and proximate result of the defective and unreasonably dangerous
5 condition of the TrapEase and OptEase filters, Plaintiffs suffered injuries and damages.
6

7 WHEREFORE, Plaintiffs demand judgment against Defendants as hereinafter set forth.

8
9 **COUNT II:**
10 **STRICT PRODUCTS LIABILITY — INADEQUATE WARNING**

11 **By all Plaintiffs**

12 79. Plaintiffs re-allege and incorporate by reference each and every allegation contained
13 in the foregoing paragraphs as though fully set forth herein.

14 80. Prior to, on, and after the dates during which the device were implanted in Plaintiffs,
15 and at all relevant times, Defendants manufactured, designed, marketed, distributed, and sold the
16 TrapEase and OptEase filters.

17 81. The TrapEase and OptEase filters had potential risks and side effects that were
18 known or knowable to Defendants by the use of scientific knowledge available before, at, and after
19 the manufacture, distribution, and sale of the devices implanted in Plaintiffs.

20 82. Defendants knew or it was knowable at the time they distributed the devices
21 implanted in Plaintiffs that the TrapEase and OptEase filters posed a significant and higher risk of
22 failure than other similar IVC filters, including for fracture, migration, tilting, thrombosis,
23 migration, tilt, inability to retrieve and pulmonary embolism and that these failures were resulting in
24 serious patient injuries and death. Defendants also knew or it was knowable that these devices were
25 actually prothrombotic, that use of these filters did not improve patient outcomes, and the longer
26 these filters were left implanted increased the likelihood of a device failure.
27
28

1 83. Defendants' TrapEase and OptEase filters were in a defective condition that was
2 unreasonably and substantially dangerous to any user or consumer implanted with the filters, such
3 as Plaintiffs, when used in an intended and reasonably foreseeable way. Such ordinary consumers,
4 including Plaintiffs and their prescribing physician(s), would not and could not have recognized or
5 discovered the potential risks and side effects of the device, as set forth herein.
6

7 84. The warnings and directions Defendants provided with its TrapEase and OptEase
8 filters, including the devices implanted in Plaintiffs, failed to adequately warn of the above-
9 described risks and side-effects, whether as to existence of the risk, its likelihood, severity, or the
10 comparative risk to other products.

11 85. The labeling also failed to provide adequate directions on how to appropriately use
12 the product.
13

14 86. The devices were expected to and did reach Plaintiffs without substantial change in
15 its condition, labeling, or warnings as manufactured, distributed, and sold by Defendants.
16 Additionally, Plaintiffs and their prescribing physicians used the devices in the manner in which
17 they were intended to be used, making such use reasonably foreseeable to Defendants.

18 87. Defendants' lack of sufficient instructions or warnings prior to, on, and after the date
19 Plaintiffs used the devices was a substantial factor in causing Plaintiffs' injuries and damages, as
20 described herein.

21 WHEREFORE, Plaintiff demands judgment against Defendants as hereinafter set forth.

22
23 **COUNT III:**
24 **STRICT PRODUCTS LIABILITY — MANUFACTURING DEFECT**
 By all Plaintiffs

25 88. Plaintiffs re-allege and incorporate by reference each and every allegation contained
26 in the foregoing paragraphs as though fully set forth herein.
27
28

1 89. Prior to, on, and after the date the devices were implanted in Plaintiffs, and at all
2 relevant times, Defendants designed, distributed, manufactured, sold, and marketed the TrapEase
3 and OptEase filters for use in the United States.

4 90. At all times herein mentioned, Defendants designed, distributed, manufactured,
5 marketed, and sold the devices such that they were dangerous, unsafe, and defective in manufacture,
6 and contained a manufacturing defect when it left defendants' possession.

7 91. Plaintiffs are informed and believe, and on that basis allege, that the TrapEase and
8 OptEase filters, including the devices implanted in them, contained manufacturing defects, in that
9 they differed from Defendants' design or specifications, or from other typical units of the same
10 product line.

11 92. As a direct and proximate result of Defendants' defective manufacture and sale of
12 the TrapEase and OptEase filters prior to, on, and after the date Plaintiffs used the devices, Plaintiffs
13 suffered the injuries and damages herein described.

14 WHEREFORE, Plaintiffs demand judgment against Defendants as hereinafter set forth.

15 **COUNT IV:**
16 **NEGLIGENCE**
17 **By all Plaintiffs**

18 93. Plaintiffs re-allege and incorporate by reference each and every allegation contained
19 in the foregoing paragraphs as though fully set forth herein.

20 94. Prior to, on, and after the date the devices were implanted in Plaintiffs, and at all
21 relevant times, Defendants designed, distributed, manufactured, sold, and marketed the TrapEase
22 and OptEase filters for use in the United States.

23 95. Defendants had a duty to exercise reasonable and prudent care in the development,
24 testing, design, manufacture, inspection, marketing, labeling, promotion, distribution and sale of the
25 TrapEase and OptEase filters so as to avoid exposing others to foreseeable and unreasonable risks
26 of harm.

1 96. Defendants knew or reasonably should have known that the TrapEase and OptEase
2 filters were dangerous or were likely to be dangerous when used in an intended or reasonably
3 foreseeable manner.

4 97. At the time of manufacture and sale of the TrapEase and OptEase filters, Defendants
5 knew or should have known that the TrapEase and OptEase filters:

6 a. Were designed and manufactured in such a manner as to lack sufficient
7 structural integrity (fatigue resistance) and stability (tilt/migration) to meet user
8 needs when used in an intended and reasonably foreseeable manner.

9 b. Were designed and manufactured so as to present an unreasonable risk of the
10 devices perforating the vena cava wall and/or in the case of the OptEase filter
11 becoming irretrievable;

12 c. Being designed and manufactured in such a manner as to be prothrombotic.

13 98. At the time of manufacture and sale of the TrapEase and OptEase filters, including
14 the ones implanted in Plaintiffs, Defendants knew or should have known that using the TrapEase
15 and OptEase filters as intended or in a reasonably foreseeable manner created a significant risk of
16 patients suffering severe health side effects including, but not limited to: hemorrhage;
17 cardiac/pericardial tamponade; cardiac arrhythmia and other symptoms similar to myocardial
18 infarction; perforations of tissue, vessels and organs; chronic deep vein thrombosis: pulmonary
19 embolism; thrombosis; compartment syndrome; and other severe personal injuries and diseases,
20 which are permanent in nature, including, but not limited to, death, physical pain and mental
21 anguish, scarring and disfigurement, diminished enjoyment of life, continued medical care and
22 treatment due to chronic injuries/illness proximately caused by the device; and the continued risk of
23 requiring additional medical and surgical procedures including general anesthesia, with attendant
24 risk of life threatening complications.
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1 99. Defendants knew or reasonably should have known that consumers of the TrapEase
2 and OptEase filters, including Plaintiffs' prescribing physicians, would not realize the danger
3 associated with using the devices for their intended or reasonably foreseeable use.

4 100. Defendants breached their duty to exercise reasonable and prudent care in the
5 development, testing, design, manufacture, inspection, marketing, labeling, promotion, distribution
6 and sale of the TrapEase and OptEase filters in, among other ways, the following acts and
7 omissions:
8

- 9 a. Designing and distributing a product in which they knew or should have known that
10 the likelihood and severity of potential harm from the product exceeded the burden
11 of taking safety measures to reduce or avoid harm;
12 b. Designing and distributing a product in which they knew or should have known that
13 the likelihood and severity of potential harm from the product exceeded the
14 likelihood of potential harm from other devices and treatment options available for
15 the same purpose;
16 c. Failing to use reasonable care in manufacturing the product and producing a product
17 that differed from their design or specifications or from other typical units from the
18 same production line;
19 d. Failing to use reasonable care to warn or instruct, including pre and post-sale,
20 Plaintiffs, their prescribing physicians, or the general health care community about
21 the TrapEase and OptEase filters' substantially dangerous condition or about facts
22 making the products likely to be dangerous;
23 e. Failing to recall, retrofit, or provide adequate notice of such actions to Plaintiffs or
24 their health providers.
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- 1 f. Failing to perform reasonable pre and post-market testing of the TrapEase and
- 2 OptEase filters to determine whether or not the products were safe for their intended
- 3 use;
- 4 g. Failing to provide adequate instructions, guidelines, and safety precautions,
- 5 including pre and post-sale, to those persons to whom it was reasonably foreseeable
- 6 would prescribe, use, and implant the TrapEase and OptEase filters;
- 7 h. Advertising, marketing and recommending the use of the TrapEase and OptEase
- 8 filters, while concealing and failing to disclose or warn of the dangers known by
- 9 Defendants to be connected with and inherent in the use of these filter systems;
- 10 i. Representing that the TrapEase and OptEase filters were safe for their intended use
- 11 when, in fact, Defendants knew and should have known the products were not safe
- 12 for their intended uses;
- 13 j. Continuing to manufacture and sell the TrapEase and OptEase filters with the
- 14 knowledge that said products were dangerous and not reasonably safe, and failing to
- 15 comply with good manufacturing regulations;
- 16 k. Failing to use reasonable and prudent care in the design, research, manufacture, and
- 17 development of the TrapEase and OptEase filters so as to avoid the risk of serious
- 18 harm associated with the use of these filter systems;
- 19 l. Advertising, marketing, promoting and selling TrapEase and OptEase filters for uses
- 20 other than as approved and indicated in the product's label;
- 21 m. Failing to establish an adequate quality assurance program used in the design and
- 22 manufacture of the TrapEase and OptEase filters.
- 23 n. Failing to establish and maintain an adequate post-market surveillance program;
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101. A reasonable manufacturer, distributor, or seller under the same or similar
circumstances would not have engaged in the before-mentioned acts and omissions.

COUNT V:
NEGLIGENT MISREPRESENTATION
By all Plaintiffs

104. Prior to, on, and after the date the devices were implanted in Plaintiffs, and at all relevant times, Defendants negligently and carelessly represented to Plaintiffs, their health care providers, and the general public that certain material facts were true. The representations include, *inter alia*, the following:

- a. That the TrapEase and OptEase filters were safe, fit, and effective for use.
- b. that the design of the TrapEase and OptEase filters eliminated the risk that pieces of the device could perforate the vena cava, that the devices could tilt, or that fractures could occur and migrate throughout the body.
- c. That the TrapEase and OptEase filters was safer and more effective than other available IVC filters.
- d. That the OptEase filter was “easy” to remove.

105. Prior to, on, and after the dates during which Plaintiffs and their physicians purchased and used the device, said representations were not true, and there was no reasonable ground for believing said representations to be true at the times said representations were made.

106. Prior to, on, and after the dates during which Plaintiffs and their physicians purchased and used the device, Defendants intended that Plaintiffs, their physicians, and the general public would rely on said representations, which did in fact occur.

107. Defendants' negligent misrepresentations prior to, on, and after the date when Plaintiffs and their physicians purchased and used the devices were a substantial factors in causing Plaintiff's injuries and damages, as described herein.

WHEREFORE, Plaintiff demands judgment against Defendants as hereinafter set forth.

COUNT VI
FRAUD - MISREPRESENTATION
By all Plaintiffs

108. Plaintiffs re-allege and incorporate by reference each and every allegation contained in the foregoing paragraphs as though fully set forth herein.

109. At all times relevant to this cause, and as detailed above, Defendants intentionally provided Plaintiffs, their physicians, the medical community and the FDA with false or inaccurate information, and/or omitted material information concerning the Device, including, but not limited to, misrepresentations regarding the following topics:

- a. The safety of the device;
- b. The efficacy of the device;
- c. The rate of failure of the device;
- d. The pre-market testing of the device; and
- e. The approved uses of the device.

110. The information distributed by Defendants to the public, the medical community, Plaintiffs and their physicians was in the form of reports, press releases, advertising campaigns, labeling materials, print advertisements, commercial media containing material representations, and instructions for use, as well as through their officers, directors, agents, and representatives. These materials contained false and misleading material representations, which included:

- a. That the device was safe, fit, and effective when used for its intended purpose or in a reasonably foreseeable manner;
- b. that it did not pose dangerous health risks in excess of those associated with the use of other similar devices;

- c. That the design of the device would eliminate the risk that pieces of the device could perforate the vena cava, that the devices could tilt, or that fractures could occur and migrate throughout the body;
- d. That the device was safer and more effective than other available IVC filters; and
- e. That the OptEase filter was “easy” to remove.

111. Defendants made the foregoing misrepresentations knowing that they were false. These materials included instructions for use and a warning document that was included in the package of the devices implanted in Plaintiffs.

112. Defendants’ intent and purpose in making these misrepresentations was to deceive and defraud Plaintiffs and their health care providers; to gain the confidence of Plaintiffs and their health care providers; to falsely assure them of the quality of the device and its fitness for use; and to induce the public and the medical community, including Plaintiffs’ healthcare providers to request, recommend, prescribe, implant, purchase, and continue to use the device, all in reliance on Defendants’ misrepresentations.

113. The foregoing representations and omissions by Defendants were in fact false.

114. Defendants acted to serve their own interests and having reasons to know consciously disregarded the substantial risk that the device could kill or significantly harm patients.

115. In reliance upon the false representations made by Defendants, Plaintiffs and their health care providers were induced to, and did use the device, thereby causing Plaintiffs to sustain the injuries described herein.

116. Defendants knew and had reason to know that Plaintiffs, their health care providers, or the general medical community did not have the ability to determine the true facts intentionally concealed and misrepresented by Defendants, and would not have prescribed and implanted same, if the true facts regarding the device had not been concealed and misrepresented by Defendants.

117. Defendants had sole access to material facts concerning the defective nature of the TrapEase and OptEase filters and their propensity to cause serious side effects in the form of dangerous injuries and damages to persons who are implanted with the device.

1 118. At the time Defendants failed to disclose and intentionally misrepresented the
 2 foregoing facts, and at the time Plaintiffs' health care providers purchased and used these devices,
 3 Plaintiffs' health care providers were unaware of Defendants' misrepresentations.

4 119. Plaintiffs' health care providers reasonably relied upon misrepresentations made by
 5 Defendants where the concealed and misrepresented facts were critical to understanding the true
 6 dangers inherent in the use of the device.

7 120. Defendants' fraudulent misrepresentations prior to, on, and after the date Plaintiffs
 8 and their physicians purchased and used the devices were a substantial factor in causing Plaintiff's
 9 injuries and damages, as described herein.

10 WHEREFORE, Plaintiffs demand judgment against defendants as hereinafter set forth.

11 **COUNT VII**
 12 **FRAUDULENT CONCEALMENT**
 13 **By all Plaintiffs**

14 121. Plaintiffs re-allege and incorporate by reference each and every allegation contained
 15 in the foregoing paragraphs as though fully set forth herein.

16 122. In marketing and selling the device, defendants concealed material facts from
 17 Plaintiffs and their health care providers.

18 123. Defendants' concealed material facts including, but not limited to, the following:

- 19 a. That the device was unsafe and not fit when used for its intended purpose or
 in a reasonably foreseeable manner;
- 20 b. That the device posed dangerous health risks in excess of those associated
 with the use of other similar devices;
- 21 c. That there were additional side effects related to implantation and use of the
 22 device that were not accurately and completely reflected in the warnings
 associated with the device;
- 23 d. That the device was not adequately tested to withstand normal placement
 24 within the human body; and
- 25 e. That Defendants were aware at the time Plaintiffs' filters were distributed
 26 that electropolishing reduced the risk of fracture and was industry standard
 for NITINOL medical devices.

27 124. Plaintiffs and their healthcare providers were not aware of these and other facts
 28 concealed by Defendants.

127. Plaintiffs and their healthcare providers reasonably and justifiably relied on Defendants' concealment and deception.

WHEREFORE, Plaintiffs demand judgment against defendants as hereinafter set forth.

129. Plaintiffs re-allege and incorporate by reference each and every allegation contained in the foregoing paragraphs as though fully set forth herein.

131. Defendants used packaging inserts and media advertisements to represent to the medical community and consumers, including plaintiffs and their health care providers, that the TrapEase and OptEase filters: were safe for their intended use; did not pose serious health hazards

1 when used appropriately; were safer and more effective than alternative IVC filters; had been
2 adequately tested for their intended use; would not perforate the vena cava, tilt, or fracture and
3 migrate throughout the body after placement; and that the OptEase filter was “easy” to remove.

4 132. Defendants, and each of them, breached the above-described express warranties and
5 representations in that the TrapEase and OptEase filters did not conform to these express warranties
6 and representations.

7 133. Prior to, on, and after the dates during which Plaintiffs and their physicians
8 purchased and used these devices, Defendants, and each of them, were put on notice of the
9 TrapEase and OptEase filters’ inability to conform to these express warranties.

10 134. Defendants’ breach of said express warranties and representations prior to, on, and
11 after the date Plaintiffs and their physicians purchased and used the devices was a substantial factor
12 in causing Plaintiffs’ injuries and damages, as described herein.

13 WHEREFORE, Plaintiffs demand judgment against Defendants as hereinafter set forth.

14 **COUNT IX**
15 **BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY**
16 **By all Plaintiffs**

17 135. Plaintiffs re-allege and incorporate by reference each and every allegation contained
18 in the foregoing paragraphs as though fully set forth herein.

19 136. Defendants sold the TrapEase and OptEase filters for Plaintiffs’ ultimate use.

20 137. At all times hereinafter mentioned, Defendants were in the business of developing,
21 designing, licensing, manufacturing, selling, distributing and/or marketing the TrapEase and
22 OptEase filters, including the one implanted in Plaintiffs.

23 138. Defendants impliedly warranted to Plaintiffs and their physicians that the TrapEase
24 and OptEase filters were safe and of merchantable quality and for the ordinary purpose for which
25 they product was intended and marketed to be used.

26 139. The representations and implied warranties made by Defendants were false,
27 misleading, and inaccurate because the TrapEase and OptEase filters were defective, unsafe,
28 unreasonably dangerous, and not of merchantable quality, when used as they were marketed and

1 intended to be used. Specifically, at the time Plaintiffs and their physicians purchased and used the
2 devices, the products were not in a merchantable condition in that:

- 3 a. They offered no benefit to patient outcomes,
- 4 b. They suffered an unreasonably high failure and injury rates, and
- 5 c. The surface of the devices were manufactured and designed in such a way that they
6 were distributed with surface damage that substantially increased the risk of fracture.
- 7 d. They were prothrombotic;

8 140. Defendants' breach of said implied warranties and representations prior to, on, and
9 after the date Plaintiffs and their physicians purchased and used the devices was a substantial factor
10 in causing Plaintiffs' injuries and damages, as described herein.

11 WHEREFORE, Plaintiffs demand judgment against Defendants as hereinafter set forth.

12 **COUNT X**
13 **LOSS OF CONSORTIUM**
14 **By Plaintiff Carol Flanagan**

15 141. Plaintiff Carol Flanagan re-alleges and incorporates by reference each and every
16 allegation contained in the foregoing paragraphs as though fully set forth herein.

17 142. Plaintiff Carol Flanagan is, and at all time herein mentioned was, the lawful spouse
18 of Plaintiff Robert Flanagan.

19 143. As a direct, legal and proximate result of the culpability and fault of the Defendants,
20 be such fault through strict liability or negligence, Plaintiff Carol Flanagan suffered the loss of
21 support, service, love, companionship, affection, society, intimate relations, and other elements of
22 consortium, all to Plaintiff's general damage, in an amount in excess of the jurisdictional minimum
23 of this Court.

24 WHEREFORE, Plaintiff Carol Flanagan demand judgment against the Defendants as
25 hereinafter set forth.
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PUNITIVE DAMAGES ALLEGATIONS

144. Plaintiff re-alleges and incorporates by reference each and every allegation contained in the foregoing paragraphs as though fully set forth herein.

145. Upon information and belief, Plaintiffs allege that as early as 2003, Defendants were aware and had knowledge of the fact that the TrapEase and OptEase filters were defective and unreasonably dangerous and were causing injury and death to patients.

146. Data establishes that the failure rates of the TrapEase and OptEase filters are and were much higher than what Defendants have in the past and currently continue to publish to the medical community and members of the public. Further, Defendants were aware or should have been aware that the TrapEase and OptEase filters had substantially higher failure rates than other similar products on the market and are actually prothrombotic. Defendants were also aware that there was no reliable evidence indicating its devices actually improved patient outcomes. Despite these facts, Defendants continued to sell an unreasonably dangerous product while concealing and misrepresenting its risks and benefits to the public, plaintiffs, plaintiffs' health care providers, and the FDA.

147. The conduct of Defendants as alleged in this Complaint constitutes willful, wanton, gross, and outrageous corporate conduct that demonstrates a conscious disregard for the safety of Plaintiff. Defendants had actual knowledge of the dangers presented by TrapEase and OptEase filters, yet consciously failed to act reasonably to:

- a. Inform or warn Plaintiffs, Plaintiffs' physicians, or the public at large of these dangers; and
- b. Establish and maintain an adequate quality and post-market surveillance system.

148. Despite having knowledge as early as 2003 of the unreasonably dangerous and defective nature of the TrapEase and OptEase filters, Defendants consciously disregarded the known risks and continued to actively market and offer for sale the TrapEase and OptEase filters. Plaintiffs further allege that Defendants acted in willful, wanton, gross, and total disregard for the health and safety of the users or consumers of their TrapEase and OptEase filters, acted to serve

1 their own interests, and consciously disregarded the substantial risk that their product might kill or
2 significantly harm patients, or significantly injure the rights of others. Despite this knowledge,
3 Defendants consciously pursued a course of conduct knowing that such conduct created a
4 substantial risk of significant harm to other persons.

5 **PRAYER FOR DAMAGES**

6 **WHEREFORE**, Plaintiffs pray for relief against Defendants Cordis Corporation and Does
7 1 through 100, inclusive, on the entire complaint, as follows:

- 8 a. General damages according to proof at the time of trial;
9 b. Special (economic) damages, including without limitation, past and future medical
10 expenses and past and future lost wages according to proof at time of trial.
11 c. Pre-judgment and post-judgment interest pursuant to the laws of the State of
12 California;
13 d. Costs of suit incurred herein;
14 e. Punitive damages in an amount sufficient to punish Defendants and deter similar
15 conduct in the future;
16 f. For such further and other relief as this Court deems necessary, just and proper.

17 **DEMAND FOR JURY TRIAL**

18 Plaintiffs hereby demand trial by jury on all issues.

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23 DATED: April 21, 2016

Respectfully Submitted,
BRENES LAW GROUP

24 /s/ Troy A. Brenes
25 Troy A. Brenes
26 Attorney for Plaintiffs
27
28

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FILED BY FAX
ALAMEDA COUNTY
May 24, 2016
CLERK OF
THE SUPERIOR COURT
By Amrit Khan, Deputy
CASE NUMBER:
RG16812476

9 **SUPERIOR COURT OF CALIFORNIA, COUNTY OF ALAMEDA**
10 **RENE C. DAVIDSON ALAMEDA COUNTY COURTHOUSE**

11 JERRY DUNSON, JOSEPH GIEBER, CHERYL)
12 GRECH, ROBERT FLANAGAN, CAROL)
13 FLANAGAN, MARY ELDEB, DAYNA)
14 CURRIE AND HARLOWE CURRIE)

15 Plaintiffs,

16 vs.

17 CORDIS CORPORATION, a corporation,
18 CONFLUENT MEDICAL
19 TECHNOLOGIES, INC., a corporation,
20 and DOES 1 through 100, inclusive,
21 Defendants.

Case No.: RG16812476

**FIRST AMENDED COMPLAINT FOR
DAMAGES AND
DEMAND FOR JURY TRIAL**

- (1) Strict Products Liability - Design Defect
(2) Strict Products Liability - Inadequate Warning
(3) Strict Products Liability - Manufacturing Defect
(4) Negligence
(5) Negligent Misrepresentation
(6) Fraud - Misrepresentation
(7) Fraudulent Concealment
(8) Express Warranty
(9) Breach of Implied Warranty Of Merchantability
(10) Loss of Consortium

21 Plaintiffs JERRY DUNSON, JOSEPH GIEBER, CHERYL GRECH, ROBERT
22 FLANAGAN, CAROL FLANAGAN, MARY ELDEB, DAYNA CURRIE AND HARLOWE
23 CURRIE hereby sue defendants CORDIS CORPORATION, CONFLUENT MEDICAL
24 TECHNOLOGIES, INC., and DOES 1 through 100, and each of them, and allege as follows:
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1 PARTIES

2 1. Plaintiff Jerry Dunson underwent placement of a TrapEase™ Permanent Vena Cava
3 Filter (referred to as "TrapEase filter," "device" or "product" hereinafter) at Saddleback Memorial
4 Medical Center located in Laguna Hills, California. The device subsequently malfunctioned and
5 caused, *inter alia*, thrombosis of the inferior vena cava. As a result of the malfunction, Mr. Dunson
6 has suffered life-threatening injuries and damages and required extensive medical care and
7 treatment. Plaintiff has suffered and will continue to suffer significant medical expenses, extreme
8 pain and suffering, loss of enjoyment of life, disability, and other losses.

9 2. Plaintiff Joseph Gieber underwent placement of a TrapEase filter which
10 subsequently malfunctioned. The device, *inter alia*, fractured, perforated his vena cava, and caused
11 thrombosis of the vena cava and filter. As a result of these malfunctions, he suffered life-threatening
12 injuries and damages and required extensive medical care and treatment, including multiple medical
13 procedures. Plaintiff has suffered and will continue to suffer significant medical expenses, extreme
14 pain and suffering, loss of enjoyment of life, disability, and other losses.

15 3. Plaintiff Cheryl Grech underwent placement of a TrapEase filter which
16 malfunctioned after placement. The device, *inter alia*, fractured, tilted and migrated. As result of
17 these malfunctions, she has suffered and will continue to suffer significant medical expenses, pain
18 and suffering, loss of enjoyment of life, disability, and other losses.

19 4. Robert Flanagan underwent placement of a TrapEase filter, which subsequently
20 malfunctioned. The device, *inter alia*, caused thrombosis of the vena cava and filter. As a result of
21 these malfunctions, he suffered life-threatening injuries and damages and required extensive
22 medical care and treatment, including multiple medical procedures. Plaintiff has suffered and will
23 continue to suffer significant medical expenses, extreme pain and suffering, loss of enjoyment of
24 life, disability, and other losses.

25 5. Prior to the device being implanted in Robert Flanagan and to the present, Robert
26 Flanagan and Plaintiff Carol Flanagan have been and continue to be legally married. Although not
27 implanted with the device, Ms. Flanagan has suffered loss of consortium damages (economic and
28 non-economic) as a direct result of Mr. Flanagan's use of the device.

1 6. Plaintiff Mary Eldeb underwent placement of a TrapEase filter on January 7, 2016 at
2 Beth Israel Deaconess Hospital-Milton. The malfunctioned during deployment and migrated
3 towards heart. As a result, Mary Eldeb has suffered and will continue to suffer significant medical
4 expenses, extreme pain and suffering, loss of enjoyment of life, disability, and other losses. A
5 formal investigation was conducted by Beth Israel Deaconess Hospital-Milton as to the cause of the
6 event. The investigation concluded her "filter was placed in a manner consistent with expectations,
7 however its failure to deploy as it should have was due to a device malfunction."

8 7. Plaintiff Dayna Currie was implanted with a TrapEase filter at Christus Highland
9 Medical Center in Louisiana. The device subsequently malfunctioned by, *inter alia*, fracturing and
10 causing clot development in and/or thrombosis of the filter. Plaintiff has suffered and will continue
11 to suffer significant medical expenses, extreme pain and suffering, loss of enjoyment of life,
12 disability, and other losses.

13 8. Prior to the device being implanted in Dayna Currie and to the present, Dayna Currie
14 and Plaintiff Harlowe Currie have been and continue to be legally married. Although not implanted
15 with the device, Harlowe Currie has suffered loss of consortium damages (economic and non-
16 economic) as a direct result of Dayna Currie's use of the device.

17 9. Plaintiffs Jerry Dunson, Joseph Gieber, Cheryl Grech, Robret Flanagan, Mary Eldeb,
18 and Dayna Currie all underwent placement with the TrapEase filters in and were residents of the
19 United States at the time these devices were implanted and when the devices subsequently failed
20 and caused injury.

21 10. Defendant Cordis Corporation ("Cordis") is a corporation organized under the laws of
22 the State of Florida, with its principal place of business at 6500 Paseo Padre Pkwy, Fremont,
23 California, 94555. Cordis at all times relevant to this action, designed, set specifications for,
24 manufactured, prepared, compounded, assembled, processed, marketed, distributed, and sold the
25 TrapEase™ Permanent Vena Cava Filter ("TrapEase filter") and OptEase™ Permanent Vena Cava
26 Filter ("OptEase filter") to be implanted in patients throughout the United States, including
27 California. Cordis may be served with process by serving its registered agent, CT Corporation
28 System, at 818 West Seventh Street Suite 930, Los Angeles, California 90017.

1 11. Defendant Confluent Medical Technologies, Inc. (Hereinafter "Confluent") is a
2 corporation organized under the laws of the State of Delaware, with its principal place of business at
3 47533 Westinghouse Drive, Fremont, California 94539. Confluent manufactured, prepared,
4 processed and helped design the OptEase and TrapEase filters implanted in the above-named
5 plaintiffs, whether under its current name or as the successor in interest to Nitinol Development
6 Corporation. Confluent may be served with process by serving its registered agent, CT Corporation
7 System, at 818 West Seventh Street Suite 930, Los Angeles, California 90017.

8 12. Prior to 2015, Confluent was incorporated under the name of Nitinol Development
9 Corporation and did business under the name Nitinol Devices & Components, Inc. (hereinafter
10 "NDC"). NDC also had its principal place of business at 47533 Westinghouse Drive, Fremont,
11 California 94539. In 2015, NDC merged with another company and became Confluent. Defendant
12 Confluent carries on the same activities in relation to the TrapEase and OptEase filters as NDC did
13 previously.

14 13. The true names and/or capacities, whether individual, corporate, partnership,
15 associate, governmental, or otherwise, of Defendant DOES 1 through 100, inclusive, are unknown
16 to Plaintiffs at this time, who therefore sue said Defendants by such fictitious names. Plaintiffs are
17 informed and believe, and thereon allege, that each Defendant designated herein as a DOE caused
18 injuries and damages proximately thereby to Plaintiffs as is hereinafter alleged, and that each DOE
19 defendant is liable to Plaintiffs for the acts and omissions alleged herein below and the injuries and
20 damages resulting therefrom. Plaintiffs seek leave to amend this Complaint to allege the true names
21 and capacities of said DOE defendants when the same are ascertained.

22 14. Plaintiffs are informed and believe, and thereon allege, that at all times herein
23 mentioned, Defendants and each of the DOE defendants were the agent, servant, employee and/or
24 joint venturer of the other co-defendants, and each of them, and at all said times each Defendant,
25 including DOE defendants, were acting in the full course, scope, and authority of said agency,
26 service, employment and/or joint venture.

27 15. Plaintiffs are informed and believe, and thereon allege, that at all times mentioned
28 herein, Defendants and DOES 1 through 100, and each of them, were also known as, formerly

1 known as, and/or were the successors and/or predecessors in interest/business/product line/or a
2 portion thereof, assigns, a parent, a subsidiary (wholly or partially owned by, or the whole or partial
3 owner), affiliate, partner, co-venturer, merged company, alter egos, agents, equitable trustees and/or
4 fiduciaries of and/or were members in an entity or entities engaged in the funding, researching,
5 studying, manufacturing, fabricating, designing, developing, labeling, assembling, distributing,
6 supplying, leasing, buying, offering for sale, selling, inspecting, servicing, contracting others for
7 marketing, warranting, rebranding, manufacturing for others, packaging, and advertising the device.

8 16. Defendants and DOES 1 through 100, and each of them, are liable for the acts,
9 omissions and tortious conduct of its successors and/or predecessors in interest/business/product
10 line/or a portion thereof, assigns, parent, subsidiary, affiliate, partner, co-venturer, merged
11 company, alter ego, agent, equitable trustee, fiduciary and/or its alternate entities in that Defendants
12 and DOES 1 through 100, and each of them, enjoy the goodwill originally attached to each such
13 alternate entity, acquired the assets or product line (or a portion thereof), and in that there has been a
14 virtual destruction of Plaintiffs' remedy against each such alternate entity, and that each such
15 Defendant has the ability to assume the risk-spreading role of each such alternate entity.

16 17. Plaintiffs are informed and believe, and thereon allege that, at all times herein
17 mentioned, DOES 1 through 100, and each of them, were and are corporations organized and
18 existing under the laws of the State of California or the laws of some state or foreign jurisdiction;
19 that each of the said DOE defendants were and are authorized to do and are doing business in the
20 State of California and regularly conducted business in the State of California.

21 18. Upon information and belief, at all relevant times, DOES 1 through 100, and each of
22 them, were engaged in the business of researching, developing, designing, licensing, manufacturing,
23 distributing, selling, marketing, and/or introducing into interstate commerce and into the State of
24 California, either directly or indirectly through third parties or related entities, its products,
25 including the TrapEase and OptEase inferior vena cava filters.

26 19. At all relevant times, DOES 1 through 100, and each of them, conducted regular and
27 sustained business and engaged in substantial commerce and business activity in the State of
28 California, which included but was not limited to researching, developing, selling, marketing, and

1 distributing their products, including the TrapEase and OptEase inferior vena cava filters, in the
2 State of California.

3 20. Upon information and belief, at all relevant times, DOES 1 through 100, and each of
4 them, expected or should have expected that their acts would have consequences within the United
5 States including in the State of California, and said Defendants derived and continue to derive
6 substantial revenue therefrom.

7 21. "Cordis," "Confluent" and "Defendants" where used hereinafter, shall refer to all
8 subsidiaries, affiliates, divisions, franchises, partners, joint venturers, organizational units of any
9 kind, predecessors, successors, assigns, officers, directors, employees, agents and representatives of
10 Cordis Corporation, Confluent, as well as DOE Defendants 1 through 100, and each of them.

11 JURISDICTION AND VENUE

12 22. This Court has jurisdiction over all causes of action alleged in this Complaint
13 pursuant to the California Constitution, Article VI, § 10.

14 23. Venue is proper in this Court, pursuant to *Code of Civil Procedure*, as Defendant
15 Cordis has its principal place of business in Alameda County.

16 BACKGROUND

17 INFERIOR VENA CAVA FILTERS GENERALLY

18 24. Inferior vena cava ("IVC") filters first came on to the medical market in the 1960's.
19 Over the years, medical device manufacturers have introduced several different designs of IVC
20 filters.

21 25. An IVC filter is a device that is designed to filter or "catch" blood clots that travel
22 from the lower portions of the body to the heart and lungs. IVC filters are designed to be implanted,
23 either permanently or temporarily, in the inferior vena cava.

24 26. The inferior vena cava is a vein that returns deoxygenated blood to the heart from
25 the lower portions of the body. In certain people, for various reasons, blood clots travel from the
26 vessels in the legs and pelvis, through the vena cava and into the lungs. Oftentimes, these blood
27 clots develop in the deep leg veins, a condition called "deep vein thrombosis" or "DVT." Once
28

1 blood clots reach the lungs, they are considered “pulmonary emboli” or “PE.” Pulmonary emboli
2 present risks to human health.

3 27. People at risk for DVT/PE can undergo medical treatment to manage the risk. For
4 example, a doctor may prescribe medications like Heparin, Warfarin, or Lovenox to regulate the
5 clotting factor of the blood. In some people who are at high risk for DVT/PE, or who cannot
6 manage their conditions with medications, physicians may recommend surgically implanting an
7 IVC filter to prevent thromboembolic events.

8 28. As stated above, IVC filters have been on the market for decades. All IVC filters are
9 only cleared for use by the FDA for prevention of recurrent pulmonary embolism in patients at risk
10 for pulmonary embolism and where anticoagulation has failed or is contraindicated. In 2003,
11 however, an explosion in off-label use began with the introduction of IVC filters that were cleared
12 for both permanent placement and optional removal. Most of this market expansion came from
13 uses such as prophylactic prevention of pulmonary embolism without a prior history of pulmonary
14 embolism.

15 29. Indeed, from 2000 through 2003 there was a race between manufactures to bring the
16 first IVC filter to market with the added indication of optional retrieval. In 2003, the FDA cleared
17 the first three (3) IVC filters for a retrieval indication. These were the OptEase filter (Cordis &
18 J&J), the Recovery Filter (C.R. Bard, Inc.) and the Gunther Tulip Filter (Cook Medical).

19 30. Upon information and belief, Plaintiffs allege that this market expansion and off-
20 label use was driven by baseless marketing campaigns made by Defendants targeting bariatric,
21 trauma, orthopedic and cancer patient populations.

22 31. The medical community has just recently begun to awaken to the fact that despite
23 marketing claims by Defendants, there is no reliable evidence that any IVC filter offers a benefit
24 and that these products expose patients to substantial safety hazards. For example, an October 2015
25 article published in the Annals of Surgery concerning trauma patients inserted with IVC filters
26 concluded that IVC filters were not effective in preventing pulmonary emboli, and instead actually
27 caused thrombi to occur.

28

1 32. Comparing the results of over 30,000 trauma patients who had not received IVC
2 filters with those who had received them, the *Annals of Surgery* study published its alarming
3 results:

- 4 a. Almost twice the percentage of patients with IVC filters in the study died compared
5 to those that had not received them.
6 b. Over five times the relative number of patients with IVC filters developed DVTs.
7 c. Over four times the relative percentage of patients with filters developed
8 thromboemboli.

9 33. Over twice the percentage of patients developed a pulmonary embolus – the very
10 condition Defendants represented to the FDA, physicians, and the public that its IVC filters would
11 prevent.

12 34. Other studies have also revealed that these devices suffer common failure modes
13 such as migration, perforation, thrombosis, fracture all of which can cause serious injury or death.
14 For example, recent studies for Defendants IVC Filters have revealed fracture rates as high as 50%
15 and recommend medical monitoring and/or removal.

16 35. These studies, including the *Annals of Surgery* study, have now shown that not only
17 is there no reliable evidence establishing that IVC filters are efficacious but that they also pose
18 substantial health hazards.

19 **THE TRAPEASE™ AND OPTEASE™ IVC FILTERS**

20 36. On January 10, 2001, Defendants bypassed the more onerous Food and Drug
21 Administration's ("FDA's") approval process for new devices and obtained "clearance" under
22 Section 510(k) of the Medical Device Amendments to the Food, Drug, and Cosmetic Act to market
23 the Trap Ease™ Permanent Vena Cava Filter and Introduction Kit ("TrapEase filter") as a
24 permanent filter by claiming it was substantially equivalent in respect to safety, efficacy, design,
25 and materials as the then already available IVC filters.

26 37. Section 510(k) permits the marketing of medical devices if the device is
27 substantially equivalent to other legally marketed predicate devices without formal review for the
28 safety or efficacy of the device. The FDA explained the difference between the 510(k) process and

1 the more rigorous “premarket approval” (“PMA”) process in its amicus brief filed with the Third
2 Circuit in *Horn v. Thoratec Corp.*, which the court quoted from:

3 A manufacture can obtain an FDA findings of ‘substantial equivalence’ by
4 submitting a premarket notification to the agency in accordance with section
5 510(k) of the [Food Drug and Cosmetic Act.] 21 U.S.C. § 360(k). A device found
6 to be ‘substantially equivalent’ to a predicate device is said to be ‘cleared’ by the
7 FDA (as opposed to “approved” by the agency under a PMA).

8 376 F.3d 163, 167 (3d. Cir. 2004). A pre-market notification submitted under 510(k) is thus
9 entirely different from a PMA, which must include data sufficient to demonstrate that the produce
10 involved is safe and effective.

11 38. In *Medtronic, Inc. v. Lohr*, the U.S. Supreme Court similarly described the 510(k)
12 process, observing:

13 If the FDA concludes on the basis of the [manufacturer’s] § 510(k) notification
14 that the device is ‘substantially equivalent’ to a pre-existing device, it can be
15 marketed without further regulatory analysis.... The § 510(k) notification process
16 is by no means comparable to the PMA process; in contrast to the 1,200 hours
17 necessary to complete a PMA review, the § 510(k) review is completed in average
18 of 20 hours As on commentator noted: “The attraction of substantial
19 equivalence to manufacturers is clear. Section 510(k) notification required little
20 information, rarely elicits a negative response form the FDA, and gets processed
21 quickly.

22 518 U.S. 470, 478-79 (1996).

23 39. Pursuant to *Wyeth v. Levine*, 555 U.S. 555 (2009), once a product is cleared “the
24 manufacturer remains under an obligation to investigate and report any adverse associated with the
25 drug...and must periodically submit any new information that may affect the FDA’s previous
26 conclusions about the safety, effectiveness, or labeling” This obligation extends to post-market
27 monitoring of adverse events/complaints.

28 40. On July 7, 2000, Defendants obtained clearance through this 510(k) process to begin
marketing the Trap Ease filter as a permanent filter.

41. The TrapEase filter is made of NITINOL (a nickel titanium alloy whose full name is
Nickel Titanium Naval Ordinance Laboratory) and has a symmetrical double-basket design with six
straight struts connecting the proximal and distal baskets. The device has proximal and distal

1 anchoring barbs located on each connecting strut for fixation of the filter to the vena cava wall to
2 prevent movement after placement.

3 42. On September 18, 2002, Defendants sought clearance through the 510(k) process to
4 market the Cordis OptEase™ Permanent Vena Cava Filter ("OptEase filter") for the same indicated
5 uses as the TrapEase Filter. Defendants represented that the OptEase filter had the same basic
6 fundamental technology and was substantially equivalent in respect to safety and efficacy as the
7 predicate devices (TrapEase Filter, Gunther Tulip filter, and the Vena Tech LGM Vena Cava
8 Filter).

9 43. Defendants have further represented that the OptEase filter has the same design as
10 TrapEase filter except that unlike the TrapEase filter, which has proximal and distal anchoring barbs
11 located on each connecting strut for fixation of the filter to the vena cava wall, the OptEase filter
12 has anchoring barbs for fixation of the filter only on the superior end of each of the six straight
13 struts and has a hook at the inferior end of the basket to allow retrieval with a snare.

14 44. Both designs suffer similar design flaws rendering them defective and unreasonably
15 dangerous. Defendants filters are designed in such way that when exposed to expected and
16 reasonably foreseeable *in-vivo* conditions the devices will fracture, migrate, tilt, perforate internal
17 organs and vasculature, and lead to the formation of thromboembolism and pulmonary embolism.

18 45. For instance, Defendants chose not to electropolish their filters. The manufacturing
19 process used to manufacture NITINOL medical devices leads to surface blemishes, draw marking,
20 pitting, gouges and cracks, which can act as stress concentrators leading to fatigue failure.
21 Electropolishing removes these conditions, which substantially increase fatigue and corrosion
22 resistance. Electropolishing has been industry standard for implanted NITINOL medical devices
23 since at least the 1990's.

24 46. The anchoring mechanism of Defendants' filters is also insufficient to prevent tilting
25 and migration post-placement.

26 47. The configuration of Defendants' filters also renders them prothrombotic. This
27 means that these filters actually lead to the formation of blood clots and pulmonary embolism – the
28 exact condition that devices are meant to prevent.

1 48. That Defendants allowed these devices to proceed to market indicates that they failed
2 to establish and maintain an appropriate Quality System in respect to design and risk analysis.

3 49. At a minimum, a manufacturer must undertake sufficient research and testing to
4 understand the anatomy of where a medical device will be implanted so as to understand what
5 forces the device may be exposed to once implanted in the human body. This design input must
6 then be used to determine the minimum safety requirements or attributes the device must have to
7 meet user needs. In the case of an IVC filter, user needs include: a device that will capture DVTs of
8 sufficient size to cause harmful consequences and that will not fracture, migrate, tilt, perforate the
9 vena cava or be prothrombotic.

10 50. Prior to bringing a product to market, a manufacturer must also conduct sufficient
11 testing under real world or simulated use conditions to ensure that the device will meet user needs
12 even when exposed to reasonably foreseeable worst case conditions.

13 51. Defendants failed to adequately establish and maintain such policies and procedures
14 in respect to their IVC filter devices.

15 52. Once brought to market, Defendants' post-market surveillance system should have
16 revealed that the TrapEase and OptEase filters were unreasonably dangerous and substantially more
17 prone to failing and causing injury than other available treatment options.

18 53. For instance soon after market release, Defendants began receiving large numbers of
19 adverse event reports ("AERs") from health care providers reporting that the TrapEase and OptEase
20 filters were fracturing post-implantation and that fractured pieces and/or the entire device was
21 migrating throughout the human body, including the heart and lungs. Defendants also received
22 large numbers of AERs reporting that the TrapEase and OptEase filters were found to have
23 excessively tilted, perforated the inferior vena cava, or caused thrombosis or stenosis of the vena
24 cava post-implantation. These device malfunctions were often associated with reports of inability to
25 retrieve the device and/or severe patient injuries such as:

- 26 a. Death;
27 b. Hemorrhage;
28 c. Cardiac/pericardial tamponade;

- d. Cardiac arrhythmia and other symptoms similar to myocardial infarction;
- e. Severe and persistent pain;
- f. Perforation of tissue, vessels and organs;
- g. compartment syndrome.

54. Recent medical studies have confirmed what Defendants have known or should have known since shortly after the release of each of these filters - not only do TrapEase and OptEase filters fail at alarming rates, but they also fail at rates substantially higher than other available IVC Filters. For instance, a recent large medical study found that OptEase and TrapEase filters suffer fracture rates of 37.5% and 23.1%, respectively, when left implanted a minimum of 46 months. Another recent study found that the TrapEase filter had a 64% fracture rate when left in more than four (4) years. Another study found a statistically significant increased rate of caval thrombosis with the OptEase filter compared to Gunther Tulip and Recovery Filters.

55. As a minimum safety requirement, manufacturers must establish and maintain post-market procedures to timely identify the cause of device failures and other quality problems and to take adequate corrective action to prevent the recurrence of these problems.

56. Defendants, however, failed to take timely and adequate action to correct known design and manufacturing defects with the OptEase and TrapEase filters.

57. Defendants also misrepresented and concealed the risks and benefits of the TrapEase and OptEase filters in labeling and marketing distributed to the FDA, physicians and the public.

58. For instance, Defendants represented that these devices were safe and effective. As discussed above, however, there is no reliable evidence establishing that these devices actually improve patient outcomes.

59. Defendants also represented that the design of these devices would eliminate the risk that pieces of the devices could perforate the vena cava, that the devices could tilt, or that fractures could occur and migrate throughout the body. The medical literature and AERS have proven these claims to be false.

1 60. Defendants also represented that these devices were more effective and safer than
2 other available IVC filters. As discussed above, there is no reliable basis for such claims and the
3 evidence indicates otherwise.

4 61. Defendants also marketed the OptEase filter as being “easy” to remove. However,
5 the OptEase filter is one of the most difficult filters to remove after implantation and quite often
6 cannot be removed at all. As Dr. William T. Kuo, one of the leading authors on IVC filters, recently
7 explained in *the Journal of Vascular Interventional Radiology*:

8 “...we thought the OPTease and TRAPEASE filter types were subjectively
9 among the most difficult to remove in our study, often requiring aggressive blunt
10 dissection force in addition to laser tissue ablation to achieve removal. A possible
11 explanation is the relatively large amount of contact these filters make with the
underlying vena cava and the possible induction of greater reactive tissue
formation.”

12 62. This is particularly concerning because having an IVC filter for a prolonged period
13 of time increases the risk of developing chronic deep venous thrombosis, PE, IVC occlusion, post-
14 thrombotic syndrome, filter fracture, and caval perforation with pain and organ injury. Many
15 patients with IVC filters are now routinely managed with lifelong anticoagulation solely to reduce
16 the risk of having the filter in place, subjecting patients to the risks and inconvenience of
17 anticoagulation.

18 63. Defendants also failed to adequately disclose the risks of these filters, such as
19 migration, fracture, perforation, tilt, thrombosis, the prothrombotic nature of the devices, that the
20 devices may not be retrievable, or that these failures were known to be causing severe injuries and
21 death or the rate at which these events were occurring.

22 64. Defendants labeling was additionally defective in that it directed physicians to
23 implant the OptEase filter upside down. When the OptEase was placed as directed by the labeling,
24 the hooks designed to ensure stability were facing in the wrong direction, rendering an already
25 inadequate anchoring system even further defective. As Defendants’ now explain in their labeling,
26 implanting the device in this fashion “can result in life threatening or serious injury including, but
27 not limited to dissection, vessel perforation, migration of the filter with secondary damage to
28 cardiac structures, ineffective pulmonary embolism prevention or death.”

1 65. Defendants began a series of recalls on March 29, 2013 relating to its labeling, which
2 instructed physicians to implant the devices upside down. These recalls were not timely, nor did
3 they fully correct the defects in Defendants' labeling. Further, Defendants downplayed the danger
4 patients were exposed to and failed to take adequate steps to ensure patients actually received notice
5 of the recall.

6 66. The FDA classified the initial recall as a Class I recall, which are the most serious
7 type of recall and involve situations in which the FDA has determined there is a reasonable
8 probability that use of these products will cause serious adverse health consequences or death.

9 67. Defendants have admitted that any patients implanted with one of these recalled
10 units should receive medical monitoring. Specifically, these patients should undergo imaging to
11 ascertain whether or not the device was properly deployed and, if not, be assessed for removal.

12 68. Given the unreasonably high failure and injury rates associated with Defendants
13 filters when left implanted long-term, Defendants should be required to pay for medical monitoring
14 to assess the condition of these devices and whether or not retrieval should be undertaken.

15 **ESTOPPEL FROM PLEADING STATUTES OF LIMITATIONS OR REPOSE**

16 69. Plaintiffs incorporate by reference all prior allegations.

17 70. Plaintiffs are within the applicable statute of limitations for their claims because
18 Plaintiffs (and their healthcare professionals) did not discover, and could not reasonably discover,
19 the defects and unreasonably dangerous condition of Defendants' IVC filters.

20 71. Plaintiffs' ignorance of the defective and unreasonably dangers nature of
21 Defendants' IVC filters, and the causal connection between these defects and Plaintiffs' injuries and
22 damages, is due in large part to Defendants' acts and omissions in fraudulently concealing
23 information from the public and misrepresenting and/or downplaying the serious threat to public
24 safety its products present.

25 72. In addition, Defendants are estopped from relying on any statutes of limitation or
26 repose by virtue of its unclean hands, acts of fraudulent concealment, affirmative misrepresentations
27 and omissions.

28

1 73. Such conduct includes intentional concealment from Plaintiffs, Plaintiffs' prescribing
2 health care professionals, the general consuming public and the FDA of material information that
3 Defendants' filters had not been demonstrated to be safe or effective, and carried with them the
4 risks and dangerous defects described above.

5 74. Defendants had a duty to disclose the fact that Defendants' filters are not safe or
6 effective, not as safe as other filters on the market, defective, and unreasonably dangerous, and that
7 their implantation and use carried the above described risks.

8 **COUNT I:**
9 **STRICT PRODUCTS LIABILITY- DESIGN DEFECT**
10 **By all Plaintiffs**

11 75. Plaintiffs re-allege and incorporate by reference each and every allegation contained
12 in the foregoing paragraphs as though fully set forth herein.

13 76. At all times relevant to this action, Defendants developed, tested, designed,
14 manufactured, inspected, labeled, promoted, distributed and sold into the stream of commerce the
15 TrapEase and OptEase filters, including the devices implanted in Plaintiffs.

16 77. The devices implanted in plaintiffs were in a condition unreasonably dangerous at
17 the time they left Defendants' control.

18 78. The devices implanted in Plaintiffs were expected to, and did, reach their intended
19 consumers without substantial change in the condition in which they were in when they left
20 Defendants' possession. In the alternative, any changes that were made to the devices implanted in
21 Plaintiffs were reasonably foreseeable to Defendants.

22 79. The TrapEase and OptEase filters, including the devices implanted in Plaintiffs, were
23 defective in design and unreasonably dangerous at the time they left Defendants' possession
24 because they failed to perform as safely as an ordinary consumer would expect when used as
25 intended or in a manner reasonably foreseeable by the Defendants, and because the foreseeable risks
26 of these devices exceeded the alleged benefits associated with their use.
27
28

1 80. At the time Defendants placed their TrapEase and OptEase filters, including the
2 device implanted in Plaintiffs, into the stream of commerce, safer alternative designs were
3 commercially, technologically, and scientifically attainable and feasible.

4 81. Plaintiffs and their health care providers used the devices in a manner that was
5 reasonably foreseeable to Defendants.

6 82. Neither Plaintiffs, nor their health care providers, could have by the exercise of
7 reasonable care discovered the defective condition or perceived the unreasonable dangers with these
8 devices prior to Plaintiffs' implantation with the devices.

9 83. As a direct and proximate result of the defective and unreasonably dangerous
10 condition of the TrapEase and OptEase filters, Plaintiffs suffered injuries and damages.

11 WHEREFORE, Plaintiffs demand judgment against Defendants as hereinafter set forth.
12

13
14 **COUNT II:**
15 **STRICT PRODUCTS LIABILITY — INADEQUATE WARNING**
16 **By all Plaintiffs**

17 84. Plaintiffs re-allege and incorporate by reference each and every allegation contained
18 in the foregoing paragraphs as though fully set forth herein.

19 85. Prior to, on, and after the dates during which the device were implanted in Plaintiffs,
20 and at all relevant times, Defendants manufactured, designed, marketed, distributed, and sold the
21 TrapEase and OptEase filters.

22 86. The TrapEase and OptEase filters had potential risks and side effects that were
23 known or knowable to Defendants by the use of scientific knowledge available before, at, and after
24 the manufacture, distribution, and sale of the devices implanted in Plaintiffs.

25 87. Defendants knew or it was knowable at the time they distributed the devices
26 implanted in Plaintiffs that the TrapEase and OptEase filters posed a significant and higher risk of
27 failure than other similar IVC filters, including for fracture, migration, tilting, thrombosis,
28

1 migration, tilt, inability to retrieve and pulmonary embolism and that these failures were resulting in
2 serious patient injuries and death. Defendants also knew or it was knowable that these devices were
3 actually prothrombotic, that use of these filters did not improve patient outcomes, and the longer
4 these filters were left implanted increased the likelihood of a device failure.

5
6 88. Defendants' TrapEase and OptEase filters were in a defective condition that was
7 unreasonably and substantially dangerous to any user or consumer implanted with the filters, such
8 as Plaintiffs, when used in an intended and reasonably foreseeable way. Such ordinary consumers,
9 including Plaintiffs and their prescribing physician(s), would not and could not have recognized or
10 discovered the potential risks and side effects of the device, as set forth herein.

11
12 89. The warnings and directions Defendants provided with its TrapEase and OptEase
13 filters, including the devices implanted in Plaintiffs, failed to adequately warn of the above-
14 described risks and side-effects, whether as to existence of the risk, its likelihood, severity, or the
15 comparative risk to other products.

16
17 90. The labeling also failed to provide adequate directions on how to appropriately use
18 the product.

19
20 91. The devices were expected to and did reach Plaintiffs without substantial change in
21 its condition, labeling, or warnings as manufactured, distributed, and sold by Defendants.
22 Additionally, Plaintiffs and their prescribing physicians used the devices in the manner in which
23 they were intended to be used, making such use reasonably foreseeable to Defendants.

24
25 92. Defendants' lack of sufficient instructions or warnings prior to, on, and after the date
26 Plaintiffs used the devices was a substantial factor in causing Plaintiffs' injuries and damages, as
27 described herein.

28
WHEREFORE, Plaintiff demands judgment against Defendants as hereinafter set forth.

COUNT III:
STRICT PRODUCTS LIABILITY — MANUFACTURING DEFECT
By all Plaintiffs

93. Plaintiffs re-allege and incorporate by reference each and every allegation contained in the foregoing paragraphs as though fully set forth herein.

94. Prior to, on, and after the date the devices were implanted in Plaintiffs, and at all relevant times, Defendants designed, distributed, manufactured, sold, and marketed the TrapEase and OptEase filters for use in the United States.

95. At all times herein mentioned, Defendants designed, distributed, manufactured, marketed, and sold the devices such that they were dangerous, unsafe, and defective in manufacture, and contained a manufacturing defect when it left defendants' possession.

96. Plaintiffs are informed and believe, and on that basis allege, that the TrapEase and OptEase filters, including the devices implanted in them, contained manufacturing defects, in that they differed from Defendants' design or specifications, or from other typical units of the same product line.

97. As a direct and proximate result of Defendants' defective manufacture and sale of the TrapEase and OptEase filters prior to, on, and after the date Plaintiffs used the devices, Plaintiffs suffered the injuries and damages herein described.

WHEREFORE, Plaintiffs demand judgment against Defendants as hereinafter set forth.

COUNT IV:
NEGLIGENCE
By all Plaintiffs

98. Plaintiffs re-allege and incorporate by reference each and every allegation contained in the foregoing paragraphs as though fully set forth herein.

99. Prior to, on, and after the date the devices were implanted in Plaintiffs, and at all relevant times, Defendants designed, distributed, manufactured, sold, and marketed the TrapEase and OptEase filters for use in the United States.

1 100. Defendants had a duty to exercise reasonable and prudent care in the development,
2 testing, design, manufacture, inspection, marketing, labeling, promotion, distribution and sale of the
3 TrapEase and OptEase filters so as to avoid exposing others to foreseeable and unreasonable risks
4 of harm.

5 101. Defendants knew or reasonably should have known that the TrapEase and OptEase
6 filters were dangerous or were likely to be dangerous when used in an intended or reasonably
7 foreseeable manner.

8 102. At the time of manufacture and sale of the TrapEase and OptEase filters, Defendants
9 knew or should have known that the TrapEase and OptEase filters:
10

11 a. Were designed and manufactured in such a manner as to lack sufficient
12 structural integrity (fatigue resistance) and stability (tilt/migration) to meet user
13 needs when used in an intended and reasonably foreseeable manner.

14 b. Were designed and manufactured so as to present an unreasonable risk of the
15 devices perforating the vena cava wall and/or in the case of the OptEase filter
16 becoming irretrievable;

17 c. Being designed and manufactured in such a manner as to be prothrombotic.
18

19 103. At the time of manufacture and sale of the TrapEase and OptEase filters, including
20 the ones implanted in Plaintiffs, Defendants knew or should have known that using the TrapEase
21 and OptEase filters as intended or in a reasonably foreseeable manner created a significant risk of
22 patients suffering severe health side effects including, but not limited to: hemorrhage;
23 cardiac/pericardial tamponade; cardiac arrhythmia and other symptoms similar to myocardial
24 infarction; perforations of tissue, vessels and organs; chronic deep vein thrombosis; pulmonary
25 embolism; thrombosis; compartment syndrome; and other severe personal injuries and diseases,
26 which are permanent in nature, including, but not limited to, death, physical pain and mental
27 anguish, scarring and disfigurement, diminished enjoyment of life, continued medical care and
28

1 treatment due to chronic injuries/illness proximately caused by the device; and the continued risk of
2 requiring additional medical and surgical procedures including general anesthesia, with attendant
3 risk of life threatening complications.

4 104. Defendants knew or reasonably should have known that consumers of the TrapEase
5 and OptEase filters, including Plaintiffs' prescribing physicians, would not realize the danger
6 associated with using the devices for their intended or reasonably foreseeable use.
7

8 105. Defendants breached their to duty to exercise reasonable and prudent care in the
9 development, testing, design, manufacture, inspection, marketing, labeling, promotion, distribution
10 and sale of the TrapEase and OptEase filters in, among other ways, the following acts and
11 omissions:

- 12 a. Designing and distributing a product in which they knew or should have known that
13 the likelihood and severity of potential harm from the product exceeded the burden
14 of taking safety measures to reduce or avoid harm;
15
16 b. Designing and distributing a product in which they knew or should have known that
17 the likelihood and severity of potential harm from the product exceeded the
18 likelihood of potential harm from other devices and treatment options available for
19 the same purpose;
20
21 c. Failing to use reasonable care in manufacturing the product and producing a product
22 that differed from their design or specifications or from other typical units from the
23 same production line;
24
25 d. Failing to use reasonable care to warn or instruct, including pre and post-sale,
26 Plaintiffs, their prescribing physicians, or the general health care community about
27 the TrapEase and OptEase filters' substantially dangerous condition or about facts
28 making the products likely to be dangerous;

- c. Failing to recall, retrofit, or provide adequate notice of such actions to Plaintiffs or their health providers.
- f. Failing to perform reasonable pre and post-market testing of the TrapEase and OptEase filters to determine whether or not the products were safe for their intended use;
- g. Failing to provide adequate instructions, guidelines, and safety precautions, including pre and post-sale, to those persons to whom it was reasonably foreseeable would prescribe, use, and implant the TrapEase and OptEase filters;
- h. Advertising, marketing and recommending the use of the TrapEase and OptEase filters, while concealing and failing to disclose or warn of the dangers known by Defendants to be connected with and inherent in the use of these filter systems;
- i. Representing that the TrapEase and OptEase filters were safe for their intended use when, in fact, Defendants knew and should have known the products were not safe for their intended uses;
- j. Continuing to manufacture and sell the TrapEase and OptEase filters with the knowledge that said products were dangerous and not reasonably safe, and failing to comply with good manufacturing regulations;
- k. Failing to use reasonable and prudent care in the design, research, manufacture, and development of the TrapEase and OptEase filters so as to avoid the risk of serious harm associated with the use of these filter systems;
- l. Advertising, marketing, promoting and selling TrapEase and OptEase filters for uses other than as approved and indicated in the product's label;
- m. Failing to establish an adequate quality assurance program used in the design and manufacture of the TrapEase and OptEase filters.
- n. Failing to establish and maintain an adequate post-market surveillance program;

1 106. A reasonable manufacturer, distributor, or seller under the same or similar
2 circumstances would not have engaged in the before-mentioned acts and omissions.

3 107. Defendants' negligence prior to, on, and after the date of implantation of the devices
4 in Plaintiffs was a substantial factor in causing Plaintiffs' injuries and damages, as described herein.

5 WHEREFORE, Plaintiff demands judgment against Defendants as hereinafter set forth.

6
7 **COUNT V:**
8 **NEGLIGENT MISREPRESENTATION**
9 **By all Plaintiffs**

10 108. Plaintiffs re-allege and incorporate by reference each and every allegation contained
11 in the foregoing paragraphs as though fully set forth herein.

12 109. Prior to, on, and after the date the devices were implanted in Plaintiffs, and at all
13 relevant times, Defendants negligently and carelessly represented to Plaintiffs, their health care
14 providers, and the general public that certain material facts were true. The representations include,
15 *inter alia*, the following:

- 16 a. That the TrapEase and OptEase filters were safe, fit, and effective for use.
17 b. that the design of the TrapEase and OptEase filters eliminated the risk that pieces of
18 the device could perforate the vena cava, that the devices could tilt, or that fractures
19 could occur and migrate throughout the body.
20 c. That the TrapEase and OptEase filters was safer and more effective than other
21 available IVC filters.
22 d. That the OptEase filter was "easy" to remove.

23
24 110. Prior to, on, and after the dates during which Plaintiffs and their physicians
25 purchased and used the device, said representations were not true, and there was no reasonable
26 ground for believing said representations to be true at the times said representations were made.
27
28

1 111. Prior to, on, and after the dates during which Plaintiffs and their physicians
2 purchased and used the device, Defendants intended that Plaintiffs, their physicians, and the general
3 public would rely on said representations, which did in fact occur.

4 112. Defendants' negligent misrepresentations prior to, on, and after the date when
5 Plaintiffs and their physicians purchased and used the devices were a substantial factors in causing
6 Plaintiff's injuries and damages, as described herein.

7 WHEREFORE, Plaintiff demands judgment against Defendants as hereinafter set forth.

8
9 **COUNT VI**
FRAUD - MISREPRESENTATION
10 **By all Plaintiffs**

11 113. Plaintiffs re-allege and incorporate by reference each and every allegation contained
12 in the foregoing paragraphs as though fully set forth herein.

13 114. At all times relevant to this cause, and as detailed above, Defendants intentionally
14 provided Plaintiffs, their physicians, the medical community and the FDA with false or inaccurate
15 information, and/or omitted material information concerning the Device, including, but not limited
16 to, misrepresentations regarding the following topics:

- 17 a. The safety of the device;
18 b. The efficacy of the device;
19 c. The rate of failure of the device;
20 d. The pre-market testing of the device; and
21 e. The approved uses of the device.

22 115. The information distributed by Defendants to the public, the medical community,
23 Plaintiffs and their physicians was in the form of reports, press releases, advertising campaigns,
24 labeling materials, print advertisements, commercial media containing material representations, and
25 instructions for use, as well as through their officers, directors, agents, and representatives. These
26 materials contained false and misleading material representations, which included:

- 27 a. That the device was safe, fit, and effective when used for its intended purpose or in a
28 reasonably foreseeable manner;

- 1 b. that it did not pose dangerous health risks in excess of those associated with the use
2 of other similar devices;
- 3 c. That the design of the device would eliminate the risk that pieces of the device could
4 perforate the vena cava, that the devices could tilt, or that fractures could occur and
5 migrate throughout the body;
- 6 d. That the device was safer and more effective than other available IVC filters; and
7 e. That the OptEase filter was "easy" to remove.

8 116. Defendants made the foregoing misrepresentations knowing that they were false.
9 These materials included instructions for use and a warning document that was included in the
10 package of the devices implanted in Plaintiffs.

11 117. Defendants' intent and purpose in making these misrepresentations was to deceive
12 and defraud Plaintiffs and their health care providers; to gain the confidence of Plaintiffs and their
13 health care providers; to falsely assure them of the quality of the device and its fitness for use; and
14 to induce the public and the medical community, including Plaintiffs' healthcare providers to
15 request, recommend, prescribe, implant, purchase, and continue to use the device, all in reliance on
16 Defendants' misrepresentations.

17 118. The foregoing representations and omissions by Defendants were in fact false.

18 119. Defendants acted to serve their own interests and having reasons to know
19 consciously disregarded the substantial risk that the device could kill or significantly harm patients.

20 120. In reliance upon the false representations made by Defendants, Plaintiffs and their
21 health care providers were induced to, and did use the device, thereby causing Plaintiffs to sustain
22 the injuries described herein.

23 121. Defendants knew and had reason to know that Plaintiffs, their health care providers,
24 or the general medical community did not have the ability to determine the true facts intentionally
25 concealed and misrepresented by Defendants, and would not have prescribed and implanted same, if
26 the true facts regarding the device had not been concealed and misrepresented by Defendants.
27
28

122. Defendants had sole access to material facts concerning the defective nature of the TrapEase and OptEase filters and their propensity to cause serious side effects in the form of dangerous injuries and damages to persons who are implanted with the device.

123. At the time Defendants failed to disclose and intentionally misrepresented the foregoing facts, and at the time Plaintiffs' health care providers purchased and used these devices, Plaintiffs' health care providers were unaware of Defendants' misrepresentations.

124. Plaintiffs' health care providers reasonably relied upon misrepresentations made by Defendants where the concealed and misrepresented facts were critical to understanding the true dangers inherent in the use of the device.

125. Defendants' fraudulent misrepresentations prior to, on, and after the date Plaintiffs and their physicians purchased and used the devices were a substantial factor in causing Plaintiff's injuries and damages, as described herein.

WHEREFORE, Plaintiffs demand judgment against defendants as hereinafter set forth.

COUNT VII
FRAUDULENT CONCEALMENT
By all Plaintiffs

126. Plaintiffs re-allege and incorporate by reference each and every allegation contained in the foregoing paragraphs as though fully set forth herein.

127. In marketing and selling the device, defendants concealed material facts from Plaintiffs and their health care providers.

128. Defendants' concealed material facts including, but not limited to, the following:

- a. That the device was unsafe and not fit when used for its intended purpose or in a reasonably foreseeable manner;
- b. That the device posed dangerous health risks in excess of those associated with the use of other similar devices;
- c. That there were additional side effects related to implantation and use of the device that were not accurately and completely reflected in the warnings associated with the device;
- d. That the device was not adequately tested to withstand normal placement within the human body; and

1 e. That Defendants were aware at the time Plaintiffs' filters were distributed
2 that electropolishing reduced the risk of fracture and was industry standard
3 for NITINOL medical devices.

4 129. Plaintiffs and their healthcare providers were not aware of these and other facts
5 concealed by Defendants.

6 130. The Defendants are and were under a continuing duty to disclose the true character,
7 quality and nature of the device that was implanted in Plaintiff, but instead they concealed them.
8 Defendants' conduct, as described in this complaint, amounts to conduct purposely committed,
9 which Defendants must have realized was dangerous, heedless and reckless, without regard to the
10 consequences or the rights and safety of Plaintiff.

11 131. In concealing these and other facts, Defendants intended to deceive Plaintiffs and
12 their health care providers by concealing said facts.

13 132. Plaintiffs and their healthcare providers reasonably and justifiably relied on
14 Defendants' concealment and deception.

15 133. Defendants' concealment prior to, on, and after the date Plaintiffs and their
16 healthcare providers purchased and used the devices implanted in Plaintiffs was a substantial factor
17 in causing Plaintiffs' injuries and damages, as described herein.

18 WHEREFORE, Plaintiffs demand judgment against defendants as hereinafter set forth.

19 **COUNT VIII**
20 **EXPRESS WARRANTY**
21 **By all Plaintiffs**

22 134. Plaintiffs re-allege and incorporate by reference each and every allegation contained
23 in the foregoing paragraphs as though fully set forth herein.

24 135. Prior to, on, and after the dates during which Plaintiffs were implanted with these
25 devices, and at all relevant times, Defendants, and each of them, had knowledge of the purpose for
26 which the devices were to be used, and represented the devices to be in all respects safe, effective,
27 and proper for such purpose. Said warranties and representations were made to Plaintiffs and their
28 treating physicians. Plaintiffs and their treating physicians relied on said warranties and
representations in deciding to use the device.

1 136. Defendants used packaging inserts and media advertisements to represent to the
2 medical community and consumers, including plaintiffs and their health care providers, that the
3 TrapEase and OptEase filters: were safe for their intended use; did not pose serious health hazards
4 when used appropriately; were safer and more effective than alternative IVC filters; had been
5 adequately tested for their intended use; would not perforate the vena cava, tilt, or fracture and
6 migrate throughout the body after placement; and that the OptEase filter was "easy" to remove.

7 137. Defendants, and each of them, breached the above-described express warranties and
8 representations in that the TrapEase and OptEase filters did not conform to these express warranties
9 and representations.

10 138. Prior to, on, and after the dates during which Plaintiffs and their physicians
11 purchased and used these devices, Defendants, and each of them, were put on notice of the
12 TrapEase and OptEase filters' inability to conform to these express warranties.

13 139. Defendants' breach of said express warranties and representations prior to, on, and
14 after the date Plaintiffs and their physicians purchased and used the devices was a substantial factor
15 in causing Plaintiffs' injuries and damages, as described herein.

16 WHEREFORE, Plaintiffs demand judgment against Defendants as hereinafter set forth.

17 **COUNT IX**
18 **BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY**
19 **By all Plaintiffs**

20 140. Plaintiffs re-allege and incorporate by reference each and every allegation contained
21 in the foregoing paragraphs as though fully set forth herein.

22 141. Defendants sold the TrapEase and OptEase filters for Plaintiffs' ultimate use.

23 142. At all times hereinafter mentioned, Defendants were in the business of developing,
24 designing, licensing, manufacturing, selling, distributing and/or marketing the TrapEase and
25 OptEase filters, including the one implanted in Plaintiffs.

26 143. Defendants impliedly warranted to Plaintiffs and their physicians that the TrapEase
27 and OptEase filters were safe and of merchantable quality and for the ordinary purpose for which
28 they product was intended and marketed to be used.

1 144. The representations and implied warranties made by Defendants were false,
2 misleading, and inaccurate because the TrapEase and OptEase filters were defective, unsafe,
3 unreasonably dangerous, and not of merchantable quality, when used as they were marketed and
4 intended to be used. Specifically, at the time Plaintiffs and their physicians purchased and used the
5 devices, the products were not in a merchantable condition in that:

- 6 a. They offered no benefit to patient outcomes,
7 b. They suffered an unreasonably high failure and injury rates, and
8 c. The surface of the devices were manufactured and designed in such a way that they
9 were distributed with surface damage that substantially increased the risk of fracture.
10 d. They were prothrombotic;

11 145. Defendants' breach of said implied warranties and representations prior to, on, and
12 after the date Plaintiffs and their physicians purchased and used the devices was a substantial factor
13 in causing Plaintiffs' injuries and damages, as described herein.

14 WHEREFORE, Plaintiffs demand judgment against Defendants as hereinafter set forth.

15 **COUNT X**
16 **LOSS OF CONSORTIUM**
By Plaintiff Carol Flanagan

17 146. Plaintiffs Carol Flanagan and Harlowe Currie re-allege and incorporate by reference
18 each and every allegation contained in the foregoing paragraphs as though fully set forth herein.

19 147. Plaintiff Carol Flanagan is, and at all time herein mentioned was, the lawful spouse
20 of Plaintiff Robert Flanagan.

21 148. Plaintiff Harlowe Currie is, and at all time herein mentioned was, the lawful spouse
22 of Plaintiff Robert Flanagan.

23 149. As a direct, legal and proximate result of the culpability and fault of the Defendants,
24 be such fault through strict liability or negligence, Plaintiffs Carol Flanagan and Harlowe Currie
25 suffered the loss of support, service, love, companionship, affection, society, intimate relations, and
26 other elements of consortium, all to their general damage, in an amount in excess of the
27 jurisdictional minimum of this Court.
28

1 WHEREFORE, Plaintiffs Carol Flanagan and Harlowe Currie demand judgment against the
2 Defendants as hereinafter set forth.

3 **PUNITIVE DAMAGES ALLEGATIONS**

4 150. Plaintiff re-alleges and incorporates by reference each and every allegation contained
5 in the foregoing paragraphs as though fully set forth herein.

6 151. Upon information and belief, Plaintiffs allege that as early as 2003, Defendants were
7 aware and had knowledge of the fact that the TrapEase and OptEase filters were defective and
8 unreasonably dangerous and were causing injury and death to patients.

9 152. Data establishes that the failure rates of the TrapEase and OptEase filters are and
10 were much higher than what Defendants have in the past and currently continue to publish to the
11 medical community and members of the public. Further, Defendants were aware or should have
12 been aware that the TrapEase and OptEase filters had substantially higher failure rates than other
13 similar products on the market and are actually prothrombotic. Defendants were also aware that
14 there was no reliable evidence indicating its devices actually improved patient outcomes. Despite
15 these facts, Defendants continued to sell an unreasonably dangerous product while concealing and
16 misrepresenting its risks and benefits to the public, plaintiffs, plaintiffs' health care providers, and
17 the FDA.

18 153. The conduct of Defendants as alleged in this Complaint constitutes willful, wanton,
19 gross, and outrageous corporate conduct that demonstrates a conscious disregard for the safety of
20 Plaintiff. Defendants had actual knowledge of the dangers presented by TrapEase and OptEase
21 filters, yet consciously failed to act reasonably to:

- 22 a. Inform or warn Plaintiffs, Plaintiffs' physicians, or the public at large of these
23 dangers; and
24 b. Establish and maintain an adequate quality and post-market surveillance
25 system.

26 154. Despite having knowledge as early as 2003 of the unreasonably dangerous and
27 defective nature of the TrapEase and OptEase filters, Defendants consciously disregarded the
28 known risks and continued to actively market and offer for sale the TrapEase and OptEase filters.

1 Plaintiffs further allege that Defendants acted in willful, wanton, gross, and total disregard for the
2 health and safety of the users or consumers of their TrapEase and OptEase filters, acted to serve
3 their own interests, and consciously disregarded the substantial risk that their product might kill or
4 significantly harm patients, or significantly injure the rights of others. Despite this knowledge,
5 Defendants consciously pursued a course of conduct knowing that such conduct created a
6 substantial risk of significant harm to other persons.

7 **PRAYER FOR DAMAGES**

8 **WHEREFORE**, Plaintiffs pray for relief against Defendants Cordis Corporation, Confluent
9 Medical Technologies, Inc., and Does 1 through 100, inclusive, on the entire complaint, as follows:

- 10 a. General damages according to proof at the time of trial;
- 11 b. Special (economic) damages, including without limitation, past and future medical
12 expenses and past and future lost wages according to proof at time of trial.
- 13 c. Pre-judgment and post-judgment interest pursuant to the laws of the State of
14 California;
- 15 d. Costs of suit incurred herein;
- 16 e. Punitive damages in an amount sufficient to punish Defendants and deter similar
17 conduct in the future;
- 18 f. For such further and other relief as this Court deems necessary, just and proper.
- 19
- 20

21 **DEMAND FOR JURY TRIAL**

22 Plaintiffs hereby demand trial by jury on all issues.

23

24 DATED: May 24, 2016

Respectfully Submitted,

BRENES LAW GROUP

26 /s/ Troy A. Brenes

27 Troy A. Brenes
28 Attorney for Plaintiffs

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12 Attorneys for Plaintiffs

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**SUPERIOR COURT OF THE STATE OF CALIFORNIA
FOR THE COUNTY OF ALAMEDA**

HEATHER QUINN and BRIAN QUINN,
individually and as wife and husband;
KATHRYNN KIRBY, an individual;
ALLISON BRAUER, an individual; EDWARD
BROWN and PATRICIA BROWN,
individually and as husband and wife;
MICHAEL HICKSON, an individual;
WILLIAM SCHENK, an individual; and
CHRISTINA JONES, an individual;

Plaintiffs,

vs.

CORDIS CORPORATION; JOHNSON &
JOHNSON; and DOES 1 through 50;

Defendants.

Case No.:

COMPLAINT FOR DAMAGES

1. STRICT PRODUCTS LIABILITY -
DESIGN DEFECT
2. STRICT PRODUCTS LIABILITY -
FAILURE TO WARN
3. STRICT PRODUCTS LIABILITY -
MANUFACTURING DEFECT
4. NEGLIGENCE
5. NEGLIGENT MISREPRESENTATION
6. FRAUDULENT MISREPRESENTATION
7. FRAUDULENT CONCEALMENT
8. BREACH OF EXPRESS WARRANTY
9. BREACH OF IMPLIED WARRANTY OF
MERCHANTABILITY
10. LOSS OF CONSORTIUM

DEMAND FOR JURY TRIAL

COMES NOW, Plaintiffs, by and through their attorneys, who complain and allege against
Defendants CORDIS CORPORATION, JOHNSON & JOHNSON, and DOES 1 through 50, and each of
them, on information and belief, as follows:

**ENDORSED
FILED
ALAMEDA COUNTY**

MAY - 3 2016 *JP*

CLERK OF THE SUPERIOR COURT
By MARGARET J. DOWNI
Deputy

BY FAX

INTRODUCTION

1
2 1. Plaintiffs bring this action for personal injuries damages suffered as a direct and
3 proximate result of being implanted with a defective and unreasonably dangerous Inferior Vena Cava
4 (“IVC”) filter medical device manufactured by Defendants.

5 2. The subject IVC filters include the following devices: TrapEase Vena Cava Filter
6 (“TrapEase filter”) and OptEase Vena Cava Filter (“OptEase filter”) (for convenience, these devices will
7 be referred to in this complaint under the generic terms “Cordis IVC filters” or “Defendants’ IVC
8 filters”). At all times relevant to this action, Defendants developed, designed, licensed, manufactured,
9 sold, distributed and/or marketed the Cordis IVC filters to be implanted in patients throughout the
10 United States, including California.

11 3. Plaintiffs’ claims for damages all relate to Defendants’ design, manufacture, sale, testing,
12 marketing, labeling, advertising, promotion, and/or distribution of its IVC filters.

13 4. The Cordis IVC filters that are the subject of this action all reached Plaintiffs and
14 Plaintiffs’ physicians without substantial change in condition from the time they left Defendants’
15 possession.

16 5. Plaintiffs and Plaintiffs’ physicians used the Cordis IVC filters in the manner in which
17 they were intended.

18 6. Defendants are solely responsible for any alleged design, manufacture or information
19 defect its IVC filters contain.

20 7. Defendants do not allege that any other person or entity is comparatively at fault for any
21 alleged design, manufacture, or informational defect its IVC filters contain.

PARTIES

22
23 8. Plaintiff HEATHER QUINN at all times relevant to this action was and is a citizen and
24 resident of the State of California. Plaintiff HEATHER QUINN underwent placement of Defendants’
25 TrapEase Vena Cava Filter on or about March 19, 2001, in California. The filter subsequently
26 malfunctioned and caused injury and damages to Plaintiff HEATHER QUINN, including, but not
27 limited to, fracture, tilt, migration and perforation. As a direct and proximate result of these
28 malfunctions, Plaintiff HEATHER QUINN suffered life-threatening injuries and damages, and required

1 extensive medical care and treatment. As a further proximate result, Plaintiff HEATHER QUINN has
2 suffered and will continue to suffer significant medical expenses, and pain and suffering, and other
3 damages.

4 9. Plaintiff BRIAN QUINN at all times relevant to this action was and is a citizen and
5 resident of the State of California. Plaintiffs HEATHER QUINN and BRIAN QUINN were and are, at
6 all times relevant to this action, legally married as wife and husband. Plaintiff BRIAN QUINN brings
7 this action for, *inter alia*, the loss of consortium, comfort, and society he suffered due to the personal
8 injuries suffered by his wife, HEATHER QUINN.

9 10. Plaintiff KATHRYNN KIRBY at all times relevant to this action was and is a citizen and
10 resident of the State of South Carolina. Plaintiff KATHRYNN KIRBY underwent placement of
11 Defendants' OptEase Vena Cava Filter on or about May 22, 2007. The filter subsequently
12 malfunctioned and caused injury and damages to Plaintiff KATHRYNN KIRBY, including, but not
13 limited to, tilt, perforation, filter embedded in wall of the IVC, IVC thrombosis, unsuccessful removal
14 attempt, filter unable to be retrieved, and narrowing of her IVC. As a direct and proximate result of
15 these malfunctions, Plaintiff KATHRYNN KIRBY suffered life-threatening injuries and damages, and
16 required extensive medical care and treatment. As a further proximate result, Plaintiff KATHRYNN
17 KIRBY has suffered and will continue to suffer significant medical expenses, and pain and suffering,
18 and other damages.

19 11. Plaintiff ALLISON BRAUER at all times relevant to this action was and is a citizen and
20 resident of the State of Tennessee. Plaintiff ALLISON BRAUER underwent placement of Defendants'
21 OptEase Vena Cava Filter on or about May 1, 2013. The filter subsequently malfunctioned and caused
22 injury and damages to Plaintiff ALLISON BRAUER, including, but not limited to, tilt, filter embedded
23 in wall of the IVC, and filter unable to be retrieved. As a direct and proximate result of these
24 malfunctions, Plaintiff ALLISON BRAUER suffered life-threatening injuries and damages, and required
25 extensive medical care and treatment. As a further proximate result, Plaintiff ALLISON BRAUER has
26 suffered and will continue to suffer significant medical expenses, and pain and suffering, and other
27 damages.

1 12. Plaintiff EDWARD BROWN at all times relevant to this action was and is a citizen and
2 resident of the State of Texas. Plaintiff EDWARD BROWN underwent placement of Defendants'
3 OptEase Vena Cava Filter on or about September 1, 2005. The filter subsequently malfunctioned and
4 caused injury and damages to Plaintiff EDWARD BROWN, including, but not limited to, migration, tilt,
5 filter embedded in wall of the IVC, and filter unable to be retrieved. As a direct and proximate result of
6 these malfunctions, Plaintiff EDWARD BROWN suffered life-threatening injuries and damages, and
7 required extensive medical care and treatment. As a further proximate result, Plaintiff EDWARD
8 BROWN has suffered and will continue to suffer significant medical expenses, and pain and suffering,
9 and other damages.

10 13. Plaintiff PATRICIA BROWN at all times relevant to this action was and is a citizen and
11 resident of the State of Texas. Plaintiffs EDWARD BROWN and PATRICIA BROWN were and are, at
12 all times relevant to this action, legally married as husband and wife. Plaintiff PATRICIA BROWN
13 brings this action for, *inter alia*, the loss of consortium, comfort, and society he suffered due to the
14 personal injuries suffered by her husband, EDWARD BROWN.

15 14. Plaintiff MICHAEL HICKSON at all times relevant to this action was and is a citizen
16 and resident of the State of Tennessee. Plaintiff MICHAEL HICKSON underwent placement of
17 Defendants' TrapEase Vena Cava Filter on or about January 11, 2008. The filter subsequently
18 malfunctioned and caused injury and damages to Plaintiff MICHAEL HICKSON, including, but not
19 limited to, fracture, migration of entire filter to heart, perforation of filter struts into vena cava and
20 organs, tilt, filter embedded in wall of the IVC, requiring emergency open-heart surgery. As a direct and
21 proximate result of these malfunctions, Plaintiff MICHAEL HICKSON suffered life-threatening injuries
22 and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff
23 MICHAEL HICKSON has suffered and will continue to suffer significant medical expenses, and pain
24 and suffering, and other damages.

25 15. Plaintiff WILLIAM SCHENK at all times relevant to this action was and is a citizen and
26 resident of the State of Illinois. Plaintiff WILLIAM SCHENK underwent placement of Defendants'
27 OptEase Vena Cava Filter on or about December 28, 2004. The filter subsequently malfunctioned and
28 caused injury and damages to Plaintiff WILLIAM SCHENK, including, but not limited to, tilt, filter

1 embedded in wall of the IVC, unsuccessful removal attempt, and filter unable to be retrieved. As a
2 direct and proximate result of these malfunctions, Plaintiff WILLIAM SCHENK suffered life-
3 threatening injuries and damages, and required extensive medical care and treatment. As a further
4 proximate result, Plaintiff WILLIAM SCHENK has suffered and will continue to suffer significant
5 medical expenses, and pain and suffering, and other damages.

6 16. Plaintiff CHRISTINA JONES at all times relevant to this action was and is a citizen and
7 resident of the State of Kentucky. Plaintiff CHRISTINA JONES underwent placement of Defendants'
8 OptEase Vena Cava Filter on or about December 9, 2010. The filter subsequently malfunctioned and
9 caused injury and damages to Plaintiff CHRISTINA JONES, including, but not limited to, tilt, filter
10 embedded in wall of the IVC, unsuccessful removal attempt, and filter unable to be retrieved. As a
11 direct and proximate result of these malfunctions, Plaintiff CHRISTINA JONES suffered life-
12 threatening injuries and damages, and required extensive medical care and treatment. As a further
13 proximate result, Plaintiff CHRISTINA JONES has suffered and will continue to suffer significant
14 medical expenses, and pain and suffering, and other damages.

15 17. Defendant CORDIS CORPORATION ("Cordis"), including its department, division, and
16 subsidiary, Cordis Endovascular, is a corporation or business entity organized and existing under the
17 laws of the State of California with its headquarters located at 6500 Paseo Padre Pkwy., Fremont,
18 California, 94555. Cordis may be served with process by serving its registered agent, CT Corporation
19 System, at 818 West Seventh Street, Suite 930, Los Angeles, California, 90017.

20 18. Defendant CORDIS COPORATION was a wholly-owned subsidiary of Defendant
21 JOHNSON & JOHNSON ("J&J") and part of the J&J family of companies until in or around October
22 2015. J&J is a corporation or business entity organized and existing under the laws of the State of New
23 Jersey with its headquarters located in New Jersey.

24 19. The true names or capacities, whether individual, corporate, or otherwise, of Defendants
25 Does 1-50, are unknown to Plaintiffs who therefore sue said Defendants by such fictitious names.
26 Plaintiffs believe and allege that each of the Defendants designated herein by fictitious names is in some
27 manner legally responsible for the events and happenings herein referred to and proximately caused
28 foreseeable damages to Plaintiffs as alleged herein.

20. All Defendants are authorized to do business in California and derive substantial income from doing business in this state.

21. As used herein, "Defendants" includes all named Defendants as well as Does 1-50.

22. Upon information and belief, Defendants did act together to design, sell, advertise, manufacture and /or distribute Cordis IVC Filters, with full knowledge of their dangerous and defective nature.

JURISDICTION AND VENUE

23. This Court has jurisdiction under the California Constitution, Article VI, Section 10 and *Code of Civil Procedure* Section 410.10. Plaintiffs' damages exceed the jurisdictional minimum of this Court.

24. Venue is proper in this Court pursuant to *Code of Civil Procedure* Sections 395 and 395.5 because the principal place of business for Defendant CORDIS CORPORATION is situated in Alameda County. Further, a substantial amount of Defendants' conduct, as alleged herein by Plaintiffs, took place in Alameda County.

BACKGROUND

INFERIOR VENA CAVA FILTERS GENERALLY

25. IVC filters were first made commercially available to the medical community in the 1960s. Over the years, medical device manufacturers have introduced several different designs of IVC filters.

26. An IVC filter is a device that is designed to filter or “catch” blood clots that travel from the lower portions of the body to the heart and lungs. IVC filters were originally designed to be permanently implanted in the IVC.

27. The IVC is a vein that returns blood to the heart from the lower portions of the body. In certain people, for various reasons, blood clots travel from the vessels in the legs and pelvis, through the vena cava and into the lungs. Oftentimes, these blood clots develop in the deep leg veins, a condition called "deep-vein thrombosis" or "DVT." Once blood clots reach the lungs, they are considered "pulmonary emboli" or "PE." Pulmonary emboli present risks to human health.

1 28. People at risk for DVT/PE can undergo medical treatment to manage the risk. For
2 example, a doctor may prescribe anticoagulant therapies such as medications like Heparin, Warfarin, or
3 Lovenox to regulate the clotting factor of the blood. In some people who are at high risk for DVT/PE
4 and who cannot manage their conditions with medications, physicians may recommend surgically
5 implanting an IVC filter to prevent thromboembolic events.

6 29. As stated above, IVC filters have been on the market for decades. All IVC filters are
7 only cleared for use by the Food & Drug Administration ("FDA") for prevention of recurrent pulmonary
8 embolism in patients at risk for pulmonary embolism and where anticoagulation therapy has failed or is
9 contraindicated.

10 30. In order to increase sales of these devices, Defendants sought to expand the market for
11 prophylactic use among nontraditional patient populations that were temporarily at risk of developing
12 blood clots.

13 31. Defendants Cordis and J&J engaged in marketing campaigns directed toward the
14 bariatric, trauma, orthopedic and cancer patient population. Expansion to these new patient groups
15 would substantially increase sales and the first manufacturer to market would capture market share.

16 32. Other manufacturers also saw this opportunity, which triggered a race to market a device
17 that provided physicians the option to retrieve the filter after the clot risk subsided.

18 33. From 2000 through 2003, manufacturers of IVC filters, including Defendants, raced
19 against each other to bring the first IVC filter to the market with the added indication of optional
20 retrieval. In 2003, the FDA cleared three different IVC filters for a retrieval indication, one of which
21 was the OptEase filter by Defendants Cordis and J&J.

22 34. There is no evidence that Defendants' IVC filters were effective in preventing pulmonary
23 embolism (the very condition the products were indicated to prevent).

24 35. Years after the implantation of retrievable filters into the bodies of patients, scientists
25 began to study the effectiveness of the retrievable filters. As recently as October 2015, an expansive
26 article published in the *Annals of Surgery* concerning trauma patients inserted with IVC filters
27 concluded that IVC filters were not effective in preventing pulmonary emboli, and instead actually
28 caused thrombi to occur.

1 36. Comparing the results of over 30,000 trauma patients who had not received IVC filters
2 with those who had received them, the *Annals of Surgery* study published its alarming results:

- 3 a. Almost twice the percentage of patients with IVC filters in the study died compared to
- 4 those that had not received them.
- 5 b. Over five times the relative number of patients with IVC filters developed DVTs.
- 6 c. Over four times the relative percentage of patients with filters developed thromboemboli.
- 7 d. Over twice the percentage of patients developed a pulmonary embolus – the very
- 8 condition Defendants Cordis and J&J told the FDA, physicians, and the public that its
- 9 IVC filters were designed to prevent.

10 37. This *Annals of Surgery* study – and many others referenced by it – have shown there is no
11 evidence establishing that IVC filters are effective and that these devices suffer common failure modes,
12 including, but not limited to, migration, perforation, thrombosis, tilt and fracture, all of which can cause
13 serious injury or death. Thus, the current state of scientific and medical evidence indicates that IVC
14 filters are not only ineffective but that they are themselves a health hazard.

15 **THE TRAPEASE AND OPTASE IVC FILTERS**

16 38. On or about January 10, 2001, Defendants bypassed the more onerous FDA's approval
17 process for new devices and obtained "clearance" under Section 510(k) of the Medical Device
18 Amendments to the Food, Drug, and Cosmetic Act to market the TrapEase Vena Cava Filter as a
19 *permanent* filter by claiming it was substantially similar in respect to safety, efficacy, design, and
20 materials as the IVC filters already available on the market.

21 39. Section 510(k) permits the marketing of medical devices if the device is substantially
22 equivalent to other legally marketed predicate devices without formal review for the safety or efficacy of
23 the said device. The FDA explained the difference between the 510(k) process and the more rigorous
24 "premarket approval" (PMA) process in its amicus brief filed with the Third Circuit in *Horn v. Thoratec*
25 *Corp.*, which the court quoted from:

26 A manufacturer can obtain an FDA finding of 'substantial equivalence' by submitting a
27 premarket notification to the agency in accordance with section 510(k) of the [Food Drug
28 and Cosmetic Act]. 21 U.S.C. § 360(k). A device found to be 'substantially equivalent'
to a predicate device is said to be 'cleared' by FDA (as opposed to 'approved' by the
agency under a PMA. A pre-market notification submitted under 510(k) is thus entirely

1 different from a PMA which must include data sufficient to demonstrate that the IVC
2 Filters is safe and effective.

3 376 F.3d 163, 167 (3d Cir. 2004) (emphasis in original).

4 40. In *Medtronic, Inc. v. Lohr*, the U.S. Supreme Court similarly described the 510(k)
5 process, observing:

6 If the FDA concludes on the basis of the [manufacturer's] § 510(k) notification that the
7 device is "substantially equivalent" to a pre-existing device, it can be marketed without
8 further regulatory analysis. . . . The § 510(k) notification process is by no means
9 comparable to the PMA process; in contrast to the 1,200 hours necessary to complete a
10 PMA review, the § 510(k) review is completed in average of 20 hours. . . . As one
commentator noted: "The attraction of substantial equivalence to manufacturers is clear.
Section 510(k) notification requires little information, rarely elicits a negative response
from the FDA, and gets processed quickly."

11 518 U.S. 470, 478-79 (1996) (quoting Adler, *The 1976 Medical Device Amendments: A Step in the*
12 *Right Direction Needs Another Step in the Right Direction*, 43 Food Drug Cosm. L.J. 511, 516 (1988)).

13 41. Pursuant to *Wyeth v. Levine*, 555 U.S. 555 (2009), once a product is cleared "the
14 manufacturer remains under an obligation to investigate and report any adverse events associated with
15 the drug . . . and must periodically submit any new information that may affect the FDA's previous
16 conclusions about the safety, effectiveness, or labeling" This obligation extends to post-market
17 monitoring of adverse events/complaints.

18 42. In July 2000, through this 510(k) process, Defendants obtained clearance from the FDA
19 to market the TrapEase filter as a permanent filter.

20 43. The TrapEase filter is made with Nitinol – a nickel titanium alloy. The filter utilizes a
21 design known as a double basket or double filter for the capture of blood clots and/or emboli. This
22 design consists of a basket made of six diamond-shaped struts proximally and six diamond-shaped struts
23 distally, forming proximal and distal baskets, which are connected by six straight struts to create a single
24 symmetric filter. The filter has proximal and distal anchoring barbs located on each connecting strut for
25 fixation of the filter to the vena cava wall to prevent movement after placement.

26 44. Nitinol alloy is used in a number of different medical device applications. It is beneficial
27 for these applications and is employed as material in stents and other medical device applications. It is
28 also used in the manufacture of the TrapEase filter, and other brands of IVC filters.

1 45. Specific manufacturing processes need to be utilized when using Nitinol as a component
2 for medical devices, including IVC filters. Primarily, the Nitinol material should be electro-polished
3 prior to assembly of the finished medical device.

4 46. Electro-polishing is a manner of removing surface blemishes, “draw marking” and
5 circumferential grinding markings on the exterior of the surface of the Nitinol material. The existence
6 of these surface blemishes, “draw markings” and “circumferential grind-markings” causes/results in the
7 weakening of the structural integrity of the end product, whether it is an IVC filter or other medical
8 device.

9 47. In or around September 2002, Defendants sought clearance through the 510(k) process to
10 market the OptEase Vena Cava Filter for the same indicated uses as the TrapEase filter. Defendants
11 represented that the OptEase filter contained the same fundamental technology and was substantially
12 equivalent in terms of safety and efficacy as the predicate devices already available on the market.

13 48. Unlike the TrapEase filter, which has proximal and distal anchoring barbs located on
14 each connecting strut for fixation of the filter to the vena cava wall, the OptEase filter has anchoring
15 barbs for fixation of the filter only on the superior end of each of the six straight struts and has a hook at
16 the inferior end of the basket to allow retrieval with a snare.

17 49. Both designs for the TrapEase filter and OptEase filter suffer flaws making them
18 defective and unreasonably dangerous. Defendants’ IVC filters are designed in such a way that when
19 exposed to expected and reasonably foreseeable *in-vivo* conditions, the devices will fracture, migrate,
20 tilt, perforate internal organs and vasculature, and lead to the formation of thromboembolism and
21 pulmonary embolism.

22 50. For years, it has been known by manufacturers of the Nitinol medical devices and the
23 medical device industry that electro-polishing Nitinol results in increased structural integrity of the
24 device and resistance to fatigue and fatigue failures.

25 51. The exterior surfaces of the Cordis IVC Filters were not electro-polished prior to
26 completion of the manufacturing process. This is a manufacturing defect that exists in the TrapEase and
27 OptEase filters which causes these filters to be structurally weak and susceptible to a significant risk of
28 failure/fracture.

1 52. Additionally, Defendants represented that the self-centering design of the TrapEase filter
2 allows accurate, predictable placement, and that its site struts help reduce the risk of tilting and
3 migration, while in reality the filters regularly tilt, migrate, and become embedded in the vena cava wall.

4 53. The anchoring mechanism of Defendants' filters is also insufficient to prevent tilting and
5 migration post-placement.

6 54. The configuration of the Cordis IVC Filters actually leads to the formation of blood clots
7 and pulmonary embolism – the exact condition the devices are meant to protect against.

8 55. That Defendants allowed these devices to proceed to market indicates that they failed to
9 establish and maintain an appropriate Quality System concerning design and risk analysis.

10 56. A manufacturer must, at a minimum, undertake research and testing to understand the
11 anatomy of where a medical device will be implanted and understand the forces the device may be
12 exposed to once implanted in a human body. This design input must then be used to determine the
13 minimum safety requirements or attributes the device must have to meet user needs. In the case of an
14 IVC filter, user needs include a device that will capture blood clots of sufficient size to cause harmful
15 consequences and that will not fracture, migrate, tilt, perforate the vena cava, or malfunction in some
16 other way, or be prothombotic. Defendants failed to undertake any such efforts in these regards.

17 57. Prior to bringing a product to market, a manufacturer must also conduct sufficient testing
18 under real world or simulated use conditions to ensure that the device will meet user needs even when
19 exposed to reasonably foreseeable worst-case conditions. Defendants failed to adequately establish and
20 maintain such policies, procedures or protocols with respect to their IVC filters.

21 58. Once placed on the market, Defendants' post-market surveillance system should have
22 revealed to Defendants that the TrapEase and OptEase filters were unreasonably dangerous and
23 substantially more prone to fail or malfunction, and cause great bodily harm to patients compared to
24 other available treatment options.

25 59. MAUDE is a database maintained by the FDA to house medical device reports submitted
26 by mandatory reporters (such as manufacturers and device user facilities) and voluntary reporters (such
27 as health care providers and patients).
28

1 60. Shortly after going on market, Defendants began receiving large numbers of adverse
2 event reports ("AERs") from health care providers reporting that the Cordis IVC filters were fracturing
3 post-implantation and that fractured pieces and/or the entire device was migrating to other areas of the
4 body, including the heart and lungs.

5 61. Defendants also received large numbers of AERs reporting that the TrapEase filters and
6 OptEase filters were found to have excessively tilted, perforated the IVC, or caused thrombosis or
7 stenosis of the vena cava post-implantation.

8 62. These failures were often associated with severe patient injuries such as:

- 9 a. Death;
10 b. Hemorrhage;
11 c. Cardiac/pericardial tamponade (pressure caused by a collection of blood in the area
12 around the heart);
13 d. Cardiac arrhythmia and other symptoms similar to myocardial infarction;
14 e. Severe and persistent pain; and
15 f. Perforations of tissue, vessels and organs.

16 63. These failures and resulting injuries are attributable, in part, to the fact that the Cordis
17 IVC Filter design was unable to withstand the normal anatomical and physiological loading cycles
18 exerted *in vivo*.

19 64. Defendants failed to identify or acknowledge these device failures or determine their
20 causes.

21 65. Defendants failed to take timely and adequate remedial measures to correct known design
22 and manufacturing defects with the Cordis IVC Filters.

23 66. Defendants also misrepresented and concealed the risks and benefits of the Cordis IVC
24 filters in its labeling and marketing distributed to the FDA, physicians and the public. For instance,
25 Defendants represented that their filters were safe and effective – more safe and effective than other
26 available IVC filters. As discussed above, however, there is no reliable evidence to support these claims
27 and, to the contrary, the Cordis IVC filters have been associated with a high rate of failure.
28

**THE MEDICAL LITERATURE ESTABLISHES THAT CORDIS IVC FILTERS HAVE A
HIGH RATE OF FAILURE AND COMPLICATIONS**

67. There are reports in the peer-reviewed published medical literature of TrapEase filters migrating to the heart:

- a. It was reported in 2002 that a TrapEase filter migrated to a patient's right ventricle. Porcellini, *et al.*, "Intracardiac migration of nitinol TrapEase vena cava filter and paradoxical embolism," *Euro. J. of Cardio-Thoracic Surg.* 2002, 22:460-61.
- b. It was reported in 2008 that a TrapEase filter migrated to a patient's tricuspid valve, causing her death. Haddadian, *et al.*, "Sudden Cardiac Death Caused by Migration of a TrapEase Inferior Vena Cava Filter: A Case Report and Review of the Literature," *Clin. Cardiol.* 2008, 31:84-87.
- c. It was reported in 2011 that a TrapEase filter migrated to a patient's tricuspid valve, leading to his death. Dreyer, *et al.*, "Inferior Vena Cava Filter Migration to the Right Ventricle: A Case Report and Review of Filter Migration and Misdeployment," *J. Med. Cases* 2011; 2(5):201-05.

68. Additionally, as early as March 2005, Defendants knew or should have known that any short-term beneficial effect of the insertion of a Cordis IVC filter was outweighed by a significant increase in the risk of DVT, that the filter would not be able to be removed, filter fracture and/or migration, and, ultimately, by the fact that the filters had no beneficial effect on overall mortality.

69. By March 2005, there had been only one long-term randomized study of filter placement in the prevention of pulmonary embolism. See PREPIC Study Group, "Eight-year follow-up of patients with permanent vena cava filters in the prevention of pulmonary embolism: the PREPIC (Prevention du Risque d'Embolie Pulmonaire par Interruption Cave) randomized study," *Circulation* 2005, 112(3):416-22. In 400 patients with proximal DVT, the insertion of a vena cava filter in combination with standard anticoagulation was associated with a reduction in the occurrence of pulmonary embolism compared with anticoagulation alone. This beneficial effect was offset, however, by a significant increase in DVT, and the filters had no impact on mortality. The study followed the patients for up to eight years to assess

1 the very long-term effect of IVC filters on the recurrence of venous thromboembolism, the development
2 of post-thrombotic syndrome, and mortality.

3 70. Two years later, in or around 2007, a group of engineers and members of the surgery
4 department of the University of Toronto conducted a study in order to determine whether IVC filter
5 design might be linked to an increased risk of thrombosis and recurrent pulmonary embolism. *See*
6 Harlal, *et al.*, "Vena cava filter performance based on hemodynamics and reported thrombosis and
7 pulmonary embolism patterns," *J Vasc Interv Radiol.* 2007, 18(1): 103-15. The authors wrote that the
8 design of the TrapEase filter "promotes the lodging of a clot along the vessel wall, resulting in the
9 formation of stagnation zones along the vessel wall, which can contribute to further clot development."
10 The study further explained that the TrapEase filters' effect on blood flow increased the likelihood of
11 thrombosis. The study found a significantly higher rate of PE and thrombosis from use of the TrapEase
12 filter relative to a competitor's filter.

13 71. Less than three years later, on or about August 9, 2010, the FDA issued a Safety Alert
14 entitled: "Removing Retrievable Inferior Vena Cava Filters: Initial Communication." The purpose of
15 the communication was to warn against leaving IVC filters in for extended periods of time because they
16 have a tendency to cause life-threatening complications. The FDA noted that the use of IVC filters had
17 increased dramatically in the last several years and observed that the number of adverse event reports
18 had also increased substantially since 2005. The FDA expressed concern that retrievable IVC filters
19 were frequently left in patients beyond the time when the risk for PE had passed, thus unnecessarily
20 exposing patients to the risks of DVT as well as to filter fracture, migration, embolization, and
21 perforation.

22 72. Dr. William T. Kuo, an expert in the removal of IVC filters and vascular surgery, has
23 established an IVC Filter Clinic at Stanford University where his team specializes in the removal of IVC
24 filters that other vascular surgeons refuse to remove for fear of rupturing the vena cava or other internal
25 organs and causing great bodily harm or death to the patient. In 2011, Dr. Kuo wrote in *the Journal of*
26 *Vascular Interventional Radiology* that the Cordis filters were the most difficult to retrieve from
27 patients, at least partially due to the design of the filters, which create greater contact with the vein walls
28 than competitors' filters. *See* Kuo, *et al.*, "Photothermal Ablation with the Excimer Laser Sheath

1 Technique for Embedded Inferior Vena Cava Filter Removal: Initial Results from a Perspective Study,”
2 *J. Vasc. Interv. Radiol.* 2011; 22:813-23.

3 73. In the same article, Dr. Kuo observed that “[p]atients with embedded filters seem to be at
4 increased risk of IVC occlusion, chronic deep venous thrombosis, post-thrombotic syndrome, filter
5 fracture with component migration, and caval perforation with pain and organ injury. Additionally,
6 many patients with permanent filters are now routinely managed with lifelong anticoagulation to reduce
7 thrombotic risks related to prolonged filter implantation, subjecting them not only to the inconvenience
8 of anticoagulation therapy but also to its inherent bleeding risks.” These concerns were heightened by
9 the difficulty of removing a Cordis filter.

10 74. In 2010, Dr. Gred Usoh also found in a study published in the *Journal of Vascular*
11 *Surgery* that the TrapEase filter was associated with an increased likelihood of thrombosis. See Usoh, *et*
12 *al.*, “Prospective Randomized Study Comparing the Clinical Outcomes Between Inferior Vena Cava
13 Greenfield and TrapEase Filters,” *J. Vasc. Surg.* 2010, 52(2):394-99. Thus, the TrapEase filter
14 increased the risk of harm without any proven benefit.

15 75. In a letter to the *Archives of Internal Medicine* published November 28, 2011, a group led
16 by Dr. Masaki Sano of the Hamamatsu University School of Medicine in Japan described a study in
17 which the Cordis TrapEase filter had fractured in 10 out of 20 patients (50%) at an average follow-up of
18 50 months. See Sano, *et al.*, “Frequent Fracture of TrapEase Inferior Vena Cave Filters: A Long-term
19 Follow Up Assessment,” *Arch. Intern Med* 2012; 172(2):189-91. Furthermore, nine out of 14 filters
20 (64%) that had been inserted for longer than 14 months showed fractures. Among the 10 fractured
21 filters, eight had a single fractured strut, while two had multiple fractured struts. Additionally, thrombus
22 was detected inside the filter in two cases. Based on these results, Dr. Sano criticized previous studies
23 that had found the TrapEase filter to be safe as being conducted over too short a period of time and
24 concluded that “patients undergoing permanent TrapEase IVCF insertion are at extremely high risk of
25 strut fractures as early as two to three years after IVCF placement.”

26 76. On May 6, 2014, the FDA issued another Safety Alert involving IVC filters. In this
27 safety communication, the FDA wrote that it had received adverse event reports concerning “device
28 migration, filter fracture, embolization (movement of the entire filter or fracture fragments to the heart

or lungs), perforation of the IVC, and difficulty removing the device.” The FDA reiterated that the risks presented by the filters should be avoided by removing the filters “once the risk of pulmonary embolism has subsided” and expressed concern that the filters were not being timely removed in this manner. Based on the medical literature, the FDA recommended removal between 29 and 54 days after implantation.

77. On April 5, 2016, at the annual Society of Interventional Radiology in Vancouver, Canada, Dr. Steven Wang, an interventional radiologist from Palo Alto, California who is affiliated with Kaiser Permanente, presented the results of a retrospective study involving 96 patients in which he sought to understand the prevalence of long-term (greater than 46 months) complications of both permanent and retrievable IVC filters. The study looked at all inferior vena cava filters implanted in patients from January 2007 through December 2009 at multiple health care facilities across the United States. Dr. Wang then identified all patients who had imaging of the filter taken at four years or more after implantation. Of those patients (96), he then evaluated the imaging to determine whether the IVC filter had malfunctioned. After reviewing the data, the authors concluded that device complications at four or more years after implantation “are relatively common.” They also found that the Cordis OptEase and TrapEase IVC filters suffered fracture rates of 37.5% and 23.1%, respectively.

ESTOPPEL FROM PLEADING STATUTES OF LIMITATIONS OR REPOSE

78. Plaintiffs incorporate by reference all prior allegations.

79. Plaintiffs are within the applicable statute of limitations for their claims because Plaintiffs (and their healthcare professionals) did not discover, and could not reasonably discover, the defects and unreasonably dangerous condition of their Cordis IVC filters.

80. Plaintiffs’ ignorance of the defective and unreasonably dangerous nature of the Cordis IVC filters, and the causal connection between these defects and each Plaintiff’s injuries and damages, is due in large part to Defendants’ acts and omissions in fraudulently concealing information from the public and misrepresenting and/or downplaying the serious threat to public safety its products present.

81. In addition, Defendants are estopped from relying on any statutes of limitation or repose by virtue of its unclean hands, acts of fraudulent concealment, affirmative misrepresentations and omissions.

1 82. Such conduct includes intentional concealment from Plaintiffs, their health care
2 professionals, and the general consuming public of material information that Cordis IVC filters had not
3 been demonstrated to be safe or effective, and carried with them the risks and dangerous defects
4 described above.

5 83. Defendants had a duty to disclose the fact that Cordis IVC filters are not safe or effective,
6 not as safe as other filters on the market, defective, and unreasonably dangerous, and that their
7 implantation and use carried with it the serious risk of developing perforation, migration, tilting, and/or
8 fracture.

9 **FIRST CAUSE OF ACTION**

10 **STRICT PRODUCTS LIABILITY – DESIGN DEFECT**

11 **(By All Plaintiffs, As to All Defendants)**

12 84. Plaintiffs incorporate by reference all prior allegations.

13 85. At all relevant times, Defendants designed, tested, distributed, manufactured, advertised,
14 sold, marketed and otherwise placed into the stream of commerce Cordis IVC filters – the TrapEase
15 filters and the OptEase filters – for use by consumers, such as Plaintiffs, in the United States.

16 86. Defendants' Cordis IVC filters were expected to, and did, reach Defendants' intended
17 consumers, handlers, and persons coming into contact with the product without substantial change in the
18 condition in which they were researched, tested, developed, designed, licensed, manufactured, packaged,
19 labeled, distributed, sold, and marketed by Defendants.

20 87. At all times relevant, Cordis IVC filters were manufactured, designed and labeled in an
21 unsafe, defective, and inherently dangerous condition which was dangerous for use by the public in
22 general and Plaintiffs in particular.

23 88. Defendants' Cordis IVC filters, as researched, tested, developed, designed, licensed,
24 manufactured, packaged, labeled, distributed, sold, and marketed by Defendants were defective in
25 design and formulation and unreasonably dangerous in that when they left the hands of Defendants'
26 manufacturers and/or suppliers, the foreseeable risks exceeded the alleged benefits associated with the
27 use of Cordis IVC filters, and the devices were more dangerous than the ordinary customer would
28 expect.

89. Physicians implanted Cordis IVC filters as instructed via the Instructions for Use and in a foreseeable manner as normally intended, recommended, promoted, and marketed by Defendants.

90. Plaintiffs received and utilized Defendants' IVC filters in a foreseeable manner as normally intended, recommended, promoted, and marketed by Defendants.

91. At the time Defendants placed their defective and unreasonably dangerous Cordis IVC filters into the stream of commerce commercially, technologically, and scientifically feasible alternative designs were attainable and available.

92. These alternative designs would have prevented the harm resulting in each Plaintiff's Injuries and Damages without substantially impairing the reasonably anticipated or intended function of Cordis IVC filters.

93. Neither Plaintiffs nor their health care providers could have, by the exercise of reasonable care, discovered the defective condition or perceived the unreasonable dangers with these devices prior to Plaintiffs' implantation with the Cordis IVC filters.

94. As a direct and proximate result of the defective and unreasonably dangerous condition of Cordis IVC filters, Plaintiffs suffered Injuries and Damages.

SECOND CAUSE OF ACTION

STRICT PRODUCTS LIABILITY – INADEQUATE WARNING

(By All Plaintiffs, As to All Defendants)

95. Plaintiffs incorporate by reference all prior allegations.

96. At all relevant times, Defendants engaged in the business of testing, developing, designing, manufacturing, packaging, labeling, marketing and/or promoting, selling and/or distributing Cordis IVC filters – the TrapEase filters and the OptEase filters – and through that conduct have knowingly and intentionally placed Cordis IVC filters into the stream of commerce with full knowledge that they reach consumers such as Plaintiffs who would become implanted with them.

97. Defendants did, in fact, test, develop, design, manufacture, package, label, market and/or promote, sell and/or distribute their Cordis IVC filters to Plaintiffs, their prescribing health care professionals, and the consuming public. Additionally, Defendants expected that the Cordis IVC filters they were selling, distributing, supplying, manufacturing, and/or promoting to reach, and did, in fact,

1 reach, prescribing health care professionals and consumers, including Plaintiffs and their prescribing
2 health care professionals, without any substantial change in the condition of the product from when it
3 was initially distributed by Defendants.

4 98. The Cordis IVC filters had potential risks and side effects that were known or knowable
5 to Defendants by the use of scientific inquiry and information available before, at, and after the
6 manufacture, distribution, and sale of the Cordis IVC filters.

7 99. Defendants knew or should have known of the defective condition, characteristics, and
8 risks associated with Cordis IVC filters. These defective conditions included, but were not limited to:
9 (1) Cordis IVC filters posed a significant and higher risk of failure than other similar IVC filters
10 (fracture, migration, tilting, and perforation of the vena cava wall); (2) Cordis IVC filter failures result in
11 serious injuries and death; (3) certain conditions or post-implant procedures, such as morbid obesity or
12 open abdominal procedures, could affect the safety and integrity of Cordis IVC filters; (4) leaving
13 Cordis IVC filters in for a period longer than necessary to prevent immediate risk of pulmonary
14 embolism increases the risk for patients of failures and complications with the filter, such as the filter
15 becoming deeply embedded in the vena cava, making them difficult or impossible for removal.

16 100. Defendants placed into the stream of commerce for ultimate use by users like Plaintiffs
17 and their health care providers, Cordis IVC filters that were in an unreasonably dangerous and defective
18 condition due to warnings and instructions for use that were inadequate, including, but not limited to
19 Defendants' failure to:

- 20 a. Provide adequate instructions for how long in patients the filter should remain;
- 21 b. Highlight the importance of removing the filter;
- 22 c. Warn of the known risk of great bodily harm or death if the filter was not removed;
- 23 d. Highlight the known risk of great bodily harm or death in the event of occlusion of the
24 vein caused by the filter itself;
- 25 e. Warn of the risk of new DVT if the filter was left in too long; Warn of the risk of new
26 pulmonary embolism, thrombosis, swelling, and pain in the lower extremities if the filter
27 was left in too long; and
- 28 f. Warn of the risk of filter perforation, fracture, or migration.

102. The warnings and directions Defendants provided with their Cordis IVC filters failed to adequately warn of the potential risks and side effects of Cordis IVC filters.

103. These risks were known or were reasonably scientifically knowable to Defendants, but not known or recognizable to ordinary consumers, such as Plaintiffs, or their treating doctors.

104. Defendants' IVC filters were expected to and did reach Plaintiffs without substantial change in their condition, labeling, or warnings as manufactured, distributed, and sold by Defendants.

105. Additionally, Plaintiffs and their physicians used Cordis IVC filters – the TrapEase filters or the OptEase filters – in the manner in which they were intended to be used, making such use reasonably foreseeable to Defendants.

106. As a direct and proximate result of Defendants' information defects, lack of sufficient instructions or warnings prior to, on, and after the date Plaintiffs used Cordis IVC filters, Plaintiffs suffered Injuries and Damages.

THIRD CAUSE OF ACTION

STRICT PRODUCTS LIABILITY – MANUFACTURING DEFECT

(By All Plaintiffs, As to All Defendants)

107. Plaintiffs incorporate by reference all prior allegations.

108. Prior to, on, and after the date the Cordis IVC filters – the TrapEase filter or the OptEase filter – were implanted in Plaintiffs, Defendants designed, distributed, manufactured, sold, and marketed Cordis IVC filters for use in the United States, including California.

109. At all relevant times, Defendants designed, distributed, manufactured, marketed, and sold Cordis IVC filters that were unreasonably dangerous, unsafe, and defective in manufacture when they left Defendants' possession.

110. Upon information and belief, Cordis IVC filters contain a manufacturing defect, in that they differed from the manufacturer's design or specifications, or from other typical units of the same product line.

111. As a direct and proximate cause of Defendants' design, manufacture, marketing, and sale of Cordis IVC filters prior to, on, and after the date Plaintiffs used the Cordis IVC filters, Plaintiffs suffered Injuries and Damages.

FOURTH CAUSE OF ACTION

NEGLIGENCE

(By All Plaintiffs, As to All Defendants)

112. Plaintiffs incorporate by reference all prior allegations.

113. At the time of the design, distribution, manufacture, advertising, sale, and marketing of Cordis IVC filters – the TrapEase filters and the OptEase filters – and their implantation in Plaintiffs, Defendants were aware that Cordis IVC filters were designed and manufactured in a manner presenting:

- a. An unreasonable risk of fracture of portions of the filters;
- b. An unreasonable risk of migration of the filters and/or portions of the filters;
- c. An unreasonable risk of filters tilting and/or perforating the vena cava wall; and
- d. Insufficient strength or structural integrity to withstand normal placement within the human body.

114. At the time of the design, distribution, manufacture, advertising, sale, and marketing of Cordis IVC filters, and their implantation in Plaintiffs, Defendants were also aware that Cordis IVC filters:

- a. Would be used without inspection for defects;
- b. Would be used by patients with special medical conditions such as Plaintiffs;
- c. Had previously caused serious bodily injury to its users with special medical conditions such as Plaintiffs;
- d. Had no established efficacy;
- e. Were less safe and effective than the predicate IVC filters already available on market;
- f. Would be implanted in patients where the risk outweighed any benefit or utility of the filters;
- g. Contained instructions for use and warnings that were inadequate; and
- h. Were prothombotic.

1 115. Defendants had a duty to exercise due care and avoid unreasonable risk of harm to others
2 in the design of Cordis IVC filters.

3 116. Defendants breached these duties by, among other things:

- 4 a. Designing and distributing a product in which it knew or should have known that the
5 likelihood and severity of potential harm from the product exceeded the burden of taking
6 safety measures to reduce or avoid harm;
- 7 b. Designing and distributing a product which it knew or should have known that the
8 likelihood and severity of potential harm from the product exceeded the likelihood of
9 potential harm from other IVC filters available for the same purpose;
- 10 c. Failing to perform reasonable pre- and post-market testing of Cordis IVC filters to
11 determine whether or not the products were safe for their intended use;
- 12 d. Failing to use reasonable and prudent care in the design, research, manufacture, and
13 development of Cordis IVC filters so as to avoid the risk of serious harm associated with
14 the use of Cordis IVC filters;
- 15 e. Advertising, marketing, promoting, and selling Cordis IVC filters for uses other than as
16 approved and indicated in the products' labels;
- 17 f. Failing to establish an adequate quality assurance program used in the manufacturing of
18 Cordis IVC filters; and
- 19 g. Failing to perform adequate evaluation and testing of Cordis IVC filters when such
20 evaluation and testing would have revealed the propensity of Cordis IVC filters to cause
21 injuries similar to those that Plaintiffs suffered.

22 117. At all relevant times, Defendants had a duty to exercise due care in the manufacturing of
23 Cordis IVC filters.

24 118. Defendants breached this duty by, among other things:

- 25 a. Failing to adopt manufacturing processes that would reduce the foreseeable risk of
26 product failure;
- 27
- 28

- 1 b. Failing to use reasonable care in manufacturing the product and by producing a product
2 that differed from their design or specifications or from other typical units from the same
3 production line;
4 c. Failing to use reasonable and prudent care in the design, research, manufacture, and
5 development of Cordis IVC filters and their manufacturing process so as to avoid the risk
6 of serious harm associated with the use of Cordis IVC filters; and
7 d. Failing to establish an adequate quality assurance program used in the manufacturing of
8 their IVC filters.

9 119. At this time, all Cordis IVC filters – the TrapEase filters and the OptEase filters – are
10 misbranded and adulterated by virtue of them failing to be the substantial equivalent of predicate IVC
11 filter devices, making them subject to corrective action, including recall, in the interest of patient safety.

12 120. Prior to, on, and after the date of Plaintiffs' implantation with a Cordis IVC filter, and at
13 all relevant times, Defendants knew or reasonably should have known that Cordis IVC filters and their
14 warnings were defective and dangerous or were likely to be dangerous when used in a reasonably
15 foreseeable manner.

16 121. Prior to, on, and after the date of Plaintiffs' implantation with a Cordis IVC filter and at
17 all relevant times thereafter, Defendants became aware that the defects of Cordis IVC filters resulted in
18 Cordis IVC filters causing injuries similar to those Plaintiffs suffered.

19 122. Reasonable manufacturers and distributors under the same or similar circumstances
20 would have recalled or retrofitted Cordis IVC filters, and would thereby have avoided and prevented
21 harm to many patients, including Plaintiffs.

22 123. In light of this information and Defendants' knowledge described above, Defendants had
23 a duty to recall and/or retrofit Cordis IVC filters.

24 124. Defendants breached its duty to recall and/or retrofit Cordis IVC filters.

25 125. At all relevant times, Defendants knew or should have known that Cordis IVC filters
26 were defective and dangerous or were likely to be dangerous when used in a reasonably foreseeable
27 manner.
28

1 126. Such danger included the propensity of Cordis IVC filters to cause injuries similar to
2 those suffered by Plaintiffs.

3 127. At all relevant times, Defendants also knew or reasonably should have known that the
4 users of Cordis IVC filters, including Plaintiffs and their health care providers, would not realize or
5 discover on their own the dangers presented by Cordis IVC filters.

6 128. Reasonable manufacturers and reasonable distributors, under the same or similar
7 circumstances as those of Defendants prior to, on, and after the date of Plaintiffs' use of a Cordis IVC
8 filter, would have warned of the dangers presented by Cordis IVC filters, or instructed on the safe use of
9 Cordis IVC filters.

10 129. Prior to, on, and after the date of each Plaintiff's use of the IVC filter, Defendants had a
11 duty to adequately warn of the dangers presented by Cordis IVC filters and/or instruct on the safe use of
12 Cordis IVC filters.

13 130. Defendants breached these duties by failing to provide adequate warnings to Plaintiffs
14 communicating the information and dangers described above and/or providing instruction for safe use of
15 Cordis IVC filters.

16 131. As a direct and proximate result of Defendants' negligent conduct described herein,
17 Plaintiffs suffered Injuries and Damages.

18 **FIFTH CAUSE OF ACTION**

19 **NEGLIGENT MISREPRESENTATION**

20 **(By All Plaintiffs, As to All Defendants)**

21 132. Plaintiffs incorporate by reference all prior allegations.

22 133. Prior to, on, and after the dates during which Plaintiffs were implanted with the Cordis
23 IVC filters – the TrapEase filters and the OptEase filters – Defendants negligently and carelessly
24 represented to Plaintiffs, their treating physicians, and the general public that Cordis IVC filters were
25 safe, fit, and effective for use.

26 134. These representations were untrue.
27
28

1 135. Defendants owed a duty in all of its undertakings, including the dissemination of
2 information concerning its IVC filters, to exercise reasonable care to ensure that it did not in those
3 undertakings create unreasonable risks of personal injury to others.

4 136. Defendants disseminated to health care professionals and consumers through published
5 labels, labeling, marketing materials, and otherwise information concerning the properties and effects of
6 Cordis IVC filters with the intention that health care professionals and consumers would rely upon that
7 information in their decisions concerning whether to prescribe and use Defendants' IVC filters.

8 137. Defendants, as medical device designers, manufacturers, sellers, promoters and/or
9 distributors, knew or should reasonably have known that health care professionals and consumers, in
10 weighing the potential benefits and potential risks of prescribing or using Cordis IVC filters, would rely
11 upon information disseminated and marketed by Defendants to them regarding the Cordis IVC filters.

12 138. Defendants failed to exercise reasonable care to ensure that the information they
13 disseminated to health care professionals and consumers concerning the properties and effects of Cordis
14 IVC filters was accurate, complete, and not misleading and, as a result, disseminated information to
15 health care professionals and consumers that was negligently and materially inaccurate, misleading,
16 false, and unreasonably dangerous to consumers such as Plaintiffs.

17 139. Defendants, as designers, manufacturers, sellers, promoters, and/or distributors, also
18 knew or reasonably should have known that patients receiving Cordis IVC filters as recommended by
19 health care professionals in reliance upon information disseminated by Defendants as the
20 manufacturer/distributor of Defendants' IVC filters would be placed in peril of developing the serious,
21 life-threatening, and life-long injuries including, but not limited to, tilting, migration, perforation,
22 fracture, lack of efficacy, and increased risk of the development of blood clots, if the information
23 disseminated and relied upon was materially inaccurate, misleading, or otherwise false.

24 140. Defendants had a duty to promptly correct material misstatements it knew others were
25 relying upon in making healthcare decisions.

26 141. Defendants failed in each of these duties by misrepresenting to Plaintiffs and the medical
27 community the safety and efficacy of Cordis IVC filters and failing to correct known misstatements and
28 misrepresentations.

142. As a direct and proximate result of Defendants' negligent misrepresentations, Plaintiffs suffered Injuries and Damages.

SIXTH CAUSE OF ACTION

FRAUDULENT MISREPRESENTATION

(By All Plaintiffs, As to All Defendants)

143. Plaintiffs incorporate by reference all prior allegations.

144. At all times relevant to this cause, and as detailed above, Defendants intentionally provided Plaintiffs, their physicians, the medical community, and the public at large with false or inaccurate information. Defendants also omitted material information concerning Cordis IVC filters (the TrapEase filters and the OptEase filters), including, but not limited to, misrepresentations regarding the following topics:

- a. The safety of the Cordis IVC filters;
- b. The efficacy of the Cordis IVC filters;
- c. The rate of failure of the Cordis IVC filters;
- d. The pre-market testing of the Cordis IVC filters;
- e. The approved uses of the Cordis IVC filters; and
- f. The ability to retrieve the device at any time over a person's life.

145. The information Defendants distributed to the public, the medical community, and Plaintiffs was in the form of reports, press releases, advertising campaigns, labeling materials, print advertisements, commercial media containing material representations, and instructions for use, as well as through their officers, directors, agents, and representatives.

146. These materials contained false and misleading material representations, which included: that Cordis IVC filters were safe and fit when used for their intended purpose or in a reasonably foreseeable manner; that they did not pose dangerous health risks in excess of those associated with the use of other similar IVC filters; that any and all side effects were accurately reflected in the warnings; and that they were adequately tested to withstand normal placement within the human body.

1 147. Defendants made the foregoing misrepresentations knowing that they were false or
2 without reasonable basis. These materials included instructions for use and a warning document that
3 was included in the package of the Cordis IVC filters that were implanted in Plaintiffs.

4 148. Defendants' intent and purpose in making these misrepresentations was to deceive and
5 defraud the public and the medical community, including Plaintiffs' health care providers; to gain the
6 confidence of the public and the medical community, including Plaintiffs' health care providers; to
7 falsely assure the public and the medical community of the quality of Cordis IVC filters and their fitness
8 for use; and to induce the public and the medical community, including Plaintiffs' health care providers
9 to request, recommend, prescribe, implant, purchase, and continue to use Cordis IVC filters, all in
10 reliance on Defendants' misrepresentations.

11 149. The foregoing representations and omissions by Defendants were false.

12 150. Defendants' IVC filters are not safe, fit, and effective for human use in their intended and
13 reasonably foreseeable manner.

14 151. Further, the use of Cordis IVC filters is hazardous to the users' health, and Cordis IVC
15 filters have a serious propensity to cause users to suffer serious injuries, including without limitation the
16 injuries Plaintiffs suffered.

17 152. Finally, Defendants' IVC filters have a statistically significant higher rate of failure and
18 injury than do other comparable IVC filters.

19 153. In reliance upon the false and negligent misrepresentations and omissions made by
20 Defendants, Plaintiffs and their health care providers were induced to, and did use Cordis IVC filters,
21 thereby causing Plaintiffs to sustain severe and permanent personal injuries.

22 154. Defendants knew and had reason to know that Plaintiffs, their health care providers, and
23 the general medical community did not have the ability to determine the true facts intentionally and/or
24 negligently concealed and misrepresented by Defendants, and would not have prescribed and implanted
25 Cordis IVC filters if the true facts regarding Defendants' IVC filters had not been concealed and
26 misrepresented by Defendants.

1 155. Defendants had sole access to material facts concerning the defective nature of the
2 products and their propensities to cause serious and dangerous side effects in the form of dangerous
3 injuries and damages to persons who were implanted with Cordis IVC filters.

4 156. At the time Defendants failed to disclose and intentionally misrepresented the foregoing
5 facts, and at the time Plaintiffs used Cordis IVC filters, Plaintiffs and their health care providers were
6 unaware of Defendants' misrepresentations and omissions.

7 157. As a direct and proximate result of Defendants' fraudulent misrepresentations, Plaintiffs
8 suffered Injuries and Damages.

9 **SEVENTH CAUSE OF ACTION**

10 **FRAUDULENT CONCEALMENT**

11 **(By All Plaintiffs, As to All Defendants)**

12 158. Plaintiffs incorporate by reference all prior allegations.

13 159. In marketing and selling Cordis IVC filters (the TrapEase filters and the OptEase filters),
14 Defendants concealed material facts from Plaintiffs and their healthcare providers.

15 160. These concealed material facts include, but are not limited to:

- 16 a. Cordis IVC filters were unsafe and not fit when used for their intended purpose or in a
17 reasonably foreseeable manner;
18 b. Cordis IVC filters posed dangerous health risks in excess of those associated with the use
19 of other similar IVC filters;
20 c. That there were additional side effects related to implantation and use of Cordis IVC
21 filters that were not accurately and completely reflected in the warnings associated with
22 Cordis IVC filters; and
23 d. That Cordis IVC filters were not adequately tested to withstand normal placement within
24 the human body.

25 161. Plaintiffs and their health care providers were not aware of these and other facts
26 concealed by Defendants.

27 162. In concealing these and other facts, Defendants intended to deceive Plaintiffs and their
28 health care providers.

1 163. Plaintiffs and their health care providers were ignorant of and could not reasonably
 2 discover the facts Defendants fraudulently concealed and reasonably and justifiably relied on
 3 Defendants' representations concerning the supposed safety and efficacy of Cordis IVC filters.

4 164. As a direct and proximate result of Defendants' fraudulent concealment of material facts,
 5 Plaintiffs suffered Injuries and Damages.

6 **EIGHTH CAUSE OF ACTION**

7 **BREACH OF EXPRESS WARRANTY**

8 **(By All Plaintiffs, As to All Defendants)**

9 165. Plaintiffs incorporate by reference all prior allegations.

10 166. Plaintiffs, through their medical providers, purchased a Cordis IVC filter from
 11 Defendants.

12 167. At all relevant times, Defendants were merchants of goods of the kind including medical
 13 devices and vena cava filters (i.e., Cordis IVC filters).

14 168. At the time and place of sale, distribution, and supply of Cordis IVC filters to Plaintiffs
 15 (and to other consumer and the medical community), Defendants expressly represented and warranted
 16 that Cordis IVC filters were safe; that they were well-tolerated, efficacious, fit for their intended
 17 purpose, and of marketable quality; that they did not produce any unwarned-of dangerous side effects;
 18 and that they was adequately tested.

19 169. At the time of Plaintiffs' purchase from Defendants, Cordis IVC filters were not in a
 20 merchantable condition, and Defendants breached its expressed warranties, in that Cordis IVC filters,
 21 among other things:

- 22 a. Were designed in such a manner so as to be prone to an unreasonably high incidence of
- 23 fracture, perforation of vessels and organs, and/or migration;
- 24 b. Were designed in such a manner so as to result in a unreasonably high incidence of injury
- 25 to the vessels and organs of its purchaser;
- 26 c. Were manufactured in such a manner that the exterior surface of the filter was
- 27 inadequately, improperly, and inappropriately constituted, causing the device to weaken
- 28 and fail;

- d. Were unable to be removed at any time during a person's life;
- e. Were not efficacious in the prevention of pulmonary emboli;
- f. Carried a risk of use outweighed any benefit; and
- g. Were not self-centering.

170. As a direct and proximate result of Defendants' breach of express warranty, Plaintiffs suffered Injuries and Damages.

NINTH CAUSE OF ACTION

BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY

(By All Plaintiffs, As to All Defendants)

171. Plaintiffs incorporate by reference all prior allegations.

172. Defendants impliedly warranted that Cordis IVC filters were of merchantable quality and safe and fit for the use for which Defendants intended them, and Plaintiff in fact used them.

173. Defendants breached its implied warranties by, among other things:

- a. Failing to provide adequate instruction that a manufacturer exercising reasonable care would have provided concerning the likelihood that Cordis IVC filters would cause harm;
- b. Manufacturing and/or selling Cordis IVC filters when those filters did not conform to representations made by Defendants when they left Defendants' control;
- c. Manufacturing and/or selling Cordis IVC filters that were more dangerous than an ordinary consumer would expect when used in an intended or reasonably foreseeable manner;
- d. Manufacturing and/or selling Cordis IVC filters that carried foreseeable risks associated with the Cordis IVC filter design or formulation which exceeded the benefits associated with that design;
- e. Manufacturing and/or selling Cordis IVC filters when they deviated in a material way from the design specifications, formulas, or performance standards or from otherwise identical units manufactured to the same design specifications, formulas, or performance standards; and

f. Impliedly representing that its filters would be effective in the prevention of pulmonary emboli.

174. As a direct and proximate result of Defendants' breach of its implied warranty, Plaintiffs suffered Injuries and Damages.

TENTH CAUSE OF ACTION

LOSS OF CONSORTIUM

(By Plaintiffs BRIAN QUINN and PATRICIA BROWN, As to All Defendants)

175. Plaintiffs incorporate by reference all prior allegations

176. As a proximate result of the personal injuries suffered by Plaintiffs HEATHER QUINN and EDWARD BROWN, as described in this Complaint, Plaintiffs BRIAN QUINN and PATRICIA BROWN have been deprived of the benefits of their marriage including love, affection, society, and consortium, and other spousal duties and actions. Plaintiffs BRIAN QUINN and PATRICIA BROWN were provided with all of the benefits of a marriage between husband and wife, prior to the use of a Cordis IVC filter by their respective Plaintiff spouses and the resulting injuries described herein.

177. Plaintiffs BRIAN QUINN and PATRICIA BROWN have also suffered the permanent loss of their respective Plaintiff spouses' daily and regular contribution to the household duties and services, which each provides to the household as husband and wife.

178. Plaintiffs BRIAN QUINN and PATRICIA BROWN have also incurred the costs and expenses related to the medical care, treatment, medications, and hospitalization to which their respective Plaintiff spouses were subjected for the physical injuries they suffered as a proximate result of their use of a Cordis IVC filter. Plaintiffs BRIAN QUINN and PATRICIA BROWN will continue to incur the future costs and expenses related to the care, treatment, medications, and hospitalization of their respective Plaintiff spouses due to their injuries.

179. Plaintiffs BRIAN QUINN and PATRICIA BROWN have suffered loss of consortium, as described herein, including the past, present, and future loss of their spouses' companionship, services, society, and the ability of their spouses to provide Plaintiffs BRIAN QUINN and PATRICIA BROWN with the benefits of marriage, including *inter alia*, loss of contribution to household income and loss of

1 household services, all of which has resulted in pain, suffering, and mental and emotional distress and
2 worry for Plaintiffs BRIAN QUINN and PATRICIA BROWN.

3 **PUNITIVE DAMAGES ALLEGATIONS**

4 **(By All Plaintiffs, As to All Defendants)**

5 180. Plaintiffs incorporate by reference all prior allegations.

6 181. At all times material hereto, Defendants knew or should have known that Cordis IVC
7 filters were unreasonably dangerous with respect to the risk of tilt, fracture, migration and/or
8 perforation.

9 182. At all times material hereto, Defendants attempted to misrepresent and did knowingly
10 misrepresent facts concerning the safety of Cordis IVC filters.

11 183. Defendants' misrepresentations included knowingly withholding material information
12 from the medical community and the public, including Plaintiffs' physicians, concerning the safety of its
13 Cordis IVC filters.

14 184. Defendants' conduct, alleged throughout this Complaint, was willful, wanton, and
15 undertaken with a conscious indifference and disregard to the consequences that consumers of their
16 products faced, including Plaintiffs.

17 185. At all times material hereto, Defendants knew and recklessly disregarded the fact that
18 Cordis IVC filters have an unreasonably high rate of tilt, fracture, migration, and/or perforation.

19 186. Notwithstanding the foregoing, Defendants continued to market Cordis IVC filters
20 aggressively to consumers, including Plaintiffs, without disclosing the aforesaid side effects.

21 187. Defendants knew of their Cordis IVC Filters' lack of warnings regarding the risk of
22 fracture, migration, and/or perforation, but intentionally concealed and/or recklessly failed to disclose
23 that risk and continued to market, distribute, and sell its filters without said warnings so as to maximize
24 sales and profits at the expense of the health and safety of the public, including Plaintiffs, in conscious
25 disregard of the foreseeable harm caused by Cordis IVC filters.

26 188. Defendants' intentional and/or reckless failure to disclose information deprived
27 Plaintiffs' physicians of necessary information to enable them to weigh the true risks of using Cordis
28 IVC filters against its benefits.

189. Defendants' conduct is reprehensible, evidencing an evil hand guided by an evil mind and was undertaken for pecuniary gain in reckless and conscious disregard for the substantial risk of death and physical injury to consumers, including Plaintiffs.

190. Such conduct justifies an award of punitive or exemplary damages in an amount sufficient to punish Defendants' conduct and deter like conduct by Defendants and other similarly situated persons and entities in the future.

PRAYER FOR DAMAGES

WHEREFORE, Plaintiffs demand judgment against Defendants for:

a. General (non-economic) damages, including, without limitation, past and future pain and suffering; past and future emotional distress; past and future loss of enjoyment of life; and other consequential damages as allowed by law;

b. Special (economic) damages, including, without limitation, past and future medical expenses; past and future lost wages and loss of earning capacity; and other consequential damages as allowed by law;

c. Punitive damages in an amount sufficient to punish Defendants and deter similar conduct in the future;

d. Disgorgement of profits;

e. Restitution;

f. Statutory damages, where authorized;

g. Costs of suit;

h. Reasonable attorneys' fees, where authorized;

i. Prejudgment interest as allowed by law;

j. Post-judgment interest at the highest applicable statutory or common law rate from the date of judgment until satisfaction of judgment;

k. Such other additional and further relief as Plaintiffs may be entitled to in law or in equity.

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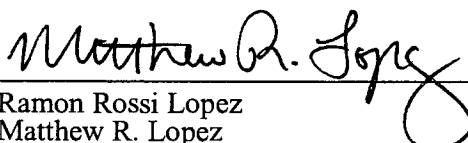
DEMAND FOR JURY TRIAL

Plaintiffs hereby demand a trial by jury on all triable issues.

Dated: May 3, 2016

Respectfully submitted,

LOPEZ McHUGH LLP

By: 
Ramon Rossi Lopez
Matthew R. Lopez
Amorina P. Lopez

Attorneys for Plaintiffs

ENDORSED
FILED
ALAMEDA COUNTY

MAY 13 2016

CLERK OF THE SUPERIOR COURT
By STEPHANIE MONROE
Deputy

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SUPERIOR COURT OF THE STATE OF CALIFORNIA

FOR THE COUNTY OF ALAMEDA

HEATHER QUINN and BRIAN QUINN,
individually and as wife and husband;
KATHRYNN KIRBY, an individual;
ALLISON BRAUER, an individual; EDWARD
BROWN and PATRICIA BROWN,
individually and as husband and wife;
MICHAEL HICKSON, an individual;
WILLIAM SCHENK, an individual;
CHRISTINA JONES, an individual;
NANCY FOLZ, an individual;
EDWARD CHIZEK, an individual; and
ANDREW CHAPMAN, an individual;

Plaintiffs,

vs.

CORDIS CORPORATION; and DOES 1
through 50;

Defendants.

Case No.: RG16814166

FIRST AMENDED COMPLAINT FOR DAMAGES

1. STRICT PRODUCTS LIABILITY – DESIGN DEFECT
2. STRICT PRODUCTS LIABILITY – FAILURE TO WARN
3. STRICT PRODUCTS LIABILITY – MANUFACTURING DEFECT
4. NEGLIGENCE
5. NEGLIGENT MISREPRESENTATION
6. FRAUDULENT MISREPRESENTATION
7. FRAUDULENT CONCEALMENT
8. BREACH OF EXPRESS WARRANTY
9. BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY
10. LOSS OF CONSORTIUM

DEMAND FOR JURY TRIAL

BY FAX

COMES NOW, Plaintiffs, by and through their attorneys, who complain and allege against Defendants CORDIS CORPORATION and DOES 1 through 50, and each of them, on information and belief, as follows:

INTRODUCTION

1. Plaintiffs bring this action for personal injuries damages suffered as a direct and proximate result of being implanted with a defective and unreasonably dangerous Inferior Vena Cava (“IVC”) filter medical device manufactured by Defendants.

2. The subject IVC filters include the following devices: TrapEase™ Permanent Vena Cava Filter (“TrapEase filter”) and OptEase™ Vena Cava Filter (“OptEase filter”) (for convenience, these devices will be referred to in this complaint under the generic terms “Cordis IVC filters” or “Defendants’ IVC filters”). At all times relevant to this action, Defendants developed, designed, set specifications for, licensed, manufactured, prepared, compounded, assembled, processed, sold, distributed and/or marketed the Cordis IVC filters to be implanted in patients throughout the United States, including California.

3. Plaintiffs’ claims for damages all relate to Defendants’ design, manufacture, sale, testing, marketing, labeling, advertising, promotion, and/or distribution of Cordis IVC filters.

4. The Cordis IVC filters that are the subject of this action all reached Plaintiffs and Plaintiffs’ physicians without substantial change in condition from the time they left Defendants’ possession.

5. Plaintiffs and Plaintiffs’ physicians used the Cordis IVC filters in the manner in which they were intended.

6. Defendants are solely responsible for any alleged design, manufacture or information defect its IVC filters contain.

7. Defendants do not allege that any other person or entity is comparatively at fault for any alleged design, manufacture, or informational defect its IVC filters contain.

PARTIES

8. Plaintiff HEATHER QUINN at all times relevant to this action was and is a citizen and resident of the State of California. Plaintiff HEATHER QUINN underwent placement of Defendants’

1 TrapEase Vena Cava Filter on or about March 19, 2001, in California. The filter subsequently
2 malfunctioned and caused injury and damages to Plaintiff HEATHER QUINN, including, but not
3 limited to, fracture, tilt, migration and perforation. As a direct and proximate result of these
4 malfunctions, Plaintiff HEATHER QUINN suffered life-threatening injuries and damages, and required
5 extensive medical care and treatment. As a further proximate result, Plaintiff HEATHER QUINN has
6 suffered and will continue to suffer significant medical expenses, and pain and suffering, and other
7 damages.

8 9. Plaintiff BRIAN QUINN at all times relevant to this action was and is a citizen and
9 resident of the State of California. Plaintiffs HEATHER QUINN and BRIAN QUINN were and are, at
10 all times relevant to this action, legally married as wife and husband. Plaintiff BRIAN QUINN brings
11 this action for, *inter alia*, the loss of consortium, comfort, and society he suffered due to the personal
12 injuries suffered by his wife, HEATHER QUINN.

13 10. Plaintiff KATHRYNN KIRBY at all times relevant to this action was and is a citizen and
14 resident of the State of South Carolina. Plaintiff KATHRYNN KIRBY underwent placement of
15 Defendants' OptEase Vena Cava Filter on or about May 22, 2007. The filter subsequently
16 malfunctioned and caused injury and damages to Plaintiff KATHRYNN KIRBY, including, but not
17 limited to, tilt, perforation, filter embedded in wall of the IVC, IVC thrombosis, unsuccessful removal
18 attempt, filter unable to be retrieved, and narrowing of her IVC. As a direct and proximate result of
19 these malfunctions, Plaintiff KATHRYNN KIRBY suffered life-threatening injuries and damages, and
20 required extensive medical care and treatment. As a further proximate result, Plaintiff KATHRYNN
21 KIRBY has suffered and will continue to suffer significant medical expenses, and pain and suffering,
22 and other damages.

23 11. Plaintiff ALLISON BRAUER at all times relevant to this action was and is a citizen and
24 resident of the State of Tennessee. Plaintiff ALLISON BRAUER underwent placement of Defendants'
25 OptEase Vena Cava Filter on or about May 1, 2013. The filter subsequently malfunctioned and caused
26 injury and damages to Plaintiff ALLISON BRAUER, including, but not limited to, tilt, filter embedded
27 in wall of the IVC, and filter unable to be retrieved. As a direct and proximate result of these
28 malfunctions, Plaintiff ALLISON BRAUER suffered life-threatening injuries and damages, and required

1 extensive medical care and treatment. As a further proximate result, Plaintiff ALLISON BRAUER has
2 suffered and will continue to suffer significant medical expenses, and pain and suffering, and other
3 damages.

4 12. Plaintiff EDWARD BROWN at all times relevant to this action was and is a citizen and
5 resident of the State of Texas. Plaintiff EDWARD BROWN underwent placement of Defendants'
6 OptEase Vena Cava Filter on or about September 1, 2005. The filter subsequently malfunctioned and
7 caused injury and damages to Plaintiff EDWARD BROWN, including, but not limited to, migration, tilt,
8 filter embedded in wall of the IVC, and filter unable to be retrieved. As a direct and proximate result of
9 these malfunctions, Plaintiff EDWARD BROWN suffered life-threatening injuries and damages, and
10 required extensive medical care and treatment. As a further proximate result, Plaintiff EDWARD
11 BROWN has suffered and will continue to suffer significant medical expenses, and pain and suffering,
12 and other damages.

13 13. Plaintiff PATRICIA BROWN at all times relevant to this action was and is a citizen and
14 resident of the State of Texas. Plaintiffs EDWARD BROWN and PATRICIA BROWN were and are, at
15 all times relevant to this action, legally married as husband and wife. Plaintiff PATRICIA BROWN
16 brings this action for, *inter alia*, the loss of consortium, comfort, and society he suffered due to the
17 personal injuries suffered by her husband, EDWARD BROWN.

18 14. Plaintiff MICHAEL HICKSON at all times relevant to this action was and is a citizen
19 and resident of the State of Tennessee. Plaintiff MICHAEL HICKSON underwent placement of
20 Defendants' TrapEase Vena Cava Filter on or about January 11, 2008. The filter subsequently
21 malfunctioned and caused injury and damages to Plaintiff MICHAEL HICKSON, including, but not
22 limited to, fracture, migration of entire filter to heart, perforation of filter struts into vena cava and
23 organs, tilt, filter embedded in wall of the IVC, requiring emergency open-heart surgery. As a direct and
24 proximate result of these malfunctions, Plaintiff MICHAEL HICKSON suffered life-threatening injuries
25 and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff
26 MICHAEL HICKSON has suffered and will continue to suffer significant medical expenses, and pain
27 and suffering, and other damages.
28

1 15. Plaintiff WILLIAM SCHENK at all times relevant to this action was and is a citizen and
2 resident of the State of Illinois. Plaintiff WILLIAM SCHENK underwent placement of Defendants'
3 OptEase Vena Cava Filter on or about December 28, 2004. The filter subsequently malfunctioned and
4 caused injury and damages to Plaintiff WILLIAM SCHENK, including, but not limited to, tilt, filter
5 embedded in wall of the IVC, unsuccessful removal attempt, and filter unable to be retrieved. As a
6 direct and proximate result of these malfunctions, Plaintiff WILLIAM SCHENK suffered life-
7 threatening injuries and damages, and required extensive medical care and treatment. As a further
8 proximate result, Plaintiff WILLIAM SCHENK has suffered and will continue to suffer significant
9 medical expenses, and pain and suffering, and other damages.

10 16. Plaintiff CHRISTINA JONES at all times relevant to this action was and is a citizen and
11 resident of the State of Kentucky. Plaintiff CHRISTINA JONES underwent placement of Defendants'
12 OptEase Vena Cava Filter on or about December 9, 2010. The filter subsequently malfunctioned and
13 caused injury and damages to Plaintiff CHRISTINA JONES, including, but not limited to, tilt, filter
14 embedded in wall of the IVC, unsuccessful removal attempt, and filter unable to be retrieved. As a
15 direct and proximate result of these malfunctions, Plaintiff CHRISTINA JONES suffered life-
16 threatening injuries and damages, and required extensive medical care and treatment. As a further
17 proximate result, Plaintiff CHRISTINA JONES has suffered and will continue to suffer significant
18 medical expenses, and pain and suffering, and other damages.

19 17. Plaintiff NANCY FOLZ at all times relevant to this action was a citizen and resident of
20 the State of Ohio. Plaintiff NANCY FOLZ underwent placement of Defendants' OptEase Vena Cava
21 Filter on or about August 22, 2007. The filter subsequently malfunctioned and caused injury and
22 damages to Plaintiff NANCY FOLZ, including, but not limited to, tilt, filter embedded in wall of the
23 IVC, and filter unable to be retrieved. As a direct and proximate result of these malfunctions, Plaintiff
24 NANCY FOLZ suffered life-threatening injuries and damages, and required extensive medical care and
25 treatment. As a further proximate result, Plaintiff NANCY FOLZ has suffered and will continue to
26 suffer significant medical expenses, and pain and suffering, and other damages.

27 18. Plaintiff EDWARD CHIZEK at all times relevant to this action was and is a citizen and
28 resident of the State of Ohio. Plaintiff EDWARD CHIZEK underwent placement of Defendants'

1 TrapEase Vena Cava Filter on or about November 16, 2005. The filter subsequently malfunctioned and
2 caused injury and damages to Plaintiff EDWARD CHIZEK, including, but not limited to, tilt, filter
3 embedded in wall of the IVC, filter unable to be retrieved, blood clots, clotting and occlusion of IVC
4 filter. As a direct and proximate result of these malfunctions, Plaintiff EDWARD CHIZEK suffered
5 life-threatening injuries and damages, and required extensive medical care and treatment. As a further
6 proximate result, Plaintiff EDWARD CHIZEK has suffered and will continue to suffer significant
7 medical expenses, and pain and suffering, and other damages.

8 19. Plaintiff ANDREW CHAPMAN at all times relevant to this action was and is a citizen
9 and resident of the State of Florida. Plaintiff ANDREW CHAPMAN underwent placement of
10 Defendants' TrapEase Vena Cava Filter on or about May 30, 2010. The filter subsequently
11 malfunctioned and caused injury and damages to Plaintiff ANDREW CHAPMAN, including, but not
12 limited to, migration of the IVC filter. As a direct and proximate result of these malfunctions, Plaintiff
13 ANDREW CHAPMAN suffered life-threatening injuries and damages, and required extensive medical
14 care and treatment. As a further proximate result, Plaintiff ANDREW CHAPMAN has suffered and will
15 continue to suffer significant medical expenses, and pain and suffering, and other damages.

16 20. Defendant CORDIS CORPORATION ("Cordis"), including its department, division, and
17 subsidiary, Cordis Endovascular, is a corporation or business entity organized and existing under the
18 laws of the State of Florida with its headquarters located at 6500 Paseo Padre Pkwy., Fremont,
19 California, 94555.

20 21. Cordis may be served with process by serving its registered agent, CT Corporation
21 System, at 818 West Seventh Street Suite 930, Los Angeles, California 90017.

22 22. The true names and/or capacities, whether individual, corporate, partnership, associate,
23 governmental, or otherwise, of Defendant DOES 1 through 50, inclusive, are unknown to Plaintiffs at
24 this time, who therefore sue said Defendants by such fictitious names. Plaintiffs are informed and
25 believe, and thereon allege, that each Defendant designated herein as a DOE caused injuries and
26 damages proximately thereby to Plaintiffs as is hereinafter alleged, and that each DOE defendant is
27 liable to Plaintiffs for the acts and omissions alleged herein below and the injuries and damages resulting
28

1 therefrom. Plaintiffs seek leave to amend this Complaint to allege the true names and capacities of said
2 DOE defendants when the same are ascertained.

3 23. Plaintiffs are informed and believe, and thereon allege, that at all times herein mentioned,
4 the Defendant and each of the DOE defendants were the agent, servant, employee and/or joint venturer
5 of the other co-defendants, and each of them, and at all said times each Defendant, including DOE
6 defendants, were acting in the full course, scope, and authority of said agency, service, employment
7 and/or joint venture.

8 24. Plaintiffs are informed and believe, and thereon allege, that at all times mentioned herein,
9 Defendant and DOES 1 through 50, and each of them, were also known as, formerly known as, and/or
10 were the successors and/or predecessors in interest/business/product line/or a portion thereof, assigns, a
11 parent, a subsidiary (wholly or partially owned by, or the whole or partial owner), affiliate, partner, co-
12 venturer, merged company, alter egos, agents, equitable trustees and/or fiduciaries of and/or were
13 members in an entity or entities engaged in the funding, researching, studying, manufacturing,
14 fabricating, designing, developing, labeling, assembling, distributing, supplying, leasing, buying,
15 offering for sale, selling, inspecting, servicing, contracting others for marketing, warranting, rebranding,
16 manufacturing for others, packaging, and advertising the device.

17 25. Defendant and DOES 1 through 50, and each of them, are liable for the acts, omissions
18 and tortious conduct of its successors and/or predecessors in interest/business/product line/or a portion
19 thereof, assigns, parent, subsidiary, affiliate, partner, co-venturer, merged company, alter ego, agent,
20 equitable trustee, fiduciary and/or its alternate entities in that Defendant and DOES 1 through 50, and
21 each of them, enjoy the goodwill originally attached to each such alternate entity, acquired the assets or
22 product line (or a portion thereof), and in that there has been a virtual destruction of Plaintiffs' remedy
23 against each such alternate entity, and that each such Defendant has the ability to assume the risk-
24 spreading role of each such alternate entity.

25 26. Plaintiffs are informed and believe, and thereon allege that, at all times herein mentioned,
26 DOES 1 through 50, and each of them, were and are corporations organized and existing under the laws
27 of the State of California or the laws of some state or foreign jurisdiction; that each of the said DOE
28

1 defendants were and are authorized to do and are doing business in the State of California and regularly
2 conducted business in the State of California.

3 27. Upon information and belief, Defendants at all relevant times were engaged in the
4 business of researching, developing, designing, licensing, manufacturing, distributing, selling,
5 marketing, and/or introducing into interstate commerce and into the State of California, either directly or
6 indirectly through third parties or related entities, its products, including the TrapEase and OptEase IVC
7 filters, and derived substantial income from doing business in California.

8 28. "Cordis" and "Defendants" where used hereinafter, shall refer to all subsidiaries,
9 affiliates, divisions, franchises, partners, joint venturers, organizational units of any kind, predecessors,
10 successors, assigns, officers, directors, employees, agents and representatives of Cordis Corporation; as
11 well as DOE Defendants 1 through 50, and each of them.

12 29. Joinder of Plaintiffs in this First Amended Complaint for Damages is proper pursuant to
13 *Code of Civil Procedure* Section 378 because Plaintiffs assert a right to relief in respect of or arising out
14 of the same transaction, occurrence, or series of transactions or occurrences, and questions of law and
15 fact common to all Plaintiffs will arise in the action.

16 **JURISDICTION AND VENUE**

17 30. This Court has jurisdiction under the California Constitution, Article VI, Section 10 and
18 *Code of Civil Procedure* Section 410.10. Plaintiffs' damages exceed the jurisdictional minimum of this
19 Court.

20 31. Venue is proper in this Court pursuant to *Code of Civil Procedure* Sections 395 and 395.5
21 because the principal place of business for Defendant CORDIS CORPORATION is situated in Alameda
22 County. Further, a substantial amount of Defendants' conduct, as alleged herein by Plaintiffs, took
23 place in Alameda County.

24 32. Requiring Defendants to litigate these claims in California does not offend traditional
25 notions of fair play and substantial justice and is permitted by the United States Constitution.

26 Defendants are "at home" in the State of California. Cordis maintains campuses and facilities in Fremont
27 and Oakland, California, in Alameda County, and has its headquarters here. Cordis' website lists its
28 address as 6500 Paseo Padre Parkway, Fremont, CA 94555 (*see* <https://www.cordis.com/> (last visited

1 May 13, 2016)). A Cordis-affiliate website represents that Cordis' "North American operations are
2 based out of the San Francisco Bay Area" and also lists the 6500 Paseo Padre Parkway, Fremont, CA
3 94555 address (see <http://www.cardinalhealth.com/en/cmp/ext/cor/cordis.html> (last visited May 13,
4 2016)). Thus, Cordis affirmatively represents to the public that its headquarters is in California.

5 33. Defendants systematically availed themselves of the State of California by conducting
6 regular and sustained business and engaging in substantial commerce and business activity in California,
7 including without limitation researching, developing, designing, licensing, manufacturing, distributing,
8 selling, marketing, and/or introducing into interstate commerce in the state of California, either directly
9 or indirectly, its products, including Cordis IVC filters.

10 34. Plaintiffs' claims arise from and relate to Cordis' purposeful avail of the State of
11 California because Cordis' wrongful conduct in developing, designing, selling, marketing,
12 manufacturing and/or distributing Cordis IVC filters took place, in whole or in part, in the State of
13 California. Therefore, the claims of California-plaintiffs *and* out-of-state plaintiffs relate to and arise
14 from Defendants' explicit contacts and purposeful avail of the State of California. Further and
15 independently, Cordis consented to jurisdiction in the State of California by appointing an agent for
16 service of process in this State and by conducting substantial systematic business in this State.

17 35. The instant First Amended Complaint for Damages does not confer diversity jurisdiction
18 upon the federal courts pursuant to 28 U.S.C. § 1332. Likewise, federal question subject matter
19 jurisdiction pursuant to 28 U.S.C. § 1331 is not invoked by the instant Complaint, as it sets forth herein
20 exclusively state law claims against the Defendants. Nowhere do Plaintiffs plead, expressly or
21 implicitly, any cause of action or request any remedy that arises under or is founded upon federal law,
22 and any alleged federal rights or remedies are expressly disavowed. The issues presented by Plaintiffs
23 do not implicate substantial federal questions, do not turn on the necessary interpretation of federal law,
24 and do not affect the federal system as a whole. The assertion of federal jurisdiction over claims made
25 herein would improperly disturb the congressionally approved balance of federal and state
26 responsibilities.

27
28 ///

BACKGROUND

INFERIOR VENA CAVA FILTERS GENERALLY

36. IVC filters were first made commercially available to the medical community in the 1960s. Over the years, medical device manufacturers have introduced several different designs of IVC filters.

37. An IVC filter is a device that is designed to filter or “catch” blood clots that travel from the lower portions of the body to the heart and lungs. IVC filters were originally designed to be permanently implanted in the IVC.

38. The IVC is a vein that returns blood to the heart from the lower portions of the body. In certain people, for various reasons, blood clots travel from the vessels in the legs and pelvis, through the vena cava and into the lungs. Oftentimes, these blood clots develop in the deep leg veins, a condition called “deep-vein thrombosis” or “DVT.” Once blood clots reach the lungs, they are considered “pulmonary emboli” or “PE.” Pulmonary emboli present risks to human health.

39. People at risk for DVT/PE can undergo medical treatment to manage the risk. For example, a doctor may prescribe anticoagulant therapies such as medications like Heparin, Warfarin, or Lovenox to regulate the clotting factor of the blood. In some people who are at high risk for DVT/PE and who cannot manage their conditions with medications, physicians may recommend surgically implanting an IVC filter to prevent thromboembolic events.

40. As stated above, IVC filters have been on the market for decades. All IVC filters are only cleared for use by the Food & Drug Administration (“FDA”) for prevention of recurrent pulmonary embolism in patients at risk for pulmonary embolism and where anticoagulation therapy has failed or is contraindicated.

41. In order to increase sales of these devices, Defendants sought to expand the market for prophylactic use among nontraditional patient populations that were temporarily at risk of developing blood clots.

42. Defendant Cordis engaged in marketing campaigns directed toward the bariatric, trauma, orthopedic and cancer patient population. Expansion to these new patient groups would substantially increase sales and the first manufacturer to market would capture market share.

1 43. Other manufacturers also saw this opportunity, which triggered a race to market a device
2 that provided physicians the option to retrieve the filter after the clot risk subsided.

3 44. From 2000 through 2003, manufacturers of IVC filters, including Defendants, raced
4 against each other to bring the first IVC filter to the market with the added indication of optional
5 retrieval. In 2003, the FDA cleared three different IVC filters for a retrieval indication, one of which
6 was the OptEase filter by Defendant Cordis.

7 45. There is no evidence that Defendants' IVC filters were effective in preventing pulmonary
8 embolism (the very condition the products were indicated to prevent).

9 46. Years after the implantation of retrievable filters into the bodies of patients, scientists
10 began to study the effectiveness of the retrievable filters. As recently as October 2015, an expansive
11 article published in the *Annals of Surgery* concerning trauma patients inserted with IVC filters
12 concluded that IVC filters were not effective in preventing pulmonary emboli, and instead actually
13 caused thrombi to occur.

14 47. Comparing the results of over 30,000 trauma patients who had not received IVC filters
15 with those who had received them, the *Annals of Surgery* study published its alarming results:

- 16 a. Almost twice the percentage of patients with IVC filters in the study died compared to
17 those that had not received them.
18 b. Over five times the relative number of patients with IVC filters developed DVTs.
19 c. Over four times the relative percentage of patients with filters developed thromboemboli.
20 d. Over twice the percentage of patients developed a pulmonary embolus – the very
21 condition Defendant Cordis told the FDA, physicians, and the public that its IVC filters
22 were designed to prevent.

23 48. Other studies also have revealed that these devices suffer common failure modes such as
24 migration, perforation, thrombosis, and fracture, all of which can cause serious injury or death. For
25 example, recent studies of Cordis IVC filters have revealed fracture rates as high as 50% and
26 recommend medical monitoring and/or removal.

27 49. These studies, including the *Annals of Surgery* study, have shown there is no evidence
28 establishing that IVC filters are effective and that these devices suffer common failure modes, including,

1 but not limited to, migration, perforation, thrombosis, tilt and fracture, all of which can cause serious
 2 injury or death. Thus, the current state of scientific and medical evidence indicates that IVC filters are
 3 not only ineffective but that they are themselves a health hazard.

4 THE TRAPEASE™ AND OPTEASE™ IVC FILTERS

5 50. On or about January 10, 2001, Defendants bypassed the more onerous FDA's approval
 6 process for new devices and obtained "clearance" under Section 510(k) of the Medical Device
 7 Amendments to the Food, Drug, and Cosmetic Act to market the TrapEase Vena Cava Filter as a
 8 *permanent* filter by claiming it was substantially similar in respect to safety, efficacy, design, and
 9 materials as the IVC filters already available on the market.

10 51. Section 510(k) permits the marketing of medical devices if the device is substantially
 11 equivalent to other legally marketed predicate devices without formal review for the safety or efficacy of
 12 the said device. The FDA explained the difference between the 510(k) process and the more rigorous
 13 "premarket approval" (PMA) process in its amicus brief filed with the Third Circuit in *Horn v. Thoratec*
 14 *Corp.*, which the court quoted from:

15 A manufacturer can obtain an FDA finding of 'substantial equivalence' by submitting a
 16 premarket notification to the agency in accordance with section 510(k) of the [Food Drug
 17 and Cosmetic Act]. 21 U.S.C. § 360(k). A device found to be 'substantially equivalent'
 18 to a predicate device is said to be 'cleared' by FDA (as opposed to 'approved' by the
 19 agency under a PMA. A pre-market notification submitted under 510(k) is thus entirely
 20 different from a PMA which must include data sufficient to demonstrate that the IVC
 21 Filters is safe and effective.

22 376 F.3d 163, 167 (3d Cir. 2004) (emphasis in original).

23 52. In *Medtronic, Inc. v. Lohr*, the U.S. Supreme Court similarly described the 510(k)
 24 process, observing:

25 If the FDA concludes on the basis of the [manufacturer's] § 510(k) notification that the
 26 device is "substantially equivalent" to a pre-existing device, it can be marketed without
 27 further regulatory analysis. . . . The § 510(k) notification process is by no means
 28 comparable to the PMA process; in contrast to the 1,200 hours necessary to complete a
 PMA review, the § 510(k) review is completed in average of 20 hours. . . . As one
 commentator noted: "The attraction of substantial equivalence to manufacturers is clear.
 Section 510(k) notification requires little information, rarely elicits a negative response
 from the FDA, and gets processed quickly."

1 518 U.S. 470, 478-79 (1996) (quoting Adler, *The 1976 Medical Device Amendments: A Step in the*
2 *Right Direction Needs Another Step in the Right Direction*, 43 Food Drug Cosm. L.J. 511, 516 (1988)).

3 53. Pursuant to *Wyeth v. Levine*, 555 U.S. 555 (2009), once a product is cleared “the
4 manufacturer remains under an obligation to investigate and report any adverse events associated with
5 the drug . . . and must periodically submit any new information that may affect the FDA’s previous
6 conclusions about the safety, effectiveness, or labeling” This obligation extends to post-market
7 monitoring of adverse events/complaints.

8 54. In July 2000, through this 510(k) process, Defendants obtained clearance from the FDA
9 to market the TrapEase filter as a permanent filter.

10 55. The TrapEase filter is made with Nitinol – a nickel titanium alloy. The filter utilizes a
11 design known as a double basket or double filter for the capture of blood clots and/or emboli. This
12 design consists of a basket made of six diamond-shaped struts proximally and six diamond-shaped struts
13 distally, forming proximal and distal baskets, which are connected by six straight struts to create a single
14 symmetric filter. The filter has proximal and distal anchoring barbs located on each connecting strut for
15 fixation of the filter to the vena cava wall to prevent movement after placement.

16 56. Nitinol alloy is used in a number of different medical device applications. It is beneficial
17 for these applications and is employed as material in stents and other medical device applications. It is
18 also used in the manufacture of the TrapEase filter, and other brands of IVC filters.

19 57. Specific manufacturing processes need to be utilized when using Nitinol as a component
20 for medical devices, including IVC filters. Primarily, the Nitinol material should be electro-polished
21 prior to assembly of the finished medical device.

22 58. Electro-polishing is a manner of removing surface blemishes, “draw marking” and
23 circumferential grinding markings on the exterior of the surface of the Nitinol material. The existence
24 of these surface blemishes, “draw markings” and “circumferential grind-markings” causes/results in the
25 weakening of the structural integrity of the end product, whether it is an IVC filter or other medical
26 device.

27 59. In or around September 2002, Defendants sought clearance through the 510(k) process to
28 market the OptEase Vena Cava Filter for the same indicated uses as the TrapEase filter. Defendants

1 represented that the OptEase filter contained the same fundamental technology and was substantially
2 equivalent in terms of safety and efficacy as the predicate devices already available on the market.

3 60. Unlike the TrapEase filter, which has proximal and distal anchoring barbs located on
4 each connecting strut for fixation of the filter to the vena cava wall, the OptEase filter has anchoring
5 barbs for fixation of the filter only on the superior end of each of the six straight struts and has a hook at
6 the inferior end of the basket to allow retrieval with a snare.

7 61. Both designs for the TrapEase filter and OptEase filter suffer flaws making them
8 defective and unreasonably dangerous. Defendants' IVC filters are designed in such a way that when
9 exposed to expected and reasonably foreseeable *in-vivo* conditions, the devices will fracture, migrate,
10 tilt, perforate internal organs and vasculature, and lead to the formation of thromboembolism and
11 pulmonary embolism.

12 62. For years, it has been known by manufacturers of the Nitinol medical devices and the
13 medical device industry that electro-polishing Nitinol results in increased structural integrity of the
14 device and resistance to fatigue and fatigue failures.

15 63. The exterior surfaces of the Cordis IVC filters were not electro-polished prior to
16 completion of the manufacturing process. This is a manufacturing defect that exists in the TrapEase and
17 OptEase filters which causes these filters to be structurally weak and susceptible to a significant risk of
18 failure/fracture.

19 64. Additionally, Defendants represented that the self-centering design of the TrapEase filter
20 allows accurate, predictable placement, and that its site struts help reduce the risk of tilting and
21 migration, while in reality the filters regularly tilt, migrate, and become embedded in the vena cava wall.

22 65. The anchoring mechanism of Defendants' filters is also insufficient to prevent tilting and
23 migration post-placement.

24 66. The configuration of the Cordis IVC filters actually leads to the formation of blood clots
25 and pulmonary embolism – the exact condition the devices are meant to protect against.

26 67. That Defendants allowed these devices to proceed to market indicates that they failed to
27 establish and maintain an appropriate Quality System concerning design and risk analysis.
28

1 68. A manufacturer must, at a minimum, undertake research and testing to understand the
2 anatomy of where a medical device will be implanted and understand the forces the device may be
3 exposed to once implanted in a human body. This design input must then be used to determine the
4 minimum safety requirements or attributes the device must have to meet user needs. In the case of an
5 IVC filter, user needs include a device that will capture blood clots of sufficient size to cause harmful
6 consequences and that will not fracture, migrate, tilt, perforate the vena cava, or malfunction in some
7 other way, or be prothombotic. Defendants failed to undertake any such efforts in these regards.

8 69. Prior to bringing a product to market, a manufacturer must also conduct sufficient testing
9 under real world or simulated use conditions to ensure that the device will meet user needs even when
10 exposed to reasonably foreseeable worst-case conditions. Defendants failed to adequately establish and
11 maintain such policies, procedures or protocols with respect to their IVC filters.

12 70. Once placed on the market, Defendants' post-market surveillance system should have
13 revealed to Defendants that the TrapEase and OptEase filters were unreasonably dangerous and
14 substantially more prone to fail or malfunction, and cause great bodily harm to patients compared to
15 other available treatment options.

16 71. MAUDE is a database maintained by the FDA to house medical device reports submitted
17 by mandatory reporters (such as manufacturers and device user facilities) and voluntary reporters (such
18 as health care providers and patients).

19 72. Shortly after going on market, Defendants began receiving large numbers of adverse
20 event reports ("AERs") from health care providers reporting that the Cordis IVC filters were fracturing
21 post-implantation and that fractured pieces and/or the entire device was migrating to other areas of the
22 body, including the heart and lungs.

23 73. Defendants also received large numbers of AERs reporting that the TrapEase filters and
24 OptEase filters were found to have excessively tilted, perforated the IVC, or caused thrombosis or
25 stenosis of the vena cava post-implantation.

26 74. These failures were often associated with severe patient injuries such as:

- 27 a. Death;
28 b. Hemorrhage;

- c. Cardiac/pericardial tamponade (pressure caused by a collection of blood in the area around the heart);
- d. Cardiac arrhythmia and other symptoms similar to myocardial infarction;
- e. Severe and persistent pain;
- f. Perforations of tissue, vessels and organs;
- g. Chronic deep vein thrombosis;
- h. Pulmonary embolism; and,
- i. Compartment syndrome.

75. These failures and resulting injuries are attributable, in part, to the fact that the Cordis IVC filter design was unable to withstand the normal anatomical and physiological loading cycles exerted *in vivo*.

76. Recent medical studies have confirmed what Defendants have known or should have known since shortly after the release of each of these filters – not only do Cordis IVC filters fail at alarming rates, but they also fail at rates substantially higher than other available IVC filters. For instance, a recent large medical study found that OptEase and TrapEase filters suffer fracture rates of 37.5% and 23.1% respectively, when left implanted a minimum of 46 months. Another recent study found that the TrapEase filter had a 64% fracture rate when left in more than four years. Another study found a statistically significant increased rate of caval thrombosis with the ObtEase filter compared to Gunther Tulip and Recovery Filters.

77. As a minimum safety requirement, manufacturers must establish and maintain post-market procedures to timely identify the cause of device failures and other quality problems and to take adequate corrective action to prevent the recurrence of these problems.

78. Defendants failed to identify or acknowledge these device failures or determine their causes.

79. Defendants failed to take timely and adequate remedial measures to correct known design and manufacturing defects with the Cordis IVC filters.

80. Defendants also misrepresented and concealed the risks and benefits of the Cordis IVC filters in the labeling and marketing distributed to the FDA, physicians and the public. For instance,

1 Defendants represented that their filters were safe and effective – more safe and effective than other
2 available IVC filters. However, there is no reliable evidence to support these claims and, to the
3 contrary, the Cordis IVC filters have been associated with a high rate of failure.

4 81. Defendants also represented that the design of these devices would eliminate the risk that
5 pieces of the devices could perforate the vena cava, that the devices could tilt, or that fractures could
6 occur and migrate throughout the body. The medical literature and AERs have proven these claims to be
7 false.

8 82. Defendants also marketed the OptEase filter as being “easy” to remove. However, it is
9 one of the most difficult filters to remove. Dr. William T. Kuo, an expert in the removal of IVC filters
10 and vascular surgery, has established an IVC Filter Clinic at Stanford University where his team
11 specializes in the removal of IVC filters that other vascular surgeons refuse to remove for fear of
12 rupturing the vena cava or other internal organs and causing great bodily harm or death to the patient.
13 Dr. Kuo wrote in *the Journal of Vascular Interventional Radiology* that the Cordis filters were the most
14 difficult to retrieve from patients, at least partially due to the design of the filters, which create greater
15 contact with the vein walls than competitors’ filters.

16 83. This is particularly concerning because having an IVC filter for a prolonged period of
17 time increases the risk of developing chronic deep venous thrombosis, PE, IVC occlusion, post-
18 thrombotic syndrome, filter fracture, and caval perforation with pain and organ injury. Many patients
19 with IVC filters are now routinely managed with lifelong anticoagulation solely to reduce the risk of
20 having the filter in place, subjecting patients to the risks and inconvenience of anticoagulation.

21 84. Defendants also failed to adequately disclose the risks of these filters, such as migration,
22 fracture, perforation, tilt, thrombosis, the prothrombotic nature of the devices, that the devices may not
23 be retrievable, or that these failures were known to be causing severe injuries and death or the rate at
24 which these events were occurring.

25 85. Cordis’ labeling was additionally defective in that it directed physicians to implant the
26 OptEase filter upside down. When the OptEase filter was placed as directed by the labeling, the hooks
27 designed to ensure stability were facing in the wrong direction, rendering an already inadequate
28 anchoring system even further defective. As Cordis now explain in its labeling, implanting the device in

1 this fashion “can result in life threatening or serious injury including, but not limited to dissection, vessel
2 perforation, migration of the filter with secondary damage to cardiac structures, ineffective pulmonary
3 embolism prevention or death.”

4 86. Cordis began a series of recalls on March 29, 2013 relating to its labeling, which
5 instructed physicians to implant the devices upside down. These recalls were not timely, nor did they
6 fully correct the defects in Defendants’ labeling. Further, Defendants downplayed the danger patients
7 were exposed to and failed to take adequate steps to ensure patients actually received notice of the recall.

8 87. The FDA classified the initial recall as a Class I recall, which is the most serious type of
9 recall and involves situations in which the FDA has determined there is a reasonable probability that use
10 of these products will cause serious adverse health consequences or death.

11 88. Defendants have admitted that any patients implanted with one of these recalled units
12 should receive medical monitoring. Specifically, these patients should undergo imaging to ascertain
13 whether or not the device was properly deployed and, if not, be assessed for removal.

14 89. Given the unreasonably high failure and injury rates associated with Cordis IVC filters
15 when left implanted long-term, Defendants should be required to pay for medical monitoring to assess
16 the condition of these devices and whether or not retrieval should be undertaken.

17 90. On April 5, 2016, at the annual Society of Interventional Radiology in Vancouver,
18 Canada, Dr. Steven Wang, an interventional radiologist from Palo Alto, California who is affiliated with
19 Kaiser Permanente, presented the results of a retrospective study involving 96 patients in which he
20 sought to understand the prevalence of long-term (greater than 46 months) complications of both
21 permanent and retrievable IVC filters. The study looked at all inferior vena cava filters implanted in
22 patients from January 2007 through December 2009 at multiple health care facilities across the United
23 States. Dr. Wang then identified all patients who had imaging of the filter taken at four years or more
24 after implantation. Of those patients (96), he then evaluated the imaging to determine whether the IVC
25 filter had malfunctioned. After reviewing the data, the authors concluded that device complications at
26 four or more years after implantation “are relatively common.” They also found that the Cordis OptEase
27 and TrapEase IVC filters suffered fracture rates of 37.5% and 23.1%, respectively.
28

ESTOPPEL FROM PLEADING STATUTES OF LIMITATIONS OR REPOSE

91. Plaintiffs incorporate by reference all prior allegations.

92. Plaintiffs are within the applicable statute of limitations for their claims because Plaintiffs (and their healthcare professionals) did not discover, and could not reasonably discover, the defects and unreasonably dangerous condition of their Cordis IVC filters.

93. Plaintiffs' ignorance of the defective and unreasonably dangerous nature of the Cordis IVC filters, and the causal connection between these defects and each Plaintiff's injuries and damages, is due in large part to Defendants' acts and omissions in fraudulently concealing information from the public and misrepresenting and/or downplaying the serious threat to public safety its products present.

94. In addition, Defendants are estopped from relying on any statutes of limitation or repose by virtue of unclean hands, acts of fraudulent concealment, affirmative misrepresentations and omissions.

95. Such conduct includes intentional concealment from Plaintiffs, their health care professionals, and the general consuming public of material information that Cordis IVC filters had not been demonstrated to be safe or effective, and carried with them the risks and dangerous defects described herein.

96. Defendants had a duty to disclose the fact that Cordis IVC filters are not safe or effective, not as safe as other filters on the market, defective, and unreasonably dangerous, and that their implantation and use carried with it the serious risk of developing perforation, migration, tilting, and/or fracture, and/or other injuries referenced herein.

FIRST CAUSE OF ACTION

STRICT PRODUCTS LIABILITY – DESIGN DEFECT

(By All Plaintiffs, As to All Defendants)

97. Plaintiffs incorporate by reference all prior allegations.

98. At all relevant times, Defendants designed, tested, distributed, manufactured, advertised, sold, marketed and otherwise placed into the stream of commerce Cordis IVC filters – the TrapEase filters and the OptEase filters – for use by consumers, such as Plaintiffs, in the United States.

1 99. Defendants' Cordis IVC filters were expected to, and did, reach Defendants' intended
2 consumers, handlers, and persons coming into contact with the product without substantial change in the
3 condition in which they were researched, tested, developed, designed, licensed, manufactured, packaged,
4 labeled, distributed, sold, and marketed by Defendants.

5 100. The devices implanted in Plaintiffs were in an unreasonably dangerous condition at the
6 time they left Defendants' control.

7 101. At all times relevant, Cordis IVC filters were manufactured, designed and labeled in an
8 unsafe, defective, and inherently dangerous condition which was dangerous for use by the public in
9 general and Plaintiffs in particular.

10 102. Defendants' Cordis IVC filters, as researched, tested, developed, designed, licensed,
11 manufactured, packaged, labeled, distributed, sold, and marketed by Defendants were defective in
12 design and formulation and unreasonably dangerous in that when they left the hands of Defendants'
13 manufacturers and/or suppliers, the foreseeable risks exceeded the alleged benefits associated with the
14 use of Cordis IVC filters, and the devices were more dangerous than the ordinary customer would
15 expect.

16 103. Physicians implanted Cordis IVC filters as instructed via the Instructions for Use and in a
17 foreseeable manner as normally intended, recommended, promoted, and marketed by Defendants.

18 104. Plaintiffs received and utilized Defendants' IVC filters in a foreseeable manner as
19 normally intended, recommended, promoted, and marketed by Defendants.

20 105. At the time Defendants placed their defective and unreasonably dangerous Cordis IVC
21 filters into the stream of commerce commercially, technologically, and scientifically feasible alternative
22 designs were attainable and available.

23 106. These alternative designs would have prevented the harm resulting in each Plaintiff's
24 Injuries and Damages without substantially impairing the reasonably anticipated or intended function of
25 Cordis IVC filters.

26 107. Neither Plaintiffs nor their health care providers could have, by the exercise of reasonable
27 care, discovered the defective condition or perceived the unreasonable dangers with these devices prior
28 to Plaintiffs' implantation with the Cordis IVC filters.

108. As a direct and proximate result of the defective and unreasonably dangerous condition of Cordis IVC filters, Plaintiffs suffered Injuries and Damages.

SECOND CAUSE OF ACTION

STRICT PRODUCTS LIABILITY – INADEQUATE WARNING

(By All Plaintiffs, As to All Defendants)

109. Plaintiffs incorporate by reference all prior allegations.

110. At all relevant times, Defendants engaged in the business of testing, developing, designing, manufacturing, packaging, labeling, marketing and/or promoting, selling and/or distributing Cordis IVC filters – the TrapEase filters and the OptEase filters – and through that conduct have knowingly and intentionally placed Cordis IVC filters into the stream of commerce with full knowledge that they reach consumers such as Plaintiffs who would become implanted with them.

111. Defendants did, in fact, test, develop, design, manufacture, package, label, market and/or promote, sell and/or distribute their Cordis IVC filters to Plaintiffs, their prescribing health care professionals, and the consuming public. Additionally, Defendants expected that the Cordis IVC filters they were selling, distributing, supplying, manufacturing, and/or promoting to reach, and did, in fact, reach, prescribing health care professionals and consumers, including Plaintiffs and their prescribing health care professionals, without any substantial change in the condition of the product from when it was initially distributed by Defendants.

112. The Cordis IVC filters had potential risks and side effects that were known or knowable to Defendants by the use of scientific inquiry and information available before, at, and after the manufacture, distribution, and sale of the Cordis IVC filters.

113. Defendants knew or should have known of the defective condition, characteristics, and risks associated with Cordis IVC filters. These defective conditions included, but were not limited to: (1) Cordis IVC filters posed a significant and higher risk of failure than other similar IVC filters (fracture, migration, tilting, and perforation of the vena cava wall); (2) Cordis IVC filter failures result in serious injuries and death; (3) certain conditions or post-implant procedures, such as morbid obesity or open abdominal procedures, could affect the safety and integrity of Cordis IVC filters; (4) leaving Cordis IVC filters in for a period longer than necessary to prevent immediate risk of pulmonary

1 embolism increases the risk for patients of failures and complications with the filter, such as the filter
2 becoming deeply embedded in the vena cava, making them difficult or impossible for removal.

3 114. Defendants placed into the stream of commerce for ultimate use by users like Plaintiffs
4 and their health care providers, Cordis IVC filters that were in an unreasonably dangerous and defective
5 condition due to warnings and instructions for use that were inadequate, including, but not limited to
6 Defendants' failure to:

- 7 a. Provide adequate instructions for how long in patients the filter should remain;
- 8 b. Highlight the importance of removing the filter;
- 9 c. Warn of the known risk of great bodily harm or death if the filter was not removed;
- 10 d. Highlight the known risk of great bodily harm or death in the event of occlusion of the
11 vein caused by the filter itself;
- 12 e. Warn of the risk of new DVT if the filter was left in too long; Warn of the risk of new
13 pulmonary embolism, thrombosis, swelling, and pain in the lower extremities if the filter
14 was left in too long; and
- 15 f. Warn of the risk of filter perforation, fracture, or migration.

16 115. Cordis IVC filters were in a defective and unsafe condition that was unreasonably and
17 substantially dangerous to any user or consumer implanted with Cordis IVC filters, such as Plaintiffs,
18 when used in an intended or reasonably foreseeable way.

19 116. The warnings and directions Defendants provided with their Cordis IVC filters failed to
20 adequately warn of the potential risks and side effects of Cordis IVC filters.

21 117. These risks were known or were reasonably scientifically knowable to Defendants, but
22 not known or recognizable to ordinary consumers, such as Plaintiffs, or their treating doctors.

23 118. Defendants' IVC filters were expected to and did reach Plaintiffs without substantial
24 change in their condition, labeling, or warnings as manufactured, distributed, and sold by Defendants.

25 119. Additionally, Plaintiffs and their physicians used Cordis IVC filters – the TrapEase filters
26 or the OptEase filters – in the manner in which they were intended to be used, making such use
27 reasonably foreseeable to Defendants.
28

120. As a direct and proximate result of Defendants' information defects, lack of sufficient instructions or warnings prior to, on, and after the date Plaintiffs used Cordis IVC filters, Plaintiffs suffered Injuries and Damages.

THIRD CAUSE OF ACTION

STRICT PRODUCTS LIABILITY – MANUFACTURING DEFECT

(By All Plaintiffs, As to All Defendants)

121. Plaintiffs incorporate by reference all prior allegations.

122. Prior to, on, and after the date the Cordis IVC filters – the TrapEase filter or the OptEase filter – were implanted in Plaintiffs, Defendants designed, distributed, manufactured, sold, and marketed Cordis IVC filters for use in the United States, including California.

123. At all relevant times, Defendants designed, distributed, manufactured, marketed, and sold Cordis IVC filters that were unreasonably dangerous, unsafe, and defective in manufacture when they left Defendants' possession.

124. Upon information and belief, Cordis IVC filters contain a manufacturing defect, in that they differed from the manufacturer's design or specifications, or from other typical units of the same product line.

125. As a direct and proximate cause of Defendants' design, manufacture, marketing, and sale of Cordis IVC filters prior to, on, and after the date Plaintiffs used the Cordis IVC filters, Plaintiffs suffered Injuries and Damages.

FOURTH CAUSE OF ACTION

NEGLIGENCE

(By All Plaintiffs, As to All Defendants)

126. Plaintiffs incorporate by reference all prior allegations.

127. At the time of the design, distribution, manufacture, advertising, sale, and marketing of Cordis IVC filters – the TrapEase filters and the OptEase filters – and their implantation in Plaintiffs, Defendants were aware that Cordis IVC filters were designed and manufactured in a manner presenting:

- a. An unreasonable risk of fracture of portions of the filters;
- b. An unreasonable risk of migration of the filters and/or portions of the filters;

- c. An unreasonable risk of filters tilting and/or perforating the vena cava wall; and
- d. Insufficient strength or structural integrity to withstand normal placement within the human body.

128. At the time of the design, distribution, manufacture, advertising, sale, and marketing of Cordis IVC filters, and their implantation in Plaintiffs, Defendants were also aware that Cordis IVC filters:

- a. Would be used without inspection for defects;
- b. Would be used by patients with special medical conditions such as Plaintiffs;...
- c. Had previously caused serious bodily injury to its users with special medical conditions such as Plaintiffs;
- d. Had no established efficacy;
- e. Were less safe and effective than the predicate IVC filters already available on market;
- f. Would be implanted in patients where the risk outweighed any benefit or utility of the filters;
- g. Contained instructions for use and warnings that were inadequate; and
- h. Were prothombotic.

129. At the time of manufacture and sale of the TrapEase and OptEase filters, including the ones implanted in Plaintiffs, Defendants knew or should have known that using the TrapEase and OptEase filters as intended or in a reasonably foreseeable manner created a significant risk of patients suffering severe health side effects including, but not limited to: hemorrhage; cardiac/pericardial tamponade; cardiac arrhythmia and other symptoms similar to myocardial infarction; perforations of tissue, vessels and organs; chronic deep vein thrombosis; pulmonary embolism; thrombosis; compartment syndrome; and other severe personal injuries and diseases, which are permanent in nature, including, but not limited to, death, physical pain and mental anguish, scarring and disfigurement, diminished enjoyment of life, continued medical care and treatment due to chronic injuries/illness proximately caused by the device; and the continued risk of requiring additional medical and surgical procedures including general anesthesia, with attendant risk of life threatening complications.

1 130. Defendants had a duty to exercise due care and avoid unreasonable risk of harm to others
2 in the design of Cordis IVC filters.

3 131. Defendants breached these duties by, among other things:

- 4 a. Designing and distributing a product in which it knew or should have known that the
5 likelihood and severity of potential harm from the product exceeded the burden of taking
6 safety measures to reduce or avoid harm;
- 7 b. Designing and distributing a product which it knew or should have known that the
8 likelihood and severity of potential harm from the product exceeded the likelihood of
9 potential harm from other IVC filters available for the same purpose;
- 10 c. Failing to perform reasonable pre- and post-market testing of Cordis IVC filters to
11 determine whether or not the products were safe for their intended use;
- 12 d. Failing to use reasonable and prudent care in the design, research, manufacture, and
13 development of Cordis IVC filters so as to avoid the risk of serious harm associated with
14 the use of Cordis IVC filters;
- 15 e. Advertising, marketing, promoting, and selling Cordis IVC filters for uses other than as
16 approved and indicated in the products' labels;
- 17 f. Failing to use reasonable care to warn or instruct, including pre and post-sale, Plaintiffs,
18 their prescribing physicians, or the general health care community about the TrapEase
19 and OptEase filters' substantially dangerous condition or about facts making the products
20 likely to be dangerous;
- 21 g. Advertising, marketing and recommending the use of the TrapEase and OptEase filters,
22 while concealing and failing to disclose or warn of the dangers known by Defendants to
23 be connected with and inherent in the use of these filter systems;
- 24 h. Representing that the TrapEase and OptEase filters were safe for their intended use when,
25 in fact, Defendants knew and should have known the products were not safe for their
26 intended uses;
27
28

- i. Continuing to manufacture and sell the TrapEase and OptEase filters with the knowledge that said products were dangerous and not reasonably safe, and failing to comply with good manufacturing regulations;
- j. Failing to establish an adequate quality assurance program used in the manufacturing of Cordis IVC filters; and
- k. Failing to perform adequate evaluation and testing of Cordis IVC filters when such evaluation and testing would have revealed the propensity of Cordis IVC filters to cause injuries similar to those that Plaintiffs suffered.

132. At all relevant times, Defendants had a duty to exercise due care in the manufacturing of Cordis IVC filters.

133. Defendants breached this duty by, among other things:

- a. Failing to adopt manufacturing processes that would reduce the foreseeable risk of product failure;
- b. Failing to use reasonable care in manufacturing the product and by producing a product that differed from their design or specifications or from other typical units from the same production line;
- c. Failing to use reasonable and prudent care in the design, research, manufacture, and development of Cordis IVC filters and their manufacturing process so as to avoid the risk of serious harm associated with the use of Cordis IVC filters; and
- d. Failing to establish an adequate quality assurance program used in the manufacturing of their IVC filters.

134. At this time, all Cordis IVC filters – the TrapEase filters and the OptEase filters – are misbranded and adulterated by virtue of them failing to be the substantial equivalent of predicate IVC filter devices, making them subject to corrective action, including recall, in the interest of patient safety.

135. Prior to, on, and after the date of Plaintiffs' implantation with a Cordis IVC filter, and at all relevant times, Defendants knew or reasonably should have known that Cordis IVC filters and their warnings were defective and dangerous or were likely to be dangerous when used in a reasonably foreseeable manner.

1 136. Prior to, on, and after the date of Plaintiffs' implantation with a Cordis IVC filter and at
2 all relevant times thereafter, Defendants became aware that the defects of Cordis IVC filters resulted in
3 Cordis IVC filters causing injuries similar to those Plaintiffs suffered.

4 137. Reasonable manufacturers and distributors under the same or similar circumstances
5 would have recalled or retrofitted Cordis IVC filters, and would thereby have avoided and prevented
6 harm to many patients, including Plaintiffs.

7 138. In light of this information and Defendants' knowledge described above, Defendants had
8 a duty to recall and/or retrofit Cordis IVC filters.

9 139. Defendants breached its duty to recall and/or retrofit Cordis IVC filters.

10 140. At all relevant times, Defendants knew or should have known that Cordis IVC filters
11 were defective and dangerous or were likely to be dangerous when used in a reasonably foreseeable
12 manner.

13 141. Such danger included the propensity of Cordis IVC filters to cause injuries similar to
14 those suffered by Plaintiffs.

15 142. At all relevant times, Defendants also knew or reasonably should have known that the
16 users of Cordis IVC filters, including Plaintiffs and their health care providers, would not realize or
17 discover on their own the dangers presented by Cordis IVC filters.

18 143. Reasonable manufacturers and reasonable distributors, under the same or similar
19 circumstances as those of Defendants prior to, on, and after the date of Plaintiffs' use of a Cordis IVC
20 filter, would have warned of the dangers presented by Cordis IVC filters, or instructed on the safe use of
21 Cordis IVC filters.

22 144. Prior to, on, and after the date of each Plaintiff's use of the IVC filter, Defendants had a
23 duty to adequately warn of the dangers presented by Cordis IVC filters and/or instruct on the safe use of
24 Cordis IVC filters.

25 145. Defendants breached these duties by failing to provide adequate warnings to Plaintiffs
26 communicating the information and dangers described above and/or providing instruction for safe use of
27 Cordis IVC filters.

1 146. As a direct and proximate result of Defendants' negligent conduct described herein,
2 Plaintiffs suffered Injuries and Damages.

3 **FIFTH CAUSE OF ACTION**

4 **NEGLIGENT MISREPRESENTATION**

5 **(By All Plaintiffs, As to All Defendants)**

6 147. Plaintiffs incorporate by reference all prior allegations.

7 148. Prior to, on, and after the dates during which Plaintiffs were implanted with the Cordis
8 IVC filters – the TrapEase filters and the OptEase filters – Defendants negligently and carelessly
9 represented to Plaintiffs, their treating physicians, and the general public that certain material facts were
10 true. The representations include, *inter alia*, the following:

- 11 a. That the Cordis IVC filters were safe, fit, and effective for use;
12 b. That the design of the Cordis IVC filters eliminated the risk that pieces of the device
13 could perforate the vena cava, that the devices could tilt, or that fractures could occur and
14 migrate throughout the body;
15 c. That the Cordis IVC filters were safe and more effective than other available IVC filters.
16 d. That the OptEase fiber was “easy” to remove; and,

17 149. Prior to, on, and after the dates during which Plaintiffs and their physicians purchased
18 and used the device, said representations were untrue, and there was no reasonable ground for
19 Defendants to believe said representations were true when Defendants made said representations.

20 150. Prior to, on, and after the dates during which Plaintiffs and their physicians purchased
21 and used the device, Defendants intended that Plaintiffs, their physicians, and the general public would
22 rely on said representations, which did in fact occur.

23 151. Defendants owed a duty in all of its undertakings, including the dissemination of
24 information concerning its IVC filters, to exercise reasonable care to ensure that it did not in those
25 undertakings create unreasonable risks of personal injury to others.

26 152. Defendants disseminated to health care professionals and consumers through published
27 labels, labeling, marketing materials, and otherwise information concerning the properties and effects of
28

1 Cordis IVC filters with the intention that health care professionals and consumers would rely upon that
2 information in their decisions concerning whether to prescribe and use Defendants' IVC filters.

3 153. Defendants, as medical device designers, manufacturers, sellers, promoters and/or
4 distributors, knew or should reasonably have known that health care professionals and consumers, in
5 weighing the potential benefits and potential risks of prescribing or using Cordis IVC filters, would rely
6 upon information disseminated and marketed by Defendants to them regarding the Cordis IVC filters.

7 154. Defendants failed to exercise reasonable care to ensure that the information they
8 disseminated to health care professionals and consumers concerning the properties and effects of Cordis
9 IVC filters was accurate, complete, and not misleading and, as a result, disseminated information to
10 health care professionals and consumers that was negligently and materially inaccurate, misleading,
11 false, and unreasonably dangerous to consumers such as Plaintiffs.

12 155. Defendants, as designers, manufacturers, sellers, promoters, and/or distributors, also
13 knew or reasonably should have known that patients receiving Cordis IVC filters as recommended by
14 health care professionals in reliance upon information disseminated by Defendants as the
15 manufacturer/distributor of Defendants' IVC filters would be placed in peril of developing the serious,
16 life-threatening, and life-long injuries including, but not limited to, tilting, migration, perforation,
17 fracture, lack of efficacy, and increased risk of the development of blood clots, if the information
18 disseminated and relied upon was materially inaccurate, misleading, or otherwise false.

19 156. Defendants had a duty to promptly correct material misstatements Defendants' knew
20 others were relying upon in making healthcare decisions.

21 157. Defendants failed in each of these duties by misrepresenting to Plaintiffs and the medical
22 community the safety and efficacy of Cordis IVC filters and failing to correct known misstatements and
23 misrepresentations.

24 158. As a direct and proximate result of Defendants' negligent misrepresentations, Plaintiffs
25 suffered Injuries and Damages.

26
27 ///

28 ///

SIXTH CAUSE OF ACTION
FRAUDULENT MISREPRESENTATION

(By All Plaintiffs, As to All Defendants)

159. Plaintiffs incorporate by reference all prior allegations.

160. At all times relevant to this cause, and as detailed above, Defendants intentionally provided Plaintiffs, their physicians, the medical community, and the public at large with false or inaccurate information. Defendants also omitted material information concerning Cordis IVC filters (the TrapEase filters and the OptEase filters), including, but not limited to, misrepresentations regarding the following topics:

- a. The safety of the Cordis IVC filters;
- b. The efficacy of the Cordis IVC filters;
- c. The rate of failure of the Cordis IVC filters;
- d. The pre-market testing of the Cordis IVC filters;
- e. The approved uses of the Cordis IVC filters; and
- f. The ability to retrieve the device at any time over a person's life.

161. The information Defendants distributed to the public, the medical community, and Plaintiffs was in the form of reports, press releases, advertising campaigns, labeling materials, print advertisements, commercial media containing material representations, and instructions for use, as well as through their officers, directors, agents, and representatives.

162. These materials contained false and misleading material representations, which included: that Cordis IVC filters were safe and fit when used for their intended purpose or in a reasonably foreseeable manner; that they did not pose dangerous health risks in excess of those associated with the use of other similar IVC filters; that any and all side effects were accurately reflected in the warnings; and that they were adequately tested to withstand normal placement within the human body.

163. Defendants made the foregoing misrepresentations knowing that they were false or without reasonable basis. These materials included instructions for use and a warning document that was included in the package of the Cordis IVC filters that were implanted in Plaintiffs.

1 164. Defendants' intent and purpose in making these misrepresentations was to deceive and
2 defraud the public and the medical community, including Plaintiffs' health care providers; to gain the
3 confidence of the public and the medical community, including Plaintiffs' health care providers; to
4 falsely assure the public and the medical community of the quality of Cordis IVC filters and their fitness
5 for use; and to induce the public and the medical community, including Plaintiffs' health care providers
6 to request, recommend, prescribe, implant, purchase, and continue to use Cordis IVC filters, all in
7 reliance on Defendants' misrepresentations.

8 165. The foregoing representations and omissions by Defendants were false.

9 166. Defendants' IVC filters are not safe, fit, and effective for human use in their intended and
10 reasonably foreseeable manner.

11 167. Further, the use of Cordis IVC filters is hazardous to the users' health, and Cordis IVC
12 filters have a serious propensity to cause users to suffer serious injuries, including without limitation the
13 injuries Plaintiffs suffered.

14 168. Finally, Defendants' IVC filters have a statistically significant higher rate of failure and
15 injury than do other comparable IVC filters.

16 169. In reliance upon the false and negligent misrepresentations and omissions made by
17 Defendants, Plaintiffs and their health care providers were induced to, and did use Cordis IVC filters,
18 thereby causing Plaintiffs to sustain severe and permanent personal injuries.

19 170. Defendants knew and had reason to know that Plaintiffs, their health care providers, and
20 the general medical community did not have the ability to determine the true facts intentionally and/or
21 negligently concealed and misrepresented by Defendants, and would not have prescribed and implanted
22 Cordis IVC filters if the true facts regarding Defendants' IVC filters had not been concealed and
23 misrepresented by Defendants.

24 171. Defendants had sole access to material facts concerning the defective nature of the
25 products and their propensities to cause serious and dangerous side effects in the form of dangerous
26 injuries and damages to persons who were implanted with Cordis IVC filters.

172. At the time Defendants failed to disclose and intentionally misrepresented the foregoing facts, and at the time Plaintiffs used Cordis IVC filters, Plaintiffs and their health care providers were unaware of Defendants' misrepresentations and omissions.

173. As a direct and proximate result of Defendants' fraudulent misrepresentations, Plaintiffs suffered Injuries and Damages.

SEVENTH CAUSE OF ACTION

FRAUDULENT CONCEALMENT

(By All Plaintiffs, As to All Defendants)

174. Plaintiffs incorporate by reference all prior allegations.

175. In marketing and selling Cordis IVC filters (the TrapEase filters and the OptEase filters), Defendants concealed material facts from Plaintiffs and their healthcare providers.

176. These concealed material facts include, but are not limited to:

- a. Cordis IVC filters were unsafe and not fit when used for their intended purpose or in a reasonably foreseeable manner;
- b. Cordis IVC filters posed dangerous health risks in excess of those associated with the use of other similar IVC filters;
- c. That there were additional side effects related to implantation and use of Cordis IVC filters that were not accurately and completely reflected in the warnings associated with Cordis IVC filters; and
- d. That Cordis IVC filters were not adequately tested to withstand normal placement within the human body.

177. Plaintiffs and their health care providers were not aware of these and other facts concealed by Defendants.

178. In concealing these and other facts, Defendants intended to deceive Plaintiffs and their health care providers.

179. Plaintiffs and their health care providers were ignorant of and could not reasonably discover the facts Defendants fraudulently concealed and reasonably and justifiably relied on Defendants' representations concerning the supposed safety and efficacy of Cordis IVC filters.

180. As a direct and proximate result of Defendants' fraudulent concealment of material facts, Plaintiffs suffered Injuries and Damages.

EIGHTH CAUSE OF ACTION

BREACH OF EXPRESS WARRANTY

(By All Plaintiffs, As to All Defendants)

181. Plaintiffs incorporate by reference all prior allegations.

182. Plaintiffs, through their medical providers, purchased a Cordis IVC filter from Defendants.

183. At all relevant times, Defendants were merchants of goods of the kind including medical devices and vena cava filters (i.e., Cordis IVC filters).

184. At the time and place of sale, distribution, and supply of Cordis IVC filters to Plaintiffs (and to other consumer and the medical community), Defendants expressly represented and warranted that Cordis IVC filters were safe; that they were well-tolerated, efficacious, fit for their intended purpose, and of marketable quality; that they did not produce any unwarned-of dangerous side effects; and that they was adequately tested.

185. At the time of Plaintiffs' purchase from Defendants, Cordis IVC filters were not in a merchantable condition, and Defendants breached its expressed warranties, in that Cordis IVC filters, among other things:

- a. Were designed in such a manner so as to be prone to an unreasonably high incidence of fracture, perforation of vessels and organs, and/or migration;
- b. Were designed in such a manner so as to result in a unreasonably high incidence of injury to the vessels and organs of its purchaser;
- c. Were manufactured in such a manner that the exterior surface of the filter was inadequately, improperly, and inappropriately constituted, causing the device to weaken and fail;
- d. Were unable to be removed at any time during a person's life;
- e. Were not efficacious in the prevention of pulmonary emboli;
- f. Carried a risk of use outweighed any benefit; and

g. Were not self-centering.

186. As a direct and proximate result of Defendants' breach of express warranty, Plaintiffs suffered Injuries and Damages.

NINTH CAUSE OF ACTION

BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY

(By All Plaintiffs, As to All Defendants)

187. Plaintiffs incorporate by reference all prior allegations.

188. Defendants impliedly warranted that Cordis IVC filters were of merchantable quality and safe and fit for the use for which Defendants intended them, and Plaintiff in fact used them.

189. Defendants breached its implied warranties by, among other things:

- a. Failing to provide adequate instruction that a manufacturer exercising reasonable care would have provided concerning the likelihood that Cordis IVC filters would cause harm;
- b. Manufacturing and/or selling Cordis IVC filters when those filters did not conform to representations made by Defendants when they left Defendants' control;
- c. Manufacturing and/or selling Cordis IVC filters that were more dangerous than an ordinary consumer would expect when used in an intended or reasonably foreseeable manner;
- d. Manufacturing and/or selling Cordis IVC filters that carried foreseeable risks associated with the Cordis IVC filter design or formulation which exceeded the benefits associated with that design;
- e. Manufacturing and/or selling Cordis IVC filters when they deviated in a material way from the design specifications, formulas, or performance standards or from otherwise identical units manufactured to the same design specifications, formulas, or performance standards; and
- f. Impliedly representing that its filters would be effective in the prevention of pulmonary emboli.

190. At the time Plaintiffs and their physicians purchased and used the devices, the products were not in a merchantable condition in that:

- a. They offered no benefit to patient outcomes,
- b. They suffered an unreasonably high failure and injury rates,
- c. The surface of the devices were manufactured and designed in such a way that they were distributed with surface damage that substantially increased the risk of fracture, and
- d. They were prothrombotic;

191. As a direct and proximate result of Defendants' breach of its implied warranty, Plaintiffs suffered Injuries and Damages.

TENTH CAUSE OF ACTION

LOSS OF CONSORTIUM

(By Plaintiffs BRIAN QUINN and PATRICIA BROWN, As to All Defendants)

192. Plaintiffs incorporate by reference all prior allegations

193. As a proximate result of the personal injuries suffered by Plaintiffs HEATHER QUINN and EDWARD BROWN, as described in this Complaint, Plaintiffs BRIAN QUINN and PATRICIA BROWN have been deprived of the benefits of their marriage including love, affection, society, and consortium, and other spousal duties and actions. Plaintiffs BRIAN QUINN and PATRICIA BROWN were provided with all of the benefits of a marriage between husband and wife, prior to the use of a Cordis IVC filter by their respective Plaintiff spouses and the resulting injuries described herein.

194. Plaintiffs BRIAN QUINN and PATRICIA BROWN have also suffered the permanent loss of their respective Plaintiff spouses' daily and regular contribution to the household duties and services, which each provides to the household as husband and wife.

195. Plaintiffs BRIAN QUINN and PATRICIA BROWN have also incurred the costs and expenses related to the medical care, treatment, medications, and hospitalization to which their respective Plaintiff spouses were subjected for the physical injuries they suffered as a proximate result of their use of a Cordis IVC filter. Plaintiffs BRIAN QUINN and PATRICIA BROWN will continue to incur the future costs and expenses related to the care, treatment, medications, and hospitalization of their respective Plaintiff spouses due to their injuries.

196. Plaintiffs BRIAN QUINN and PATRICIA BROWN have suffered loss of consortium, as described herein, including the past, present, and future loss of their spouses' companionship, services,

society, and the ability of their spouses to provide Plaintiffs BRIAN QUINN and PATRICIA BROWN with the benefits of marriage, including inter alia, loss of contribution to household income and loss of household services, all of which has resulted in pain, suffering, and mental and emotional distress and worry for Plaintiffs BRIAN QUINN and PATRICIA BROWN.

PUNITIVE DAMAGES ALLEGATIONS

(By All Plaintiffs, As to All Defendants)

197. Plaintiffs incorporate by reference all prior allegations.

198. At all times material hereto, Defendants knew or should have known that Cordis IVC filters were unreasonably dangerous with respect to the risk of tilt, fracture, migration and/or perforation.

199. At all times material hereto, Defendants attempted to misrepresent and did knowingly misrepresent facts concerning the safety of Cordis IVC filters.

200. Defendants' misrepresentations included knowingly withholding material information from the medical community and the public, including Plaintiffs' physicians, concerning the safety of its Cordis IVC filters. Data establishes that the failure rates of the TrapEase and OptEase filters are and were much higher than what Defendants have in the past and currently continue to publish to the medical community and members of the public.

201. Defendants' conduct, alleged throughout this Complaint, was willful, wanton, and undertaken with a conscious indifference and disregard to the consequences that consumers of their products faced, including Plaintiffs. Defendants had actual knowledge of the dangers presented by Cordis IVC filters, yet consciously failed to act reasonably to inform or warn Plaintiffs, Plaintiffs' physicians or the public at large of these dangers. Defendants consciously failed to establish and maintain an adequate quality and post-market surveillance system.

202. At all times material hereto, Defendants knew and recklessly disregarded the fact that Cordis IVC filters have an unreasonably high rate of tilt, fracture, migration, and/or perforation.

203. Notwithstanding the foregoing, Defendants continued to market Cordis IVC filters aggressively to consumers, including Plaintiffs, without disclosing the aforesaid side effects.

206. Defendants' conduct is reprehensible, evidencing an evil hand guided by an evil mind and was undertaken for pecuniary gain in reckless and conscious disregard for the substantial risk of death and physical injury to consumers, including Plaintiffs.

g. Costs of suit;

- 1 h. Reasonable attorneys' fees, where authorized;
- 2 i. Prejudgment interest as allowed by law;
- 3 j. Post-judgment interest at the highest applicable statutory or common law rate from the
- 4 date of judgment until satisfaction of judgment;
- 5 k. Such other additional and further relief as Plaintiffs may be entitled to in law or in equity.

6 **DEMAND FOR JURY TRIAL**

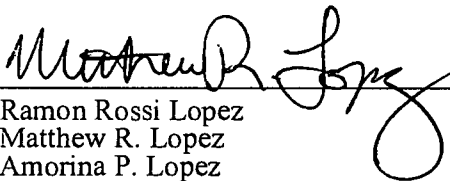
7 Plaintiffs hereby demand a trial by jury on all triable issues.

8

9 Dated: May 13, 2016

Respectfully submitted,

10 LOPEZ McHUGH LLP

11 By: 

12

13 Ramon Rossi Lopez
Matthew R. Lopez
Amorina P. Lopez

14 -And-

15

16 Thomas P. Cartmell (for *pro hac vice* consideration)
17 David C. DeGreeff (for *pro hac vice* consideration)
WAGSTAFF & CARTMELL, LLP

18 Attorneys for Plaintiffs

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**SUPERIOR COURT OF THE STATE OF CALIFORNIA
 FOR THE COUNTY OF ALAMEDA**

WALTER HERBERT, an individual;
 RUSSELL ANDERSON, an individual;
 MARTHA GRAHAM and FRANK GRAHAM,
 individually and as wife and husband;
 TAMARRA GRAYSON, an individual;
 TIMOTHY HOWARD, an individual; TED
 MICHAEL MARTINEZ and CYNTHIA
 MARTINEZ, individually and as husband and
 wife; and JUDY SHAFFER and JOHN
 SHAFFER, JR., individually and as wife and
 husband;

Plaintiffs,

vs.

CORDIS CORPORATION; JOHNSON &
 JOHNSON; and DOES 1 through 50;

Defendants.

Case No.: **RG16814569**

COMPLAINT FOR DAMAGES

1. STRICT PRODUCTS LIABILITY –
DESIGN DEFECT
2. STRICT PRODUCTS LIABILITY –
FAILURE TO WARN
3. STRICT PRODUCTS LIABILITY –
MANUFACTURING DEFECT
4. NEGLIGENCE
5. NEGLIGENT MISREPRESENTATION
6. FRAUDULENT MISREPRESENTATION
7. FRAUDULENT CONCEALMENT
8. BREACH OF EXPRESS WARRANTY
9. BREACH OF IMPLIED WARRANTY OF
MERCHANTABILITY
10. LOSS OF CONSORTIUM

BY FAX

DEMAND FOR JURY TRIAL

COMES NOW, Plaintiffs, by and through their attorneys, who complain and allege against Defendants CORDIS CORPORATION, JOHNSON & JOHNSON, and DOES 1 through 50, and each of them, on information and belief, as follows:

INTRODUCTION

1. Plaintiffs bring this action for personal injuries damages suffered as a direct and proximate result of being implanted with a defective and unreasonably dangerous Inferior Vena Cava (“IVC”) filter medical device manufactured by Defendants.

2. The subject IVC filters include the following devices: TrapEase Vena Cava Filter (“TrapEase filter”) and OptEase Vena Cava Filter (“OptEase filter”) (for convenience, these devices will be referred to in this complaint under the generic terms “Cordis IVC filters” or “Defendants’ IVC filters”). At all times relevant to this action, Defendants developed, designed, licensed, manufactured, sold, distributed and/or marketed the Cordis IVC filters to be implanted in patients throughout the United States, including California.

3. Plaintiffs’ claims for damages all relate to Defendants’ design, manufacture, sale, testing, marketing, labeling, advertising, promotion, and/or distribution of its IVC filters.

4. The Cordis IVC filters that are the subject of this action all reached Plaintiffs and Plaintiffs’ physicians without substantial change in condition from the time they left Defendants’ possession.

5. Plaintiffs and Plaintiffs’ physicians used the Cordis IVC filters in the manner in which they were intended.

6. Defendants are solely responsible for any alleged design, manufacture or information defect its IVC filters contain.

7. Defendants do not allege that any other person or entity is comparatively at fault for any alleged design, manufacture, or informational defect its IVC filters contain.

PARTIES

8. Plaintiff WALTER HERBERT at all times relevant to this action was a citizen and resident of the State of California. Plaintiff WALTER HERBERT underwent placement of Defendants’ OptEase Vena Cava Filter on or about October 25, 2005, in California. The filter subsequently

1 malfunctioned and caused injury and damages to Plaintiff WALTER HERBERT, including, but not
2 limited to, tilt, filter embedded in wall of the IVC, unsuccessful removal attempt, and filter unable to be
3 retrieved. As a direct and proximate result of these malfunctions, Plaintiff WALTER HERBERT
4 suffered life-threatening injuries and damages, and required extensive medical care and treatment. As a
5 further proximate result, Plaintiff WALTER HERBERT has suffered and will continue to suffer
6 significant medical expenses, and pain and suffering, and other damages.

7 9. Plaintiff RUSSELL ANDERSON at all times relevant to this action was and is a citizen
8 and resident of the State of Arizona. Plaintiff RUSSELL ANDERSON underwent placement of
9 Defendants' OptEase Vena Cava Filter on or about January 29, 2008. The filter subsequently
10 malfunctioned and caused injury and damages to Plaintiff RUSSELL ANDERSON, including, but not
11 limited to, tilt, filter embedded in wall of the IVC, unsuccessful removal attempt, and filter unable to be
12 retrieved. As a direct and proximate result of these malfunctions, Plaintiff RUSSELL ANDERSON
13 suffered life-threatening injuries and damages, and required extensive medical care and treatment. As a
14 further proximate result, Plaintiff RUSSELL ANDERSON has suffered and will continue to suffer
15 significant medical expenses, and pain and suffering, and other damages.

16 10. Plaintiff MARTHA GRAHAM at all times relevant to this action was and is a citizen and
17 resident of the State of Maryland. Plaintiff MARTHA GRAHAM underwent placement of Defendants'
18 OptEase Vena Cava Filter on or about June 2, 2006. The filter subsequently malfunctioned and caused
19 injury and damages to Plaintiff MARTHA GRAHAM, including, but not limited to, tilt, filter embedded
20 in wall of the IVC, unsuccessful removal attempt, and filter unable to be retrieved. As a direct and
21 proximate result of these malfunctions, Plaintiff MARTHA GRAHAM suffered life-threatening injuries
22 and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff
23 MARTHA GRAHAM has suffered and will continue to suffer significant medical expenses, and pain
24 and suffering, and other damages.

25 11. Plaintiff FRANK GRAHAM at all times relevant to this action was and is a citizen and
26 resident of the State of Arizona. Plaintiffs MARTHA GRAHAM and FRANK GRAHAM were and are,
27 at all times relevant to this action, legally married as wife and husband. Plaintiff FRANK GRAHAM
28

1 brings this action for, *inter alia*, the loss of consortium, comfort, and society he suffered due to the
2 personal injuries suffered by his wife, MARTHA GRAHAM.

3 12. Plaintiff TAMARRA GRAYSON at all times relevant to this action was and is a citizen
4 and resident of the State of Oklahoma. Plaintiff TAMARRA GRAYSON underwent placement of
5 Defendants' OptEase Vena Cava Filter on or about September 10, 2009. The filter subsequently
6 malfunctioned and caused injury and damages to Plaintiff TAMARRA GRAYSON, including, but not
7 limited to, tilt, filter embedded in wall of the IVC, unsuccessful removal attempt, and filter unable to be
8 retrieved. As a direct and proximate result of these malfunctions, Plaintiff TAMARRA GRAYSON
9 suffered life-threatening injuries and damages, and required extensive medical care and treatment. As a
10 further proximate result, Plaintiff TAMARRA GRAYSON has suffered and will continue to suffer
11 significant medical expenses, and pain and suffering, and other damages.

12 13. Plaintiff TIMOTHY HOWARD at all times relevant to this action was and is a citizen
13 and resident of the State of Tennessee. Plaintiff TIMOTHY HOWARD underwent placement of
14 Defendants' TrapEase Vena Cava Filter on or about November 6, 2014. The filter subsequently
15 malfunctioned and caused injury and damages to Plaintiff TIMOTHY HOWARD, including, but not
16 limited to, migration of the filter. As a direct and proximate result of these malfunctions, Plaintiff
17 TIMOTHY HOWARD suffered life-threatening injuries and damages, and required extensive medical
18 care and treatment. As a further proximate result, Plaintiff TIMOTHY HOWARD has suffered and will
19 continue to suffer significant medical expenses, and pain and suffering, and other damages.

20 14. Plaintiff TED MICHAEL MARTINEZ at all times relevant to this action was and is a
21 citizen and resident of the State of Nevada. Plaintiff TED MICHAEL MARTINEZ underwent
22 placement of Defendants' TrapEase Vena Cava Filter on or about June 25, 2006. The filter
23 subsequently malfunctioned and caused injury and damages to Plaintiff TED MICHAEL MARTINEZ,
24 including, but not limited to, migration of the filter. As a direct and proximate result of these
25 malfunctions, Plaintiff TED MICHAEL MARTINEZ suffered life-threatening injuries and damages, and
26 required extensive medical care and treatment. As a further proximate result, Plaintiff TED MICHAEL
27 MARTINEZ has suffered and will continue to suffer significant medical expenses, and pain and
28 suffering, and other damages.

1 15. Plaintiff CYNTHIA MARTINEZ at all times relevant to this action was and is a citizen
2 and resident of the State of Nevada. Plaintiffs TED MICHAEL MARTINEZ and CYNTHIA
3 MARTINEZ were and are, at all times relevant to this action, legally married as husband and wife.
4 Plaintiff CYNTHIA MARTINEZ brings this action for, *inter alia*, the loss of consortium, comfort, and
5 society he suffered due to the personal injuries suffered by her husband, TED MICHAEL MARTINEZ.

6 16. Plaintiff JUDY SHAFFER at all times relevant to this action was a citizen and resident of
7 the State of Maryland. Plaintiff JUDY SHAFFER underwent placement of Defendants' OptEase Vena
8 Cava Filter on or about February 3, 2015. The filter subsequently malfunctioned and caused injury and
9 damages to Plaintiff JUDY SHAFFER, including, but not limited to, tilt, filter embedded in wall of the
10 IVC, unsuccessful removal attempt, and filter unable to be retrieved. As a direct and proximate result of
11 these malfunctions, Plaintiff JUDY SHAFFER suffered life-threatening injuries and damages, and
12 required extensive medical care and treatment. As a further proximate result, Plaintiff JUDY SHAFFER
13 has suffered and will continue to suffer significant medical expenses, and pain and suffering, and other
14 damages.

15 17. Plaintiff JOHN SHAFFER, JR. at all times relevant to this action was a citizen and
16 resident of the State of Maryland. Plaintiffs JUDY SHAFFER and JOHN SHAFFER, JR. were and are,
17 at all times relevant to this action, legally married as wife and husband. Plaintiff JOHN SHAFFER, JR.
18 brings this action for, *inter alia*, the loss of consortium, comfort, and society he suffered due to the
19 personal injuries suffered by his wife, JUDY SHAFFER.

20 18. Defendant CORDIS CORPORATION ("Cordis"), including its department, division, and
21 subsidiary, Cordis Endovascular, is a corporation or business entity organized and existing under the
22 laws of the State of Florida with its headquarters located at 6500 Paseo Padre Pkwy., Fremont,
23 California, 94555. Cordis may be served with process by serving its registered agent, CT Corporation
24 System, at 818 West Seventh Street, Suite 930, Los Angeles, California, 90017.

25 19. Defendant CORDIS COPORATION was a wholly-owned subsidiary of Defendant
26 JOHNSON & JOHNSON ("J&J") and part of the J&J family of companies until in or around October
27 2015. J&J is a corporation or business entity organized and existing under the laws of the State of New
28 Jersey with its headquarters located in New Jersey.

22. As used herein, “Defendants” includes all named Defendants as well as Does 1-50.

24. This Court has jurisdiction under the California Constitution, Article VI, Section 10 and *Code of Civil Procedure* Section 410.10. Plaintiffs' damages exceed the jurisdictional minimum of this Court.

26. IVC filters were first made commercially available to the medical community in the 1960s. Over the years, medical device manufacturers have introduced several different designs of IVC filters.

27. An IVC filter is a device that is designed to filter or “catch” blood clots that travel from the lower portions of the body to the heart and lungs. IVC filters were originally designed to be permanently implanted in the IVC.

1 28. The IVC is a vein that returns blood to the heart from the lower portions of the body. In
2 certain people, for various reasons, blood clots travel from the vessels in the legs and pelvis, through the
3 vena cava and into the lungs. Oftentimes, these blood clots develop in the deep leg veins, a condition
4 called “deep-vein thrombosis” or “DVT.” Once blood clots reach the lungs, they are considered
5 “pulmonary emboli” or “PE.” Pulmonary emboli present risks to human health.

6 29. People at risk for DVT/PE can undergo medical treatment to manage the risk. For
7 example, a doctor may prescribe anticoagulant therapies such as medications like Heparin, Warfarin, or
8 Lovenox to regulate the clotting factor of the blood. In some people who are at high risk for DVT/PE
9 and who cannot manage their conditions with medications, physicians may recommend surgically
10 implanting an IVC filter to prevent thromboembolic events.

11 30. As stated above, IVC filters have been on the market for decades. All IVC filters are
12 only cleared for use by the Food & Drug Administration (“FDA”) for prevention of recurrent pulmonary
13 embolism in patients at risk for pulmonary embolism and where anticoagulation therapy has failed or is
14 contraindicated.

15 31. In order to increase sales of these devices, Defendants sought to expand the market for
16 prophylactic use among nontraditional patient populations that were temporarily at risk of developing
17 blood clots.

18 32. Defendants Cordis and J&J engaged in marketing campaigns directed toward the
19 bariatric, trauma, orthopedic and cancer patient population. Expansion to these new patient groups
20 would substantially increase sales and the first manufacturer to market would capture market share.

21 33. Other manufacturers also saw this opportunity, which triggered a race to market a device
22 that provided physicians the option to retrieve the filter after the clot risk subsided.

23 34. From 2000 through 2003, manufacturers of IVC filters, including Defendants, raced
24 against each other to bring the first IVC filter to the market with the added indication of optional
25 retrieval. In 2003, the FDA cleared three different IVC filters for a retrieval indication, one of which
26 was the OptEase filter by Defendants Cordis and J&J.

27 35. There is no evidence that Defendants’ IVC filters were effective in preventing pulmonary
28 embolism (the very condition the products were indicated to prevent).

1 36. Years after the implantation of retrievable filters into the bodies of patients, scientists
2 began to study the effectiveness of the retrievable filters. As recently as October 2015, an expansive
3 article published in the *Annals of Surgery* concerning trauma patients inserted with IVC filters
4 concluded that IVC filters were not effective in preventing pulmonary emboli, and instead actually
5 caused thrombi to occur.

6 37. Comparing the results of over 30,000 trauma patients who had not received IVC filters
7 with those who had received them, the *Annals of Surgery* study published its alarming results:

- 8 a. Almost twice the percentage of patients with IVC filters in the study died compared to
- 9 those that had not received them.
- 10 b. Over five times the relative number of patients with IVC filters developed DVTs.
- 11 c. Over four times the relative percentage of patients with filters developed thromboemboli.
- 12 d. Over twice the percentage of patients developed a pulmonary embolus – the very
- 13 condition Defendants Cordis and J&J told the FDA, physicians, and the public that its
- 14 IVC filters were designed to prevent.

15 38. This *Annals of Surgery* study – and many others referenced by it – have shown there is no
16 evidence establishing that IVC filters are effective and that these devices suffer common failure modes,
17 including, but not limited to, migration, perforation, thrombosis, tilt and fracture, all of which can cause
18 serious injury or death. Thus, the current state of scientific and medical evidence indicates that IVC
19 filters are not only ineffective but that they are themselves a health hazard.

20 **THE TRAPEASE AND OPTEASE IVC FILTERS**

21 39. On or about January 10, 2001, Defendants bypassed the more onerous FDA's approval
22 process for new devices and obtained "clearance" under Section 510(k) of the Medical Device
23 Amendments to the Food, Drug, and Cosmetic Act to market the TrapEase Vena Cava Filter as a
24 *permanent* filter by claiming it was substantially similar in respect to safety, efficacy, design, and
25 materials as the IVC filters already available on the market.

26 40. Section 510(k) permits the marketing of medical devices if the device is substantially
27 equivalent to other legally marketed predicate devices without formal review for the safety or efficacy of
28 the said device. The FDA explained the difference between the 510(k) process and the more rigorous

1 “premarket approval” (PMA) process in its amicus brief filed with the Third Circuit in *Horn v. Thoratec*
2 *Corp.*, which the court quoted from:

3 A manufacturer can obtain an FDA finding of ‘substantial equivalence’ by submitting a
4 premarket notification to the agency in accordance with section 510(k) of the [Food Drug
5 and Cosmetic Act]. 21 U.S.C. § 360(k). A device found to be ‘substantially equivalent’
6 to a predicate device is said to be ‘cleared’ by FDA (as opposed to ‘approved’ by the
7 agency under a PMA. A pre-market notification submitted under 510(k) is thus entirely
8 different from a PMA which must include data sufficient to demonstrate that the IVC
9 Filters is safe and effective.

10 376 F.3d 163, 167 (3d Cir. 2004) (emphasis in original).

11 41. In *Medtronic, Inc. v. Lohr*, the U.S. Supreme Court similarly described the 510(k)
12 process, observing:

13 If the FDA concludes on the basis of the [manufacturer’s] § 510(k) notification that the
14 device is “substantially equivalent” to a pre-existing device, it can be marketed without
15 further regulatory analysis. . . . The § 510(k) notification process is by no means
16 comparable to the PMA process; in contrast to the 1,200 hours necessary to complete a
17 PMA review, the § 510(k) review is completed in average of 20 hours. . . . As one
18 commentator noted: “The attraction of substantial equivalence to manufacturers is clear.
19 Section 510(k) notification requires little information, rarely elicits a negative response
20 from the FDA, and gets processed quickly.”

21 518 U.S. 470, 478-79 (1996) (quoting Adler, *The 1976 Medical Device Amendments: A Step in the*
22 *Right Direction Needs Another Step in the Right Direction*, 43 *Food Drug Cosm. L.J.* 511, 516 (1988)).

23 42. Pursuant to *Wyeth v. Levine*, 555 U.S. 555 (2009), once a product is cleared “the
24 manufacturer remains under an obligation to investigate and report any adverse events associated with
25 the drug . . . and must periodically submit any new information that may affect the FDA’s previous
26 conclusions about the safety, effectiveness, or labeling” This obligation extends to post-market
27 monitoring of adverse events/complaints.

28 43. In July 2000, through this 510(k) process, Defendants obtained clearance from the FDA
to market the TrapEase filter as a permanent filter.

44. The TrapEase filter is made with Nitinol – a nickel titanium alloy. The filter utilizes a
design known as a double basket or double filter for the capture of blood clots and/or emboli. This
design consists of a basket made of six diamond-shaped struts proximally and six diamond-shaped struts
distally, forming proximal and distal baskets, which are connected by six straight struts to create a single

1 symmetric filter. The filter has proximal and distal anchoring barbs located on each connecting strut for
2 fixation of the filter to the vena cava wall to prevent movement after placement.

3 45. Nitinol alloy is used in a number of different medical device applications. It is beneficial
4 for these applications and is employed as material in stents and other medical device applications. It is
5 also used in the manufacture of the TrapEase filter, and other brands of IVC filters.

6 46. Specific manufacturing processes need to be utilized when using Nitinol as a component
7 for medical devices, including IVC filters. Primarily, the Nitinol material should be electro-polished
8 prior to assembly of the finished medical device.

9 47. Electro-polishing is a manner of removing surface blemishes, “draw marking” and
10 circumferential grinding markings on the exterior of the surface of the Nitinol material. The existence
11 of these surface blemishes, “draw markings” and “circumferential grind-markings” causes/results in the
12 weakening of the structural integrity of the end product, whether it is an IVC filter or other medical
13 device.

14 48. In or around September 2002, Defendants sought clearance through the 510(k) process to
15 market the OptEase Vena Cava Filter for the same indicated uses as the TrapEase filter. Defendants
16 represented that the OptEase filter contained the same fundamental technology and was substantially
17 equivalent in terms of safety and efficacy as the predicate devices already available on the market.

18 49. Unlike the TrapEase filter, which has proximal and distal anchoring barbs located on
19 each connecting strut for fixation of the filter to the vena cava wall, the OptEase filter has anchoring
20 barbs for fixation of the filter only on the superior end of each of the six straight struts and has a hook at
21 the inferior end of the basket to allow retrieval with a snare.

22 50. Both designs for the TrapEase filter and OptEase filter suffer flaws making them
23 defective and unreasonably dangerous. Defendants’ IVC filters are designed in such a way that when
24 exposed to expected and reasonably foreseeable *in-vivo* conditions, the devices will fracture, migrate,
25 tilt, perforate internal organs and vasculature, and lead to the formation of thromboembolism and
26 pulmonary embolism.

1 51. For years, it has been known by manufacturers of the Nitinol medical devices and the
2 medical device industry that electro-polishing Nitinol results in increased structural integrity of the
3 device and resistance to fatigue and fatigue failures.

4 52. The exterior surfaces of the Cordis IVC Filters were not electro-polished prior to
5 completion of the manufacturing process. This is a manufacturing defect that exists in the TrapEase and
6 OptEase filters which causes these filters to be structurally weak and susceptible to a significant risk of
7 failure/fracture.

8 53. Additionally, Defendants represented that the self-centering design of the TrapEase filter
9 allows accurate, predictable placement, and that its site struts help reduce the risk of tilting and
10 migration, while in reality the filters regularly tilt, migrate, and become embedded in the vena cava wall.

11 54. The anchoring mechanism of Defendants' filters is also insufficient to prevent tilting and
12 migration post-placement.

13 55. The configuration of the Cordis IVC Filters actually leads to the formation of blood clots
14 and pulmonary embolism – the exact condition the devices are meant to protect against.

15 56. That Defendants allowed these devices to proceed to market indicates that they failed to
16 establish and maintain an appropriate Quality System concerning design and risk analysis.

17 57. A manufacturer must, at a minimum, undertake research and testing to understand the
18 anatomy of where a medical device will be implanted and understand the forces the device may be
19 exposed to once implanted in a human body. This design input must then be used to determine the
20 minimum safety requirements or attributes the device must have to meet user needs. In the case of an
21 IVC filter, user needs include a device that will capture blood clots of sufficient size to cause harmful
22 consequences and that will not fracture, migrate, tilt, perforate the vena cava, or malfunction in some
23 other way, or be prothombotic. Defendants failed to undertake any such efforts in these regards.

24 58. Prior to bringing a product to market, a manufacturer must also conduct sufficient testing
25 under real world or simulated use conditions to ensure that the device will meet user needs even when
26 exposed to reasonably foreseeable worst-case conditions. Defendants failed to adequately establish and
27 maintain such policies, procedures or protocols with respect to their IVC filters.
28

1 59. Once placed on the market, Defendants' post-market surveillance system should have
2 revealed to Defendants that the TrapEase and OptEase filters were unreasonably dangerous and
3 substantially more prone to fail or malfunction, and cause great bodily harm to patients compared to
4 other available treatment options.

5 60. MAUDE is a database maintained by the FDA to house medical device reports submitted
6 by mandatory reporters (such as manufacturers and device user facilities) and voluntary reporters (such
7 as health care providers and patients).

8 61. Shortly after going on market, Defendants began receiving large numbers of adverse
9 event reports ("AERs") from health care providers reporting that the Cordis IVC filters were fracturing
10 post-implantation and that fractured pieces and/or the entire device was migrating to other areas of the
11 body, including the heart and lungs.

12 62. Defendants also received large numbers of AERs reporting that the TrapEase filters and
13 OptEase filters were found to have excessively tilted, perforated the IVC, or caused thrombosis or
14 stenosis of the vena cava post-implantation.

15 63. These failures were often associated with severe patient injuries such as:

- 16 a. Death;
17 b. Hemorrhage;
18 c. Cardiac/pericardial tamponade (pressure caused by a collection of blood in the area
19 around the heart);
20 d. Cardiac arrhythmia and other symptoms similar to myocardial infarction;
21 e. Severe and persistent pain; and
22 f. Perforations of tissue, vessels and organs.

23 64. These failures and resulting injuries are attributable, in part, to the fact that the Cordis
24 IVC Filter design was unable to withstand the normal anatomical and physiological loading cycles
25 exerted *in vivo*.

26 65. Defendants failed to identify or acknowledge these device failures or determine their
27 causes.
28

66. Defendants failed to take timely and adequate remedial measures to correct known design and manufacturing defects with the Cordis IVC Filters.

67. Defendants also misrepresented and concealed the risks and benefits of the Cordis IVC filters in its labeling and marketing distributed to the FDA, physicians and the public. For instance, Defendants represented that their filters were safe and effective – more safe and effective than other available IVC filters. As discussed above, however, there is no reliable evidence to support these claims and, to the contrary, the Cordis IVC filters have been associated with a high rate of failure.

**THE MEDICAL LITERATURE ESTABLISHES THAT CORDIS IVC FILTERS HAVE A
HIGH RATE OF FAILURE AND COMPLICATIONS**

68. There are reports in the peer-reviewed published medical literature of TrapEase filters migrating to the heart:

- a. It was reported in 2002 that a TrapEase filter migrated to a patient's right ventricle. Porcellini, *et al.*, "Intracardiac migration of nitinol TrapEase vena cava filter and paradoxical embolism," *Euro. J. of Cardio-Thoracic Surg.* 2002, 22:460-61.
- b. It was reported in 2008 that a TrapEase filter migrated to a patient's tricuspid valve, causing her death. Haddadian, *et al.*, "Sudden Cardiac Death Caused by Migration of a TrapEase Inferior Vena Cava Filter: A Case Report and Review of the Literature," *Clin. Cardiol.* 2008, 31:84-87.
- c. It was reported in 2011 that a TrapEase filter migrated to a patient's tricuspid valve, leading to his death. Dreyer, *et al.*, "Inferior Vena Cava Filter Migration to the Right Ventricle: A Case Report and Review of Filter Migration and Misdeployment," *J. Med. Cases* 2011; 2(5):201-05.

69. Additionally, as early as March 2005, Defendants knew or should have known that any short-term beneficial effect of the insertion of a Cordis IVC filter was outweighed by a significant increase in the risk of DVT, that the filter would not be able to be removed, filter fracture and/or migration, and, ultimately, by the fact that the filters had no beneficial effect on overall mortality.

70. By March 2005, there had been only one long-term randomized study of filter placement in the prevention of pulmonary embolism. *See* PREPIC Study Group, "Eight-year follow-up of patients

1 with permanent vena cava filters in the prevention of pulmonary embolism: the PREPIC (Prevention du
2 Risque d'Embolie Pulmonaire par Interruption Cave) randomized study," *Circulation* 2005, 112(3):416-
3 22. In 400 patients with proximal DVT, the insertion of a vena cava filter in combination with standard
4 anticoagulation was associated with a reduction in the occurrence of pulmonary embolism compared
5 with anticoagulation alone. This beneficial effect was offset, however, by a significant increase in DVT,
6 and the filters had no impact on mortality. The study followed the patients for up to eight years to assess
7 the very long-term effect of IVC filters on the recurrence of venous thromboembolism, the development
8 of post-thrombotic syndrome, and mortality.

9 71. Two years later, in or around 2007, a group of engineers and members of the surgery
10 department of the University of Toronto conducted a study in order to determine whether IVC filter
11 design might be linked to an increased risk of thrombosis and recurrent pulmonary embolism. *See*
12 Harlal, *et al.*, "Vena cava filter performance based on hemodynamics and reported thrombosis and
13 pulmonary embolism patterns," *J Vasc Interv Radiol.* 2007, 18(1): 103-15. The authors wrote that the
14 design of the TrapEase filter "promotes the lodging of a clot along the vessel wall, resulting in the
15 formation of stagnation zones along the vessel wall, which can contribute to further clot development."
16 The study further explained that the TrapEase filters' effect on blood flow increased the likelihood of
17 thrombosis. The study found a significantly higher rate of PE and thrombosis from use of the TrapEase
18 filter relative to a competitor's filter.

19 72. Less than three years later, on or about August 9, 2010, the FDA issued a Safety Alert
20 entitled: "Removing Retrievable Inferior Vena Cava Filters: Initial Communication." The purpose of
21 the communication was to warn against leaving IVC filters in for extended periods of time because they
22 have a tendency to cause life-threatening complications. The FDA noted that the use of IVC filters had
23 increased dramatically in the last several years and observed that the number of adverse event reports
24 had also increased substantially since 2005. The FDA expressed concern that retrievable IVC filters
25 were frequently left in patients beyond the time when the risk for PE had passed, thus unnecessarily
26 exposing patients to the risks of DVT as well as to filter fracture, migration, embolization, and
27 perforation.
28

73. Dr. William T. Kuo, an expert in the removal of IVC filters and vascular surgery, has established an IVC Filter Clinic at Stanford University where his team specializes in the removal of IVC filters that other vascular surgeons refuse to remove for fear of rupturing the vena cava or other internal organs and causing great bodily harm or death to the patient. In 2011, Dr. Kuo wrote in *the Journal of Vascular Interventional Radiology* that the Cordis filters were the most difficult to retrieve from patients, at least partially due to the design of the filters, which create greater contact with the vein walls than competitors' filters. See Kuo, *et al.*, "Photothermal Ablation with the Excimer Laser Sheath Technique for Embedded Inferior Vena Cava Filter Removal: Initial Results from a Perspective Study," *J. Vasc. Interv. Radiol.* 2011; 22:813-23.

74. In the same article, Dr. Kuo observed that "[p]atients with embedded filters seem to be at increased risk of IVC occlusion, chronic deep venous thrombosis, post-thrombotic syndrome, filter fracture with component migration, and caval perforation with pain and organ injury. Additionally, many patients with permanent filters are now routinely managed with lifelong anticoagulation to reduce thrombotic risks related to prolonged filter implantation, subjecting them not only to the inconvenience of anticoagulation therapy but also to its inherent bleeding risks." These concerns were heightened by the difficulty of removing a Cordis filter.

75. In 2010, Dr. Gred Usch also found in a study published in the *Journal of Vascular Surgery* that the TrapEase filter was associated with an increased likelihood of thrombosis. See Usch, *et al.*, "Prospective Randomized Study Comparing the Clinical Outcomes Between Inferior Vena Cava Greenfield and TrapEase Filters," *J. Vasc. Surg.* 2010, 52(2):394-99. Thus, the TrapEase filter increased the risk of harm without any proven benefit.

76. In a letter to the *Archives of Internal Medicine* published November 28, 2011, a group led by Dr. Masaki Sano of the Hamamatsu University School of Medicine in Japan described a study in which the Cordis TrapEase filter had fractured in 10 out of 20 patients (50%) at an average follow-up of 50 months. See Sano, *et al.*, "Frequent Fracture of TrapEase Inferior Vena Cave Filters: A Long-term Follow Up Assessment," *Arch. Intern Med* 2012; 172(2):189-91. Furthermore, nine out of 14 filters (64%) that had been inserted for longer than 14 months showed fractures. Among the 10 fractured filters, eight had a single fractured strut, while two had multiple fractured struts. Additionally, thrombus

1 was detected inside the filter in two cases. Based on these results, Dr. Sano criticized previous studies
2 that had found the TrapEase filter to be safe as being conducted over too short a period of time and
3 concluded that “patients undergoing permanent TrapEase IVCF insertion are at extremely high risk of
4 strut fractures as early as two to three years after IVCF placement.”

5 77. On May 6, 2014, the FDA issued another Safety Alert involving IVC filters. In this
6 safety communication, the FDA wrote that it had received adverse event reports concerning “device
7 migration, filter fracture, embolization (movement of the entire filter or fracture fragments to the heart
8 or lungs), perforation of the IVC, and difficulty removing the device.” The FDA reiterated that the risks
9 presented by the filters should be avoided by removing the filters “once the risk of pulmonary embolism
10 has subsided” and expressed concern that the filters were not being timely removed in this manner.
11 Based on the medical literature, the FDA recommended removal between 29 and 54 days after
12 implantation.

13 78. On April 5, 2016, at the annual Society of Interventional Radiology in Vancouver,
14 Canada, Dr. Steven Wang, an interventional radiologist from Palo Alto, California who is affiliated with
15 Kaiser Permanente, presented the results of a retrospective study involving 96 patients in which he
16 sought to understand the prevalence of long-term (greater than 46 months) complications of both
17 permanent and retrievable IVC filters. The study looked at all inferior vena cava filters implanted in
18 patients from January 2007 through December 2009 at multiple health care facilities across the United
19 States. Dr. Wang then identified all patients who had imaging of the filter taken at four years or more
20 after implantation. Of those patients (96), he then evaluated the imaging to determine whether the IVC
21 filter had malfunctioned. After reviewing the data, the authors concluded that device complications at
22 four or more years after implantation “are relatively common.” They also found that the Cordis OptEase
23 and TrapEase IVC filters suffered fracture rates of 37.5% and 23.1%, respectively.

24 **ESTOPPEL FROM PLEADING STATUTES OF LIMITATIONS OR REPOSE**

25 79. Plaintiffs incorporate by reference all prior allegations.

26 80. Plaintiffs are within the applicable statute of limitations for their claims because Plaintiffs
27 (and their healthcare professionals) did not discover, and could not reasonably discover, the defects and
28 unreasonably dangerous condition of their Cordis IVC filters.

83. Such conduct includes intentional concealment from Plaintiffs, their health care professionals, and the general consuming public of material information that Cordis IVC filters had not been demonstrated to be safe or effective, and carried with them the risks and dangerous defects described above.

84. Defendants had a duty to disclose the fact that Cordis IVC filters are not safe or effective, not as safe as other filters on the market, defective, and unreasonably dangerous, and that their implantation and use carried with it the serious risk of developing perforation, migration, tilting, and/or fracture.

STRICT PRODUCTS LIABILITY – DESIGN DEFECT

85. Plaintiffs incorporate by reference all prior allegations.

86. At all relevant times, Defendants designed, tested, distributed, manufactured, advertised, sold, marketed and otherwise placed into the stream of commerce Cordis IVC filters – the TrapEase filters and the OptEase filters – for use by consumers, such as Plaintiffs, in the United States.

87. Defendants' Cordis IVC filters were expected to, and did, reach Defendants' intended consumers, handlers, and persons coming into contact with the product without substantial change in the condition in which they were researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Defendants.

1 88. At all times relevant, Cordis IVC filters were manufactured, designed and labeled in an
2 unsafe, defective, and inherently dangerous condition which was dangerous for use by the public in
3 general and Plaintiffs in particular.

4 89. Defendants' Cordis IVC filters, as researched, tested, developed, designed, licensed,
5 manufactured, packaged, labeled, distributed, sold, and marketed by Defendants were defective in
6 design and formulation and unreasonably dangerous in that when they left the hands of Defendants'
7 manufacturers and/or suppliers, the foreseeable risks exceeded the alleged benefits associated with the
8 use of Cordis IVC filters, and the devices were more dangerous than the ordinary customer would
9 expect.

10 90. Physicians implanted Cordis IVC filters as instructed via the Instructions for Use and in a
11 foreseeable manner as normally intended, recommended, promoted, and marketed by Defendants.

12 91. Plaintiffs received and utilized Defendants' IVC filters in a foreseeable manner as
13 normally intended, recommended, promoted, and marketed by Defendants.

14 92. At the time Defendants placed their defective and unreasonably dangerous Cordis IVC
15 filters into the stream of commerce commercially, technologically, and scientifically feasible alternative
16 designs were attainable and available.

17 93. These alternative designs would have prevented the harm resulting in each Plaintiff's
18 Injuries and Damages without substantially impairing the reasonably anticipated or intended function of
19 Cordis IVC filters.

20 94. Neither Plaintiffs nor their health care providers could have, by the exercise of reasonable
21 care, discovered the defective condition or perceived the unreasonable dangers with these devices prior
22 to Plaintiffs' implantation with the Cordis IVC filters.

23 95. As a direct and proximate result of the defective and unreasonably dangerous condition
24 of Cordis IVC filters, Plaintiffs suffered Injuries and Damages.

25 **SECOND CAUSE OF ACTION**

26 **STRICT PRODUCTS LIABILITY – INADEQUATE WARNING**

27 **(By All Plaintiffs, As to All Defendants)**

28 96. Plaintiffs incorporate by reference all prior allegations.

1 97. At all relevant times, Defendants engaged in the business of testing, developing,
2 designing, manufacturing, packaging, labeling, marketing and/or promoting, selling and/or distributing
3 Cordis IVC filters – the TrapEase filters and the OptEase filters – and through that conduct have
4 knowingly and intentionally placed Cordis IVC filters into the stream of commerce with full knowledge
5 that they reach consumers such as Plaintiffs who would become implanted with them.

6 98. Defendants did, in fact, test, develop, design, manufacture, package, label, market and/or
7 promote, sell and/or distribute their Cordis IVC filters to Plaintiffs, their prescribing health care
8 professionals, and the consuming public. Additionally, Defendants expected that the Cordis IVC filters
9 they were selling, distributing, supplying, manufacturing, and/or promoting to reach, and did, in fact,
10 reach, prescribing health care professionals and consumers, including Plaintiffs and their prescribing
11 health care professionals, without any substantial change in the condition of the product from when it
12 was initially distributed by Defendants.

13 99. The Cordis IVC filters had potential risks and side effects that were known or knowable
14 to Defendants by the use of scientific inquiry and information available before, at, and after the
15 manufacture, distribution, and sale of the Cordis IVC filters.

16 100. Defendants knew or should have known of the defective condition, characteristics, and
17 risks associated with Cordis IVC filters. These defective conditions included, but were not limited to:
18 (1) Cordis IVC filters posed a significant and higher risk of failure than other similar IVC filters
19 (fracture, migration, tilting, and perforation of the vena cava wall); (2) Cordis IVC filter failures result in
20 serious injuries and death; (3) certain conditions or post-implant procedures, such as morbid obesity or
21 open abdominal procedures, could affect the safety and integrity of Cordis IVC filters; (4) leaving
22 Cordis IVC filters in for a period longer than necessary to prevent immediate risk of pulmonary
23 embolism increases the risk for patients of failures and complications with the filter, such as the filter
24 becoming deeply embedded in the vena cava, making them difficult or impossible for removal.

25 101. Defendants placed into the stream of commerce for ultimate use by users like Plaintiffs
26 and their health care providers, Cordis IVC filters that were in an unreasonably dangerous and defective
27 condition due to warnings and instructions for use that were inadequate, including, but not limited to
28 Defendants' failure to:

- a. Provide adequate instructions for how long in patients the filter should remain;
- b. Highlight the importance of removing the filter;
- c. Warn of the known risk of great bodily harm or death if the filter was not removed;
- d. Highlight the known risk of great bodily harm or death in the event of occlusion of the vein caused by the filter itself;
- e. Warn of the risk of new DVT if the filter was left in too long; Warn of the risk of new pulmonary embolism, thrombosis, swelling, and pain in the lower extremities if the filter was left in too long; and
- f. Warn of the risk of filter perforation, fracture, or migration.

102. Cordis IVC filters were in a defective and unsafe condition that was unreasonably and substantially dangerous to any user or consumer implanted with Cordis IVC filters, such as Plaintiffs, when used in an intended or reasonably foreseeable way.

103. The warnings and directions Defendants provided with their Cordis IVC filters failed to adequately warn of the potential risks and side effects of Cordis IVC filters.

104. These risks were known or were reasonably scientifically knowable to Defendants, but not known or recognizable to ordinary consumers, such as Plaintiffs, or their treating doctors.

105. Defendants' IVC filters were expected to and did reach Plaintiffs without substantial change in their condition, labeling, or warnings as manufactured, distributed, and sold by Defendants.

106. Additionally, Plaintiffs and their physicians used Cordis IVC filters – the TrapEase filters or the OptEase filters – in the manner in which they were intended to be used, making such use reasonably foreseeable to Defendants.

107. As a direct and proximate result of Defendants' information defects, lack of sufficient instructions or warnings prior to, on, and after the date Plaintiffs used Cordis IVC filters, Plaintiffs suffered Injuries and Damages.

THIRD CAUSE OF ACTION

STRICT PRODUCTS LIABILITY – MANUFACTURING DEFECT

(By All Plaintiffs, As to All Defendants)

108. Plaintiffs incorporate by reference all prior allegations.

109. Prior to, on, and after the date the Cordis IVC filters – the TrapEase filter or the OptEase filter – were implanted in Plaintiffs, Defendants designed, distributed, manufactured, sold, and marketed Cordis IVC filters for use in the United States, including California.

110. At all relevant times, Defendants designed, distributed, manufactured, marketed, and sold Cordis IVC filters that were unreasonably dangerous, unsafe, and defective in manufacture when they left Defendants' possession.

111. Upon information and belief, Cordis IVC filters contain a manufacturing defect, in that they differed from the manufacturer's design or specifications, or from other typical units of the same product line.

112. As a direct and proximate cause of Defendants' design, manufacture, marketing, and sale of Cordis IVC filters prior to, on, and after the date Plaintiffs used the Cordis IVC filters, Plaintiffs suffered Injuries and Damages.

FOURTH CAUSE OF ACTION

NEGLIGENCE

(By All Plaintiffs, As to All Defendants)

113. Plaintiffs incorporate by reference all prior allegations.

114. At the time of the design, distribution, manufacture, advertising, sale, and marketing of Cordis IVC filters – the TrapEase filters and the OptEase filters – and their implantation in Plaintiffs, Defendants were aware that Cordis IVC filters were designed and manufactured in a manner presenting:

- a. An unreasonable risk of fracture of portions of the filters;
- b. An unreasonable risk of migration of the filters and/or portions of the filters;
- c. An unreasonable risk of filters tilting and/or perforating the vena cava wall; and
- d. Insufficient strength or structural integrity to withstand normal placement within the human body.

115. At the time of the design, distribution, manufacture, advertising, sale, and marketing of Cordis IVC filters, and their implantation in Plaintiffs, Defendants were also aware that Cordis IVC filters:

- a. Would be used without inspection for defects;

- b. Would be used by patients with special medical conditions such as Plaintiffs;
- c. Had previously caused serious bodily injury to its users with special medical conditions such as Plaintiffs;
- d. Had no established efficacy;
- e. Were less safe and effective than the predicate IVC filters already available on market;
- f. Would be implanted in patients where the risk outweighed any benefit or utility of the filters;
- g. Contained instructions for use and warnings that were inadequate; and
- h. Were prothombotic.

116. Defendants had a duty to exercise due care and avoid unreasonable risk of harm to others in the design of Cordis IVC filters.

117. Defendants breached these duties by, among other things:

- a. Designing and distributing a product in which it knew or should have known that the likelihood and severity of potential harm from the product exceeded the burden of taking safety measures to reduce or avoid harm;
- b. Designing and distributing a product which it knew or should have known that the likelihood and severity of potential harm from the product exceeded the likelihood of potential harm from other IVC filters available for the same purpose;
- c. Failing to perform reasonable pre- and post-market testing of Cordis IVC filters to determine whether or not the products were safe for their intended use;
- d. Failing to use reasonable and prudent care in the design, research, manufacture, and development of Cordis IVC filters so as to avoid the risk of serious harm associated with the use of Cordis IVC filters;
- e. Advertising, marketing, promoting, and selling Cordis IVC filters for uses other than as approved and indicated in the products' labels;
- f. Failing to establish an adequate quality assurance program used in the manufacturing of Cordis IVC filters; and

- 1 g. Failing to perform adequate evaluation and testing of Cordis IVC filters when such
2 evaluation and testing would have revealed the propensity of Cordis IVC filters to cause
3 injuries similar to those that Plaintiffs suffered.

4 118. At all relevant times, Defendants had a duty to exercise due care in the manufacturing of
5 Cordis IVC filters.

6 119. Defendants breached this duty by, among other things:

- 7 a. Failing to adopt manufacturing processes that would reduce the foreseeable risk of
8 product failure;
9 b. Failing to use reasonable care in manufacturing the product and by producing a product
10 that differed from their design or specifications or from other typical units from the same
11 production line;
12 c. Failing to use reasonable and prudent care in the design, research, manufacture, and
13 development of Cordis IVC filters and their manufacturing process so as to avoid the risk
14 of serious harm associated with the use of Cordis IVC filters; and
15 d. Failing to establish an adequate quality assurance program used in the manufacturing of
16 their IVC filters.

17 120. At this time, all Cordis IVC filters – the TrapEase filters and the OptEase filters – are
18 misbranded and adulterated by virtue of them failing to be the substantial equivalent of predicate IVC
19 filter devices, making them subject to corrective action, including recall, in the interest of patient safety.

20 121. Prior to, on, and after the date of Plaintiffs' implantation with a Cordis IVC filter, and at
21 all relevant times, Defendants knew or reasonably should have known that Cordis IVC filters and their
22 warnings were defective and dangerous or were likely to be dangerous when used in a reasonably
23 foreseeable manner.

24 122. Prior to, on, and after the date of Plaintiffs' implantation with a Cordis IVC filter and at
25 all relevant times thereafter, Defendants became aware that the defects of Cordis IVC filters resulted in
26 Cordis IVC filters causing injuries similar to those Plaintiffs suffered.

1 123. Reasonable manufacturers and distributors under the same or similar circumstances
2 would have recalled or retrofitted Cordis IVC filters, and would thereby have avoided and prevented
3 harm to many patients, including Plaintiffs.

4 124. In light of this information and Defendants' knowledge described above, Defendants had
5 a duty to recall and/or retrofit Cordis IVC filters.

6 125. Defendants breached its duty to recall and/or retrofit Cordis IVC filters.

7 126. At all relevant times, Defendants knew or should have known that Cordis IVC filters
8 were defective and dangerous or were likely to be dangerous when used in a reasonably foreseeable
9 manner.

10 127. Such danger included the propensity of Cordis IVC filters to cause injuries similar to
11 those suffered by Plaintiffs.

12 128. At all relevant times, Defendants also knew or reasonably should have known that the
13 users of Cordis IVC filters, including Plaintiffs and their health care providers, would not realize or
14 discover on their own the dangers presented by Cordis IVC filters.

15 129. Reasonable manufacturers and reasonable distributors, under the same or similar
16 circumstances as those of Defendants prior to, on, and after the date of Plaintiffs' use of a Cordis IVC
17 filter, would have warned of the dangers presented by Cordis IVC filters, or instructed on the safe use of
18 Cordis IVC filters.

19 130. Prior to, on, and after the date of each Plaintiff's use of the IVC filter, Defendants had a
20 duty to adequately warn of the dangers presented by Cordis IVC filters and/or instruct on the safe use of
21 Cordis IVC filters.

22 131. Defendants breached these duties by failing to provide adequate warnings to Plaintiffs
23 communicating the information and dangers described above and/or providing instruction for safe use of
24 Cordis IVC filters.

25 132. As a direct and proximate result of Defendants' negligent conduct described herein,
26 Plaintiffs suffered Injuries and Damages.

27 **FIFTH CAUSE OF ACTION**

28 **NEGLIGENT MISREPRESENTATION**

(By All Plaintiffs, As to All Defendants)

133. Plaintiffs incorporate by reference all prior allegations.

134. Prior to, on, and after the dates during which Plaintiffs were implanted with the Cordis IVC filters – the TrapEase filters and the OptEase filters – Defendants negligently and carelessly represented to Plaintiffs, their treating physicians, and the general public that Cordis IVC filters were safe, fit, and effective for use.

135. These representations were untrue.

136. Defendants owed a duty in all of its undertakings, including the dissemination of information concerning its IVC filters, to exercise reasonable care to ensure that it did not in those undertakings create unreasonable risks of personal injury to others.

137. Defendants disseminated to health care professionals and consumers through published labels, labeling, marketing materials, and otherwise information concerning the properties and effects of Cordis IVC filters with the intention that health care professionals and consumers would rely upon that information in their decisions concerning whether to prescribe and use Defendants' IVC filters.

138. Defendants, as medical device designers, manufacturers, sellers, promoters and/or distributors, knew or should reasonably have known that health care professionals and consumers, in weighing the potential benefits and potential risks of prescribing or using Cordis IVC filters, would rely upon information disseminated and marketed by Defendants to them regarding the Cordis IVC filters.

139. Defendants failed to exercise reasonable care to ensure that the information they disseminated to health care professionals and consumers concerning the properties and effects of Cordis IVC filters was accurate, complete, and not misleading and, as a result, disseminated information to health care professionals and consumers that was negligently and materially inaccurate, misleading, false, and unreasonably dangerous to consumers such as Plaintiffs.

140. Defendants, as designers, manufacturers, sellers, promoters, and/or distributors, also knew or reasonably should have known that patients receiving Cordis IVC filters as recommended by health care professionals in reliance upon information disseminated by Defendants as the manufacturer/distributor of Defendants' IVC filters would be placed in peril of developing the serious, life-threatening, and life-long injuries including, but not limited to, tilting, migration, perforation,

1 fracture, lack of efficacy, and increased risk of the development of blood clots, if the information
2 disseminated and relied upon was materially inaccurate, misleading, or otherwise false.

3 141. Defendants had a duty to promptly correct material misstatements it knew others were
4 relying upon in making healthcare decisions.

5 142. Defendants failed in each of these duties by misrepresenting to Plaintiffs and the medical
6 community the safety and efficacy of Cordis IVC filters and failing to correct known misstatements and
7 misrepresentations.

8 143. As a direct and proximate result of Defendants' negligent misrepresentations, Plaintiffs
9 suffered Injuries and Damages.

10 **SIXTH CAUSE OF ACTION**

11 **FRAUDULENT MISREPRESENTATION**

12 **(By All Plaintiffs, As to All Defendants)**

13 144. Plaintiffs incorporate by reference all prior allegations.

14 145. At all times relevant to this cause, and as detailed above, Defendants intentionally
15 provided Plaintiffs, their physicians, the medical community, and the public at large with false or
16 inaccurate information. Defendants also omitted material information concerning Cordis IVC filters
17 (the TrapEase filters and the OptEase filters), including, but not limited to, misrepresentations regarding
18 the following topics:

- 19 a. The safety of the Cordis IVC filters;
- 20 b. The efficacy of the Cordis IVC filters;
- 21 c. The rate of failure of the Cordis IVC filters;
- 22 d. The pre-market testing of the Cordis IVC filters;
- 23 e. The approved uses of the Cordis IVC filters; and
- 24 f. The ability to retrieve the device at any time over a person's life.

25 146. The information Defendants distributed to the public, the medical community, and
26 Plaintiffs was in the form of reports, press releases, advertising campaigns, labeling materials, print
27 advertisements, commercial media containing material representations, and instructions for use, as well
28 as through their officers, directors, agents, and representatives.

1 147. These materials contained false and misleading material representations, which included:
2 that Cordis IVC filters were safe and fit when used for their intended purpose or in a reasonably
3 foreseeable manner; that they did not pose dangerous health risks in excess of those associated with the
4 use of other similar IVC filters; that any and all side effects were accurately reflected in the warnings;
5 and that they were adequately tested to withstand normal placement within the human body.

6 148. Defendants made the foregoing misrepresentations knowing that they were false or
7 without reasonable basis. These materials included instructions for use and a warning document that
8 was included in the package of the Cordis IVC filters that were implanted in Plaintiffs.

9 149. Defendants' intent and purpose in making these misrepresentations was to deceive and
10 defraud the public and the medical community, including Plaintiffs' health care providers; to gain the
11 confidence of the public and the medical community, including Plaintiffs' health care providers; to
12 falsely assure the public and the medical community of the quality of Cordis IVC filters and their fitness
13 for use; and to induce the public and the medical community, including Plaintiffs' health care providers
14 to request, recommend, prescribe, implant, purchase, and continue to use Cordis IVC filters, all in
15 reliance on Defendants' misrepresentations.

16 150. The foregoing representations and omissions by Defendants were false.

17 151. Defendants' IVC filters are not safe, fit, and effective for human use in their intended and
18 reasonably foreseeable manner.

19 152. Further, the use of Cordis IVC filters is hazardous to the users' health, and Cordis IVC
20 filters have a serious propensity to cause users to suffer serious injuries, including without limitation the
21 injuries Plaintiffs suffered.

22 153. Finally, Defendants' IVC filters have a statistically significant higher rate of failure and
23 injury than do other comparable IVC filters.

24 154. In reliance upon the false and negligent misrepresentations and omissions made by
25 Defendants, Plaintiffs and their health care providers were induced to, and did use Cordis IVC filters,
26 thereby causing Plaintiffs to sustain severe and permanent personal injuries.

27 155. Defendants knew and had reason to know that Plaintiffs, their health care providers, and
28 the general medical community did not have the ability to determine the true facts intentionally and/or

1 negligently concealed and misrepresented by Defendants, and would not have prescribed and implanted
2 Cordis IVC filters if the true facts regarding Defendants' IVC filters had not been concealed and
3 misrepresented by Defendants.

4 156. Defendants had sole access to material facts concerning the defective nature of the
5 products and their propensities to cause serious and dangerous side effects in the form of dangerous
6 injuries and damages to persons who were implanted with Cordis IVC filters.

7 157. At the time Defendants failed to disclose and intentionally misrepresented the foregoing
8 facts, and at the time Plaintiffs used Cordis IVC filters, Plaintiffs and their health care providers were
9 unaware of Defendants' misrepresentations and omissions.

10 158. As a direct and proximate result of Defendants' fraudulent misrepresentations, Plaintiffs
11 suffered Injuries and Damages.

12 **SEVENTH CAUSE OF ACTION**

13 **FRAUDULENT CONCEALMENT**

14 **(By All Plaintiffs, As to All Defendants)**

15 159. Plaintiffs incorporate by reference all prior allegations.

16 160. In marketing and selling Cordis IVC filters (the TrapEase filters and the OptEase filters),
17 Defendants concealed material facts from Plaintiffs and their healthcare providers.

18 161. These concealed material facts include, but are not limited to:

- 19 a. Cordis IVC filters were unsafe and not fit when used for their intended purpose or in a
20 reasonably foreseeable manner;
 - 21 b. Cordis IVC filters posed dangerous health risks in excess of those associated with the use
22 of other similar IVC filters;
 - 23 c. That there were additional side effects related to implantation and use of Cordis IVC
24 filters that were not accurately and completely reflected in the warnings associated with
25 Cordis IVC filters; and
 - 26 d. That Cordis IVC filters were not adequately tested to withstand normal placement within
27 the human body.
- 28

1 162. Plaintiffs and their health care providers were not aware of these and other facts
2 concealed by Defendants.

3 163. In concealing these and other facts, Defendants intended to deceive Plaintiffs and their
4 health care providers.

5 164. Plaintiffs and their health care providers were ignorant of and could not reasonably
6 discover the facts Defendants fraudulently concealed and reasonably and justifiably relied on
7 Defendants' representations concerning the supposed safety and efficacy of Cordis IVC filters.

8 165. As a direct and proximate result of Defendants' fraudulent concealment of material facts,
9 Plaintiffs suffered Injuries and Damages.

10 **EIGHTH CAUSE OF ACTION**

11 **BREACH OF EXPRESS WARRANTY**

12 **(By All Plaintiffs, As to All Defendants)**

13 166. Plaintiffs incorporate by reference all prior allegations.

14 167. Plaintiffs, through their medical providers, purchased a Cordis IVC filter from
15 Defendants.

16 168. At all relevant times, Defendants were merchants of goods of the kind including medical
17 devices and vena cava filters (i.e., Cordis IVC filters).

18 169. At the time and place of sale, distribution, and supply of Cordis IVC filters to Plaintiffs
19 (and to other consumer and the medical community), Defendants expressly represented and warranted
20 that Cordis IVC filters were safe; that they were well-tolerated, efficacious, fit for their intended
21 purpose, and of marketable quality; that they did not produce any unwarned-of dangerous side effects;
22 and that they was adequately tested.

23 170. At the time of Plaintiffs' purchase from Defendants, Cordis IVC filters were not in a
24 merchantable condition, and Defendants breached its expressed warranties, in that Cordis IVC filters,
25 among other things:

- 26 a. Were designed in such a manner so as to be prone to an unreasonably high incidence of
27 fracture, perforation of vessels and organs, and/or migration;
28

- b. Were designed in such a manner so as to result in a unreasonably high incidence of injury to the vessels and organs of its purchaser;
- c. Were manufactured in such a manner that the exterior surface of the filter was inadequately, improperly, and inappropriately constituted, causing the device to weaken and fail;
- d. Were unable to be removed at any time during a person's life;
- e. Were not efficacious in the prevention of pulmonary emboli;
- f. Carried a risk of use outweighed any benefit; and
- g. Were not self-centering.

171. As a direct and proximate result of Defendants' breach of express warranty, Plaintiffs suffered Injuries and Damages.

NINTH CAUSE OF ACTION

BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY

(By All Plaintiffs, As to All Defendants)

172. Plaintiffs incorporate by reference all prior allegations.

173. Defendants impliedly warranted that Cordis IVC filters were of merchantable quality and safe and fit for the use for which Defendants intended them, and Plaintiff in fact used them.

174. Defendants breached its implied warranties by, among other things:

- a. Failing to provide adequate instruction that a manufacturer exercising reasonable care would have provided concerning the likelihood that Cordis IVC filters would cause harm;
- b. Manufacturing and/or selling Cordis IVC filters when those filters did not conform to representations made by Defendants when they left Defendants' control;
- c. Manufacturing and/or selling Cordis IVC filters that were more dangerous than an ordinary consumer would expect when used in an intended or reasonably foreseeable manner;
- d. Manufacturing and/or selling Cordis IVC filters that carried foreseeable risks associated with the Cordis IVC filter design or formulation which exceeded the benefits associated with that design;

- e. Manufacturing and/or selling Cordis IVC filters when they deviated in a material way from the design specifications, formulas, or performance standards or from otherwise identical units manufactured to the same design specifications, formulas, or performance standards; and
- f. Impliedly representing that its filters would be effective in the prevention of pulmonary emboli.

175. As a direct and proximate result of Defendants' breach of its implied warranty, Plaintiffs suffered Injuries and Damages.

TENTH CAUSE OF ACTION

LOSS OF CONSORTIUM

(By Plaintiffs FRANK GRAHAM, CYNTHIA MARTINEZ and JOHN SHAFFER, JR., As to All Defendants)

176. Plaintiffs incorporate by reference all prior allegations

177. As a proximate result of the personal injuries suffered by Plaintiffs MARTHA GRAHAM, TED MICHAEL MARTINEZ and JUDY SHAFFER, as described in this Complaint, Plaintiffs FRANK GRAHAM, CYNTHIA MARTINEZ and JOHN SHAFFER, JR. have been deprived of the benefits of their marriage including love, affection, society, and consortium, and other spousal duties and actions. Plaintiffs FRANK GRAHAM, CYNTHIA MARTINEZ and JOHN SHAFFER, JR. were provided with all of the benefits of a marriage between husband and wife, prior to the use of a Cordis IVC filter by their respective Plaintiff spouses and the resulting injuries described herein.

178. Plaintiffs FRANK GRAHAM, CYNTHIA MARTINEZ and JOHN SHAFFER, JR. have also suffered the permanent loss of their respective Plaintiff spouses' daily and regular contribution to the household duties and services, which each provides to the household as husband and wife.

179. Plaintiffs FRANK GRAHAM, CYNTHIA MARTINEZ and JOHN SHAFFER, JR. have also incurred the costs and expenses related to the medical care, treatment, medications, and hospitalization to which their respective Plaintiff spouses were subjected for the physical injuries they suffered as a proximate result of their use of a Cordis IVC filter. Plaintiffs FRANK GRAHAM, CYNTHIA MARTINEZ and JOHN SHAFFER, JR. will continue to incur the future costs and expenses

1 related to the care, treatment, medications, and hospitalization of their respective Plaintiff spouses due to
2 their injuries.

3 180. Plaintiffs FRANK GRAHAM, CYNTHIA MARTINEZ and JOHN SHAFFER, JR. have
4 suffered loss of consortium, as described herein, including the past, present, and future loss of their
5 spouses' companionship, services, society, and the ability of their spouses to provide Plaintiffs FRANK
6 GRAHAM, CYNTHIA MARTINEZ and JOHN SHAFFER, JR. with the benefits of marriage, including
7 *inter alia*, loss of contribution to household income and loss of household services, all of which has
8 resulted in pain, suffering, and mental and emotional distress and worry for Plaintiffs FRANK
9 GRAHAM, CYNTHIA MARTINEZ and JOHN SHAFFER, JR.

10 **PUNITIVE DAMAGES ALLEGATIONS**

11 **(By All Plaintiffs, As to All Defendants)**

12 181. Plaintiffs incorporate by reference all prior allegations.

13 182. At all times material hereto, Defendants knew or should have known that Cordis IVC
14 filters were unreasonably dangerous with respect to the risk of tilt, fracture, migration and/or
15 perforation.

16 183. At all times material hereto, Defendants attempted to misrepresent and did knowingly
17 misrepresent facts concerning the safety of Cordis IVC filters.

18 184. Defendants' misrepresentations included knowingly withholding material information
19 from the medical community and the public, including Plaintiffs' physicians, concerning the safety of its
20 Cordis IVC filters.

21 185. Defendants' conduct, alleged throughout this Complaint, was willful, wanton, and
22 undertaken with a conscious indifference and disregard to the consequences that consumers of their
23 products faced, including Plaintiffs.

24 186. At all times material hereto, Defendants knew and recklessly disregarded the fact that
25 Cordis IVC filters have an unreasonably high rate of tilt, fracture, migration, and/or perforation.

26 187. Notwithstanding the foregoing, Defendants continued to market Cordis IVC filters
27 aggressively to consumers, including Plaintiffs, without disclosing the aforesaid side effects.
28

190. Defendants' conduct is reprehensible, evidencing an evil hand guided by an evil mind and was undertaken for pecuniary gain in reckless and conscious disregard for the substantial risk of death and physical injury to consumers, including Plaintiffs.

191. Such conduct justifies an award of punitive or exemplary damages in an amount sufficient to punish Defendants' conduct and deter like conduct by Defendants and other similarly situated persons and entities in the future.

WHEREFORE, Plaintiffs demand judgment against Defendants for:

b. Special (economic) damages, including, without limitation, past and future medical expenses; past and future lost wages and loss of earning capacity; and other consequential damages as allowed by law;

d. Disgorgement of profits;

e. Restitution;

f. Statutory damages, where authorized;

g. Costs of suit;

- 1 h. Reasonable attorneys' fees, where authorized;
2 i. Prejudgment interest as allowed by law;
3 j. Post-judgment interest at the highest applicable statutory or common law rate from the
4 date of judgment until satisfaction of judgment;
5 k. Such other additional and further relief as Plaintiffs may be entitled to in law or in equity.

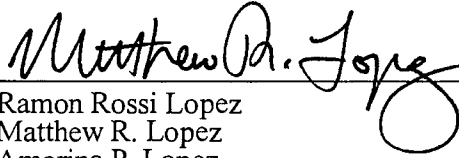
6 **DEMAND FOR JURY TRIAL**

7 Plaintiffs hereby demand a trial by jury on all triable issues.
8

9 Dated: May 5, 2016

Respectfully submitted,

10 LOPEZ McHUGH LLP

11 By: 
12
13 Ramon Rossi Lopez
14 Matthew R. Lopez
15 Amorina P. Lopez

16 -And-

17 Howard Nations
18 (for *pro hac vice* consideration)
19 THE NATIONS LAW FIRM

20 Attorneys for Plaintiffs
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ENDORSED
FILED
ALAMEDA COUNTY

MAY 13 2016

CLERK OF THE SUPERIOR COURT
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**SUPERIOR COURT OF THE STATE OF CALIFORNIA
FOR THE COUNTY OF ALAMEDA**

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RUSSELL ANDERSON, an individual;
MARTHA GRAHAM and FRANK GRAHAM,
individually and as wife and husband;
TAMARRA GRAYSON, an individual;
TIMOTHY HOWARD, an individual; TED
MICHAEL MARTINEZ and CYNTHIA
MARTINEZ, individually and as husband and
wife; JUDY SHAFFER and JOHN SHAFFER,
JR., individually and as wife and husband;
CLARICE STEPP, an individual; and
ALLISON FISHER, an individual,

Plaintiffs

vs.

CORDIS CORPORATION; and DOES 1
through 50;

Defendants.

Case No.: RG16814569

**FIRST AMENDED COMPLAINT FOR
DAMAGES**

1. STRICT PRODUCTS LIABILITY –
DESIGN DEFECT
2. STRICT PRODUCTS LIABILITY –
FAILURE TO WARN
3. STRICT PRODUCTS LIABILITY –
MANUFACTURING DEFECT
4. NEGLIGENCE
5. NEGLIGENT MISREPRESENTATION
6. FRAUDULENT MISREPRESENTATION
7. FRAUDULENT CONCEALMENT
8. BREACH OF EXPRESS WARRANTY
9. BREACH OF IMPLIED WARRANTY OF
MERCHANTABILITY
10. LOSS OF CONSORTIUM

DEMAND FOR JURY TRIAL

BY FAX

COMES NOW, Plaintiffs, by and through their attorneys, who complain and allege against Defendants CORDIS CORPORATION and DOES 1 through 50, and each of them, on information and belief, as follows:

INTRODUCTION

1. Plaintiffs bring this action for personal injuries damages suffered as a direct and proximate result of being implanted with a defective and unreasonably dangerous Inferior Vena Cava (“IVC”) filter medical device manufactured by Defendants.

2. The subject IVC filters include the following devices: TrapEase™ Permanent Vena Cava Filter (“TrapEase filter”) and OptEase™ Vena Cava Filter (“OptEase filter”) (for convenience, these devices will be referred to in this complaint under the generic terms “Cordis IVC filters” or “Defendants’ IVC filters”). At all times relevant to this action, Defendants developed, designed, set specifications for, licensed, manufactured, prepared, compounded, assembled, processed, sold, distributed and/or marketed the Cordis IVC filters to be implanted in patients throughout the United States, including California.

3. Plaintiffs’ claims for damages all relate to Defendants’ design, manufacture, sale, testing, marketing, labeling, advertising, promotion, and/or distribution of Cordis IVC filters.

4. The Cordis IVC filters that are the subject of this action all reached Plaintiffs and Plaintiffs’ physicians without substantial change in condition from the time they left Defendants’ possession.

5. Plaintiffs and Plaintiffs’ physicians used the Cordis IVC filters in the manner in which they were intended.

6. Defendants are solely responsible for any alleged design, manufacture or information defect its IVC filters contain.

7. Defendants do not allege that any other person or entity is comparatively at fault for any alleged design, manufacture, or informational defect its IVC filters contain.

PARTIES

8. Plaintiff WALTER HERBERT at all times relevant to this action was a citizen and resident of the State of California. Plaintiff WALTER HERBERT underwent placement of Defendants’

1 OptEase Vena Cava Filter on or about October 25, 2005, in California. The filter subsequently
2 malfunctioned and caused injury and damages to Plaintiff WALTER HERBERT, including, but not
3 limited to, tilt, filter embedded in wall of the IVC, unsuccessful removal attempt, and filter unable to be
4 retrieved. As a direct and proximate result of these malfunctions, Plaintiff WALTER HERBERT
5 suffered life-threatening injuries and damages, and required extensive medical care and treatment. As a
6 further proximate result, Plaintiff WALTER HERBERT has suffered and will continue to suffer
7 significant medical expenses, and pain and suffering, and other damages.

8 9. Plaintiff RUSSELL ANDERSON at all times relevant to this action was and is a citizen
9 and resident of the State of Arizona. Plaintiff RUSSELL ANDERSON underwent placement of
10 Defendants' OptEase Vena Cava Filter on or about January 29, 2008. The filter subsequently
11 malfunctioned and caused injury and damages to Plaintiff RUSSELL ANDERSON, including, but not
12 limited to, tilt, filter embedded in wall of the IVC, unsuccessful removal attempt, and filter unable to be
13 retrieved. As a direct and proximate result of these malfunctions, Plaintiff RUSSELL ANDERSON
14 suffered life-threatening injuries and damages, and required extensive medical care and treatment. As a
15 further proximate result, Plaintiff RUSSELL ANDERSON has suffered and will continue to suffer
16 significant medical expenses, and pain and suffering, and other damages.

17 10. Plaintiff MARTHA GRAHAM at all times relevant to this action was and is a citizen and
18 resident of the State of Maryland. Plaintiff MARTHA GRAHAM underwent placement of Defendants'
19 OptEase Vena Cava Filter on or about June 2, 2006. The filter subsequently malfunctioned and caused
20 injury and damages to Plaintiff MARTHA GRAHAM, including, but not limited to, tilt, filter embedded
21 in wall of the IVC, unsuccessful removal attempt, and filter unable to be retrieved. As a direct and
22 proximate result of these malfunctions, Plaintiff MARTHA GRAHAM suffered life-threatening injuries
23 and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff
24 MARTHA GRAHAM has suffered and will continue to suffer significant medical expenses, and pain
25 and suffering, and other damages.

26 11. Plaintiff FRANK GRAHAM at all times relevant to this action was and is a citizen and
27 resident of the State of Arizona. Plaintiffs MARTHA GRAHAM and FRANK GRAHAM were and are,
28 at all times relevant to this action, legally married as wife and husband. Plaintiff FRANK GRAHAM

1 brings this action for, inter alia, the loss of consortium, comfort, and society he suffered due to the
2 personal injuries suffered by his wife, MARTHA GRAHAM.

3 12. Plaintiff TAMARRA GRAYSON at all times relevant to this action was and is a citizen
4 and resident of the State of Oklahoma. Plaintiff TAMARRA GRAYSON underwent placement of
5 Defendants' OptEase Vena Cava Filter on or about September 10, 2009. The filter subsequently
6 malfunctioned and caused injury and damages to Plaintiff TAMARRA GRAYSON, including, but not
7 limited to, tilt, filter embedded in wall of the IVC, unsuccessful removal attempt, and filter unable to be
8 retrieved. As a direct and proximate result of these malfunctions, Plaintiff TAMARRA GRAYSON
9 suffered life-threatening injuries and damages, and required extensive medical care and treatment. As a
10 further proximate result, Plaintiff TAMARRA GRAYSON has suffered and will continue to suffer
11 significant medical expenses, and pain and suffering, and other damages.

12 13. Plaintiff TIMOTHY HOWARD at all times relevant to this action was and is a citizen
13 and resident of the State of Tennessee. Plaintiff TIMOTHY HOWARD underwent placement of
14 Defendants' TrapEase Vena Cava Filter on or about November 6, 2014. The filter subsequently
15 malfunctioned and caused injury and damages to Plaintiff TIMOTHY HOWARD, including, but not
16 limited to, migration of the filter. As a direct and proximate result of these malfunctions, Plaintiff
17 TIMOTHY HOWARD suffered life-threatening injuries and damages, and required extensive medical
18 care and treatment. As a further proximate result, Plaintiff TIMOTHY HOWARD has suffered and will
19 continue to suffer significant medical expenses, and pain and suffering, and other damages.

20 14. Plaintiff TED MICHAEL MARTINEZ at all times relevant to this action was and is a
21 citizen and resident of the State of Nevada. Plaintiff TED MICHAEL MARTINEZ underwent
22 placement of Defendants' TrapEase Vena Cava Filter on or about June 25, 2006. The filter
23 subsequently malfunctioned and caused injury and damages to Plaintiff TED MICHAEL MARTINEZ,
24 including, but not limited to, migration of the filter. As a direct and proximate result of these
25 malfunctions, Plaintiff TED MICHAEL MARTINEZ suffered life-threatening injuries and damages, and
26 required extensive medical care and treatment. As a further proximate result, Plaintiff TED MICHAEL
27 MARTINEZ has suffered and will continue to suffer significant medical expenses, and pain and
28 suffering, and other damages.

1 15. Plaintiff CYNTHIA MARTINEZ at all times relevant to this action was and is a citizen
2 and resident of the State of Nevada. Plaintiffs TED MICHAEL MARTINEZ and CYNTHIA
3 MARTINEZ were and are, at all times relevant to this action, legally married as husband and wife.
4 Plaintiff CYNTHIA MARTINEZ brings this action for, inter alia, the loss of consortium, comfort, and
5 society he suffered due to the personal injuries suffered by her husband, TED MICHAEL MARTINEZ.

6 16. Plaintiff JUDY SHAFFER at all times relevant to this action was a citizen and resident of
7 the State of Maryland. Plaintiff JUDY SHAFFER underwent placement of Defendants' OptEase Vena
8 Cava Filter on or about February 3, 2015. The filter subsequently malfunctioned and caused injury and
9 damages to Plaintiff JUDY SHAFFER, including, but not limited to, tilt, filter embedded in wall of the
10 IVC, unsuccessful removal attempt, and filter unable to be retrieved. As a direct and proximate result of
11 these malfunctions, Plaintiff JUDY SHAFFER suffered life-threatening injuries and damages, and
12 required extensive medical care and treatment. As a further proximate result, Plaintiff JUDY SHAFFER
13 has suffered and will continue to suffer significant medical expenses, and pain and suffering, and other
14 damages.

15 17. Plaintiff JOHN SHAFFER, JR. at all times relevant to this action was a citizen and
16 resident of the State of Maryland. Plaintiffs JUDY SHAFFER and JOHN SHAFFER, JR. were and are,
17 at all times relevant to this action, legally married as wife and husband. Plaintiff JOHN SHAFFER, JR.
18 brings this action for, inter alia, the loss of consortium, comfort, and society he suffered due to the
19 personal injuries suffered by his wife, JUDY SHAFFER.

20 18. Plaintiff CLARICE STEPP at all times relevant to this action was and is a citizen and
21 resident of the State of Ohio. Plaintiff CLARICE STEPP underwent placement of Defendants'
22 TrapEase Vena Cava Filter on or about December 14, 2005. The filter subsequently malfunctioned and
23 caused injury and damages to Plaintiff CLARICE STEPP, including, but not limited to, blood clots,
24 clotting and occlusion of IVC filter. As a direct and proximate result of these malfunctions, Plaintiff
25 CLARICE STEPP suffered life-threatening injuries and damages, and required extensive medical care
26 and treatment. As a further proximate result, Plaintiff CLARICE STEPP has suffered and will continue
27 to suffer significant medical expenses, and pain and suffering, and other damages.
28

1 19. Plaintiff ALLISON FISHER at all times relevant to this action was and is a citizen and
2 resident of the State of North Carolina. Plaintiff ALLISON FISHER underwent placement of
3 Defendants' OptEase Vena Cava Filter on or about August 24, 2009. The filter subsequently
4 malfunctioned and caused injury and damages to Plaintiff ALLISON FISHER, including, but not limited
5 to, filter embedded in wall of the IVC, filter unable to be retrieved, blood clots, clotting and occlusion of
6 IVC filter. As a direct and proximate result of these malfunctions, Plaintiff ALLISON FISHER suffered
7 life-threatening injuries and damages, and required extensive medical care and treatment. As a further
8 proximate result, Plaintiff ALLISON FISHER has suffered and will continue to suffer significant
9 medical expenses, and pain and suffering, and other damages.

10 20. Defendant CORDIS CORPORATION ("Cordis"), including its department, division, and
11 subsidiary, Cordis Endovascular, is a corporation or business entity organized and existing under the
12 laws of the State of Florida with its headquarters located at 6500 Paseo Padre Pkwy., Fremont,
13 California, 94555.

14 21. Cordis may be served with process by serving its registered agent, CT Corporation
15 System, at 818 West Seventh Street Suite 930, Los Angeles, California 90017.

16 22. The true names and/or capacities, whether individual, corporate, partnership, associate,
17 governmental, or otherwise, of Defendant DOES 1 through 50, inclusive, are unknown to Plaintiffs at
18 this time, who therefore sue said Defendants by such fictitious names. Plaintiffs are informed and
19 believe, and thereon allege, that each Defendant designated herein as a DOE caused injuries and
20 damages proximately thereby to Plaintiffs as is hereinafter alleged, and that each DOE defendant is
21 liable to Plaintiffs for the acts and omissions alleged herein below and the injuries and damages resulting
22 therefrom. Plaintiffs seek leave to amend this Complaint to allege the true names and capacities of said
23 DOE defendants when the same are ascertained.

24 23. Plaintiffs are informed and believe, and thereon allege, that at all times herein mentioned,
25 the Defendant and each of the DOE defendants were the agent, servant, employee and/or joint venturer
26 of the other co-defendants, and each of them, and at all said times each Defendant, including DOE
27 defendants, were acting in the full course, scope, and authority of said agency, service, employment
28 and/or joint venture.

1 24. Plaintiffs are informed and believe, and thereon allege, that at all times mentioned herein,
2 Defendant and DOES 1 through 50, and each of them, were also known as, formerly known as, and/or
3 were the successors and/or predecessors in interest/business/product line/or a portion thereof, assigns, a
4 parent, a subsidiary (wholly or partially owned by, or the whole or partial owner), affiliate, partner, co-
5 venturer, merged company, alter egos, agents, equitable trustees and/or fiduciaries of and/or were
6 members in an entity or entities engaged in the funding, researching, studying, manufacturing,
7 fabricating, designing, developing, labeling, assembling, distributing, supplying, leasing, buying,
8 offering for sale, selling, inspecting, servicing, contracting others for marketing, warranting, rebranding,
9 manufacturing for others, packaging, and advertising the device.

10 25. Defendant and DOES 1 through 50, and each of them, are liable for the acts, omissions
11 and tortious conduct of its successors and/or predecessors in interest/business/product line/or a portion
12 thereof, assigns, parent, subsidiary, affiliate, partner, co-venturer, merged company, alter ego, agent,
13 equitable trustee, fiduciary and/or its alternate entities in that Defendant and DOES 1 through 50, and
14 each of them, enjoy the goodwill originally attached to each such alternate entity, acquired the assets or
15 product line (or a portion thereof), and in that there has been a virtual destruction of Plaintiffs' remedy
16 against each such alternate entity, and that each such Defendant has the ability to assume the risk-
17 spreading role of each such alternate entity.

18 26. Plaintiffs are informed and believe, and thereon allege that, at all times herein mentioned,
19 DOES 1 through 50, and each of them, were and are corporations organized and existing under the laws
20 of the State of California or the laws of some state or foreign jurisdiction; that each of the said DOE
21 defendants were and are authorized to do and are doing business in the State of California and regularly
22 conducted business in the State of California.

23 27. Upon information and belief, Defendants at all relevant times were engaged in the
24 business of researching, developing, designing, licensing, manufacturing, distributing, selling,
25 marketing, and/or introducing into interstate commerce and into the State of California, either directly or
26 indirectly through third parties or related entities, its products, including the TrapEase and OptEase IVC
27 filters, and derived substantial income from doing business in California.
28

28. “Cordis” and “Defendants” where used hereinafter, shall refer to all subsidiaries, affiliates, divisions, franchises, partners, joint venturers, organizational units of any kind, predecessors, successors, assigns, officers, directors, employees, agents and representatives of Cordis Corporation; as well as DOE Defendants 1 through 50, and each of them.

29. Joinder of Plaintiffs in this First Amended Complaint for Damages is proper pursuant to *Code of Civil Procedure* Section 378 because Plaintiffs assert a right to relief in respect of or arising out of the same transaction, occurrence, or series of transactions or occurrences, and questions of law and fact common to all Plaintiffs will arise in the action.

JURISDICTION AND VENUE

30. This Court has jurisdiction under the California Constitution, Article VI, Section 10 and *Code of Civil Procedure* Section 410.10. Plaintiffs’ damages exceed the jurisdictional minimum of this Court.

31. Venue is proper in this Court pursuant to *Code of Civil Procedure* Sections 395 and 395.5 because the principal place of business for Defendant CORDIS CORPORATION is situated in Alameda County. Further, a substantial amount of Defendants’ conduct, as alleged herein by Plaintiffs, took place in Alameda County.

32. Requiring Defendants to litigate these claims in California does not offend traditional notions of fair play and substantial justice and is permitted by the United States Constitution. Defendants are “at home” in the State of California. Cordis maintains campuses and facilities in Fremont and Oakland, California, in Alameda County, and has its headquarters here. Cordis’ website lists its address as 6500 Paseo Padre Parkway, Fremont, CA 94555 (*see* <https://www.cordis.com/> (last visited May 13, 2016)). A Cordis-affiliate website represents that Cordis’ “North American operations are based out of the San Francisco Bay Area” and also lists the 6500 Paseo Padre Parkway, Fremont, CA 94555 address (*see* <http://www.cardinalhealth.com/en/cmp/ext/cor/cordis.html> (last visited May 13, 2016)). Thus, Cordis affirmatively represents to the public that its headquarters is in California.

33. Defendants systematically availed themselves of the State of California by conducting regular and sustained business and engaging in substantial commerce and business activity in California, including without limitation researching, developing, designing, licensing, manufacturing, distributing,

1 selling, marketing, and/or introducing into interstate commerce in the state of California, either directly
2 or indirectly, its products, including Cordis IVC filters.

3 34. Plaintiffs' claims arise from and relate to Cordis' purposeful avail of the State of
4 California because Cordis' wrongful conduct in developing, designing, selling, marketing,
5 manufacturing and/or distributing Cordis IVC filters took place, in whole or in part, in the State of
6 California. Therefore, the claims of California-plaintiffs *and* out-of-state plaintiffs relate to and arise
7 from Defendants' explicit contacts and purposeful avail of the State of California. Further and
8 independently, Cordis consented to jurisdiction in the State of California by appointing an agent for
9 service of process in this State and by conducting substantial systematic business in this State.

10 35. The instant First Amended Complaint for Damages does not confer diversity jurisdiction
11 upon the federal courts pursuant to 28 U.S.C. § 1332. Likewise, federal question subject matter
12 jurisdiction pursuant to 28 U.S.C. § 1331 is not invoked by the instant Complaint, as it sets forth herein
13 exclusively state law claims against the Defendants. Nowhere do Plaintiffs plead, expressly or
14 implicitly, any cause of action or request any remedy that arises under or is founded upon federal law,
15 and any alleged federal rights or remedies are expressly disavowed. The issues presented by Plaintiffs do
16 not implicate substantial federal questions, do not turn on the necessary interpretation of federal law, and
17 do not affect the federal system as a whole. The assertion of federal jurisdiction over claims made herein
18 would improperly disturb the congressionally approved balance of federal and state responsibilities.

19 **BACKGROUND**

20 **INFERIOR VENA CAVA FILTERS GENERALLY**

21 36. IVC filters were first made commercially available to the medical community in the
22 1960s. Over the years, medical device manufacturers have introduced several different designs of IVC
23 filters.

24 37. An IVC filter is a device that is designed to filter or "catch" blood clots that travel from
25 the lower portions of the body to the heart and lungs. IVC filters were originally designed to be
26 permanently implanted in the IVC.

27 38. The IVC is a vein that returns blood to the heart from the lower portions of the body. In
28 certain people, for various reasons, blood clots travel from the vessels in the legs and pelvis, through the

1 vena cava and into the lungs. Oftentimes, these blood clots develop in the deep leg veins, a condition
2 called “deep-vein thrombosis” or “DVT.” Once blood clots reach the lungs, they are considered
3 “pulmonary emboli” or “PE.” Pulmonary emboli present risks to human health.

4 39. People at risk for DVT/PE can undergo medical treatment to manage the risk. For
5 example, a doctor may prescribe anticoagulant therapies such as medications like Heparin, Warfarin, or
6 Lovenox to regulate the clotting factor of the blood. In some people who are at high risk for DVT/PE
7 and who cannot manage their conditions with medications, physicians may recommend surgically
8 implanting an IVC filter to prevent thromboembolic events.

9 40. As stated above, IVC filters have been on the market for decades. All IVC filters are
10 only cleared for use by the Food & Drug Administration (“FDA”) for prevention of recurrent pulmonary
11 embolism in patients at risk for pulmonary embolism and where anticoagulation therapy has failed or is
12 contraindicated.

13 41. In order to increase sales of these devices, Defendants sought to expand the market for
14 prophylactic use among nontraditional patient populations that were temporarily at risk of developing
15 blood clots.

16 42. Defendant Cordis engaged in marketing campaigns directed toward the bariatric, trauma,
17 orthopedic and cancer patient population. Expansion to these new patient groups would substantially
18 increase sales and the first manufacturer to market would capture market share.

19 43. Other manufacturers also saw this opportunity, which triggered a race to market a device
20 that provided physicians the option to retrieve the filter after the clot risk subsided.

21 44. From 2000 through 2003, manufacturers of IVC filters, including Defendants, raced
22 against each other to bring the first IVC filter to the market with the added indication of optional
23 retrieval. In 2003, the FDA cleared three different IVC filters for a retrieval indication, one of which
24 was the OptEase filter by Defendant Cordis.

25 45. There is no evidence that Defendants’ IVC filters were effective in preventing pulmonary
26 embolism (the very condition the products were indicated to prevent).

27 46. Years after the implantation of retrievable filters into the bodies of patients, scientists
28 began to study the effectiveness of the retrievable filters. As recently as October 2015, an expansive

1 article published in the *Annals of Surgery* concerning trauma patients inserted with IVC filters
 2 concluded that IVC filters were not effective in preventing pulmonary emboli, and instead actually
 3 caused thrombi to occur.

4 47. Comparing the results of over 30,000 trauma patients who had not received IVC filters
 5 with those who had received them, the *Annals of Surgery* study published its alarming results:

- 6 a. Almost twice the percentage of patients with IVC filters in the study died compared to
 7 those that had not received them.
- 8 b. Over five times the relative number of patients with IVC filters developed DVTs.
- 9 c. Over four times the relative percentage of patients with filters developed thromboemboli.
- 10 d. Over twice the percentage of patients developed a pulmonary embolus – the very
 11 condition Defendant Cordis told the FDA, physicians, and the public that its IVC filters
 12 were designed to prevent.

13 48. Other studies also have revealed that these devices suffer common failure modes such as
 14 migration, perforation, thrombosis, and fracture, all of which can cause serious injury or death. For
 15 example, recent studies of Cordis IVC filters have revealed fracture rates as high as 50% and
 16 recommend medical monitoring and/or removal.

17 49. These studies, including the *Annals of Surgery* study, have shown there is no evidence
 18 establishing that IVC filters are effective and that these devices suffer common failure modes, including,
 19 but not limited to, migration, perforation, thrombosis, tilt and fracture, all of which can cause serious
 20 injury or death. Thus, the current state of scientific and medical evidence indicates that IVC filters are
 21 not only ineffective but that they are themselves a health hazard.

22 **THE TRAPEASE[™] AND OPTEASE[™] IVC FILTERS**

23 50. On or about January 10, 2001, Defendants bypassed the more onerous FDA's approval
 24 process for new devices and obtained "clearance" under Section 510(k) of the Medical Device
 25 Amendments to the Food, Drug, and Cosmetic Act to market the TrapEase Vena Cava Filter as a
 26 *permanent* filter by claiming it was substantially similar in respect to safety, efficacy, design, and
 27 materials as the IVC filters already available on the market.

1 51. Section 510(k) permits the marketing of medical devices if the device is substantially
 2 equivalent to other legally marketed predicate devices without formal review for the safety or efficacy of
 3 the said device. The FDA explained the difference between the 510(k) process and the more rigorous
 4 “premarket approval” (PMA) process in its amicus brief filed with the Third Circuit in *Horn v. Thoratec*
 5 *Corp.*, which the court quoted from:

6 A manufacturer can obtain an FDA finding of ‘substantial equivalence’ by submitting a
 7 premarket notification to the agency in accordance with section 510(k) of the [Food Drug
 8 and Cosmetic Act]. 21 U.S.C. § 360(k). A device found to be ‘substantially equivalent’
 9 to a predicate device is said to be ‘cleared’ by FDA (as opposed to ‘approved’ by the
 10 agency under a PMA. A pre-market notification submitted under 510(k) is thus entirely
 11 different from a PMA which must include data sufficient to demonstrate that the IVC
 12 Filters is safe and effective.

13 376 F.3d 163, 167 (3d Cir. 2004) (emphasis in original).

14 52. In *Medtronic, Inc. v. Lohr*, the U.S. Supreme Court similarly described the 510(k)
 15 process, observing:

16 If the FDA concludes on the basis of the [manufacturer’s] § 510(k) notification that the
 17 device is “substantially equivalent” to a pre-existing device, it can be marketed without
 18 further regulatory analysis. . . . The § 510(k) notification process is by no means
 19 comparable to the PMA process; in contrast to the 1,200 hours necessary to complete a
 20 PMA review, the § 510(k) review is completed in average of 20 hours. . . . As one
 21 commentator noted: “The attraction of substantial equivalence to manufacturers is clear.
 22 Section 510(k) notification requires little information, rarely elicits a negative response
 23 from the FDA, and gets processed quickly.”

24 518 U.S. 470, 478-79 (1996) (quoting Adler, *The 1976 Medical Device Amendments: A Step in the*
 25 *Right Direction Needs Another Step in the Right Direction*, 43 Food Drug Cosm. L.J. 511, 516 (1988)).

26 53. Pursuant to *Wyeth v. Levine*, 555 U.S. 555 (2009), once a product is cleared “the
 27 manufacturer remains under an obligation to investigate and report any adverse events associated with
 28 the drug . . . and must periodically submit any new information that may affect the FDA’s previous
 conclusions about the safety, effectiveness, or labeling” This obligation extends to post-market
 monitoring of adverse events/complaints.

 54. In July 2000, through this 510(k) process, Defendants obtained clearance from the FDA
 to market the TrapEase filter as a permanent filter.

1 55. The TrapEase filter is made with Nitinol – a nickel titanium alloy. The filter utilizes a
2 design known as a double basket or double filter for the capture of blood clots and/or emboli. This
3 design consists of a basket made of six diamond-shaped struts proximally and six diamond-shaped struts
4 distally, forming proximal and distal baskets, which are connected by six straight struts to create a single
5 symmetric filter. The filter has proximal and distal anchoring barbs located on each connecting strut for
6 fixation of the filter to the vena cava wall to prevent movement after placement.

7 56. Nitinol alloy is used in a number of different medical device applications. It is beneficial
8 for these applications and is employed as material in stents and other medical device applications. It is
9 also used in the manufacture of the TrapEase filter, and other brands of IVC filters.

10 57. Specific manufacturing processes need to be utilized when using Nitinol as a component
11 for medical devices, including IVC filters. Primarily, the Nitinol material should be electro-polished
12 prior to assembly of the finished medical device.

13 58. Electro-polishing is a manner of removing surface blemishes, “draw marking” and
14 circumferential grinding markings on the exterior of the surface of the Nitinol material. The existence
15 of these surface blemishes, “draw markings” and “circumferential grind-markings” causes/results in the
16 weakening of the structural integrity of the end product, whether it is an IVC filter or other medical
17 device.

18 59. In or around September 2002, Defendants sought clearance through the 510(k) process to
19 market the OptEase Vena Cava Filter for the same indicated uses as the TrapEase filter. Defendants
20 represented that the OptEase filter contained the same fundamental technology and was substantially
21 equivalent in terms of safety and efficacy as the predicate devices already available on the market.

22 60. Unlike the TrapEase filter, which has proximal and distal anchoring barbs located on
23 each connecting strut for fixation of the filter to the vena cava wall, the OptEase filter has anchoring
24 barbs for fixation of the filter only on the superior end of each of the six straight struts and has a hook at
25 the inferior end of the basket to allow retrieval with a snare.

26 61. Both designs for the TrapEase filter and OptEase filter suffer flaws making them
27 defective and unreasonably dangerous. Defendants’ IVC filters are designed in such a way that when
28 exposed to expected and reasonably foreseeable *in-vivo* conditions, the devices will fracture, migrate,

1 tilt, perforate internal organs and vasculature, and lead to the formation of thromboembolism and
2 pulmonary embolism.

3 62. For years, it has been known by manufacturers of the Nitinol medical devices and the
4 medical device industry that electro-polishing Nitinol results in increased structural integrity of the
5 device and resistance to fatigue and fatigue failures.

6 63. The exterior surfaces of the Cordis IVC filters were not electro-polished prior to
7 completion of the manufacturing process. This is a manufacturing defect that exists in the TrapEase and
8 OptEase filters which causes these filters to be structurally weak and susceptible to a significant risk of
9 failure/fracture.

10 64. Additionally, Defendants represented that the self-centering design of the TrapEase filter
11 allows accurate, predictable placement, and that its site struts help reduce the risk of tilting and
12 migration, while in reality the filters regularly tilt, migrate, and become embedded in the vena cava wall.

13 65. The anchoring mechanism of Defendants' filters is also insufficient to prevent tilting and
14 migration post-placement.

15 66. The configuration of the Cordis IVC filters actually leads to the formation of blood clots
16 and pulmonary embolism – the exact condition the devices are meant to protect against.

17 67. That Defendants allowed these devices to proceed to market indicates that they failed to
18 establish and maintain an appropriate Quality System concerning design and risk analysis.

19 68. A manufacturer must, at a minimum, undertake research and testing to understand the
20 anatomy of where a medical device will be implanted and understand the forces the device may be
21 exposed to once implanted in a human body. This design input must then be used to determine the
22 minimum safety requirements or attributes the device must have to meet user needs. In the case of an
23 IVC filter, user needs include a device that will capture blood clots of sufficient size to cause harmful
24 consequences and that will not fracture, migrate, tilt, perforate the vena cava, or malfunction in some
25 other way, or be prothombotic. Defendants failed to undertake any such efforts in these regards.

26 69. Prior to bringing a product to market, a manufacturer must also conduct sufficient testing
27 under real world or simulated use conditions to ensure that the device will meet user needs even when
28

1 exposed to reasonably foreseeable worst-case conditions. Defendants failed to adequately establish and
2 maintain such policies, procedures or protocols with respect to their IVC filters.

3 70. Once placed on the market, Defendants' post-market surveillance system should have
4 revealed to Defendants that the TrapEase and OptEase filters were unreasonably dangerous and
5 substantially more prone to fail or malfunction, and cause great bodily harm to patients compared to
6 other available treatment options.

7 71. MAUDE is a database maintained by the FDA to house medical device reports submitted
8 by mandatory reporters (such as manufacturers and device user facilities) and voluntary reporters (such
9 as health care providers and patients).

10 72. Shortly after going on market, Defendants began receiving large numbers of adverse
11 event reports ("AERs") from health care providers reporting that the Cordis IVC filters were fracturing
12 post-implantation and that fractured pieces and/or the entire device was migrating to other areas of the
13 body, including the heart and lungs.

14 73. Defendants also received large numbers of AERs reporting that the TrapEase filters and
15 OptEase filters were found to have excessively tilted, perforated the IVC, or caused thrombosis or
16 stenosis of the vena cava post-implantation.

17 74. These failures were often associated with severe patient injuries such as:

- 18 a. Death;
 - 19 b. Hemorrhage;
 - 20 c. Cardiac/pericardial tamponade (pressure caused by a collection of blood in the area
21 around the heart);
 - 22 d. Cardiac arrhythmia and other symptoms similar to myocardial infarction;
 - 23 e. Severe and persistent pain;
 - 24 f. Perforations of tissue, vessels and organs;
 - 25 g. Chronic deep vein thrombosis;
 - 26 h. Pulmonary embolism; and,
 - 27 i. Compartment syndrome.
- 28

1 75. These failures and resulting injuries are attributable, in part, to the fact that the Cordis
2 IVC filter design was unable to withstand the normal anatomical and physiological loading cycles
3 exerted *in vivo*.

4 76. Recent medical studies have confirmed what Defendants have known or should have
5 known since shortly after the release of each of these filters – not only do Cordis IVC filters fail at
6 alarming rates, but they also fail at rates substantially higher than other available IVC filters. For
7 instance, a recent large medical study found that OptEase and TrapEase filters suffer fracture rates of
8 37.5% and 23.1% respectively, when left implanted a minimum of 46 months. Another recent study
9 found that the TrapEase filter had a 64% fracture rate when left in more than four years. Another study
10 found a statistically significant increased rate of caval thrombosis with the ObtEase filter compared to
11 Gunther Tulip and Recovery Filters.

12 77. As a minimum safety requirement, manufacturers must establish and maintain post-
13 market procedures to timely identify the cause of device failures and other quality problems and to take
14 adequate corrective action to prevent the recurrence of these problems.

15 78. Defendants failed to identify or acknowledge these device failures or determine their
16 causes.

17 79. Defendants failed to take timely and adequate remedial measures to correct known design
18 and manufacturing defects with the Cordis IVC filters.

19 80. Defendants also misrepresented and concealed the risks and benefits of the Cordis IVC
20 filters in the labeling and marketing distributed to the FDA, physicians and the public. For instance,
21 Defendants represented that their filters were safe and effective – more safe and effective than other
22 available IVC filters. However, there is no reliable evidence to support these claims and, to the
23 contrary, the Cordis IVC filters have been associated with a high rate of failure.

24 81. Defendants also represented that the design of these devices would eliminate the risk that
25 pieces of the devices could perforate the vena cava, that the devices could tilt, or that fractures could
26 occur and migrate throughout the body. The medical literature and AERs have proven these claims to be
27 false.
28

1 82. Defendants also marketed the OptEase filter as being “easy” to remove. However, it is
2 one of the most difficult filters to remove. Dr. William T. Kuo, an expert in the removal of IVC filters
3 and vascular surgery, has established an IVC Filter Clinic at Stanford University where his team
4 specializes in the removal of IVC filters that other vascular surgeons refuse to remove for fear of
5 rupturing the vena cava or other internal organs and causing great bodily harm or death to the patient.
6 Dr. Kuo wrote in *the Journal of Vascular Interventional Radiology* that the Cordis filters were the most
7 difficult to retrieve from patients, at least partially due to the design of the filters, which create greater
8 contact with the vein walls than competitors’ filters.

9 83. This is particularly concerning because having an IVC filter for a prolonged period of
10 time increases the risk of developing chronic deep venous thrombosis, PE, IVC occlusion, post-
11 thrombotic syndrome, filter fracture, and caval perforation with pain and organ injury. Many patients
12 with IVC filters are now routinely managed with lifelong anticoagulation solely to reduce the risk of
13 having the filter in place, subjecting patients to the risks and inconvenience of anticoagulation.

14 84. Defendants also failed to adequately disclose the risks of these filters, such as migration,
15 fracture, perforation, tilt, thrombosis, the prothrombotic nature of the devices, that the devices may not
16 be retrievable, or that these failures were known to be causing severe injuries and death or the rate at
17 which these events were occurring.

18 85. Cordis’ labeling was additionally defective in that it directed physicians to implant the
19 OptEase filter upside down. When the OptEase filter was placed as directed by the labeling, the hooks
20 designed to ensure stability were facing in the wrong direction, rendering an already inadequate
21 anchoring system even further defective. As Cordis now explain in its labeling, implanting the device in
22 this fashion “can result in life threatening or serious injury including, but not limited to dissection, vessel
23 perforation, migration of the filter with secondary damage to cardiac structures, ineffective pulmonary
24 embolism prevention or death.”

25 86. Cordis began a series of recalls on March 29, 2013 relating to its labeling, which
26 instructed physicians to implant the devices upside down. These recalls were not timely, nor did they
27 fully correct the defects in Defendants’ labeling. Further, Defendants downplayed the danger patients
28 were exposed to and failed to take adequate steps to ensure patients actually received notice of the recall.

1 87. The FDA classified the initial recall as a Class I recall, which is the most serious type of
2 recall and involves situations in which the FDA has determined there is a reasonable probability that use
3 of these products will cause serious adverse health consequences or death.

4 88. Defendants have admitted that any patients implanted with one of these recalled units
5 should receive medical monitoring. Specifically, these patients should undergo imaging to ascertain
6 whether or not the device was properly deployed and, if not, be assessed for removal.

7 89. Given the unreasonably high failure and injury rates associated with Cordis IVC filters
8 when left implanted long-term, Defendants should be required to pay for medical monitoring to assess
9 the condition of these devices and whether or not retrieval should be undertaken.

10 90. On April 5, 2016, at the annual Society of Interventional Radiology in Vancouver,
11 Canada, Dr. Steven Wang, an interventional radiologist from Palo Alto, California who is affiliated with
12 Kaiser Permanente, presented the results of a retrospective study involving 96 patients in which he
13 sought to understand the prevalence of long-term (greater than 46 months) complications of both
14 permanent and retrievable IVC filters. The study looked at all inferior vena cava filters implanted in
15 patients from January 2007 through December 2009 at multiple health care facilities across the United
16 States. Dr. Wang then identified all patients who had imaging of the filter taken at four years or more
17 after implantation. Of those patients (96), he then evaluated the imaging to determine whether the IVC
18 filter had malfunctioned. After reviewing the data, the authors concluded that device complications at
19 four or more years after implantation "are relatively common." They also found that the Cordis OptEase
20 and TrapEase IVC filters suffered fracture rates of 37.5% and 23.1%, respectively.

21 **ESTOPPEL FROM PLEADING STATUTES OF LIMITATIONS OR REPOSE**

22 91. Plaintiffs incorporate by reference all prior allegations.

23 92. Plaintiffs are within the applicable statute of limitations for their claims because Plaintiffs
24 (and their healthcare professionals) did not discover, and could not reasonably discover, the defects and
25 unreasonably dangerous condition of their Cordis IVC filters.

26 93. Plaintiffs' ignorance of the defective and unreasonably dangerous nature of the Cordis
27 IVC filters, and the causal connection between these defects and each Plaintiff's injuries and damages, is
28

1 due in large part to Defendants' acts and omissions in fraudulently concealing information from the
2 public and misrepresenting and/or downplaying the serious threat to public safety its products present.

3 94. In addition, Defendants are estopped from relying on any statutes of limitation or repose
4 by virtue of unclean hands, acts of fraudulent concealment, affirmative misrepresentations and
5 omissions.

6 95. Such conduct includes intentional concealment from Plaintiffs, their health care
7 professionals, and the general consuming public of material information that Cordis IVC filters had not
8 been demonstrated to be safe or effective, and carried with them the risks and dangerous defects
9 described herein.

10 96. Defendants had a duty to disclose the fact that Cordis IVC filters are not safe or effective,
11 not as safe as other filters on the market, defective, and unreasonably dangerous, and that their
12 implantation and use carried with it the serious risk of developing perforation, migration, tilting, and/or
13 fracture, and/or other injuries referenced herein.

14 **FIRST CAUSE OF ACTION**

15 **STRICT PRODUCTS LIABILITY – DESIGN DEFECT**

16 **(By All Plaintiffs, As to All Defendants)**

17 97. Plaintiffs incorporate by reference all prior allegations.

18 98. At all relevant times, Defendants designed, tested, distributed, manufactured, advertised,
19 sold, marketed and otherwise placed into the stream of commerce Cordis IVC filters – the TrapEase
20 filters and the OptEase filters – for use by consumers, such as Plaintiffs, in the United States.

21 99. Defendants' Cordis IVC filters were expected to, and did, reach Defendants' intended
22 consumers, handlers, and persons coming into contact with the product without substantial change in the
23 condition in which they were researched, tested, developed, designed, licensed, manufactured, packaged,
24 labeled, distributed, sold, and marketed by Defendants.

25 100. The devices implanted in Plaintiffs were in an unreasonably dangerous condition at the
26 time they left Defendants' control.

101. At all times relevant, Cordis IVC filters were manufactured, designed and labeled in an unsafe, defective, and inherently dangerous condition which was dangerous for use by the public in general and Plaintiffs in particular.

102. Defendants' Cordis IVC filters, as researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Defendants were defective in design and formulation and unreasonably dangerous in that when they left the hands of Defendants' manufacturers and/or suppliers, the foreseeable risks exceeded the alleged benefits associated with the use of Cordis IVC filters, and the devices were more dangerous than the ordinary customer would expect.

103. Physicians implanted Cordis IVC filters as instructed via the Instructions for Use and in a foreseeable manner as normally intended, recommended, promoted, and marketed by Defendants.

104. Plaintiffs received and utilized Defendants' IVC filters in a foreseeable manner as normally intended, recommended, promoted, and marketed by Defendants.

105. At the time Defendants placed their defective and unreasonably dangerous Cordis IVC filters into the stream of commerce commercially, technologically, and scientifically feasible alternative designs were attainable and available.

106. These alternative designs would have prevented the harm resulting in each Plaintiff's Injuries and Damages without substantially impairing the reasonably anticipated or intended function of Cordis IVC filters.

107. Neither Plaintiffs nor their health care providers could have, by the exercise of reasonable care, discovered the defective condition or perceived the unreasonable dangers with these devices prior to Plaintiffs' implantation with the Cordis IVC filters.

108. As a direct and proximate result of the defective and unreasonably dangerous condition of Cordis IVC filters, Plaintiffs suffered Injuries and Damages.

SECOND CAUSE OF ACTION

STRICT PRODUCTS LIABILITY – INADEQUATE WARNING

(By All Plaintiffs, As to All Defendants)

109. Plaintiffs incorporate by reference all prior allegations.

110. At all relevant times, Defendants engaged in the business of testing, developing, designing, manufacturing, packaging, labeling, marketing and/or promoting, selling and/or distributing Cordis IVC filters – the TrapEase filters and the OptEase filters – and through that conduct have knowingly and intentionally placed Cordis IVC filters into the stream of commerce with full knowledge that they reach consumers such as Plaintiffs who would become implanted with them.

111. Defendants did, in fact, test, develop, design, manufacture, package, label, market and/or promote, sell and/or distribute their Cordis IVC filters to Plaintiffs, their prescribing health care professionals, and the consuming public. Additionally, Defendants expected that the Cordis IVC filters they were selling, distributing, supplying, manufacturing, and/or promoting to reach, and did, in fact, reach, prescribing health care professionals and consumers, including Plaintiffs and their prescribing health care professionals, without any substantial change in the condition of the product from when it was initially distributed by Defendants.

112. The Cordis IVC filters had potential risks and side effects that were known or knowable to Defendants by the use of scientific inquiry and information available before, at, and after the manufacture, distribution, and sale of the Cordis IVC filters.

113. Defendants knew or should have known of the defective condition, characteristics, and risks associated with Cordis IVC filters. These defective conditions included, but were not limited to: (1) Cordis IVC filters posed a significant and higher risk of failure than other similar IVC filters (fracture, migration, tilting, and perforation of the vena cava wall); (2) Cordis IVC filter failures result in serious injuries and death; (3) certain conditions or post-implant procedures, such as morbid obesity or open abdominal procedures, could affect the safety and integrity of Cordis IVC filters; (4) leaving Cordis IVC filters in for a period longer than necessary to prevent immediate risk of pulmonary embolism increases the risk for patients of failures and complications with the filter, such as the filter becoming deeply embedded in the vena cava, making them difficult or impossible for removal.

114. Defendants placed into the stream of commerce for ultimate use by users like Plaintiffs and their health care providers, Cordis IVC filters that were in an unreasonably dangerous and defective condition due to warnings and instructions for use that were inadequate, including, but not limited to Defendants' failure to:

- a. Provide adequate instructions for how long in patients the filter should remain;
- b. Highlight the importance of removing the filter;
- c. Warn of the known risk of great bodily harm or death if the filter was not removed;
- d. Highlight the known risk of great bodily harm or death in the event of occlusion of the vein caused by the filter itself;
- e. Warn of the risk of new DVT if the filter was left in too long; Warn of the risk of new pulmonary embolism, thrombosis, swelling, and pain in the lower extremities if the filter was left in too long; and
- f. Warn of the risk of filter perforation, fracture, or migration.

115. Cordis IVC filters were in a defective and unsafe condition that was unreasonably and substantially dangerous to any user or consumer implanted with Cordis IVC filters, such as Plaintiffs, when used in an intended or reasonably foreseeable way.

116. The warnings and directions Defendants provided with their Cordis IVC filters failed to adequately warn of the potential risks and side effects of Cordis IVC filters.

117. These risks were known or were reasonably scientifically knowable to Defendants, but not known or recognizable to ordinary consumers, such as Plaintiffs, or their treating doctors.

118. Defendants' IVC filters were expected to and did reach Plaintiffs without substantial change in their condition, labeling, or warnings as manufactured, distributed, and sold by Defendants.

119. Additionally, Plaintiffs and their physicians used Cordis IVC filters – the TrapEase filters or the OptEase filters – in the manner in which they were intended to be used, making such use reasonably foreseeable to Defendants.

120. As a direct and proximate result of Defendants' information defects, lack of sufficient instructions or warnings prior to, on, and after the date Plaintiffs used Cordis IVC filters, Plaintiffs suffered Injuries and Damages.

THIRD CAUSE OF ACTION

STRICT PRODUCTS LIABILITY – MANUFACTURING DEFECT

(By All Plaintiffs, As to All Defendants)

121. Plaintiffs incorporate by reference all prior allegations.

1 122. Prior to, on, and after the date the Cordis IVC filters – the TrapEase filter or the OptEase
2 filter – were implanted in Plaintiffs, Defendants designed, distributed, manufactured, sold, and marketed
3 Cordis IVC filters for use in the United States, including California.

4 123. At all relevant times, Defendants designed, distributed, manufactured, marketed, and sold
5 Cordis IVC filters that were unreasonably dangerous, unsafe, and defective in manufacture when they
6 left Defendants' possession.

7 124. Upon information and belief, Cordis IVC filters contain a manufacturing defect, in that
8 they differed from the manufacturer's design or specifications, or from other typical units of the same
9 product line.

10 125. As a direct and proximate cause of Defendants' design, manufacture, marketing, and sale
11 of Cordis IVC filters prior to, on, and after the date Plaintiffs used the Cordis IVC filters, Plaintiffs
12 suffered Injuries and Damages.

13 **FOURTH CAUSE OF ACTION**

14 **NEGLIGENCE**

15 **(By All Plaintiffs, As to All Defendants)**

16 126. Plaintiffs incorporate by reference all prior allegations.

17 127. At the time of the design, distribution, manufacture, advertising, sale, and marketing of
18 Cordis IVC filters – the TrapEase filters and the OptEase filters – and their implantation in Plaintiffs,
19 Defendants were aware that Cordis IVC filters were designed and manufactured in a manner presenting:

- 20 a. An unreasonable risk of fracture of portions of the filters;
21 b. An unreasonable risk of migration of the filters and/or portions of the filters;
22 c. An unreasonable risk of filters tilting and/or perforating the vena cava wall; and
23 d. Insufficient strength or structural integrity to withstand normal placement within the
24 human body.

25 128. At the time of the design, distribution, manufacture, advertising, sale, and marketing of
26 Cordis IVC filters, and their implantation in Plaintiffs, Defendants were also aware that Cordis IVC
27 filters:

- 28 a. Would be used without inspection for defects;

- b. Would be used by patients with special medical conditions such as Plaintiffs;
- c. Had previously caused serious bodily injury to its users with special medical conditions such as Plaintiffs;
- d. Had no established efficacy;
- e. Were less safe and effective than the predicate IVC filters already available on market;
- f. Would be implanted in patients where the risk outweighed any benefit or utility of the filters;
- g. Contained instructions for use and warnings that were inadequate; and
- h. Were prothombotic.

129. At the time of manufacture and sale of the TrapEase and OptEase filters, including the ones implanted in Plaintiffs, Defendants knew or should have known that using the TrapEase and OptEase filters as intended or in a reasonably foreseeable manner created a significant risk of patients suffering severe health side effects including, but not limited to: hemorrhage; cardiac/pericardial tamponade; cardiac arrhythmia and other symptoms similar to myocardial infarction; perforations of tissue, vessels and organs; chronic deep vein thrombosis; pulmonary embolism; thrombosis; compartment syndrome; and other severe personal injuries and diseases, which are permanent in nature, including, but not limited to, death, physical pain and mental anguish, scarring and disfigurement, diminished enjoyment of life, continued medical care and treatment due to chronic injuries/illness proximately caused by the device; and the continued risk of requiring additional medical and surgical procedures including general anesthesia, with attendant risk of life threatening complications.

130. Defendants had a duty to exercise due care and avoid unreasonable risk of harm to others in the design of Cordis IVC filters.

131. Defendants breached these duties by, among other things:

- a. Designing and distributing a product in which it knew or should have known that the likelihood and severity of potential harm from the product exceeded the burden of taking safety measures to reduce or avoid harm;

- b. Designing and distributing a product which it knew or should have known that the likelihood and severity of potential harm from the product exceeded the likelihood of potential harm from other IVC filters available for the same purpose;
- c. Failing to perform reasonable pre- and post-market testing of Cordis IVC filters to determine whether or not the products were safe for their intended use;
- d. Failing to use reasonable and prudent care in the design, research, manufacture, and development of Cordis IVC filters so as to avoid the risk of serious harm associated with the use of Cordis IVC filters;
- e. Advertising, marketing, promoting, and selling Cordis IVC filters for uses other than as approved and indicated in the products' labels;
- f. Failing to use reasonable care to warn or instruct, including pre and post-sale, Plaintiffs, their prescribing physicians, or the general health care community about the TrapEase and OptEase filters' substantially dangerous condition or about facts making the products likely to be dangerous;
- g. Advertising, marketing and recommending the use of the TrapEase and OptEase filters, while concealing and failing to disclose or warn of the dangers known by Defendants to be connected with and inherent in the use of these filter systems;
- h. Representing that the TrapEase and OptEase filters were safe for their intended use when, in fact, Defendants knew and should have known the products were not safe for their intended uses;
- i. Continuing to manufacture and sell the TrapEase and OptEase filters with the knowledge that said products were dangerous and not reasonably safe, and failing to comply with good manufacturing regulations;
- j. Failing to establish an adequate quality assurance program used in the manufacturing of Cordis IVC filters; and

- 1 k. Failing to perform adequate evaluation and testing of Cordis IVC filters when such
2 evaluation and testing would have revealed the propensity of Cordis IVC filters to cause
3 injuries similar to those that Plaintiffs suffered.

4 132. At all relevant times, Defendants had a duty to exercise due care in the manufacturing of
5 Cordis IVC filters.

6 133. Defendants breached this duty by, among other things:

- 7 a. Failing to adopt manufacturing processes that would reduce the foreseeable risk of
8 product failure;
9 b. Failing to use reasonable care in manufacturing the product and by producing a product
10 that differed from their design or specifications or from other typical units from the same
11 production line;
12 c. Failing to use reasonable and prudent care in the design, research, manufacture, and
13 development of Cordis IVC filters and their manufacturing process so as to avoid the risk
14 of serious harm associated with the use of Cordis IVC filters; and
15 d. Failing to establish an adequate quality assurance program used in the manufacturing of
16 their IVC filters.

17 134. At this time, all Cordis IVC filters – the TrapEase filters and the OptEase filters – are
18 misbranded and adulterated by virtue of them failing to be the substantial equivalent of predicate IVC
19 filter devices, making them subject to corrective action, including recall, in the interest of patient safety.

20 135. Prior to, on, and after the date of Plaintiffs' implantation with a Cordis IVC filter, and at
21 all relevant times, Defendants knew or reasonably should have known that Cordis IVC filters and their
22 warnings were defective and dangerous or were likely to be dangerous when used in a reasonably
23 foreseeable manner.

24 136. Prior to, on, and after the date of Plaintiffs' implantation with a Cordis IVC filter and at
25 all relevant times thereafter, Defendants became aware that the defects of Cordis IVC filters resulted in
26 Cordis IVC filters causing injuries similar to those Plaintiffs suffered.

1 137. Reasonable manufacturers and distributors under the same or similar circumstances
2 would have recalled or retrofitted Cordis IVC filters, and would thereby have avoided and prevented
3 harm to many patients, including Plaintiffs.

4 138. In light of this information and Defendants' knowledge described above, Defendants had
5 a duty to recall and/or retrofit Cordis IVC filters.

6 139. Defendants breached its duty to recall and/or retrofit Cordis IVC filters.

7 140. At all relevant times, Defendants knew or should have known that Cordis IVC filters
8 were defective and dangerous or were likely to be dangerous when used in a reasonably foreseeable
9 manner.

10 141. Such danger included the propensity of Cordis IVC filters to cause injuries similar to
11 those suffered by Plaintiffs.

12 142. At all relevant times, Defendants also knew or reasonably should have known that the
13 users of Cordis IVC filters, including Plaintiffs and their health care providers, would not realize or
14 discover on their own the dangers presented by Cordis IVC filters.

15 143. Reasonable manufacturers and reasonable distributors, under the same or similar
16 circumstances as those of Defendants prior to, on, and after the date of Plaintiffs' use of a Cordis IVC
17 filter, would have warned of the dangers presented by Cordis IVC filters, or instructed on the safe use of
18 Cordis IVC filters.

19 144. Prior to, on, and after the date of each Plaintiff's use of the IVC filter, Defendants had a
20 duty to adequately warn of the dangers presented by Cordis IVC filters and/or instruct on the safe use of
21 Cordis IVC filters.

22 145. Defendants breached these duties by failing to provide adequate warnings to Plaintiffs
23 communicating the information and dangers described above and/or providing instruction for safe use of
24 Cordis IVC filters.

25 146. As a direct and proximate result of Defendants' negligent conduct described herein,
26 Plaintiffs suffered Injuries and Damages.

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FIFTH CAUSE OF ACTION

NEGLIGENT MISREPRESENTATION

(By All Plaintiffs, As to All Defendants)

147. Plaintiffs incorporate by reference all prior allegations.

148. Prior to, on, and after the dates during which Plaintiffs were implanted with the Cordis IVC filters – the TrapEase filters and the OptEase filters – Defendants negligently and carelessly represented to Plaintiffs, their treating physicians, and the general public that certain material facts were true. The representations include, *inter alia*, the following:

- a. That the Cordis IVC filters were safe, fit, and effective for use;
- b. That the design of the Cordis IVC filters eliminated the risk that pieces of the device could perforate the vena cava, that the devices could tilt, or that fractures could occur and migrate throughout the body;
- c. That the Cordis IVC filters were safe and more effective than other available IVC filters.
- d. That the OptEase fiber was “easy” to remove; and,

149. Prior to, on, and after the dates during which Plaintiffs and their physicians purchased and used the device, said representations were untrue, and there was no reasonable ground for Defendants to believe said representations were true when Defendants made said representations.

150. Prior to, on, and after the dates during which Plaintiffs and their physicians purchased and used the device, Defendants intended that Plaintiffs, their physicians, and the general public would rely on said representations, which did in fact occur.

151. Defendants owed a duty in all of its undertakings, including the dissemination of information concerning its IVC filters, to exercise reasonable care to ensure that it did not in those undertakings create unreasonable risks of personal injury to others.

152. Defendants disseminated to health care professionals and consumers through published labels, labeling, marketing materials, and otherwise information concerning the properties and effects of Cordis IVC filters with the intention that health care professionals and consumers would rely upon that information in their decisions concerning whether to prescribe and use Defendants’ IVC filters.

153. Defendants, as medical device designers, manufacturers, sellers, promoters and/or distributors, knew or should reasonably have known that health care professionals and consumers, in weighing the potential benefits and potential risks of prescribing or using Cordis IVC filters, would rely upon information disseminated and marketed by Defendants to them regarding the Cordis IVC filters.

154. Defendants failed to exercise reasonable care to ensure that the information they disseminated to health care professionals and consumers concerning the properties and effects of Cordis IVC filters was accurate, complete, and not misleading and, as a result, disseminated information to health care professionals and consumers that was negligently and materially inaccurate, misleading, false, and unreasonably dangerous to consumers such as Plaintiffs.

155. Defendants, as designers, manufacturers, sellers, promoters, and/or distributors, also knew or reasonably should have known that patients receiving Cordis IVC filters as recommended by health care professionals in reliance upon information disseminated by Defendants as the manufacturer/distributor of Defendants' IVC filters would be placed in peril of developing the serious, life-threatening, and life-long injuries including, but not limited to, tilting, migration, perforation, fracture, lack of efficacy, and increased risk of the development of blood clots, if the information disseminated and relied upon was materially inaccurate, misleading, or otherwise false.

156. Defendants had a duty to promptly correct material misstatements Defendants' knew others were relying upon in making healthcare decisions.

157. Defendants failed in each of these duties by misrepresenting to Plaintiffs and the medical community the safety and efficacy of Cordis IVC filters and failing to correct known misstatements and misrepresentations.

158. As a direct and proximate result of Defendants' negligent misrepresentations, Plaintiffs suffered Injuries and Damages.

SIXTH CAUSE OF ACTION

FRAUDULENT MISREPRESENTATION

(By All Plaintiffs, As to All Defendants)

159. Plaintiffs incorporate by reference all prior allegations.

1 160. At all times relevant to this cause, and as detailed above, Defendants intentionally
2 provided Plaintiffs, their physicians, the medical community, and the public at large with false or
3 inaccurate information. Defendants also omitted material information concerning Cordis IVC filters
4 (the TrapEase filters and the OptEase filters), including, but not limited to, misrepresentations regarding
5 the following topics:

- 6 a. The safety of the Cordis IVC filters;
- 7 b. The efficacy of the Cordis IVC filters;
- 8 c. The rate of failure of the Cordis IVC filters;
- 9 d. The pre-market testing of the Cordis IVC filters;
- 10 e. The approved uses of the Cordis IVC filters; and
- 11 f. The ability to retrieve the device at any time over a person's life.

12 161. The information Defendants distributed to the public, the medical community, and
13 Plaintiffs was in the form of reports, press releases, advertising campaigns, labeling materials, print
14 advertisements, commercial media containing material representations, and instructions for use, as well
15 as through their officers, directors, agents, and representatives.

16 162. These materials contained false and misleading material representations, which included:
17 that Cordis IVC filters were safe and fit when used for their intended purpose or in a reasonably
18 foreseeable manner; that they did not pose dangerous health risks in excess of those associated with the
19 use of other similar IVC filters; that any and all side effects were accurately reflected in the warnings;
20 and that they were adequately tested to withstand normal placement within the human body.

21 163. Defendants made the foregoing misrepresentations knowing that they were false or
22 without reasonable basis. These materials included instructions for use and a warning document that
23 was included in the package of the Cordis IVC filters that were implanted in Plaintiffs.

24 164. Defendants' intent and purpose in making these misrepresentations was to deceive and
25 defraud the public and the medical community, including Plaintiffs' health care providers; to gain the
26 confidence of the public and the medical community, including Plaintiffs' health care providers; to
27 falsely assure the public and the medical community of the quality of Cordis IVC filters and their fitness
28 for use; and to induce the public and the medical community, including Plaintiffs' health care providers

1 to request, recommend, prescribe, implant, purchase, and continue to use Cordis IVC filters, all in
2 reliance on Defendants' misrepresentations.

3 165. The foregoing representations and omissions by Defendants were false.

4 166. Defendants' IVC filters are not safe, fit, and effective for human use in their intended and
5 reasonably foreseeable manner.

6 167. Further, the use of Cordis IVC filters is hazardous to the users' health, and Cordis IVC
7 filters have a serious propensity to cause users to suffer serious injuries, including without limitation the
8 injuries Plaintiffs suffered.

9 168. Finally, Defendants' IVC filters have a statistically significant higher rate of failure and
10 injury than do other comparable IVC filters.

11 169. In reliance upon the false and negligent misrepresentations and omissions made by
12 Defendants, Plaintiffs and their health care providers were induced to, and did use Cordis IVC filters,
13 thereby causing Plaintiffs to sustain severe and permanent personal injuries.

14 170. Defendants knew and had reason to know that Plaintiffs, their health care providers, and
15 the general medical community did not have the ability to determine the true facts intentionally and/or
16 negligently concealed and misrepresented by Defendants, and would not have prescribed and implanted
17 Cordis IVC filters if the true facts regarding Defendants' IVC filters had not been concealed and
18 misrepresented by Defendants.

19 171. Defendants had sole access to material facts concerning the defective nature of the
20 products and their propensities to cause serious and dangerous side effects in the form of dangerous
21 injuries and damages to persons who were implanted with Cordis IVC filters.

22 172. At the time Defendants failed to disclose and intentionally misrepresented the foregoing
23 facts, and at the time Plaintiffs used Cordis IVC filters, Plaintiffs and their health care providers were
24 unaware of Defendants' misrepresentations and omissions.

25 173. As a direct and proximate result of Defendants' fraudulent misrepresentations, Plaintiffs
26 suffered Injuries and Damages.

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SEVENTH CAUSE OF ACTION

FRAUDULENT CONCEALMENT

(By All Plaintiffs, As to All Defendants)

174. Plaintiffs incorporate by reference all prior allegations.

175. In marketing and selling Cordis IVC filters (the TrapEase filters and the OptEase filters), Defendants concealed material facts from Plaintiffs and their healthcare providers.

176. These concealed material facts include, but are not limited to:

- a. Cordis IVC filters were unsafe and not fit when used for their intended purpose or in a reasonably foreseeable manner;
- b. Cordis IVC filters posed dangerous health risks in excess of those associated with the use of other similar IVC filters;
- c. That there were additional side effects related to implantation and use of Cordis IVC filters that were not accurately and completely reflected in the warnings associated with Cordis IVC filters; and
- d. That Cordis IVC filters were not adequately tested to withstand normal placement within the human body.

177. Plaintiffs and their health care providers were not aware of these and other facts concealed by Defendants.

178. In concealing these and other facts, Defendants intended to deceive Plaintiffs and their health care providers.

179. Plaintiffs and their health care providers were ignorant of and could not reasonably discover the facts Defendants fraudulently concealed and reasonably and justifiably relied on Defendants' representations concerning the supposed safety and efficacy of Cordis IVC filters.

180. As a direct and proximate result of Defendants' fraudulent concealment of material facts, Plaintiffs suffered Injuries and Damages.

///

EIGHTH CAUSE OF ACTION

BREACH OF EXPRESS WARRANTY

(By All Plaintiffs, As to All Defendants)

181. Plaintiffs incorporate by reference all prior allegations.

182. Plaintiffs, through their medical providers, purchased a Cordis IVC filter from Defendants.

183. At all relevant times, Defendants were merchants of goods of the kind including medical devices and vena cava filters (i.e., Cordis IVC filters).

184. At the time and place of sale, distribution, and supply of Cordis IVC filters to Plaintiffs (and to other consumer and the medical community), Defendants expressly represented and warranted that Cordis IVC filters were safe; that they were well-tolerated, efficacious, fit for their intended purpose, and of marketable quality; that they did not produce any unwarned-of dangerous side effects; and that they was adequately tested.

185. At the time of Plaintiffs' purchase from Defendants, Cordis IVC filters were not in a merchantable condition, and Defendants breached its expressed warranties, in that Cordis IVC filters, among other things:

- a. Were designed in such a manner so as to be prone to an unreasonably high incidence of fracture, perforation of vessels and organs, and/or migration;
- b. Were designed in such a manner so as to result in a unreasonably high incidence of injury to the vessels and organs of its purchaser;
- c. Were manufactured in such a manner that the exterior surface of the filter was inadequately, improperly, and inappropriately constituted, causing the device to weaken and fail;
- d. Were unable to be removed at any time during a person's life;
- e. Were not efficacious in the prevention of pulmonary emboli;
- f. Carried a risk of use outweighed any benefit; and
- g. Were not self-centering.

186. As a direct and proximate result of Defendants' breach of express warranty, Plaintiffs suffered Injuries and Damages.

NINTH CAUSE OF ACTION

BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY

(By All Plaintiffs, As to All Defendants)

187. Plaintiffs incorporate by reference all prior allegations.

188. Defendants impliedly warranted that Cordis IVC filters were of merchantable quality and safe and fit for the use for which Defendants intended them, and Plaintiff in fact used them.

189. Defendants breached its implied warranties by, among other things:

- a. Failing to provide adequate instruction that a manufacturer exercising reasonable care would have provided concerning the likelihood that Cordis IVC filters would cause harm;
- b. Manufacturing and/or selling Cordis IVC filters when those filters did not conform to representations made by Defendants when they left Defendants' control;
- c. Manufacturing and/or selling Cordis IVC filters that were more dangerous than an ordinary consumer would expect when used in an intended or reasonably foreseeable manner;
- d. Manufacturing and/or selling Cordis IVC filters that carried foreseeable risks associated with the Cordis IVC filter design or formulation which exceeded the benefits associated with that design;
- e. Manufacturing and/or selling Cordis IVC filters when they deviated in a material way from the design specifications, formulas, or performance standards or from otherwise identical units manufactured to the same design specifications, formulas, or performance standards; and
- f. Impliedly representing that its filters would be effective in the prevention of pulmonary emboli.

190. At the time Plaintiffs and their physicians purchased and used the devices, the products were not in a merchantable condition in that:

- a. They offered no benefit to patient outcomes,

b. They suffered an unreasonably high failure and injury rates,

c. The surface of the devices were manufactured and designed in such a way that they were distributed with surface damage that substantially increased the risk of fracture, and

d. They were prothrombotic;

191. As a direct and proximate result of Defendants' breach of its implied warranty, Plaintiffs suffered Injuries and Damages.

TENTH CAUSE OF ACTION

LOSS OF CONSORTIUM

(By Plaintiffs FRANK GRAHAM, CYNTHIA MARTINEZ and JOHN SHAFFER, JR., As to All Defendants)

192. Plaintiffs incorporate by reference all prior allegations

193. As a proximate result of the personal injuries suffered by Plaintiffs MARTHA GRAHAM, TED MICHAEL MARTINEZ and JUDY SHAFFER, as described in this Complaint, Plaintiffs FRANK GRAHAM, CYNTHIA MARTINEZ and JOHN SHAFFER, JR. have been deprived of the benefits of their marriage including love, affection, society, and consortium, and other spousal duties and actions. Plaintiffs FRANK GRAHAM, CYNTHIA MARTINEZ and JOHN SHAFFER, JR. were provided with all of the benefits of a marriage between husband and wife, prior to the use of a Cordis IVC filter by their respective Plaintiff spouses and the resulting injuries described herein.

194. Plaintiffs FRANK GRAHAM, CYNTHIA MARTINEZ and JOHN SHAFFER, JR. have also suffered the permanent loss of their respective Plaintiff spouses' daily and regular contribution to the household duties and services, which each provides to the household as husband and wife.

195. Plaintiffs FRANK GRAHAM, CYNTHIA MARTINEZ and JOHN SHAFFER, JR. have also incurred the costs and expenses related to the medical care, treatment, medications, and hospitalization to which their respective Plaintiff spouses were subjected for the physical injuries they suffered as a proximate result of their use of a Cordis IVC filter. Plaintiffs FRANK GRAHAM, CYNTHIA MARTINEZ and JOHN SHAFFER, JR. will continue to incur the future costs and expenses related to the care, treatment, medications, and hospitalization of their respective Plaintiff spouses due to their injuries.

1 196. Plaintiffs FRANK GRAHAM, CYNTHIA MARTINEZ and JOHN SHAFFER, JR. have
 2 suffered loss of consortium, as described herein, including the past, present, and future loss of their
 3 spouses' companionship, services, society, and the ability of their spouses to provide Plaintiffs FRANK
 4 GRAHAM, CYNTHIA MARTINEZ and JOHN SHAFFER, JR. with the benefits of marriage, including
 5 inter alia, loss of contribution to household income and loss of household services, all of which has
 6 resulted in pain, suffering, and mental and emotional distress and worry for Plaintiffs FRANK
 7 GRAHAM, CYNTHIA MARTINEZ and JOHN SHAFFER, JR.

8 **PUNITIVE DAMAGES ALLEGATIONS**

9 **(By All Plaintiffs, As to All Defendants)**

10 197. Plaintiffs incorporate by reference all prior allegations.

11 198. At all times material hereto, Defendants knew or should have known that Cordis IVC
 12 filters were unreasonably dangerous with respect to the risk of tilt, fracture, migration and/or
 13 perforation.

14 199. At all times material hereto, Defendants attempted to misrepresent and did knowingly
 15 misrepresent facts concerning the safety of Cordis IVC filters.

16 200. Defendants' misrepresentations included knowingly withholding material information
 17 from the medical community and the public, including Plaintiffs' physicians, concerning the safety of its
 18 Cordis IVC filters. Data establishes that the failure rates of the TrapEase and OptEase filters are and
 19 were much higher than what Defendants have in the past and currently continue to publish to the
 20 medical community and members of the public.

21 201. Defendants' conduct, alleged throughout this Complaint, was willful, wanton, and
 22 undertaken with a conscious indifference and disregard to the consequences that consumers of their
 23 products faced, including Plaintiffs. Defendants had actual knowledge of the dangers presented by
 24 Cordis IVC filters, yet consciously failed to act reasonably to inform or warn Plaintiffs, Plaintiffs'
 25 physicians or the public at large of these dangers. Defendants consciously failed to establish and
 26 maintain an adequate quality and post-market surveillance system.

27 202. At all times material hereto, Defendants knew and recklessly disregarded the fact that
 28 Cordis IVC filters have an unreasonably high rate of tilt, fracture, migration, and/or perforation.

3 204. Defendants knew of their Cordis IVC filters' lack of warnings regarding the risk of
4 fracture, migration, and/or perforation, but intentionally concealed and/or recklessly failed to disclose
5 that risk and continued to market, distribute, and sell its filters without said warnings so as to maximize
6 sales and profits at the expense of the health and safety of the public, including Plaintiffs, in conscious
7 disregard of the foreseeable harm caused by Cordis IVC filters.

8 205. Defendants' intentional and/or reckless failure to disclose information deprived
9 Plaintiffs' physicians of necessary information to enable them to weigh the true risks of using Cordis
10 IVC filters against its benefits.

206. Defendants' conduct is reprehensible, evidencing an evil hand guided by an evil mind and was undertaken for pecuniary gain in reckless and conscious disregard for the substantial risk of death and physical injury to consumers, including Plaintiffs.

14 207. Such conduct justifies an award of punitive or exemplary damages in an amount
15 sufficient to punish Defendants' conduct and deter like conduct by Defendants and other similarly
16 situated persons and entities in the future.

PRAYER FOR DAMAGES

18 WHEREFORE, Plaintiffs demand judgment against Defendants for:

19 a. General (non-economic) damages, including, without limitation, past and future pain and
20 suffering; past and future emotional distress; past and future loss of enjoyment of life; and other
21 consequential damages as allowed by law;

b. Special (economic) damages, including, without limitation, past and future medical expenses; past and future lost wages and loss of earning capacity; and other consequential damages as allowed by law;

25 c. Punitive damages in an amount sufficient to punish Defendants and deter similar conduct
26 in the future;

27	d. Disgorgement of profits;
----	-----------------------------

28 e. Restitution:

- 1 f. Statutory damages, where authorized;
2 g. Costs of suit;
3 h. Reasonable attorneys' fees, where authorized;
4 i. Prejudgment interest as allowed by law;
5 j. Post-judgment interest at the highest applicable statutory or common law rate from the
6 date of judgment until satisfaction of judgment;
7 k. Such other additional and further relief as Plaintiffs may be entitled to in law or in equity.

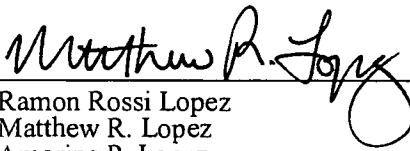
8 **DEMAND FOR JURY TRIAL**

9 Plaintiffs hereby demand a trial by jury on all triable issues.

10
11 Dated: May 13, 2016

Respectfully submitted,

12 LOPEZ McHUGH LLP

13
14 By: 
15 Ramon Rossi Lopez
16 Matthew R. Lopez
17 Amorina P. Lopez

18 -And-

19 Gregory D. Rueb
20 REUB & MOTTA, PLC

21 -And-

22 Howard Nations (for *pro hac vice* consideration)
23 THE NATIONS LAW FIRM

24 Attorneys for Plaintiffs
25
26
27
28

EXHIBIT A Part 2

ENDORSED
FILED
ALAMEDA COUNTY

2016 MAY -6 PM 4:31

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11 Attorneys for Plaintiffs

12 **SUPERIOR COURT OF THE STATE OF CALIFORNIA**

13 **FOR THE COUNTY OF ALAMEDA**

14 GEANICE GRANT, an individual; VIOLET
ELAINE KERN, an individual; RUSSELL
15 HOPKINS, an individual; ANTHONY
BURBINE, an individual; COURTNEY
16 COMER, an individual; WILLIAM GOUGE,
an individual; RHONDA GAIL SCHENK, an
17 individual; JENNIFER ALLISON, an
18 individual; BOBBY FULLER, an individual;
19 ROBERT EDWARD BECKER, an individual;
TERRY ANN FOUNTAIN, an individual;
20 MARGUERITE NORTON, an individual;
JAMES FRANKLIN WILLIAMS, SR.; an
21 individual; BETTY REED, an individual;
22 CLINT HURTADO, an individual; MARK
WEHMEIER, an individual; JENNIFER
23 SCHOCK, an individual; JORDAN DEED, an
individual;

24
25 Plaintiffs,

26 vs.

27 CORDIS CORPORATION; JOHNSON &
JOHNSON; and DOES 1 through 50;

28 Defendants.

Case No.:

RG 16814688

COMPLAINT FOR DAMAGES

1. STRICT PRODUCTS LIABILITY -
DESIGN DEFECT
2. STRICT PRODUCTS LIABILITY -
FAILURE TO WARN
3. STRICT PRODUCTS LIABILITY -
MANUFACTURING DEFECT
4. NEGLIGENCE
5. NEGLIGENT MISREPRESENTATION
6. FRAUDULENT MISREPRESENTATION
7. FRAUDULENT CONCEALMENT
8. BREACH OF EXPRESS WARRANTY
9. BREACH OF IMPLIED WARRANTY OF
MERCHANTABILITY

DEMAND FOR JURY TRIAL

BY FAX

COMES NOW, Plaintiffs, by and through their attorneys, who complain and allege against Defendants CORDIS CORPORATION, JOHNSON & JOHNSON, and DOES 1 through 50, and each of them, on information and belief, as follows:

INTRODUCTION

1. Plaintiffs bring this action for personal injuries damages suffered as a direct and proximate result of being implanted with a defective and unreasonably dangerous Inferior Vena Cava ("IVC") filter medical device manufactured by Defendants.

2. The subject IVC filters include the following devices: TrapEase Vena Cava Filter ("TrapEase filter") and OptEase Vena Cava Filter ("OptEase filter") (for convenience, these devices will be referred to in this complaint under the generic terms "Cordis IVC filters" or "Defendants' IVC filters"). At all times relevant to this action, Defendants developed, designed, licensed, manufactured, sold, distributed and/or marketed the Cordis IVC filters to be implanted in patients throughout the United States, including California.

3. Plaintiffs' claims for damages all relate to Defendants' design, manufacture, sale, testing, marketing, labeling, advertising, promotion, and/or distribution of its IVC filters.

4. The Cordis IVC filters that are the subject of this action all reached Plaintiffs and Plaintiffs' physicians without substantial change in condition from the time they left Defendants' possession.

5. Plaintiffs and Plaintiffs' physicians used the Cordis IVC filters in the manner in which they were intended.

6. Defendants are solely responsible for any alleged design, manufacture or information defect its IVC filters contain.

7. Defendants do not allege that any other person or entity is comparatively at fault for any alleged design, manufacture, or informational defect its IVC filters contain.

PARTIES

8. Plaintiff GEANICE GRANT at all times relevant to this action was a citizen and resident of the State of California. Plaintiff GEANICE GRANT underwent placement of Defendants' OptEase Vena Cava Filter on or August 13, 2014, in California. The filter subsequently malfunctioned and

1 caused injury and damages to Plaintiff GEANICE GRANT, including, but not limited to, severe and
2 constant chest pains and compromised respiratory system. As a direct and proximate result of these
3 malfunctions, Plaintiff GEANICE GRANT suffered serious injuries and damages, and will require
4 extensive medical care and treatment. As a further proximate result, Plaintiff GEANICE GRANT has
5 suffered and will continue to suffer significant medical expenses, and pain and suffering, and other
6 damages.

7 9. Plaintiff VIOLET ELAINE KERN at all times relevant to this action was and is a citizen
8 and resident of the State of Texas. Plaintiff VIOLET ELAINE KERN underwent placement of
9 Defendants' OptEase Vena Cava Filter on or about March 28, 2012. The filter subsequently
10 malfunctioned and caused injury and damages to Plaintiff VIOLET ELAINE KERN, including, but not
11 limited to, filter embedded in wall of the IVC, unsuccessful removal attempt, and filter unable to be
12 retrieved. As a direct and proximate result of these malfunctions, Plaintiff VIOLET ELAINE KERN
13 suffered life-threatening injuries and damages, and required extensive medical care and treatment. As a
14 further proximate result, Plaintiff VIOLET ELAINE KERN has suffered and will continue to suffer
15 significant medical expenses, and pain and suffering, and other damages.

16 10. Plaintiff RUSSELL HOPKINS at all times relevant to this action was and is a citizen and
17 resident of the State of Texas. Plaintiff RUSSELL HOPKINS underwent placement of Defendants'
18 OptEase Vena Cava Filter on or about April 27, 2011. The filter subsequently malfunctioned and
19 caused injury and damages to Plaintiff RUSSELL HOPKINS, including, but not limited to, filter
20 embedded in wall of the IVC and unable to be retrieved. As a direct and proximate result of these
21 malfunctions, Plaintiff RUSSELL HOPKINS suffered life-threatening injuries and damages, and
22 required extensive medical care and treatment. As a further proximate result, Plaintiff RUSSELL
23 HOPKINS has suffered and will continue to suffer significant medical expenses, and pain and suffering,
24 and other damages.

25 11. Plaintiff ANTHONY BURBINE at all times relevant to this action was and is a citizen
26 and resident of the State of Massachusetts. Plaintiff ANTHONY BURBINE underwent placement of
27 Defendants' OptEase Vena Cava Filter on or about April 11, 2012. The filter subsequently
28 malfunctioned and caused injury and damages to Plaintiff ANTHONY BURBINE, including, but not

1 limited to, filter embedded in wall of the IVC and unable to be retrieved. As a direct and proximate
2 result of these malfunctions, Plaintiff ANTHONY BURBINE suffered life-threatening injuries and
3 damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff
4 ANTHONY BURBINE has suffered and will continue to suffer significant medical expenses, and pain
5 and suffering, and other damages.

6 12. Plaintiff COURTNEY COMER at all times relevant to this action was a citizen and
7 resident of the State of Maryland and, subsequently, became a citizen and resident of the State of Texas.
8 Plaintiff COURTNEY COMER underwent placement of Defendants' TrapEase Vena Cava Filter on or
9 about May 5, 2005. The filter subsequently malfunctioned and caused injury and damages to Plaintiff
10 COURTNEY COMER, including, but not limited to, fracture of the filter. As a direct and proximate
11 result of these malfunctions, Plaintiff COURTNEY COMER suffered life-threatening injuries and
12 damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff
13 COURTNEY COMER has suffered and will continue to suffer significant medical expenses, and pain
14 and suffering, and other damages.

15 13. Plaintiff WILLIAM GOUGE at all times relevant to this action was and is a citizen and
16 resident of the State of Maryland. Plaintiff WILLIAM GOUGE underwent placement of Defendants'
17 TrapEase Vena Cava Filter on or about August 13, 2010. The filter subsequently malfunctioned and
18 caused injury and damages to Plaintiff WILLIAM GOUGE, including, but not limited to, migration of
19 the filter to heart requiring emergency open-heart surgery. As a direct and proximate result of these
20 malfunctions, Plaintiff WILLIAM GOUGE suffered life-threatening injuries and damages, and required
21 extensive medical care and treatment. As a further proximate result, Plaintiff WILLIAM GOUGE has
22 suffered and will continue to suffer significant medical expenses, and pain and suffering, and other
23 damages.

24 14. Plaintiff RHONDA GAIL SCHENK at all times relevant to this action was a citizen and
25 resident of the State of Maryland. Plaintiff RHONDA GAIL SCHENK underwent placement of
26 Defendants' OptEase Vena Cava Filter on or about March 1, 2010. The filter subsequently
27 malfunctioned and caused injury and damages to Plaintiff RHONDA GAIL SCHENK, including, but
28 not limited to, filter embedded in wall of the IVC and unable to be retrieved, and recurrent DVTs. As a

1 direct and proximate result of these malfunctions, Plaintiff RHONDA GAIL SCHENK suffered life-
2 threatening injuries and damages, and required extensive medical care and treatment. As a further
3 proximate result, Plaintiff RHONDA GAIL SCHENK has suffered and will continue to suffer
4 significant medical expenses, and pain and suffering, and other damages.

5 15. Plaintiff JENNIFER ALLISON at all times relevant to this action was and is a citizen and
6 resident of the State of Maryland. Plaintiff JENNIFER ALLISON underwent placement of Defendants'
7 OptEase Vena Cava Filter on or about January 14, 2011. The filter subsequently malfunctioned and
8 caused injury and damages to Plaintiff JENNIFER ALLISON, including, but not limited to, tilt,
9 migration, filter embedded in wall of the IVC, unsuccessful removal attempt, and filter unable to be
10 retrieved. As a direct and proximate result of these malfunctions, Plaintiff JENNIFER ALLISON
11 suffered life-threatening injuries and damages, and required extensive medical care and treatment. As a
12 further proximate result, Plaintiff JENNIFER ALLISON has suffered and will continue to suffer
13 significant medical expenses, and pain and suffering, and other damages.

14 16. Plaintiff BOBBY FULLER at all times relevant to this action was and is a citizen and
15 resident of the State of North Carolina. Plaintiff BOBBY FULLER underwent placement of
16 Defendants' OptEase Vena Cava Filter on or about May 18, 2006. The filter subsequently
17 malfunctioned and caused injury and damages to Plaintiff BOBBY FULLER, including, but not limited
18 to, filter embedded in wall of the IVC. As a direct and proximate result of these malfunctions, Plaintiff
19 BOBBY FULLER suffered life-threatening injuries and damages, and required extensive medical care
20 and treatment. As a further proximate result, Plaintiff BOBBY FULLER has suffered and will continue
21 to suffer significant medical expenses, and pain and suffering, and other damages.

22 17. Plaintiff ROBERT EDWARD BECKER at all times relevant to this action was and is a
23 citizen and resident of the State of Wisconsin. Plaintiff ROBERT EDWARD BECKER underwent
24 placement of Defendants' TrapEase Vena Cava Filter on or about June 21, 2010. The filter
25 subsequently malfunctioned and caused injury and damages to Plaintiff ROBERT EDWARD BECKER,
26 including, but not limited to, hematoma and recurrent pulmonary embolisms. As a direct and proximate
27 result of these malfunctions, Plaintiff ROBERT EDWARD BECKER suffered life-threatening injuries
28 and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff

1 ROBERT EDWARD BECKER has suffered and will continue to suffer significant medical expenses,
2 and pain and suffering, and other damages.

3 18. Plaintiff TERRY ANN FOUNTAIN at all times relevant to this action was and is a
4 citizen and resident of the State of Georgia. Plaintiff TERRY ANN FOUNTAIN underwent placement
5 of Defendants' TrapEase Vena Cava Filter on or about June 2, 2007. The filter subsequently
6 malfunctioned and caused injury and damages to Plaintiff TERRY ANN FOUNTAIN, including, but not
7 limited to, blood clots, clotting and occlusion of IVC filter. As a direct and proximate result of these
8 malfunctions, Plaintiff TERRY ANN FOUNTAIN suffered life-threatening injuries and damages, and
9 required extensive medical care and treatment. As a further proximate result, Plaintiff TERRY ANN
10 FOUNTAIN has suffered and will continue to suffer significant medical expenses, and pain and
11 suffering, and other damages.

12 19. Plaintiff MARGUERITE NORTON at all times relevant to this action was and is a
13 citizen and resident of the State of Pennsylvania. Plaintiff MARGUERITE NORTON underwent
14 placement of Defendants' OptEase Vena Cava Filter on or about April 15, 2010. The filter subsequently
15 malfunctioned and caused injury and damages to Plaintiff MARGUERITE NORTON, including, but not
16 limited to, fracture of the filter. As a direct and proximate result of these malfunctions, Plaintiff
17 MARGUERITE NORTON suffered life-threatening injuries and damages, and required extensive
18 medical care and treatment. As a further proximate result, Plaintiff MARGUERITE NORTON has
19 suffered and will continue to suffer significant medical expenses, and pain and suffering, and other
20 damages.

21 20. Plaintiff JAMES FRANKLIN WILLIAMS, SR. at all times relevant to this action was
22 and is a citizen and resident of the State of Maryland. Plaintiff JAMES FRANKLIN WILLIAMS, SR.
23 underwent placement of Defendants' TrapEase Vena Cava Filter on or about June 27, 2013. The filter
24 subsequently malfunctioned and caused injury and damages to Plaintiff JAMES FRANKLIN
25 WILLIAMS, SR., including, but not limited to, DVT. As a direct and proximate result of these
26 malfunctions, Plaintiff JAMES FRANKLIN WILLIAMS, SR. suffered life-threatening injuries and
27 damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff
28

1 JAMES FRANKLIN WILLIAMS, SR. has suffered and will continue to suffer significant medical
2 expenses, and pain and suffering, and other damages.

3 21. Plaintiff BETTY REED at all times relevant to this action was and is a citizen and
4 resident of the State of West Virginia. Plaintiff BETTY REED underwent placement of Defendants'
5 TrapEase Vena Cava Filter on or about October 14, 2014. The filter subsequently malfunctioned and
6 caused injury and damages to Plaintiff BETTY REED, including, but not limited to, migration of the
7 filter. As a direct and proximate result of these malfunctions, Plaintiff BETTY REED suffered life-
8 threatening injuries and damages, and required extensive medical care and treatment. As a further
9 proximate result, Plaintiff BETTY REED has suffered and will continue to suffer significant medical
10 expenses, and pain and suffering, and other damages.

11 22. Plaintiff CLINT HURTADO at all times relevant to this action was and is a citizen and
12 resident of the State of Wyoming. Plaintiff CLINT HURTADO underwent placement of Defendants'
13 OptEase Vena Cava Filter on or about August 19, 2010. The filter subsequently malfunctioned and
14 caused injury and damages to Plaintiff CLINT HURTADO, including, but not limited to, fracture of the
15 filter. As a direct and proximate result of these malfunctions, Plaintiff CLINT HURTADO suffered life-
16 threatening injuries and damages, and required extensive medical care and treatment. As a further
17 proximate result, Plaintiff CLINT HURTADO has suffered and will continue to suffer significant
18 medical expenses, and pain and suffering, and other damages.

19 23. Plaintiff MARK WEHMEIER at all times relevant to this action was and is a citizen and
20 resident of the State of Wisconsin. Plaintiff MARK WEHMEIER underwent placement of Defendants'
21 TrapEase Vena Cava Filter on or about October 20, 2012. The filter subsequently malfunctioned and
22 caused injury and damages to Plaintiff MARK WEHMEIER, including, but not limited to, filter
23 embedded in wall of the IVC, unsuccessful removal attempt, and filter unable to be retrieved. As a
24 direct and proximate result of these malfunctions, Plaintiff MARK WEHMEIER suffered life-
25 threatening injuries and damages, and required extensive medical care and treatment. As a further
26 proximate result, Plaintiff MARK WEHMEIER has suffered and will continue to suffer significant
27 medical expenses, and pain and suffering, and other damages.
28

1 24. Plaintiff JENNIFER SCHOCK at all times relevant to this action was and is a citizen and
2 resident of the State of Wisconsin. Plaintiff JENNIFER SCHOCK underwent placement of Defendants'
3 TrapEase Vena Cava Filter on or about November 16, 2005. The filter subsequently malfunctioned and
4 caused injury and damages to Plaintiff JENNIFER SCHOCK, including, but not limited to, fracture of
5 the filter and perforation of filter struts into vena cava. As a direct and proximate result of these
6 malfunctions, Plaintiff JENNIFER SCHOCK suffered life-threatening injuries and damages, and
7 required extensive medical care and treatment. As a further proximate result, Plaintiff JENNIFER
8 SCHOCK has suffered and will continue to suffer significant medical expenses, and pain and suffering,
9 and other damages.

10 25. Plaintiff JORDAN DEED at all times relevant to this action was and is a citizen and
11 resident of the State of Wisconsin. Plaintiff JORDAN DEED underwent placement of Defendants'
12 OptEase Vena Cava Filter on or about November 28, 2010. The filter subsequently malfunctioned and
13 caused injury and damages to Plaintiff JORDAN DEED, including, but not limited to, severe pain and
14 swelling of lower extremity, blood clots, clotting and occlusion of IVC filter, requiring emergency
15 surgery to remove the filter. As a direct and proximate result of these malfunctions, Plaintiff JORDAN
16 DEED suffered life-threatening injuries and damages, and required extensive medical care and
17 treatment. As a further proximate result, Plaintiff JORDAN DEED has suffered and will continue to
18 suffer significant medical expenses, and pain and suffering, and other damages.

19 26. Defendant CORDIS CORPORATION ("Cordis"), including its department, division, and
20 subsidiary, Cordis Endovascular, is a corporation or business entity organized and existing under the
21 laws of the State of Florida with its headquarters located at 6500 Paseo Padre Pkwy., Fremont,
22 California, 94555. Cordis may be served with process by serving its registered agent, CT Corporation
23 System, at 818 West Seventh Street, Suite 930, Los Angeles, California, 90017.

24 27. Defendant CORDIS CORPORATION was a wholly-owned subsidiary of Defendant
25 JOHNSON & JOHNSON ("J&J") and part of the J&J family of companies until in or around October
26 2015. J&J is a corporation or business entity organized and existing under the laws of the State of New
27 Jersey with its headquarters located in New Jersey.

1 28. The true names or capacities, whether individual, corporate, or otherwise, of Defendants
2 Does 1-50, are unknown to Plaintiffs who therefore sue said Defendants by such fictitious names.
3 Plaintiffs believe and allege that each of the Defendants designated herein by fictitious names is in some
4 manner legally responsible for the events and happenings herein referred to and proximately caused
5 foreseeable damages to Plaintiffs as alleged herein.

6 29. All Defendants are authorized to do business in California and derive substantial income
7 from doing business in this state.

8 30. As used herein, "Defendants" includes all named Defendants as well as Does 1-50.

9 31. Upon information and belief, Defendants did act together to design, sell, advertise,
10 manufacture and /or distribute Cordis IVC Filters, with full knowledge of their dangerous and defective
11 nature.

12 **JURISDICTION AND VENUE**

13 32. This Court has jurisdiction under the California Constitution, Article VI, Section 10 and
14 *Code of Civil Procedure* Section 410.10. Plaintiffs' damages exceed the jurisdictional minimum of this
15 Court.

16 33. Venue is proper in this Court pursuant to *Code of Civil Procedure* Sections 395 and 395.5
17 because the principal place of business for Defendant CORDIS CORPORATION is situated in Alameda
18 County. Further, a substantial amount of Defendants' conduct, as alleged herein by Plaintiffs, took
19 place in Alameda County.

20 **BACKGROUND**

21 **INFERIOR VENA CAVA FILTERS GENERALLY**

22 34. IVC filters were first made commercially available to the medical community in the
23 1960s. Over the years, medical device manufacturers have introduced several different designs of IVC
24 filters.

25 35. An IVC filter is a device that is designed to filter or "catch" blood clots that travel from
26 the lower portions of the body to the heart and lungs. IVC filters were originally designed to be
27 permanently implanted in the IVC.
28

1 36. The IVC is a vein that returns blood to the heart from the lower portions of the body. In
2 certain people, for various reasons, blood clots travel from the vessels in the legs and pelvis, through the
3 vena cava and into the lungs. Oftentimes, these blood clots develop in the deep leg veins, a condition
4 called “deep-vein thrombosis” or “DVT.” Once blood clots reach the lungs, they are considered
5 “pulmonary emboli” or “PE.” Pulmonary emboli present risks to human health.

6 37. People at risk for DVT/PE can undergo medical treatment to manage the risk. For
7 example, a doctor may prescribe anticoagulant therapies such as medications like Heparin, Warfarin, or
8 Lovenox to regulate the clotting factor of the blood. In some people who are at high risk for DVT/PE
9 and who cannot manage their conditions with medications, physicians may recommend surgically
10 implanting an IVC filter to prevent thromboembolic events.

11 38. As stated above, IVC filters have been on the market for decades. All IVC filters are
12 only cleared for use by the Food & Drug Administration (“FDA”) for prevention of recurrent pulmonary
13 embolism in patients at risk for pulmonary embolism and where anticoagulation therapy has failed or is
14 contraindicated.

15 39. In order to increase sales of these devices, Defendants sought to expand the market for
16 prophylactic use among nontraditional patient populations that were temporarily at risk of developing
17 blood clots.

18 40. Defendants Cordis and J&J engaged in marketing campaigns directed toward the
19 bariatric, trauma, orthopedic and cancer patient population. Expansion to these new patient groups
20 would substantially increase sales and the first manufacturer to market would capture market share.

21 41. Other manufacturers also saw this opportunity, which triggered a race to market a device
22 that provided physicians the option to retrieve the filter after the clot risk subsided.

23 42. From 2000 through 2003, manufacturers of IVC filters, including Defendants, raced
24 against each other to bring the first IVC filter to the market with the added indication of optional
25 retrieval. In 2003, the FDA cleared three different IVC filters for a retrieval indication, one of which
26 was the OptEase filter by Defendants Cordis and J&J.

27 43. There is no evidence that Defendants’ IVC filters were effective in preventing pulmonary
28 embolism (the very condition the products were indicated to prevent).

1 44. Years after the implantation of retrievable filters into the bodies of patients, scientists
2 began to study the effectiveness of the retrievable filters. As recently as October 2015, an expansive
3 article published in the *Annals of Surgery* concerning trauma patients inserted with IVC filters
4 concluded that IVC filters were not effective in preventing pulmonary emboli, and instead actually
5 caused thrombi to occur.

6 45. Comparing the results of over 30,000 trauma patients who had not received IVC filters
7 with those who had received them, the *Annals of Surgery* study published its alarming results:

- 8 a. Almost twice the percentage of patients with IVC filters in the study died compared to
9 those that had not received them.
- 10 b. Over five times the relative number of patients with IVC filters developed DVTs.
- 11 c. Over four times the relative percentage of patients with filters developed thromboemboli.
- 12 d. Over twice the percentage of patients developed a pulmonary embolus – the very
13 condition Defendants Cordis and J&J told the FDA, physicians, and the public that its
14 IVC filters were designed to prevent.

15 46. This *Annals of Surgery* study – and many others referenced by it – have shown there is no
16 evidence establishing that IVC filters are effective and that these devices suffer common failure modes,
17 including, but not limited to, migration, perforation, thrombosis, tilt and fracture, all of which can cause
18 serious injury or death. Thus, the current state of scientific and medical evidence indicates that IVC
19 filters are not only ineffective but that they are themselves a health hazard.

20 **THE TRAPEASE AND OPTASE IVC FILTERS**

21 47. On or about January 10, 2001, Defendants bypassed the more onerous FDA's approval
22 process for new devices and obtained "clearance" under Section 510(k) of the Medical Device
23 Amendments to the Food, Drug, and Cosmetic Act to market the TrapEase Vena Cava Filter as a
24 *permanent* filter by claiming it was substantially similar in respect to safety, efficacy, design, and
25 materials as the IVC filters already available on the market.

26 48. Section 510(k) permits the marketing of medical devices if the device is substantially
27 equivalent to other legally marketed predicate devices without formal review for the safety or efficacy of
28 the said device. The FDA explained the difference between the 510(k) process and the more rigorous

1 “premarket approval” (PMA) process in its amicus brief filed with the Third Circuit in *Horn v. Thoratec*
 2 *Corp.*, which the court quoted from:

3 A manufacturer can obtain an FDA finding of ‘substantial equivalence’ by submitting a
 4 premarket notification to the agency in accordance with section 510(k) of the [Food Drug
 5 and Cosmetic Act]. 21 U.S.C. § 360(k). A device found to be ‘substantially equivalent’
 6 to a predicate device is said to be ‘cleared’ by FDA (as opposed to ‘approved’ by the
 7 agency under a PMA. A pre-market notification submitted under 510(k) is thus entirely
 8 different from a PMA which must include data sufficient to demonstrate that the IVC
 9 Filters is safe and effective.

10 376 F.3d 163, 167 (3d Cir. 2004) (emphasis in original).

11 49. In *Medtronic, Inc. v. Lohr*, the U.S. Supreme Court similarly described the 510(k)
 12 process, observing:

13 If the FDA concludes on the basis of the [manufacturer’s] § 510(k) notification that the
 14 device is “substantially equivalent” to a pre-existing device, it can be marketed without
 15 further regulatory analysis. . . . The § 510(k) notification process is by no means
 16 comparable to the PMA process; in contrast to the 1,200 hours necessary to complete a
 17 PMA review, the § 510(k) review is completed in average of 20 hours. . . . As one
 18 commentator noted: “The attraction of substantial equivalence to manufacturers is clear.
 19 Section 510(k) notification requires little information, rarely elicits a negative response
 20 from the FDA, and gets processed quickly.”

21 518 U.S. 470, 478-79 (1996) (quoting Adler, *The 1976 Medical Device Amendments: A Step in the*
 22 *Right Direction Needs Another Step in the Right Direction*, 43 Food Drug Cosm. L.J. 511, 516 (1988)).

23 50. Pursuant to *Wyeth v. Levine*, 555 U.S. 555 (2009), once a product is cleared “the
 24 manufacturer remains under an obligation to investigate and report any adverse events associated with
 25 the drug . . . and must periodically submit any new information that may affect the FDA’s previous
 26 conclusions about the safety, effectiveness, or labeling” This obligation extends to post-market
 27 monitoring of adverse events/complaints.

28 51. In July 2000, through this 510(k) process, Defendants obtained clearance from the FDA
 to market the TrapEase filter as a permanent filter.

52. The TrapEase filter is made with Nitinol – a nickel titanium alloy. The filter utilizes a
 design known as a double basket or double filter for the capture of blood clots and/or emboli. This
 design consists of a basket made of six diamond-shaped struts proximally and six diamond-shaped struts
 distally, forming proximal and distal baskets, which are connected by six straight struts to create a single

1 symmetric filter. The filter has proximal and distal anchoring barbs located on each connecting strut for
2 fixation of the filter to the vena cava wall to prevent movement after placement.

3 53. Nitinol alloy is used in a number of different medical device applications. It is beneficial
4 for these applications and is employed as material in stents and other medical device applications. It is
5 also used in the manufacture of the TrapEase filter, and other brands of IVC filters.

6 54. Specific manufacturing processes need to be utilized when using Nitinol as a component
7 for medical devices, including IVC filters. Primarily, the Nitinol material should be electro-polished
8 prior to assembly of the finished medical device.

9 55. Electro-polishing is a manner of removing surface blemishes, "draw marking" and
10 circumferential grinding markings on the exterior of the surface of the Nitinol material. The existence
11 of these surface blemishes, "draw markings" and "circumferential grind-markings" causes/results in the
12 weakening of the structural integrity of the end product, whether it is an IVC filter or other medical
13 device.

14 56. In or around September 2002, Defendants sought clearance through the 510(k) process to
15 market the OptEase Vena Cava Filter for the same indicated uses as the TrapEase filter. Defendants
16 represented that the OptEase filter contained the same fundamental technology and was substantially
17 equivalent in terms of safety and efficacy as the predicate devices already available on the market.

18 57. Unlike the TrapEase filter, which has proximal and distal anchoring barbs located on
19 each connecting strut for fixation of the filter to the vena cava wall, the OptEase filter has anchoring
20 barbs for fixation of the filter only on the superior end of each of the six straight struts and has a hook at
21 the inferior end of the basket to allow retrieval with a snare.

22 58. Both designs for the TrapEase filter and OptEase filter suffer flaws making them
23 defective and unreasonably dangerous. Defendants' IVC filters are designed in such a way that when
24 exposed to expected and reasonably foreseeable *in-vivo* conditions, the devices will fracture, migrate,
25 tilt, perforate internal organs and vasculature, and lead to the formation of thromboembolism and
26 pulmonary embolism.

1 59. For years, it has been known by manufacturers of the Nitinol medical devices and the
2 medical device industry that electro-polishing Nitinol results in increased structural integrity of the
3 device and resistance to fatigue and fatigue failures.

4 60. The exterior surfaces of the Cordis IVC Filters were not electro-polished prior to
5 completion of the manufacturing process. This is a manufacturing defect that exists in the TrapEase and
6 OptEase filters which causes these filters to be structurally weak and susceptible to a significant risk of
7 failure/fracture.

8 61. Additionally, Defendants represented that the self-centering design of the TrapEase filter
9 allows accurate, predictable placement, and that its site struts help reduce the risk of tilting and
10 migration, while in reality the filters regularly tilt, migrate, and become embedded in the vena cava wall.

11 62. The anchoring mechanism of Defendants' filters is also insufficient to prevent tilting and
12 migration post-placement.

13 63. The configuration of the Cordis IVC Filters actually leads to the formation of blood clots
14 and pulmonary embolism – the exact condition the devices are meant to protect against.

15 64. That Defendants allowed these devices to proceed to market indicates that they failed to
16 establish and maintain an appropriate Quality System concerning design and risk analysis.

17 65. A manufacturer must, at a minimum, undertake research and testing to understand the
18 anatomy of where a medical device will be implanted and understand the forces the device may be
19 exposed to once implanted in a human body. This design input must then be used to determine the
20 minimum safety requirements or attributes the device must have to meet user needs. In the case of an
21 IVC filter, user needs include a device that will capture blood clots of sufficient size to cause harmful
22 consequences and that will not fracture, migrate, tilt, perforate the vena cava, or malfunction in some
23 other way, or be prothombotic. Defendants failed to undertake any such efforts in these regards.

24 66. Prior to bringing a product to market, a manufacturer must also conduct sufficient testing
25 under real world or simulated use conditions to ensure that the device will meet user needs even when
26 exposed to reasonably foreseeable worst-case conditions. Defendants failed to adequately establish and
27 maintain such policies, procedures or protocols with respect to their IVC filters.

28

1 67. Once placed on the market, Defendants' post-market surveillance system should have
2 revealed to Defendants that the TrapEase and OptEase filters were unreasonably dangerous and
3 substantially more prone to fail or malfunction, and cause great bodily harm to patients compared to
4 other available treatment options.

5 68. MAUDE is a database maintained by the FDA to house medical device reports submitted
6 by mandatory reporters (such as manufacturers and device user facilities) and voluntary reporters (such
7 as health care providers and patients).

8 69. Shortly after going on market, Defendants began receiving large numbers of adverse
9 event reports ("AERs") from health care providers reporting that the Cordis IVC filters were fracturing
10 post-implantation and that fractured pieces and/or the entire device was migrating to other areas of the
11 body, including the heart and lungs.

12 70. Defendants also received large numbers of AERs reporting that the TrapEase filters and
13 OptEase filters were found to have excessively tilted, perforated the IVC, or caused thrombosis or
14 stenosis of the vena cava post-implantation.

15 71. These failures were often associated with severe patient injuries such as:

- 16 a. Death;
- 17 b. Hemorrhage;
- 18 c. Cardiac/pericardial tamponade (pressure caused by a collection of blood in the area
19 around the heart);
- 20 d. Cardiac arrhythmia and other symptoms similar to myocardial infarction;
- 21 e. Severe and persistent pain; and
- 22 f. Perforations of tissue, vessels and organs.

23 72. These failures and resulting injuries are attributable, in part, to the fact that the Cordis
24 IVC Filter design was unable to withstand the normal anatomical and physiological loading cycles
25 exerted *in vivo*.

26 73. Defendants failed to identify or acknowledge these device failures or determine their
27 causes.
28

74. Defendants failed to take timely and adequate remedial measures to correct known design and manufacturing defects with the Cordis IVC Filters.

75. Defendants also misrepresented and concealed the risks and benefits of the Cordis IVC filters in its labeling and marketing distributed to the FDA, physicians and the public. For instance, Defendants represented that their filters were safe and effective – more safe and effective than other available IVC filters. As discussed above, however, there is no reliable evidence to support these claims and, to the contrary, the Cordis IVC filters have been associated with a high rate of failure.

**THE MEDICAL LITERATURE ESTABLISHES THAT CORDIS IVC FILTERS HAVE A
HIGH RATE OF FAILURE AND COMPLICATIONS**

76. There are reports in the peer-reviewed published medical literature of TrapEase filters migrating to the heart:

- a. It was reported in 2002 that a TrapEase filter migrated to a patient's right ventricle. Porcellini, *et al.*, "Intracardiac migration of nitinol TrapEase vena cava filter and paradoxical embolism," *Euro. J. of Cardio-Thoracic Surg.* 2002, 22:460-61.
- b. It was reported in 2008 that a TrapEase filter migrated to a patient's tricuspid valve, causing her death. Haddadian, *et al.*, "Sudden Cardiac Death Caused by Migration of a TrapEase Inferior Vena Cava Filter: A Case Report and Review of the Literature," *Clin. Cardiol.* 2008, 31:84-87.
- c. It was reported in 2011 that a TrapEase filter migrated to a patient's tricuspid valve, leading to his death. Dreyer, *et al.*, "Inferior Vena Cava Filter Migration to the Right Ventricle: A Case Report and Review of Filter Migration and Misdeployment," *J. Med. Cases* 2011; 2(5):201-05.

77. Additionally, as early as March 2005, Defendants knew or should have known that any short-term beneficial effect of the insertion of a Cordis IVC filter was outweighed by a significant increase in the risk of DVT, that the filter would not be able to be removed, filter fracture and/or migration, and, ultimately, by the fact that the filters had no beneficial effect on overall mortality.

78. By March 2005, there had been only one long-term randomized study of filter placement in the prevention of pulmonary embolism. *See* PREPIC Study Group, "Eight-year follow-up of patients

1 with permanent vena cava filters in the prevention of pulmonary embolism: the PREPIC (Prevention du
2 Risque d'Embolie Pulmonaire par Interruption Cave) randomized study," *Circulation* 2005, 112(3):416-
3 22. In 400 patients with proximal DVT, the insertion of a vena cava filter in combination with standard
4 anticoagulation was associated with a reduction in the occurrence of pulmonary embolism compared
5 with anticoagulation alone. This beneficial effect was offset, however, by a significant increase in DVT,
6 and the filters had no impact on mortality. The study followed the patients for up to eight years to assess
7 the very long-term effect of IVC filters on the recurrence of venous thromboembolism, the development
8 of post-thrombotic syndrome, and mortality.

9 79. Two years later, in or around 2007, a group of engineers and members of the surgery
10 department of the University of Toronto conducted a study in order to determine whether IVC filter
11 design might be linked to an increased risk of thrombosis and recurrent pulmonary embolism. *See*
12 Harlal, *et al.*, "Vena cava filter performance based on hemodynamics and reported thrombosis and
13 pulmonary embolism patterns," *J Vasc Interv Radiol.* 2007, 18(1): 103-15. The authors wrote that the
14 design of the TrapEase filter "promotes the lodging of a clot along the vessel wall, resulting in the
15 formation of stagnation zones along the vessel wall, which can contribute to further clot development."
16 The study further explained that the TrapEase filters' effect on blood flow increased the likelihood of
17 thrombosis. The study found a significantly higher rate of PE and thrombosis from use of the TrapEase
18 filter relative to a competitor's filter.

19 80. Less than three years later, on or about August 9, 2010, the FDA issued a Safety Alert
20 entitled: "Removing Retrievable Inferior Vena Cava Filters: Initial Communication." The purpose of
21 the communication was to warn against leaving IVC filters in for extended periods of time because they
22 have a tendency to cause life-threatening complications. The FDA noted that the use of IVC filters had
23 increased dramatically in the last several years and observed that the number of adverse event reports
24 had also increased substantially since 2005. The FDA expressed concern that retrievable IVC filters
25 were frequently left in patients beyond the time when the risk for PE had passed, thus unnecessarily
26 exposing patients to the risks of DVT as well as to filter fracture, migration, embolization, and
27 perforation.
28

1 81. Dr. William T. Kuo, an expert in the removal of IVC filters and vascular surgery, has
2 established an IVC Filter Clinic at Stanford University where his team specializes in the removal of IVC
3 filters that other vascular surgeons refuse to remove for fear of rupturing the vena cava or other internal
4 organs and causing great bodily harm or death to the patient. In 2011, Dr. Kuo wrote in *the Journal of*
5 *Vascular Interventional Radiology* that the Cordis filters were the most difficult to retrieve from
6 patients, at least partially due to the design of the filters, which create greater contact with the vein walls
7 than competitors' filters. See Kuo, *et al.*, "Photothermal Ablation with the Excimer Laser Sheath
8 Technique for Embedded Inferior Vena Cava Filter Removal: Initial Results from a Perspective Study,"
9 *J. Vasc. Interv. Radiol.* 2011; 22:813-23.

10 82. In the same article, Dr. Kuo observed that "[p]atients with embedded filters seem to be at
11 increased risk of IVC occlusion, chronic deep venous thrombosis, post-thrombotic syndrome, filter
12 fracture with component migration, and caval perforation with pain and organ injury. Additionally,
13 many patients with permanent filters are now routinely managed with lifelong anticoagulation to reduce
14 thrombotic risks related to prolonged filter implantation, subjecting them not only to the inconvenience
15 of anticoagulation therapy but also to its inherent bleeding risks." These concerns were heightened by
16 the difficulty of removing a Cordis filter.

17 83. In 2010, Dr. Gred Usoh also found in a study published in the *Journal of Vascular*
18 *Surgery* that the TrapEase filter was associated with an increased likelihood of thrombosis. See Usoh, *et*
19 *al.*, "Prospective Randomized Study Comparing the Clinical Outcomes Between Inferior Vena Cava
20 Greenfield and TrapEase Filters," *J. Vasc. Surg.* 2010, 52(2):394-99. Thus, the TrapEase filter
21 increased the risk of harm without any proven benefit.

22 84. In a letter to the *Archives of Internal Medicine* published November 28, 2011, a group led
23 by Dr. Masaki Sano of the Hamamatsu University School of Medicine in Japan described a study in
24 which the Cordis TrapEase filter had fractured in 10 out of 20 patients (50%) at an average follow-up of
25 50 months. See Sano, *et al.*, "Frequent Fracture of TrapEase Inferior Vena Cave Filters: A Long-term
26 Follow Up Assessment," *Arch. Intern Med* 2012; 172(2):189-91. Furthermore, nine out of 14 filters
27 (64%) that had been inserted for longer than 14 months showed fractures. Among the 10 fractured
28 filters, eight had a single fractured strut, while two had multiple fractured struts. Additionally, thrombus

1 was detected inside the filter in two cases. Based on these results, Dr. Sano criticized previous studies
2 that had found the TrapEase filter to be safe as being conducted over too short a period of time and
3 concluded that “patients undergoing permanent TrapEase IVCF insertion are at extremely high risk of
4 strut fractures as early as two to three years after IVCF placement.”

5 85. On May 6, 2014, the FDA issued another Safety Alert involving IVC filters. In this
6 safety communication, the FDA wrote that it had received adverse event reports concerning “device
7 migration, filter fracture, embolization (movement of the entire filter or fracture fragments to the heart
8 or lungs), perforation of the IVC, and difficulty removing the device.” The FDA reiterated that the risks
9 presented by the filters should be avoided by removing the filters “once the risk of pulmonary embolism
10 has subsided” and expressed concern that the filters were not being timely removed in this manner.
11 Based on the medical literature, the FDA recommended removal between 29 and 54 days after
12 implantation.

13 86. On April 5, 2016, at the annual Society of Interventional Radiology in Vancouver,
14 Canada, Dr. Steven Wang, an interventional radiologist from Palo Alto, California who is affiliated with
15 Kaiser Permanente, presented the results of a retrospective study involving 96 patients in which he
16 sought to understand the prevalence of long-term (greater than 46 months) complications of both
17 permanent and retrievable IVC filters. The study looked at all inferior vena cava filters implanted in
18 patients from January 2007 through December 2009 at multiple health care facilities across the United
19 States. Dr. Wang then identified all patients who had imaging of the filter taken at four years or more
20 after implantation. Of those patients (96), he then evaluated the imaging to determine whether the IVC
21 filter had malfunctioned. After reviewing the data, the authors concluded that device complications at
22 four or more years after implantation “are relatively common.” They also found that the Cordis OptEase
23 and TrapEase IVC filters suffered fracture rates of 37.5% and 23.1%, respectively.

24 **ESTOPPEL FROM PLEADING STATUTES OF LIMITATIONS OR REPOSE**

25 87. Plaintiffs incorporate by reference all prior allegations.

26 88. Plaintiffs are within the applicable statute of limitations for their claims because Plaintiffs
27 (and their healthcare professionals) did not discover, and could not reasonably discover, the defects and
28 unreasonably dangerous condition of their Cordis IVC filters.

89. Plaintiffs' ignorance of the defective and unreasonably dangerous nature of the Cordis IVC filters, and the causal connection between these defects and each Plaintiff's injuries and damages, is due in large part to Defendants' acts and omissions in fraudulently concealing information from the public and misrepresenting and/or downplaying the serious threat to public safety its products present.

90. In addition, Defendants are estopped from relying on any statutes of limitation or repose by virtue of its unclean hands, acts of fraudulent concealment, affirmative misrepresentations and omissions.

91. Such conduct includes intentional concealment from Plaintiffs, their health care professionals, and the general consuming public of material information that Cordis IVC filters had not been demonstrated to be safe or effective, and carried with them the risks and dangerous defects described above.

92. Defendants had a duty to disclose the fact that Cordis IVC filters are not safe or effective, not as safe as other filters on the market, defective, and unreasonably dangerous, and that their implantation and use carried with it the serious risk of developing perforation, migration, tilting, and/or fracture.

FIRST CAUSE OF ACTION

STRICT PRODUCTS LIABILITY – DESIGN DEFECT

(By All Plaintiffs, As to All Defendants)

93. Plaintiffs incorporate by reference all prior allegations.

94. At all relevant times, Defendants designed, tested, distributed, manufactured, advertised, sold, marketed and otherwise placed into the stream of commerce Cordis IVC filters – the TrapEase filters and the OptEase filters – for use by consumers, such as Plaintiffs, in the United States.

95. Defendants' Cordis IVC filters were expected to, and did, reach Defendants' intended consumers, handlers, and persons coming into contact with the product without substantial change in the condition in which they were researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Defendants.

1 96. At all times relevant, Cordis IVC filters were manufactured, designed and labeled in an
2 unsafe, defective, and inherently dangerous condition which was dangerous for use by the public in
3 general and Plaintiffs in particular.

4 97. Defendants' Cordis IVC filters, as researched, tested, developed, designed, licensed,
5 manufactured, packaged, labeled, distributed, sold, and marketed by Defendants were defective in
6 design and formulation and unreasonably dangerous in that when they left the hands of Defendants'
7 manufacturers and/or suppliers, the foreseeable risks exceeded the alleged benefits associated with the
8 use of Cordis IVC filters, and the devices were more dangerous than the ordinary customer would
9 expect.

10 98. Physicians implanted Cordis IVC filters as instructed via the Instructions for Use and in a
11 foreseeable manner as normally intended, recommended, promoted, and marketed by Defendants.

12 99. Plaintiffs received and utilized Defendants' IVC filters in a foreseeable manner as
13 normally intended, recommended, promoted, and marketed by Defendants.

14 100. At the time Defendants placed their defective and unreasonably dangerous Cordis IVC
15 filters into the stream of commerce commercially, technologically, and scientifically feasible alternative
16 designs were attainable and available.

17 101. These alternative designs would have prevented the harm resulting in each Plaintiff's
18 Injuries and Damages without substantially impairing the reasonably anticipated or intended function of
19 Cordis IVC filters.

20 102. Neither Plaintiffs nor their health care providers could have, by the exercise of reasonable
21 care, discovered the defective condition or perceived the unreasonable dangers with these devices prior
22 to Plaintiffs' implantation with the Cordis IVC filters.

23 103. As a direct and proximate result of the defective and unreasonably dangerous condition
24 of Cordis IVC filters, Plaintiffs suffered Injuries and Damages.

25 **SECOND CAUSE OF ACTION**

26 **STRICT PRODUCTS LIABILITY – INADEQUATE WARNING**

27 **(By All Plaintiffs, As to All Defendants)**

28 104. Plaintiffs incorporate by reference all prior allegations.

1 105. At all relevant times, Defendants engaged in the business of testing, developing,
2 designing, manufacturing, packaging, labeling, marketing and/or promoting, selling and/or distributing
3 Cordis IVC filters – the TrapEase filters and the OptEase filters – and through that conduct have
4 knowingly and intentionally placed Cordis IVC filters into the stream of commerce with full knowledge
5 that they reach consumers such as Plaintiffs who would become implanted with them.

6 106. Defendants did, in fact, test, develop, design, manufacture, package, label, market and/or
7 promote, sell and/or distribute their Cordis IVC filters to Plaintiffs, their prescribing health care
8 professionals, and the consuming public. Additionally, Defendants expected that the Cordis IVC filters
9 they were selling, distributing, supplying, manufacturing, and/or promoting to reach, and did, in fact,
10 reach, prescribing health care professionals and consumers, including Plaintiffs and their prescribing
11 health care professionals, without any substantial change in the condition of the product from when it
12 was initially distributed by Defendants.

13 107. The Cordis IVC filters had potential risks and side effects that were known or knowable
14 to Defendants by the use of scientific inquiry and information available before, at, and after the
15 manufacture, distribution, and sale of the Cordis IVC filters.

16 108. Defendants knew or should have known of the defective condition, characteristics, and
17 risks associated with Cordis IVC filters. These defective conditions included, but were not limited to:
18 (1) Cordis IVC filters posed a significant and higher risk of failure than other similar IVC filters
19 (fracture, migration, tilting, and perforation of the vena cava wall); (2) Cordis IVC filter failures result in
20 serious injuries and death; (3) certain conditions or post-implant procedures, such as morbid obesity or
21 open abdominal procedures, could affect the safety and integrity of Cordis IVC filters; (4) leaving
22 Cordis IVC filters in for a period longer than necessary to prevent immediate risk of pulmonary
23 embolism increases the risk for patients of failures and complications with the filter, such as the filter
24 becoming deeply embedded in the vena cava, making them difficult or impossible for removal.

25 109. Defendants placed into the stream of commerce for ultimate use by users like Plaintiffs
26 and their health care providers, Cordis IVC filters that were in an unreasonably dangerous and defective
27 condition due to warnings and instructions for use that were inadequate, including, but not limited to
28 Defendants' failure to:

- a. Provide adequate instructions for how long in patients the filter should remain;
- b. Highlight the importance of removing the filter;
- c. Warn of the known risk of great bodily harm or death if the filter was not removed;
- d. Highlight the known risk of great bodily harm or death in the event of occlusion of the vein caused by the filter itself;
- e. Warn of the risk of new DVT if the filter was left in too long; Warn of the risk of new pulmonary embolism, thrombosis, swelling, and pain in the lower extremities if the filter was left in too long; and
- f. Warn of the risk of filter perforation, fracture, or migration.

110. Cordis IVC filters were in a defective and unsafe condition that was unreasonably and substantially dangerous to any user or consumer implanted with Cordis IVC filters, such as Plaintiffs, when used in an intended or reasonably foreseeable way.

111. The warnings and directions Defendants provided with their Cordis IVC filters failed to adequately warn of the potential risks and side effects of Cordis IVC filters.

112. These risks were known or were reasonably scientifically knowable to Defendants, but not known or recognizable to ordinary consumers, such as Plaintiffs, or their treating doctors.

113. Defendants' IVC filters were expected to and did reach Plaintiffs without substantial change in their condition, labeling, or warnings as manufactured, distributed, and sold by Defendants.

114. Additionally, Plaintiffs and their physicians used Cordis IVC filters – the TrapEase filters or the OptEase filters – in the manner in which they were intended to be used, making such use reasonably foreseeable to Defendants.

115. As a direct and proximate result of Defendants' information defects, lack of sufficient instructions or warnings prior to, on, and after the date Plaintiffs used Cordis IVC filters, Plaintiffs suffered Injuries and Damages.

THIRD CAUSE OF ACTION

STRICT PRODUCTS LIABILITY – MANUFACTURING DEFECT

(By All Plaintiffs, As to All Defendants)

116. Plaintiffs incorporate by reference all prior allegations.

1 117. Prior to, on, and after the date the Cordis IVC filters – the TrapEase filter or the OptEase
 2 filter – were implanted in Plaintiffs, Defendants designed, distributed, manufactured, sold, and marketed
 3 Cordis IVC filters for use in the United States, including California.

4 118. At all relevant times, Defendants designed, distributed, manufactured, marketed, and sold
 5 Cordis IVC filters that were unreasonably dangerous, unsafe, and defective in manufacture when they
 6 left Defendants' possession.

7 119. Upon information and belief, Cordis IVC filters contain a manufacturing defect, in that
 8 they differed from the manufacturer's design or specifications, or from other typical units of the same
 9 product line.

10 120. As a direct and proximate cause of Defendants' design, manufacture, marketing, and sale
 11 of Cordis IVC filters prior to, on, and after the date Plaintiffs used the Cordis IVC filters, Plaintiffs
 12 suffered Injuries and Damages.

13 **FOURTH CAUSE OF ACTION**

14 **NEGLIGENCE**

15 **(By All Plaintiffs, As to All Defendants)**

16 121. Plaintiffs incorporate by reference all prior allegations.

17 122. At the time of the design, distribution, manufacture, advertising, sale, and marketing of
 18 Cordis IVC filters – the TrapEase filters and the OptEase filters – and their implantation in Plaintiffs,
 19 Defendants were aware that Cordis IVC filters were designed and manufactured in a manner presenting:

- 20 a. An unreasonable risk of fracture of portions of the filters;
- 21 b. An unreasonable risk of migration of the filters and/or portions of the filters;
- 22 c. An unreasonable risk of filters tilting and/or perforating the vena cava wall; and
- 23 d. Insufficient strength or structural integrity to withstand normal placement within the
- 24 human body.

25 123. At the time of the design, distribution, manufacture, advertising, sale, and marketing of
 26 Cordis IVC filters, and their implantation in Plaintiffs, Defendants were also aware that Cordis IVC
 27 filters:

- 28 a. Would be used without inspection for defects;

- b. Would be used by patients with special medical conditions such as Plaintiffs;
- c. Had previously caused serious bodily injury to its users with special medical conditions such as Plaintiffs;
- d. Had no established efficacy;
- e. Were less safe and effective than the predicate IVC filters already available on market;
- f. Would be implanted in patients where the risk outweighed any benefit or utility of the filters;
- g. Contained instructions for use and warnings that were inadequate; and
- h. Were prothombotic.

124. Defendants had a duty to exercise due care and avoid unreasonable risk of harm to others in the design of Cordis IVC filters.

125. Defendants breached these duties by, among other things:

- a. Designing and distributing a product in which it knew or should have known that the likelihood and severity of potential harm from the product exceeded the burden of taking safety measures to reduce or avoid harm;
- b. Designing and distributing a product which it knew or should have known that the likelihood and severity of potential harm from the product exceeded the likelihood of potential harm from other IVC filters available for the same purpose;
- c. Failing to perform reasonable pre- and post-market testing of Cordis IVC filters to determine whether or not the products were safe for their intended use;
- d. Failing to use reasonable and prudent care in the design, research, manufacture, and development of Cordis IVC filters so as to avoid the risk of serious harm associated with the use of Cordis IVC filters;
- e. Advertising, marketing, promoting, and selling Cordis IVC filters for uses other than as approved and indicated in the products' labels;
- f. Failing to establish an adequate quality assurance program used in the manufacturing of Cordis IVC filters; and

- 1 g. Failing to perform adequate evaluation and testing of Cordis IVC filters when such
2 evaluation and testing would have revealed the propensity of Cordis IVC filters to cause
3 injuries similar to those that Plaintiffs suffered.

4 126. At all relevant times, Defendants had a duty to exercise due care in the manufacturing of
5 Cordis IVC filters.

6 127. Defendants breached this duty by, among other things:

- 7 a. Failing to adopt manufacturing processes that would reduce the foreseeable risk of
8 product failure;
9 b. Failing to use reasonable care in manufacturing the product and by producing a product
10 that differed from their design or specifications or from other typical units from the same
11 production line;
12 c. Failing to use reasonable and prudent care in the design, research, manufacture, and
13 development of Cordis IVC filters and their manufacturing process so as to avoid the risk
14 of serious harm associated with the use of Cordis IVC filters; and
15 d. Failing to establish an adequate quality assurance program used in the manufacturing of
16 their IVC filters.

17 128. At this time, all Cordis IVC filters – the TrapEase filters and the OptEase filters – are
18 misbranded and adulterated by virtue of them failing to be the substantial equivalent of predicate IVC
19 filter devices, making them subject to corrective action, including recall, in the interest of patient safety.

20 129. Prior to, on, and after the date of Plaintiffs' implantation with a Cordis IVC filter, and at
21 all relevant times, Defendants knew or reasonably should have known that Cordis IVC filters and their
22 warnings were defective and dangerous or were likely to be dangerous when used in a reasonably
23 foreseeable manner.

24 130. Prior to, on, and after the date of Plaintiffs' implantation with a Cordis IVC filter and at
25 all relevant times thereafter, Defendants became aware that the defects of Cordis IVC filters resulted in
26 Cordis IVC filters causing injuries similar to those Plaintiffs suffered.

1 131. Reasonable manufacturers and distributors under the same or similar circumstances
2 would have recalled or retrofitted Cordis IVC filters, and would thereby have avoided and prevented
3 harm to many patients, including Plaintiffs.

4 132. In light of this information and Defendants' knowledge described above, Defendants had
5 a duty to recall and/or retrofit Cordis IVC filters.

6 133. Defendants breached its duty to recall and/or retrofit Cordis IVC filters.

7 134. At all relevant times, Defendants knew or should have known that Cordis IVC filters
8 were defective and dangerous or were likely to be dangerous when used in a reasonably foreseeable
9 manner.

10 135. Such danger included the propensity of Cordis IVC filters to cause injuries similar to
11 those suffered by Plaintiffs.

12 136. At all relevant times, Defendants also knew or reasonably should have known that the
13 users of Cordis IVC filters, including Plaintiffs and their health care providers, would not realize or
14 discover on their own the dangers presented by Cordis IVC filters.

15 137. Reasonable manufacturers and reasonable distributors, under the same or similar
16 circumstances as those of Defendants prior to, on, and after the date of Plaintiffs' use of a Cordis IVC
17 filter, would have warned of the dangers presented by Cordis IVC filters, or instructed on the safe use of
18 Cordis IVC filters.

19 138. Prior to, on, and after the date of each Plaintiff's use of the IVC filter, Defendants had a
20 duty to adequately warn of the dangers presented by Cordis IVC filters and/or instruct on the safe use of
21 Cordis IVC filters.

22 139. Defendants breached these duties by failing to provide adequate warnings to Plaintiffs
23 communicating the information and dangers described above and/or providing instruction for safe use of
24 Cordis IVC filters.

25 140. As a direct and proximate result of Defendants' negligent conduct described herein,
26 Plaintiffs suffered Injuries and Damages.

27
28 ///

FIFTH CAUSE OF ACTION

NEGLIGENT MISREPRESENTATION

(By All Plaintiffs, As to All Defendants)

141. Plaintiffs incorporate by reference all prior allegations.

142. Prior to, on, and after the dates during which Plaintiffs were implanted with the Cordis IVC filters – the TrapEase filters and the OptEase filters – Defendants negligently and carelessly represented to Plaintiffs, their treating physicians, and the general public that Cordis IVC filters were safe, fit, and effective for use.

143. These representations were untrue.

144. Defendants owed a duty in all of its undertakings, including the dissemination of information concerning its IVC filters, to exercise reasonable care to ensure that it did not in those undertakings create unreasonable risks of personal injury to others.

145. Defendants disseminated to health care professionals and consumers through published labels, labeling, marketing materials, and otherwise information concerning the properties and effects of Cordis IVC filters with the intention that health care professionals and consumers would rely upon that information in their decisions concerning whether to prescribe and use Defendants' IVC filters.

146. Defendants, as medical device designers, manufacturers, sellers, promoters and/or distributors, knew or should reasonably have known that health care professionals and consumers, in weighing the potential benefits and potential risks of prescribing or using Cordis IVC filters, would rely upon information disseminated and marketed by Defendants to them regarding the Cordis IVC filters.

147. Defendants failed to exercise reasonable care to ensure that the information they disseminated to health care professionals and consumers concerning the properties and effects of Cordis IVC filters was accurate, complete, and not misleading and, as a result, disseminated information to health care professionals and consumers that was negligently and materially inaccurate, misleading, false, and unreasonably dangerous to consumers such as Plaintiffs.

148. Defendants, as designers, manufacturers, sellers, promoters, and/or distributors, also knew or reasonably should have known that patients receiving Cordis IVC filters as recommended by health care professionals in reliance upon information disseminated by Defendants as the

1 manufacturer/distributor of Defendants' IVC filters would be placed in peril of developing the serious,
 2 life-threatening, and life-long injuries including, but not limited to, tilting, migration, perforation,
 3 fracture, lack of efficacy, and increased risk of the development of blood clots, if the information
 4 disseminated and relied upon was materially inaccurate, misleading, or otherwise false.

5 149. Defendants had a duty to promptly correct material misstatements it knew others were
 6 relying upon in making healthcare decisions.

7 150. Defendants failed in each of these duties by misrepresenting to Plaintiffs and the medical
 8 community the safety and efficacy of Cordis IVC filters and failing to correct known misstatements and
 9 misrepresentations.

10 151. As a direct and proximate result of Defendants' negligent misrepresentations, Plaintiffs
 11 suffered Injuries and Damages.

12 **SIXTH CAUSE OF ACTION**

13 **FRAUDULENT MISREPRESENTATION**

14 **(By All Plaintiffs, As to All Defendants)**

15 152. Plaintiffs incorporate by reference all prior allegations.

16 153. At all times relevant to this cause, and as detailed above, Defendants intentionally
 17 provided Plaintiffs, their physicians, the medical community, and the public at large with false or
 18 inaccurate information. Defendants also omitted material information concerning Cordis IVC filters
 19 (the TrapEase filters and the OptEase filters), including, but not limited to, misrepresentations regarding
 20 the following topics:

- 21 a. The safety of the Cordis IVC filters;
- 22 b. The efficacy of the Cordis IVC filters;
- 23 c. The rate of failure of the Cordis IVC filters;
- 24 d. The pre-market testing of the Cordis IVC filters;
- 25 e. The approved uses of the Cordis IVC filters; and
- 26 f. The ability to retrieve the device at any time over a person's life.

27 154. The information Defendants distributed to the public, the medical community, and
 28 Plaintiffs was in the form of reports, press releases, advertising campaigns, labeling materials, print

1 advertisements, commercial media containing material representations, and instructions for use, as well
2 as through their officers, directors, agents, and representatives.

3 155. These materials contained false and misleading material representations, which included:
4 that Cordis IVC filters were safe and fit when used for their intended purpose or in a reasonably
5 foreseeable manner; that they did not pose dangerous health risks in excess of those associated with the
6 use of other similar IVC filters; that any and all side effects were accurately reflected in the warnings;
7 and that they were adequately tested to withstand normal placement within the human body.

8 156. Defendants made the foregoing misrepresentations knowing that they were false or
9 without reasonable basis. These materials included instructions for use and a warning document that
10 was included in the package of the Cordis IVC filters that were implanted in Plaintiffs.

11 157. Defendants' intent and purpose in making these misrepresentations was to deceive and
12 defraud the public and the medical community, including Plaintiffs' health care providers; to gain the
13 confidence of the public and the medical community, including Plaintiffs' health care providers; to
14 falsely assure the public and the medical community of the quality of Cordis IVC filters and their fitness
15 for use; and to induce the public and the medical community, including Plaintiffs' health care providers
16 to request, recommend, prescribe, implant, purchase, and continue to use Cordis IVC filters, all in
17 reliance on Defendants' misrepresentations.

18 158. The foregoing representations and omissions by Defendants were false.

19 159. Defendants' IVC filters are not safe, fit, and effective for human use in their intended and
20 reasonably foreseeable manner.

21 160. Further, the use of Cordis IVC filters is hazardous to the users' health, and Cordis IVC
22 filters have a serious propensity to cause users to suffer serious injuries, including without limitation the
23 injuries Plaintiffs suffered.

24 161. Finally, Defendants' IVC filters have a statistically significant higher rate of failure and
25 injury than do other comparable IVC filters.

26 162. In reliance upon the false and negligent misrepresentations and omissions made by
27 Defendants, Plaintiffs and their health care providers were induced to, and did use Cordis IVC filters,
28 thereby causing Plaintiffs to sustain severe and permanent personal injuries.

163. Defendants knew and had reason to know that Plaintiffs, their health care providers, and the general medical community did not have the ability to determine the true facts intentionally and/or negligently concealed and misrepresented by Defendants, and would not have prescribed and implanted Cordis IVC filters if the true facts regarding Defendants' IVC filters had not been concealed and misrepresented by Defendants.

164. Defendants had sole access to material facts concerning the defective nature of the products and their propensities to cause serious and dangerous side effects in the form of dangerous injuries and damages to persons who were implanted with Cordis IVC filters.

165. At the time Defendants failed to disclose and intentionally misrepresented the foregoing facts, and at the time Plaintiffs used Cordis IVC filters, Plaintiffs and their health care providers were unaware of Defendants' misrepresentations and omissions.

166. As a direct and proximate result of Defendants' fraudulent misrepresentations, Plaintiffs suffered Injuries and Damages.

SEVENTH CAUSE OF ACTION

FRAUDULENT CONCEALMENT

(By All Plaintiffs, As to All Defendants)

167. Plaintiffs incorporate by reference all prior allegations.

168. In marketing and selling Cordis IVC filters (the TrapEase filters and the OptEase filters), Defendants concealed material facts from Plaintiffs and their healthcare providers.

169. These concealed material facts include, but are not limited to:

- a. Cordis IVC filters were unsafe and not fit when used for their intended purpose or in a reasonably foreseeable manner;
- b. Cordis IVC filters posed dangerous health risks in excess of those associated with the use of other similar IVC filters;
- c. That there were additional side effects related to implantation and use of Cordis IVC filters that were not accurately and completely reflected in the warnings associated with Cordis IVC filters; and

1 d. That Cordis IVC filters were not adequately tested to withstand normal placement within
2 the human body.

3 170. Plaintiffs and their health care providers were not aware of these and other facts
4 concealed by Defendants.

5 171. In concealing these and other facts, Defendants intended to deceive Plaintiffs and their
6 health care providers.

7 172. Plaintiffs and their health care providers were ignorant of and could not reasonably
8 discover the facts Defendants fraudulently concealed and reasonably and justifiably relied on
9 Defendants' representations concerning the supposed safety and efficacy of Cordis IVC filters.

10 173. As a direct and proximate result of Defendants' fraudulent concealment of material facts,
11 Plaintiffs suffered Injuries and Damages.

12 **EIGHTH CAUSE OF ACTION**

13 **BREACH OF EXPRESS WARRANTY**

14 **(By All Plaintiffs, As to All Defendants)**

15 174. Plaintiffs incorporate by reference all prior allegations.

16 175. Plaintiffs, through their medical providers, purchased a Cordis IVC filter from
17 Defendants.

18 176. At all relevant times, Defendants were merchants of goods of the kind including medical
19 devices and vena cava filters (i.e., Cordis IVC filters).

20 177. At the time and place of sale, distribution, and supply of Cordis IVC filters to Plaintiffs
21 (and to other consumer and the medical community), Defendants expressly represented and warranted
22 that Cordis IVC filters were safe; that they were well-tolerated, efficacious, fit for their intended
23 purpose, and of marketable quality; that they did not produce any unwarned-of dangerous side effects;
24 and that they was adequately tested.

25 178. At the time of Plaintiffs' purchase from Defendants, Cordis IVC filters were not in a
26 merchantable condition, and Defendants breached its expressed warranties, in that Cordis IVC filters,
27 among other things:
28

- a. Were designed in such a manner so as to be prone to an unreasonably high incidence of fracture, perforation of vessels and organs, and/or migration;
- b. Were designed in such a manner so as to result in a unreasonably high incidence of injury to the vessels and organs of its purchaser;
- c. Were manufactured in such a manner that the exterior surface of the filter was inadequately, improperly, and inappropriately constituted, causing the device to weaken and fail;
- d. Were unable to be removed at any time during a person's life;
- e. Were not efficacious in the prevention of pulmonary emboli;
- f. Carried a risk of use outweighed any benefit; and
- g. Were not self-centering.

179. As a direct and proximate result of Defendants' breach of express warranty, Plaintiffs suffered Injuries and Damages.

NINTH CAUSE OF ACTION

BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY

(By All Plaintiffs, As to All Defendants)

180. Plaintiffs incorporate by reference all prior allegations.

181. Defendants impliedly warranted that Cordis IVC filters were of merchantable quality and safe and fit for the use for which Defendants intended them, and Plaintiff in fact used them.

182. Defendants breached its implied warranties by, among other things:

- a. Failing to provide adequate instruction that a manufacturer exercising reasonable care would have provided concerning the likelihood that Cordis IVC filters would cause harm;
- b. Manufacturing and/or selling Cordis IVC filters when those filters did not conform to representations made by Defendants when they left Defendants' control;
- c. Manufacturing and/or selling Cordis IVC filters that were more dangerous than an ordinary consumer would expect when used in an intended or reasonably foreseeable manner;

- d. Manufacturing and/or selling Cordis IVC filters that carried foreseeable risks associated with the Cordis IVC filter design or formulation which exceeded the benefits associated with that design;
- e. Manufacturing and/or selling Cordis IVC filters when they deviated in a material way from the design specifications, formulas, or performance standards or from otherwise identical units manufactured to the same design specifications, formulas, or performance standards; and
- f. Impliedly representing that its filters would be effective in the prevention of pulmonary emboli.

183. As a direct and proximate result of Defendants' breach of its implied warranty, Plaintiffs suffered Injuries and Damages.

PUNITIVE DAMAGES ALLEGATIONS

(By All Plaintiffs, As to All Defendants)

184. Plaintiffs incorporate by reference all prior allegations.

185. At all times material hereto, Defendants knew or should have known that Cordis IVC filters were unreasonably dangerous with respect to the risk of tilt, fracture, migration and/or perforation.

186. At all times material hereto, Defendants attempted to misrepresent and did knowingly misrepresent facts concerning the safety of Cordis IVC filters.

187. Defendants' misrepresentations included knowingly withholding material information from the medical community and the public, including Plaintiffs' physicians, concerning the safety of its Cordis IVC filters.

188. Defendants' conduct, alleged throughout this Complaint, was willful, wanton, and undertaken with a conscious indifference and disregard to the consequences that consumers of their products faced, including Plaintiffs.

189. At all times material hereto, Defendants knew and recklessly disregarded the fact that Cordis IVC filters have an unreasonably high rate of tilt, fracture, migration, and/or perforation.

190. Notwithstanding the foregoing, Defendants continued to market Cordis IVC filters aggressively to consumers, including Plaintiffs, without disclosing the aforesaid side effects.

191. Defendants knew of their Cordis IVC Filters' lack of warnings regarding the risk of fracture, migration, and/or perforation, but intentionally concealed and/or recklessly failed to disclose that risk and continued to market, distribute, and sell its filters without said warnings so as to maximize sales and profits at the expense of the health and safety of the public, including Plaintiffs, in conscious disregard of the foreseeable harm caused by Cordis IVC filters.

192. Defendants' intentional and/or reckless failure to disclose information deprived Plaintiffs' physicians of necessary information to enable them to weigh the true risks of using Cordis IVC filters against its benefits.

193. Defendants' conduct is reprehensible, evidencing an evil hand guided by an evil mind and was undertaken for pecuniary gain in reckless and conscious disregard for the substantial risk of death and physical injury to consumers, including Plaintiffs.

194. Such conduct justifies an award of punitive or exemplary damages in an amount sufficient to punish Defendants' conduct and deter like conduct by Defendants and other similarly situated persons and entities in the future.

PRAYER FOR DAMAGES

WHEREFORE, Plaintiffs demand judgment against Defendants for:

a. General (non-economic) damages, including, without limitation, past and future pain and suffering; past and future emotional distress; past and future loss of enjoyment of life; and other consequential damages as allowed by law;

b. Special (economic) damages, including, without limitation, past and future medical expenses; past and future lost wages and loss of earning capacity; and other consequential damages as allowed by law;

c. Punitive damages in an amount sufficient to punish Defendants and deter similar conduct in the future;

d. Disgorgement of profits;

e. Restitution;

- 1 f. Statutory damages, where authorized;
2 g. Costs of suit;
3 h. Reasonable attorneys' fees, where authorized;
4 i. Prejudgment interest as allowed by law;
5 j. Post-judgment interest at the highest applicable statutory or common law rate from the
6 date of judgment until satisfaction of judgment;
7 k. Such other additional and further relief as Plaintiffs may be entitled to in law or in equity.

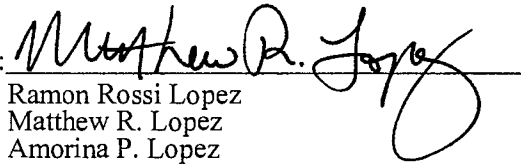
8 **DEMAND FOR JURY TRIAL**

9 Plaintiffs hereby demand a trial by jury on all triable issues.

10
11 Dated: May 6, 2016

Respectfully submitted,

12 LOPEZ McHUGH LLP

13
14 By: 
15 Ramon Rossi Lopez
16 Matthew R. Lopez
Amorina P. Lopez

17 -And-

18 Laura J. Baughman
19 BARON & BUDD, P.C.

20 Attorneys for Plaintiffs
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**ENDORSED
FILED
ALAMEDA COUNTY**

MAY 13 2016

CLERK OF THE SUPERIOR COURT

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**SUPERIOR COURT OF THE STATE OF CALIFORNIA
FOR THE COUNTY OF ALAMEDA**

GEANICE GRANT, an individual; VIOLET
ELAINE KERN, an individual; RUSSELL
HOPKINS, an individual; ANTHONY
BURBINE, an individual; COURTNEY
COMER, an individual; WILLIAM GOUGE,
an individual; RHONDA GAIL SCHENK, an
individual; JENNIFER ALLISON, an
individual; BOBBY FULLER, an individual;
ROBERT EDWARD BECKER, an individual;
TERRY ANN FOUNTAIN, an individual;
MARGUERITE NORTON, an individual;
JAMES FRANKLIN WILLIAMS, SR.; an
individual; BETTY REED, an individual;
CLINT HURTADO, an individual; MARK
WEHMEIER, an individual; JENNIFER
SCHOCK, an individual; JORDAN DEED, an
individual; MICHELLE YOUNG, an
individual; and VICTOR BLAIR, an individual;

Plaintiffs,

vs.

CORDIS CORPORATION; and DOES 1
through 50;

Defendants.

Case No.: RG16814688

**FIRST AMENDED COMPLAINT FOR
DAMAGES**

1. STRICT PRODUCTS LIABILITY –
DESIGN DEFECT
2. STRICT PRODUCTS LIABILITY –
FAILURE TO WARN
3. STRICT PRODUCTS LIABILITY –
MANUFACTURING DEFECT
4. NEGLIGENCE
5. NEGLIGENT MISREPRESENTATION
6. FRAUDULENT MISREPRESENTATION
7. FRAUDULENT CONCEALMENT
8. BREACH OF EXPRESS WARRANTY
9. BREACH OF IMPLIED WARRANTY OF
MERCHANTABILITY

DEMAND FOR JURY TRIAL

COMES NOW, Plaintiffs, by and through their attorneys, who complain and allege against Defendants CORDIS CORPORATION and DOES 1 through 50, and each of them, on information and belief, as follows:

INTRODUCTION

1. Plaintiffs bring this action for personal injuries damages suffered as a direct and proximate result of being implanted with a defective and unreasonably dangerous Inferior Vena Cava (“IVC”) filter medical device manufactured by Defendants.

2. The subject IVC filters include the following devices: TrapEase™ Permanent Vena Cava Filter (“TrapEase filter”) and OptEase™ Vena Cava Filter (“OptEase filter”) (for convenience, these devices will be referred to in this complaint under the generic terms “Cordis IVC filters” or “Defendants’ IVC filters”). At all times relevant to this action, Defendants developed, designed, set specifications for, licensed, manufactured, prepared, compounded, assembled, processed, sold, distributed and/or marketed the Cordis IVC filters to be implanted in patients throughout the United States, including California.

3. Plaintiffs’ claims for damages all relate to Defendants’ design, manufacture, sale, testing, marketing, labeling, advertising, promotion, and/or distribution of Cordis IVC filters.

4. The Cordis IVC filters that are the subject of this action all reached Plaintiffs and Plaintiffs’ physicians without substantial change in condition from the time they left Defendants’ possession.

5. Plaintiffs and Plaintiffs’ physicians used the Cordis IVC filters in the manner in which they were intended.

6. Defendants are solely responsible for any alleged design, manufacture or information defect its IVC filters contain.

7. Defendants do not allege that any other person or entity is comparatively at fault for any alleged design, manufacture, or informational defect its IVC filters contain.

PARTIES

8. Plaintiff GEANICE GRANT at all times relevant to this action was a citizen and resident of the State of California. Plaintiff GEANICE GRANT underwent placement of Defendants’ OptEase

1 Vena Cava Filter on or August 13, 2014, in California. The filter subsequently malfunctioned and
2 caused injury and damages to Plaintiff GEANICE GRANT, including, but not limited to, severe and
3 constant chest pains and compromised respiratory system. As a direct and proximate result of these
4 malfunctions, Plaintiff GEANICE GRANT suffered serious injuries and damages, and will require
5 extensive medical care and treatment. As a further proximate result, Plaintiff GEANICE GRANT has
6 suffered and will continue to suffer significant medical expenses, and pain and suffering, and other
7 damages.

8 9. Plaintiff VIOLET ELAINE KERN at all times relevant to this action was and is a citizen
9 and resident of the State of Texas. Plaintiff VIOLET ELAINE KERN underwent placement of
10 Defendants' OptEase Vena Cava Filter on or about March 28, 2012. The filter subsequently
11 malfunctioned and caused injury and damages to Plaintiff VIOLET ELAINE KERN, including, but not
12 limited to, filter embedded in wall of the IVC, unsuccessful removal attempt, and filter unable to be
13 retrieved. As a direct and proximate result of these malfunctions, Plaintiff VIOLET ELAINE KERN
14 suffered life-threatening injuries and damages, and required extensive medical care and treatment. As a
15 further proximate result, Plaintiff VIOLET ELAINE KERN has suffered and will continue to suffer
16 significant medical expenses, and pain and suffering, and other damages.

17 10. Plaintiff RUSSELL HOPKINS at all times relevant to this action was and is a citizen and
18 resident of the State of Texas. Plaintiff RUSSELL HOPKINS underwent placement of Defendants'
19 OptEase Vena Cava Filter on or about April 27, 2011. The filter subsequently malfunctioned and
20 caused injury and damages to Plaintiff RUSSELL HOPKINS, including, but not limited to, filter
21 embedded in wall of the IVC and unable to be retrieved. As a direct and proximate result of these
22 malfunctions, Plaintiff RUSSELL HOPKINS suffered life-threatening injuries and damages, and
23 required extensive medical care and treatment. As a further proximate result, Plaintiff RUSSELL
24 HOPKINS has suffered and will continue to suffer significant medical expenses, and pain and suffering,
25 and other damages.

26 11. Plaintiff ANTHONY BURBINE at all times relevant to this action was and is a citizen
27 and resident of the State of Massachusetts. Plaintiff ANTHONY BURBINE underwent placement of
28 Defendants' OptEase Vena Cava Filter on or about April 11, 2012. The filter subsequently

1 malfunctioned and caused injury and damages to Plaintiff ANTHONY BURBINE, including, but not
2 limited to, filter embedded in wall of the IVC and unable to be retrieved. As a direct and proximate
3 result of these malfunctions, Plaintiff ANTHONY BURBINE suffered life-threatening injuries and
4 damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff
5 ANTHONY BURBINE has suffered and will continue to suffer significant medical expenses, and pain
6 and suffering, and other damages.

7 12. Plaintiff COURTNEY COMER at all times relevant to this action was a citizen and
8 resident of the State of Maryland and, subsequently, became a citizen and resident of the State of Texas.
9 Plaintiff COURTNEY COMER underwent placement of Defendants' TrapEase Vena Cava Filter on or
10 about May 5, 2005. The filter subsequently malfunctioned and caused injury and damages to Plaintiff
11 COURTNEY COMER, including, but not limited to, fracture of the filter. As a direct and proximate
12 result of these malfunctions, Plaintiff COURTNEY COMER suffered life-threatening injuries and
13 damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff
14 COURTNEY COMER has suffered and will continue to suffer significant medical expenses, and pain
15 and suffering, and other damages.

16 13. Plaintiff WILLIAM GOUGE at all times relevant to this action was and is a citizen and
17 resident of the State of Maryland. Plaintiff WILLIAM GOUGE underwent placement of Defendants'
18 TrapEase Vena Cava Filter on or about August 13, 2010. The filter subsequently malfunctioned and
19 caused injury and damages to Plaintiff WILLIAM GOUGE, including, but not limited to, migration of
20 the filter to heart requiring emergency open-heart surgery. As a direct and proximate result of these
21 malfunctions, Plaintiff WILLIAM GOUGE suffered life-threatening injuries and damages, and required
22 extensive medical care and treatment. As a further proximate result, Plaintiff WILLIAM GOUGE has
23 suffered and will continue to suffer significant medical expenses, and pain and suffering, and other
24 damages.

25 14. Plaintiff RHONDA GAIL SCHENK at all times relevant to this action was a citizen and
26 resident of the State of Maryland. Plaintiff RHONDA GAIL SCHENK underwent placement of
27 Defendants' OptEase Vena Cava Filter on or about March 1, 2010. The filter subsequently
28 malfunctioned and caused injury and damages to Plaintiff RHONDA GAIL SCHENK, including, but

1 not limited to, filter embedded in wall of the IVC and unable to be retrieved, and recurrent DVTs. As a
2 direct and proximate result of these malfunctions, Plaintiff RHONDA GAIL SCHENK suffered life-
3 threatening injuries and damages, and required extensive medical care and treatment. As a further
4 proximate result, Plaintiff RHONDA GAIL SCHENK has suffered and will continue to suffer
5 significant medical expenses, and pain and suffering, and other damages.

6 15. Plaintiff JENNIFER ALLISON at all times relevant to this action was and is a citizen and
7 resident of the State of Maryland. Plaintiff JENNIFER ALLISON underwent placement of Defendants'
8 OptEase Vena Cava Filter on or about January 14, 2011. The filter subsequently malfunctioned and
9 caused injury and damages to Plaintiff JENNIFER ALLISON, including, but not limited to, tilt,
10 migration, filter embedded in wall of the IVC, unsuccessful removal attempt, and filter unable to be
11 retrieved. As a direct and proximate result of these malfunctions, Plaintiff JENNIFER ALLISON
12 suffered life-threatening injuries and damages, and required extensive medical care and treatment. As a
13 further proximate result, Plaintiff JENNIFER ALLISON has suffered and will continue to suffer
14 significant medical expenses, and pain and suffering, and other damages.

15 16. Plaintiff BOBBY FULLER at all times relevant to this action was and is a citizen and
16 resident of the State of North Carolina. Plaintiff BOBBY FULLER underwent placement of
17 Defendants' OptEase Vena Cava Filter on or about May 18, 2006. The filter subsequently
18 malfunctioned and caused injury and damages to Plaintiff BOBBY FULLER, including, but not limited
19 to, filter embedded in wall of the IVC. As a direct and proximate result of these malfunctions, Plaintiff
20 BOBBY FULLER suffered life-threatening injuries and damages, and required extensive medical care
21 and treatment. As a further proximate result, Plaintiff BOBBY FULLER has suffered and will continue
22 to suffer significant medical expenses, and pain and suffering, and other damages.

23 17. Plaintiff ROBERT EDWARD BECKER at all times relevant to this action was and is a
24 citizen and resident of the State of Wisconsin. Plaintiff ROBERT EDWARD BECKER underwent
25 placement of Defendants' TrapEase Vena Cava Filter on or about June 21, 2010. The filter
26 subsequently malfunctioned and caused injury and damages to Plaintiff ROBERT EDWARD BECKER,
27 including, but not limited to, hematoma and recurrent pulmonary embolisms. As a direct and proximate
28 result of these malfunctions, Plaintiff ROBERT EDWARD BECKER suffered life-threatening injuries

1 and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff
2 ROBERT EDWARD BECKER has suffered and will continue to suffer significant medical expenses,
3 and pain and suffering, and other damages.

4 18. Plaintiff TERRY ANN FOUNTAIN at all times relevant to this action was and is a
5 citizen and resident of the State of Georgia. Plaintiff TERRY ANN FOUNTAIN underwent placement
6 of Defendants' TrapEase Vena Cava Filter on or about June 2, 2007. The filter subsequently
7 malfunctioned and caused injury and damages to Plaintiff TERRY ANN FOUNTAIN, including, but not
8 limited to, blood clots, clotting and occlusion of IVC filter. As a direct and proximate result of these
9 malfunctions, Plaintiff TERRY ANN FOUNTAIN suffered life-threatening injuries and damages, and
10 required extensive medical care and treatment. As a further proximate result, Plaintiff TERRY ANN
11 FOUNTAIN has suffered and will continue to suffer significant medical expenses, and pain and
12 suffering, and other damages.

13 19. Plaintiff MARGUERITE NORTON at all times relevant to this action was and is a
14 citizen and resident of the State of Pennsylvania. Plaintiff MARGUERITE NORTON underwent
15 placement of Defendants' OptEase Vena Cava Filter on or about April 15, 2010. The filter subsequently
16 malfunctioned and caused injury and damages to Plaintiff MARGUERITE NORTON, including, but not
17 limited to, fracture of the filter. As a direct and proximate result of these malfunctions, Plaintiff
18 MARGUERITE NORTON suffered life-threatening injuries and damages, and required extensive
19 medical care and treatment. As a further proximate result, Plaintiff MARGUERITE NORTON has
20 suffered and will continue to suffer significant medical expenses, and pain and suffering, and other
21 damages.

22 20. Plaintiff JAMES FRANKLIN WILLIAMS, SR. at all times relevant to this action was
23 and is a citizen and resident of the State of Maryland. Plaintiff JAMES FRANKLIN WILLIAMS, SR.
24 underwent placement of Defendants' TrapEase Vena Cava Filter on or about June 27, 2013. The filter
25 subsequently malfunctioned and caused injury and damages to Plaintiff JAMES FRANKLIN
26 WILLIAMS, SR., including, but not limited to, DVT. As a direct and proximate result of these
27 malfunctions, Plaintiff JAMES FRANKLIN WILLIAMS, SR. suffered life-threatening injuries and
28 damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff

1 JAMES FRANKLIN WILLIAMS, SR. has suffered and will continue to suffer significant medical
2 expenses, and pain and suffering, and other damages.

3 21. Plaintiff BETTY REED at all times relevant to this action was and is a citizen and
4 resident of the State of West Virginia. Plaintiff BETTY REED underwent placement of Defendants'
5 TrapEase Vena Cava Filter on or about October 14, 2014. The filter subsequently malfunctioned and
6 caused injury and damages to Plaintiff BETTY REED, including, but not limited to, migration of the
7 filter. As a direct and proximate result of these malfunctions, Plaintiff BETTY REED suffered life-
8 threatening injuries and damages, and required extensive medical care and treatment. As a further
9 proximate result, Plaintiff BETTY REED has suffered and will continue to suffer significant medical
10 expenses, and pain and suffering, and other damages.

11 22. Plaintiff CLINT HURTADO at all times relevant to this action was and is a citizen and
12 resident of the State of Wyoming. Plaintiff CLINT HURTADO underwent placement of Defendants'
13 OptEase Vena Cava Filter on or about August 19, 2010. The filter subsequently malfunctioned and
14 caused injury and damages to Plaintiff CLINT HURTADO, including, but not limited to, fracture of the
15 filter. As a direct and proximate result of these malfunctions, Plaintiff CLINT HURTADO suffered life-
16 threatening injuries and damages, and required extensive medical care and treatment. As a further
17 proximate result, Plaintiff CLINT HURTADO has suffered and will continue to suffer significant
18 medical expenses, and pain and suffering, and other damages.

19 23. Plaintiff MARK WEHMEIER at all times relevant to this action was and is a citizen and
20 resident of the State of Wisconsin. Plaintiff MARK WEHMEIER underwent placement of Defendants'
21 TrapEase Vena Cava Filter on or about October 20, 2012. The filter subsequently malfunctioned and
22 caused injury and damages to Plaintiff MARK WEHMEIER, including, but not limited to, filter
23 embedded in wall of the IVC, unsuccessful removal attempt, and filter unable to be retrieved. As a
24 direct and proximate result of these malfunctions, Plaintiff MARK WEHMEIER suffered life-
25 threatening injuries and damages, and required extensive medical care and treatment. As a further
26 proximate result, Plaintiff MARK WEHMEIER has suffered and will continue to suffer significant
27 medical expenses, and pain and suffering, and other damages.
28

1 24. Plaintiff JENNIFER SCHOCK at all times relevant to this action was and is a citizen and
2 resident of the State of Wisconsin. Plaintiff JENNIFER SCHOCK underwent placement of Defendants'
3 TrapEase Vena Cava Filter on or about November 16, 2005. The filter subsequently malfunctioned and
4 caused injury and damages to Plaintiff JENNIFER SCHOCK, including, but not limited to, fracture of
5 the filter and perforation of filter struts into vena cava. As a direct and proximate result of these
6 malfunctions, Plaintiff JENNIFER SCHOCK suffered life-threatening injuries and damages, and
7 required extensive medical care and treatment. As a further proximate result, Plaintiff JENNIFER
8 SCHOCK has suffered and will continue to suffer significant medical expenses, and pain and suffering,
9 and other damages.

10 25. Plaintiff JORDAN DEED at all times relevant to this action was and is a citizen and
11 resident of the State of Wisconsin. Plaintiff JORDAN DEED underwent placement of Defendants'
12 OptEase Vena Cava Filter on or about November 28, 2010. The filter subsequently malfunctioned and
13 caused injury and damages to Plaintiff JORDAN DEED, including, but not limited to, severe pain and
14 swelling of lower extremity, blood clots, clotting and occlusion of IVC filter, requiring emergency
15 surgery to remove the filter. As a direct and proximate result of these malfunctions, Plaintiff JORDAN
16 DEED suffered life-threatening injuries and damages, and required extensive medical care and
17 treatment. As a further proximate result, Plaintiff JORDAN DEED has suffered and will continue to
18 suffer significant medical expenses, and pain and suffering, and other damages.

19 26. Plaintiff MICHELLE YOUNG at all times relevant to this action was a citizen and
20 resident of the State of Ohio. Plaintiff MICHELLE YOUNG underwent placement of Defendants'
21 TrapEase Vena Cava Filter on or about February 10, 2011. The filter subsequently malfunctioned and
22 caused injury and damages to Plaintiff MICHELLE YOUNG, including, but not limited to, severe and
23 constant chest pains and pulmonary embolisms. As a direct and proximate result of these malfunctions,
24 Plaintiff MICHELLE YOUNG suffered serious injuries and damages, and will require extensive
25 medical care and treatment. As a further proximate result, Plaintiff MICHELLE YOUNG has suffered
26 and will continue to suffer significant medical expenses, and pain and suffering, and other damages.

27 27. Plaintiff VICTOR BLAIR at all times relevant to this action was and is a citizen and
28 resident of the State of Ohio. Plaintiff VICTOR BLAIR underwent placement of Defendants' TrapEase

1 Vena Cava Filter on or about August 17, 2005. The filter subsequently malfunctioned and caused injury
2 and damages to Plaintiff VICTOR BLAIR, including, but not limited to, severe and constant chest pains
3 and compromised respiratory system. As a direct and proximate result of these malfunctions, Plaintiff
4 VICTOR BLAIR suffered life-threatening injuries and damages, and required extensive medical care
5 and treatment. As a further proximate result, Plaintiff VICTOR BLAIR has suffered and will continue
6 to suffer significant medical expenses, and pain and suffering, and other damages.

7 28. Defendant CORDIS CORPORATION ("Cordis"), including its department, division, and
8 subsidiary, Cordis Endovascular, is a corporation or business entity organized and existing under the
9 laws of the State of Florida with its headquarters located at 6500 Paseo Padre Pkwy., Fremont,
10 California, 94555.

11 29. Cordis may be served with process by serving its registered agent, CT Corporation
12 System, at 818 West Seventh Street Suite 930, Los Angeles, California 90017.

13 30. The true names and/or capacities, whether individual, corporate, partnership, associate,
14 governmental, or otherwise, of Defendant DOES 1 through 50, inclusive, are unknown to Plaintiffs at
15 this time, who therefore sue said Defendants by such fictitious names. Plaintiffs are informed and
16 believe, and thereon allege, that each Defendant designated herein as a DOE caused injuries and
17 damages proximately thereby to Plaintiffs as is hereinafter alleged, and that each DOE defendant is
18 liable to Plaintiffs for the acts and omissions alleged herein below and the injuries and damages resulting
19 therefrom. Plaintiffs seek leave to amend this Complaint to allege the true names and capacities of said
20 DOE defendants when the same are ascertained.

21 31. Plaintiffs are informed and believe, and thereon allege, that at all times herein mentioned,
22 the Defendant and each of the DOE defendants were the agent, servant, employee and/or joint venturer
23 of the other co-defendants, and each of them, and at all said times each Defendant, including DOE
24 defendants, were acting in the full course, scope, and authority of said agency, service, employment
25 and/or joint venture.

26 32. Plaintiffs are informed and believe, and thereon allege, that at all times mentioned herein,
27 Defendant and DOES 1 through 50, and each of them, were also known as, formerly known as, and/or
28 were the successors and/or predecessors in interest/business/product line/or a portion thereof, assigns, a

1 parent, a subsidiary (wholly or partially owned by, or the whole or partial owner), affiliate, partner, co-
2 venturer, merged company, alter egos, agents, equitable trustees and/or fiduciaries of and/or were
3 members in an entity or entities engaged in the funding, researching, studying, manufacturing,
4 fabricating, designing, developing, labeling, assembling, distributing, supplying, leasing, buying,
5 offering for sale, selling, inspecting, servicing, contracting others for marketing, warranting, rebranding,
6 manufacturing for others, packaging, and advertising the device.

7 33. Defendant and DOES 1 through 50, and each of them, are liable for the acts, omissions
8 and tortious conduct of its successors and/or predecessors in interest/business/product line/or a portion
9 thereof, assigns, parent, subsidiary, affiliate, partner, co-venturer, merged company, alter ego, agent,
10 equitable trustee, fiduciary and/or its alternate entities in that Defendant and DOES 1 through 50, and
11 each of them, enjoy the goodwill originally attached to each such alternate entity, acquired the assets or
12 product line (or a portion thereof), and in that there has been a virtual destruction of Plaintiffs' remedy
13 against each such alternate entity, and that each such Defendant has the ability to assume the risk-
14 spreading role of each such alternate entity.

15 34. Plaintiffs are informed and believe, and thereon allege that, at all times herein mentioned,
16 DOES 1 through 50, and each of them, were and are corporations organized and existing under the laws
17 of the State of California or the laws of some state or foreign jurisdiction; that each of the said DOE
18 defendants were and are authorized to do and are doing business in the State of California and regularly
19 conducted business in the State of California.

20 35. Upon information and belief, Defendants at all relevant times were engaged in the
21 business of researching, developing, designing, licensing, manufacturing, distributing, selling,
22 marketing, and/or introducing into interstate commerce and into the State of California, either directly or
23 indirectly through third parties or related entities, its products, including the TrapEase and OptEase IVC
24 filters, and derived substantial income from doing business in California.

25 36. "Cordis" and "Defendants" where used hereinafter, shall refer to all subsidiaries,
26 affiliates, divisions, franchises, partners, joint venturers, organizational units of any kind, predecessors,
27 successors, assigns, officers, directors, employees, agents and representatives of Cordis Corporation; as
28 well as DOE Defendants 1 through 50, and each of them.

37. Joinder of Plaintiffs in this First Amended Complaint for Damages is proper pursuant to *Code of Civil Procedure* Section 378 because Plaintiffs assert a right to relief in respect of or arising out of the same transaction, occurrence, or series of transactions or occurrences, and questions of law and fact common to all Plaintiffs will arise in the action.

JURISDICTION AND VENUE

38. This Court has jurisdiction under the California Constitution, Article VI, Section 10 and *Code of Civil Procedure* Section 410.10. Plaintiffs' damages exceed the jurisdictional minimum of this Court.

39. Venue is proper in this Court pursuant to *Code of Civil Procedure* Sections 395 and 395.5 because the principal place of business for Defendant CORDIS CORPORATION is situated in Alameda County. Further, a substantial amount of Defendants' conduct, as alleged herein by Plaintiffs, took place in Alameda County.

40. Requiring Defendants to litigate these claims in California does not offend traditional notions of fair play and substantial justice and is permitted by the United States Constitution. Defendants are "at home" in the State of California. Cordis maintains campuses and facilities in Fremont and Oakland, California, in Alameda County, and has its headquarters here. Cordis' website lists its address as 6500 Paseo Padre Parkway, Fremont, CA 94555 (*see* <https://www.cordis.com/> (last visited May 13, 2016)). A Cordis-affiliate website represents that Cordis' "North American operations are based out of the San Francisco Bay Area" and also lists the 6500 Paseo Padre Parkway, Fremont, CA 94555 address (*see* <http://www.cardinalhealth.com/en/cmp/ext/cor/cordis.html> (last visited May 13, 2016)). Thus, Cordis affirmatively represents to the public that its headquarters is in California.

41. Defendants systematically availed themselves of the State of California by conducting regular and sustained business and engaging in substantial commerce and business activity in California, including without limitation researching, developing, designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce in the state of California, either directly or indirectly, its products, including Cordis IVC filters.

42. Plaintiffs' claims arise from and relate to Cordis' purposeful avail of the State of California because Cordis' wrongful conduct in developing, designing, selling, marketing,

1 manufacturing and/or distributing Cordis IVC filters took place, in whole or in part, in the State of
2 California. Therefore, the claims of California-plaintiffs *and* out-of-state plaintiffs relate to and arise
3 from Defendants' explicit contacts and purposeful avail of the State of California. Further and
4 independently, Cordis consented to jurisdiction in the State of California by appointing an agent for
5 service of process in this State and by conducting substantial systematic business in this State.

6 43. The instant First Amended Complaint for Damages does not confer diversity jurisdiction
7 upon the federal courts pursuant to 28 U.S.C. § 1332. Likewise, federal question subject matter
8 jurisdiction pursuant to 28 U.S.C. § 1331 is not invoked by the instant Complaint, as it sets forth herein
9 exclusively state law claims against the Defendants. Nowhere do Plaintiffs plead, expressly or
10 implicitly, any cause of action or request any remedy that arises under or is founded upon federal law,
11 and any alleged federal rights or remedies are expressly disavowed. The issues presented by Plaintiffs do
12 not implicate substantial federal questions, do not turn on the necessary interpretation of federal law, and
13 do not affect the federal system as a whole. The assertion of federal jurisdiction over claims made herein
14 would improperly disturb the congressionally approved balance of federal and state responsibilities.

15 **BACKGROUND**

16 **INFERIOR VENA CAVA FILTERS GENERALLY**

17 44. IVC filters were first made commercially available to the medical community in the
18 1960s. Over the years, medical device manufacturers have introduced several different designs of IVC
19 filters.

20 45. An IVC filter is a device that is designed to filter or "catch" blood clots that travel from
21 the lower portions of the body to the heart and lungs. IVC filters were originally designed to be
22 permanently implanted in the IVC.

23 46. The IVC is a vein that returns blood to the heart from the lower portions of the body. In
24 certain people, for various reasons, blood clots travel from the vessels in the legs and pelvis, through the
25 vena cava and into the lungs. Oftentimes, these blood clots develop in the deep leg veins, a condition
26 called "deep-vein thrombosis" or "DVT." Once blood clots reach the lungs, they are considered
27 "pulmonary emboli" or "PE." Pulmonary emboli present risks to human health.
28

1 47. People at risk for DVT/PE can undergo medical treatment to manage the risk. For
2 example, a doctor may prescribe anticoagulant therapies such as medications like Heparin, Warfarin, or
3 Lovenox to regulate the clotting factor of the blood. In some people who are at high risk for DVT/PE
4 and who cannot manage their conditions with medications, physicians may recommend surgically
5 implanting an IVC filter to prevent thromboembolic events.

6 48. As stated above, IVC filters have been on the market for decades. All IVC filters are
7 only cleared for use by the Food & Drug Administration ("FDA") for prevention of recurrent pulmonary
8 embolism in patients at risk for pulmonary embolism and where anticoagulation therapy has failed or is
9 contraindicated.

10 49. In order to increase sales of these devices, Defendants sought to expand the market for
11 prophylactic use among nontraditional patient populations that were temporarily at risk of developing
12 blood clots.

13 50. Defendant Cordis engaged in marketing campaigns directed toward the bariatric, trauma,
14 orthopedic and cancer patient population. Expansion to these new patient groups would substantially
15 increase sales and the first manufacturer to market would capture market share.

16 51. Other manufacturers also saw this opportunity, which triggered a race to market a device
17 that provided physicians the option to retrieve the filter after the clot risk subsided.

18 52. From 2000 through 2003, manufacturers of IVC filters, including Defendants, raced
19 against each other to bring the first IVC filter to the market with the added indication of optional
20 retrieval. In 2003, the FDA cleared three different IVC filters for a retrieval indication, one of which
21 was the OptEase filter by Defendant Cordis.

22 53. There is no evidence that Defendants' IVC filters were effective in preventing pulmonary
23 embolism (the very condition the products were indicated to prevent).

24 54. Years after the implantation of retrievable filters into the bodies of patients, scientists
25 began to study the effectiveness of the retrievable filters. As recently as October 2015, an expansive
26 article published in the *Annals of Surgery* concerning trauma patients inserted with IVC filters
27 concluded that IVC filters were not effective in preventing pulmonary emboli, and instead actually
28 caused thrombi to occur.

1 55. Comparing the results of over 30,000 trauma patients who had not received IVC filters
2 with those who had received them, the *Annals of Surgery* study published its alarming results:

- 3 a. Almost twice the percentage of patients with IVC filters in the study died compared to
4 those that had not received them.
5 b. Over five times the relative number of patients with IVC filters developed DVTs.
6 c. Over four times the relative percentage of patients with filters developed thromboemboli.
7 d. Over twice the percentage of patients developed a pulmonary embolus – the very
8 condition Defendant Cordis told the FDA, physicians, and the public that its IVC filters
9 were designed to prevent.

10 56. Other studies also have revealed that these devices suffer common failure modes such as
11 migration, perforation, thrombosis, and fracture, all of which can cause serious injury or death. For
12 example, recent studies of Cordis IVC filters have revealed fracture rates as high as 50% and
13 recommend medical monitoring and/or removal.

14 57. These studies, including the *Annals of Surgery* study, have shown there is no evidence
15 establishing that IVC filters are effective and that these devices suffer common failure modes, including,
16 but not limited to, migration, perforation, thrombosis, tilt and fracture, all of which can cause serious
17 injury or death. Thus, the current state of scientific and medical evidence indicates that IVC filters are
18 not only ineffective but that they are themselves a health hazard.

19 **THE TRAPEASE™ AND OPTEASE™ IVC FILTERS**

20 58. On or about January 10, 2001, Defendants bypassed the more onerous FDA's approval
21 process for new devices and obtained "clearance" under Section 510(k) of the Medical Device
22 Amendments to the Food, Drug, and Cosmetic Act to market the TrapEase Vena Cava Filter as a
23 *permanent* filter by claiming it was substantially similar in respect to safety, efficacy, design, and
24 materials as the IVC filters already available on the market.

25 59. Section 510(k) permits the marketing of medical devices if the device is substantially
26 equivalent to other legally marketed predicate devices without formal review for the safety or efficacy of
27 the said device. The FDA explained the difference between the 510(k) process and the more rigorous
28

1 “premarket approval” (PMA) process in its amicus brief filed with the Third Circuit in *Horn v. Thoratec*
2 *Corp.*, which the court quoted from:

3 A manufacturer can obtain an FDA finding of ‘substantial equivalence’ by submitting a
4 premarket notification to the agency in accordance with section 510(k) of the [Food Drug
5 and Cosmetic Act]. 21 U.S.C. § 360(k). A device found to be ‘substantially equivalent’
6 to a predicate device is said to be ‘cleared’ by FDA (as opposed to ‘approved’ by the
7 agency under a PMA. A pre-market notification submitted under 510(k) is thus entirely
8 different from a PMA which must include data sufficient to demonstrate that the IVC
9 Filters is safe and effective.

10 376 F.3d 163, 167 (3d Cir. 2004) (emphasis in original).

11 60. In *Medtronic, Inc. v. Lohr*, the U.S. Supreme Court similarly described the 510(k)
12 process, observing:

13 If the FDA concludes on the basis of the [manufacturer’s] § 510(k) notification that the
14 device is “substantially equivalent” to a pre-existing device, it can be marketed without
15 further regulatory analysis. . . . The § 510(k) notification process is by no means
16 comparable to the PMA process; in contrast to the 1,200 hours necessary to complete a
17 PMA review, the § 510(k) review is completed in average of 20 hours. . . . As one
18 commentator noted: “The attraction of substantial equivalence to manufacturers is clear.
19 Section 510(k) notification requires little information, rarely elicits a negative response
20 from the FDA, and gets processed quickly.”

21 518 U.S. 470, 478-79 (1996) (quoting Adler, *The 1976 Medical Device Amendments: A Step in the*
22 *Right Direction Needs Another Step in the Right Direction*, 43 Food Drug Cosm. L.J. 511, 516 (1988)).

23 61. Pursuant to *Wyeth v. Levine*, 555 U.S. 555 (2009), once a product is cleared “the
24 manufacturer remains under an obligation to investigate and report any adverse events associated with
25 the drug . . . and must periodically submit any new information that may affect the FDA’s previous
26 conclusions about the safety, effectiveness, or labeling” This obligation extends to post-market
27 monitoring of adverse events/complaints.

28 62. In July 2000, through this 510(k) process, Defendants obtained clearance from the FDA
to market the TrapEase filter as a permanent filter.

63. The TrapEase filter is made with Nitinol – a nickel titanium alloy. The filter utilizes a
design known as a double basket or double filter for the capture of blood clots and/or emboli. This
design consists of a basket made of six diamond-shaped struts proximally and six diamond-shaped struts
distally, forming proximal and distal baskets, which are connected by six straight struts to create a single

1 symmetric filter. The filter has proximal and distal anchoring barbs located on each connecting strut for
2 fixation of the filter to the vena cava wall to prevent movement after placement.

3 64. Nitinol alloy is used in a number of different medical device applications. It is beneficial
4 for these applications and is employed as material in stents and other medical device applications. It is
5 also used in the manufacture of the TrapEase filter, and other brands of IVC filters.

6 65. Specific manufacturing processes need to be utilized when using Nitinol as a component
7 for medical devices, including IVC filters. Primarily, the Nitinol material should be electro-polished
8 prior to assembly of the finished medical device.

9 66. Electro-polishing is a manner of removing surface blemishes, "draw marking" and
10 circumferential grinding markings on the exterior of the surface of the Nitinol material. The existence
11 of these surface blemishes, "draw markings" and "circumferential grind-markings" causes/results in the
12 weakening of the structural integrity of the end product, whether it is an IVC filter or other medical
13 device.

14 67. In or around September 2002, Defendants sought clearance through the 510(k) process to
15 market the OptEase Vena Cava Filter for the same indicated uses as the TrapEase filter. Defendants
16 represented that the OptEase filter contained the same fundamental technology and was substantially
17 equivalent in terms of safety and efficacy as the predicate devices already available on the market.

18 68. Unlike the TrapEase filter, which has proximal and distal anchoring barbs located on
19 each connecting strut for fixation of the filter to the vena cava wall, the OptEase filter has anchoring
20 barbs for fixation of the filter only on the superior end of each of the six straight struts and has a hook at
21 the inferior end of the basket to allow retrieval with a snare.

22 69. Both designs for the TrapEase filter and OptEase filter suffer flaws making them
23 defective and unreasonably dangerous. Defendants' IVC filters are designed in such a way that when
24 exposed to expected and reasonably foreseeable *in-vivo* conditions, the devices will fracture, migrate,
25 tilt, perforate internal organs and vasculature, and lead to the formation of thromboembolism and
26 pulmonary embolism.

1 70. For years, it has been known by manufacturers of the Nitinol medical devices and the
2 medical device industry that electro-polishing Nitinol results in increased structural integrity of the
3 device and resistance to fatigue and fatigue failures.

4 71. The exterior surfaces of the Cordis IVC filters were not electro-polished prior to
5 completion of the manufacturing process. This is a manufacturing defect that exists in the TrapEase and
6 OptEase filters which causes these filters to be structurally weak and susceptible to a significant risk of
7 failure/fracture.

8 72. Additionally, Defendants represented that the self-centering design of the TrapEase filter
9 allows accurate, predictable placement, and that its site struts help reduce the risk of tilting and
10 migration, while in reality the filters regularly tilt, migrate, and become embedded in the vena cava wall.

11 73. The anchoring mechanism of Defendants' filters is also insufficient to prevent tilting and
12 migration post-placement.

13 74. The configuration of the Cordis IVC filters actually leads to the formation of blood clots
14 and pulmonary embolism – the exact condition the devices are meant to protect against.

15 75. That Defendants allowed these devices to proceed to market indicates that they failed to
16 establish and maintain an appropriate Quality System concerning design and risk analysis.

17 76. A manufacturer must, at a minimum, undertake research and testing to understand the
18 anatomy of where a medical device will be implanted and understand the forces the device may be
19 exposed to once implanted in a human body. This design input must then be used to determine the
20 minimum safety requirements or attributes the device must have to meet user needs. In the case of an
21 IVC filter, user needs include a device that will capture blood clots of sufficient size to cause harmful
22 consequences and that will not fracture, migrate, tilt, perforate the vena cava, or malfunction in some
23 other way, or be prothombotic. Defendants failed to undertake any such efforts in these regards.

24 77. Prior to bringing a product to market, a manufacturer must also conduct sufficient testing
25 under real world or simulated use conditions to ensure that the device will meet user needs even when
26 exposed to reasonably foreseeable worst-case conditions. Defendants failed to adequately establish and
27 maintain such policies, procedures or protocols with respect to their IVC filters.
28

1 78. Once placed on the market, Defendants' post-market surveillance system should have
2 revealed to Defendants that the TrapEase and OptEase filters were unreasonably dangerous and
3 substantially more prone to fail or malfunction, and cause great bodily harm to patients compared to
4 other available treatment options.

5 79. MAUDE is a database maintained by the FDA to house medical device reports submitted
6 by mandatory reporters (such as manufacturers and device user facilities) and voluntary reporters (such
7 as health care providers and patients).

8 80. Shortly after going on market, Defendants began receiving large numbers of adverse
9 event reports ("AERs") from health care providers reporting that the Cordis IVC filters were fracturing
10 post-implantation and that fractured pieces and/or the entire device was migrating to other areas of the
11 body, including the heart and lungs.

12 81. Defendants also received large numbers of AERs reporting that the TrapEase filters and
13 OptEase filters were found to have excessively tilted, perforated the IVC, or caused thrombosis or
14 stenosis of the vena cava post-implantation.

15 82. These failures were often associated with severe patient injuries such as:

- 16 a. Death;
- 17 b. Hemorrhage;
- 18 c. Cardiac/pericardial tamponade (pressure caused by a collection of blood in the area
19 around the heart);
- 20 d. Cardiac arrhythmia and other symptoms similar to myocardial infarction;
- 21 e. Severe and persistent pain;
- 22 f. Perforations of tissue, vessels and organs;
- 23 g. Chronic deep vein thrombosis;
- 24 h. Pulmonary embolism; and,
- 25 i. Compartment syndrome.

26 83. These failures and resulting injuries are attributable, in part, to the fact that the Cordis
27 IVC filter design was unable to withstand the normal anatomical and physiological loading cycles
28 exerted *in vivo*.

1 84. Recent medical studies have confirmed what Defendants have known or should have
2 known since shortly after the release of each of these filters – not only do Cordis IVC filters fail at
3 alarming rates, but they also fail at rates substantially higher than other available IVC filters. For
4 instance, a recent large medical study found that OptEase and TrapEase filters suffer fracture rates of
5 37.5% and 23.1% respectively, when left implanted a minimum of 46 months. Another recent study
6 found that the TrapEase filter had a 64% fracture rate when left in more than four years. Another study
7 found a statistically significant increased rate of caval thrombosis with the ObtEase filter compared to
8 Gunther Tulip and Recovery Filters.

9 85. As a minimum safety requirement, manufacturers must establish and maintain post-
10 market procedures to timely identify the cause of device failures and other quality problems and to take
11 adequate corrective action to prevent the recurrence of these problems.

12 86. Defendants failed to identify or acknowledge these device failures or determine their
13 causes.

14 87. Defendants failed to take timely and adequate remedial measures to correct known design
15 and manufacturing defects with the Cordis IVC filters.

16 88. Defendants also misrepresented and concealed the risks and benefits of the Cordis IVC
17 filters in the labeling and marketing distributed to the FDA, physicians and the public. For instance,
18 Defendants represented that their filters were safe and effective – more safe and effective than other
19 available IVC filters. However, there is no reliable evidence to support these claims and, to the
20 contrary, the Cordis IVC filters have been associated with a high rate of failure.

21 89. Defendants also represented that the design of these devices would eliminate the risk that
22 pieces of the devices could perforate the vena cava, that the devices could tilt, or that fractures could
23 occur and migrate throughout the body. The medical literature and AERs have proven these claims to be
24 false.

25 90. Defendants also marketed the OptEase filter as being “easy” to remove. However, it is
26 one of the most difficult filters to remove. Dr. William T. Kuo, an expert in the removal of IVC filters
27 and vascular surgery, has established an IVC Filter Clinic at Stanford University where his team
28 specializes in the removal of IVC filters that other vascular surgeons refuse to remove for fear of

1 rupturing the vena cava or other internal organs and causing great bodily harm or death to the patient.
2 Dr. Kuo wrote in *the Journal of Vascular Interventional Radiology* that the Cordis filters were the most
3 difficult to retrieve from patients, at least partially due to the design of the filters, which create greater
4 contact with the vein walls than competitors' filters.

5 91. This is particularly concerning because having an IVC filter for a prolonged period of
6 time increases the risk of developing chronic deep venous thrombosis, PE, IVC occlusion, post-
7 thrombotic syndrome, filter fracture, and caval perforation with pain and organ injury. Many patients
8 with IVC filters are now routinely managed with lifelong anticoagulation solely to reduce the risk of
9 having the filter in place, subjecting patients to the risks and inconvenience of anticoagulation.

10 92. Defendants also failed to adequately disclose the risks of these filters, such as migration,
11 fracture, perforation, tilt, thrombosis, the prothrombotic nature of the devices, that the devices may not
12 be retrievable, or that these failures were known to be causing severe injuries and death or the rate at
13 which these events were occurring.

14 93. Cordis' labeling was additionally defective in that it directed physicians to implant the
15 OptEase filter upside down. When the OptEase filter was placed as directed by the labeling, the hooks
16 designed to ensure stability were facing in the wrong direction, rendering an already inadequate
17 anchoring system even further defective. As Cordis now explain in its labeling, implanting the device in
18 this fashion "can result in life threatening or serious injury including, but not limited to dissection, vessel
19 perforation, migration of the filter with secondary damage to cardiac structures, ineffective pulmonary
20 embolism prevention or death."

21 94. Cordis began a series of recalls on March 29, 2013 relating to its labeling, which
22 instructed physicians to implant the devices upside down. These recalls were not timely, nor did they
23 fully correct the defects in Defendants' labeling. Further, Defendants downplayed the danger patients
24 were exposed to and failed to take adequate steps to ensure patients actually received notice of the recall.

25 95. The FDA classified the initial recall as a Class I recall, which is the most serious type of
26 recall and involves situations in which the FDA has determined there is a reasonable probability that use
27 of these products will cause serious adverse health consequences or death.
28

1 96. Defendants have admitted that any patients implanted with one of these recalled units
2 should receive medical monitoring. Specifically, these patients should undergo imaging to ascertain
3 whether or not the device was properly deployed and, if not, be assessed for removal.

4 97. Given the unreasonably high failure and injury rates associated with Cordis IVC filters
5 when left implanted long-term, Defendants should be required to pay for medical monitoring to assess
6 the condition of these devices and whether or not retrieval should be undertaken.

7 98. On April 5, 2016, at the annual Society of Interventional Radiology in Vancouver,
8 Canada, Dr. Steven Wang, an interventional radiologist from Palo Alto, California who is affiliated with
9 Kaiser Permanente, presented the results of a retrospective study involving 96 patients in which he
10 sought to understand the prevalence of long-term (greater than 46 months) complications of both
11 permanent and retrievable IVC filters. The study looked at all inferior vena cava filters implanted in
12 patients from January 2007 through December 2009 at multiple health care facilities across the United
13 States. Dr. Wang then identified all patients who had imaging of the filter taken at four years or more
14 after implantation. Of those patients (96), he then evaluated the imaging to determine whether the IVC
15 filter had malfunctioned. After reviewing the data, the authors concluded that device complications at
16 four or more years after implantation "are relatively common." They also found that the Cordis OptEase
17 and TrapEase IVC filters suffered fracture rates of 37.5% and 23.1%, respectively.

18 **ESTOPPEL FROM PLEADING STATUTES OF LIMITATIONS OR REPOSE**

19 99. Plaintiffs incorporate by reference all prior allegations.

20 100. Plaintiffs are within the applicable statute of limitations for their claims because Plaintiffs
21 (and their healthcare professionals) did not discover, and could not reasonably discover, the defects and
22 unreasonably dangerous condition of their Cordis IVC filters.

23 101. Plaintiffs' ignorance of the defective and unreasonably dangerous nature of the Cordis
24 IVC filters, and the causal connection between these defects and each Plaintiff's injuries and damages, is
25 due in large part to Defendants' acts and omissions in fraudulently concealing information from the
26 public and misrepresenting and/or downplaying the serious threat to public safety its products present.
27
28

102. In addition, Defendants are estopped from relying on any statutes of limitation or repose by virtue of unclean hands, acts of fraudulent concealment, affirmative misrepresentations and omissions.

103. Such conduct includes intentional concealment from Plaintiffs, their health care professionals, and the general consuming public of material information that Cordis IVC filters had not been demonstrated to be safe or effective, and carried with them the risks and dangerous defects described herein.

104. Defendants had a duty to disclose the fact that Cordis IVC filters are not safe or effective, not as safe as other filters on the market, defective, and unreasonably dangerous, and that their implantation and use carried with it the serious risk of developing perforation, migration, tilting, and/or fracture, and/or other injuries referenced herein.

FIRST CAUSE OF ACTION

STRICT PRODUCTS LIABILITY – DESIGN DEFECT

(By All Plaintiffs, As to All Defendants)

105. Plaintiffs incorporate by reference all prior allegations.

106. At all relevant times, Defendants designed, tested, distributed, manufactured, advertised, sold, marketed and otherwise placed into the stream of commerce Cordis IVC filters – the TrapEase filters and the OptEase filters – for use by consumers, such as Plaintiffs, in the United States.

107. Defendants' Cordis IVC filters were expected to, and did, reach Defendants' intended consumers, handlers, and persons coming into contact with the product without substantial change in the condition in which they were researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Defendants.

108. The devices implanted in Plaintiffs were in an unreasonably dangerous condition at the time they left Defendants' control.

109. At all times relevant, Cordis IVC filters were manufactured, designed and labeled in an unsafe, defective, and inherently dangerous condition which was dangerous for use by the public in general and Plaintiffs in particular.

110. Defendants' Cordis IVC filters, as researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Defendants were defective in design and formulation and unreasonably dangerous in that when they left the hands of Defendants' manufacturers and/or suppliers, the foreseeable risks exceeded the alleged benefits associated with the use of Cordis IVC filters, and the devices were more dangerous than the ordinary customer would expect.

111. Physicians implanted Cordis IVC filters as instructed via the Instructions for Use and in a foreseeable manner as normally intended, recommended, promoted, and marketed by Defendants.

112. Plaintiffs received and utilized Defendants' IVC filters in a foreseeable manner as normally intended, recommended, promoted, and marketed by Defendants.

113. At the time Defendants placed their defective and unreasonably dangerous Cordis IVC filters into the stream of commerce commercially, technologically, and scientifically feasible alternative designs were attainable and available.

114. These alternative designs would have prevented the harm resulting in each Plaintiff's Injuries and Damages without substantially impairing the reasonably anticipated or intended function of Cordis IVC filters.

115. Neither Plaintiffs nor their health care providers could have, by the exercise of reasonable care, discovered the defective condition or perceived the unreasonable dangers with these devices prior to Plaintiffs' implantation with the Cordis IVC filters.

116. As a direct and proximate result of the defective and unreasonably dangerous condition of Cordis IVC filters, Plaintiffs suffered Injuries and Damages.

SECOND CAUSE OF ACTION

STRICT PRODUCTS LIABILITY – INADEQUATE WARNING

(By All Plaintiffs, As to All Defendants)

117. Plaintiffs incorporate by reference all prior allegations.

118. At all relevant times, Defendants engaged in the business of testing, developing, designing, manufacturing, packaging, labeling, marketing and/or promoting, selling and/or distributing Cordis IVC filters – the TrapEase filters and the OptEase filters – and through that conduct have

1 knowingly and intentionally placed Cordis IVC filters into the stream of commerce with full knowledge
2 that they reach consumers such as Plaintiffs who would become implanted with them.

3 119. Defendants did, in fact, test, develop, design, manufacture, package, label, market and/or
4 promote, sell and/or distribute their Cordis IVC filters to Plaintiffs, their prescribing health care
5 professionals, and the consuming public. Additionally, Defendants expected that the Cordis IVC filters
6 they were selling, distributing, supplying, manufacturing, and/or promoting to reach, and did, in fact,
7 reach, prescribing health care professionals and consumers, including Plaintiffs and their prescribing
8 health care professionals, without any substantial change in the condition of the product from when it
9 was initially distributed by Defendants.

10 120. The Cordis IVC filters had potential risks and side effects that were known or knowable
11 to Defendants by the use of scientific inquiry and information available before, at, and after the
12 manufacture, distribution, and sale of the Cordis IVC filters.

13 121. Defendants knew or should have known of the defective condition, characteristics, and
14 risks associated with Cordis IVC filters. These defective conditions included, but were not limited to:
15 (1) Cordis IVC filters posed a significant and higher risk of failure than other similar IVC filters
16 (fracture, migration, tilting, and perforation of the vena cava wall); (2) Cordis IVC filter failures result in
17 serious injuries and death; (3) certain conditions or post-implant procedures, such as morbid obesity or
18 open abdominal procedures, could affect the safety and integrity of Cordis IVC filters; (4) leaving
19 Cordis IVC filters in for a period longer than necessary to prevent immediate risk of pulmonary
20 embolism increases the risk for patients of failures and complications with the filter, such as the filter
21 becoming deeply embedded in the vena cava, making them difficult or impossible for removal.

22 122. Defendants placed into the stream of commerce for ultimate use by users like Plaintiffs
23 and their health care providers, Cordis IVC filters that were in an unreasonably dangerous and defective
24 condition due to warnings and instructions for use that were inadequate, including, but not limited to
25 Defendants' failure to:

- 26 a. Provide adequate instructions for how long in patients the filter should remain;
- 27 b. Highlight the importance of removing the filter;
- 28 c. Warn of the known risk of great bodily harm or death if the filter was not removed;

d. Highlight the known risk of great bodily harm or death in the event of occlusion of the vein caused by the filter itself;

e. Warn of the risk of new DVT if the filter was left in too long; Warn of the risk of new pulmonary embolism, thrombosis, swelling, and pain in the lower extremities if the filter was left in too long; and

f. Warn of the risk of filter perforation, fracture, or migration.

123. Cordis IVC filters were in a defective and unsafe condition that was unreasonably and substantially dangerous to any user or consumer implanted with Cordis IVC filters, such as Plaintiffs, when used in an intended or reasonably foreseeable way.

124. The warnings and directions Defendants provided with their Cordis IVC filters failed to adequately warn of the potential risks and side effects of Cordis IVC filters.

125. These risks were known or were reasonably scientifically knowable to Defendants, but not known or recognizable to ordinary consumers, such as Plaintiffs, or their treating doctors.

126. Defendants' IVC filters were expected to and did reach Plaintiffs without substantial change in their condition, labeling, or warnings as manufactured, distributed, and sold by Defendants.

127. Additionally, Plaintiffs and their physicians used Cordis IVC filters – the TrapEase filters or the OptEase filters – in the manner in which they were intended to be used, making such use reasonably foreseeable to Defendants.

128. As a direct and proximate result of Defendants' information defects, lack of sufficient instructions or warnings prior to, on, and after the date Plaintiffs used Cordis IVC filters, Plaintiffs suffered Injuries and Damages.

THIRD CAUSE OF ACTION

STRICT PRODUCTS LIABILITY – MANUFACTURING DEFECT

(By All Plaintiffs, As to All Defendants)

129. Plaintiffs incorporate by reference all prior allegations.

130. Prior to, on, and after the date the Cordis IVC filters – the TrapEase filter or the OptEase filter – were implanted in Plaintiffs, Defendants designed, distributed, manufactured, sold, and marketed Cordis IVC filters for use in the United States, including California.

131. At all relevant times, Defendants designed, distributed, manufactured, marketed, and sold Cordis IVC filters that were unreasonably dangerous, unsafe, and defective in manufacture when they left Defendants' possession.

132. Upon information and belief, Cordis IVC filters contain a manufacturing defect, in that they differed from the manufacturer's design or specifications, or from other typical units of the same product line.

133. As a direct and proximate cause of Defendants' design, manufacture, marketing, and sale of Cordis IVC filters prior to, on, and after the date Plaintiffs used the Cordis IVC filters, Plaintiffs suffered Injuries and Damages.

FOURTH CAUSE OF ACTION

NEGLIGENCE

(By All Plaintiffs, As to All Defendants)

134. Plaintiffs incorporate by reference all prior allegations.

135. At the time of the design, distribution, manufacture, advertising, sale, and marketing of Cordis IVC filters – the TrapEase filters and the OptEase filters – and their implantation in Plaintiffs, Defendants were aware that Cordis IVC filters were designed and manufactured in a manner presenting:

- a. An unreasonable risk of fracture of portions of the filters;
- b. An unreasonable risk of migration of the filters and/or portions of the filters;
- c. An unreasonable risk of filters tilting and/or perforating the vena cava wall; and
- d. Insufficient strength or structural integrity to withstand normal placement within the human body.

136. At the time of the design, distribution, manufacture, advertising, sale, and marketing of Cordis IVC filters, and their implantation in Plaintiffs, Defendants were also aware that Cordis IVC filters:

- a. Would be used without inspection for defects;
- b. Would be used by patients with special medical conditions such as Plaintiffs;
- c. Had previously caused serious bodily injury to its users with special medical conditions such as Plaintiffs;

- d. Had no established efficacy;
- e. Were less safe and effective than the predicate IVC filters already available on market;
- f. Would be implanted in patients where the risk outweighed any benefit or utility of the filters;
- g. Contained instructions for use and warnings that were inadequate; and
- h. Were prothombotic.

137. At the time of manufacture and sale of the TrapEase and OptEase filters, including the ones implanted in Plaintiffs, Defendants knew or should have known that using the TrapEase and OptEase filters as intended or in a reasonably foreseeable manner created a significant risk of patients suffering severe health side effects including, but not limited to: hemorrhage; cardiac/pericardial tamponade; cardiac arrhythmia and other symptoms similar to myocardial infarction; perforations of tissue, vessels and organs; chronic deep vein thrombosis; pulmonary embolism; thrombosis; compartment syndrome; and other severe personal injuries and diseases, which are permanent in nature, including, but not limited to, death, physical pain and mental anguish, scarring and disfigurement, diminished enjoyment of life, continued medical care and treatment due to chronic injuries/illness proximately caused by the device; and the continued risk of requiring additional medical and surgical procedures including general anesthesia, with attendant risk of life threatening complications.

138. Defendants had a duty to exercise due care and avoid unreasonable risk of harm to others in the design of Cordis IVC filters.

139. Defendants breached these duties by, among other things:

- a. Designing and distributing a product in which it knew or should have known that the likelihood and severity of potential harm from the product exceeded the burden of taking safety measures to reduce or avoid harm;
- b. Designing and distributing a product which it knew or should have known that the likelihood and severity of potential harm from the product exceeded the likelihood of potential harm from other IVC filters available for the same purpose;
- c. Failing to perform reasonable pre- and post-market testing of Cordis IVC filters to determine whether or not the products were safe for their intended use;

- d. Failing to use reasonable and prudent care in the design, research, manufacture, and development of Cordis IVC filters so as to avoid the risk of serious harm associated with the use of Cordis IVC filters;
 - e. Advertising, marketing, promoting, and selling Cordis IVC filters for uses other than as approved and indicated in the products' labels;
 - f. Failing to use reasonable care to warn or instruct, including pre and post-sale, Plaintiffs, their prescribing physicians, or the general health care community about the TrapEase and OptEase filters' substantially dangerous condition or about facts making the products likely to be dangerous;
 - g. Advertising, marketing and recommending the use of the TrapEase and OptEase filters, while concealing and failing to disclose or warn of the dangers known by Defendants to be connected with and inherent in the use of these filter systems;
 - h. Representing that the TrapEase and OptEase filters were safe for their intended use when, in fact, Defendants knew and should have known the products were not safe for their intended uses;
 - i. Continuing to manufacture and sell the TrapEase and OptEase filters with the knowledge that said products were dangerous and not reasonably safe, and failing to comply with good manufacturing regulations;
 - j. Failing to establish an adequate quality assurance program used in the manufacturing of Cordis IVC filters; and
 - k. Failing to perform adequate evaluation and testing of Cordis IVC filters when such evaluation and testing would have revealed the propensity of Cordis IVC filters to cause injuries similar to those that Plaintiffs suffered.
140. At all relevant times, Defendants had a duty to exercise due care in the manufacturing of Cordis IVC filters.
141. Defendants breached this duty by, among other things:

- a. Failing to adopt manufacturing processes that would reduce the foreseeable risk of product failure;
- b. Failing to use reasonable care in manufacturing the product and by producing a product that differed from their design or specifications or from other typical units from the same production line;
- c. Failing to use reasonable and prudent care in the design, research, manufacture, and development of Cordis IVC filters and their manufacturing process so as to avoid the risk of serious harm associated with the use of Cordis IVC filters; and
- d. Failing to establish an adequate quality assurance program used in the manufacturing of their IVC filters.

142. At this time, all Cordis IVC filters – the TrapEase filters and the OptEase filters – are misbranded and adulterated by virtue of them failing to be the substantial equivalent of predicate IVC filter devices, making them subject to corrective action, including recall, in the interest of patient safety.

143. Prior to, on, and after the date of Plaintiffs' implantation with a Cordis IVC filter, and at all relevant times, Defendants knew or reasonably should have known that Cordis IVC filters and their warnings were defective and dangerous or were likely to be dangerous when used in a reasonably foreseeable manner.

144. Prior to, on, and after the date of Plaintiffs' implantation with a Cordis IVC filter and at all relevant times thereafter, Defendants became aware that the defects of Cordis IVC filters resulted in Cordis IVC filters causing injuries similar to those Plaintiffs suffered.

145. Reasonable manufacturers and distributors under the same or similar circumstances would have recalled or retrofitted Cordis IVC filters, and would thereby have avoided and prevented harm to many patients, including Plaintiffs.

146. In light of this information and Defendants' knowledge described above, Defendants had a duty to recall and/or retrofit Cordis IVC filters.

147. Defendants breached its duty to recall and/or retrofit Cordis IVC filters.

FIFTH CAUSE OF ACTION

NEGLIGENT MISREPRESENTATION

(By All Plaintiffs, As to All Defendants)

155. Plaintiffs incorporate by reference all prior allegations.

156. Prior to, on, and after the dates during which Plaintiffs were implanted with the Cordis IVC filters – the TrapEase filters and the OptEase filters – Defendants negligently and carelessly represented to Plaintiffs, their treating physicians, and the general public that certain material facts were true. The representations include, *inter alia*, the following:

- a. That the Cordis IVC filters were safe, fit, and effective for use;
- b. That the design of the Cordis IVC filters eliminated the risk that pieces of the device could perforate the vena cava, that the devices could tilt, or that fractures could occur and migrate throughout the body;
- c. That the Cordis IVC filters were safe and more effective than other available IVC filters.
- d. That the OptEase fiber was “easy” to remove; and,

157. Prior to, on, and after the dates during which Plaintiffs and their physicians purchased and used the device, said representations were untrue, and there was no reasonable ground for Defendants to believe said representations were true when Defendants made said representations.

158. Prior to, on, and after the dates during which Plaintiffs and their physicians purchased and used the device, Defendants intended that Plaintiffs, their physicians, and the general public would rely on said representations, which did in fact occur.

159. Defendants owed a duty in all of its undertakings, including the dissemination of information concerning its IVC filters, to exercise reasonable care to ensure that it did not in those undertakings create unreasonable risks of personal injury to others.

160. Defendants disseminated to health care professionals and consumers through published labels, labeling, marketing materials, and otherwise information concerning the properties and effects of Cordis IVC filters with the intention that health care professionals and consumers would rely upon that information in their decisions concerning whether to prescribe and use Defendants’ IVC filters.

161. Defendants, as medical device designers, manufacturers, sellers, promoters and/or distributors, knew or should reasonably have known that health care professionals and consumers, in weighing the potential benefits and potential risks of prescribing or using Cordis IVC filters, would rely upon information disseminated and marketed by Defendants to them regarding the Cordis IVC filters.

162. Defendants failed to exercise reasonable care to ensure that the information they disseminated to health care professionals and consumers concerning the properties and effects of Cordis IVC filters was accurate, complete, and not misleading and, as a result, disseminated information to health care professionals and consumers that was negligently and materially inaccurate, misleading, false, and unreasonably dangerous to consumers such as Plaintiffs.

163. Defendants, as designers, manufacturers, sellers, promoters, and/or distributors, also knew or reasonably should have known that patients receiving Cordis IVC filters as recommended by health care professionals in reliance upon information disseminated by Defendants as the manufacturer/distributor of Defendants' IVC filters would be placed in peril of developing the serious, life-threatening, and life-long injuries including, but not limited to, tilting, migration, perforation; fracture, lack of efficacy, and increased risk of the development of blood clots, if the information disseminated and relied upon was materially inaccurate, misleading, or otherwise false.

164. Defendants had a duty to promptly correct material misstatements Defendants' knew others were relying upon in making healthcare decisions.

165. Defendants failed in each of these duties by misrepresenting to Plaintiffs and the medical community the safety and efficacy of Cordis IVC filters and failing to correct known misstatements and misrepresentations.

166. As a direct and proximate result of Defendants' negligent misrepresentations, Plaintiffs suffered Injuries and Damages.

SIXTH CAUSE OF ACTION

FRAUDULENT MISREPRESENTATION

(By All Plaintiffs, As to All Defendants)

167. Plaintiffs incorporate by reference all prior allegations.

168. At all times relevant to this cause, and as detailed above, Defendants intentionally provided Plaintiffs, their physicians, the medical community, and the public at large with false or inaccurate information. Defendants also omitted material information concerning Cordis IVC filters (the TrapEase filters and the OptEase filters), including, but not limited to, misrepresentations regarding the following topics:

- a. The safety of the Cordis IVC filters;
- b. The efficacy of the Cordis IVC filters;
- c. The rate of failure of the Cordis IVC filters;
- d. The pre-market testing of the Cordis IVC filters;
- e. The approved uses of the Cordis IVC filters; and

1 f. The ability to retrieve the device at any time over a person's life.

2 169. The information Defendants distributed to the public, the medical community, and
3 Plaintiffs was in the form of reports, press releases, advertising campaigns, labeling materials, print
4 advertisements, commercial media containing material representations, and instructions for use, as well
5 as through their officers, directors, agents, and representatives.

6 170. These materials contained false and misleading material representations, which included:
7 that Cordis IVC filters were safe and fit when used for their intended purpose or in a reasonably
8 foreseeable manner; that they did not pose dangerous health risks in excess of those associated with the
9 use of other similar IVC filters; that any and all side effects were accurately reflected in the warnings;
10 and that they were adequately tested to withstand normal placement within the human body.

11 171. Defendants made the foregoing misrepresentations knowing that they were false or
12 without reasonable basis. These materials included instructions for use and a warning document that
13 was included in the package of the Cordis IVC filters that were implanted in Plaintiffs.

14 172. Defendants' intent and purpose in making these misrepresentations was to deceive and
15 defraud the public and the medical community, including Plaintiffs' health care providers; to gain the
16 confidence of the public and the medical community, including Plaintiffs' health care providers; to
17 falsely assure the public and the medical community of the quality of Cordis IVC filters and their fitness
18 for use; and to induce the public and the medical community, including Plaintiffs' health care providers
19 to request, recommend, prescribe, implant, purchase, and continue to use Cordis IVC filters, all in
20 reliance on Defendants' misrepresentations.

21 173. The foregoing representations and omissions by Defendants were false.

22 174. Defendants' IVC filters are not safe, fit, and effective for human use in their intended and
23 reasonably foreseeable manner.

24 175. Further, the use of Cordis IVC filters is hazardous to the users' health, and Cordis IVC
25 filters have a serious propensity to cause users to suffer serious injuries, including without limitation the
26 injuries Plaintiffs suffered.

27 176. Finally, Defendants' IVC filters have a statistically significant higher rate of failure and
28 injury than do other comparable IVC filters.

177. In reliance upon the false and negligent misrepresentations and omissions made by Defendants, Plaintiffs and their health care providers were induced to, and did use Cordis IVC filters, thereby causing Plaintiffs to sustain severe and permanent personal injuries.

178. Defendants knew and had reason to know that Plaintiffs, their health care providers, and the general medical community did not have the ability to determine the true facts intentionally and/or negligently concealed and misrepresented by Defendants, and would not have prescribed and implanted Cordis IVC filters if the true facts regarding Defendants' IVC filters had not been concealed and misrepresented by Defendants.

179. Defendants had sole access to material facts concerning the defective nature of the products and their propensities to cause serious and dangerous side effects in the form of dangerous injuries and damages to persons who were implanted with Cordis IVC filters.

180. At the time Defendants failed to disclose and intentionally misrepresented the foregoing facts, and at the time Plaintiffs used Cordis IVC filters, Plaintiffs and their health care providers were unaware of Defendants' misrepresentations and omissions.

181. As a direct and proximate result of Defendants' fraudulent misrepresentations, Plaintiffs suffered Injuries and Damages.

SEVENTH CAUSE OF ACTION

FRAUDULENT CONCEALMENT

(By All Plaintiffs, As to All Defendants)

182. Plaintiffs incorporate by reference all prior allegations.

183. In marketing and selling Cordis IVC filters (the TrapEase filters and the OptEase filters), Defendants concealed material facts from Plaintiffs and their healthcare providers.

184. These concealed material facts include, but are not limited to:

- a. Cordis IVC filters were unsafe and not fit when used for their intended purpose or in a reasonably foreseeable manner;
- b. Cordis IVC filters posed dangerous health risks in excess of those associated with the use of other similar IVC filters;

1 c. That there were additional side effects related to implantation and use of Cordis IVC
2 filters that were not accurately and completely reflected in the warnings associated with
3 Cordis IVC filters; and

4 d. That Cordis IVC filters were not adequately tested to withstand normal placement within
5 the human body.

6 185. Plaintiffs and their health care providers were not aware of these and other facts
7 concealed by Defendants.

8 186. In concealing these and other facts, Defendants intended to deceive Plaintiffs and their
9 health care providers.

10 187. Plaintiffs and their health care providers were ignorant of and could not reasonably
11 discover the facts Defendants fraudulently concealed and reasonably and justifiably relied on
12 Defendants' representations concerning the supposed safety and efficacy of Cordis IVC filters.

13 188. As a direct and proximate result of Defendants' fraudulent concealment of material facts,
14 Plaintiffs suffered Injuries and Damages.

15 **EIGHTH CAUSE OF ACTION**

16 **BREACH OF EXPRESS WARRANTY**

17 **(By All Plaintiffs, As to All Defendants)**

18 189. Plaintiffs incorporate by reference all prior allegations.

19 190. Plaintiffs, through their medical providers, purchased a Cordis IVC filter from
20 Defendants.

21 191. At all relevant times, Defendants were merchants of goods of the kind including medical
22 devices and vena cava filters (i.e.. Cordis IVC filters).

23 192. At the time and place of sale, distribution, and supply of Cordis IVC filters to Plaintiffs
24 (and to other consumer and the medical community), Defendants expressly represented and warranted
25 that Cordis IVC filters were safe; that they were well-tolerated, efficacious, fit for their intended
26 purpose, and of marketable quality; that they did not produce any unwarned-of dangerous side effects;
27 and that they was adequately tested.
28

193. At the time of Plaintiffs' purchase from Defendants, Cordis IVC filters were not in a merchantable condition, and Defendants breached its expressed warranties, in that Cordis IVC filters, among other things:

- a. Were designed in such a manner so as to be prone to an unreasonably high incidence of fracture, perforation of vessels and organs, and/or migration;
- b. Were designed in such a manner so as to result in a unreasonably high incidence of injury to the vessels and organs of its purchaser;
- c. Were manufactured in such a manner that the exterior surface of the filter was inadequately, improperly, and inappropriately constituted, causing the device to weaken and fail;
- d. Were unable to be removed at any time during a person's life;
- e. Were not efficacious in the prevention of pulmonary emboli;
- f. Carried a risk of use outweighed any benefit; and
- g. Were not self-centering.

194. As a direct and proximate result of Defendants' breach of express warranty, Plaintiffs suffered Injuries and Damages.

NINTH CAUSE OF ACTION

BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY

(By All Plaintiffs, As to All Defendants)

195. Plaintiffs incorporate by reference all prior allegations.

196. Defendants impliedly warranted that Cordis IVC filters were of merchantable quality and safe and fit for the use for which Defendants intended them, and Plaintiff in fact used them.

197. Defendants breached its implied warranties by, among other things:

- a. Failing to provide adequate instruction that a manufacturer exercising reasonable care would have provided concerning the likelihood that Cordis IVC filters would cause harm;
- b. Manufacturing and/or selling Cordis IVC filters when those filters did not conform to representations made by Defendants when they left Defendants' control;

- c. Manufacturing and/or selling Cordis IVC filters that were more dangerous than an ordinary consumer would expect when used in an intended or reasonably foreseeable manner;
- d. Manufacturing and/or selling Cordis IVC filters that carried foreseeable risks associated with the Cordis IVC filter design or formulation which exceeded the benefits associated with that design;
- e. Manufacturing and/or selling Cordis IVC filters when they deviated in a material way from the design specifications, formulas, or performance standards or from otherwise identical units manufactured to the same design specifications, formulas, or performance standards; and
- f. Impliedly representing that its filters would be effective in the prevention of pulmonary emboli.

198. At the time Plaintiffs and their physicians purchased and used the devices, the products were not in a merchantable condition in that:

- a. They offered no benefit to patient outcomes,
- b. They suffered an unreasonably high failure and injury rates,
- c. The surface of the devices were manufactured and designed in such a way that they were distributed with surface damage that substantially increased the risk of fracture, and
- d. They were prothrombotic;

199. As a direct and proximate result of Defendants' breach of its implied warranty, Plaintiffs suffered Injuries and Damages.

PUNITIVE DAMAGES ALLEGATIONS

(By All Plaintiffs, As to All Defendants)

200. Plaintiffs incorporate by reference all prior allegations.

201. At all times material hereto, Defendants knew or should have known that Cordis IVC filters were unreasonably dangerous with respect to the risk of tilt, fracture, migration and/or perforation.

1 202. At all times material hereto, Defendants attempted to misrepresent and did knowingly
2 misrepresent facts concerning the safety of Cordis IVC filters.

3 203. Defendants' misrepresentations included knowingly withholding material information
4 from the medical community and the public, including Plaintiffs' physicians, concerning the safety of its
5 Cordis IVC filters. Data establishes that the failure rates of the TrapEase and OptEase filters are and
6 were much higher than what Defendants have in the past and currently continue to publish to the
7 medical community and members of the public.

8 204. Defendants' conduct, alleged throughout this Complaint, was willful, wanton, and
9 undertaken with a conscious indifference and disregard to the consequences that consumers of their
10 products faced, including Plaintiffs. Defendants had actual knowledge of the dangers presented by
11 Cordis IVC filters, yet consciously failed to act reasonably to inform or warn Plaintiffs, Plaintiffs'
12 physicians or the public at large of these dangers. Defendants consciously failed to establish and
13 maintain an adequate quality and post-market surveillance system.

14 205. At all times material hereto, Defendants knew and recklessly disregarded the fact that
15 Cordis IVC filters have an unreasonably high rate of tilt, fracture, migration, and/or perforation.

16 206. Notwithstanding the foregoing, Defendants continued to market Cordis IVC filters
17 aggressively to consumers, including Plaintiffs, without disclosing the aforesaid side effects.

18 207. Defendants knew of their Cordis IVC filters' lack of warnings regarding the risk of
19 fracture, migration, and/or perforation, but intentionally concealed and/or recklessly failed to disclose
20 that risk and continued to market, distribute, and sell its filters without said warnings so as to maximize
21 sales and profits at the expense of the health and safety of the public, including Plaintiffs, in conscious
22 disregard of the foreseeable harm caused by Cordis IVC filters.

23 208. Defendants' intentional and/or reckless failure to disclose information deprived
24 Plaintiffs' physicians of necessary information to enable them to weigh the true risks of using Cordis
25 IVC filters against its benefits.

26 209. Defendants' conduct is reprehensible, evidencing an evil hand guided by an evil mind
27 and was undertaken for pecuniary gain in reckless and conscious disregard for the substantial risk of
28 death and physical injury to consumers, including Plaintiffs.

1 210. Such conduct justifies an award of punitive or exemplary damages in an amount
2 sufficient to punish Defendants' conduct and deter like conduct by Defendants and other similarly
3 situated persons and entities in the future.

4 **PRAYER FOR DAMAGES**

5 WHEREFORE, Plaintiffs demand judgment against Defendants for:

6 a. General (non-economic) damages, including, without limitation, past and future pain and
7 suffering; past and future emotional distress; past and future loss of enjoyment of life; and other
8 consequential damages as allowed by law;

9 b. Special (economic) damages, including, without limitation, past and future medical
10 expenses; past and future lost wages and loss of earning capacity; and other consequential damages as
11 allowed by law;

12 c. Punitive damages in an amount sufficient to punish Defendants and deter similar conduct
13 in the future;

14 d. Disgorgement of profits;

15 e. Restitution;

16 f. Statutory damages, where authorized;

17 g. Costs of suit;

18 h. Reasonable attorneys' fees, where authorized;

19 i. Prejudgment interest as allowed by law;

20 j. Post-judgment interest at the highest applicable statutory or common law rate from the
21 date of judgment until satisfaction of judgment;

22 k. Such other additional and further relief as Plaintiffs may be entitled to in law or in equity.
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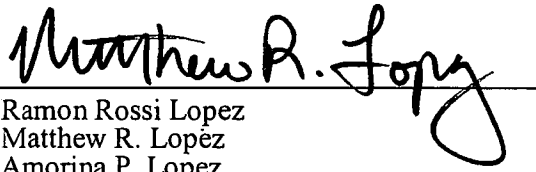
DEMAND FOR JURY TRIAL

Plaintiffs hereby demand a trial by jury on all triable issues.

Dated: May 13, 2016

Respectfully submitted,

LOPEZ McHUGH LLP

By: 
Ramon Rossi Lopez
Matthew R. Lopez
Amorina P. Lopez

-And-

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FILED
 ALAMEDA COUNTY

MAY 06 2016

CLERK OF THE SUPERIOR COURT
 By [Signature] Deputy

**SUPERIOR COURT OF CALIFORNIA, COUNTY OF ALAMEDA
 RENE C. DAVIDSON ALAMEDA COUNTY COURTHOUSE**

8
 9 DAVID RESOVSKY, GEORGE TODD, DAVID)
 BROWN, GWEN KRAMER)

Case No.

RG16814745

Plaintiff(s),

COMPLAINT FOR DAMAGES

vs.

DEMAND FOR JURY TRIAL

12
 13 CORDIS CORPORATION, a corporation,
 and DOES 1 through 100, inclusive,

Defendant(s).

17
 18 Plaintiffs DAVID RESOVSKY, GEORGE TODD, DAVID BROWN, AND GWEN

19 KRAMER hereby sue defendants CORDIS CORPORATION and DOES 1 through 100 and allege
 20 as follows:

PARTIES

22 1. Plaintiff David Resovsky underwent placement of an OptEase™ Permanent Vena
 23 Cava Filter (referred to as "filter," "device" or "product" hereinafter) at Cleveland Clinic in Ohio.
 24 The device subsequently malfunctioned and caused, *inter alia*, thrombosis of the inferior vena cava.
 25 As a result of the malfunction, Mr. Resovsky has suffered life-threatening injuries and damages and
 26 required extensive medical care and treatment. Plaintiff has suffered and will continue to suffer
 27

1 significant medical expenses, extreme pain and suffering, loss of enjoyment of life, disability, and
2 other losses.

3 2. Plaintiff George Todd was implanted with an OptEase™ filter in October 2006 at
4 Aventura Hospital & Medical Center in Florida. The device subsequently tilted and perforated the
5 vena cava. As a result, he suffered, *inter alia*, bilateral pulmonary emboli and the device cannot be
6 removed. Plaintiff has suffered and will continue to suffer significant medical expenses, extreme
7 pain and suffering, loss of enjoyment of life, disability, and other losses.

8 3. Plaintiff David Brown was implanted with an OptEase™ filter on November 4, 2014
9 at Hannibal Regional Hospital in Missouri. On February 5, 2015 he underwent a procedure to
10 remove the device. The attempt failed secondary to the device having tilted and migrated after
11 placement. Plaintiff has suffered medical expenses, pain and suffering, loss of enjoyment of life,
12 and other losses.

13 4. Plaintiff Gwen Kramer underwent implantation of two OptEase™ filters on October
14 28, 2013. The first filter immediately migrated to the “origin of the left iliac vein.” This filter was
15 removed percutaneously. Another OptEase™ filter was then placed and this filter also migrated
16 proximally with the distal portion of the filter being proximal to the renal veins. This filter was left
17 in place. Given the migration of the second filter, Ms. Kramer is at increased risk of fracture,
18 perforation and the device will be less effective at stopping clots. Plaintiff has suffered and will
19 continue to suffer significant medical expenses, extreme pain and suffering, loss of enjoyment of
20 life, disability, and other losses.

21 5. All of the above plaintiffs underwent placement in, and were residents of, the United
22 States at the time these devices were implanted and when the devices subsequently failed and
23 caused injury.

24 6. Defendant Cordis Corporation (“Cordis”) is a corporation organized under the laws of
25 the State of Florida, with its principal place of business at 6500 Paseo Padre Pkwy, Fremont,
26

1 California, 94555. Cordis at all times relevant to this action, designed, set specifications for,
2 manufactured, prepared, compounded, assembled, processed, marketed, distributed, and sold the
3 OptEase™ Vena Cava Filter ("OptEase filter") to be implanted in patients throughout the United
4 States, including California. Cordis may be served with process by serving its registered agent, CT
5 Corporation System, at 818 West Seventh Street Suite 930, Los Angeles, California 90017.
6

7 7. The true names and/or capacities, whether individual, corporate, partnership,
8 associate, governmental, or otherwise, of Defendant DOES 1 through 100, inclusive, are unknown
9 to Plaintiffs at this time, who therefore sue said Defendants by such fictitious names. Plaintiffs are
10 informed and believe, and thereon allege, that each Defendant designated herein as a DOE caused
11 injuries and damages proximately thereby to Plaintiffs as is hereinafter alleged, and that each DOE
12 defendant is liable to Plaintiffs for the acts and omissions alleged herein below and the injuries and
13 damages resulting therefrom. Plaintiffs seek leave to amend this Complaint to allege the true names
14 and capacities of said DOE defendants when the same are ascertained.

15 8. Plaintiffs are informed and believe, and thereon allege, that at all times herein
16 mentioned, the Defendant and each of the DOE defendants were the agent, servant, employee
17 and/or joint venturer of the other co-defendants, and each of them, and at all said times each
18 Defendant, including DOE defendants, were acting in the full course, scope, and authority of said
19 agency, service, employment and/or joint venture.

20 9. Plaintiffs are informed and believe, and thereon allege, that at all times mentioned
21 herein, Defendant and DOES 1 through 100, and each of them, were also known as, formerly
22 known as, and/or were the successors and/or predecessors in interest/business/product line/or a
23 portion thereof, assigns, a parent, a subsidiary (wholly or partially owned by, or the whole or partial
24 owner), affiliate, partner, co-venturer, merged company, alter egos, agents, equitable trustees and/or
25 fiduciaries of and/or were members in an entity or entities engaged in the funding, researching,
26 studying, manufacturing, fabricating, designing, developing, labeling, assembling, distributing,
27 supplying, leasing, buying, offering for sale, selling, inspecting, servicing, contracting others for
28 marketing, warranting, rebranding, manufacturing for others, packaging, and advertising the device.

1 10. Defendant and DOES 1 through 100, and each of them, are liable for the acts,
2 omissions and tortious conduct of its successors and/or predecessors in interest/business/product
3 line/or a portion thereof, assigns, parent, subsidiary, affiliate, partner, co-venturer, merged
4 company, alter ego, agent, equitable trustee, fiduciary and/or its alternate entities in that Defendant
5 and DOES 1 through 100, and each of them, enjoy the goodwill originally attached to each such
6 alternate entity, acquired the assets or product line (or a portion thereof), and in that there has been a
7 virtual destruction of Plaintiffs' remedy against each such alternate entity, and that each such
8 Defendant has the ability to assume the risk-spreading role of each such alternate entity.

9 11. Plaintiffs are informed and believe, and thereon allege that, at all times herein
10 mentioned, DOES 1 through 100, and each of them, were and are corporations organized and
11 existing under the laws of the State of California or the laws of some state or foreign jurisdiction;
12 that each of the said DOE defendants were and are authorized to do and are doing business in the
13 State of California and regularly conducted business in the State of California.

14 12. Upon information and belief, at all relevant times, DOES 1 through 100, and each of
15 them, were engaged in the business of researching, developing, designing, licensing, manufacturing,
16 distributing, selling, marketing, and/or introducing into interstate commerce and into the State of
17 California, either directly or indirectly through third parties or related entities, its products,
18 including the TrapEase and OptEase inferior vena cava filters.

19 13. At all relevant times, DOES 1 through 100, and each of them, conducted regular and
20 sustained business and engaged in substantial commerce and business activity in the State of
21 California, which included but was not limited to researching, developing, selling, marketing, and
22 distributing their products, including the TrapEase and OptEase inferior vena cava filters, in the
23 State of California.

24 14. Upon information and belief, at all relevant times, DOES 1 through 100, and each of
25 them, expected or should have expected that their acts would have consequences within the United
26 States including in the State of California, and said Defendants derived and continue to derive
27 substantial revenue therefrom.

28

1 15. "Cordis" and "Defendants" where used hereinafter, shall refer to all subsidiaries,
2 affiliates, divisions, franchises, partners, joint venturers, organizational units of any kind,
3 predecessors, successors, assigns, officers, directors, employees, agents and representatives of
4 Cordis Corporation; as well as DOE Defendants 1 through 100, and each of them.

5
6 **JURISDICTION AND VENUE**

7 16. This Court has jurisdiction over all causes of action alleged in this Complaint
8 pursuant to the California Constitution, Article VI, § 10.

9 17. Venue is proper in this Court, pursuant to *Code of Civil Procedure*, as Defendant
10 Cordis has its principal place of business in Alameda County.
11

12 **BACKGROUND**

13 **INFERIOR VENA CAVA FILTERS GENERALLY**

14 18. Inferior vena cava ("IVC") filters first came on to the medical market in the 1960's.
15 Over the years, medical device manufacturers have introduced several different designs of IVC
16 filters.

17 19. An IVC filter is a device that is designed to filter or "catch" blood clots that travel
18 from the lower portions of the body to the heart and lungs. IVC filters are designed to be implanted,
19 either permanently or temporarily, in the inferior vena cava.

20 20. The inferior vena cava is a vein that returns deoxygenated blood to the heart from the
21 lower portions of the body. In certain people, for various reasons, blood clots travel from the
22 vessels in the legs and pelvis, through the vena cava and into the lungs. Oftentimes, these blood
23 clots develop in the deep leg veins, a condition called "deep vein thrombosis" or "DVT." Once
24 blood clots reach the lungs, they are considered "pulmonary emboli" or "PE." Pulmonary emboli
25 present risks to human health.

26 21. People at risk for DVT/PE can undergo medical treatment to manage the risk. For
27 example, a doctor may prescribe medications like Heparin, Warfarin, or Lovenox to regulate the
28

1 clotting factor of the blood. In some people who are at high risk for DVT/PE, or who cannot
2 manage their conditions with medications, physicians may recommend surgically implanting an
3 IVC filter to prevent thromboembolic events.

4 22. As stated above, IVC filters have been on the market for decades. All IVC filters are
5 only cleared for use by the FDA for prevention of recurrent pulmonary embolism in patients at risk
6 for pulmonary embolism and where anticoagulation has failed or is contraindicated. In 2003,
7 however, an explosion in off-label use began with the introduction of IVC filters that were cleared
8 for both permanent placement and optional removal. Most of this market expansion came from
9 uses such as prophylactic prevention of pulmonary embolism without a prior history of pulmonary
10 embolism.

11 23. Indeed, from 2000 through 2003 there was a race between manufactures to bring the
12 first IVC filter to market with the added indication of optional retrieval. In 2003, the FDA cleared
13 the first three (3) IVC filters for a retrieval indication. These were the OptEase filter (Cordis &
14 J&J), the Recovery Filter (C.R. Bard, Inc.) and the Gunther Tulip Filter (Cook Medical).

15 24. Upon information and belief, Plaintiffs allege that this market expansion and off-
16 label use was driven by baseless marketing campaigns made by Defendants targeting bariatric,
17 trauma, orthopedic and cancer patient populations.

18 25. The medical community has just recently begun to awaken to the fact that despite
19 marketing claims by Defendants, there is no reliable evidence that any IVC filter offers a benefit
20 and that these products expose patients to substantial safety hazards. For example, an October 2015
21 article published in the Annals of Surgery concerning trauma patients inserted with IVC filters
22 concluded that IVC filters were not effective in preventing pulmonary emboli, and instead actually
23 caused thrombi to occur.

24 26. Comparing the results of over 30,000 trauma patients who had not received IVC
25 filters with those who had received them, the Annals of Surgery study published its alarming
26 results: a) Almost twice the percentage of patients with IVC filters in the study died compared to
27 those that had not received them; b) Over five times the relative number of patients with IVC filters
28 developed DVTs. c) Over four times the relative percentage of patients with filters developed

1 thromboemboli. d) Over twice the percentage of patients developed a pulmonary embolus – the very
 2 condition Defendants represented to the FDA, physicians, and the public that its IVC filters would
 3 prevent.

4 27. Other studies have also revealed that these devices suffer common failure modes
 5 such as migration, perforation, thrombosis, fracture all of which can cause serious injury or death.
 6 For example, recent studies for Defendants IVC Filters have revealed fracture rates as high as 50%
 7 and recommend medical monitoring and/or removal.

8 28. These studies, including the *Annals of Surgery* study, have now shown that not only
 9 is there no reliable evidence establishing that IVC filters are efficacious but that they also pose
 10 substantial health hazards.

11 THE TRAPEASE™ AND OPTEASE™ IVC FILTERS

12
 13 29. On January 10, 2001, Defendants bypassed the more onerous Food and Drug
 14 Administration's ("FDA's") approval process for new devices and obtained "clearance" under
 15 Section 510(k) of the Medical Device Amendments to the Food, Drug, and Cosmetic Act to market
 16 the Trap Ease™ Permanent Vena Cava Filter and Introduction Kit ("TrapEase filter") as a
 17 permanent filter by claiming it was substantially equivalent in respect to safety, efficacy, design,
 18 and materials as the then already available IVC filters.

19 30. Section 510(k) permits the marketing of medical devices if the device is
 20 substantially equivalent to other legally marketed predicate devices without formal review for the
 21 safety or efficacy of the device. The FDA explained the difference between the 510(k) process and
 22 the more rigorous "premarket approval" ("PMA") process in its amicus brief filed with the Third
 23 Circuit in *Horn v. Thoratec Corp.*, which the court quoted from:

24 A manufacture can obtain an FDA findings of 'substantial equivalence' by
 25 submitting a premarket notification to the agency in accordance with section
 26 510(k) of the [Food Drug and Cosmetic Act.] 21 U.S.C. § 360(k). A device found
 27 to be 'substantially equivalent' to a predicate device is said to be 'cleared' by the
 28 FDA (as opposed to "approved" by the agency under a PMA).

1 376 F.3d 163, 167 (3d. Cir. 2004). A pre-market notification submitted under 510(k) is thus
2 entirely different from a PMA, which must include data sufficient to demonstrate that the produce
3 involved is safe and effective.

4 31. In *Medtronic, Inc. v. Lohr*, the U.S. Supreme Court similarly described the 510(k)
5 process, observing:

6
7 If the FDA concludes on the basis of the [manufacturer's] § 510(k) notification
8 that the device is 'substantially equivalent' to a pre-existing device, it can be
9 marketed without further regulatory analysis.... The § 510(k) notification process
10 is by no means comparable to the PMA process; in contrast to the 1,200 hours
11 necessary to complete a PMA review, the § 510(k) review is completed in average
12 of 20 hours As one commentator noted: "The attraction of substantial
13 equivalence to manufacturers is clear. Section 510(k) notification required little
14 information, rarely elicits a negative response from the FDA, and gets processed
15 quickly.

16 518 U.S. 470, 478-79 (1996).

17 32. Pursuant to *Wyeth v. Levine*, 555 U.S. 555 (2009), once a product is cleared "the
18 manufacturer remains under an obligation to investigate and report any adverse associated with the
19 drug...and must periodically submit any new information that may affect the FDA's previous
20 conclusions about the safety, effectiveness, or labeling" This obligation extends to post-market
21 monitoring of adverse events/complaints.

22 33. On September 18, 2002, Defendants sought clearance through the 510(k) process to
23 market the Cordis OptEase™ Permanent Vena Cava Filter ("OptEase filter") for the same indicated
24 uses as the TrapEase Filter. Defendants represented that the OptEase filter had the same basic
25 fundamental technology and was substantially equivalent in respect to safety and efficacy as the
26 predicate devices (TrapEase Filter, Gunther Tulip filter, and the Vena Tech LGM Vena Cava
27 Filter).

28 34. Defendants have further represented that the OptEase filter has the same design as
TrapEase filter except that unlike the TrapEase filter, which has proximal and distal anchoring barbs
located on each connecting strut for fixation of the filter to the vena cava wall, the OptEase filter

1 has anchoring barbs for fixation of the filter only on the superior end of each of the six straight
2 struts and has a hook at the inferior end of the basket to allow retrieval with a snare.

3 35. Both designs suffer similar design flaws rendering them defective and unreasonably
4 dangerous. Defendants filters are designed in such way that when exposed to expected and
5 reasonably foreseeable *in-vivo* conditions the devices will fracture, migrate, tilt, perforate internal
6 organs and vasculature, and lead to the formation of thromboembolism and pulmonary embolism.

7 36. For instance, Defendants chose not to electropolish their filters. The manufacturing
8 process used to manufacture NITINOL medical devices leads to surface blemishes, draw marking,
9 pitting, gouges and cracks, which can act as stress concentrators leading to fatigue failure.
10 Electropolishing removes these conditions, which substantially increase fatigue and corrosion
11 resistance. Electropolishing has been industry standard for implanted NITINOL medical devices
12 since at least the 1990's.

13 37. The anchoring mechanism of Defendants' filters is also insufficient to prevent tilting
14 and migration post-placement.

15 38. The configuration of Defendants' filters also renders them prothrombotic. This
16 means that these filters actually lead to the formation of blood clots and pulmonary embolism – the
17 exact condition that devices are meant to prevent.

18 39. That Defendants allowed these devices to proceed to market indicates that they failed
19 to establish and maintain an appropriate Quality System in respect to design and risk analysis.

20 40. At a minimum, a manufacturer must undertake sufficient research and testing to
21 understand the anatomy of where a medical device will be implanted so as to understand what
22 forces the device may be exposed to once implanted in the human body. This design input must
23 then be used to determine the minimum safety requirements or attributes the device must have to
24 meet user needs. In the case of an IVC filter, user needs include: a device that will capture DVTs of
25 sufficient size to cause harmful consequences and that will not fracture, migrate, tilt, perforate the
26 vena cava or be prothrombotic.

1 41. Prior to bringing a product to market, a manufacturer must also conduct sufficient
2 testing under real world or simulated use conditions to ensure that the device will meet user needs
3 even when exposed to reasonably foreseeable worst case conditions.

4 42. Defendants failed to adequately establish and maintain such policies and procedures
5 in respect to their IVC filter devices.

6 43. Once brought to market, Defendants' post-market surveillance system should have
7 revealed that the OptEase filters were unreasonably dangerous and substantially more prone to
8 failing and causing injury than other available treatment options.

9 44. For instance soon after market release, Defendants began receiving large numbers of
10 adverse event reports ("AERs") from health care providers reporting that the OptEase filters were
11 fracturing post-implantation and that fractured pieces and/or the entire device was migrating
12 throughout the human body, including the heart and lungs. Defendants also received large numbers
13 of AERs reporting that the OptEase filters were found to have excessively tilted, perforated the
14 inferior vena cava, or caused thrombosis or stenosis of the vena cava post-implantation. These
15 device malfunctions were often associated with reports of inability to retrieve the device and/or
16 severe patient injuries such as:

- 17 a. Death;
- 18 b. Hemorrhage;
- 19 c. Cardiac/pericardial tamponade;
- 20 d. Cardiac arrhythmia and other symptoms similar to myocardial infarction;
- 21 e. Severe and persistent pain;
- 22 f. Perforation of tissue, vessels and organs;
- 23 g. compartment syndrome.

24 45. Recent medical studies have confirmed what Defendants have known or should have
25 known since shortly after the release of each of these filters - not only do OptEase filters fail at
26 alarming rates, but they also fail at rates substantially higher than other available IVC Filters. For
27 instance, a recent large medical study found that OptEase and TrapEase filters suffer fracture rates
28 of 37.5% and 23.1%, respectively, when left implanted a minimum of 46 months. Another recent

1 study found that the TrapEase filter had a 64% fracture rate when left in more than four (4) years.
2 Another study found a statistically significant increased rate of caval thrombosis with the OptEase
3 filter compared to Gunther Tulip and Recovery Filters.

4 46. As a minimum safety requirement, manufacturers must establish and maintain post-
5 market procedures to timely identify the cause of device failures and other quality problems and to
6 take adequate corrective action to prevent the recurrence of these problems.

7 47. Defendants, however, failed to take timely and adequate action to correct known
8 design and manufacturing defects with the OptEase filter.

9 48. Defendants also misrepresented and concealed the risks and benefits of the OptEase
10 filters in labeling and marketing distributed to the FDA, physicians and the public.

11 49. For instance, Defendants represented that these devices were safe and effective. As
12 discussed above, however, there is no reliable evidence establishing that these devices actually
13 improve patient outcomes.

14 50. Defendants also represented that the design of these devices would eliminate the risk
15 that pieces of the devices could perforate the vena cava, that the devices could tilt, or that fractures
16 could occur and migrate throughout the body. The medical literature and AERS have proven these
17 claims to be false.

18 51. Defendants also represented that these devices were more effective and safer than
19 other available IVC filters. As discussed above, there is no reliable basis for such claims and the
20 evidence indicates otherwise.

21 52. Defendants also marketed the OptEase filter as being "easy" to remove. However,
22 the OptEase filter is one of the most difficult filters to remove after implantation and quite often
23 cannot be removed at all. As Dr. William T. Kuo, one of the leading authors on IVC filters, recently
24 explained in *the Journal of Vascular Interventional Radiology*:

25 "...we thought the OPTease and TRAPEASE filter types were subjectively
26 among the most difficult to remove in our study, often requiring aggressive blunt
27 dissection force in addition to laser tissue ablation to achieve removal. A possible
28 explanation is the relatively large amount of contact these filters make with the
underlying vena cava and the possible induction of greater reactive tissue
formation."

1 53. This is particularly concerning because having an IVC filter for a prolonged period
2 of time increases the risk of developing chronic deep venous thrombosis, PE, IVC occlusion, post-
3 thrombotic syndrome, filter fracture, and caval perforation with pain and organ injury. Many
4 patients with IVC filters are now routinely managed with lifelong anticoagulation solely to reduce
5 the risk of having the filter in place, subjecting patients to the risks and inconvenience of
6 anticoagulation.

7 54. Defendants also failed to adequately disclose the risks of these filters, such as
8 migration, fracture, perforation, tilt, thrombosis, the prothrombotic nature of the devices, that the
9 devices may not be retrievable, or that these failures were known to be causing severe injuries and
10 death or the rate at which these events were occurring.

11 55. Defendants labeling was additionally defective in that it directed physicians to
12 implant the OptEase filter upside down. When the OptEase was placed as directed by the labeling,
13 the hooks designed to ensure stability were facing in the wrong direction, rendering an already
14 inadequate anchoring system even further defective. As Defendants' now explain in their labeling,
15 implanting the device in this fashion "can result in life threatening or serious injury including, but
16 not limited to dissection, vessel perforation, migration of the filter with secondary damage to
17 cardiac structures, ineffective pulmonary embolism prevention or death."

18 56. Defendants began a series of recalls on March 29, 2013 relating to its labeling, which
19 instructed physicians to implant the devices upside down. These recalls were not timely, nor did
20 they fully correct the defects in Defendants' labeling. Further, Defendants downplayed the danger
21 patients were exposed to and failed to take adequate steps to ensure patients actually received notice
22 of the recall.

23 57. The FDA classified the initial recall as a Class I recall, which are the most serious
24 type of recall and involve situations in which the FDA has determined there is a reasonable
25 probability that use of these products will cause serious adverse health consequences or death.

26 58. Defendants have admitted that any patients implanted with one of these recalled
27 units should receive medical monitoring. Specifically, these patients should undergo imaging to
28 ascertain whether or not the device was properly deployed and, if not, be assessed for removal.

1 59. Given the unreasonably high failure and injury rates associated with Defendants
2 filters when left implanted long-term, Defendants should be required to pay for medical monitoring
3 to assess the condition of these devices and whether or not retrieval should be undertaken.

4
5 **ESTOPPEL FROM PLEADING STATUTES OF LIMITATIONS OR REPOSE**

6 60. Plaintiffs incorporate by reference all prior allegations.

7 61. Plaintiffs are within the applicable statute of limitations for their claims because
8 Plaintiffs (and their healthcare professionals) did not discover, and could not reasonably discover,
9 the defects and unreasonably dangerous condition of Defendants' IVC filters.

10 62. Plaintiffs' ignorance of the defective and unreasonably dangerous nature of
11 Defendants' IVC filters, and the causal connection between these defects and Plaintiffs' injuries and
12 damages, is due in large part to Defendants' acts and omissions in fraudulently concealing
13 information from the public and misrepresenting and/or downplaying the serious threat to public
14 safety its products present.

15 63. In addition, Defendants are estopped from relying on any statutes of limitation or
16 repose by virtue of its unclean hands, acts of fraudulent concealment, affirmative misrepresentations
17 and omissions.

18 64. Such conduct includes intentional concealment from Plaintiffs, Plaintiffs' prescribing
19 health care professionals, the general consuming public and the FDA of material information that
20 Defendants' filters had not been demonstrated to be safe or effective, and carried with them the
21 risks and dangerous defects described above.

22 65. Defendants had a duty to disclose the fact that Defendants' filters are not safe or
23 effective, not as safe as other filters on the market, defective, and unreasonably dangerous, and that
24 their implantation and use carried the above described risks.

25 ///

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28 ///

COUNT I:
STRICT PRODUCTS LIABILITY- DESIGN DEFECT
By all Plaintiffs

66. Plaintiffs re-allege and incorporate by reference each and every allegation contained in the foregoing paragraphs as though fully set forth herein.

67. At all times relevant to this action, Defendants developed, tested, designed, manufactured, inspected, labeled, promoted, distributed and sold into the stream of commerce the OptEase filters, including the devices implanted in Plaintiffs.

68. The devices implanted in plaintiffs were in a condition unreasonably dangerous at the time they left Defendants' control.

69. The devices implanted in Plaintiffs were expected to, and did, reach their intended consumers without substantial change in the condition in which they were in when they left Defendants' possession. In the alternative, any changes that were made to the devices implanted in Plaintiffs were reasonably foreseeable to Defendants.

70. The OptEase filters, including the devices implanted in Plaintiffs, were defective in design and unreasonably dangerous at the time they left Defendants' possession because they failed to perform as safely as an ordinary consumer would expect when used as intended or in a manner reasonably foreseeable by the Defendants, and because the foreseeable risks of these devices exceeded the alleged benefits associated with their use.

71. At the time Defendants placed their OptEase filters, including the device implanted in Plaintiffs, into the stream of commerce, safer alternative designs were commercially, technologically, and scientifically attainable and feasible.

72. Plaintiffs and their health care providers used the devices in a manner that was reasonably foreseeable to Defendants.

73. Neither Plaintiffs, nor their health care providers, could have by the exercise of reasonable care discovered the defective condition or perceived the unreasonable dangers with these devices prior to Plaintiffs' implantation with the devices.

74. As a direct and proximate result of the defective and unreasonably dangerous condition of the OptEase filters, Plaintiffs suffered injuries and damages.

WHEREFORE, Plaintiffs demand judgment against Defendants as hereinafter set forth.

COUNT II:
STRICT PRODUCTS LIABILITY — INADEQUATE WARNING
By all Plaintiffs

75. Plaintiffs re-allege and incorporate by reference each and every allegation contained in the foregoing paragraphs as though fully set forth herein.

76. Prior to, on, and after the dates during which the device were implanted in Plaintiffs, and at all relevant times, Defendants manufactured, designed, marketed, distributed, and sold the OptEase filters.

77. The OptEase filters had potential risks and side effects that were known or knowable to Defendants by the use of scientific knowledge available before, at, and after the manufacture, distribution, and sale of the devices implanted in Plaintiffs.

78. Defendants knew or it was knowable at the time they distributed the devices implanted in Plaintiffs that the OptEase filters posed a significant and higher risk of failure than other similar IVC filters, including for fracture, migration, tilting, thrombosis, migration, tilt, inability to retrieve and pulmonary embolism and that these failures were resulting in serious patient injuries and death. Defendants also knew or it was knowable that these devices were actually prothrombotic, that use of these filters did not improve patient outcomes, and the longer these filters were left implanted increased the likelihood of a device failure.

79. Defendants' OptEase filters were in a defective condition that was unreasonably and substantially dangerous to any user or consumer implanted with the filters, such as Plaintiffs, when

1 used in an intended and reasonably foreseeable way. Such ordinary consumers, including Plaintiffs
2 and their prescribing physician(s), would not and could not have recognized or discovered the
3 potential risks and side effects of the device, as set forth herein.

4 80. The warnings and directions Defendants provided with its OptEase filters, including
5 the devices implanted in Plaintiffs, failed to adequately warn of the above-described risks and side-
6 effects, whether as to existence of the risk, its likelihood, severity, or the comparative risk to other
7 products.

8
9 81. The labeling also failed to provide adequate directions on how to appropriately use
10 the product.

11 82. The devices were expected to and did reach Plaintiffs without substantial change in
12 its condition, labeling, or warnings as manufactured, distributed, and sold by Defendants.
13 Additionally, Plaintiffs and their prescribing physicians used the devices in the manner in which
14 they were intended to be used, making such use reasonably foreseeable to Defendants.

15 83. Defendants' lack of sufficient instructions or warnings prior to, on, and after the date
16 Plaintiffs used the devices was a substantial factor in causing Plaintiffs' injuries and damages, as
17 described herein.

18 WHEREFORE, Plaintiff demands judgment against Defendants as hereinafter set forth.
19

20 **COUNT III:**
21 **STRICT PRODUCTS LIABILITY — MANUFACTURING DEFECT**
22 **By all Plaintiffs**

23 84. Plaintiffs re-allege and incorporate by reference each and every allegation contained
24 in the foregoing paragraphs as though fully set forth herein.

25 85. Prior to, on, and after the date the devices were implanted in Plaintiffs, and at all
26 relevant times, Defendants designed, distributed, manufactured, sold, and marketed the OptEase
27 filters for use in the United States.
28

1 86. At all times herein mentioned, Defendants designed, distributed, manufactured,
2 marketed, and sold the devices such that they were dangerous, unsafe, and defective in manufacture,
3 and contained a manufacturing defect when it left defendants' possession.

4 87. Plaintiffs are informed and believe, and on that basis allege, that the OptEase filters,
5 including the devices implanted in them, contained manufacturing defects, in that they differed from
6 Defendants' design or specifications, or from other typical units of the same product line.

7 88. As a direct and proximate result of Defendants' defective manufacture and sale of
8 the OptEase filters prior to, on, and after the date Plaintiffs used the devices, Plaintiffs suffered the
9 injuries and damages herein described.

10 WHEREFORE, Plaintiffs demand judgment against Defendants as hereinafter set forth.

11
12 **COUNT IV:**
13 **NEGLIGENCE**
14 **By all Plaintiffs**

15 89. Plaintiffs re-allege and incorporate by reference each and every allegation contained
16 in the foregoing paragraphs as though fully set forth herein.

17 90. Prior to, on, and after the date the devices were implanted in Plaintiffs, and at all
18 relevant times, Defendants designed, distributed, manufactured, sold, and marketed the OptEase
19 filters for use in the United States.

20 91. Defendants had a duty to exercise reasonable and prudent care in the development,
21 testing, design, manufacture, inspection, marketing, labeling, promotion, distribution and sale of the
22 OptEase filters so as to avoid exposing others to foreseeable and unreasonable risks of harm.

23 92. Defendants knew or reasonably should have known that the OptEase filters were
24 dangerous or were likely to be dangerous when used in an intended or reasonably foreseeable
25 manner.

26 93. At the time of manufacture and sale of the OptEase filters, Defendants knew or
27 should have known that the OptEase filters:
28

- a. Were designed and manufactured in such a manner as to lack sufficient structural integrity (fatigue resistance) and stability (tilt/migration) to meet user needs when used in an intended and reasonably foreseeable manner.
- b. Were designed and manufactured so as to present an unreasonable risk of the devices perforating the vena cava wall and/or in the case of the OptEase filter becoming irretrievable;
- c. Being designed and manufactured in such a manner as to be prothrombotic.

94. At the time of manufacture and sale of the OptEase filters, including the ones implanted in Plaintiffs, Defendants knew or should have known that using the OptEase filters as intended or in a reasonably foreseeable manner created a significant risk of patients suffering severe health side effects including, but not limited to: hemorrhage; cardiac/pericardial tamponade; cardiac arrhythmia and other symptoms similar to myocardial infarction; perforations of tissue, vessels and organs; chronic deep vein thrombosis; pulmonary embolism; thrombosis; compartment syndrome; and other severe personal injuries and diseases, which are permanent in nature, including, but not limited to, death, physical pain and mental anguish, scarring and disfigurement, diminished enjoyment of life, continued medical care and treatment due to chronic injuries/illness proximately caused by the device; and the continued risk of requiring additional medical and surgical procedures including general anesthesia, with attendant risk of life threatening complications.

95. Defendants knew or reasonably should have known that consumers of the OptEase filters, including Plaintiffs' prescribing physicians, would not realize the danger associated with using the devices for their intended or reasonably foreseeable use.

96. Defendants breached their duty to exercise reasonable and prudent care in the development, testing, design, manufacture, inspection, marketing, labeling, promotion, distribution and sale of the OptEase filters in, among other ways, the following acts and omissions:

- 1 a. Designing and distributing a product in which they knew or should have known
2 that the likelihood and severity of potential harm from the product exceeded the
3 burden of taking safety measures to reduce or avoid harm;
- 4 b. Designing and distributing a product in which they knew or should have known
5 that the likelihood and severity of potential harm from the product exceeded the
6 likelihood of potential harm from other devices and treatment options available
7 for the same purpose;
- 8 c. Failing to use reasonable care in manufacturing the product and producing a
9 product that differed from their design or specifications or from other typical
10 units from the same production line;
- 11 d. Failing to use reasonable care to warn or instruct, including pre and post-sale,
12 Plaintiffs, their prescribing physicians, or the general health care community
13 about the OptEase filters' substantially dangerous condition or about facts
14 making the products likely to be dangerous;
- 15 e. Failing to recall, retrofit, or provide adequate notice of such actions to Plaintiffs
16 or their health providers.
- 17 f. Failing to perform reasonable pre and post-market testing of the TrapEase and
18 OptEase filters to determine whether or not the products were safe for their
19 intended use;
- 20 g. Failing to provide adequate instructions, guidelines, and safety precautions,
21 including pre and post-sale, to those persons to whom it was reasonably
22 foreseeable would prescribe, use, and implant the OptEase filters;
- 23 h. Advertising, marketing and recommending the use of the OptEase filters, while
24 concealing and failing to disclose or warn of the dangers known by Defendants
25 to be connected with and inherent in the use of these filter systems;
- 26
27
28

- i. Representing that the OptEase filters were safe for their intended use when, in fact, Defendants knew and should have known the products were not safe for their intended uses;
- j. Continuing to manufacture and sell the OptEase filters with the knowledge that said products were dangerous and not reasonably safe, and failing to comply with good manufacturing regulations;
- k. Failing to use reasonable and prudent care in the design, research, manufacture, and development of the OptEase filters so as to avoid the risk of serious harm associated with the use of these filter systems;
- l. Advertising, marketing, promoting and selling OptEase filters for uses other than as approved and indicated in the product's label;
- m. Failing to establish an adequate quality assurance program used in the design and manufacture of the OptEase filters.
- n. Failing to establish and maintain an adequate post-market surveillance program;

97. A reasonable manufacturer, distributor, or seller under the same or similar circumstances would not have engaged in the before-mentioned acts and omissions.

98. Defendants' negligence prior to, on, and after the date of implantation of the devices in Plaintiffs was a substantial factor in causing Plaintiffs' injuries and damages, as described herein.

WHEREFORE, Plaintiff demands judgment against Defendants as hereinafter set forth.

COUNT V:
NEGLIGENT MISREPRESENTATION
By all Plaintiffs

99. Plaintiffs re-allege and incorporate by reference each and every allegation contained in the foregoing paragraphs as though fully set forth herein.

100. Prior to, on, and after the date the devices were implanted in Plaintiffs, and at all relevant times, Defendants negligently and carelessly represented to Plaintiffs, their health care providers, and the general public that certain material facts were true. The representations include, *inter alia*, the following:

- a. That the OptEase filters were safe, fit, and effective for use.
- b. that the design of the OptEase filters eliminated the risk that pieces of the device could perforate the vena cava, that the devices could tilt, or that fractures could occur and migrate throughout the body.
- c. That the OptEase filters were safer and more effective than other available IVC filters.
- d. That the OptEase filter was "easy" to remove.

101. Prior to, on, and after the dates during which Plaintiffs and their physicians purchased and used the device, said representations were not true, and there was no reasonable ground for believing said representations to be true at the times said representations were made.

102. Prior to, on, and after the dates during which Plaintiffs and their physicians purchased and used the device, Defendants intended that Plaintiffs, their physicians, and the general public would rely on said representations, which did in fact occur.

103. Defendants' negligent misrepresentations prior to, on, and after the date when Plaintiffs and their physicians purchased and used the devices were a substantial factors in causing Plaintiff's injuries and damages, as described herein.

WHEREFORE, Plaintiff demands judgment against Defendants as hereinafter set forth.

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///

///

COUNT VI
FRAUD - MISREPRESENTATION
By all Plaintiffs

104. Plaintiffs re-allege and incorporate by reference each and every allegation contained in the foregoing paragraphs as though fully set forth herein.

105. At all times relevant to this cause, and as detailed above, Defendants intentionally provided Plaintiffs, their physicians, the medical community and the FDA with false or inaccurate information, and/or omitted material information concerning the Device, including, but not limited to, misrepresentations regarding the following topics:

- a. The safety of the device;
- b. The efficacy of the device;
- c. The rate of failure of the device;
- d. The pre-market testing of the device; and
- e. The approved uses of the device.

106. The information distributed by Defendants to the public, the medical community, Plaintiffs and their physicians was in the form of reports, press releases, advertising campaigns, labeling materials, print advertisements, commercial media containing material representations, and instructions for use, as well as through their officers, directors, agents, and representatives. These materials contained false and misleading material representations, which included:

- a. That the device was safe, fit, and effective when used for its intended purpose or in a reasonably foreseeable manner;
- b. that it did not pose dangerous health risks in excess of those associated with the use of other similar devices;
- c. That the design of the device would eliminate the risk that pieces of the device could perforate the vena cava, that the devices could tilt, or that fractures could occur and migrate throughout the body;
- d. That the device was safer and more effective than other available IVC filters; and
- e. That the OptEase filter was "easy" to remove.

1 107. Defendants made the foregoing misrepresentations knowing that they were false.
2 These materials included instructions for use and a warning document that was included in the
3 package of the devices implanted in Plaintiffs.

4 108. Defendants' intent and purpose in making these misrepresentations was to deceive
5 and defraud Plaintiffs and their health care providers; to gain the confidence of Plaintiffs and their
6 health care providers; to falsely assure them of the quality of the device and its fitness for use; and
7 to induce the public and the medical community, including Plaintiffs' healthcare providers to
8 request, recommend, prescribe, impiant, purchase, and continue to use the device, all in reliance on
9 Defendants' misrepresentations.

10 109. The foregoing representations and omissions by Defendants were in fact false.

11 110. Defendants acted to serve their own interests and having reasons to know
12 consciously disregarded the substantial risk that the device could kill or significantly harm patients.

13 111. In reliance upon the false representations made by Defendants, Plaintiffs and their
14 health care providers were induced to, and did use the device, thereby causing Plaintiffs to sustain
15 the injuries described herein.

16 112. Defendants knew and had reason to know that Plaintiffs, their health care providers,
17 or the general medical community did not have the ability to determine the true facts intentionally
18 concealed and misrepresented by Defendants, and would not have prescribed and implanted same, if
19 the true facts regarding the device had not been concealed and misrepresented by Defendants.

20 113. Defendants had sole access to material facts concerning the defective nature of the
21 OptEase filters and their propensity to cause serious side effects in the form of dangerous injuries
22 and damages to persons who are implanted with the device.

23 114. At the time Defendants failed to disclose and intentionally misrepresented the
24 foregoing facts, and at the time Plaintiffs' health care providers purchased and used these devices,
25 Plaintiffs' health care providers were unaware of Defendants' misrepresentations.

26 115. Plaintiffs' health care providers reasonably relied upon misrepresentations made by
27 Defendants where the concealed and misrepresented facts were critical to understanding the true
28 dangers inherent in the use of the device.

1 116. Defendants' fraudulent misrepresentations prior to, on, and after the date Plaintiffs
2 and their physicians purchased and used the devices were a substantial factor in causing Plaintiff's
3 injuries and damages, as described herein.

4 WHEREFORE, Plaintiffs demand judgment against defendants as hereinafter set forth.

5
6 **COUNT VII**
FRAUDULENT CONCEALMENT
7 **By all Plaintiffs**

8 117. Plaintiffs re-allege and incorporate by reference each and every allegation contained
9 in the foregoing paragraphs as though fully set forth herein.

10 118. In marketing and selling the device, defendants concealed material facts from
11 Plaintiffs and their health care providers.

- 12 119. Defendants' concealed material facts including, but not limited to, the following:
- 13 a. That the device was unsafe and not fit when used for its intended purpose or
14 in a reasonably foreseeable manner;
 - 15 b. That the device posed dangerous health risks in excess of those associated
16 with the use of other similar devices;
 - 17 c. That there were additional side effects related to implantation and use of the
18 device that were not accurately and completely reflected in the warnings
19 associated with the device;
 - 20 d. That the device was not adequately tested to withstand normal placement
21 within the human body; and
 - 22 e. That Defendants were aware at the time Plaintiffs' filters were distributed
23 that electropolishing reduced the risk of fracture and was industry standard
24 for NITINOL medical devices.

25 120. Plaintiffs and their healthcare providers were not aware of these and other facts
26 concealed by Defendants.

27 121. The Defendants are and were under a continuing duty to disclose the true character,
28 quality and nature of the device that was implanted in Plaintiff, but instead they concealed them.
Defendants' conduct, as described in this complaint, amounts to conduct purposely committed,
which Defendants must have realized was dangerous, heedless and reckless, without regard to the
consequences or the rights and safety of Plaintiff.

1 122. In concealing these and other facts, Defendants intended to deceive Plaintiffs and
2 their health care providers by concealing said facts.

3 123. Plaintiffs and their healthcare providers reasonably and justifiably relied on
4 Defendants' concealment and deception.

5 124. Defendants' concealment prior to, on, and after the date Plaintiffs and their
6 healthcare providers purchased and used the devices implanted in Plaintiffs was a substantial factor
7 in causing Plaintiffs' injuries and damages, as described herein.

8 WHEREFORE, Plaintiffs demand judgment against defendants as hereinafter set forth.

9
10 **COUNT VIII**
 EXPRESS WARRANTY
 By all Plaintiffs

11 125. Plaintiffs re-allege and incorporate by reference each and every allegation contained
12 in the foregoing paragraphs as though fully set forth herein.

13 126. Prior to, on, and after the dates during which Plaintiffs were implanted with these
14 devices, and at all relevant times, Defendants, and each of them, had knowledge of the purpose for
15 which the devices were to be used, and represented the devices to be in all respects safe, effective,
16 and proper for such purpose. Said warranties and representations were made to Plaintiffs and their
17 treating physicians. Plaintiffs and their treating physicians relied on said warranties and
18 representations in deciding to use the device.

19 127. Defendants used packaging inserts and media advertisements to represent to the
20 medical community and consumers, including plaintiffs and their health care providers, that the
21 OptEase filters: were safe for their intended use; did not pose serious health hazards when used
22 appropriately; were safer and more effective than alternative IVC filters; had been adequately tested
23 for their intended use; would not perforate the vena cava, tilt, or fracture and migrate throughout the
24 body after placement; and that the OptEase filter was "easy" to remove.

25 128. Defendants, and each of them, breached the above-described express warranties and
26 representations in that the OptEase filters did not conform to these express warranties and
27 representations.
28

1 129. Prior to, on, and after the dates during which Plaintiffs and their physicians
2 purchased and used these devices, Defendants, and each of them, were put on notice of the OptEase
3 filters' inability to conform to these express warranties.

130. Defendants' breach of said express warranties and representations prior to, on, and after the date Plaintiffs and their physicians purchased and used the devices was a substantial factor in causing Plaintiffs' injuries and damages, as described herein.

7 WHEREFORE, Plaintiffs demand judgment against Defendants as hereinafter set forth.

COUNT IX
BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY
By all Plaintiffs

10 131. Plaintiffs re-allege and incorporate by reference each and every allegation contained
11 in the foregoing paragraphs as though fully set forth herein.

132. Defendants sold the OptEase filters for Plaintiffs' ultimate use.

13 133. At all times hereinafter mentioned, Defendants were in the business of developing,
14 designing, licensing, manufacturing, selling, distributing and/or marketing the TrapEase and
15 OptEase filters, including the one implanted in Plaintiffs.

16 134. Defendants impliedly warranted to Plaintiffs and their physicians that the OptEase
17 filters were safe and of merchantable quality and for the ordinary purpose for which they product
18 was intended and marketed to be used.

19 135. The representations and implied warranties made by Defendants were false,
20 misleading, and inaccurate because the OptEase filters were defective, unsafe, unreasonably
21 dangerous, and not of merchantable quality, when used as they were marketed and intended to be
22 used. Specifically, at the time Plaintiffs and their physicians purchased and used the devices, the
23 products were not in a merchantable condition in that:

- 24 a. They offered no benefit to patient outcomes,
25 b. They suffered an unreasonably high failure and injury rates, and

1 c. The surface of the devices were manufactured and designed in such a way that
2 they were distributed with surface damage that substantially increased the risk
3 of fracture.

4 d. They were prothrombotic;

5 136. Defendants' breach of said implied warranties and representations prior to, on, and
6 after the date Plaintiffs and their physicians purchased and used the devices was a substantial factor
7 in causing Plaintiffs' injuries and damages, as described herein.

8 WHEREFORE, Plaintiffs demand judgment against Defendants as hereinafter set forth.
9

10 **PUNITIVE DAMAGES ALLEGATIONS**

11 137. Plaintiff re-alleges and incorporates by reference each and every allegation contained
12 in the foregoing paragraphs as though fully set forth herein.

13 138. Upon information and belief, Plaintiffs allege that as early as 2003, Defendants were
14 aware and had knowledge of the fact that the OptEase filters were defective and unreasonably
15 dangerous and were causing injury and death to patients.

16 139. Data establishes that the failure rates of the OptEase filters are and were much higher
17 than what Defendants have in the past and currently continue to publish to the medical community
18 and members of the public. Further, Defendants were aware or should have been aware that the
19 OptEase filters had substantially higher failure rates than other similar products on the market and
20 are actually prothrombotic. Defendants were also aware that there was no reliable evidence
21 indicating its devices actually improved patient outcomes. Despite these facts, Defendants
22 continued to sell an unreasonably dangerous product while concealing and misrepresenting its risks
23 and benefits to the public, plaintiffs, plaintiffs' health care providers, and the FDA.

24 140. The conduct of Defendants as alleged in this Complaint constitutes willful, wanton,
25 gross, and outrageous corporate conduct that demonstrates a conscious disregard for the safety of
26 Plaintiff. Defendants had actual knowledge of the dangers presented by OptEase filters, yet
27 consciously failed to act reasonably to:
28

- a. Inform or warn Plaintiffs, Plaintiffs' physicians, or the public at large of these dangers; and
- b. Establish and maintain an adequate quality and post-market surveillance system.

141. Despite having knowledge as early as 2003 of the unreasonably dangerous and defective nature of the OptEase filters, Defendants consciously disregarded the known risks and continued to actively market and offer for sale the OptEase filters. Plaintiffs further allege that Defendants acted in willful, wanton, gross, and total disregard for the health and safety of the users or consumers of their OptEase filters, acted to serve their own interests, and consciously disregarded the substantial risk that their product might kill or significantly harm patients, or significantly injure the rights of others. Despite this knowledge, Defendants consciously pursued a course of conduct knowing that such conduct created a substantial risk of significant harm to other persons.

PRAYER FOR DAMAGES

WHEREFORE, Plaintiffs pray for relief against Defendants Cordis Corporation and Does 1 through 100, inclusive, on the entire complaint, as follows:

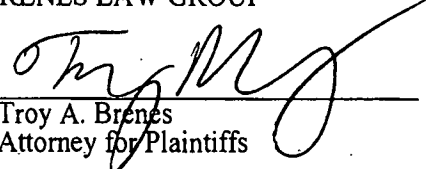
- a. General damages according to proof at the time of trial;
- b. Special (economic) damages, including without limitation, past and future medical expenses and past and future lost wages according to proof at time of trial.
- c. Pre-judgment and post-judgment interest pursuant to the laws of the State of California;
- d. Costs of suit incurred herein;
- e. Punitive damages in an amount sufficient to punish Defendants and deter similar conduct in the future;
- f. For such further and other relief as this Court deems necessary, just and proper.

DEMAND FOR JURY TRIAL

Plaintiffs hereby demand trial by jury on all issues.

DATED: May 6, 2016

Respectfully Submitted,
BRENES LAW GROUP


Troy A. Brenes
Attorney for Plaintiffs

FILED BY FAX
ALAMEDA COUNTY

May 24, 2016

CLERK OF
THE SUPERIOR COURT
By Amrit Khan, Deputy

CASE NUMBER:
RG16814745

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Attorney for Plaintiffs

**SUPERIOR COURT OF CALIFORNIA, COUNTY OF ALAMEDA
RENE C. DAVIDSON ALAMEDA COUNTY COURTHOUSE**

DAVID RESOVSKY, GEORGE TODD,
DAVID BROWN, GWEN KRAMER,
RICHARD LONGSTON, RONALD
MARESKI, and LINDA MARESKI

Plaintiffs,

vs.

CORDIS CORPORATION, a
corporation, CONFLUENT
MEDICAL TECHNOLOGIES, INC.,
a corporation, and DOES 1 through
100, inclusive,

Defendants.

Case No.: RG16814745

**FIRST AMENDED COMPLAINT FOR
DAMAGES AND
DEMAND FOR JURY TRIAL**

- (1) Strict Products Liability - Design Defect
- (2) Strict Products Liability - Inadequate Warning
- (3) Strict Products Liability - Manufacturing Defect
- (4) Negligence
- (5) Negligent Misrepresentation
- (6) Fraud - Misrepresentation
- (7) Fraudulent Concealment
- (8) Express Warranty
- (9) Breach of Implied Warranty Of Merchantability
- (10) Loss of Consortium

Plaintiffs DAVID RESOVSKY, GEORGE TODD, DAVID BROWN, AND GWEN
KRAMER hereby sue defendants CORDIS CORPORATION, CONFLUENT MEDICAL
TECHNOLOGIES, INC., and DOES 1 through 100 and allege as follows:

PARTIES

1. Plaintiff David Resovsky underwent placement of an OptEase™ Permanent Vena
Cava Filter (referred to as "filter," "device" or "product" hereinafter) at Cleveland Clinic in Ohio.
The device subsequently malfunctioned and caused, *inter alia*, thrombosis of the inferior vena cava.

1 As a result of the malfunction, Mr. Resovsky has suffered life-threatening injuries and damages and
2 required extensive medical care and treatment. Plaintiff has suffered and will continue to suffer
3 significant medical expenses, extreme pain and suffering, loss of enjoyment of life, disability, and
4 other losses.

5 2. Plaintiff George Todd was implanted with an OptEase™ filter in October 2006 at
6 Aventura Hospital & Medical Center in Florida. The device subsequently tilted and perforated the
7 vena cava. As a result, he suffered, *inter alia*, bilateral pulmonary emboli and the device cannot be
8 removed. Plaintiff has suffered and will continue to suffer significant medical expenses, extreme
9 pain and suffering, loss of enjoyment of life, disability, and other losses.

10 3. Plaintiff David Brown was implanted with an OptEase™ filter on November 4, 2014
11 at Hannibal Regional Hospital in Missouri. On February 5, 2015 he underwent a procedure to
12 remove the device. The attempt failed secondary to the device having tilted and migrated after
13 placement. Plaintiff has suffered medical expenses, pain and suffering, loss of enjoyment of life,
14 and other losses.

15 4. Plaintiff Gwen Kramer underwent implantation of two OptEase™ filters on October
16 28, 2013. The first filter immediately migrated to the “origin of the left iliac vein.” This filter was
17 removed percutaneously. Another OptEase™ filter was then placed and this filter also migrated
18 proximally with the distal portion of the filter being proximal to the renal veins. This filter was left
19 in place. Given the migration of the second filter, Ms. Kramer is at increased risk of fracture,
20 perforation and the device will be less effective at stopping clots. Plaintiff has suffered and will
21 continue to suffer significant medical expenses, extreme pain and suffering, loss of enjoyment of
22 life, disability, and other losses.

23 5. Plaintiff Richard Longston underwent placement of an OptEase™ filter on March
24 13, 2015 in the State of Florida. At the time of placement, Mr. Longston was and still is a resident
25 of the State of Florida. The device subsequently suffered a malfunction in its anchoring system

1 resulting in severe tilt, embedment, perforation and inability to remove. Plaintiff has suffered and
2 will continue to suffer medical expenses, pain and suffering, loss of enjoyment of life, and other
3 losses.

4 6. Plaintiff Ronald Mareski underwent placement of an OptEase™ filter on August 15,
5 2006. The device subsequently malfunctioned and migrated to his heart, which required open heart
6 surgery. Plaintiff has suffered and will continue to suffer significant medical expenses, extreme
7 pain and suffering, loss of enjoyment of life, disability, and other losses.

8 7. All of the above plaintiffs underwent placement in and were residents of the United
9 States at the time these devices were implanted and when the devices subsequently failed and
10 caused injury.

11 8. Prior to the device being implanted in Ronald Mareski and to the present, Ronald
12 Mareski and Plaintiff Linda Mareski have been and continue to be legally married. Although not
13 implanted with the device, Linda Mareski has suffered loss of consortium damages (economic and
14 non-economic) as a direct result of Ronald Mareski's use of the device.

15 9. Defendant Cordis Corporation ("Cordis") is a corporation organized under the laws
16 of the State of Florida, with its principal place of business at 6500 Paseo Padre Pkwy, Fremont,
17 California, 94555. Cordis at all times relevant to this action, designed, set specifications for,
18 manufactured, prepared, compounded, assembled, processed, marketed, distributed, and sold the
19 OptEase™ Vena Cava Filter ("OptEase filter") to be implanted in patients throughout the United
20 States, including California. Cordis may be served with process by serving its registered agent, CT
21 Corporation System, at 818 West Seventh Street Suite 930, Los Angeles, California 90017.

22 10. Defendant Confluent Medical Technologies, Inc. (Hereinafter "Confluent") is a
23 corporation organized under the laws of the State of Delaware, with its principal place of business at
24 47533 Westinghouse Drive, Fremont, California 94539. Confluent manufactured, prepared,
25 processed and helped design the OptEase and TrapEase filters implanted in the above-named
26
27
28

1 plaintiffs, whether under its current name or as the successor in interest to Nitinol Development
2 Corporation. Confluent may be served with process by serving its registered agent, CT Corporation
3 System, at 818 West Seventh Street Suite 930, Los Angeles, California 90017.

4 11. Prior to 2015, Confluent was incorporated under the name of Nitinol Development
5 Corporation and did business under the name Nitinol Devices & Components, Inc. (hereinafter
6 "NDC"). NDC also had its principal place of business at 47533 Westinghouse Drive, Fremont,
7 California 94539. In 2015, NDC merged with another company and became Confluent. Defendant
8 Confluent carries on the same activities in relation to the TrapEase and OptEase filters as NDC did
9 previously.
10

11 12. The true names and/or capacities, whether individual, corporate, partnership,
12 associate, governmental, or otherwise, of Defendant DOES 1 through 100, inclusive, are unknown
13 to Plaintiffs at this time, who therefore sue said Defendants by such fictitious names. Plaintiffs are
14 informed and believe, and thereon allege, that each Defendant designated herein as a DOE caused
15 injuries and damages proximately thereby to Plaintiffs as is hereinafter alleged, and that each DOE
16 defendant is liable to Plaintiffs for the acts and omissions alleged herein below and the injuries and
17 damages resulting therefrom. Plaintiffs seek leave to amend this Complaint to allege the true names
18 and capacities of said DOE defendants when the same are ascertained.
19

20 13. Plaintiffs are informed and believe, and thereon allege, that at all times herein
21 mentioned, Defendants and each of the DOE defendants were the agent, servant, employee and/or
22 joint venturer of the other co-defendants, and each of them, and at all said times each Defendant,
23 including DOE defendants, were acting in the full course, scope, and authority of said agency,
24 service, employment and/or joint venture.
25

26 14. Plaintiffs are informed and believe, and thereon allege, that at all times mentioned
27 herein, Defendants and DOES 1 through 100, and each of them, were also known as, formerly
28 known as, and/or were the successors and/or predecessors in interest/business/product line/or a

1 portion thereof, assigns, a parent, a subsidiary (wholly or partially owned by, or the whole or partial
2 owner), affiliate, partner, co-venturer, merged company, alter egos, agents, equitable trustees and/or
3 fiduciaries of and/or were members in an entity or entities engaged in the funding, researching,
4 studying, manufacturing, fabricating, designing, developing, labeling, assembling, distributing,
5 supplying, leasing, buying, offering for sale, selling, inspecting, servicing, contracting others for
6 marketing, warranting, rebranding, manufacturing for others, packaging, and advertising the device.

7
8 15. Defendants and DOES 1 through 100, and each of them, are liable for the acts,
9 omissions and tortious conduct of its successors and/or predecessors in interest/business/product
10 line/or a portion thereof, assigns, parent, subsidiary, affiliate, partner, co-venturer, merged
11 company, alter ego, agent, equitable trustee, fiduciary and/or its alternate entities in that Defendants
12 and DOES 1 through 100, and each of them, enjoy the goodwill originally attached to each such
13 alternate entity, acquired the assets or product line (or a portion thereof), and in that there has been a
14 virtual destruction of Plaintiffs' remedy against each such alternate entity, and that each such
15 Defendant has the ability to assume the risk-spreading role of each such alternate entity.

16
17 16. Plaintiffs are informed and believe, and thereon allege that, at all times herein
18 mentioned, DOES 1 through 100, and each of them, were and are corporations organized and
19 existing under the laws of the State of California or the laws of some state or foreign jurisdiction;
20 that each of the said DOE defendants were and are authorized to do and are doing business in the
21 State of California and regularly conducted business in the State of California.

22
23 17. Upon information and belief, at all relevant times, DOES 1 through 100, and each of
24 them, were engaged in the business of researching, developing, designing, licensing, manufacturing,
25 distributing, selling, marketing, and/or introducing into interstate commerce and into the State of
26 California, either directly or indirectly through third parties or related entities, its products,
27 including the TrapEase and OptEase inferior vena cava filters.

28

1 18. At all relevant times, DOES 1 through 100, and each of them, conducted regular and
2 sustained business and engaged in substantial commerce and business activity in the State of
3 California, which included but was not limited to researching, developing, selling, marketing, and
4 distributing their products, including the TrapEase and OptEase inferior vena cava filters, in the
5 State of California.

6 19. Upon information and belief, at all relevant times, DOES 1 through 100, and each of
7 them, expected or should have expected that their acts would have consequences within the United
8 States including in the State of California, and said Defendants derived and continue to derive
9 substantial revenue therefrom.

10 20. “Cordis,” “Confluent” and “Defendants” where used hereinafter, shall refer to all
11 subsidiaries, affiliates, divisions, franchises, partners, joint venturers, organizational units of any
12 kind, predecessors, successors, assigns, officers, directors, employees, agents and representatives of
13 Cordis Corporation, Confluent, as well as DOE Defendants 1 through 100, and each of them.

14 **JURISDICTION AND VENUE**

15 21. This Court has jurisdiction over all causes of action alleged in this Complaint
16 pursuant to the California Constitution, Article VI, § 10.

17 22. Venue is proper in this Court, pursuant to *Code of Civil Procedure*, as Defendant
18 Cordis has its principal place of business in Alameda County.

19 **BACKGROUND**

20 **INFERIOR VENA CAVA FILTERS GENERALLY**

21 23. Inferior vena cava (“IVC”) filters first came on to the medical market in the 1960’s.
22 Over the years, medical device manufacturers have introduced several different designs of IVC
23 filters.
24
25
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1 24. An IVC filter is a device that is designed to filter or “catch” blood clots that travel
2 from the lower portions of the body to the heart and lungs. IVC filters are designed to be implanted,
3 either permanently or temporarily, in the inferior vena cava.

4 25. The inferior vena cava is a vein that returns deoxygenated blood to the heart from the
5 lower portions of the body. In certain people, for various reasons, blood clots travel from the
6 vessels in the legs and pelvis, through the vena cava and into the lungs. Oftentimes, these blood
7 clots develop in the deep leg veins, a condition called “deep vein thrombosis” or “DVT.” Once
8 blood clots reach the lungs, they are considered “pulmonary emboli” or “PE.” Pulmonary emboli
9 present risks to human health.

10 26. People at risk for DVT/PE can undergo medical treatment to manage the risk. For
11 example, a doctor may prescribe medications like Heparin, Warfarin, or Lovenox to regulate the
12 clotting factor of the blood. In some people who are at high risk for DVT/PE, or who cannot
13 manage their conditions with medications, physicians may recommend surgically implanting an
14 IVC filter to prevent thromboembolic events.

15 27. As stated above, IVC filters have been on the market for decades. All IVC filters are
16 only cleared for use by the FDA for prevention of recurrent pulmonary embolism in patients at risk
17 for pulmonary embolism and where anticoagulation has failed or is contraindicated. In 2003,
18 however, an explosion in off-label use began with the introduction of IVC filters that were cleared
19 for both permanent placement and optional removal. Most of this market expansion came from
20 uses such as prophylactic prevention of pulmonary embolism without a prior history of pulmonary
21 embolism.

22 28. Indeed, from 2000 through 2003 there was a race between manufactures to bring the
23 first IVC filter to market with the added indication of optional retrieval. In 2003, the FDA cleared
24 the first three (3) IVC filters for a retrieval indication. These were the OptEase filter (Cordis &
25 J&J), the Recovery Filter (C.R. Bard, Inc.) and the Gunther Tulip Filter (Cook Medical).

26 29. Upon information and belief, Plaintiffs allege that this market expansion and off-
27 label use was driven by baseless marketing campaigns made by Defendants targeting bariatric,
28 trauma, orthopedic and cancer patient populations.

1 30. The medical community has just recently begun to awaken to the fact that despite
2 marketing claims by Defendants, there is no reliable evidence that any IVC filter offers a benefit
3 and that these products expose patients to substantial safety hazards. For example, an October 2015
4 article published in the *Annals of Surgery* concerning trauma patients inserted with IVC filters
5 concluded that IVC filters were not effective in preventing pulmonary emboli, and instead actually
6 caused thrombi to occur.

7 31. Comparing the results of over 30,000 trauma patients who had not received IVC
8 filters with those who had received them, the *Annals of Surgery* study published its alarming
9 results: a) Almost twice the percentage of patients with IVC filters in the study died compared to
10 those that had not received them; b) Over five times the relative number of patients with IVC filters
11 developed DVTs. c) Over four times the relative percentage of patients with filters developed
12 thromboemboli. d) Over twice the percentage of patients developed a pulmonary embolus – the very
13 condition Defendants represented to the FDA, physicians, and the public that its IVC filters would
14 prevent.

15 32. Other studies have also revealed that these devices suffer common failure modes
16 such as migration, perforation, thrombosis, fracture all of which can cause serious injury or death.
17 For example, recent studies for Defendants IVC Filters have revealed fracture rates as high as 50%
18 and recommend medical monitoring and/or removal.

19 33. These studies, including the *Annals of Surgery* study, have now shown that not only
20 is there no reliable evidence establishing that IVC filters are efficacious but that they also pose
21 substantial health hazards.

22
23 **THE TRAPEASE™ AND OPTEASE™ IVC FILTERS**

24 34. On January 10, 2001, Defendants bypassed the more onerous Food and Drug
25 Administration's ("FDA's") approval process for new devices and obtained "clearance" under
26 Section 510(k) of the Medical Device Amendments to the Food, Drug, and Cosmetic Act to market
27 the Trap Ease™ Permanent Vena Cava Filter and Introduction Kit ("TrapEase filter") as a
28

1 permanent filter by claiming it was substantially equivalent in respect to safety, efficacy, design,
2 and materials as the then already available IVC filters.

3 35. Section 510(k) permits the marketing of medical devices if the device is
4 substantially equivalent to other legally marketed predicate devices without formal review for the
5 safety or efficacy of the device. The FDA explained the difference between the 510(k) process and
6 the more rigorous “premarket approval” (“PMA”) process in its amicus brief filed with the Third
7 Circuit in *Horn v. Thoratec Corp.*, which the court quoted from:

8
9 A manufacture can obtain an FDA findings of ‘substantial equivalence’ by
10 submitting a premarket notification to the agency in accordance with
11 section 510(k) of the [Food Drug and Cosmetic Act.] 21 U.S.C. § 360(k).
12 A device found to be ‘substantially equivalent’ to a predicate device is
13 said to be ‘cleared’ by the FDA (as opposed to “approved” by the agency
14 under a PMA.

15 376 F.3d 163, 167 (3d. Cir. 2004). A pre-market notification submitted under 510(k) is thus
16 entirely different from a PMA, which must include data sufficient to demonstrate that the produce
17 involved is safe and effective.

18 36. In *Medtronic, Inc. v. Lohr*, the U.S. Supreme Court similarly described the 510(k)
19 process, observing:

20 If the FDA concludes on the basis of the [manufacturer’s] § 510(k)
21 notification that the device is ‘substantially equivalent’ to a pre-existing
22 device, it can be marketed without further regulatory analysis.... The §
23 510(k) notification process is by no means comparable to the PMA
24 process; in contrast to the 1,200 hours necessary to complete a PMA
25 review, the § 510(k) review is completed in average of 20 hours As on
26 commentator noted: “The attraction of substantial equivalence to
27 manufacturers is clear. Section 510(k) notification required little
28 information, rarely elicits a negative response form the FDA, and gets
29 processed quickly.

30 518 U.S. 470, 478-79 (1996).

31 37. Pursuant to *Wyeth v. Levine*, 555 U.S. 555 (2009), once a product is cleared “the
32 manufacturer remains under an obligation to investigate and report any adverse associated with the
33 drug... and must periodically submit any new information that may affect the FDA’s previous

1 conclusions about the safety, effectiveness, or labeling” This obligation extends to post-market
2 monitoring of adverse events/complaints.

3 38. On September 18, 2002, Defendants sought clearance through the 510(k) process to
4 market the Cordis OptEase™ Permanent Vena Cava Filter (“OptEase filter”) for the same indicated
5 uses as the TrapEase Filter. Defendants represented that the OptEase filter had the same basic
6 fundamental technology and was substantially equivalent in respect to safety and efficacy as the
7 predicate devices (TrapEase Filter, Gunther Tulip filter, and the Vena Tech LGM Vena Cava
8 Filter).

9 39. Defendants have further represented that the OptEase filter has the same design as
10 TrapEase filter except that unlike the TrapEase filter, which has proximal and distal anchoring barbs
11 located on each connecting strut for fixation of the filter to the vena cava wall, the OptEase filter
12 has anchoring barbs for fixation of the filter only on the superior end of each of the six straight
13 struts and has a hook at the inferior end of the basket to allow retrieval with a snare.

14 40. Both designs suffer similar design flaws rendering them defective and unreasonably
15 dangerous. Defendants filters are designed in such way that when exposed to expected and
16 reasonably foreseeable *in-vivo* conditions the devices will fracture, migrate, tilt, perforate internal
17 organs and vasculature, and lead to the formation of thromboembolism and pulmonary embolism.

18 41. For instance, Defendants chose not to electropolish their filters. The manufacturing
19 process used to manufacture NITINOL medical devices leads to surface blemishes, draw marking,
20 pitting, gouges and cracks, which can act as stress concentrators leading to fatigue failure.
21 Electropolishing removes these conditions, which substantially increase fatigue and corrosion
22 resistance. Electropolishing has been industry standard for implanted NITINOL medical devices
23 since at least the 1990’s.

24 42. The anchoring mechanism of Defendants’ filters is also insufficient to prevent tilting
25 and migration post-placement.

26 43. The configuration of Defendants’ filters also renders them prothrombotic. This
27 means that these filters actually lead to the formation of blood clots and pulmonary embolism – the
28 exact condition that devices are meant to prevent.

1 44. That Defendants allowed these devices to proceed to market indicates that they failed
2 to establish and maintain an appropriate Quality System in respect to design and risk analysis.

3 45. At a minimum, a manufacturer must undertake sufficient research and testing to
4 understand the anatomy of where a medical device will be implanted so as to understand what
5 forces the device may be exposed to once implanted in the human body. This design input must
6 then be used to determine the minimum safety requirements or attributes the device must have to
7 meet user needs. In the case of an IVC filter, user needs include: a device that will capture DVTs of
8 sufficient size to cause harmful consequences and that will not fracture, migrate, tilt, perforate the
9 vena cava or be prothrombotic.

10 46. Prior to bringing a product to market, a manufacturer must also conduct sufficient
11 testing under real world or simulated use conditions to ensure that the device will meet user needs
12 even when exposed to reasonably foreseeable worst case conditions.

13 47. Defendants failed to adequately establish and maintain such policies and procedures
14 in respect to their IVC filter devices.

15 48. Once brought to market, Defendants' post-market surveillance system should have
16 revealed that the OptEase filters were unreasonably dangerous and substantially more prone to
17 failing and causing injury than other available treatment options.

18 49. For instance soon after market release, Defendants began receiving large numbers of
19 adverse event reports ("AERs") from health care providers reporting that the OptEase filters were
20 fracturing post-implantation and that fractured pieces and/or the entire device was migrating
21 throughout the human body, including the heart and lungs. Defendants also received large numbers
22 of AERs reporting that the OptEase filters were found to have excessively tilted, perforated the
23 inferior vena cava, or caused thrombosis or stenosis of the vena cava post-implantation. These
24 device malfunctions were often associated with reports of inability to retrieve the device and/or
25 severe patient injuries such as:

- 26 a. Death;
27 b. Hemorrhage;
28 c. Cardiac/pericardial tamponade;

- d. Cardiac arrhythmia and other symptoms similar to myocardial infarction;
- e. Severe and persistent pain;
- f. Perforation of tissue, vessels and organs;
- g. compartment syndrome.

50. Recent medical studies have confirmed what Defendants have known or should have known since shortly after the release of each of these filters - not only do OptEase filters fail at alarming rates, but they also fail at rates substantially higher than other available IVC Filters. For instance, a recent large medical study found that OptEase and TrapEase filters suffer fracture rates of 37.5% and 23.1%, respectively, when left implanted a minimum of 46 months. Another recent study found that the TrapEase filter had a 64% fracture rate when left in more than four (4) years. Another study found a statistically significant increased rate of caval thrombosis with the OptEase filter compared to Gunther Tulip and Recovery Filters.

51. As a minimum safety requirement, manufacturers must establish and maintain post-market procedures to timely identify the cause of device failures and other quality problems and to take adequate corrective action to prevent the recurrence of these problems.

52. Defendants, however, failed to take timely and adequate action to correct known design and manufacturing defects with the OptEase filter.

53. Defendants also misrepresented and concealed the risks and benefits of the OptEase filters in labeling and marketing distributed to the FDA, physicians and the public.

54. For instance, Defendants represented that these devices were safe and effective. As discussed above, however, there is no reliable evidence establishing that these devices actually improve patient outcomes.

55. Defendants also represented that the design of these devices would eliminate the risk that pieces of the devices could perforate the vena cava, that the devices could tilt, or that fractures could occur and migrate throughout the body. The medical literature and AERS have proven these claims to be false.

1 56. Defendants also represented that these devices were more effective and safer than
2 other available IVC filters. As discussed above, there is no reliable basis for such claims and the
3 evidence indicates otherwise.

4 57. Defendants also marketed the OptEase filter as being “easy” to remove. However,
5 the OptEase filter is one of the most difficult filters to remove after implantation and quite often
6 cannot be removed at all. As Dr. William T. Kuo, one of the leading authors on IVC filters, recently
7 explained, in the *Journal of Vascular Interventional Radiology*:

8 “... we thought the OPTease and TRAPEase filter types were subjectively
9 among the most difficult to remove in our study, often requiring aggressive blunt
10 dissection force in addition to laser tissue ablation to achieve removal. A possible
11 explanation is the relatively large amount of contact these filters make with the
underlying vena cava and the possible induction of greater reactive tissue
formation.”

12 58. This is particularly concerning because having an IVC filter for a prolonged period
13 of time increases the risk of developing chronic deep venous thrombosis, PE, IVC occlusion, post-
14 thrombotic syndrome, filter fracture, and caval perforation with pain and organ injury. Many
15 patients with IVC filters are now routinely managed with lifelong anticoagulation solely to reduce
16 the risk of having the filter in place, subjecting patients to the risks and inconvenience of
17 anticoagulation.

18 59. Defendants also failed to adequately disclose the risks of these filters, such as
19 migration, fracture, perforation, tilt, thrombosis, the prothrombotic nature of the devices, that the
20 devices may not be retrievable, or that these failures were known to be causing severe injuries and
21 death or the rate at which these events were occurring.

22 60. Defendants labeling was additionally defective in that it directed physicians to
23 implant the OptEase filter upside down. When the OptEase was placed as directed by the labeling,
24 the hooks designed to ensure stability were facing in the wrong direction, rendering an already
25 inadequate anchoring system even further defective. As Defendants’ now explain in their labeling,
26 implanting the device in this fashion “can result in life threatening or serious injury including, but
27 not limited to dissection, vessel perforation, migration of the filter with secondary damage to
28 cardiac structures, ineffective pulmonary embolism prevention or death.”

1 61. Defendants began a series of recalls on March 29, 2013 relating to its labeling, which
2 instructed physicians to implant the devices upside down. These recalls were not timely, nor did
3 they fully correct the defects in Defendants' labeling. Further, Defendants downplayed the danger
4 patients were exposed to and failed to take adequate steps to ensure patients actually received notice
5 of the recall.

6 62. The FDA classified the initial recall as a Class I recall, which are the most serious
7 type of recall and involve situations in which the FDA has determined there is a reasonable
8 probability that use of these products will cause serious adverse health consequences or death.

9 63. Defendants have admitted that any patients implanted with one of these recalled
10 units should receive medical monitoring. Specifically, these patients should undergo imaging to
11 ascertain whether or not the device was properly deployed and, if not, be assessed for removal.

12 64. Given the unreasonably high failure and injury rates associated with Defendants
13 filters when left implanted long-term, Defendants should be required to pay for medical monitoring
14 to assess the condition of these devices and whether or not retrieval should be undertaken.

15 **ESTOPPEL FROM PLEADING STATUTES OF LIMITATIONS OR REPOSE**

16 65. Plaintiffs incorporate by reference all prior allegations.

17 66. Plaintiffs are within the applicable statute of limitations for their claims because
18 Plaintiffs (and their healthcare professionals) did not discover, and could not reasonably discover,
19 the defects and unreasonably dangerous condition of Defendants' IVC filters.

20 67. Plaintiffs' ignorance of the defective and unreasonably dangerous nature of
21 Defendants' IVC filters, and the causal connection between these defects and Plaintiffs' injuries and
22 damages, is due in large part to Defendants' acts and omissions in fraudulently concealing
23 information from the public and misrepresenting and/or downplaying the serious threat to public
24 safety its products present.

25 68. In addition, Defendants are estopped from relying on any statutes of limitation or
26 repose by virtue of its unclean hands, acts of fraudulent concealment, affirmative misrepresentations
27 and omissions.

28

1 76. At the time Defendants placed their OptEase filters, including the device implanted
2 in Plaintiffs, into the stream of commerce, safer alternative designs were commercially,
3 technologically, and scientifically attainable and feasible.

4 77. Plaintiffs and their health care providers used the devices in a manner that was
5 reasonably foreseeable to Defendants.

6 78. Neither Plaintiffs, nor their health care providers, could have by the exercise of
7 reasonable care discovered the defective condition or perceived the unreasonable dangers with these
8 devices prior to Plaintiffs' implantation with the devices.

9 79. As a direct and proximate result of the defective and unreasonably dangerous
10 condition of the OptEase filters, Plaintiffs suffered injuries and damages.

11
12 WHEREFORE, Plaintiffs demand judgment against Defendants as hereinafter set forth.

13
14 **COUNT II:**
15 **STRICT PRODUCTS LIABILITY — INADEQUATE WARNING**
16 **By all Plaintiffs**

17 80. Plaintiffs re-allege and incorporate by reference each and every allegation contained
18 in the foregoing paragraphs as though fully set forth herein.

19 81. Prior to, on, and after the dates during which the device were implanted in Plaintiffs,
20 and at all relevant times, Defendants manufactured, designed, marketed, distributed, and sold the
21 OptEase filters.

22 82. The OptEase filters had potential risks and side effects that were known or knowable
23 to Defendants by the use of scientific knowledge available before, at, and after the manufacture,
24 distribution, and sale of the devices implanted in Plaintiffs.

25 83. Defendants knew or it was knowable at the time they distributed the devices
26 implanted in Plaintiffs that the OptEase filters posed a significant and higher risk of failure than
27 other similar IVC filters, including for fracture, migration, tilting, thrombosis, migration, tilt,
28 inability to retrieve and pulmonary embolism and that these failures were resulting in serious patient

1 injuries and death. Defendants also knew or it was knowable that these devices were actually
2 prothrombotic, that use of these filters did not improve patient outcomes, and the longer these filters
3 were left implanted increased the likelihood of a device failure.

4 84. Defendants' OptEase filters were in a defective condition that was unreasonably and
5 substantially dangerous to any user or consumer implanted with the filters, such as Plaintiffs, when
6 used in an intended and reasonably foreseeable way. Such ordinary consumers, including Plaintiffs
7 and their prescribing physician(s), would not and could not have recognized or discovered the
8 potential risks and side effects of the device, as set forth herein.
9

10 85. The warnings and directions Defendants provided with its OptEase filters, including
11 the devices implanted in Plaintiffs, failed to adequately warn of the above-described risks and side-
12 effects, whether as to existence of the risk, its likelihood, severity, or the comparative risk to other
13 products.

14 86. The labeling also failed to provide adequate directions on how to appropriately use
15 the product.
16

17 87. The devices were expected to and did reach Plaintiffs without substantial change in
18 its condition, labeling, or warnings as manufactured, distributed, and sold by Defendants.
19 Additionally, Plaintiffs and their prescribing physicians used the devices in the manner in which
20 they were intended to be used, making such use reasonably foreseeable to Defendants.

21 88. Defendants' lack of sufficient instructions or warnings prior to, on, and after the date
22 Plaintiffs used the devices was a substantial factor in causing Plaintiffs' injuries and damages, as
23 described herein.

24 WHEREFORE, Plaintiff demands judgment against Defendants as hereinafter set forth.
25

26 ///

27 ///

28 ///

COUNT III:
STRICT PRODUCTS LIABILITY — MANUFACTURING DEFECT
By all Plaintiffs

89. Plaintiffs re-allege and incorporate by reference each and every allegation contained in the foregoing paragraphs as though fully set forth herein.

90. Prior to, on, and after the date the devices were implanted in Plaintiffs, and at all relevant times, Defendants designed, distributed, manufactured, sold, and marketed the OptEase filters for use in the United States.

91. At all times herein mentioned, Defendants designed, distributed, manufactured, marketed, and sold the devices such that they were dangerous, unsafe, and defective in manufacture, and contained a manufacturing defect when it left defendants' possession.

92. Plaintiffs are informed and believe, and on that basis allege, that the OptEase filters, including the devices implanted in them, contained manufacturing defects, in that they differed from Defendants' design or specifications, or from other typical units of the same product line.

93. As a direct and proximate result of Defendants' defective manufacture and sale of the OptEase filters prior to, on, and after the date Plaintiffs used the devices, Plaintiffs suffered the injuries and damages herein described.

WHEREFORE, Plaintiffs demand judgment against Defendants as hereinafter set forth.

COUNT IV:
NEGLIGENCE
By all Plaintiffs

94. Plaintiffs re-allege and incorporate by reference each and every allegation contained in the foregoing paragraphs as though fully set forth herein.

95. Prior to, on, and after the date the devices were implanted in Plaintiffs, and at all relevant times, Defendants designed, distributed, manufactured, sold, and marketed the OptEase filters for use in the United States.

96. Defendants had a duty to exercise reasonable and prudent care in the development, testing, design, manufacture, inspection, marketing, labeling, promotion, distribution and sale of the OptEase filters so as to avoid exposing others to foreseeable and unreasonable risks of harm.

1 97. Defendants knew or reasonably should have known that the OptEase filters were
2 dangerous or were likely to be dangerous when used in an intended or reasonably foreseeable
3 manner.

4 98. At the time of manufacture and sale of the OptEase filters, Defendants knew or
5 should have known that the OptEase filters:

- 6 a. Were designed and manufactured in such a manner as to lack sufficient
7 structural integrity (fatigue resistance) and stability (tilt/migration) to meet
8 user needs when used in an intended and reasonably foreseeable manner.
9
10 b. Were designed and manufactured so as to present an unreasonable risk of the
11 devices perforating the vena cava wall and/or in the case of the OptEase filter
12 becoming irretrievable;
13
14 c. Being designed and manufactured in such a manner as to be prothrombotic.

15 99. At the time of manufacture and sale of the OptEase filters, including the ones
16 implanted in Plaintiffs, Defendants knew or should have known that using the OptEase filters as
17 intended or in a reasonably foreseeable manner created a significant risk of patients suffering severe
18 health side effects including, but not limited to: hemorrhage; cardiac/pericardial tamponade; cardiac
19 arrhythmia and other symptoms similar to myocardial infarction; perforations of tissue, vessels and
20 organs; chronic deep vein thrombosis; pulmonary embolism; thrombosis; compartment syndrome;
21 and other severe personal injuries and diseases, which are permanent in nature, including, but not
22 limited to, death, physical pain and mental anguish, scarring and disfigurement, diminished
23 enjoyment of life, continued medical care and treatment due to chronic injuries/illness proximately
24 caused by the device; and the continued risk of requiring additional medical and surgical procedures
25 including general anesthesia, with attendant risk of life threatening complications.
26
27
28

1 100. Defendants knew or reasonably should have known that consumers of the OptEase
2 filters, including Plaintiffs' prescribing physicians, would not realize the danger associated with
3 using the devices for their intended or reasonably foreseeable use.

4 101. Defendants breached their duty to exercise reasonable and prudent care in the
5 development, testing, design, manufacture, inspection, marketing, labeling, promotion, distribution
6 and sale of the OptEase filters in, among other ways, the following acts and omissions:

- 7 a. Designing and distributing a product in which they knew or should have known
8 that the likelihood and severity of potential harm from the product exceeded the
9 burden of taking safety measures to reduce or avoid harm;
10 b. Designing and distributing a product in which they knew or should have known
11 that the likelihood and severity of potential harm from the product exceeded the
12 likelihood of potential harm from other devices and treatment options available
13 for the same purpose;
14 c. Failing to use reasonable care in manufacturing the product and producing a
15 product that differed from their design or specifications or from other typical
16 units from the same production line;
17 d. Failing to use reasonable care to warn or instruct, including pre and post-sale,
18 Plaintiffs, their prescribing physicians, or the general health care community
19 about the OptEase filters' substantially dangerous condition or about facts
20 making the products likely to be dangerous;
21 e. Failing to recall, retrofit, or provide adequate notice of such actions to Plaintiffs
22 or their health providers.
23 f. Failing to perform reasonable pre and post-market testing of the TrapEase and
24 OptEase filters to determine whether or not the products were safe for their
25 intended use;
26
27
28

- 1 g. Failing to provide adequate instructions, guidelines, and safety precautions,
2 including pre and post-sale, to those persons to whom it was reasonably
3 foreseeable would prescribe, use, and implant the OptEase filters;
4 h. Advertising, marketing and recommending the use of the OptEase filters, while
5 concealing and failing to disclose or warn of the dangers known by Defendants to
6 be connected with and inherent in the use of these filter systems;
7 i. Representing that the OptEase filters were safe for their intended use when, in
8 fact, Defendants knew and should have known the products were not safe for
9 their intended uses;
10 j. Continuing to manufacture and sell the OptEase filters with the knowledge that
11 said products were dangerous and not reasonably safe, and failing to comply with
12 good manufacturing regulations;
13 k. Failing to use reasonable and prudent care in the design, research, manufacture,
14 and development of the OptEase filters so as to avoid the risk of serious harm
15 associated with the use of these filter systems;
16 l. Advertising, marketing, promoting and selling OptEase filters for uses other than
17 as approved and indicated in the product's label;
18 m. Failing to establish an adequate quality assurance program used in the design and
19 manufacture of the OptEase filters.
20 n. Failing to establish and maintain an adequate post-market surveillance program;
21 o. A reasonable manufacturer, distributor, or seller under the same or similar
22 circumstances would not have engaged in the before-mentioned acts and
23 omissions.
24
25
26

27 102. Defendants' negligence prior to, on, and after the date of implantation of the devices
28 in Plaintiffs was a substantial factor in causing Plaintiffs' injuries and damages, as described herein.

1 WHEREFORE, Plaintiff demands judgment against Defendants as hereinafter set forth.

2 **COUNT V:**
3 **NEGLIGENT MISREPRESENTATION**
4 **By all Plaintiffs**

5 103. Plaintiffs re-allege and incorporate by reference each and every allegation contained
6 in the foregoing paragraphs as though fully set forth herein.

7 104. Prior to, on, and after the date the devices were implanted in Plaintiffs, and at all
8 relevant times, Defendants negligently and carelessly represented to Plaintiffs, their health care
9 providers, and the general public that certain material facts were true. The representations include,
10 *inter alia*, the following:

- 11 a. That the OptEase filters were safe, fit, and effective for use.
12 b. that the design of the OptEase filters eliminated the risk that pieces of the device
13 could perforate the vena cava, that the devices could tilt, or that fractures could
14 occur and migrate throughout the body.
15 c. That the OptEase filters were safer and more effective than other available IVC
16 filters.
17 d. That the OptEase filter was "easy" to remove.
18

19 105. Prior to, on, and after the dates during which Plaintiffs and their physicians
20 purchased and used the device, said representations were not true, and there was no reasonable
21 ground for believing said representations to be true at the times said representations were made.
22

23 106. Prior to, on, and after the dates during which Plaintiffs and their physicians
24 purchased and used the device, Defendants intended that Plaintiffs, their physicians, and the general
25 public would rely on said representations, which did in fact occur.
26
27
28

1 107. Defendants' negligent misrepresentations prior to, on, and after the date when
2 Plaintiffs and their physicians purchased and used the devices were a substantial factors in causing
3 Plaintiff's injuries and damages, as described herein.

4 WHEREFORE, Plaintiff demands judgment against Defendants as hereinafter set forth.

5
6 **COUNT VI**
7 **FRAUD - MISREPRESENTATION**
8 **By all Plaintiffs**

9 108. Plaintiffs re-allege and incorporate by reference each and every allegation contained
10 in the foregoing paragraphs as though fully set forth herein.

11 109. At all times relevant to this cause, and as detailed above, Defendants intentionally
12 provided Plaintiffs, their physicians, the medical community and the FDA with false or inaccurate
13 information, and/or omitted material information concerning the Device, including, but not limited
14 to, misrepresentations regarding the following topics:

- 15 a. The safety of the device;
16 b. The efficacy of the device;
17 c. The rate of failure of the device;
18 d. The pre-market testing of the device; and
19 e. The approved uses of the device.
20

21 110. The information distributed by Defendants to the public, the medical community,
22 Plaintiffs and their physicians was in the form of reports, press releases, advertising campaigns,
23 labeling materials, print advertisements, commercial media containing material representations, and
24 instructions for use, as well as through their officers, directors, agents, and representatives. These
25 materials contained false and misleading material representations, which included:

- 26 a. That the device was safe, fit, and effective when used for its intended purpose or in
27 a reasonably foreseeable manner;
28

- b. that it did not pose dangerous health risks in excess of those associated with the use of other similar devices;
- c. That the design of the device would eliminate the risk that pieces of the device could perforate the vena cava, that the devices could tilt, or that fractures could occur and migrate throughout the body;
- d. That the device was safer and more effective than other available IVC filters; and
- c. That the OptEase filter was “easy” to remove.

111. Defendants made the foregoing misrepresentations knowing that they were false. These materials included instructions for use and a warning document that was included in the package of the devices implanted in Plaintiffs.

112. Defendants’ intent and purpose in making these misrepresentations was to deceive and defraud Plaintiffs and their health care providers; to gain the confidence of Plaintiffs and their health care providers; to falsely assure them of the quality of the device and its fitness for use; and to induce the public and the medical community, including Plaintiffs’ healthcare providers to request, recommend, prescribe, implant, purchase, and continue to use the device, all in reliance on Defendants’ misrepresentations.

113. The foregoing representations and omissions by Defendants were in fact false.

114. Defendants acted to serve their own interests and having reasons to know consciously disregarded the substantial risk that the device could kill or significantly harm patients.

115. In reliance upon the false representations made by Defendants, Plaintiffs and their health care providers were induced to, and did use the device, thereby causing Plaintiffs to sustain the injuries described herein.

116. Defendants knew and had reason to know that Plaintiffs, their health care providers, or the general medical community did not have the ability to determine the true facts intentionally concealed and misrepresented by Defendants, and would not have prescribed and implanted same, if the true facts regarding the device had not been concealed and misrepresented by Defendants.

1 117. Defendants had sole access to material facts concerning the defective nature of the
2 OptEase filters and their propensity to cause serious side effects in the form of dangerous injuries
3 and damages to persons who are implanted with the device.

4 118. At the time Defendants failed to disclose and intentionally misrepresented the
5 foregoing facts, and at the time Plaintiffs' health care providers purchased and used these devices,
6 Plaintiffs' health care providers were unaware of Defendants' misrepresentations.

7 119. Plaintiffs' health care providers reasonably relied upon misrepresentations made by
8 Defendants where the concealed and misrepresented facts were critical to understanding the true
9 dangers inherent in the use of the device.

10 120. Defendants' fraudulent misrepresentations prior to, on, and after the date Plaintiffs
11 and their physicians purchased and used the devices were a substantial factor in causing Plaintiff's
12 injuries and damages, as described herein.

13 WHEREFORE, Plaintiffs demand judgment against defendants as hereinafter set forth.

14 **COUNT VII**
15 **FRAUDULENT CONCEALMENT**
16 **By all Plaintiffs**

17 121. Plaintiffs re-allege and incorporate by reference each and every allegation contained
18 in the foregoing paragraphs as though fully set forth herein.

19 122. In marketing and selling the device, defendants concealed material facts from
20 Plaintiffs and their health care providers.

- 21 123. Defendants' concealed material facts including, but not limited to, the following:
- 22 a. That the device was unsafe and not fit when used for its intended purpose or
23 in a reasonably foreseeable manner;
 - 24 b. That the device posed dangerous health risks in excess of those associated
25 with the use of other similar devices;
 - 26 c. That there were additional side effects related to implantation and use of the
27 device that were not accurately and completely reflected in the warnings
28 associated with the device;
 - d. That the device was not adequately tested to withstand normal placement
within the human body; and

1 e. That Defendants were aware at the time Plaintiffs' filters were distributed
2 that electropolishing reduced the risk of fracture and was industry standard
3 for NITINOL medical devices.

4 124. Plaintiffs and their healthcare providers were not aware of these and other facts
5 concealed by Defendants.

6 125. The Defendants are and were under a continuing duty to disclose the true character,
7 quality and nature of the device that was implanted in Plaintiff, but instead they concealed them.
8 Defendants' conduct, as described in this complaint, amounts to conduct purposely committed,
9 which Defendants must have realized was dangerous, heedless and reckless, without regard to the
10 consequences or the rights and safety of Plaintiff.

11 126. In concealing these and other facts, Defendants intended to deceive Plaintiffs and
12 their health care providers by concealing said facts.

13 127. Plaintiffs and their healthcare providers reasonably and justifiably relied on
14 Defendants' concealment and deception.

15 128. Defendants' concealment prior to, on, and after the date Plaintiffs and their
16 healthcare providers purchased and used the devices implanted in Plaintiffs was a substantial factor
17 in causing Plaintiffs' injuries and damages, as described herein.

18 WHEREFORE, Plaintiffs demand judgment against defendants as hereinafter set forth.

19 **COUNT VIII**
20 **EXPRESS WARRANTY**
21 **By all Plaintiffs**

22 129. Plaintiffs re-allege and incorporate by reference each and every allegation contained
23 in the foregoing paragraphs as though fully set forth herein.

24 130. Prior to, on, and after the dates during which Plaintiffs were implanted with these
25 devices, and at all relevant times, Defendants, and each of them, had knowledge of the purpose for
26 which the devices were to be used, and represented the devices to be in all respects safe, effective,
27 and proper for such purpose. Said warranties and representations were made to Plaintiffs and their
28

1 treating physicians. Plaintiffs and their treating physicians relied on said warranties and
2 representations in deciding to use the device.

3 131. Defendants used packaging inserts and media advertisements to represent to the
4 medical community and consumers, including plaintiffs and their health care providers, that the
5 OptEase filters: were safe for their intended use; did not pose serious health hazards when used
6 appropriately; were safer and more effective than alternative IVC filters; had been adequately tested
7 for their intended use; would not perforate the vena cava, tilt, or fracture and migrate throughout the
8 body after placement; and that the OptEase filter was "easy" to remove.

9 132. Defendants, and each of them, breached the above-described express warranties and
10 representations in that the OptEase filters did not conform to these express warranties and
11 representations.

12 133. Prior to, on, and after the dates during which Plaintiffs and their physicians
13 purchased and used these devices, Defendants, and each of them, were put on notice of the OptEase
14 filters' inability to conform to these express warranties.

15 134. Defendants' breach of said express warranties and representations prior to, on, and
16 after the date Plaintiffs and their physicians purchased and used the devices was a substantial factor
17 in causing Plaintiffs' injuries and damages, as described herein.

18 WHEREFORE, Plaintiffs demand judgment against Defendants as hereinafter set forth.

19 **COUNT IX**
20 **BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY**
21 **By all Plaintiffs**

22 135. Plaintiffs re-allege and incorporate by reference each and every allegation contained
23 in the foregoing paragraphs as though fully set forth herein.

24 136. Defendants sold the OptEase filters for Plaintiffs' ultimate use.

25 137. At all times hereinafter mentioned, Defendants were in the business of developing,
26 designing, licensing, manufacturing, selling, distributing and/or marketing the TrapEase and
27 OptEase filters, including the one implanted in Plaintiffs.
28

138. Defendants impliedly warranted to Plaintiffs and their physicians that the OptEase filters were safe and of merchantable quality and for the ordinary purpose for which they product was intended and marketed to be used.

139. The representations and implied warranties made by Defendants were false, misleading, and inaccurate because the OptEase filters were defective, unsafe, unreasonably dangerous, and not of merchantable quality, when used as they were marketed and intended to be used. Specifically, at the time Plaintiffs and their physicians purchased and used the devices, the products were not in a merchantable condition in that:

- a. They offered no benefit to patient outcomes,
- b. They suffered an unreasonably high failure and injury rates, and
- c. The surface of the devices were manufactured and designed in such a way that they were distributed with surface damage that substantially increased the risk of fracture.
- d. They were prothrombotic;

140. Defendants' breach of said implied warranties and representations prior to, on, and after the date Plaintiffs and their physicians purchased and used the devices was a substantial factor in causing Plaintiffs' injuries and damages, as described herein.

WHEREFORE, Plaintiffs demand judgment against Defendants as hereinafter set forth.

COUNT X
LOSS OF CONSORTIUM
By Plaintiff Linda Mareski

141. Plaintiff Linda Mareski re-alleges and incorporates by reference each and every allegation contained in the foregoing paragraphs as though fully set forth herein.

142. Plaintiff Linda Mareski is, and at all time herein mentioned was, the lawful spouse of Plaintiff Ronald Mareski.

143. As a direct, legal and proximate result of the culpability and fault of the Defendants, be such fault through strict liability or negligence, Plaintiff Linda Mareski suffered the loss of support, service, love, companionship, affection, society, intimate relations, and other elements of

1 consortium, all to her general damage, in an amount in excess of the jurisdictional minimum of this
2 Court.

3 WHEREFORE, Plaintiff Linda Mareski demand judgment against the Defendants as
4 hereinafter set forth.

5 **PUNITIVE DAMAGES ALLEGATIONS**

6 144. Plaintiff re-alleges and incorporates by reference each and every allegation contained
7 in the foregoing paragraphs as though fully set forth herein.

8 145. Upon information and belief, Plaintiffs allege that as early as 2003, Defendants were
9 aware and had knowledge of the fact that the OptEase filters were defective and unreasonably
10 dangerous and were causing injury and death to patients.

11 146. Data establishes that the failure rates of the OptEase filters are and were much higher
12 than what Defendants have in the past and currently continue to publish to the medical community
13 and members of the public. Further, Defendants were aware or should have been aware that the
14 OptEase filters had substantially higher failure rates than other similar products on the market and
15 are actually prothrombotic. Defendants were also aware that there was no reliable evidence
16 indicating its devices actually improved patient outcomes. Despite these facts, Defendants
17 continued to sell an unreasonably dangerous product while concealing and misrepresenting its risks
18 and benefits to the public, plaintiffs, plaintiffs' health care providers, and the FDA.

19 147. The conduct of Defendants as alleged in this Complaint constitutes willful, wanton,
20 gross, and outrageous corporate conduct that demonstrates a conscious disregard for the safety of
21 Plaintiff. Defendants had actual knowledge of the dangers presented by OptEase filters, yet
22 consciously failed to act reasonably to:

- 23 a. Inform or warn Plaintiffs, Plaintiffs' physicians, or the public at large of these
24 dangers; and
25 b. Establish and maintain an adequate quality and post-market surveillance system.

26 148. Despite having knowledge as early as 2003 of the unreasonably dangerous and
27 defective nature of the OptEase filters, Defendants consciously disregarded the known risks and
28 continued to actively market and offer for sale the OptEase filters.

1 149. Plaintiffs further allege that Defendants acted in willful, wanton, gross, and total
2 disregard for the health and safety of the users or consumers of their OptEase filters, acted to serve
3 their own interests, and consciously disregarded the substantial risk that their product might kill or
4 significantly harm patients, or significantly injure the rights of others. Despite this knowledge,
5 Defendants consciously pursued a course of conduct knowing that such conduct created a
6 substantial risk of significant harm to other persons.

7 **PRAYER FOR DAMAGES**

8 **WHEREFORE**, Plaintiffs pray for relief against Defendants Cordis Corporation,
9 Confluent Medical Technologies, Inc., and Does 1 through 100, inclusive, on the entire complaint,
10 as follows:

- 11 a. General damages according to proof at the time of trial;
12 b. Special (economic) damages, including without limitation, past and future medical
13 expenses and past and future lost wages according to proof at time of trial.
14 c. Pre-judgment and post-judgment interest pursuant to the laws of the State of
15 California;
16 d. Costs of suit incurred herein;
17 e. Punitive damages in an amount sufficient to punish Defendants and deter similar
18 conduct in the future;
19 f. For such further and other relief as this Court deems necessary, just and proper.

20 **DEMAND FOR JURY TRIAL**

21 Plaintiffs hereby demand trial by jury on all issues.
22

23 Respectfully Submitted,

24 DATED: May 24, 2016

BRENES LAW GROUP

25
26 /s/ Troy A. Brenes

27 Troy A. Brenes
28 Attorney for Plaintiffs

Exhibit 11

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 Matthew Ramon Lopez, Bar No. 263134
 Amorina Patrice Lopez, Bar No. 278002
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MAY 20 2016

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CLERK OF THE SUPERIOR COURT
 By Samuel Mena
 Deputy

Attorneys for Plaintiffs

**SUPERIOR COURT OF THE STATE OF CALIFORNIA
 FOR THE COUNTY OF ALAMEDA**

MICHAEL BARBER, an individual;
 ANDREW CLOS, an individual;
 JACQUELYN HANSON, an individual;
 DONALD HERNANDEZ, SR. and RHONDA
 HERNANDEZ, individually and as husband
 and wife; JAMES LEWIS, an individual;
 CONNIE PATTERSON, an individual;
 CAROLYN SIMMONS and WALTER
 SIMMONS, individually and as wife and
 husband; MICHAEL DONLIN, an individual;
 DAVID HAMILTON, an individual;
 STEPHEN VANDALL and HEATHER
 VANDALL, individually and as husband and
 wife; DOROTHY MILLS, an individual;
 LAKISHA HOOKS, an individual;
 DEBORAH JARVIS, an individual;
 CAROLINE CARR, an individual;
 GERALDINE CLARK, an individual;
 ROBERT SPISHAK and BARBARA
 SPISHAK, individually and as husband and
 wife; REINA JONES, an individual;
 VENESIA JOHNSON, an individual;
 DARNELL KILGORE, an individual;
 JOSEPH HERSHBERGER, an individual;
 RUSSELL ZUKRIGIL and BRIAN
 ZUKRIGIL, individually and as husband and

Case No.: **RG16816487**

COMPLAINT FOR DAMAGES

1. STRICT PRODUCTS LIABILITY –
DESIGN DEFECT
2. STRICT PRODUCTS LIABILITY –
FAILURE TO WARN
3. STRICT PRODUCTS LIABILITY –
MANUFACTURING DEFECT
4. NEGLIGENCE
5. NEGLIGENT MISREPRESENTATION
6. FRAUDULENT MISREPRESENTATION
7. FRAUDULENT CONCEALMENT
8. BREACH OF EXPRESS WARRANTY
9. BREACH OF IMPLIED WARRANTY OF
MERCHANTABILITY
10. LOSS OF CONSORTIUM

DEMAND FOR JURY TRIAL

BY FAX

1 husband;
 2
 3 vs.
 4 CORDIS CORPORATION, a corporation;
 5 JOHNSON & JOHNSON, a corporation;
 6 CARDINAL HEALTH, INC., a corporation;
 and DOES 1 through 50;
 7 Defendants.

8
 9 COMES NOW, Plaintiffs, by and through their attorneys, who complain and allege against
 10 Defendants, CORDIS CORPORATION ("Cordis"), JOHNSON & JOHNSON ("J&J"), CARDINAL
 11 HEALTH, INC. ("Cardinal"), and DOES 1 through 50, and each of them, on information and belief, as
 12 follows:

13 INTRODUCTION

14 1. Plaintiffs bring this action for personal injuries damages suffered as a direct and
 15 proximate result of being implanted with a defective and unreasonably dangerous Inferior Vena Cava
 16 ("IVC") filter medical device manufactured by Defendants.

17 2. The subject IVC filters include the following devices: TrapEase™ Permanent Vena Cava
 18 Filter ("TrapEase filter") and OptEase™ Retrievable Vena Cava Filter ("OptEase filter") (for
 19 convenience, these devices will be referred to in this complaint under the generic terms "Cordis IVC
 20 filters" or "Defendants' IVC filters"). At all times relevant to this action, Defendants developed,
 21 designed, set specifications for, licensed, manufactured, prepared, compounded, assembled, processed,
 22 sold, distributed and/or marketed the Cordis IVC filters to be implanted in patients throughout the
 23 United States, including California.

24 3. Plaintiffs' claims for damages all relate to Defendants' design, manufacture, sale, testing,
 25 marketing, labeling, advertising, promotion, and/or distribution of Cordis IVC filters.

26 4. The Cordis IVC filters that are the subject of this action all reached Plaintiffs and
 27 Plaintiffs' physicians without substantial change in condition from the time they left Defendants'
 28 possession.

6. Defendants are solely responsible for any alleged design, manufacture or information defect its IVC filters contain.

7. Defendants do not allege that any other person or entity is comparatively at fault for any alleged design, manufacture, or informational defect its IVC filters contain.

PARTIES

PARTIES

8. Plaintiff MICHAEL BARBER at all times relevant to this action was and is a citizen and resident of the State of California. Plaintiff MICHAEL BARBER underwent placement of Defendants' TrapEase Vena Cava Filter on or about August 30, 2013, in California. The filter subsequently malfunctioned and caused injury and damages to Plaintiff MICHAEL BARBER, including, but not limited to, blood clots, clotting and occlusion of IVC filter, clotting and pain in lower extremities, and filter unable to be retrieved. As a direct and proximate result of these malfunctions, Plaintiff MICHAEL BARBER suffered life-threatening injuries and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff MICHAEL BARBER has suffered and will continue to suffer significant medical expenses, and pain and suffering, and other damages.

9. Plaintiff ANDREW CLOS at all times relevant to this action was and is a citizen and resident of the State of New York. Plaintiff ANDREW CLOS underwent placement of Defendants' OptEase Vena Cava Filter on or about January 21, 2011. The filter subsequently malfunctioned and caused injury and damages to Plaintiff ANDREW CLOS, including, but not limited to, tilt, perforation, filter embedded in wall of the IVC, unsuccessful removal attempt, and filter unable to be retrieved. As a direct and proximate result of these malfunctions, Plaintiff ANDREW CLOS suffered life-threatening injuries and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff ANDREW CLOS has suffered and will continue to suffer significant medical expenses, and pain and suffering, and other damages.

10. Plaintiff JACQUELYN HANSON at all times relevant to this action was and is a citizen and resident of the State of Washington. Plaintiff JACQUELYN HANSON underwent placement of Defendants' OptEase Vena Cava Filter on or about May 14, 2007. The filter subsequently

1 malfunctioned and caused injury and damages to Plaintiff JACQUELYN HANSON, including, but not
2 limited to, tilt, filter embedded in wall of the IVC, defect of the IVC, and trauma to her IVC. As a direct
3 and proximate result of these malfunctions, Plaintiff JACQUELYN HANSON suffered life-threatening
4 injuries and damages, and required extensive medical care and treatment. As a further proximate result,
5 Plaintiff JACQUELYN HANSON has suffered and will continue to suffer significant medical expenses,
6 and pain and suffering, and other damages.

7 11. Plaintiff DONALD HERNANDEZ, SR. at all times relevant to this action was and is a
8 citizen and resident of the State of Texas. Plaintiff DONALD HERNANDEZ, SR. underwent placement
9 of Defendants' OptEase Vena Cava Filter on or about April 25, 2012. The filter subsequently
10 malfunctioned and caused injury and damages to Plaintiff DONALD HERNANDEZ, SR., including, but
11 not limited to, filter embedded in wall of the IVC and unable to be retrieved. As a direct and proximate
12 result of these malfunctions, Plaintiff DONALD HERNANDEZ, SR. suffered life-threatening injuries
13 and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff
14 DONALD HERNANDEZ, SR. has suffered and will continue to suffer significant medical expenses,
15 and pain and suffering, and other damages.

16 12. Plaintiff RHONDA HERNANDEZ at all times relevant to this action was and is a citizen
17 and resident of the State of Texas. Plaintiffs DONALD HERNANDEZ, SR. and RHONDA
18 HERNANDEZ were and are, at all times relevant to this action, legally married as husband and wife.
19 Plaintiff RHONDA HERNANDEZ brings this action for, *inter alia*, the loss of consortium, comfort, and
20 society she suffered due to the personal injuries suffered by her husband, DONALD HERNANDEZ, SR.

21 13. Plaintiff JAMES LEWIS at all times relevant to this action was and is a citizen and
22 resident of the State of Ohio. Plaintiff JAMES LEWIS underwent placement of Defendants' TrapEase
23 Vena Cava Filter on or about July 29, 2008. The filter subsequently malfunctioned and caused injury
24 and damages to Plaintiff JAMES LEWIS, including, but not limited to, tilt, filter embedded in wall of
25 the IVC, and filter unable to be retrieved. As a direct and proximate result of these malfunctions,
26 Plaintiff JAMES LEWIS suffered life-threatening injuries and damages, and required extensive medical
27 care and treatment. As a further proximate result, Plaintiff JAMES LEWIS has suffered and will
28 continue to suffer significant medical expenses, and pain and suffering, and other damages.

1 14. Plaintiff CONNIE PATTERSON at all times relevant to this action was and is a citizen
2 and resident of the State of Ohio. Plaintiff CONNIE PATTERSON underwent placement of
3 Defendants' TrapEase Vena Cava Filter on or about July 15, 2005. The filter subsequently
4 malfunctioned and caused injury and damages to Plaintiff CONNIE PATTERSON, including, but not
5 limited to, migration of the filter. As a direct and proximate result of these malfunctions, Plaintiff
6 CONNIE PATTERSON suffered life-threatening injuries and damages, and required extensive medical
7 care and treatment. As a further proximate result, Plaintiff CONNIE PATTERSON has suffered and
8 will continue to suffer significant medical expenses, and pain and suffering, and other damages.

9 15. Plaintiff CAROLYN SIMMONS at all times relevant to this action was and is a citizen
10 and resident of the State of Florida. Plaintiff CAROLYN SIMMONS underwent placement of
11 Defendants' TrapEase Vena Cava Filter on or about February 27, 2015. The filter subsequently
12 malfunctioned and caused injury and damages to Plaintiff CAROLYN SIMMONS, including, but not
13 limited to, pain at filter site. As a direct and proximate result of these malfunctions, Plaintiff
14 CAROLYN SIMMONS suffered life-threatening injuries and damages, and required extensive medical
15 care and treatment. As a further proximate result, Plaintiff CAROLYN SIMMONS has suffered and
16 will continue to suffer significant medical expenses, and pain and suffering, and other damages.

17 16. Plaintiff WALTER SIMMONS at all times relevant to this action was and is a citizen and
18 resident of the State of Florida. Plaintiffs CAROLYN SIMMONS and WALTER SIMMONS were and
19 are, at all times relevant to this action, legally married as wife and husband. Plaintiff WALTER
20 SIMMONS brings this action for, *inter alia*, the loss of consortium, comfort, and society he suffered due
21 to the personal injuries suffered by his wife, CAROLYN SIMMONS.

22 17. Plaintiff MICHAEL DONLIN at all times relevant to this action was and is a citizen and
23 resident of the State of New York. Plaintiff MICHAEL DONLIN underwent placement of Defendants'
24 TrapEase Vena Cava Filter on or about May 30, 2010. The filter subsequently malfunctioned and
25 caused injury and damages to Plaintiff MICHAEL DONLIN, including, but not limited to, filter
26 embedded in wall of the IVC and unable to be retrieved. As a direct and proximate result of these
27 malfunctions, Plaintiff MICHAEL DONLIN suffered life-threatening injuries and damages, and
28 required extensive medical care and treatment. As a further proximate result, Plaintiff MICHAEL

1 DONLIN has suffered and will continue to suffer significant medical expenses, and pain and suffering,
2 and other damages.

3 18. Plaintiff DAVID HAMILTON at all times relevant to this action was and is a citizen and
4 resident of the State of Georgia. Plaintiff DAVID HAMILTON underwent placement of Defendants'
5 OptEase Vena Cava Filter on or about January 30, 2011. The filter subsequently malfunctioned and
6 caused injury and damages to Plaintiff DAVID HAMILTON, including, but not limited to, pain at filter
7 site. As a direct and proximate result of these malfunctions, Plaintiff DAVID HAMILTON suffered
8 life-threatening injuries and damages, and required extensive medical care and treatment. As a further
9 proximate result, Plaintiff DAVID HAMILTON has suffered and will continue to suffer significant
10 medical expenses, and pain and suffering, and other damages.

11 19. Plaintiff STEPHEN VANDALL at all times relevant to this action was and is a citizen
12 and resident of the State of West Virginia. Plaintiff STEPHEN VANDALL underwent placement of
13 Defendants' TrapEase Vena Cava Filter on or about October 10, 2008. The filter subsequently
14 malfunctioned and caused injury and damages to Plaintiff STEPHEN VANDALL, including, but not
15 limited to, filter embedded in wall of the IVC and unable to be retrieved. As a direct and proximate
16 result of these malfunctions, Plaintiff STEPHEN VANDALL suffered life-threatening injuries and
17 damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff
18 STEPHEN VANDALL has suffered and will continue to suffer significant medical expenses, and pain
19 and suffering, and other damages.

20 20. Plaintiff HEATHER VANDALL at all times relevant to this action was and is a citizen
21 and resident of the State of Texas. Plaintiffs STEPHEN VANDALL and HEATHER VANDALL were
22 and are, at all times relevant to this action, legally married as husband and wife. Plaintiff HEATHER
23 VANDALL brings this action for, *inter alia*, the loss of consortium, comfort, and society she suffered
24 due to the personal injuries suffered by her husband, STEPHEN VANDALL.

25 21. Plaintiff DOROTHY MILLS at all times relevant to this action was a citizen and resident
26 of the State of West Virginia and, subsequently, became a citizen and resident of the State of Oklahoma.
27 Plaintiff DOROTHY MILLS underwent placement of Defendants' TrapEase Vena Cava Filter on or
28 about May 23, 2005. The filter subsequently malfunctioned and caused injury and damages to Plaintiff

1 DOROTHY MILLS, including, but not limited to, tilt, pain at filter site. As a direct and proximate
2 result of these malfunctions, Plaintiff DOROTHY MILLS suffered life-threatening injuries and
3 damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff
4 DOROTHY MILLS has suffered and will continue to suffer significant medical expenses, and pain and
5 suffering, and other damages.

6 22. Plaintiff LAKISHA HOOKS at all times relevant to this action was and is a citizen and
7 resident of the State of Texas. Plaintiff LAKISHA HOOKS underwent placement of Defendants'
8 OptEase Vena Cava Filter on or about May 1, 2014. The filter subsequently malfunctioned and caused
9 injury and damages to Plaintiff LAKISHA HOOKS, including, but not limited to, blood clots, clotting
10 and occlusion of IVC filter. As a direct and proximate result of these malfunctions, Plaintiff LAKISHA
11 HOOKS suffered life-threatening injuries and damages, and required extensive medical care and
12 treatment. As a further proximate result, Plaintiff LAKISHA HOOKS has suffered and will continue to
13 suffer significant medical expenses, and pain and suffering, and other damages.

14 23. Plaintiff DEBORAH JARVIS at all times relevant to this action was and is a citizen and
15 resident of the State of Pennsylvania. Plaintiff DEBORAH JARVIS underwent placement of
16 Defendants' TrapEase Vena Cava Filter on or about September 25, 2007. The filter subsequently
17 malfunctioned and caused injury and damages to Plaintiff DEBORAH JARVIS, including, but not
18 limited to, pain at filter site. As a direct and proximate result of these malfunctions, Plaintiff
19 DEBORAH JARVIS suffered life-threatening injuries and damages, and required extensive medical care
20 and treatment. As a further proximate result, Plaintiff DEBORAH JARVIS has suffered and will
21 continue to suffer significant medical expenses, and pain and suffering, and other damages.

22 24. Plaintiff CAROLINE CARR at all times relevant to this action was and is a citizen and
23 resident of the State of Pennsylvania. Plaintiff CAROLINE CARR underwent placement of Defendants'
24 TrapEase Vena Cava Filter on or about May 13, 2011. The filter subsequently malfunctioned and
25 caused injury and damages to Plaintiff CAROLINE CARR, including, but not limited to, blood clots,
26 clotting and occlusion of IVC filter. As a direct and proximate result of these malfunctions, Plaintiff
27 CAROLINE CARR suffered life-threatening injuries and damages, and required extensive medical care
28

1 and treatment. As a further proximate result, Plaintiff CAROLINE CARR has suffered and will
2 continue to suffer significant medical expenses, and pain and suffering, and other damages.

3 25. Plaintiff GERALDINE CLARK at all times relevant to this action was and is a citizen
4 and resident of the State of Tennessee. Plaintiff GERALDINE CLARK underwent placement of
5 Defendants' TrapEase Vena Cava Filter on or about January 9, 2015. The filter subsequently
6 malfunctioned and caused injury and damages to Plaintiff GERALDINE CLARK, including, but not
7 limited to, blood clots, clotting and occlusion of IVC filter. As a direct and proximate result of these
8 malfunctions, Plaintiff GERALDINE CLARK suffered life-threatening injuries and damages, and
9 required extensive medical care and treatment. As a further proximate result, Plaintiff GERALDINE
10 CLARK has suffered and will continue to suffer significant medical expenses, and pain and suffering,
11 and other damages.

12 26. Plaintiff ROBERT SPISHAK at all times relevant to this action was and is a citizen and
13 resident of the State of Ohio. Plaintiff ROBERT SPISHAK underwent placement of Defendants'
14 TrapEase Vena Cava Filter on or about April 8, 2009. The filter subsequently malfunctioned and caused
15 injury and damages to Plaintiff ROBERT SPISHAK, including, but not limited to, severe shortness of
16 breath, dizziness, and pain at filter site. As a direct and proximate result of these malfunctions, Plaintiff
17 ROBERT SPISHAK suffered life-threatening injuries and damages, and required extensive medical care
18 and treatment. As a further proximate result, Plaintiff ROBERT SPISHAK has suffered and will
19 continue to suffer significant medical expenses, and pain and suffering, and other damages.

20 27. Plaintiff BARBARA SPISHAK at all times relevant to this action was and is a citizen
21 and resident of the State of Ohio. Plaintiffs ROBERT SPISHAK and BARBARA SPISHAK were and
22 are, at all times relevant to this action, legally married as husband and wife. Plaintiff BARBARA
23 SPISHAK brings this action for, *inter alia*, the loss of consortium, comfort, and society she suffered due
24 to the personal injuries suffered by her husband, ROBERT SPISHAK.

25 28. Plaintiff REINA JONES at all times relevant to this action was and is a citizen and
26 resident of the State of New York. Plaintiff REINA JONES underwent placement of Defendants'
27 OptEase Vena Cava Filter on or about August 14, 2006. The filter subsequently malfunctioned and
28 caused injury and damages to Plaintiff REINA JONES, including, but not limited to, blood clots,

1 clotting and occlusion of the IVC filter. As a direct and proximate result of these malfunctions, Plaintiff
2 REINA JONES suffered life-threatening injuries and damages, and required extensive medical care and
3 treatment. As a further proximate result, Plaintiff REINA JONES has suffered and will continue to
4 suffer significant medical expenses, and pain and suffering, and other damages.

5 29. Plaintiff VANESIA JOHNSON at all times relevant to this action was and is a citizen and
6 resident of the State of Texas. Plaintiff VANESIA JOHNSON underwent placement of Defendants'
7 OptEase Vena Cava Filter on or about February 23, 2009. The filter subsequently malfunctioned and
8 caused injury and damages to Plaintiff VANESIA JOHNSON, including, but not limited to, filter
9 embedded to wall of IVC and cannot be retrieved. As a direct and proximate result of these
10 malfunctions, Plaintiff VANESIA JOHNSON suffered life-threatening injuries and damages, and
11 required extensive medical care and treatment. As a further proximate result, Plaintiff VANESIA
12 JOHNSON has suffered and will continue to suffer significant medical expenses, and pain and suffering,
13 and other damages.

14 30. Plaintiff DARNELL KILGORE at all times relevant to this action was and is a citizen
15 and resident of the State of South Carolina. Plaintiff DARNELL KILGORE underwent placement of
16 Defendants' OptEase Vena Cava Filter on or about February 10, 2009. The filter subsequently
17 malfunctioned and caused injury and damages to Plaintiff DARNELL KILGORE, including, but not
18 limited to, blood clots, clotting and occlusion of the IVC filter. As a direct and proximate result of these
19 malfunctions, Plaintiff DARNELL KILGORE suffered life-threatening injuries and damages, and
20 required extensive medical care and treatment. As a further proximate result, Plaintiff DARNELL
21 KILGORE has suffered and will continue to suffer significant medical expenses, and pain and suffering,
22 and other damages.

23 31. Plaintiff JOSEPH HERSHBERGER at all times relevant to this action was a citizen and
24 resident of the State of Arizona and, subsequently, became a citizen and resident of the State of
25 Colorado. Plaintiff JOSEPH HERSHBERGER underwent placement of Defendants' OptEase Vena
26 Cava Filter on or about July 14, 2013. The filter subsequently malfunctioned and caused injury and
27 damages to Plaintiff JOSEPH HERSHBERGER, including, but not limited to, perforation of the IVC
28 and blood clots. As a direct and proximate result of these malfunctions, Plaintiff JOSEPH

1 HERSHBERGER suffered life-threatening injuries and damages, and required extensive medical care
2 and treatment. As a further proximate result, Plaintiff JOSEPH HERSHBERGER has suffered and will
3 continue to suffer significant medical expenses, and pain and suffering, and other damages.

4 32. Plaintiff RUSSELL ZUKRIGIL at all times relevant to this action was and is a citizen
5 and resident of the State of New York. Plaintiff RUSSELL ZUKRIGIL underwent placement of
6 Defendants' TrapEase Vena Cava Filter on or about March 2, 2007. The filter subsequently
7 malfunctioned and caused injury and damages to Plaintiff RUSSELL ZUKRIGIL, including, but not
8 limited to, perforation of the IVC. As a direct and proximate result of these malfunctions, Plaintiff
9 RUSSELL ZUKRIGIL suffered life-threatening injuries and damages, and required extensive medical
10 care and treatment. As a further proximate result, Plaintiff RUSSELL ZUKRIGIL has suffered and will
11 continue to suffer significant medical expenses, and pain and suffering, and other damages.

12 33. Plaintiff BRIAN ZUKRIGIL at all times relevant to this action was and is a citizen and
13 resident of the State of New York. Plaintiffs RUSSELL ZUKRIGIL and BRIAN ZUKRIGIL were and
14 are, at all times relevant to this action, legally married. Plaintiff BRIAN ZUKRIGIL brings this action
15 for, *inter alia*, the loss of consortium, comfort, and society he suffered due to the personal injuries
16 suffered by his husband, RUSSELL ZUKRIGIL.

17 34. Defendant CORDIS CORPORATION ("Cordis"), including its department, division, and
18 subsidiary, Cordis Endovascular, is a corporation or business entity organized and existing under the
19 laws of the State of Florida with its headquarters located at 6500 Paseo Padre Pkwy., Fremont,
20 California, 94555.

21 35. Cordis may be served with process by serving its registered agent, CT Corporation
22 System, at 818 West Seventh Street Suite 930, Los Angeles, California 90017.

23 36. Defendant Cordis was a wholly-owned subsidiary of Defendant JOHNSON &
24 JOHNSON ("J&J") and part of the J&J family of companies until in or around October 2015. J&J is a
25 corporation or business entity organized and existing under the laws of the State of New Jersey with its
26 headquarters located in New Jersey.

1 37. In or around October 2015, Defendant CARDINAL HEALTH, INC. ("Cardinal")
2 publicly announced that it acquired J&J's Cordis business. Cardinal is a corporation or business entity
3 organized and existing under the laws of Ohio with its headquarters in Dublin, Ohio.

4 38. The true names and/or capacities, whether individual, corporate, partnership, associate,
5 governmental, or otherwise, of Defendant DOES 1 through 50, inclusive, are unknown to Plaintiffs at
6 this time, who therefore sue said Defendants by such fictitious names. Plaintiffs are informed and
7 believe, and thereon allege, that each Defendant designated herein as a DOE caused injuries and
8 damages proximately thereby to Plaintiffs as is hereinafter alleged, and that each DOE defendant is
9 liable to Plaintiffs for the acts and omissions alleged herein below and the injuries and damages resulting
10 therefrom. Plaintiffs seek leave to amend this Complaint to allege the true names and capacities of said
11 DOE defendants when the same are ascertained.

12 39. Plaintiffs are informed and believe, and thereon allege, that at all times herein mentioned,
13 the Defendants and each of the DOE defendants were the agent, servant, employee and/or joint venturer
14 of the other co-defendants, and each of them, and at all said times each Defendant, including DOE
15 defendants, were acting in the full course, scope, and authority of said agency, service, employment
16 and/or joint venture.

17 40. Plaintiffs are informed and believe, and thereon allege, that at all times mentioned herein,
18 Defendants and DOES 1 through 50, and each of them, were also known as, formerly known as, and/or
19 were the successors and/or predecessors in interest/business/product line/or a portion thereof, assigns, a
20 parent, a subsidiary (wholly or partially owned by, or the whole or partial owner), affiliate, partner, co-
21 venturer, merged company, alter egos, agents, equitable trustees and/or fiduciaries of and/or were
22 members in an entity or entities engaged in the funding, researching, studying, manufacturing,
23 fabricating, designing, developing, labeling, assembling, distributing, supplying, leasing, buying,
24 offering for sale, selling, inspecting, servicing, contracting others for marketing, warranting, rebranding,
25 manufacturing for others, packaging, and advertising the device.

26 41. Defendants and DOES 1 through 50, and each of them, are liable for the acts, omissions
27 and tortious conduct of its successors and/or predecessors in interest/business/product line/or a portion
28 thereof, assigns, parent, subsidiary, affiliate, partner, co-venturer, merged company, alter ego, agent,

1 equitable trustee, fiduciary and/or its alternate entities in that Defendants and DOES 1 through 50, and
 2 each of them, enjoy the goodwill originally attached to each such alternate entity, acquired the assets or
 3 product line (or a portion thereof), and in that there has been a virtual destruction of Plaintiffs' remedy
 4 against each such alternate entity, and that each such Defendant has the ability to assume the risk-
 5 spreading role of each such alternate entity.

6 42. Plaintiffs are informed and believe, and thereon allege that, at all times herein mentioned,
 7 DOES 1 through 50, and each of them, were and are corporations organized and existing under the laws
 8 of the State of California or the laws of some state or foreign jurisdiction; that each of the said DOE
 9 defendants were and are authorized to do and are doing business in the State of California and regularly
 10 conducted business in the State of California.

11 43. Upon information and belief, Defendants at all relevant times were engaged in the
 12 business of researching, developing, designing, licensing, manufacturing, distributing, selling,
 13 marketing, and/or introducing into interstate commerce and into the State of California, either directly or
 14 indirectly through third parties or related entities, its products, including the TrapEase and OptEase IVC
 15 filters, and derived substantial income from doing business in California.

16 44. "Cordis" and "Defendants" where used hereinafter, shall refer to all subsidiaries,
 17 affiliates, divisions, franchises, partners, joint venturers, organizational units of any kind, predecessors,
 18 successors, assigns, officers, directors, employees, agents and representatives of Cordis, J&J, Cardinal, as
 19 well as DOE Defendants 1 through 50, and each of them.

20 45. Joinder of Plaintiffs in this Complaint for Damages is proper pursuant to *Code of Civil*
 21 *Procedure* § 378 because Plaintiffs assert a right to relief in respect of or arising out of the same
 22 transaction, occurrence, or series of transactions or occurrences, and questions of law and fact common
 23 to all Plaintiffs will arise in the action.

24 **JURISDICTION AND VENUE**

25 46. This Court has jurisdiction under the California Constitution, Article VI, Section 10 and
 26 *Code of Civil Procedure* § 410.10. Plaintiffs' damages exceed the jurisdictional minimum of this Court.

27 47. Venue is proper in this Court pursuant to *Code of Civil Procedure* §§ 395 and 395.5
 28 because the principal place of business for Defendant CORDIS CORPORATION is situated in Alameda

1 County. Further, a substantial amount of Defendants' conduct, as alleged herein by Plaintiffs, took
2 place in Alameda County.

3 48. Requiring Defendants to litigate these claims in California does not offend traditional
4 notions of fair play and substantial justice and is permitted by the United States Constitution.
5 Defendants are "at home" in the State of California. Cordis maintains campuses and facilities in
6 Fremont and Oakland, California, in Alameda County, and has its headquarters here. Cordis' website
7 lists its address as 6500 Paseo Padre Parkway, Fremont, CA 94555 (*see* <https://www.cordis.com/> (last
8 visited May 19, 2016)). A Cordis-affiliate website represents that Cordis' "North American operations
9 are based out of the San Francisco Bay Area" and also lists the 6500 Paseo Padre Parkway, Fremont, CA
10 94555 address (*see* <http://www.cardinalhealth.com/en/cmp/ext/cor/cordis.html> (last visited May 19,
11 2016)). Thus, Cordis affirmatively represents to the public that its headquarters is in California.

12 49. Defendants systematically availed themselves of the State of California by conducting
13 regular and sustained business and engaging in substantial commerce and business activity in California,
14 including without limitation researching, developing, designing, licensing, manufacturing, distributing,
15 selling, marketing, and/or introducing into interstate commerce in the state of California, either directly
16 or indirectly, its products, including Cordis IVC filters.

17 50. Plaintiffs' claims arise from and relate to Cordis' purposeful avail of the State of
18 California because Cordis' wrongful conduct in developing, designing, selling, marketing,
19 manufacturing and/or distributing Cordis IVC filters took place, in whole or in part, in the State of
20 California. Therefore, the claims of California-plaintiffs *and* out-of-state plaintiffs relate to and arise
21 from Defendants' explicit contacts and purposeful avail of the State of California. Further and
22 independently, Cordis consented to jurisdiction in the State of California by appointing an agent for
23 service of process in this State and by conducting substantial systematic business in this State.

24 51. The instant Complaint for Damages does not confer diversity jurisdiction upon the
25 federal courts pursuant to 28 U.S.C. § 1332. Likewise, federal question subject matter jurisdiction
26 pursuant to 28 U.S.C. § 1331 is not invoked by the instant Complaint, as it sets forth herein exclusively
27 state law claims against the Defendants. Nowhere do Plaintiffs plead, expressly or implicitly, any cause
28 of action or request any remedy that arises under or is founded upon federal law, and any alleged federal

1 rights or remedies are expressly disavowed. The issues presented by Plaintiffs do not implicate
2 substantial federal questions, do not turn on the necessary interpretation of federal law, and do not affect
3 the federal system as a whole. The assertion of federal jurisdiction over claims made herein would
4 improperly disturb the congressionally approved balance of federal and state responsibilities.

5 **BACKGROUND**

6 **INFERIOR VENA CAVA FILTERS GENERALLY**

7 52. IVC filters were first made commercially available to the medical community in the
8 1960s. Over the years, medical device manufacturers have introduced several different designs of IVC
9 filters.

10 53. An IVC filter is a device that is designed to filter or “catch” blood clots that travel from
11 the lower portions of the body to the heart and lungs. IVC filters were originally designed to be
12 permanently implanted in the IVC.

13 54. The IVC is a vein that returns blood to the heart from the lower portions of the body. In
14 certain people, for various reasons, blood clots travel from the vessels in the legs and pelvis, through the
15 vena cava and into the lungs. Oftentimes, these blood clots develop in the deep leg veins, a condition
16 called “deep-vein thrombosis” or “DVT.” Once blood clots reach the lungs, they are considered
17 “pulmonary emboli” or “PE.” Pulmonary emboli present risks to human health.

18 55. People at risk for DVT/PE can undergo medical treatment to manage the risk. For
19 example, a doctor may prescribe anticoagulant therapies such as medications like Heparin, Warfarin, or
20 Lovenox to regulate the clotting factor of the blood. In some people who are at high risk for DVT/PE
21 and who cannot manage their conditions with medications, physicians may recommend surgically
22 implanting an IVC filter to prevent thromboembolic events.

23 56. As stated above, IVC filters have been on the market for decades. All IVC filters are
24 only cleared for use by the Food & Drug Administration (“FDA”) for prevention of recurrent pulmonary
25 embolism in patients at risk for pulmonary embolism and where anticoagulation therapy has failed or is
26 contraindicated.

1 57. In order to increase sales of these devices, Defendants sought to expand the market for
2 prophylactic use among nontraditional patient populations that were temporarily at risk of developing
3 blood clots.

4 58. Defendant Cordis engaged in marketing campaigns directed toward the bariatric, trauma,
5 orthopedic and cancer patient population. Expansion to these new patient groups would substantially
6 increase sales and the first manufacturer to market would capture market share.

7 59. Other manufacturers also saw this opportunity, which triggered a race to market a device
8 that provided physicians the option to retrieve the filter after the clot risk subsided.

9 60. From 2000 through 2003, manufacturers of IVC filters, including Defendants, raced
10 against each other to bring the first IVC filter to the market with the added indication of optional
11 retrieval. In 2003, the FDA cleared three different IVC filters for a retrieval indication, one of which
12 was the OptEase filter by Defendant Cordis.

13 61. There is no evidence that Defendants' IVC filters were effective in preventing pulmonary
14 embolism (the very condition the products were indicated to prevent).

15 62. Years after the implantation of retrievable filters into the bodies of patients, scientists
16 began to study the effectiveness of the retrievable filters. As recently as October 2015, an expansive
17 article published in the *Annals of Surgery* concerning trauma patients inserted with IVC filters
18 concluded that IVC filters were not effective in preventing pulmonary emboli, and instead actually
19 caused thrombi to occur.

20 63. Comparing the results of over 30,000 trauma patients who had not received IVC filters
21 with those who had received them, the *Annals of Surgery* study published its alarming results:

- 22 a. Almost twice the percentage of patients with IVC filters in the study died compared to
23 those that had not received them.
- 24 b. Over five times the relative number of patients with IVC filters developed DVTs.
- 25 c. Over four times the relative percentage of patients with filters developed thromboemboli.
- 26 d. Over twice the percentage of patients developed a pulmonary embolus – the very
27 condition Defendant Cordis told the FDA, physicians, and the public that its IVC filters
28 were designed to prevent.

64. Other studies also have revealed that these devices suffer common failure modes such as migration, perforation, thrombosis, and fracture, all of which can cause serious injury or death. For example, recent studies of Cordis IVC filters have revealed fracture rates as high as 50% and recommend medical monitoring and/or removal.

65. These studies, including the *Annals of Surgery* study, have shown there is no evidence establishing that IVC filters are effective and that these devices suffer common failure modes, including, but not limited to, migration, perforation, thrombosis, tilt and fracture, all of which can cause serious injury or death. Thus, the current state of scientific and medical evidence indicates that IVC filters are not only ineffective but that they are themselves a health hazard.

THE TRAPEASE™ AND OPTEASE™ IVC FILTERS

66. On or about January 10, 2001, Defendants bypassed the more onerous FDA's approval process for new devices and obtained "clearance" under Section 510(k) of the Medical Device Amendments to the Food, Drug, and Cosmetic Act to market the TrapEase Vena Cava Filter as a *permanent* filter by claiming it was substantially similar in respect to safety, efficacy, design, and materials as the IVC filters already available on the market.

67. Section 510(k) permits the marketing of medical devices if the device is substantially equivalent to other legally marketed predicate devices without formal review for the safety or efficacy of the said device. The FDA explained the difference between the 510(k) process and the more rigorous "premarket approval" (PMA) process in its amicus brief filed with the Third Circuit in *Horn v. Thoratec Corp.*, which the court quoted from:

A manufacturer can obtain an FDA finding of 'substantial equivalence' by submitting a premarket notification to the agency in accordance with section 510(k) of the [Food Drug and Cosmetic Act]. 21 U.S.C. § 360(k). A device found to be 'substantially equivalent' to a predicate device is said to be 'cleared' by FDA (as opposed to 'approved' by the agency under a PMA). A pre-market notification submitted under 510(k) is thus entirely different from a PMA which must include data sufficient to demonstrate that the IVC Filters is safe and effective.

376 F.3d 163, 167 (3d Cir. 2004) (emphasis in original).

68. In *Medtronic, Inc. v. Lohr*, the U.S. Supreme Court similarly described the 510(k) process, observing:

1 If the FDA concludes on the basis of the [manufacturer's] § 510(k) notification that the
2 device is "substantially equivalent" to a pre-existing device, it can be marketed without
3 further regulatory analysis. . . . The § 510(k) notification process is by no means
4 comparable to the PMA process; in contrast to the 1,200 hours necessary to complete a
5 PMA review, the § 510(k) review is completed in average of 20 hours. . . . As one
commentator noted: "The attraction of substantial equivalence to manufacturers is clear.
Section 510(k) notification requires little information, rarely elicits a negative response
from the FDA, and gets processed quickly."

6 518 U.S. 470, 478-79 (1996) (quoting Adler, *The 1976 Medical Device Amendments: A Step in the*
7 *Right Direction Needs Another Step in the Right Direction*, 43 Food Drug Cosm. L.J. 511, 516 (1988)).

8 69. Pursuant to *Wyeth v. Levine*, 555 U.S. 555 (2009), once a product is cleared "the
9 manufacturer remains under an obligation to investigate and report any adverse events associated with
10 the drug . . . and must periodically submit any new information that may affect the FDA's previous
11 conclusions about the safety, effectiveness, or labeling" This obligation extends to post-market
12 monitoring of adverse events/complaints.

13 70. In July 2000, through this 510(k) process, Defendants obtained clearance from the FDA
14 to market the TrapEase filter as a permanent filter.

15 71. The TrapEase filter is made with Nitinol – a nickel titanium alloy. The filter utilizes a
16 design known as a double basket or double filter for the capture of blood clots and/or emboli. This
17 design consists of a basket made of six diamond-shaped struts proximally and six diamond-shaped struts
18 distally, forming proximal and distal baskets, which are connected by six straight struts to create a single
19 symmetric filter. The filter has proximal and distal anchoring barbs located on each connecting strut for
20 fixation of the filter to the vena cava wall to prevent movement after placement.

21 72. Nitinol alloy is used in a number of different medical device applications. It is beneficial
22 for these applications and is employed as material in stents and other medical device applications. It is
23 also used in the manufacture of the TrapEase filter, and other brands of IVC filters.

24 73. Specific manufacturing processes need to be utilized when using Nitinol as a component
25 for medical devices, including IVC filters. Primarily, the Nitinol material should be electro-polished
26 prior to assembly of the finished medical device.

27 74. Electro-polishing is a manner of removing surface blemishes, "draw marking" and
28 circumferential grinding markings on the exterior of the surface of the Nitinol material. The existence

1 of these surface blemishes, “draw markings” and “circumferential grind-markings” causes/results in the
2 weakening of the structural integrity of the end product, whether it is an IVC filter or other medical
3 device.

4 75. In or around September 2002, Defendants sought clearance through the 510(k) process to
5 market the OptEase Vena Cava Filter for the same indicated uses as the TrapEase filter. Defendants
6 represented that the OptEase filter contained the same fundamental technology and was substantially
7 equivalent in terms of safety and efficacy as the predicate devices already available on the market.

8 76. Unlike the TrapEase filter, which has proximal and distal anchoring barbs located on
9 each connecting strut for fixation of the filter to the vena cava wall, the OptEase filter has anchoring
10 barbs for fixation of the filter only on the superior end of each of the six straight struts and has a hook at
11 the inferior end of the basket to allow retrieval with a snare.

12 77. Both designs for the TrapEase filter and OptEase filter suffer flaws making them
13 defective and unreasonably dangerous. Defendants’ IVC filters are designed in such a way that when
14 exposed to expected and reasonably foreseeable *in-vivo* conditions, the devices will fracture, migrate,
15 tilt, perforate internal organs and vasculature, and lead to the formation of thromboembolism and
16 pulmonary embolism.

17 78. For years, it has been known by manufacturers of the Nitinol medical devices and the
18 medical device industry that electro-polishing Nitinol results in increased structural integrity of the
19 device and resistance to fatigue and fatigue failures.

20 79. The exterior surfaces of the Cordis IVC filters were not electro-polished prior to
21 completion of the manufacturing process. This is a manufacturing defect that exists in the TrapEase and
22 OptEase filters which causes these filters to be structurally weak and susceptible to a significant risk of
23 failure/fracture.

24 80. Additionally, Defendants represented that the self-centering design of the TrapEase filter
25 allows accurate, predictable placement, and that its site struts help reduce the risk of tilting and
26 migration, while in reality the filters regularly tilt, migrate, and become embedded in the vena cava wall.

27 81. The anchoring mechanism of Defendants’ filters is also insufficient to prevent tilting and
28 migration post-placement.

1 82. The configuration of the Cordis IVC filters actually leads to the formation of blood clots
2 and pulmonary embolism – the exact condition the devices are meant to protect against.

3 83. That Defendants allowed these devices to proceed to market indicates that they failed to
4 establish and maintain an appropriate Quality System concerning design and risk analysis.

5 84. A manufacturer must, at a minimum, undertake research and testing to understand the
6 anatomy of where a medical device will be implanted and understand the forces the device may be
7 exposed to once implanted in a human body. This design input must then be used to determine the
8 minimum safety requirements or attributes the device must have to meet user needs. In the case of an
9 IVC filter, user needs include a device that will capture blood clots of sufficient size to cause harmful
10 consequences and that will not fracture, migrate, tilt, perforate the vena cava, or malfunction in some
11 other way, or be prothombotic. Defendants failed to undertake any such efforts in these regards.

12 85. Prior to bringing a product to market, a manufacturer must also conduct sufficient testing
13 under real world or simulated use conditions to ensure that the device will meet user needs even when
14 exposed to reasonably foreseeable worst-case conditions. Defendants failed to adequately establish and
15 maintain such policies, procedures or protocols with respect to their IVC filters.

16 86. Once placed on the market, Defendants' post-market surveillance system should have
17 revealed to Defendants that the TrapEase and OptEase filters were unreasonably dangerous and
18 substantially more prone to fail or malfunction, and cause great bodily harm to patients compared to
19 other available treatment options.

20 87. MAUDE is a database maintained by the FDA to house medical device reports submitted
21 by mandatory reporters (such as manufacturers and device user facilities) and voluntary reporters (such
22 as health care providers and patients).

23 88. Shortly after going on market, Defendants began receiving large numbers of adverse
24 event reports ("AERs") from health care providers reporting that the Cordis IVC filters were fracturing
25 post-implantation and that fractured pieces and/or the entire device was migrating to other areas of the
26 body, including the heart and lungs.

1 89. Defendants also received large numbers of AERs reporting that the TrapEase filters and
2 OptEase filters were found to have excessively tilted, perforated the IVC, or caused thrombosis or
3 stenosis of the vena cava post-implantation.

4 90. These failures were often associated with severe patient injuries such as:

- 5 a. Death;
- 6 b. Hemorrhage;
- 7 c. Cardiac/pericardial tamponade (pressure caused by a collection of blood in the area
8 around the heart);
- 9 d. Cardiac arrhythmia and other symptoms similar to myocardial infarction;
- 10 e. Severe and persistent pain;
- 11 f. Perforations of tissue, vessels and organs;
- 12 g. Chronic deep vein thrombosis;
- 13 h. Pulmonary embolism; and,
- 14 i. Compartment syndrome.

15 91. These failures and resulting injuries are attributable, in part, to the fact that the Cordis
16 IVC filter design was unable to withstand the normal anatomical and physiological loading cycles
17 exerted *in vivo*.

18 92. Recent medical studies have confirmed what Defendants have known or should have
19 known since shortly after the release of each of these filters – not only do Cordis IVC filters fail at
20 alarming rates, but they also fail at rates substantially higher than other available IVC filters. For
21 instance, a recent large medical study found that OptEase and TrapEase filters suffer fracture rates of
22 37.5% and 23.1% respectively, when left implanted a minimum of 46 months. Another recent study
23 found that the TrapEase filter had a 64% fracture rate when left in more than four years. Another study
24 found a statistically significant increased rate of caval thrombosis with the ObtEase filter compared to
25 Gunther Tulip and Recovery Filters.

26 93. As a minimum safety requirement, manufacturers must establish and maintain post-
27 market procedures to timely identify the cause of device failures and other quality problems and to take
28 adequate corrective action to prevent the recurrence of these problems.

1 94. Defendants failed to identify or acknowledge these device failures or determine their
2 causes.

3 95. Defendants failed to take timely and adequate remedial measures to correct known design
4 and manufacturing defects with the Cordis IVC filters.

5 96. Defendants also misrepresented and concealed the risks and benefits of the Cordis IVC
6 filters in the labeling and marketing distributed to the FDA, physicians and the public. For instance,
7 Defendants represented that their filters were safe and effective – more safe and effective than other
8 available IVC filters. However, there is no reliable evidence to support these claims and, to the
9 contrary, the Cordis IVC filters have been associated with a high rate of failure.

10 97. Defendants also represented that the design of these devices would eliminate the risk that
11 pieces of the devices could perforate the vena cava, that the devices could tilt, or that fractures could
12 occur and migrate throughout the body. The medical literature and AERs have proven these claims to be
13 false.

14 98. Defendants also marketed the OptEase filter as being “easy” to remove. However, it is
15 one of the most difficult filters to remove. Dr. William T. Kuo, an expert in the removal of IVC filters
16 and vascular surgery, has established an IVC Filter Clinic at Stanford University where his team
17 specializes in the removal of IVC filters that other vascular surgeons refuse to remove for fear of
18 rupturing the vena cava or other internal organs and causing great bodily harm or death to the patient.
19 Dr. Kuo wrote in *the Journal of Vascular Interventional Radiology* that the Cordis filters were the most
20 difficult to retrieve from patients, at least partially due to the design of the filters, which create greater
21 contact with the vein walls than competitors’ filters.

22 99. This is particularly concerning because having an IVC filter for a prolonged period of
23 time increases the risk of developing chronic deep venous thrombosis, PE, IVC occlusion, post-
24 thrombotic syndrome, filter fracture, and caval perforation with pain and organ injury. Many patients
25 with IVC filters are now routinely managed with lifelong anticoagulation solely to reduce the risk of
26 having the filter in place, subjecting patients to the risks and inconvenience of anticoagulation.

27 100. Defendants also failed to adequately disclose the risks of these filters, such as migration,
28 fracture, perforation, tilt, thrombosis, the prothrombotic nature of the devices, that the devices may not

1 be retrievable, or that these failures were known to be causing severe injuries and death or the rate at
2 which these events were occurring.

3 101. Cordis' labeling was additionally defective in that it directed physicians to implant the
4 OptEase filter upside down. When the OptEase filter was placed as directed by the labeling, the hooks
5 designed to ensure stability were facing in the wrong direction, rendering an already inadequate
6 anchoring system even further defective. As Cordis now explain in its labeling, implanting the device in
7 this fashion "can result in life threatening or serious injury including, but not limited to dissection, vessel
8 perforation, migration of the filter with secondary damage to cardiac structures, ineffective pulmonary
9 embolism prevention or death."

10 102. Cordis began a series of recalls on March 29, 2013 relating to its labeling, which
11 instructed physicians to implant the devices upside down. These recalls were not timely, nor did they
12 fully correct the defects in Defendants' labeling. Further, Defendants downplayed the danger patients
13 were exposed to and failed to take adequate steps to ensure patients actually received notice of the recall.

14 103. The FDA classified the initial recall as a Class I recall, which is the most serious type of
15 recall and involves situations in which the FDA has determined there is a reasonable probability that use
16 of these products will cause serious adverse health consequences or death.

17 104. Defendants have admitted that any patients implanted with one of these recalled units
18 should receive medical monitoring. Specifically, these patients should undergo imaging to ascertain
19 whether or not the device was properly deployed and, if not, be assessed for removal.

20 105. Given the unreasonably high failure and injury rates associated with Cordis IVC filters
21 when left implanted long-term, Defendants should be required to pay for medical monitoring to assess
22 the condition of these devices and whether or not retrieval should be undertaken.

23 106. On April 5, 2016, at the annual Society of Interventional Radiology in Vancouver,
24 Canada, Dr. Steven Wang, an interventional radiologist from Palo Alto, California who is affiliated with
25 Kaiser Permanente, presented the results of a retrospective study involving 96 patients in which he
26 sought to understand the prevalence of long-term (greater than 46 months) complications of both
27 permanent and retrievable IVC filters. The study looked at all inferior vena cava filters implanted in
28 patients from January 2007 through December 2009 at multiple health care facilities across the United

1 States. Dr. Wang then identified all patients who had imaging of the filter taken at four years or more
 2 after implantation. Of those patients (96), he then evaluated the imaging to determine whether the IVC
 3 filter had malfunctioned. After reviewing the data, the authors concluded that device complications at
 4 four or more years after implantation “are relatively common.” They also found that the Cordis OptEase
 5 and TrapEase IVC filters suffered fracture rates of 37.5% and 23.1%, respectively.

6 **ESTOPPEL FROM PLEADING STATUTES OF LIMITATIONS OR REPOSE**

7 107. Plaintiffs incorporate by reference all prior allegations.

8 108. Plaintiffs are within the applicable statute of limitations for their claims because Plaintiffs
 9 (and their healthcare professionals) did not discover, and could not reasonably discover, the defects and
 10 unreasonably dangerous condition of their Cordis IVC filters.

11 109. Plaintiffs’ ignorance of the defective and unreasonably dangerous nature of the Cordis
 12 IVC filters, and the causal connection between these defects and each Plaintiff’s injuries and damages, is
 13 due in large part to Defendants’ acts and omissions in fraudulently concealing information from the
 14 public and misrepresenting and/or downplaying the serious threat to public safety its products present.

15 110. In addition, Defendants are estopped from relying on any statutes of limitation or repose
 16 by virtue of unclean hands, acts of fraudulent concealment, affirmative misrepresentations and
 17 omissions.

18 111. Such conduct includes intentional concealment from Plaintiffs, their health care
 19 professionals, and the general consuming public of material information that Cordis IVC filters had not
 20 been demonstrated to be safe or effective, and carried with them the risks and dangerous defects
 21 described herein.

22 112. Defendants had a duty to disclose the fact that Cordis IVC filters are not safe or effective,
 23 not as safe as other filters on the market, defective, and unreasonably dangerous, and that their
 24 implantation and use carried with it the serious risk of developing perforation, migration, tilting, and/or
 25 fracture, and/or other injuries referenced herein.

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 27
 28 ///

FIRST CAUSE OF ACTION

STRICT PRODUCTS LIABILITY – DESIGN DEFECT

(By All Plaintiffs, As to All Defendants)

113. Plaintiffs incorporate by reference all prior allegations.

114. At all relevant times, Defendants designed, tested, distributed, manufactured, advertised, sold, marketed and otherwise placed into the stream of commerce Cordis IVC filters – the TrapEase filters and the OptEase filters – for use by consumers, such as Plaintiffs, in the United States.

115. Defendants' Cordis IVC filters were expected to, and did, reach Defendants' intended consumers, handlers, and persons coming into contact with the product without substantial change in the condition in which they were researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Defendants.

116. The devices implanted in Plaintiffs were in an unreasonably dangerous condition at the time they left Defendants' control.

117. At all times relevant, Cordis IVC filters were manufactured, designed and labeled in an unsafe, defective, and inherently dangerous condition which was dangerous for use by the public in general and Plaintiffs in particular.

118. Defendants' Cordis IVC filters, as researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Defendants were defective in design and formulation and unreasonably dangerous in that when they left the hands of Defendants' manufacturers and/or suppliers, the foreseeable risks exceeded the alleged benefits associated with the use of Cordis IVC filters, and the devices were more dangerous than the ordinary customer would expect.

119. Physicians implanted Cordis IVC filters as instructed via the Instructions for Use and in a foreseeable manner as normally intended, recommended, promoted, and marketed by Defendants.

120. Plaintiffs received and utilized Defendants' IVC filters in a foreseeable manner as normally intended, recommended, promoted, and marketed by Defendants.

121. At the time Defendants placed their defective and unreasonably dangerous Cordis IVC filters into the stream of commerce commercially, technologically, and scientifically feasible alternative designs were attainable and available.

122. These alternative designs would have prevented the harm resulting in each Plaintiff's Injuries and Damages without substantially impairing the reasonably anticipated or intended function of Cordis IVC filters.

123. Neither Plaintiffs nor their health care providers could have, by the exercise of reasonable care, discovered the defective condition or perceived the unreasonable dangers with these devices prior to Plaintiffs' implantation with the Cordis IVC filters.

124. As a direct and proximate result of the defective and unreasonably dangerous condition of Cordis IVC filters, Plaintiffs suffered Injuries and Damages.

SECOND CAUSE OF ACTION

STRICT PRODUCTS LIABILITY – INADEQUATE WARNING

(By All Plaintiffs, As to All Defendants)

125. Plaintiffs incorporate by reference all prior allegations.

126. At all relevant times, Defendants engaged in the business of testing, developing, designing, manufacturing, packaging, labeling, marketing and/or promoting, selling and/or distributing Cordis IVC filters – the TrapEase filters and the OptEase filters – and through that conduct have knowingly and intentionally placed Cordis IVC filters into the stream of commerce with full knowledge that they reach consumers such as Plaintiffs who would become implanted with them.

127. Defendants did, in fact, test, develop, design, manufacture, package, label, market and/or promote, sell and/or distribute their Cordis IVC filters to Plaintiffs, their prescribing health care professionals, and the consuming public. Additionally, Defendants expected that the Cordis IVC filters they were selling, distributing, supplying, manufacturing, and/or promoting to reach, and did, in fact, reach, prescribing health care professionals and consumers, including Plaintiffs and their prescribing health care professionals, without any substantial change in the condition of the product from when it was initially distributed by Defendants.

1 128. The Cordis IVC filters had potential risks and side effects that were known or knowable
2 to Defendants by the use of scientific inquiry and information available before, at, and after the
3 manufacture, distribution, and sale of the Cordis IVC filters.

4 129. Defendants knew or should have known of the defective condition, characteristics, and
5 risks associated with Cordis IVC filters. These defective conditions included, but were not limited to:
6 (1) Cordis IVC filters posed a significant and higher risk of failure than other similar IVC filters
7 (fracture, migration, tilting, and perforation of the vena cava wall); (2) Cordis IVC filter failures result in
8 serious injuries and death; (3) certain conditions or post-implant procedures, such as morbid obesity or
9 open abdominal procedures, could affect the safety and integrity of Cordis IVC filters; (4) leaving
10 Cordis IVC filters in for a period longer than necessary to prevent immediate risk of pulmonary
11 embolism increases the risk for patients of failures and complications with the filter, such as the filter
12 becoming deeply embedded in the vena cava, making them difficult or impossible for removal.

13 130. Defendants placed into the stream of commerce for ultimate use by users like Plaintiffs
14 and their health care providers, Cordis IVC filters that were in an unreasonably dangerous and defective
15 condition due to warnings and instructions for use that were inadequate, including, but not limited to
16 Defendants' failure to:

- 17 a. Provide adequate instructions for how long in patients the filter should remain;
- 18 b. Highlight the importance of removing the filter;
- 19 c. Warn of the known risk of great bodily harm or death if the filter was not removed;
- 20 d. Highlight the known risk of great bodily harm or death in the event of occlusion of the
21 vein caused by the filter itself;
- 22 e. Warn of the risk of new DVT if the filter was left in too long; Warn of the risk of new
23 pulmonary embolism, thrombosis, swelling, and pain in the lower extremities if the filter
24 was left in too long; and
- 25 f. Warn of the risk of filter perforation, fracture, or migration.

26 131. Cordis IVC filters were in a defective and unsafe condition that was unreasonably and
27 substantially dangerous to any user or consumer implanted with Cordis IVC filters, such as Plaintiffs,
28 when used in an intended or reasonably foreseeable way.

132. The warnings and directions Defendants provided with their Cordis IVC filters failed to adequately warn of the potential risks and side effects of Cordis IVC filters.

133. These risks were known or were reasonably scientifically knowable to Defendants, but not known or recognizable to ordinary consumers, such as Plaintiffs, or their treating doctors.

134. Defendants' IVC filters were expected to and did reach Plaintiffs without substantial change in their condition, labeling, or warnings as manufactured, distributed, and sold by Defendants.

135. Additionally, Plaintiffs and their physicians used Cordis IVC filters – the TrapEase filters or the OptEase filters – in the manner in which they were intended to be used, making such use reasonably foreseeable to Defendants.

136. As a direct and proximate result of Defendants' information defects, lack of sufficient instructions or warnings prior to, on, and after the date Plaintiffs used Cordis IVC filters, Plaintiffs suffered Injuries and Damages.

THIRD CAUSE OF ACTION

STRICT PRODUCTS LIABILITY – MANUFACTURING DEFECT

(By All Plaintiffs, As to All Defendants)

137. Plaintiffs incorporate by reference all prior allegations.

138. Prior to, on, and after the date the Cordis IVC filters – the TrapEase filter or the OptEase filter – were implanted in Plaintiffs, Defendants designed, distributed, manufactured, sold, and marketed Cordis IVC filters for use in the United States, including California.

139. At all relevant times, Defendants designed, distributed, manufactured, marketed, and sold Cordis IVC filters that were unreasonably dangerous, unsafe, and defective in manufacture when they left Defendants' possession.

140. Upon information and belief, Cordis IVC filters contain a manufacturing defect, in that they differed from the manufacturer's design or specifications, or from other typical units of the same product line.

141. As a direct and proximate cause of Defendants' design, manufacture, marketing, and sale of Cordis IVC filters prior to, on, and after the date Plaintiffs used the Cordis IVC filters, Plaintiffs suffered Injuries and Damages.

FOURTH CAUSE OF ACTION

NEGLIGENCE

(By All Plaintiffs, As to All Defendants)

142. Plaintiffs incorporate by reference all prior allegations.

143. At the time of the design, distribution, manufacture, advertising, sale, and marketing of Cordis IVC filters – the TrapEase filters and the OptEase filters – and their implantation in Plaintiffs, Defendants were aware that Cordis IVC filters were designed and manufactured in a manner presenting:

- a. An unreasonable risk of fracture of portions of the filters;
- b. An unreasonable risk of migration of the filters and/or portions of the filters;
- c. An unreasonable risk of filters tilting and/or perforating the vena cava wall; and
- d. Insufficient strength or structural integrity to withstand normal placement within the human body.

144. At the time of the design, distribution, manufacture, advertising, sale, and marketing of Cordis IVC filters, and their implantation in Plaintiffs, Defendants were also aware that Cordis IVC filters:

- a. Would be used without inspection for defects;
- b. Would be used by patients with special medical conditions such as Plaintiffs;
- c. Had previously caused serious bodily injury to its users with special medical conditions such as Plaintiffs;
- d. Had no established efficacy;
- e. Were less safe and effective than the predicate IVC filters already available on market;
- f. Would be implanted in patients where the risk outweighed any benefit or utility of the filters;
- g. Contained instructions for use and warnings that were inadequate; and
- h. Were prothombotic.

145. At the time of manufacture and sale of the TrapEase and OptEase filters, including the ones implanted in Plaintiffs, Defendants knew or should have known that using the TrapEase and OptEase filters as intended or in a reasonably foreseeable manner created a significant risk of patients

1 suffering severe health side effects including, but not limited to: hemorrhage; cardiac/pericardial
2 tamponade; cardiac arrhythmia and other symptoms similar to myocardial infarction; perforations of
3 tissue, vessels and organs; chronic deep vein thrombosis; pulmonary embolism; thrombosis;
4 compartment syndrome; and other severe personal injuries and diseases, which are permanent in nature,
5 including, but not limited to, death, physical pain and mental anguish, scarring and disfigurement,
6 diminished enjoyment of life, continued medical care and treatment due to chronic injuries/illness
7 proximately caused by the device; and the continued risk of requiring additional medical and surgical
8 procedures including general anesthesia, with attendant risk of life threatening complications.

9 146. Defendants had a duty to exercise due care and avoid unreasonable risk of harm to others
10 in the design of Cordis IVC filters.

11 147. Defendants breached these duties by, among other things:

- 12 a. Designing and distributing a product in which it knew or should have known that the
13 likelihood and severity of potential harm from the product exceeded the burden of taking
14 safety measures to reduce or avoid harm;
- 15 b. Designing and distributing a product which it knew or should have known that the
16 likelihood and severity of potential harm from the product exceeded the likelihood of
17 potential harm from other IVC filters available for the same purpose;
- 18 c. Failing to perform reasonable pre- and post-market testing of Cordis IVC filters to
19 determine whether or not the products were safe for their intended use;
- 20 d. Failing to use reasonable and prudent care in the design, research, manufacture, and
21 development of Cordis IVC filters so as to avoid the risk of serious harm associated with
22 the use of Cordis IVC filters;
- 23 e. Advertising, marketing, promoting, and selling Cordis IVC filters for uses other than as
24 approved and indicated in the products' labels;
- 25 f. Failing to use reasonable care to warn or instruct, including pre and post-sale, Plaintiffs,
26 their prescribing physicians, or the general health care community about the TrapEase
27 and OptEase filters' substantially dangerous condition or about facts making the products
28 likely to be dangerous;

- g. Advertising, marketing and recommending the use of the TrapEase and OptEase filters, while concealing and failing to disclose or warn of the dangers known by Defendants to be connected with and inherent in the use of these filter systems;
- h. Representing that the TrapEase and OptEase filters were safe for their intended use when, in fact, Defendants knew and should have known the products were not safe for their intended uses;
- i. Continuing to manufacture and sell the TrapEase and OptEase filters with the knowledge that said products were dangerous and not reasonably safe, and failing to comply with good manufacturing regulations;
- j. Failing to establish an adequate quality assurance program used in the manufacturing of Cordis IVC filters; and
- k. Failing to perform adequate evaluation and testing of Cordis IVC filters when such evaluation and testing would have revealed the propensity of Cordis IVC filters to cause injuries similar to those that Plaintiffs suffered.

148. At all relevant times, Defendants had a duty to exercise due care in the manufacturing of Cordis IVC filters.

149. Defendants breached this duty by, among other things:

- a. Failing to adopt manufacturing processes that would reduce the foreseeable risk of product failure;
- b. Failing to use reasonable care in manufacturing the product and by producing a product that differed from their design or specifications or from other typical units from the same production line;
- c. Failing to use reasonable and prudent care in the design, research, manufacture, and development of Cordis IVC filters and their manufacturing process so as to avoid the risk of serious harm associated with the use of Cordis IVC filters; and

1 d. Failing to establish an adequate quality assurance program used in the manufacturing of
2 their IVC filters.

3 150. At this time, all Cordis IVC filters – the TrapEase filters and the OptEase filters – are
4 misbranded and adulterated by virtue of them failing to be the substantial equivalent of predicate IVC
5 filter devices, making them subject to corrective action, including recall, in the interest of patient safety.

6 151. Prior to, on, and after the date of Plaintiffs' implantation with a Cordis IVC filter, and at
7 all relevant times, Defendants knew or reasonably should have known that Cordis IVC filters and their
8 warnings were defective and dangerous or were likely to be dangerous when used in a reasonably
9 foreseeable manner.

10 152. Prior to, on, and after the date of Plaintiffs' implantation with a Cordis IVC filter and at
11 all relevant times thereafter, Defendants became aware that the defects of Cordis IVC filters resulted in
12 Cordis IVC filters causing injuries similar to those Plaintiffs suffered.

13 153. Reasonable manufacturers and distributors under the same or similar circumstances
14 would have recalled or retrofitted Cordis IVC filters, and would thereby have avoided and prevented
15 harm to many patients, including Plaintiffs.

16 154. In light of this information and Defendants' knowledge described above, Defendants had
17 a duty to recall and/or retrofit Cordis IVC filters.

18 155. Defendants breached its duty to recall and/or retrofit Cordis IVC filters.

19 156. At all relevant times, Defendants knew or should have known that Cordis IVC filters
20 were defective and dangerous or were likely to be dangerous when used in a reasonably foreseeable
21 manner.

22 157. Such danger included the propensity of Cordis IVC filters to cause injuries similar to
23 those suffered by Plaintiffs.

24 158. At all relevant times, Defendants also knew or reasonably should have known that the
25 users of Cordis IVC filters, including Plaintiffs and their health care providers, would not realize or
26 discover on their own the dangers presented by Cordis IVC filters.

27 159. Reasonable manufacturers and reasonable distributors, under the same or similar
28 circumstances as those of Defendants prior to, on, and after the date of Plaintiffs' use of a Cordis IVC

1 filter, would have warned of the dangers presented by Cordis IVC filters, or instructed on the safe use of
2 Cordis IVC filters.

3 160. Prior to, on, and after the date of each Plaintiff's use of the IVC filter, Defendants had a
4 duty to adequately warn of the dangers presented by Cordis IVC filters and/or instruct on the safe use of
5 Cordis IVC filters.

6 161. Defendants breached these duties by failing to provide adequate warnings to Plaintiffs
7 communicating the information and dangers described above and/or providing instruction for safe use of
8 Cordis IVC filters.

9 162. As a direct and proximate result of Defendants' negligent conduct described herein,
10 Plaintiffs suffered Injuries and Damages.

11 **FIFTH CAUSE OF ACTION**

12 **NEGLIGENT MISREPRESENTATION**

13 **(By All Plaintiffs, As to All Defendants)**

14 163. Plaintiffs incorporate by reference all prior allegations.

15 164. Prior to, on, and after the dates during which Plaintiffs were implanted with the Cordis
16 IVC filters – the TrapEase filters and the OptEase filters – Defendants negligently and carelessly
17 represented to Plaintiffs, their treating physicians, and the general public that certain material facts were
18 true. The representations include, *inter alia*, the following:

- 19 a. That the Cordis IVC filters were safe, fit, and effective for use;
- 20 b. That the design of the Cordis IVC filters eliminated the risk that pieces of the device
21 could perforate the vena cava, that the devices could tilt, or that fractures could occur and
22 migrate throughout the body;
- 23 c. That the Cordis IVC filters were safe and more effective than other available IVC filters.
- 24 d. That the OptEase fiber was "easy" to remove; and,

25 165. Prior to, on, and after the dates during which Plaintiffs and their physicians purchased
26 and used the device, said representations were untrue, and there was no reasonable ground for
27 Defendants to believe said representations were true when Defendants made said representations.
28

1 166. Prior to, on, and after the dates during which Plaintiffs and their physicians purchased
2 and used the device, Defendants intended that Plaintiffs, their physicians, and the general public would
3 rely on said representations, which did in fact occur.

4 167. Defendants owed a duty in all of its undertakings, including the dissemination of
5 information concerning its IVC filters, to exercise reasonable care to ensure that it did not in those
6 undertakings create unreasonable risks of personal injury to others.

7 168. Defendants disseminated to health care professionals and consumers through published
8 labels, labeling, marketing materials, and otherwise information concerning the properties and effects of
9 Cordis IVC filters with the intention that health care professionals and consumers would rely upon that
10 information in their decisions concerning whether to prescribe and use Defendants' IVC filters.

11 169. Defendants, as medical device designers, manufacturers, sellers, promoters and/or
12 distributors, knew or should reasonably have known that health care professionals and consumers, in
13 weighing the potential benefits and potential risks of prescribing or using Cordis IVC filters, would rely
14 upon information disseminated and marketed by Defendants to them regarding the Cordis IVC filters.

15 170. Defendants failed to exercise reasonable care to ensure that the information they
16 disseminated to health care professionals and consumers concerning the properties and effects of Cordis
17 IVC filters was accurate, complete, and not misleading and, as a result, disseminated information to
18 health care professionals and consumers that was negligently and materially inaccurate, misleading,
19 false, and unreasonably dangerous to consumers such as Plaintiffs.

20 171. Defendants, as designers, manufacturers, sellers, promoters, and/or distributors, also
21 knew or reasonably should have known that patients receiving Cordis IVC filters as recommended by
22 health care professionals in reliance upon information disseminated by Defendants as the
23 manufacturer/distributor of Defendants' IVC filters would be placed in peril of developing the serious,
24 life-threatening, and life-long injuries including, but not limited to, tilting, migration, perforation,
25 fracture, lack of efficacy, and increased risk of the development of blood clots, if the information
26 disseminated and relied upon was materially inaccurate, misleading, or otherwise false.

27 172. Defendants had a duty to promptly correct material misstatements Defendants' knew
28 others were relying upon in making healthcare decisions.

173. Defendants failed in each of these duties by misrepresenting to Plaintiffs and the medical community the safety and efficacy of Cordis IVC filters and failing to correct known misstatements and misrepresentations.

174. As a direct and proximate result of Defendants' negligent misrepresentations, Plaintiffs suffered Injuries and Damages.

SIXTH CAUSE OF ACTION

FRAUDULENT MISREPRESENTATION

(By All Plaintiffs, As to All Defendants)

175. Plaintiffs incorporate by reference all prior allegations.

176. At all times relevant to this cause, and as detailed above, Defendants intentionally provided Plaintiffs, their physicians, the medical community, and the public at large with false or inaccurate information. Defendants also omitted material information concerning Cordis IVC filters (the TrapEase filters and the OptEase filters), including, but not limited to, misrepresentations regarding the following topics:

- a. The safety of the Cordis IVC filters;
- b. The efficacy of the Cordis IVC filters;
- c. The rate of failure of the Cordis IVC filters;
- d. The pre-market testing of the Cordis IVC filters;
- e. The approved uses of the Cordis IVC filters; and
- f. The ability to retrieve the device at any time over a person's life.

177. The information Defendants distributed to the public, the medical community, and Plaintiffs was in the form of reports, press releases, advertising campaigns, labeling materials, print advertisements, commercial media containing material representations, and instructions for use, as well as through their officers, directors, agents, and representatives.

178. These materials contained false and misleading material representations, which included: that Cordis IVC filters were safe and fit when used for their intended purpose or in a reasonably foreseeable manner; that they did not pose dangerous health risks in excess of those associated with the

1 use of other similar IVC filters; that any and all side effects were accurately reflected in the warnings;
2 and that they were adequately tested to withstand normal placement within the human body.

3 179. Defendants made the foregoing misrepresentations knowing that they were false or
4 without reasonable basis. These materials included instructions for use and a warning document that
5 was included in the package of the Cordis IVC filters that were implanted in Plaintiffs.

6 180. Defendants' intent and purpose in making these misrepresentations was to deceive and
7 defraud the public and the medical community, including Plaintiffs' health care providers; to gain the
8 confidence of the public and the medical community, including Plaintiffs' health care providers; to
9 falsely assure the public and the medical community of the quality of Cordis IVC filters and their fitness
10 for use; and to induce the public and the medical community, including Plaintiffs' health care providers
11 to request, recommend, prescribe, implant, purchase, and continue to use Cordis IVC filters, all in
12 reliance on Defendants' misrepresentations.

13 181. The foregoing representations and omissions by Defendants were false.

14 182. Defendants' IVC filters are not safe, fit, and effective for human use in their intended and
15 reasonably foreseeable manner.

16 183. Further, the use of Cordis IVC filters is hazardous to the users' health, and Cordis IVC
17 filters have a serious propensity to cause users to suffer serious injuries, including without limitation the
18 injuries Plaintiffs suffered.

19 184. Finally, Defendants' IVC filters have a statistically significant higher rate of failure and
20 injury than do other comparable IVC filters.

21 185. In reliance upon the false and negligent misrepresentations and omissions made by
22 Defendants, Plaintiffs and their health care providers were induced to, and did use Cordis IVC filters,
23 thereby causing Plaintiffs to sustain severe and permanent personal injuries.

24 186. Defendants knew and had reason to know that Plaintiffs, their health care providers, and
25 the general medical community did not have the ability to determine the true facts intentionally and/or
26 negligently concealed and misrepresented by Defendants, and would not have prescribed and implanted
27 Cordis IVC filters if the true facts regarding Defendants' IVC filters had not been concealed and
28 misrepresented by Defendants.

1 187. Defendants had sole access to material facts concerning the defective nature of the
2 products and their propensities to cause serious and dangerous side effects in the form of dangerous
3 injuries and damages to persons who were implanted with Cordis IVC filters.

4 188. At the time Defendants failed to disclose and intentionally misrepresented the foregoing
5 facts, and at the time Plaintiffs used Cordis IVC filters, Plaintiffs and their health care providers were
6 unaware of Defendants' misrepresentations and omissions.

7 189. As a direct and proximate result of Defendants' fraudulent misrepresentations, Plaintiffs
8 suffered Injuries and Damages.

9 **SEVENTH CAUSE OF ACTION**

10 **FRAUDULENT CONCEALMENT**

11 **(By All Plaintiffs, As to All Defendants)**

12 190. Plaintiffs incorporate by reference all prior allegations.

13 191. In marketing and selling Cordis IVC filters (the TrapEase filters and the OptEase filters),
14 Defendants concealed material facts from Plaintiffs and their healthcare providers.

15 192. These concealed material facts include, but are not limited to:

- 16 a. Cordis IVC filters were unsafe and not fit when used for their intended purpose or in a
17 reasonably foreseeable manner;
- 18 b. Cordis IVC filters posed dangerous health risks in excess of those associated with the use
19 of other similar IVC filters;
- 20 c. That there were additional side effects related to implantation and use of Cordis IVC
21 filters that were not accurately and completely reflected in the warnings associated with
22 Cordis IVC filters; and
- 23 d. That Cordis IVC filters were not adequately tested to withstand normal placement within
24 the human body.

25 193. Plaintiffs and their health care providers were not aware of these and other facts
26 concealed by Defendants.

27 194. In concealing these and other facts, Defendants intended to deceive Plaintiffs and their
28 health care providers.

195. Plaintiffs and their health care providers were ignorant of and could not reasonably discover the facts Defendants fraudulently concealed and reasonably and justifiably relied on Defendants' representations concerning the supposed safety and efficacy of Cordis IVC filters.

196. As a direct and proximate result of Defendants' fraudulent concealment of material facts, Plaintiffs suffered Injuries and Damages.

EIGHTH CAUSE OF ACTION

BREACH OF EXPRESS WARRANTY

(By All Plaintiffs, As to All Defendants)

197. Plaintiffs incorporate by reference all prior allegations.

198. Plaintiffs, through their medical providers, purchased a Cordis IVC filter from Defendants.

199. At all relevant times, Defendants were merchants of goods of the kind including medical devices and vena cava filters (i.e., Cordis IVC filters).

200. At the time and place of sale, distribution, and supply of Cordis IVC filters to Plaintiffs (and to other consumer and the medical community), Defendants expressly represented and warranted that Cordis IVC filters were safe; that they were well-tolerated, efficacious, fit for their intended purpose, and of marketable quality; that they did not produce any unwarned-of dangerous side effects; and that they was adequately tested.

201. At the time of Plaintiffs' purchase from Defendants, Cordis IVC filters were not in a merchantable condition, and Defendants breached its expressed warranties, in that Cordis IVC filters, among other things:

- a. Were designed in such a manner so as to be prone to an unreasonably high incidence of fracture, perforation of vessels and organs, and/or migration;
- b. Were designed in such a manner so as to result in a unreasonably high incidence of injury to the vessels and organs of its purchaser;
- c. Were manufactured in such a manner that the exterior surface of the filter was inadequately, improperly, and inappropriately constituted, causing the device to weaken and fail;

- d. Were unable to be removed at any time during a person's life;
- e. Were not efficacious in the prevention of pulmonary emboli;
- f. Carried a risk of use outweighed any benefit; and
- g. Were not self-centering.

202. As a direct and proximate result of Defendants' breach of express warranty, Plaintiffs suffered Injuries and Damages.

NINTH CAUSE OF ACTION

BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY

(By All Plaintiffs, As to All Defendants)

203. Plaintiffs incorporate by reference all prior allegations.

204. Defendants impliedly warranted that Cordis IVC filters were of merchantable quality and safe and fit for the use for which Defendants intended them, and Plaintiff in fact used them.

205. Defendants breached its implied warranties by, among other things:

- a. Failing to provide adequate instruction that a manufacturer exercising reasonable care would have provided concerning the likelihood that Cordis IVC filters would cause harm;
- b. Manufacturing and/or selling Cordis IVC filters when those filters did not conform to representations made by Defendants when they left Defendants' control;
- c. Manufacturing and/or selling Cordis IVC filters that were more dangerous than an ordinary consumer would expect when used in an intended or reasonably foreseeable manner;
- d. Manufacturing and/or selling Cordis IVC filters that carried foreseeable risks associated with the Cordis IVC filter design or formulation which exceeded the benefits associated with that design;
- e. Manufacturing and/or selling Cordis IVC filters when they deviated in a material way from the design specifications, formulas, or performance standards or from otherwise identical units manufactured to the same design specifications, formulas, or performance standards; and

- 1 f. Impliedly representing that its filters would be effective in the prevention of pulmonary
2 emboli.

3 206. At the time Plaintiffs and their physicians purchased and used the devices, the products
4 were not in a merchantable condition in that:

- 5 a. They offered no benefit to patient outcomes,
6 b. They suffered an unreasonably high failure and injury rates,
7 c. The surface of the devices were manufactured and designed in such a way that they were
8 distributed with surface damage that substantially increased the risk of fracture, and
9 d. They were prothrombotic;

10 207. As a direct and proximate result of Defendants' breach of its implied warranty, Plaintiffs
11 suffered Injuries and Damages.

12 **TENTH CAUSE OF ACTION**

13 **LOSS OF CONSORTIUM**

14 **(By Plaintiffs RHONDA HERNANDEZ, WALTER SIMMONS, HEATHER VANDALL,**
15 **BARBARA SPISHAK, and BRIAN ZUKRIGIL ("LOC Plaintiffs"), As to All Defendants)**

16 208. Plaintiffs incorporate by reference all prior allegations

17 209. As a proximate result of the personal injuries suffered by Plaintiffs DONALD
18 HERNANDEZ, SR., CAROLYN SIMMONS, STEPHEN VANDALL, ROBERT SPISHAK and
19 RUSSELL ZUKRIGIL, as described in this Complaint, LOC Plaintiffs have been deprived of the
20 benefits of their marriage including love, affection, society, and consortium, and other spousal duties
21 and actions. LOC Plaintiffs were provided with all of the benefits of a marriage between husband and
22 wife, prior to the use of a Cordis IVC filter by their respective Plaintiff spouses and the resulting injuries
23 described herein.

24 210. LOC Plaintiffs have also suffered the permanent loss of their respective Plaintiff spouses'
25 daily and regular contribution to the household duties and services, which each provides to the
26 household as husband and wife.

27 211. LOC Plaintiffs have also incurred the costs and expenses related to the medical care,
28 treatment, medications, and hospitalization to which their respective Plaintiff spouses were subjected for

1 the physical injuries they suffered as a proximate result of their use of a Cordis IVC filter. LOC
2 Plaintiffs will continue to incur the future costs and expenses related to the care, treatment, medications,
3 and hospitalization of their respective Plaintiff spouses due to their injuries.

4 212. LOC Plaintiffs have suffered loss of consortium, as described herein, including the past,
5 present, and future loss of their spouses' companionship, services, society, and the ability of their
6 spouses to provide LOC Plaintiffs with the benefits of marriage, including inter alia, loss of contribution
7 to household income and loss of household services, all of which has resulted in pain, suffering, and
8 mental and emotional distress and worry for LOC Plaintiffs.

9 **PUNITIVE DAMAGES ALLEGATIONS**

10 **(By All Plaintiffs, As to All Defendants)**

11 213. Plaintiffs incorporate by reference all prior allegations.

12 214. At all times material hereto, Defendants knew or should have known that Cordis IVC
13 filters were unreasonably dangerous with respect to the risk of tilt, fracture, migration and/or
14 perforation.

15 215. At all times material hereto, Defendants attempted to misrepresent and did knowingly
16 misrepresent facts concerning the safety of Cordis IVC filters.

17 216. Defendants' misrepresentations included knowingly withholding material information
18 from the medical community and the public, including Plaintiffs' physicians, concerning the safety of its
19 Cordis IVC filters. Data establishes that the failure rates of the TrapEase and OptEase filters are and
20 were much higher than what Defendants have in the past and currently continue to publish to the
21 medical community and members of the public.

22 217. Defendants' conduct, alleged throughout this Complaint, was willful, wanton, and
23 undertaken with a conscious indifference and disregard to the consequences that consumers of their
24 products faced, including Plaintiffs. Defendants had actual knowledge of the dangers presented by
25 Cordis IVC filters, yet consciously failed to act reasonably to inform or warn Plaintiffs, Plaintiffs'
26 physicians or the public at large of these dangers. Defendants consciously failed to establish and
27 maintain an adequate quality and post-market surveillance system.

219. Notwithstanding the foregoing, Defendants continued to market Cordis IVC filters aggressively to consumers, including Plaintiffs, without disclosing the aforesaid side effects.

220. Defendants knew of their Cordis IVC filters' lack of warnings regarding the risk of fracture, migration, and/or perforation, but intentionally concealed and/or recklessly failed to disclose that risk and continued to market, distribute, and sell its filters without said warnings so as to maximize sales and profits at the expense of the health and safety of the public, including Plaintiffs, in conscious disregard of the foreseeable harm caused by Cordis IVC filters.

221. Defendants' intentional and/or reckless failure to disclose information deprived Plaintiffs' physicians of necessary information to enable them to weigh the true risks of using Cordis IVC filters against its benefits.

222. Defendants' conduct is reprehensible, evidencing an evil hand guided by an evil mind and was undertaken for pecuniary gain in reckless and conscious disregard for the substantial risk of death and physical injury to consumers, including Plaintiffs.

223. Such conduct justifies an award of punitive or exemplary damages in an amount sufficient to punish Defendants' conduct and deter like conduct by Defendants and other similarly situated persons and entities in the future.

PRAYER FOR DAMAGES

PRAYER FOR DAMAGES

WHEREFORE, Plaintiffs demand judgment against Defendants for:

- a. General (non-economic) damages, including, without limitation, past and future pain and suffering; past and future emotional distress; past and future loss of enjoyment of life; and other consequential damages as allowed by law;
- b. Special (economic) damages, including, without limitation, past and future medical expenses; past and future lost wages and loss of earning capacity; and other consequential damages as allowed by law;
- c. Punitive damages in an amount sufficient to punish Defendants and deter similar conduct in the future;

- b. Special (economic) damages, including, without limitation, past and future medical expenses; past and future lost wages and loss of earning capacity; and other consequential damages as allowed by law;

- c. Punitive damages in an amount sufficient to punish Defendants and deter similar conduct in the future;

- 1 d. Disgorgement of profits;
2 e. Restitution;
3 f. Statutory damages, where authorized;
4 g. Costs of suit;
5 h. Reasonable attorneys' fees, where authorized;
6 i. Prejudgment interest as allowed by law;
7 j. Post-judgment interest at the highest applicable statutory or common law rate from the
8 date of judgment until satisfaction of judgment;
9 k. Such other additional and further relief as Plaintiffs may be entitled to in law or in equity.

10 **DEMAND FOR JURY TRIAL**

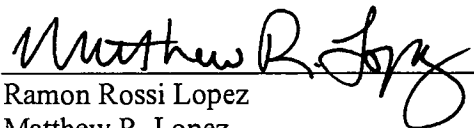
11 Plaintiffs hereby demand a trial by jury on all triable issues.

12
13 Dated: May 19, 2016

Respectfully submitted,

14 LOPEZ McHUGH LLP

15
16 By:


Ramon Rossi Lopez

Matthew R. Lopez

18 Amorina P. Lopez

19 -And-

20 Turner W. Branch (for *pro hac vice* consideration)

21 Margaret M. Branch (for *pro hac vice* consideration)

22 Adam T. Funk (for *pro hac vice* consideration)

BRANCH LAW FIRM

23 Attorneys for Plaintiffs
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 ALAMEDA COUNTY

MAY 20 2016

CLERK OF THE SUPERIOR COURT
 By *Samuel M. [Signature]*
 Deputy

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19 Attorneys for Plaintiffs

20 **SUPERIOR COURT OF THE STATE OF CALIFORNIA**
 21 **FOR THE COUNTY OF ALAMEDA**

22 LISA OEHRING, an individual; LUTHER
 23 LEATHAM, an individual; SONJI
 24 HUTCHINSON, an individual; SANDRA
 25 SUTTER, an individual; LYNDIA SMITH, an
 26 individual; ALAN GOLDBERG, an individual;
 27 BENITO BROWN and LUPE BROWN,
 28 individually and as husband and wife;
 PATRICIA BUNKER, an individual;
 CARMEN BURGESS, an individual; TRAVIS
 BURKHART and KIMBERLY BURKHART,
 individually and as husband and wife; PHILIP
 FACIANA, an individual; LOUISE HILL, an
 individual; KEITH HUNTER, an individual;
 ELLEN JUVERA-SAIZ, an individual;
 BRANDI KIRK, an individual; LISA
 KUMBIER, an individual; JESSICA
 LARIMORE, an individual; HERMAN
 MALONE, an individual; DOROTHY MAY,
 an individual; DUSTIN MERRITT, an
 individual; CINDY SEYMORE, an individual;
 FREDDIE WILSON, an individual; DONALD

Case No.: **RG16816490**

COMPLAINT FOR DAMAGES

1. STRICT PRODUCTS LIABILITY – DESIGN DEFECT
2. STRICT PRODUCTS LIABILITY – FAILURE TO WARN
3. STRICT PRODUCTS LIABILITY – MANUFACTURING DEFECT
4. NEGLIGENCE
5. NEGLIGENT MISREPRESENTATION
6. FRAUDULENT MISREPRESENTATION
7. FRAUDULENT CONCEALMENT
8. BREACH OF EXPRESS WARRANTY
9. BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY
10. LOSS OF CONSORTIUM
11. WRONGFUL DEATH

DEMAND FOR JURY TRIAL

BY FAX

HOLLAND, an individual; JAMES MCCORD,
 an individual; BILLY RICHARD and
 MELANIE RICHARD, individually and as
 husband and wife; JOHN ROGERS, an
 individual; SEAN MAGUIRE and LAURA
 MAGUIRE, individually and as husband and
 wife; GILDA SOUTHERLAND, VINCENT
 SOUTHERLAND and CHAD
 SOUTHERLAND, individually and as legal
 heirs to DUKE SOUTHERLAND, Decedent;

Plaintiffs,

vs.

CORDIS CORPORATION, a corporation;
 JOHNSON & JOHNSON, a corporation;
 CARDINAL HEALTH, INC., a corporation;
 and DOES 1 through 50;

Defendants.

COMES NOW, Plaintiffs, by and through their attorneys, who complain and allege against Defendants, CORDIS CORPORATION ("Cordis"), JOHNSON & JOHNSON ("J&J"), CARDINAL HEALTH, INC. ("Cardinal"), and DOES 1 through 50, and each of them, on information and belief, as follows:

INTRODUCTION

1. Plaintiffs bring this action for personal injuries and/or wrongful death damages suffered as a direct and proximate result of being implanted with a defective and unreasonably dangerous Inferior Vena Cava ("IVC") filter medical device manufactured by Defendants.

2. The subject IVC filters include the following devices: TrapEase™ Permanent Vena Cava Filter ("TrapEase filter") and OptEase™ Retrievable Vena Cava Filter ("OptEase filter") (for convenience, these devices will be referred to in this complaint under the generic terms "Cordis IVC filters" or "Defendants' IVC filters"). At all times relevant to this action, Defendants developed, designed, set specifications for, licensed, manufactured, prepared, compounded, assembled, processed, sold, distributed and/or marketed the Cordis IVC filters to be implanted in patients throughout the United States, including California.

3. Plaintiffs' claims for damages all relate to Defendants' design, manufacture, sale, testing, marketing, labeling, advertising, promotion, and/or distribution of Cordis IVC filters.

4. The Cordis IVC filters that are the subject of this action all reached Plaintiffs, Plaintiffs' Decedent, and their physicians without substantial change in condition from the time they left Defendants' possession.

5. Plaintiffs, Plaintiffs' Decedent, and their physicians used the Cordis IVC filters in the manner in which they were intended.

6. Defendants are solely responsible for any alleged design, manufacture or information defect its IVC filters contain.

7. Defendants do not allege that any other person or entity is comparatively at fault for any alleged design, manufacture, or informational defect its IVC filters contain.

PARTIES

8. Plaintiff LISA OEHRING at all times relevant to this action was and is a citizen and resident of the State of California. Plaintiff LISA OEHRING underwent placement of Defendants' TrapEase Vena Cava Filter on or about December 31, 2013, in California. The filter subsequently malfunctioned and caused injury and damages to Plaintiff LISA OEHRING, including, but not limited to, perforation of her IVC. As a direct and proximate result of these malfunctions, Plaintiff LISA OEHRING suffered life-threatening injuries and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff LISA OEHRING has suffered and will continue to suffer significant medical expenses, and pain and suffering, and other damages.

9. Plaintiff LUTHER LEATHEM at all times relevant to this action was and is a citizen and resident of the State of Ohio. Plaintiff LUTHER LEATHEM underwent placement of Defendants' TrapEase Vena Cava Filter on or about January 12, 2010. The filter subsequently malfunctioned and caused injury and damages to Plaintiff LUTHER LEATHEM, including, but not limited to, caval thrombosis. As a direct and proximate result of these malfunctions, Plaintiff LUTHER LEATHEM suffered life-threatening injuries and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff LUTHER LEATHEM has suffered and will continue to suffer significant medical expenses, and pain and suffering, and other damages.

1 10. Plaintiff SONJI HUTCHINSON at all times relevant to this action was and is a citizen
2 and resident of the State of Florida. Plaintiff SONJI HUTCHINSON underwent placement of
3 Defendants' TrapEase Vena Cava Filter on or about June 1, 2013. The filter subsequently
4 malfunctioned and caused injury and damages to Plaintiff SONJI HUTCHINSON, including, but not
5 limited to, recurrent DVT. As a direct and proximate result of these malfunctions, Plaintiff SONJI
6 HUTCHINSON suffered life-threatening injuries and damages, and required extensive medical care and
7 treatment. As a further proximate result, Plaintiff SONJI HUTCHINSON has suffered and will continue
8 to suffer significant medical expenses, and pain and suffering, and other damages.

9 11. Plaintiff SANDRA SUTTER at all times relevant to this action was and is a citizen and
10 resident of the State of Florida. Plaintiff SANDRA SUTTER underwent placement of Defendants'
11 TrapEase Vena Cava Filter on or about November 13, 2009. The filter subsequently malfunctioned and
12 caused injury and damages to Plaintiff SANDRA SUTTER, including, but not limited to, blood clots,
13 clotting, occlusion of the IVC filter, and recurrent DVT. As a direct and proximate result of these
14 malfunctions, Plaintiff SANDRA SUTTER suffered life-threatening injuries and damages, and required
15 extensive medical care and treatment. As a further proximate result, Plaintiff SANDRA SUTTER has
16 suffered and will continue to suffer significant medical expenses, and pain and suffering, and other
17 damages.

18 12. Plaintiff LYNDIA SMITH at all times relevant to this action was and is a citizen and
19 resident of the State of New Jersey. Plaintiff LYNDIA SMITH underwent placement of Defendants'
20 TrapEase Vena Cava Filter on or about December 20, 2010. The filter subsequently malfunctioned and
21 caused injury and damages to Plaintiff LYNDIA SMITH, including, filter embedded in wall of the IVC
22 and ensuing pain. As a direct and proximate result of these malfunctions, Plaintiff LYNDIA SMITH
23 suffered life-threatening injuries and damages, and required extensive medical care and treatment. As a
24 further proximate result, Plaintiff LYNDIA SMITH has suffered and will continue to suffer significant
25 medical expenses, and pain and suffering, and other damages.

26 13. Plaintiff ALAN GOLDBERG at all times relevant to this action was a citizen and
27 resident of the State of Pennsylvania and, subsequently, became a citizen and resident of the State of
28 New Jersey. Plaintiff ALAN GOLDBERG underwent placement of Defendants' OptEase Vena Cava

1 Filter on or about March 26, 2010. The filter subsequently malfunctioned and caused injury and
2 damages to Plaintiff ALAN GOLDBERG, including, but not limited to, perforation, filter embedded in
3 wall of the IVC, and unsuccessful removal attempt. As a direct and proximate result of these
4 malfunctions, Plaintiff ALAN GOLDBERG suffered life-threatening injuries and damages, and required
5 extensive medical care and treatment. As a further proximate result, Plaintiff ALAN GOLDBERG has
6 suffered and will continue to suffer significant medical expenses, and pain and suffering, and other
7 damages.

8 14. Plaintiff BENITO BROWN at all times relevant to this action was and is a citizen and
9 resident of the State of Colorado. Plaintiff BENITO BROWN underwent placement of Defendants'
10 OptEase Vena Cava Filter on or about March 10, 2011. The filter subsequently malfunctioned and
11 caused injury and damages to Plaintiff BENITO BROWN, including, but not limited to, filter embedded
12 in wall of the IVC. As a direct and proximate result of these malfunctions, Plaintiff BENITO BROWN
13 suffered life-threatening injuries and damages, and required extensive medical care and treatment. As a
14 further proximate result, Plaintiff BENITO BROWN has suffered and will continue to suffer significant
15 medical expenses, and pain and suffering, and other damages.

16 15. Plaintiff LUPE BROWN at all times relevant to this action was and is a citizen and
17 resident of the State of Colorado. Plaintiffs BENITO BROWN and LUPE BROWN were and are, at all
18 times relevant to this action, legally married as husband and wife. Plaintiff LUPE BROWN brings this
19 action for, *inter alia*, the loss of consortium, comfort, and society she suffered due to the personal
20 injuries suffered by her husband, BENITO BROWN.

21 16. Plaintiff PATRICIA BUNKER at all times relevant to this action was and is a citizen and
22 resident of the State of Massachusetts. Plaintiff PATRICIA BUNKER underwent placement of
23 Defendants' OptEase Vena Cava Filter on or about November 13, 2008. The filter subsequently
24 malfunctioned and caused injury and damages to Plaintiff PATRICIA BUNKER, including, but not
25 limited to, tilt, migration, and filter embedded in wall of the IVC. As a direct and proximate result of
26 these malfunctions, Plaintiff PATRICIA BUNKER suffered life-threatening injuries and damages, and
27 required extensive medical care and treatment. As a further proximate result, Plaintiff PATRICIA
28

1 BUNKER has suffered and will continue to suffer significant medical expenses, and pain and suffering,
2 and other damages.

3 17. Plaintiff CARMEN BURGESS at all times relevant to this action was and is a citizen and
4 resident of the State of South Carolina. Plaintiff CARMEN BURGESS underwent placement of
5 Defendants' OptEase Vena Cava Filter on or about February 7, 2006. The filter subsequently
6 malfunctioned and caused injury and damages to Plaintiff CARMEN BURGESS, including, but not
7 limited to, fracture of the IVC filter, perforation, and filter embedded in wall of the IVC. As a direct and
8 proximate result of these malfunctions, Plaintiff CARMEN BURGESS suffered life-threatening injuries
9 and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff
10 CARMEN BURGESS has suffered and will continue to suffer significant medical expenses, and pain
11 and suffering, and other damages.

12 18. Plaintiff TRAVIS BURKHART at all times relevant to this action was and is a citizen
13 and resident of the State of Indiana. Plaintiff TRAVIS BURKHART underwent placement of
14 Defendants' OptEase Vena Cava Filter on or about February 21, 2008. The filter subsequently
15 malfunctioned and caused injury and damages to Plaintiff TRAVIS BURKHART, including, but not
16 limited to, thrombosis and DVT. As a direct and proximate result of these malfunctions, Plaintiff
17 TRAVIS BURKHART suffered life-threatening injuries and damages, and required extensive medical
18 care and treatment. As a further proximate result, Plaintiff TRAVIS BURKHART has suffered and will
19 continue to suffer significant medical expenses, and pain and suffering, and other damages.

20 19. Plaintiff KIMBERLY BURKHART at all times relevant to this action was and is a
21 citizen and resident of the State of Indiana. Plaintiffs TRAVIS BURKHART and KIMBERLY
22 BURKHART were and are, at all times relevant to this action, legally married as husband and wife.
23 Plaintiff KIMBERLY BURKHART brings this action for, *inter alia*, the loss of consortium, comfort,
24 and society she suffered due to the personal injuries suffered by her husband, TRAVIS BURKHART.

25 20. Plaintiff PHILIP FACIANA at all times relevant to this action was a citizen and resident
26 of the State of Minnesota and, subsequently, became a citizen and resident of the State of Ohio. Plaintiff
27 PHILIP FACIANA underwent placement of Defendants' OptEase Vena Cava Filter on or about
28 September 15, 2010. The filter subsequently malfunctioned and caused injury and damages to Plaintiff

1 PHILIP FACIANA, including, but not limited to, tilt, caval thrombosis, and DVT. As a direct and
2 proximate result of these malfunctions, Plaintiff PHILIP FACIANA suffered life-threatening injuries
3 and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff
4 PHILIP FACIANA has suffered and will continue to suffer significant medical expenses, and pain and
5 suffering, and other damages.

6 21. Plaintiff LOUISE HILL at all times relevant to this action was and is a citizen and
7 resident of the State of Wyoming. Plaintiff LOUISE HILL underwent placement of Defendants'
8 OptEase Vena Cava Filter on or about August 19, 2014. The filter subsequently malfunctioned and
9 caused injury and damages to Plaintiff LOUISE HILL, including, but not limited to, migration,
10 perforation, and DVT. As a direct and proximate result of these malfunctions, Plaintiff LOUISE HILL
11 suffered life-threatening injuries and damages, and required extensive medical care and treatment. As a
12 further proximate result, Plaintiff LOUISE HILL has suffered and will continue to suffer significant
13 medical expenses, and pain and suffering, and other damages.

14 22. Plaintiff KEITH HUNTER at all times relevant to this action was and is a citizen and
15 resident of the State of Pennsylvania. Plaintiff KEITH HUNTER underwent placement of Defendants'
16 OptEase Vena Cava Filter on or about May 18, 2011. The filter subsequently malfunctioned and caused
17 injury and damages to Plaintiff KEITH HUNTER, including, but not limited to, filter embedded in wall
18 of the IVC. As a direct and proximate result of these malfunctions, Plaintiff KEITH HUNTER suffered
19 life-threatening injuries and damages, and required extensive medical care and treatment. As a further
20 proximate result, Plaintiff KEITH HUNTER has suffered and will continue to suffer significant medical
21 expenses, and pain and suffering, and other damages.

22 23. Plaintiff ELLEN JUVERA-SAIZ at all times relevant to this action was and is a citizen
23 and resident of the State of Colorado. Plaintiff ELLEN JUVERA-SAIZ underwent placement of
24 Defendants' OptEase Vena Cava Filter on or about December 26, 2006. The filter subsequently
25 malfunctioned and caused injury and damages to Plaintiff ELLEN JUVERA-SAIZ, including, but not
26 limited to, fracture of the IVC filter. As a direct and proximate result of these malfunctions, Plaintiff
27 ELLEN JUVERA-SAIZ suffered life-threatening injuries and damages, and required extensive medical
28

1 care and treatment. As a further proximate result, Plaintiff ELLEN JUVERA-SAIZ has suffered and
2 will continue to suffer significant medical expenses, and pain and suffering, and other damages.

3 24. Plaintiff BRANDI KIRK at all times relevant to this action was and is a citizen and
4 resident of the State of Arizona. Plaintiff BRANDI KIRK underwent placement of Defendants'
5 OptEase Vena Cava Filter on or about December 15, 2011. The filter subsequently malfunctioned and
6 caused injury and damages to Plaintiff BRANDI KIRK, including, but not limited to, tilt of the IVC
7 filter. As a direct and proximate result of these malfunctions, Plaintiff BRANDI KIRK suffered life-
8 threatening injuries and damages, and required extensive medical care and treatment. As a further
9 proximate result, Plaintiff BRANDI KIRK has suffered and will continue to suffer significant medical
10 expenses, and pain and suffering, and other damages.

11 25. Plaintiff LISA KUMBIER at all times relevant to this action was and is a citizen and
12 resident of the State of Wisconsin. Plaintiff LISA KUMBIER underwent placement of Defendants'
13 OptEase Vena Cava Filter on or about February 28, 2014. The filter subsequently malfunctioned and
14 caused injury and damages to Plaintiff LISA KUMBIER, including, but not limited to, filter embedded
15 in wall of the IVC. As a direct and proximate result of these malfunctions, Plaintiff LISA KUMBIER
16 suffered life-threatening injuries and damages, and required extensive medical care and treatment. As a
17 further proximate result, Plaintiff LISA KUMBIER has suffered and will continue to suffer significant
18 medical expenses, and pain and suffering, and other damages.

19 26. Plaintiff JESSICA LARIMORE at all times relevant to this action was and is a citizen
20 and resident of the State of South Carolina. Plaintiff JESSICA LARIMORE underwent placement of
21 Defendants' OptEase Vena Cava Filter on or about February 28, 2014. The filter subsequently
22 malfunctioned and caused injury and damages to Plaintiff JESSICA LARIMORE, including, but not
23 limited to, fracture of the IVC filter, migration, and filter embedded in wall of the IVC. As a direct and
24 proximate result of these malfunctions, Plaintiff JESSICA LARIMORE suffered life-threatening injuries
25 and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff
26 JESSICA LARIMORE has suffered and will continue to suffer significant medical expenses, and pain
27 and suffering, and other damages.
28

1 27. Plaintiff HERMAN MALONE at all times relevant to this action was and is a citizen and
2 resident of the State of Texas. Plaintiff HERMAN MALONE underwent placement of Defendants'
3 OptEase Vena Cava Filter on or about April 30, 2014. The filter subsequently malfunctioned and
4 caused injury and damages to Plaintiff HERMAN MALONE, including, but not limited to, migration of
5 the IVC filter. As a direct and proximate result of these malfunctions, Plaintiff HERMAN MALONE
6 suffered life-threatening injuries and damages, and required extensive medical care and treatment. As a
7 further proximate result, Plaintiff HERMAN MALONE has suffered and will continue to suffer
8 significant medical expenses, and pain and suffering, and other damages.

9 28. Plaintiff DOROTHY MAY at all times relevant to this action was and is a citizen and
10 resident of the State of Arkansas. Plaintiff DOROTHY MAY underwent placement of Defendants'
11 OptEase Vena Cava Filter on or about April 29, 2008. The filter subsequently malfunctioned and
12 caused injury and damages to Plaintiff DOROTHY MAY, including, but not limited to, filter embedded
13 in wall of the IVC. As a direct and proximate result of these malfunctions, Plaintiff DOROTHY MAY
14 suffered life-threatening injuries and damages, and required extensive medical care and treatment. As a
15 further proximate result, Plaintiff DOROTHY MAY has suffered and will continue to suffer significant
16 medical expenses, and pain and suffering, and other damages.

17 29. Plaintiff DUSTIN MERRITT at all times relevant to this action was and is a citizen and
18 resident of the State of Oklahoma. Plaintiff DUSTIN MERRITT underwent placement of Defendants'
19 OptEase Vena Cava Filter on or about July 14, 2005. The filter subsequently malfunctioned and caused
20 injury and damages to Plaintiff DUSTIN MERRITT, including, but not limited to, tilt, perforation, filter
21 embedded in wall of the IVC, DVT, and retroperitoneal hematoma. As a direct and proximate result of
22 these malfunctions, Plaintiff DUSTIN MERRITT suffered life-threatening injuries and damages, and
23 required extensive medical care and treatment. As a further proximate result, Plaintiff DUSTIN
24 MERRITT has suffered and will continue to suffer significant medical expenses, and pain and suffering,
25 and other damages.

26 30. Plaintiff CINDY SEYMORE at all times relevant to this action was and is a citizen and
27 resident of the State of Maryland. Plaintiff CINDY SEYMORE underwent placement of Defendants'
28 OptEase Vena Cava Filter on or about November 14, 2012. The filter subsequently malfunctioned and

1 caused injury and damages to Plaintiff CINDY SEYMORE, including, but not limited to, tilt of the IVC
2 filter and filter embedded in wall of the IVC. As a direct and proximate result of these malfunctions,
3 Plaintiff CINDY SEYMORE suffered life-threatening injuries and damages, and required extensive
4 medical care and treatment. As a further proximate result, Plaintiff CINDY SEYMORE has suffered
5 and will continue to suffer significant medical expenses, and pain and suffering, and other damages.

6 31. Plaintiff FREDDIE WILSON at all times relevant to this action was and is a citizen and
7 resident of Washington D.C. Plaintiff FREDDIE WILSON underwent placement of Defendants'
8 TrapEase Vena Cava Filter on or about May 21, 2012. The filter subsequently malfunctioned and
9 caused injury and damages to Plaintiff FREDDIE WILSON, including, but not limited to, filter
10 embedded in wall of the IVC. As a direct and proximate result of these malfunctions, Plaintiff
11 FREDDIE WILSON suffered life-threatening injuries and damages, and required extensive medical care
12 and treatment. As a further proximate result, Plaintiff FREDDIE WILSON has suffered and will
13 continue to suffer significant medical expenses, and pain and suffering, and other damages.

14 32. Plaintiff DONALD HOLLAND at all times relevant to this action was and is a citizen
15 and resident of Texas. Plaintiff DONALD HOLLAND underwent placement of Defendants' TrapEase
16 Vena Cava Filter on or about May 11, 2006. The filter subsequently malfunctioned and caused injury
17 and damages to Plaintiff DONALD HOLLAND, including, but not limited to, fracture of the IVC filter.
18 As a direct and proximate result of these malfunctions, Plaintiff DONALD HOLLAND suffered life-
19 threatening injuries and damages, and required extensive medical care and treatment. As a further
20 proximate result, Plaintiff DONALD HOLLAND has suffered and will continue to suffer significant
21 medical expenses, and pain and suffering, and other damages.

22 33. Plaintiff JAMES MCCORD at all times relevant to this action was and is a citizen and
23 resident of Arizona. Plaintiff JAMES MCCORD underwent placement of Defendants' OptEase Vena
24 Cava Filter on or about April 1, 2013. The filter subsequently malfunctioned and caused injury and
25 damages to Plaintiff JAMES MCCORD, including, but not limited to, migration and fracture of the IVC
26 filter, emergency open-heart surgery to remove the filter, and subsequent surgery to remove remaining
27 pieces of the filter from Plaintiff's heart. As a direct and proximate result of these malfunctions,
28 Plaintiff JAMES MCCORD suffered life-threatening injuries and damages, and required extensive

1 medical care and treatment. As a further proximate result, Plaintiff JAMES MCCORD has suffered and
2 will continue to suffer significant medical expenses, and pain and suffering, and other damages.

3 34. Plaintiff BILLY RICHARD at all times relevant to this action was and is a citizen and
4 resident of the State of Texas. Plaintiff BILLY RICHARD underwent placement of Defendants'
5 OptEase Vena Cava Filter on or about January 13, 2014. The filter subsequently malfunctioned and
6 caused injury and damages to Plaintiff BILLY RICHARD, including, but not limited to, fracture of the
7 IVC filter, caval thrombosis, DVT, and post-thrombotic syndrome. As a direct and proximate result of
8 these malfunctions, Plaintiff BILLY RICHARD suffered life-threatening injuries and damages, and ..
9 required extensive medical care and treatment. As a further proximate result, Plaintiff BILLY
10 RICHARD has suffered and will continue to suffer significant medical expenses, and pain and suffering,
11 and other damages.

12 35. Plaintiff MELANIE RICHARD at all times relevant to this action was and is a citizen
13 and resident of the State of Texas. Plaintiffs BILLY RICHARD and MELANIE RICHARD were and
14 are, at all times relevant to this action, legally married as husband and wife. Plaintiff MELANIE
15 RICHARD brings this action for, *inter alia*, the loss of consortium, comfort, and society she suffered
16 due to the personal injuries suffered by her husband, BILLY RICHARD.

17 36. Plaintiff JOHN ROGERS at all times relevant to this action was and is a citizen and
18 resident of Illinois. Plaintiff JOHN ROGERS underwent placement of Defendants' TrapEase Vena
19 Cava Filter on or about June 14, 2007. The filter subsequently malfunctioned and caused injury and
20 damages to Plaintiff JOHN ROGERS, including, but not limited to, filter embedded in wall of the IVC
21 and recurring PE. As a direct and proximate result of these malfunctions, Plaintiff JOHN ROGERS
22 suffered life-threatening injuries and damages, and required extensive medical care and treatment. As a
23 further proximate result, Plaintiff JOHN ROGERS has suffered and will continue to suffer significant
24 medical expenses, and pain and suffering, and other damages.

25 37. Plaintiff SEAN MAGUIRE at all times relevant to this action was and is a citizen and
26 resident of Missouri. Plaintiff SEAN MAGUIRE underwent placement of Defendants' TrapEase Vena
27 Cava Filter on or about August 12, 2003. The filter subsequently malfunctioned and caused injury and
28 damages to Plaintiff SEAN MAGUIRE, including, but not limited to, internal bleeding, blood clots,

1 clotting and occlusion of the IVC filter, filter embedded in wall of the IVC and cannot be retrieved. As
2 a direct and proximate result of these malfunctions, Plaintiff SEAN MAGUIRE suffered life-threatening
3 injuries and damages, and required extensive medical care and treatment. As a further proximate result,
4 Plaintiff SEAN MAGUIRE has suffered and will continue to suffer significant medical expenses, and
5 pain and suffering, and other damages.

6 38. Plaintiff LAURA MAGUIRE at all times relevant to this action was and is a citizen and
7 resident of the State of Missouri. Plaintiffs SEAN MAGUIRE and LAURA MAGUIRE were and are, at
8 all times relevant to this action, legally married as husband and wife. Plaintiff LAURA MAGUIRE
9 brings this action for, *inter alia*, the loss of consortium, comfort, and society she suffered due to the
10 personal injuries suffered by her husband, SEAN MAGUIRE.

11 39. Plaintiffs GILDA SOUTHERLAND, VINCENT SOUTHERLAND and CHAD
12 SOUTHERLAND (collectively, "Southerland Plaintiffs"), are the surviving wife and children,
13 respectively, of DUKE SOUTHERLAND (or, "Plaintiffs' Decedent") and at all times relevant to this
14 action were and are citizens and residents of the State of Connecticut. Plaintiffs bring this case in their
15 individual capacities and as the legal heirs to DUKE SOUTHERLAND.

16 40. Southerland Plaintiffs' Decedent, DUKE SOUTHERLAND, at all times relevant to this
17 action was a citizen and resident of the State of Connecticut. DUKE SOUTHERLAND underwent
18 placement of Defendants' OptEase Vena Cava Filter on or about April 14, 2008. The filter subsequently
19 malfunctioned and caused great bodily harm to DUKE SOUTHERLAND, including, but not limited to,
20 caval thrombosis, PE, and DVT. As direct and proximate results of these filter malfunctions, DUKE
21 SOUTHERLAND suffered fatal injuries, damages, and untimely death on or about July 5, 2014. As a
22 further proximate result, Plaintiffs GILDA SOUTHERLAND, VINCENT SOUTHERLAND and CHAD
23 SOUTHERLAND have suffered and will continue to suffer the wrongful and premature death of their
24 beloved husband and father, respectively.

25 41. Defendant CORDIS CORPORATION ("Cordis"), including its department, division, and
26 subsidiary, Cordis Endovascular, is a corporation or business entity organized and existing under the
27 laws of the State of Florida with its headquarters located at 6500 Paseo Padre Pkwy., Fremont,
28 California, 94555.

42. Cordis may be served with process by serving its registered agent, CT Corporation System, at 818 West Seventh Street Suite 930, Los Angeles, California 90017.

43. Defendant Cordis was a wholly-owned subsidiary of Defendant JOHNSON & JOHNSON ("J&J") and part of the J&J family of companies until in or around October 2015. J&J is a corporation or business entity organized and existing under the laws of the State of New Jersey with its headquarters located in New Jersey.

44. In or around October 2015, Defendant CARDINAL HEALTH, INC. ("Cardinal") publicly announced that it acquired J&J's Cordis business. Cardinal is a corporation or business entity organized and existing under the laws of Ohio with its headquarters in Dublin, Ohio.

45. The true names and/or capacities, whether individual, corporate, partnership, associate, governmental, or otherwise, of Defendant DOES 1 through 50, inclusive, are unknown to Plaintiffs at this time, who therefore sue said Defendants by such fictitious names. Plaintiffs are informed and believe, and thereon allege, that each Defendant designated herein as a DOE caused injuries and damages proximately thereby to Plaintiffs as is hereinafter alleged, and that each DOE defendant is liable to Plaintiffs for the acts and omissions alleged herein below and the injuries and damages resulting therefrom. Plaintiffs seek leave to amend this Complaint to allege the true names and capacities of said DOE defendants when the same are ascertained.

46. Plaintiffs are informed and believe, and thereon allege, that at all times herein mentioned, the Defendants and each of the DOE defendants were the agent, servant, employee and/or joint venturer of the other co-defendants, and each of them, and at all said times each Defendant, including DOE defendants, were acting in the full course, scope, and authority of said agency, service, employment and/or joint venture.

47. Plaintiffs are informed and believe, and thereon allege, that at all times mentioned herein, Defendants and DOES 1 through 50, and each of them, were also known as, formerly known as, and/or were the successors and/or predecessors in interest/business/product line/or a portion thereof, assigns, a parent, a subsidiary (wholly or partially owned by, or the whole or partial owner), affiliate, partner, co-venturer, merged company, alter egos, agents, equitable trustees and/or fiduciaries of and/or were members in an entity or entities engaged in the funding, researching, studying, manufacturing,

1 fabricating, designing, developing, labeling, assembling, distributing, supplying, leasing, buying,
2 offering for sale, selling, inspecting, servicing, contracting others for marketing, warranting, rebranding,
3 manufacturing for others, packaging, and advertising the device.

4 48. Defendants and DOES 1 through 50, and each of them, are liable for the acts, omissions
5 and tortious conduct of its successors and/or predecessors in interest/business/product line/or a portion
6 thereof, assigns, parent, subsidiary, affiliate, partner, co-venturer, merged company, alter ego, agent,
7 equitable trustee, fiduciary and/or its alternate entities in that Defendant and DOES 1 through 50, and
8 each of them, enjoy the goodwill originally attached to each such alternate entity, acquired the assets or
9 product line (or a portion thereof), and in that there has been a virtual destruction of Plaintiffs' remedy
10 against each such alternate entity, and that each such Defendant has the ability to assume the risk-
11 spreading role of each such alternate entity.

12 49. Plaintiffs are informed and believe, and thereon allege that, at all times herein mentioned,
13 DOES 1 through 50, and each of them, were and are corporations organized and existing under the laws
14 of the State of California or the laws of some state or foreign jurisdiction; that each of the said DOE
15 defendants were and are authorized to do and are doing business in the State of California and regularly
16 conducted business in the State of California.

17 50. Upon information and belief, Defendants at all relevant times were engaged in the
18 business of researching, developing, designing, licensing, manufacturing, distributing, selling,
19 marketing, and/or introducing into interstate commerce and into the State of California, either directly or
20 indirectly through third parties or related entities, its products, including the TrapEase and OptEase IVC
21 filters, and derived substantial income from doing business in California.

22 51. "Cordis" and "Defendants" where used hereinafter, shall refer to all subsidiaries,
23 affiliates, divisions, franchises, partners, joint venturers, organizational units of any kind, predecessors,
24 successors, assigns, officers, directors, employees, agents and representatives of Cordis, J&J, Cardinal, as
25 well as DOE Defendants 1 through 50, and each of them.

26 52. Joinder of Plaintiffs in this Complaint for Damages is proper pursuant to *Code of Civil*
27 *Procedure* § 378 because Plaintiffs assert a right to relief in respect of or arising out of the same
28

transaction, occurrence, or series of transactions or occurrences, and questions of law and fact common to all Plaintiffs will arise in the action.

JURISDICTION AND VENUE

53. This Court has jurisdiction under the California Constitution, Article VI, Section 10 and *Code of Civil Procedure* § 410.10. Plaintiffs' damages exceed the jurisdictional minimum of this Court.

54. Venue is proper in this Court pursuant to *Code of Civil Procedure* §§ 395 and 395.5 because the principal place of business for Defendant CORDIS CORPORATION is situated in Alameda County. Further, a substantial amount of Defendants' conduct, as alleged herein by Plaintiffs, took place in Alameda County.

55. Requiring Defendants to litigate these claims in California does not offend traditional notions of fair play and substantial justice and is permitted by the United States Constitution. Defendants are "at home" in the State of California. Cordis maintains campuses and facilities in Fremont and Oakland, California, in Alameda County, and has its headquarters here. Cordis' website lists its address as 6500 Paseo Padre Parkway, Fremont, CA 94555 (see <https://www.cordis.com/> (last visited May 19, 2016)). A Cordis-affiliate website represents that Cordis' "North American operations are based out of the San Francisco Bay Area" and also lists the 6500 Paseo Padre Parkway, Fremont, CA 94555 address (see <http://www.cardinalhealth.com/en/cmp/ext/cor/cordis.html> (last visited May 19, 2016)). Thus, Cordis affirmatively represents to the public that its headquarters is in California, consequently establishing, upon information and belief, that the State of California is the "nerve center" for this corporation. See *Hertz Corp. v. Friend*, 559 U.S. 77 (2010).

56. Defendants systematically availed themselves of the State of California by conducting regular and sustained business and engaging in substantial commerce and business activity in California, including without limitation researching, developing, designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce in the state of California, either directly or indirectly, its products, including Cordis IVC filters.

57. Plaintiffs' claims arise from and relate to Cordis' purposeful avail of the State of California because Cordis' wrongful conduct in developing, designing, selling, marketing, manufacturing and/or distributing Cordis IVC filters took place, in whole or in part, in the State of

1 California. Therefore, the claims of California-plaintiffs *and* out-of-state plaintiffs relate to and arise
2 from Defendants' explicit contacts and purposeful avail of the State of California. Further and
3 independently, Cordis consented to jurisdiction in the State of California by appointing an agent for
4 service of process in this State and by conducting substantial systematic business in this State.

5 58. The instant Complaint for Damages does not confer diversity jurisdiction upon the
6 federal courts pursuant to 28 U.S.C. § 1332. Likewise, federal question subject matter jurisdiction
7 pursuant to 28 U.S.C. § 1331 is not invoked by the instant Complaint, as it sets forth herein exclusively
8 state law claims against the Defendants. Nowhere do Plaintiffs plead, expressly or implicitly, any cause
9 of action or request any remedy that arises under or is founded upon federal law, and any alleged federal
10 rights or remedies are expressly disavowed. The issues presented by Plaintiffs do not implicate
11 substantial federal questions, do not turn on the necessary interpretation of federal law, and do not affect
12 the federal system as a whole. The assertion of federal jurisdiction over claims made herein would
13 improperly disturb the congressionally approved balance of federal and state responsibilities.

14 BACKGROUND

15 INFERIOR VENA CAVA FILTERS GENERALLY

16 59. IVC filters were first made commercially available to the medical community in the
17 1960s. Over the years, medical device manufacturers have introduced several different designs of IVC
18 filters.

19 60. An IVC filter is a device that is designed to filter or "catch" blood clots that travel from
20 the lower portions of the body to the heart and lungs. IVC filters were originally designed to be
21 permanently implanted in the IVC.

22 61. The IVC is a vein that returns blood to the heart from the lower portions of the body. In
23 certain people, for various reasons, blood clots travel from the vessels in the legs and pelvis, through the
24 vena cava and into the lungs. Oftentimes, these blood clots develop in the deep leg veins, a condition
25 called "deep-vein thrombosis" or "DVT." Once blood clots reach the lungs, they are considered
26 "pulmonary emboli" or "PE." Pulmonary emboli present risks to human health.

27 62. People at risk for DVT/PE can undergo medical treatment to manage the risk. For
28 example, a doctor may prescribe anticoagulant therapies such as medications like Heparin, Warfarin, or

1 Lovenox to regulate the clotting factor of the blood. In some people who are at high risk for DVT/PE
2 and who cannot manage their conditions with medications, physicians may recommend surgically
3 implanting an IVC filter to prevent thromboembolic events.

4 63. As stated above, IVC filters have been on the market for decades. All IVC filters are
5 only cleared for use by the Food & Drug Administration ("FDA") for prevention of recurrent pulmonary
6 embolism in patients at risk for pulmonary embolism and where anticoagulation therapy has failed or is
7 contraindicated.

8 64. In order to increase sales of these devices, Defendants sought to expand the market for
9 prophylactic use among nontraditional patient populations that were temporarily at risk of developing
10 blood clots.

11 65. Defendant Cordis engaged in marketing campaigns directed toward the bariatric, trauma,
12 orthopedic and cancer patient population. Expansion to these new patient groups would substantially
13 increase sales and the first manufacturer to market would capture market share.

14 66. Other manufacturers also saw this opportunity, which triggered a race to market a device
15 that provided physicians the option to retrieve the filter after the clot risk subsided.

16 67. From 2000 through 2003, manufacturers of IVC filters, including Defendants, raced
17 against each other to bring the first IVC filter to the market with the added indication of optional
18 retrieval. In 2003, the FDA cleared three different IVC filters for a retrieval indication, one of which
19 was the OptEase filter by Defendant Cordis.

20 68. There is no evidence that Defendants' IVC filters were effective in preventing pulmonary
21 embolism (the very condition the products were indicated to prevent).

22 69. Years after the implantation of retrievable filters into the bodies of patients, scientists
23 began to study the effectiveness of the retrievable filters. As recently as October 2015, an expansive
24 article published in the *Annals of Surgery* concerning trauma patients inserted with IVC filters
25 concluded that IVC filters were not effective in preventing pulmonary emboli, and instead actually
26 caused thrombi to occur.

27 70. Comparing the results of over 30,000 trauma patients who had not received IVC filters
28 with those who had received them, the *Annals of Surgery* study published its alarming results:

- a. Almost twice the percentage of patients with IVC filters in the study died compared to those that had not received them.
- b. Over five times the relative number of patients with IVC filters developed DVTs.
- c. Over four times the relative percentage of patients with filters developed thromboemboli.
- d. Over twice the percentage of patients developed a pulmonary embolus – the very condition Defendant Cordis told the FDA, physicians, and the public that its IVC filters were designed to prevent.

71. Other studies also have revealed that these devices suffer common failure modes such as migration, perforation, thrombosis, and fracture, all of which can cause serious injury or death. For example, recent studies of Cordis IVC filters have revealed fracture rates as high as 50% and recommend medical monitoring and/or removal.

72. These studies, including the *Annals of Surgery* study, have shown there is no evidence establishing that IVC filters are effective and that these devices suffer common failure modes, including, but not limited to, migration, perforation, thrombosis, tilt and fracture, all of which can cause serious injury or death. Thus, the current state of scientific and medical evidence indicates that IVC filters are not only ineffective but that they are themselves a health hazard.

THE TRAPEASE[™] AND OPTEASE[™] IVC FILTERS

73. On or about January 10, 2001, Defendants bypassed the more onerous FDA's approval process for new devices and obtained "clearance" under Section 510(k) of the Medical Device Amendments to the Food, Drug, and Cosmetic Act to market the TrapEase Vena Cava Filter as a *permanent* filter by claiming it was substantially similar in respect to safety, efficacy, design, and materials as the IVC filters already available on the market.

74. Section 510(k) permits the marketing of medical devices if the device is substantially equivalent to other legally marketed predicate devices without formal review for the safety or efficacy of the said device. The FDA explained the difference between the 510(k) process and the more rigorous "premarket approval" (PMA) process in its amicus brief filed with the Third Circuit in *Horn v. Thoratec Corp.*, which the court quoted from:

A manufacturer can obtain an FDA finding of 'substantial equivalence' by submitting a premarket notification to the agency in accordance with section 510(k) of the [Food Drug

1 and Cosmetic Act]. 21 U.S.C. § 360(k). A device found to be ‘substantially equivalent’
2 to a predicate device is said to be ‘cleared’ by FDA (as opposed to ‘approved’ by the
3 agency under a PMA. A pre-market notification submitted under 510(k) is thus entirely
4 different from a PMA which must include data sufficient to demonstrate that the IVC
Filters is safe and effective.

376 F.3d 163, 167 (3d Cir. 2004) (emphasis in original).

5 75. In *Medtronic, Inc. v. Lohr*, the U.S. Supreme Court similarly described the 510(k)
6 process, observing:

7 If the FDA concludes on the basis of the [manufacturer’s] § 510(k) notification that the
8 device is “substantially equivalent” to a pre-existing device, it can be marketed without
9 further regulatory analysis. . . . The § 510(k) notification process is by no means
10 comparable to the PMA process; in contrast to the 1,200 hours necessary to complete a
11 PMA review, the § 510(k) review is completed in average of 20 hours. . . . As one
12 commentator noted: “The attraction of substantial equivalence to manufacturers is clear.
Section 510(k) notification requires little information, rarely elicits a negative response
from the FDA, and gets processed quickly.”

13 518 U.S. 470, 478-79 (1996) (quoting Adler, *The 1976 Medical Device Amendments: A Step in the*
14 *Right Direction Needs Another Step in the Right Direction*, 43 Food Drug Cosm. L.J. 511, 516 (1988)).

15 76. Pursuant to *Wyeth v. Levine*, 555 U.S. 555 (2009), once a product is cleared “the
16 manufacturer remains under an obligation to investigate and report any adverse events associated with
17 the drug . . . and must periodically submit any new information that may affect the FDA’s previous
18 conclusions about the safety, effectiveness, or labeling” This obligation extends to post-market
19 monitoring of adverse events/complaints.

20 77. In July 2000, through this 510(k) process, Defendants obtained clearance from the FDA
21 to market the TrapEase filter as a permanent filter.

22 78. The TrapEase filter is made with Nitinol – a nickel titanium alloy. The filter utilizes a
23 design known as a double basket or double filter for the capture of blood clots and/or emboli. This
24 design consists of a basket made of six diamond-shaped struts proximally and six diamond-shaped struts
25 distally, forming proximal and distal baskets, which are connected by six straight struts to create a single
26 symmetric filter. The filter has proximal and distal anchoring barbs located on each connecting strut for
27 fixation of the filter to the vena cava wall to prevent movement after placement.
28

1 79. Nitinol alloy is used in a number of different medical device applications. It is beneficial
2 for these applications and is employed as material in stents and other medical device applications. It is
3 also used in the manufacture of the TrapEase filter, and other brands of IVC filters.

4 80. Specific manufacturing processes need to be utilized when using Nitinol as a component
5 for medical devices, including IVC filters. Primarily, the Nitinol material should be electro-polished
6 prior to assembly of the finished medical device.

7 81. Electro-polishing is a manner of removing surface blemishes, “draw marking” and
8 circumferential grinding markings on the exterior of the surface of the Nitinol material. The existence
9 of these surface blemishes, “draw markings” and “circumferential grind-markings” causes/results in the
10 weakening of the structural integrity of the end product, whether it is an IVC filter or other medical
11 device.

12 82. In or around September 2002, Defendants sought clearance through the 510(k) process to
13 market the OptEase Vena Cava Filter for the same indicated uses as the TrapEase filter. Defendants
14 represented that the OptEase filter contained the same fundamental technology and was substantially
15 equivalent in terms of safety and efficacy as the predicate devices already available on the market.

16 83. Unlike the TrapEase filter, which has proximal and distal anchoring barbs located on
17 each connecting strut for fixation of the filter to the vena cava wall, the OptEase filter has anchoring
18 barbs for fixation of the filter only on the superior end of each of the six straight struts and has a hook at
19 the inferior end of the basket to allow retrieval with a snare.

20 84. Both designs for the TrapEase filter and OptEase filter suffer flaws making them
21 defective and unreasonably dangerous. Defendants’ IVC filters are designed in such a way that when
22 exposed to expected and reasonably foreseeable *in-vivo* conditions, the devices will fracture, migrate,
23 tilt, perforate internal organs and vasculature, and lead to the formation of thromboembolism and
24 pulmonary embolism.

25 85. For years, it has been known by manufacturers of the Nitinol medical devices and the
26 medical device industry that electro-polishing Nitinol results in increased structural integrity of the
27 device and resistance to fatigue and fatigue failures.
28

1 86. The exterior surfaces of the Cordis IVC filters were not electro-polished prior to
2 completion of the manufacturing process. This is a manufacturing defect that exists in the TrapEase and
3 OptEase filters which causes these filters to be structurally weak and susceptible to a significant risk of
4 failure/fracture.

5 87. Additionally, Defendants represented that the self-centering design of the TrapEase filter
6 allows accurate, predictable placement, and that its site struts help reduce the risk of tilting and
7 migration, while in reality the filters regularly tilt, migrate, and become embedded in the vena cava wall.

8 88. The anchoring mechanism of Defendants' filters is also insufficient to prevent tilting and
9 migration post-placement.

10 89. The configuration of the Cordis IVC filters actually leads to the formation of blood clots
11 and pulmonary embolism – the exact condition the devices are meant to protect against.

12 90. That Defendants allowed these devices to proceed to market indicates that they failed to
13 establish and maintain an appropriate Quality System concerning design and risk analysis.

14 91. A manufacturer must, at a minimum, undertake research and testing to understand the
15 anatomy of where a medical device will be implanted and understand the forces the device may be
16 exposed to once implanted in a human body. This design input must then be used to determine the
17 minimum safety requirements or attributes the device must have to meet user needs. In the case of an
18 IVC filter, user needs include a device that will capture blood clots of sufficient size to cause harmful
19 consequences and that will not fracture, migrate, tilt, perforate the vena cava, or malfunction in some
20 other way, or be prothombotic. Defendants failed to undertake any such efforts in these regards.

21 92. Prior to bringing a product to market, a manufacturer must also conduct sufficient testing
22 under real world or simulated use conditions to ensure that the device will meet user needs even when
23 exposed to reasonably foreseeable worst-case conditions. Defendants failed to adequately establish and
24 maintain such policies, procedures or protocols with respect to their IVC filters.

25 93. Once placed on the market, Defendants' post-market surveillance system should have
26 revealed to Defendants that the TrapEase and OptEase filters were unreasonably dangerous and
27 substantially more prone to fail or malfunction, and cause great bodily harm to patients compared to
28 other available treatment options.

1 94. MAUDE is a database maintained by the FDA to house medical device reports submitted
2 by mandatory reporters (such as manufacturers and device user facilities) and voluntary reporters (such
3 as health care providers and patients).

4 95. Shortly after going on market, Defendants began receiving large numbers of adverse
5 event reports (“AERs”) from health care providers reporting that the Cordis IVC filters were fracturing
6 post-implantation and that fractured pieces and/or the entire device was migrating to other areas of the
7 body, including the heart and lungs.

8 96. Defendants also received large numbers of AERs reporting that the TrapEase filters and
9 OptEase filters were found to have excessively tilted, perforated the IVC, or caused thrombosis or
10 stenosis of the vena cava post-implantation.

11 97. These failures were often associated with severe patient injuries such as:

- 12 a. Death;
- 13 b. Hemorrhage;
- 14 c. Cardiac/pericardial tamponade (pressure caused by a collection of blood in the area
15 around the heart);
- 16 d. Cardiac arrhythmia and other symptoms similar to myocardial infarction;
- 17 e. Severe and persistent pain;
- 18 f. Perforations of tissue, vessels and organs;
- 19 g. Chronic deep vein thrombosis;
- 20 h. Pulmonary embolism; and,
- 21 i. Compartment syndrome.

22 98. These failures and resulting injuries are attributable, in part, to the fact that the Cordis
23 IVC filter design was unable to withstand the normal anatomical and physiological loading cycles
24 exerted *in vivo*.

25 99. Recent medical studies have confirmed what Defendants have known or should have
26 known since shortly after the release of each of these filters – not only do Cordis IVC filters fail at
27 alarming rates, but they also fail at rates substantially higher than other available IVC filters. For
28 instance, a recent large medical study found that OptEase and TrapEase filters suffer fracture rates of

1 37.5% and 23.1% respectively, when left implanted a minimum of 46 months. Another recent study
2 found that the TrapEase filter had a 64% fracture rate when left in more than four years. Another study
3 found a statistically significant increased rate of caval thrombosis with the ObtEase filter compared to
4 Gunther Tulip and Recovery Filters.

5 100. As a minimum safety requirement, manufacturers must establish and maintain post-
6 market procedures to timely identify the cause of device failures and other quality problems and to take
7 adequate corrective action to prevent the recurrence of these problems.

8 101. Defendants failed to identify or acknowledge these device failures or determine their
9 causes.

10 102. Defendants failed to take timely and adequate remedial measures to correct known design
11 and manufacturing defects with the Cordis IVC filters.

12 103. Defendants also misrepresented and concealed the risks and benefits of the Cordis IVC
13 filters in the labeling and marketing distributed to the FDA, physicians and the public. For instance,
14 Defendants represented that their filters were safe and effective – more safe and effective than other
15 available IVC filters. However, there is no reliable evidence to support these claims and, to the
16 contrary, the Cordis IVC filters have been associated with a high rate of failure.

17 104. Defendants also represented that the design of these devices would eliminate the risk that
18 pieces of the devices could perforate the vena cava, that the devices could tilt, or that fractures could
19 occur and migrate throughout the body. The medical literature and AERs have proven these claims to be
20 false.

21 105. Defendants also marketed the OptEase filter as being “easy” to remove. However, it is
22 one of the most difficult filters to remove. Dr. William T. Kuo, an expert in the removal of IVC filters
23 and vascular surgery, has established an IVC Filter Clinic at Stanford University where his team
24 specializes in the removal of IVC filters that other vascular surgeons refuse to remove for fear of
25 rupturing the vena cava or other internal organs and causing great bodily harm or death to the patient.
26 Dr. Kuo wrote in *the Journal of Vascular Interventional Radiology* that the Cordis filters were the most
27 difficult to retrieve from patients, at least partially due to the design of the filters, which create greater
28 contact with the vein walls than competitors’ filters.

1 106. This is particularly concerning because having an IVC filter for a prolonged period of
2 time increases the risk of developing chronic deep venous thrombosis, PE, IVC occlusion, post-
3 thrombotic syndrome, filter fracture, and caval perforation with pain and organ injury. Many patients
4 with IVC filters are now routinely managed with lifelong anticoagulation solely to reduce the risk of
5 having the filter in place, subjecting patients to the risks and inconvenience of anticoagulation.

6 107. Defendants also failed to adequately disclose the risks of these filters, such as migration,
7 fracture, perforation, tilt, thrombosis, the prothrombotic nature of the devices, that the devices may not
8 be retrievable, or that these failures were known to be causing severe injuries and death or the rate at
9 which these events were occurring.

10 108. Cordis' labeling was additionally defective in that it directed physicians to implant the
11 OptEase filter upside down. When the OptEase filter was placed as directed by the labeling, the hooks
12 designed to ensure stability were facing in the wrong direction, rendering an already inadequate
13 anchoring system even further defective. As Cordis now explain in its labeling, implanting the device in
14 this fashion "can result in life threatening or serious injury including, but not limited to dissection, vessel
15 perforation, migration of the filter with secondary damage to cardiac structures, ineffective pulmonary
16 embolism prevention or death."

17 109. Cordis began a series of recalls on March 29, 2013 relating to its labeling, which
18 instructed physicians to implant the devices upside down. These recalls were not timely, nor did they
19 fully correct the defects in Defendants' labeling. Further, Defendants downplayed the danger patients
20 were exposed to and failed to take adequate steps to ensure patients actually received notice of the recall.

21 110. The FDA classified the initial recall as a Class I recall, which is the most serious type of
22 recall and involves situations in which the FDA has determined there is a reasonable probability that use
23 of these products will cause serious adverse health consequences or death.

24 111. Defendants have admitted that any patients implanted with one of these recalled units
25 should receive medical monitoring. Specifically, these patients should undergo imaging to ascertain
26 whether or not the device was properly deployed and, if not, be assessed for removal.

112. Given the unreasonably high failure and injury rates associated with Cordis IVC filters when left implanted long-term, Defendants should be required to pay for medical monitoring to assess the condition of these devices and whether or not retrieval should be undertaken.

113. On April 5, 2016, at the annual Society of Interventional Radiology in Vancouver, Canada, Dr. Steven Wang, an interventional radiologist from Palo Alto, California who is affiliated with Kaiser Permanente, presented the results of a retrospective study involving 96 patients in which he sought to understand the prevalence of long-term (greater than 46 months) complications of both permanent and retrievable IVC filters. The study looked at all inferior vena cava filters implanted in patients from January 2007 through December 2009 at multiple health care facilities across the United States. Dr. Wang then identified all patients who had imaging of the filter taken at four years or more after implantation. Of those patients (96), he then evaluated the imaging to determine whether the IVC filter had malfunctioned. After reviewing the data, the authors concluded that device complications at four or more years after implantation "are relatively common." They also found that the Cordis OptEase and TrapEase IVC filters suffered fracture rates of 37.5% and 23.1%, respectively.

ESTOPPEL FROM PLEADING STATUTES OF LIMITATIONS OR REPOSE

114. Plaintiffs incorporate by reference all prior allegations.

115. Plaintiffs are within the applicable statute of limitations for their claims because Plaintiffs or Plaintiffs' Decedent (and their healthcare professionals) did not discover, and could not reasonably discover, the defects and unreasonably dangerous condition of their Cordis IVC filters.

116. Plaintiffs' ignorance of the defective and unreasonably dangerous nature of the Cordis IVC filters, and the causal connection between these defects and each Plaintiff's or Plaintiffs' Decedent's injuries and damages, and/or death, is due in large part to Defendants' acts and omissions in fraudulently concealing information from the public and misrepresenting and/or downplaying the serious threat to public safety its products present.

117. In addition, Defendants are estopped from relying on any statutes of limitation or repose by virtue of unclean hands, acts of fraudulent concealment, affirmative misrepresentations and omissions.

118. Such conduct includes intentional concealment from Plaintiffs, Plaintiffs' Decedent, their health care professionals, and the general consuming public of material information that Cordis IVC filters had not been demonstrated to be safe or effective, and carried with them the risks and dangerous defects described herein.

119. Defendants had a duty to disclose the fact that Cordis IVC filters are not safe or effective, not as safe as other filters on the market, defective, and unreasonably dangerous, and that their implantation and use carried with it the serious risk of developing perforation, migration, tilting, and/or fracture, and/or other injuries referenced herein.

FIRST CAUSE OF ACTION

STRICT PRODUCTS LIABILITY – DESIGN DEFECT

(By All Plaintiffs, As to All Defendants)

120. Plaintiffs incorporate by reference all prior allegations.

121. At all relevant times, Defendants designed, tested, distributed, manufactured, advertised, sold, marketed and otherwise placed into the stream of commerce Cordis IVC filters – the TrapEase filters and the OptEase filters – for use by consumers, such as Plaintiffs, in the United States.

122. Defendants' Cordis IVC filters were expected to, and did, reach Defendants' intended consumers, handlers, and persons coming into contact with the product without substantial change in the condition in which they were researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Defendants.

123. The devices implanted in Plaintiffs (or their Decedent) were in an unreasonably dangerous condition at the time they left Defendants' control.

124. At all times relevant, Cordis IVC filters were manufactured, designed and labeled in an unsafe, defective, and inherently dangerous condition which was dangerous for use by the public in general and Plaintiffs in particular.

125. Defendants' Cordis IVC filters, as researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Defendants were defective in design and formulation and unreasonably dangerous in that when they left the hands of Defendants' manufacturers and/or suppliers, the foreseeable risks exceeded the alleged benefits associated with the

1 use of Cordis IVC filters, and the devices were more dangerous than the ordinary customer would
2 expect.

3 126. Physicians implanted Cordis IVC filters as instructed via the Instructions for Use and in a
4 foreseeable manner as normally intended, recommended, promoted, and marketed by Defendants.

5 127. Plaintiffs (or their Decedent) received and utilized Defendants' IVC filters in a
6 foreseeable manner as normally intended, recommended, promoted, and marketed by Defendants.

7 128. At the time Defendants placed their defective and unreasonably dangerous Cordis IVC
8 filters into the stream of commerce commercially, technologically, and scientifically feasible alternative
9 designs were attainable and available.

10 129. These alternative designs would have prevented the harm resulting in each Plaintiff's (or
11 their Decedent's) Injuries and Damages, and/or Death, without substantially impairing the reasonably
12 anticipated or intended function of Cordis IVC filters.

13 130. Neither Plaintiffs, Plaintiffs' Decedent, nor their health care providers could have, by the
14 exercise of reasonable care, discovered the defective condition or perceived the unreasonable dangers
15 with these devices prior to Plaintiffs' implantation with the Cordis IVC filters.

16 131. As a direct and proximate result of the defective and unreasonably dangerous condition
17 of Cordis IVC filters, Plaintiffs and Plaintiffs' Decedent suffered Injuries and Damages, and/or Death.

18 **SECOND CAUSE OF ACTION**

19 **STRICT PRODUCTS LIABILITY – INADEQUATE WARNING**

20 **(By All Plaintiffs, As to All Defendants)**

21 132. Plaintiffs incorporate by reference all prior allegations.

22 133. At all relevant times, Defendants engaged in the business of testing, developing,
23 designing, manufacturing, packaging, labeling, marketing and/or promoting, selling and/or distributing
24 Cordis IVC filters – the TrapEase filters and the OptEase filters – and through that conduct have
25 knowingly and intentionally placed Cordis IVC filters into the stream of commerce with full knowledge
26 that they reach consumers such as Plaintiffs (or their Decedent) who would become implanted with
27 them.
28

1 134. Defendants did, in fact, test, develop, design, manufacture, package, label, market and/or
2 promote, sell and/or distribute their Cordis IVC filters to Plaintiffs, Plaintiffs' Decedent, their
3 prescribing health care professionals, and the consuming public. Additionally, Defendants expected that
4 the Cordis IVC filters they were selling, distributing, supplying, manufacturing, and/or promoting to
5 reach, and did, in fact, reach, prescribing health care professionals and consumers, including Plaintiffs,
6 Plaintiffs' Decedent, and their prescribing health care professionals, without any substantial change in
7 the condition of the product from when it was initially distributed by Defendants.

8 135. The Cordis IVC filters had potential risks and side effects that were known or knowable
9 to Defendants by the use of scientific inquiry and information available before, at, and after the
10 manufacture, distribution, and sale of the Cordis IVC filters.

11 136. Defendants knew or should have known of the defective condition, characteristics, and
12 risks associated with Cordis IVC filters. These defective conditions included, but were not limited to:
13 (1) Cordis IVC filters posed a significant and higher risk of failure than other similar IVC filters
14 (fracture, migration, tilting, and perforation of the vena cava wall); (2) Cordis IVC filter failures result in
15 serious injuries and death; (3) certain conditions or post-implant procedures, such as morbid obesity or
16 open abdominal procedures, could affect the safety and integrity of Cordis IVC filters; (4) leaving
17 Cordis IVC filters in for a period longer than necessary to prevent immediate risk of pulmonary
18 embolism increases the risk for patients of failures and complications with the filter, such as the filter
19 becoming deeply embedded in the vena cava, making them difficult or impossible for removal.

20 137. Defendants placed into the stream of commerce for ultimate use by users like Plaintiffs,
21 Plaintiffs' Decedent, and their health care providers, Cordis IVC filters that were in an unreasonably
22 dangerous and defective condition due to warnings and instructions for use that were inadequate,
23 including, but not limited to Defendants' failure to:

- 24 a. Provide adequate instructions for how long in patients the filter should remain;
- 25 b. Highlight the importance of removing the filter;
- 26 c. Warn of the known risk of great bodily harm or death if the filter was not removed;
- 27 d. Highlight the known risk of great bodily harm or death in the event of occlusion of the
- 28 vein caused by the filter itself;

e. Warn of the risk of new DVT if the filter was left in too long; Warn of the risk of new pulmonary embolism, thrombosis, swelling, and pain in the lower extremities if the filter was left in too long; and

f. Warn of the risk of filter perforation, fracture, or migration.

138. Cordis IVC filters were in a defective and unsafe condition that was unreasonably and substantially dangerous to any user or consumer implanted with Cordis IVC filters, such as Plaintiffs or Plaintiffs' Decedent, when used in an intended or reasonably foreseeable way.

139. The warnings and directions Defendants provided with their Cordis IVC filters failed to adequately warn of the potential risks and side effects of Cordis IVC filters.

140. These risks were known or were reasonably scientifically knowable to Defendants, but not known or recognizable to ordinary consumers, such as Plaintiffs, Plaintiffs' Decedent, or their treating doctors.

141. Defendants' IVC filters were expected to and did reach Plaintiffs and Plaintiffs' Decedent without substantial change in their condition, labeling, or warnings as manufactured, distributed, and sold by Defendants.

142. Additionally, Plaintiffs, Southerland Plaintiffs' Decedent, and their physicians used Cordis IVC filters – the TrapEase filters or the OptEase filters – in the manner in which they were intended to be used, making such use reasonably foreseeable to Defendants.

143. As a direct and proximate result of Defendants' information defects, lack of sufficient instructions or warnings prior to, on, and after the date Plaintiffs and Plaintiffs' Decedent used Cordis IVC filters, Plaintiffs and Plaintiffs' Decedent suffered Injuries and Damages, and/or Death.

THIRD CAUSE OF ACTION

STRICT PRODUCTS LIABILITY – MANUFACTURING DEFECT

(By All Plaintiffs, As to All Defendants)

144. Plaintiffs incorporate by reference all prior allegations.

145. Prior to, on, and after the date the Cordis IVC filters – the TrapEase filter or the OptEase filter – were implanted in Plaintiffs and Plaintiffs' Decedent, Defendants designed, distributed, manufactured, sold, and marketed Cordis IVC filters for use in the United States, including California.

146. At all relevant times, Defendants designed, distributed, manufactured, marketed, and sold Cordis IVC filters that were unreasonably dangerous, unsafe, and defective in manufacture when they left Defendants' possession.

147. Upon information and belief, Cordis IVC filters contain a manufacturing defect, in that they differed from the manufacturer's design or specifications, or from other typical units of the same product line.

148. As a direct and proximate cause of Defendants' design, manufacture, marketing, and sale of Cordis IVC filters prior to, on, and after the date Plaintiffs and Plaintiffs' Decedent used the Cordis IVC filters, Plaintiffs and Plaintiffs' Decedent suffered Injuries and Damages, and/or Death.

FOURTH CAUSE OF ACTION

NEGLIGENCE

(By All Plaintiffs, As to All Defendants)

149. Plaintiffs incorporate by reference all prior allegations.

150. At the time of the design, distribution, manufacture, advertising, sale, and marketing of Cordis IVC filters – the TrapEase filters and the OptEase filters – and their implantation in Plaintiffs and Plaintiffs' Decedent, Defendants were aware that Cordis IVC filters were designed and manufactured in a manner presenting:

- a. An unreasonable risk of fracture of portions of the filters;
- b. An unreasonable risk of migration of the filters and/or portions of the filters;
- c. An unreasonable risk of filters tilting and/or perforating the vena cava wall; and
- d. Insufficient strength or structural integrity to withstand normal placement within the human body.

151. At the time of the design, distribution, manufacture, advertising, sale, and marketing of Cordis IVC filters, and their implantation in Plaintiffs and Plaintiffs' Decedent, Defendants were also aware that Cordis IVC filters:

- a. Would be used without inspection for defects;
- b. Would be used by patients with special medical conditions such as Plaintiffs and Plaintiffs' Decedent;

- c. Had previously caused serious bodily injury to its users with special medical conditions such as Plaintiffs and Plaintiffs' Decedent;
- d. Had no established efficacy;
- e. Were less safe and effective than the predicate IVC filters already available on market;
- f. Would be implanted in patients where the risk outweighed any benefit or utility of the filters;
- g. Contained instructions for use and warnings that were inadequate; and
- h. Were prothombotic.

152. At the time of manufacture and sale of the TrapEase and OptEase filters, including the ones implanted in Plaintiffs and Plaintiffs' Decedent, Defendants knew or should have known that using the TrapEase and OptEase filters as intended or in a reasonably foreseeable manner created a significant risk of patients suffering severe health side effects including, but not limited to: hemorrhage; cardiac/pericardial tamponade; cardiac arrhythmia and other symptoms similar to myocardial infarction; perforations of tissue, vessels and organs; chronic deep vein thrombosis; pulmonary embolism; thrombosis; compartment syndrome; and other severe personal injuries and diseases, which are permanent in nature, including, but not limited to, death, physical pain and mental anguish, scarring and disfigurement, diminished enjoyment of life, continued medical care and treatment due to chronic injuries/illness proximately caused by the device; and the continued risk of requiring additional medical and surgical procedures including general anesthesia, with attendant risk of life threatening complications.

153. Defendants had a duty to exercise due care and avoid unreasonable risk of harm to others in the design of Cordis IVC filters.

154. Defendants breached these duties by, among other things:

- a. Designing and distributing a product in which it knew or should have known that the likelihood and severity of potential harm from the product exceeded the burden of taking safety measures to reduce or avoid harm;

- b. Designing and distributing a product which it knew or should have known that the likelihood and severity of potential harm from the product exceeded the likelihood of potential harm from other IVC filters available for the same purpose;
- c. Failing to perform reasonable pre- and post-market testing of Cordis IVC filters to determine whether or not the products were safe for their intended use;
- d. Failing to use reasonable and prudent care in the design, research, manufacture, and development of Cordis IVC filters so as to avoid the risk of serious harm associated with the use of Cordis IVC filters;
- e. Advertising, marketing, promoting, and selling Cordis IVC filters for uses other than as approved and indicated in the products' labels;
- f. Failing to use reasonable care to warn or instruct, including pre and post-sale, Plaintiffs, Plaintiffs' Decedent, their prescribing physicians, or the general health care community about the TrapEase and OptEase filters' substantially dangerous condition or about facts making the products likely to be dangerous;
- g. Advertising, marketing and recommending the use of the TrapEase and OptEase filters, while concealing and failing to disclose or warn of the dangers known by Defendants to be connected with and inherent in the use of these filter systems;
- h. Representing that the TrapEase and OptEase filters were safe for their intended use when, in fact, Defendants knew and should have known the products were not safe for their intended uses;
- i. Continuing to manufacture and sell the TrapEase and OptEase filters with the knowledge that said products were dangerous and not reasonably safe, and failing to comply with good manufacturing regulations;
- j. Failing to establish an adequate quality assurance program used in the manufacturing of Cordis IVC filters; and
- k. Failing to perform adequate evaluation and testing of Cordis IVC filters when such evaluation and testing would have revealed the propensity of Cordis IVC filters to cause injuries similar to those that Plaintiffs and Plaintiffs' Decedent suffered.

1 155. At all relevant times, Defendants had a duty to exercise due care in the manufacturing of
2 Cordis IVC filters.

3 156. Defendants breached this duty by, among other things:

- 4 a. Failing to adopt manufacturing processes that would reduce the foreseeable risk of
5 product failure;
- 6 b. Failing to use reasonable care in manufacturing the product and by producing a product
7 that differed from their design or specifications or from other typical units from the same
8 production line;
- 9 c. Failing to use reasonable and prudent care in the design, research, manufacture, and
10 development of Cordis IVC filters and their manufacturing process so as to avoid the risk
11 of serious harm associated with the use of Cordis IVC filters; and
- 12 d. Failing to establish an adequate quality assurance program used in the manufacturing of
13 their IVC filters.

14 157. At this time, all Cordis IVC filters – the TrapEase filters and the OptEase filters – are
15 misbranded and adulterated by virtue of them failing to be the substantial equivalent of predicate IVC
16 filter devices, making them subject to corrective action, including recall, in the interest of patient safety.

17 158. Prior to, on, and after the date of Plaintiffs' and Plaintiffs' Decedent's implantation with a
18 Cordis IVC filter, and at all relevant times, Defendants knew or reasonably should have known that
19 Cordis IVC filters and their warnings were defective and dangerous or were likely to be dangerous when
20 used in a reasonably foreseeable manner.

21 159. Prior to, on, and after the date of Plaintiffs' and Plaintiffs' Decedent's implantation with a
22 Cordis IVC filter and at all relevant times thereafter, Defendants became aware that the defects of
23 Cordis IVC filters resulted in Cordis IVC filters causing injuries similar to those Plaintiffs and Plaintiffs'
24 Decedent suffered.

25 160. Reasonable manufacturers and distributors under the same or similar circumstances
26 would have recalled or retrofitted Cordis IVC filters, and would thereby have avoided and prevented
27 harm to many patients, including Plaintiffs and Plaintiffs' Decedent.
28

1 161. In light of this information and Defendants' knowledge described above, Defendants had
2 a duty to recall and/or retrofit Cordis IVC filters.

3 162. Defendants breached its duty to recall and/or retrofit Cordis IVC filters.

4 163. At all relevant times, Defendants knew or should have known that Cordis IVC filters
5 were defective and dangerous or were likely to be dangerous when used in a reasonably foreseeable
6 manner.

7 164. Such danger included the propensity of Cordis IVC filters to cause injuries similar to
8 those suffered by Plaintiffs and Plaintiffs' Decedent.

9 165. At all relevant times, Defendants also knew or reasonably should have known that the
10 users of Cordis IVC filters, including Plaintiffs and their health care providers, would not realize or
11 discover on their own the dangers presented by Cordis IVC filters.

12 166. Reasonable manufacturers and reasonable distributors, under the same or similar
13 circumstances as those of Defendants prior to, on, and after the date of each Plaintiff's and Plaintiffs'
14 Decedent's use of a Cordis IVC filter, would have warned of the dangers presented by Cordis IVC
15 filters, or instructed on the safe use of Cordis IVC filters.

16 167. Prior to, on, and after the date of each Plaintiff's and Plaintiffs' Decedent's use of the
17 IVC filter, Defendants had a duty to adequately warn of the dangers presented by Cordis IVC filters
18 and/or instruct on the safe use of Cordis IVC filters.

19 168. Defendants breached these duties by failing to provide adequate warnings to Plaintiffs
20 and Plaintiffs' Decedent communicating the information and dangers described above and/or providing
21 instruction for safe use of Cordis IVC filters.

22 169. As a direct and proximate result of Defendants' negligent conduct described herein,
23 Plaintiffs and Plaintiffs' Decedent suffered Injuries and Damages, and/or Death.

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FIFTH CAUSE OF ACTION
NEGLIGENT MISREPRESENTATION

(By All Plaintiffs, As to All Defendants)

170. Plaintiffs incorporate by reference all prior allegations.

171. Prior to, on, and after the dates during which Plaintiffs and Plaintiffs' Decedent were implanted with the Cordis IVC filters – the TrapEase filters and the OptEase filters – Defendants negligently and carelessly represented to Plaintiffs, Plaintiffs' Decedent, their treating physicians, and the general public that certain material facts were true. The representations include, *inter alia*, the following:

- a. That the Cordis IVC filters were safe, fit, and effective for use;
- b. That the design of the Cordis IVC filters eliminated the risk that pieces of the device could perforate the vena cava, that the devices could tilt, or that fractures could occur and migrate throughout the body;
- c. That the Cordis IVC filters were safe and more effective than other available IVC filters.
- d. That the OptEase fiber was “easy” to remove; and,

172. Prior to, on, and after the dates during which Plaintiffs, Plaintiffs' Decedent, and their physicians purchased and used the device, said representations were untrue, and there was no reasonable ground for Defendants to believe said representations were true when Defendants made said representations.

173. Prior to, on, and after the dates during which Plaintiffs, Plaintiffs' Decedent, and their physicians purchased and used the device, Defendants intended that Plaintiffs, Plaintiffs' Decedent, their physicians, and the general public would rely on said representations, which did in fact occur.

174. Defendants owed a duty in all of its undertakings, including the dissemination of information concerning its IVC filters, to exercise reasonable care to ensure that it did not in those undertakings create unreasonable risks of personal injury to others.

175. Defendants disseminated to health care professionals and consumers through published labels, labeling, marketing materials, and otherwise information concerning the properties and effects of

1 Cordis IVC filters with the intention that health care professionals and consumers would rely upon that
2 information in their decisions concerning whether to prescribe and use Defendants' IVC filters.

3 176. Defendants, as medical device designers, manufacturers, sellers, promoters and/or
4 distributors, knew or should reasonably have known that health care professionals and consumers, in
5 weighing the potential benefits and potential risks of prescribing or using Cordis IVC filters, would rely
6 upon information disseminated and marketed by Defendants to them regarding the Cordis IVC filters.

7 177. Defendants failed to exercise reasonable care to ensure that the information they
8 disseminated to health care professionals and consumers concerning the properties and effects of Cordis
9 IVC filters was accurate, complete, and not misleading and, as a result, disseminated information to
10 health care professionals and consumers that was negligently and materially inaccurate, misleading,
11 false, and unreasonably dangerous to consumers such as Plaintiffs and Plaintiffs' Decedent.

12 178. Defendants, as designers, manufacturers, sellers, promoters, and/or distributors, also
13 knew or reasonably should have known that patients receiving Cordis IVC filters as recommended by
14 health care professionals in reliance upon information disseminated by Defendants as the
15 manufacturer/distributor of Defendants' IVC filters would be placed in peril of developing the serious,
16 life-threatening, and life-long injuries including, but not limited to, tilting, migration, perforation,
17 fracture, lack of efficacy, and increased risk of the development of blood clots, if the information
18 disseminated and relied upon was materially inaccurate, misleading, or otherwise false.

19 179. Defendants had a duty to promptly correct material misstatements Defendants' knew
20 others were relying upon in making healthcare decisions.

21 180. Defendants failed in each of these duties by misrepresenting to Plaintiffs, Plaintiffs'
22 Decedent, and the medical community the safety and efficacy of Cordis IVC filters and failing to correct
23 known misstatements and misrepresentations.

24 181. As a direct and proximate result of Defendants' negligent misrepresentations, Plaintiffs
25 and Plaintiffs' Decedent suffered Injuries and Damages, and/or Death.

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SIXTH CAUSE OF ACTION

FRAUDULENT MISREPRESENTATION

(By All Plaintiffs, As to All Defendants)

182. Plaintiffs incorporate by reference all prior allegations.

183. At all times relevant to this cause, and as detailed above, Defendants intentionally provided Plaintiffs, Plaintiffs' Decedent, their physicians, the medical community, and the public at large with false or inaccurate information. Defendants also omitted material information concerning Cordis IVC filters (the TrapEase filters and the OptEase filters), including, but not limited to, misrepresentations regarding the following topics:

- a. The safety of the Cordis IVC filters;
- b. The efficacy of the Cordis IVC filters;
- c. The rate of failure of the Cordis IVC filters;
- d. The pre-market testing of the Cordis IVC filters;
- e. The approved uses of the Cordis IVC filters; and
- f. The ability to retrieve the device at any time over a person's life.

184. The information Defendants distributed to the public, the medical community, Plaintiffs and Plaintiffs' Decedent was in the form of reports, press releases, advertising campaigns, labeling materials, print advertisements, commercial media containing material representations, and instructions for use, as well as through their officers, directors, agents, and representatives.

185. These materials contained false and misleading material representations, which included: that Cordis IVC filters were safe and fit when used for their intended purpose or in a reasonably foreseeable manner; that they did not pose dangerous health risks in excess of those associated with the use of other similar IVC filters; that any and all side effects were accurately reflected in the warnings; and that they were adequately tested to withstand normal placement within the human body.

186. Defendants made the foregoing misrepresentations knowing that they were false or without reasonable basis. These materials included instructions for use and a warning document that was included in the package of the Cordis IVC filters that were implanted in Plaintiffs and Plaintiffs' Decedent.

1 187. Defendants' intent and purpose in making these misrepresentations was to deceive and
2 defraud the public and the medical community, including Plaintiffs' and Plaintiffs' Decedent's health
3 care providers; to gain the confidence of the public and the medical community, including Plaintiffs' and
4 Plaintiffs' Decedent's health care providers; to falsely assure the public and the medical community of
5 the quality of Cordis IVC filters and their fitness for use; and to induce the public and the medical
6 community, including Plaintiffs' and Plaintiffs' Decedent's health care providers to request,
7 recommend, prescribe, implant, purchase, and continue to use Cordis IVC filters, all in reliance on
8 Defendants' misrepresentations.

9 188. The foregoing representations and omissions by Defendants were false.

10 189. Defendants' IVC filters are not safe, fit, and effective for human use in their intended and
11 reasonably foreseeable manner.

12 190. Further, the use of Cordis IVC filters is hazardous to the users' health, and Cordis IVC
13 filters have a serious propensity to cause users to suffer serious injuries, including without limitation the
14 injuries and/or death Plaintiffs and Plaintiffs' Decedent suffered.

15 191. Finally, Defendants' IVC filters have a statistically significant higher rate of failure and
16 injury than do other comparable IVC filters.

17 192. In reliance upon the false and negligent misrepresentations and omissions made by
18 Defendants, Plaintiffs and their health care providers were induced to, and did use Cordis IVC filters,
19 thereby causing Plaintiffs and Plaintiffs' Decedent to sustain severe and permanent personal injuries,
20 and/or death.

21 193. Defendants knew and had reason to know that Plaintiffs, Plaintiffs' Decedent, their health
22 care providers, and the general medical community did not have the ability to determine the true facts
23 intentionally and/or negligently concealed and misrepresented by Defendants, and would not have
24 prescribed and implanted Cordis IVC filters if the true facts regarding Defendants' IVC filters had not
25 been concealed and misrepresented by Defendants.

26 194. Defendants had sole access to material facts concerning the defective nature of the
27 products and their propensities to cause serious and dangerous side effects in the form of dangerous
28 injuries and damages to persons who were implanted with Cordis IVC filters.

195. At the time Defendants failed to disclose and intentionally misrepresented the foregoing facts, and at the time Plaintiffs used Cordis IVC filters, Plaintiffs, Plaintiffs' Decedent, and their health care providers were unaware of Defendants' misrepresentations and omissions.

196. As a direct and proximate result of Defendants' fraudulent misrepresentations, Plaintiffs and Plaintiffs' Decedent suffered Injuries and Damages, and/or Death.

SEVENTH CAUSE OF ACTION

FRAUDULENT CONCEALMENT

(By All Plaintiffs, As to All Defendants)

197. Plaintiffs incorporate by reference all prior allegations.

198. In marketing and selling Cordis IVC filters (the TrapEase filters and the OptEase filters), Defendants concealed material facts from Plaintiffs, Plaintiffs' Decedent, and their healthcare providers.

199. These concealed material facts include, but are not limited to:

- a. Cordis IVC filters were unsafe and not fit when used for their intended purpose or in a reasonably foreseeable manner;
- b. Cordis IVC filters posed dangerous health risks in excess of those associated with the use of other similar IVC filters;
- c. That there were additional side effects related to implantation and use of Cordis IVC filters that were not accurately and completely reflected in the warnings associated with Cordis IVC filters; and
- d. That Cordis IVC filters were not adequately tested to withstand normal placement within the human body.

200. Plaintiffs, Plaintiffs' Decedent, and their health care providers were not aware of these and other facts concealed by Defendants.

201. In concealing these and other facts, Defendants intended to deceive Plaintiffs, Plaintiffs' Decedent, and their health care providers.

202. Plaintiffs, Plaintiffs' Decedent, and their health care providers were ignorant of and could not reasonably discover the facts Defendants fraudulently concealed and reasonably and justifiably relied on Defendants' representations concerning the supposed safety and efficacy of Cordis IVC filters.

203. As a direct and proximate result of Defendants' fraudulent concealment of material facts, Plaintiffs and Plaintiffs' Decedent suffered Injuries and Damages, and/or Death.

EIGHTH CAUSE OF ACTION

BREACH OF EXPRESS WARRANTY

(By All Plaintiffs, As to All Defendants)

204. Plaintiffs incorporate by reference all prior allegations.

205. Plaintiffs and Plaintiffs' Decedent, through their medical providers, purchased a Cordis IVC filter from Defendants.

206. At all relevant times, Defendants were merchants of goods of the kind including medical devices and vena cava filters (i.e., Cordis IVC filters).

207. At the time and place of sale, distribution, and supply of Cordis IVC filters to Plaintiffs and Plaintiffs' Decedent (and to other consumer and the medical community), Defendants expressly represented and warranted that Cordis IVC filters were safe; that they were well-tolerated, efficacious, fit for their intended purpose, and of marketable quality; that they did not produce any unwarned-of dangerous side effects; and that they was adequately tested.

208. At the time of Plaintiffs' and Plaintiffs' Decedent's purchase from Defendants, Cordis IVC filters were not in a merchantable condition, and Defendants breached its expressed warranties, in that Cordis IVC filters, among other things:

- a. Were designed in such a manner so as to be prone to an unreasonably high incidence of fracture, perforation of vessels and organs, and/or migration;
- b. Were designed in such a manner so as to result in a unreasonably high incidence of injury to the vessels and organs of its purchaser;
- c. Were manufactured in such a manner that the exterior surface of the filter was inadequately, improperly, and inappropriately constituted, causing the device to weaken and fail;
- d. Were unable to be removed at any time during a person's life;
- e. Were not efficacious in the prevention of pulmonary emboli;
- f. Carried a risk of use outweighed any benefit; and

g. Were not self-centering.

209. As a direct and proximate result of Defendants' breach of express warranty, Plaintiffs and Plaintiffs' Decedent suffered Injuries and Damages, and/or Death.

NINTH CAUSE OF ACTION

BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY

(By All Plaintiffs, As to All Defendants)

210. Plaintiffs incorporate by reference all prior allegations.

211. Defendants impliedly warranted that Cordis IVC filters were of merchantable quality and safe and fit for the use for which Defendants intended them, and Plaintiffs and Plaintiffs' Decedent, in fact, used them.

212. Defendants breached its implied warranties by, among other things:

- a. Failing to provide adequate instruction that a manufacturer exercising reasonable care would have provided concerning the likelihood that Cordis IVC filters would cause harm;
- b. Manufacturing and/or selling Cordis IVC filters when those filters did not conform to representations made by Defendants when they left Defendants' control;
- c. Manufacturing and/or selling Cordis IVC filters that were more dangerous than an ordinary consumer would expect when used in an intended or reasonably foreseeable manner;
- d. Manufacturing and/or selling Cordis IVC filters that carried foreseeable risks associated with the Cordis IVC filter design or formulation which exceeded the benefits associated with that design;
- e. Manufacturing and/or selling Cordis IVC filters when they deviated in a material way from the design specifications, formulas, or performance standards or from otherwise identical units manufactured to the same design specifications, formulas, or performance standards; and
- f. Impliedly representing that its filters would be effective in the prevention of pulmonary emboli.

1 213. At the time Plaintiffs, Plaintiffs' Decedent, and their physicians purchased and used the
2 devices, the products were not in a merchantable condition in that:

- 3 a. They offered no benefit to patient outcomes,
- 4 b. They suffered an unreasonably high failure and injury rates,
- 5 c. The surface of the devices were manufactured and designed in such a way that they were
6 distributed with surface damage that substantially increased the risk of fracture, and
- 7 d. They were prothrombotic;

8 214. As a direct and proximate result of Defendants' breach of its implied warranty, Plaintiffs
9 and Plaintiffs' Decedent suffered Injuries and Damages, and/or Death.

10 **TENTH CAUSE OF ACTION**

11 **LOSS OF CONSORTIUM**

12 **(By Plaintiffs LUPE BROWN, KIMBERLY BURKHART, MELANIE RICHARD, and LAURA**
13 **MAGUIRE ("LOC Plaintiffs"), As to All Defendants)**

14 215. LOC Plaintiffs incorporate by reference all prior allegations

15 216. As a proximate result of the personal injuries suffered by Plaintiffs BENITO BROWN,
16 TRAVIS BURKHART, BILLY RICHARD and SEAN MAGUIRE, as described in this Complaint,
17 LOC Plaintiffs have been deprived of the benefits of their marriage including love, affection, society,
18 and consortium, and other spousal duties and actions. LOC Plaintiffs were provided with all of the
19 benefits of a marriage between husband and wife, prior to the use of a Cordis IVC filter by their
20 respective Plaintiff spouses and the resulting injuries described herein.

21 217. LOC Plaintiffs have also suffered the permanent loss of their respective Plaintiff spouses'
22 daily and regular contribution to the household duties and services, which each provides to the
23 household as husband and wife.

24 218. LOC Plaintiffs have also incurred the costs and expenses related to the medical care,
25 treatment, medications, and hospitalization to which their respective Plaintiff spouses were subjected for
26 the physical injuries they suffered as a proximate result of their use of a Cordis IVC filter. LOC
27 Plaintiffs will continue to incur the future costs and expenses related to the care, treatment, medications,
28 and hospitalization of their respective Plaintiff spouses due to their injuries.

219. LOC Plaintiffs have suffered loss of consortium, as described herein, including the past, present, and future loss of their spouses' companionship, services, society, and the ability of their spouses to provide LOC Plaintiffs with the benefits of marriage, including inter alia, loss of contribution to household income and loss of household services, all of which has resulted in pain, suffering, and mental and emotional distress and worry for LOC Plaintiffs.

ELEVENTH CAUSE OF ACTION

WRONGFUL DEATH

(By Plaintiffs GILDA SOUTHERLAND, VINCENT SOUTHERLAND and CHAD SOUTHERLAND ("WD Plaintiffs"), As to All Defendants)

220. WD Plaintiffs incorporates by reference all prior allegations.

221. WD Plaintiffs' Decedent DUKE SOUTHERLAND was prescribed, supplied with, received, took, used and was implanted with a Cordis IVC filter product as tested, studied, researched, evaluated, endorsed, designed, formulated, compounded, manufactured, produced, processed, assembled, inspected, distributed, marketed, labeled, promoted, packaged, advertised for sale, prescribed, sold or otherwise placed in the stream of interstate commerce by Defendants.

222. The injuries and damages of WD Plaintiffs' Decedent were caused by the wrongful acts, omissions, and fraudulent misrepresentations of Defendants, as described herein.

223. As a result of the conduct of Defendants and the use of Defendants' IVC filters, WD Plaintiffs' Decedent, DUKE SOUTHERLAND, suffered catastrophic and ultimately fatal injuries.

224. As a result of the death of WD Plaintiffs' Decedent, WD Plaintiffs were deprived of love, companionship, comfort, affection, society, solace and moral support of their husband and father.

225. WD Plaintiffs, as the surviving and legal heirs to DUKE SOUTHERLAND, are entitled to recover economic and non-economic damages against all Defendants for wrongful death directly and legally caused by the defects in Defendants' IVC filters, and the negligent conduct, acts, errors, omissions and intentional and negligent misrepresentations of Defendants, and each of them, as alleged throughout this Complaint for Damages.

///

PUNITIVE DAMAGES ALLEGATIONS

(By All Plaintiffs, As to All Defendants)

226. Plaintiffs incorporate by reference all prior allegations.

227. At all times material hereto, Defendants knew or should have known that Cordis IVC filters were unreasonably dangerous with respect to the risk of tilt, fracture, migration and/or perforation.

228. At all times material hereto, Defendants attempted to misrepresent and did knowingly misrepresent facts concerning the safety of Cordis IVC filters.

229. Defendants' misrepresentations included knowingly withholding material information from the medical community and the public, including Plaintiffs' and Plaintiffs' Decedent's physicians, concerning the safety of its Cordis IVC filters. Data establishes that the failure rates of the TrapEase and OptEase filters are and were much higher than what Defendants have in the past and currently continue to publish to the medical community and members of the public.

230. Defendants' conduct, alleged throughout this Complaint, was willful, wanton, and undertaken with a conscious indifference and disregard to the consequences that consumers of their products faced, including Plaintiffs and Plaintiffs' Decedent. Defendants had actual knowledge of the dangers presented by Cordis IVC filters, yet consciously failed to act reasonably to inform or warn Plaintiffs, Plaintiffs' Decedent, their physicians, or the public at large of these dangers. Defendants consciously failed to establish and maintain an adequate quality and post-market surveillance system.

231. At all times material hereto, Defendants knew and recklessly disregarded the fact that Cordis IVC filters have an unreasonably high rate of tilt, fracture, migration, and/or perforation.

232. Notwithstanding the foregoing, Defendants continued to market Cordis IVC filters aggressively to consumers, including Plaintiffs and Plaintiffs' Decedent, without disclosing the aforesaid side effects.

233. Defendants knew of their Cordis IVC filters' lack of warnings regarding the risk of fracture, migration, and/or perforation, but intentionally concealed and/or recklessly failed to disclose that risk and continued to market, distribute, and sell its filters without said warnings so as to maximize

1 sales and profits at the expense of the health and safety of the public, including Plaintiffs and Plaintiffs'
2 Decedent, in conscious disregard of the foreseeable harm caused by Cordis IVC filters.

3 234. Defendants' intentional and/or reckless failure to disclose information deprived
4 Plaintiffs' and Plaintiffs' Decedent's physicians of necessary information to enable them to weigh the
5 true risks of using Cordis IVC filters against its benefits.

6 235. Defendants' conduct is reprehensible, evidencing an evil hand guided by an evil mind
7 and was undertaken for pecuniary gain in reckless and conscious disregard for the substantial risk of
8 death and physical injury to consumers, including Plaintiffs and Plaintiffs' Decedent.

9 236. Such conduct justifies an award of punitive or exemplary damages in an amount
10 sufficient to punish Defendants' conduct and deter like conduct by Defendants and other similarly
11 situated persons and entities in the future.

12 **PRAYER FOR DAMAGES**

13 WHEREFORE, Plaintiffs demand judgment against Defendants for:

14 a. General (non-economic) damages, including, without limitation, past and future pain and
15 suffering; past and future emotional distress; past and future loss of enjoyment of life; and other
16 consequential damages as allowed by law;

17 b. Special (economic) damages, including, without limitation, past and future medical
18 expenses; past and future lost wages and loss of earning capacity; and other consequential damages as
19 allowed by law;

20 c. Punitive damages in an amount sufficient to punish Defendants and deter similar conduct
21 in the future;

22 d. Disgorgement of profits;

23 e. Restitution;

24 f. Statutory damages, where authorized;

25 g. Costs of suit;

26 h. Reasonable attorneys' fees, where authorized;

27 i. Prejudgment interest as allowed by law;

1 j. Post-judgment interest at the highest applicable statutory or common law rate from the
2 date of judgment until satisfaction of judgment;

3 k. Such other additional and further relief as Plaintiffs may be entitled to in law or in equity.

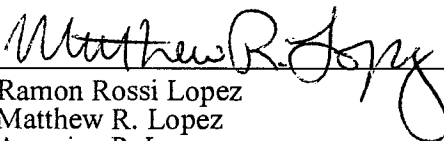
4 **DEMAND FOR JURY TRIAL**

5 Plaintiffs hereby demand a trial by jury on all triable issues.

6
7 Dated: May 19, 2016

Respectfully submitted,

8 LOPEZ McHUGH LLP

9
10 By: 
11 Ramon Rossi Lopez
12 Matthew R. Lopez
13 Amorina P. Lopez

14 -And-

15 David P. Matthews (for *pro hac vice* consideration)
16 MATTHEWS & ASSOCIATES

17 -And-

18 Richard A. Freese (for *pro hac vice* consideration)
19 Tim K. Goss (for *pro hac vice* consideration)
20 FREESE & GOSS, PLLC

21 Attorneys for Plaintiffs
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ORIGINAL

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Attorney for Plaintiffs

FILED
 ALAMEDA COUNTY

MAY 20 2016

CLERK OF THE SUPERIOR COURT
 By Deputy

**SUPERIOR COURT OF CALIFORNIA, COUNTY OF ALAMEDA
 RENE C. DAVIDSON ALAMEDA COUNTY COURTHOUSE**

WANDA HOLDEN; TAMBRA SHIFFLET)
 LANORA BARRETT; MARCELLO)
 COOGAN; WILLIE P. COOK; JOHN)
 DAWSON; FREDDERICK HALL;)
 THOMAS HUSTED; SABRINA JACKSON;)
 JUAN NELLE JEANES; STEVEN)
 JOHNSON; KENDALL MCCOY)
 MICHELLE MONTOYA; KAREN NEAL)
 DEBRA PORTER; TOMMY PORTER)
 CARL REXING; HAZEL WEBB; CHERLY)
 WRIGHT; EVELYN WRIGHT; and)
 THOMAS YAUDAS,

Plaintiff(s),

vs.

CORDIS CORPORATION, a
 corporation, CONFLUENT
 MEDICAL TECHNOLOGIES, INC.,
 a corporation, and DOES 1 through
 100, inclusive,

Defendant(s).

Case No.:

RG16816600

**COMPLAINT FOR DAMAGES
 AND
 DEMAND FOR JURY TRIAL**

- (1) Strict Products Liability - Design Defect
- (2) Strict Products Liability - Inadequate Warning
- (3) Strict Products Liability - Manufacturing Defect
- (4) Negligence
- (5) Negligent Misrepresentation
- (6) Fraud - Misrepresentation
- (7) Fraudulent Concealment
- (8) Express Warranty
- (9) Breach of Implied Warranty Of Merchantability
- (10) Gross Negligence/ Punitive Damages

Plaintiffs WANDA HOLDEN, TAMBRA SHIFFLET, LANORA BARRETT, MARCELLO
 COOGAN, WILLIE P. COOK, JOHN DAWSON, FREDDERICK HALL, THOMAS HUSTED,
 SABRINA JACKSON, JUAN NELLE JEANES, STEVEN JOHNSON, KENDALL MCCOY,
 MICHELLE MONTOYA, KAREN NEAL, DEBRA PORTER, TOMMY PORTER, CARL
 REXING, HAZEL WEBB; CHERLY WRIGHT, EVELYN WRIGHT and THOMAS YAUDAS
 hereby sue defendants CORDIS CORPORATION, CONFLUENT MEDICAL TECHNOLOGIES,
 INC., and DOES 1 through 100 and allege as follows:

By Fax

1 **PARTIES**

2 1. Plaintiff Wanda Holden (hereinafter "Plaintiff Holden") is a citizen and resident of
3 the State of California, Los Angeles County. Plaintiff underwent placement of a TrapEase™
4 Permanent Vena Cava Filter (referred to as "TrapEase filter," "device" or "product" hereinafter) at
5 Brotman Medical Center located in Culver City, California. The extent of the device failure has not
6 been fully documented by Plaintiff's treating medical provider(s). As a result of the malfunction,
7 Plaintiff has or may suffer life-threatening injuries and damages and require extensive medical care
8 and treatment. Plaintiff has or may suffer and will continue to suffer significant medical expenses,
9 extreme pain and suffering, loss of enjoyment of life, disability, and other losses.

10 2. Plaintiff Tambra Shifflet (hereinafter "Plaintiff Shifflet") is a citizen and resident of
11 the State of Ohio, Athens County. Plaintiff underwent placement of a TrapEase™ Permanent Vena
12 Cava Filter (referred to as "TrapEase filter," "device" or "product" hereinafter) at Holzer Medical
13 Center located in Gallipolis, Ohio. The extent of the device failure has not been fully documented
14 by Plaintiff's treating medical provider(s). As a result of the malfunction, Plaintiff has or may suffer
15 life-threatening injuries and damages and require extensive medical care and treatment. Plaintiff
16 has or may suffer and will continue to suffer significant medical expenses, extreme pain and
17 suffering, loss of enjoyment of life, disability, and other losses.

18 3. Plaintiff LaNora Barrett (hereinafter "Plaintiff Barrett") is a citizen and resident of
19 the State of Florida, Polk County. Plaintiff underwent placement of a TrapEase™ Permanent Vena
20 Cava Filter (referred to as "TrapEase filter," "device" or "product" hereinafter) at Heart of Florida
21 Regional Medical Center located in Davenport, Florida. The extent of the device failure has not
22 been fully documented by Plaintiff's treating medical provider(s). As a result of the malfunction,
23 Plaintiff has or may suffer life-threatening injuries and damages and require extensive medical care
24 and treatment. Plaintiff has or may suffer and will continue to suffer significant medical expenses,
25 extreme pain and suffering, loss of enjoyment of life, disability, and other losses.

26 4. Plaintiff Marcelo Coogan (hereinafter "Plaintiff Coogan") is a citizen and resident of
27 the State of Texas, Harris County. Plaintiff underwent placement of an OptEase™ Retrievable Vena
28 Cava Filter (referred to as "OptEase filter," "device" or "product" hereinafter) at Memorial Herman

1 Hospital located in Houston, TX. The device, *inter alia*, caused thrombosis of the vena cava and
2 filter. As a result of the malfunction, Plaintiff has suffered life-threatening injuries and damages and
3 require extensive medical care and treatment. Plaintiff has suffered and will continue to suffer
4 significant medical expenses, extreme pain and suffering, loss of enjoyment of life, disability, and
5 other losses.

6 5. Plaintiff Willie Cook (hereinafter "Plaintiff Cook") is a citizen and resident of the
7 State of Texas, Hill County. Plaintiff underwent placement of an OptEase™ Retrieable Vena Cava
8 Filter (referred to as "OptEase filter," "device" or "product" hereinafter) at Plaza Medical center
9 located in Irving, Texas. The extent of the device failure has not been fully documented by
10 Plaintiff's treating medical provider(s). As a result of the malfunction, Plaintiff has or may suffer
11 life-threatening injuries and damages and require extensive medical care and treatment. Plaintiff
12 has or may suffer and will continue to suffer significant medical expenses, extreme pain and
13 suffering, loss of enjoyment of life, disability, and other losses.

14 6. Plaintiff John Dawson (hereinafter "Plaintiff Dawson") is a citizen and resident of
15 the State of Louisiana, Bossier County. Plaintiff underwent placement of an OptEase™ Retrieable
16 Vena Cava Filter (referred to as "OptEase filter," "device" or "product" hereinafter) at Willis-
17 Knighton Health System located in Bossier City, Louisiana. The extent of the device failure has not
18 been fully documented by Plaintiff's treating medical provider(s). As a result of the malfunction,
19 Plaintiff has or may suffer life-threatening injuries and damages and require extensive medical care
20 and treatment. Plaintiff has or may suffer and will continue to suffer significant medical expenses,
21 extreme pain and suffering, loss of enjoyment of life, disability, and other losses.

22 7. Plaintiff Frederick Hall (hereinafter "Plaintiff Hall") is a citizen and resident of the
23 State of Pennsylvania, Harrisburg County. Plaintiff underwent placement of a TrapEase™
24 Permanent Vena Cava Filter (referred to as "TrapEase filter," "device" or "product" hereinafter) at
25 Pinnacle Health/Harrisburg Hospital located in Harrisburg, Pennsylvania. The extent of the device
26 failure has not been fully documented by Plaintiff's treating medical provider(s). As a result of the
27 malfunction, Plaintiff has or may suffer life-threatening injuries and damages and require extensive
28

1 medical care and treatment. Plaintiff has or may suffer and will continue to suffer significant
2 medical expenses, extreme pain and suffering, loss of enjoyment of life, disability, and other losses.

3 8. Plaintiff Thomas Husted (hereinafter "Plaintiff Husted") is a citizen and resident of
4 the State of South Carolina, Spartanburg County. Plaintiff underwent placement of an OptEase™
5 Retrieval Vena Cava Filter (referred to as "OptEase filter," "device" or "product" hereinafter) at
6 Spartanburg Regional Medical Center located in Spartanburg, South Carolina. The extent of the
7 device failure has not been fully documented by Plaintiff's treating medical provider(s). As a result
8 of the malfunction, Plaintiff has or may suffer life-threatening injuries and damages and require
9 extensive medical care and treatment. Plaintiff has or may suffer and will continue to suffer
10 significant medical expenses, extreme pain and suffering, loss of enjoyment of life, disability, and
11 other losses.

12 9. Plaintiff Sabrina Jackson (hereinafter "Plaintiff Jackson") is a citizen and resident of
13 the State of New Jersey, Passaic County. Plaintiff underwent placement of a TrapEase™ Permanent
14 Vena Cava Filter (referred to as "TrapEase filter," "device" or "product" hereinafter) at St. Joseph's
15 Wayne Hospital located in Wayne, New Jersey. The device, *inter alia*, caused severe and persistent
16 chest and back pain. As a result of the malfunction, Plaintiff has suffered life-threatening injuries
17 and damages and require extensive medical care and treatment. Plaintiff has suffered and will
18 continue to suffer significant medical expenses, extreme pain and suffering, loss of enjoyment of
19 life, disability, and other losses.

20 10. Plaintiff Juan Jeanes (hereinafter "Plaintiff Jeanes") is a citizen and resident of the
21 State of Oklahoma, McCurtain County. Plaintiff underwent placement of a TrapEase™ Permanent
22 Vena Cava Filter (referred to as "TrapEase filter," "device" or "product" hereinafter) at Wadley
23 Regional Medical Center located in Texarkana, Texas. The extent of the device failure has not been
24 fully documented by Plaintiff's treating medical provider(s). As a result of the malfunction, Plaintiff
25 has or may suffer life-threatening injuries and damages and require extensive medical care and
26 treatment. Plaintiff has or may suffer and will continue to suffer significant medical expenses,
27 extreme pain and suffering, loss of enjoyment of life, disability, and other losses.

28

1 11. Plaintiff Steven Johnson (hereinafter "Plaintiff Johnson") is a citizen and resident of
2 the State of Louisiana, Orleans County. Plaintiff underwent placement of an OptEase™ Retrievable
3 Vena Cava Filter (referred to as "OptEase filter," "device" or "product" hereinafter) at West
4 Jefferson Medical Center located in Marrero, Louisiana. The device, *inter alia*, caused severe and
5 persistent chest pain and shortness of breath. As a result of the malfunction, Plaintiff has suffered
6 life-threatening injuries and damages and requires extensive medical care and treatment. Plaintiff
7 has suffered and will continue to suffer significant medical expenses, extreme pain and suffering,
8 loss of enjoyment of life, disability, and other losses.

9 12. Plaintiff Kendall McCoy (hereinafter "Plaintiff McCoy") is a citizen and resident of
10 the State of Georgia, Dekalb County. Plaintiff underwent placement of an OptEase™ Retrievable
11 Vena Cava Filter (referred to as "OptEase filter," "device" or "product" hereinafter) at Emory
12 University Hospital located in Atlanta, Georgia. The extent of the device failure has not been fully
13 documented by Plaintiff's treating medical provider(s). As a result of the malfunction, Plaintiff has
14 or may suffer life-threatening injuries and damages and require extensive medical care and
15 treatment. Plaintiff has or may suffer and will continue to suffer significant medical expenses,
16 extreme pain and suffering, loss of enjoyment of life, disability, and other losses.

17 13. Plaintiff Michelle Montoya (hereinafter "Plaintiff Montoya") is a citizen and resident
18 of the State of Colorado, Rio Grande County. Plaintiff underwent placement of an OptEase™
19 Retrievable Vena Cava Filter (referred to as "OptEase filter," "device" or "product" hereinafter) at
20 Penrose-St. Francis Hospital located in Colorado Springs, Colorado. The device, *inter alia*, caused
21 a large thrombus of the vena cava and filter and is irretrievable. As a result of the malfunction,
22 Plaintiff has suffered life-threatening injuries and damages and requires extensive medical care and
23 treatment. Plaintiff has suffered and will continue to suffer significant medical expenses, extreme
24 pain and suffering, loss of enjoyment of life, disability, and other losses.

25 14. Plaintiff Karen Neal (hereinafter "Plaintiff McCoy") is a citizen and resident of the
26 State of Tennessee, Davidson County. Plaintiff underwent placement of a TrapEase™ Permanent
27 Vena Cava Filter (referred to as "TrapEase filter," "device" or "product" hereinafter) at Centennial
28 Hospital located in Nashville, Tennessee. The extent of the device failure has not been fully

1 documented by Plaintiff's treating medical provider(s). As a result of the malfunction, Plaintiff has
2 or may suffer life-threatening injuries and damages and require extensive medical care and
3 treatment. Plaintiff has or may suffer and will continue to suffer significant medical expenses,
4 extreme pain and suffering, loss of enjoyment of life, disability, and other losses.

5 15. Plaintiff Debra Porter (hereinafter "Plaintiff D. Porter") is a citizen and resident of
6 the State of North Carolina, Wake County. Plaintiff underwent placement of an OptEase™
7 Retrievable Vena Cava Filter (referred to as "OptEase filter," "device" or "product" hereinafter) at
8 Union Hospital located in Dover, Ohio. The extent of the device failure has not been fully
9 documented by Plaintiff's treating medical provider(s). As a result of the malfunction, Plaintiff has
10 or may suffer life-threatening injuries and damages and require extensive medical care and
11 treatment. Plaintiff has or may suffer and will continue to suffer significant medical expenses,
12 extreme pain and suffering, loss of enjoyment of life, disability, and other losses.

13 16. Plaintiff Tommy Porter (hereinafter "Plaintiff T. Porter") is a citizen and resident of
14 the State of Illinois, Cook County. Plaintiff underwent placement of an OptEase™ Retrievable
15 Vena Cava Filter (referred to as "OptEase filter," "device" or "product" hereinafter) at Our Lady of
16 the Resurrection Medical Center located in Chicago, Illinois. The extent of the device failure has
17 not been fully documented by Plaintiff's treating medical provider(s). As a result of the
18 malfunction, Plaintiff has or may suffer life-threatening injuries and damages and require extensive
19 medical care and treatment. Plaintiff has or may suffer and will continue to suffer significant
20 medical expenses, extreme pain and suffering, loss of enjoyment of life, disability, and other losses.

21 17. Plaintiff Carl Rexing (hereinafter "Plaintiff Rexing") is a citizen and resident of the
22 State of Illinois, Hamilton County. Plaintiff underwent placement of an OptEase™ Retrievable
23 Vena Cava Filter (referred to as "OptEase filter," "device" or "product" hereinafter) at Deaconess
24 Hospital located in Evansville, Indiana. The device, *inter alia*, caused leg aches and shortness of
25 breath. As a result of the malfunction, Plaintiff has suffered life-threatening injuries and damages
26 and requires extensive medical care and treatment. Plaintiff has suffered and will continue to suffer
27 significant medical expenses, extreme pain and suffering, loss of enjoyment of life, disability, and
28 other losses.

1 18. Plaintiff Hazel Webb (hereinafter "Plaintiff Webb") is a citizen and resident of the
2 State of Tennessee, Weakley County. Plaintiff underwent placement of an OptEase™ Retrievable
3 Vena Cava Filter (referred to as "OptEase filter," "device" or "product" hereinafter) at Regional
4 Hospital located in Jackson, Tennessee. The extent of the device failure has not been fully
5 documented by Plaintiff's treating medical provider(s). As a result of the malfunction, Plaintiff has
6 or may suffer life-threatening injuries and damages and require extensive medical care and
7 treatment. Plaintiff has or may suffer and will continue to suffer significant medical expenses,
8 extreme pain and suffering, loss of enjoyment of life, disability, and other losses.

9 19. Plaintiff Cheryl Wright (hereinafter "Plaintiff C. Wright") is a citizen and resident of
10 the State of Maryland, Anne Arundel County. Plaintiff underwent placement of an OptEase™
11 Retrievable Vena Cava Filter (referred to as "OptEase filter," "device" or "product" hereinafter) at
12 Harbor Hospital Center located in Baltimore, Maryland. The extent of the device failure has not
13 been fully documented by Plaintiff's treating medical provider(s). As a result of the malfunction,
14 Plaintiff has or may suffer life-threatening injuries and damages and require extensive medical care
15 and treatment. Plaintiff has or may suffer and will continue to suffer significant medical expenses,
16 extreme pain and suffering, loss of enjoyment of life, disability, and other losses.

17 20. Plaintiff Evelyn Wright (hereinafter "Plaintiff E. Wright") is a citizen and resident of
18 the State of Florida, Marion County. Plaintiff underwent placement of an OptEase™ Retrievable
19 Vena Cava Filter (referred to as "OptEase filter," "device" or "product" hereinafter) at Munroe
20 Regional Medical Center located in Ocala, Florida. The device, *inter alia*, caused severe and
21 persistent chest pain. As a result of the malfunction, Plaintiff has suffered life-threatening injuries
22 and damages and requires extensive medical care and treatment. Plaintiff has suffered and will
23 continue to suffer significant medical expenses, extreme pain and suffering, loss of enjoyment of
24 life, disability, and other losses.

25 21. Plaintiff Thomas Yaudas, Sr. (hereinafter "Plaintiff Yaudas") is a citizen and resident
26 of the State of Texas, Montgomery County. Plaintiff underwent placement of a TrapEase™
27 Permanent Vena Cava Filter (referred to as "TrapEase filter," "device" or "product" hereinafter) at
28 Tomball Regional Medical Center located in Tomball, TX. The extent of the device failure has not

1 been fully documented by Plaintiff's treating medical provider(s). As a result of the malfunction,
2 Plaintiff has or may suffer life-threatening injuries and damages and require extensive medical care
3 and treatment. Plaintiff has or may suffer and will continue to suffer significant medical expenses,
4 extreme pain and suffering, loss of enjoyment of life, disability, and other losses.

5 22. All of the above plaintiffs underwent placement in and were residents of the United
6 States at the time these devices were implanted and when the devices subsequently failed and
7 caused injury.

8 23. Defendant Cordis Corporation ("Cordis") is a corporation organized under the laws of
9 the State of Florida, with its principal place of business at 6500 Paseo Padre Pkwy, Fremont,
10 California, 94555. Cordis at all times relevant to this action, designed, set specifications for,
11 manufactured, prepared, compounded, assembled, processed, marketed, distributed, and sold the
12 TrapEase™ Permanent Vena Cava Filter ("TrapEase filter") and OptEase™ Retrievable Vena Cava
13 Filter ("OptEase filter") to be implanted in patients throughout the United States, including
14 California. Cordis may be served with process by serving its registered agent, CT Corporation
15 System, at 818 West Seventh Street Suite 930, Los Angeles, California 90017.

16 24. Defendant Confluent Medical Technologies, Inc. (Hereinafter "Confluent") is a
17 corporation organized under the laws of the State of Delaware, with its principal place of business at
18 47533 Westinghouse Drive, Fremont, California 94539. Confluent manufactured, prepared,
19 processed and helped design the OptEase and TrapEase filters implanted in the above-named
20 plaintiffs, whether under its current name or as the successor in interest to Nitinol Development
21 Corporation.

22 25. Prior to 2015, Confluent was incorporated under the name of Nitinol Development
23 Corporation and did business under the name Nitinol Devices & Components, Inc. (hereinafter
24 "NDC"). NDC also had its principal place of business at 47533 Westinghouse Drive, Fremont,
25 California 94539. In 2015, NDC merged with another company and became Confluent. Defendant
26 Confluent carries on the same activities in relation to the TrapEase and OptEase filters as NDC did
27 previously.

28

1 26. The true names and/or capacities, whether individual, corporate, partnership,
2 associate, governmental, or otherwise, of Defendant DOES 1 through 100, inclusive, are unknown
3 to Plaintiffs at this time, who therefore sue said Defendants by such fictitious names. Plaintiffs are
4 informed and believe, and thereon allege, that each Defendant designated herein as a DOE caused
5 injuries and damages proximately thereby to Plaintiffs as is hereinafter alleged, and that each DOE
6 defendant is liable to Plaintiffs for the acts and omissions alleged herein below and the injuries and
7 damages resulting therefrom. Plaintiffs seek leave to amend this Complaint to allege the true names
8 and capacities of said DOE defendants when the same are ascertained.

9 27. Plaintiffs are informed and believe, and thereon allege, that at all times herein
10 mentioned, Defendants and each of the DOE defendants were the agent, servant, employee and/or
11 joint venturer of the other co-defendants, and each of them, and at all said times each Defendant,
12 including DOE defendants, were acting in the full course, scope, and authority of said agency,
13 service, employment and/or joint venture.

14 28. Plaintiffs are informed and believe, and thereon allege, that at all times mentioned
15 herein, Defendants and DOES 1 through 100, and each of them, were also known as, formerly
16 known as, and/or were the successors and/or predecessors in interest/business/product line/or a
17 portion thereof, assigns, a parent, a subsidiary (wholly or partially owned by, or the whole or partial
18 owner), affiliate, partner, co-venturer, merged company, alter egos, agents, equitable trustees and/or
19 fiduciaries of and/or were members in an entity or entities engaged in the funding, researching,
20 studying, manufacturing, fabricating, designing, developing, labeling, assembling, distributing,
21 supplying, leasing, buying, offering for sale, selling, inspecting, servicing, contracting others for
22 marketing, warranting, rebranding, manufacturing for others, packaging, and advertising the device.

23 29. Defendants and DOES 1 through 100, and each of them, are liable for the acts,
24 omissions and tortious conduct of its successors and/or predecessors in interest/business/product
25 line/or a portion thereof, assigns, parent, subsidiary, affiliate, partner, co-venturer, merged
26 company, alter ego, agent, equitable trustee, fiduciary and/or its alternate entities in that Defendants
27 and DOES 1 through 100, and each of them, enjoy the goodwill originally attached to each such
28 alternate entity, acquired the assets or product line (or a portion thereof), and in that there has been a

1 virtual destruction of Plaintiffs' remedy against each such alternate entity, and that each such
2 Defendant has the ability to assume the risk-spreading role of each such alternate entity.

3 30. Plaintiffs are informed and believe, and thereon allege that, at all times herein
4 mentioned, DOES 1 through 100, and each of them, were and are corporations organized and
5 existing under the laws of the State of California or the laws of some state or foreign jurisdiction;
6 that each of the said DOE defendants were and are authorized to do and are doing business in the
7 State of California and regularly conducted business in the State of California.

8 31. Upon information and belief, at all relevant times, DOES 1 through 100, and each of
9 them, were engaged in the business of researching, developing, designing, licensing, manufacturing,
10 distributing, selling, marketing, and/or introducing into interstate commerce and into the State of
11 California, either directly or indirectly through third parties or related entities, its products,
12 including the TrapEase and OptEase inferior vena cava filters.

13 32. At all relevant times, DOES 1 through 100, and each of them, conducted regular and
14 sustained business and engaged in substantial commerce and business activity in the State of
15 California, which included but was not limited to researching, developing, selling, marketing, and
16 distributing their products, including the TrapEase and OptEase inferior vena cava filters, in the
17 State of California.

18 33. Upon information and belief, at all relevant times, DOES 1 through 100, and each of
19 them, expected or should have expected that their acts would have consequences within the United
20 States including in the State of California, and said Defendants derived and continue to derive
21 substantial revenue therefrom.

22 34. "Cordis," "Confluent" and "Defendants" where used hereinafter, shall refer to all
23 subsidiaries, affiliates, divisions, franchises, partners, joint venturers, organizational units of any
24 kind, predecessors, successors, assigns, officers, directors, employees, agents and representatives of
25 Cordis Corporation, Confluent, as well as DOE Defendants 1 through 100, and each of them.

36. Venue is proper in this Court, pursuant to *Code of Civil Procedure*, as Defendant Cordis has its principal place of business in Alameda County.

INFERIOR VENA CAVA FILTERS GENERALLY

41. As stated above, IVC filters have been on the market for decades. All IVC filters are only cleared for use by the FDA for prevention of recurrent pulmonary embolism in patients at risk for pulmonary embolism and where anticoagulation has failed or is contraindicated. In 2003,

1 however, an explosion in off-label use began with the introduction of IVC filters that were cleared
2 for both permanent placement and optional removal. Most of this market expansion came from
3 uses such as prophylactic prevention of pulmonary embolism without a prior history of pulmonary
4 embolism.

5 42. Indeed, from 2000 through 2003 there was a race between manufactures to bring the
6 first IVC filter to market with the added indication of optional retrieval. In 2003, the FDA cleared
7 the first three (3) IVC filters for a retrieval indication. These were the OptEase filter (Cordis &
8 J&J), the Recovery Filter (C.R. Bard, Inc.) and the Gunther Tulip Filter (Cook Medical).

9 43. Upon information and belief, Plaintiffs allege that this market expansion and off-
10 label use was driven by baseless marketing campaigns made by Defendants targeting bariatric,
11 trauma, orthopedic and cancer patient populations.

12 44. The medical community has just recently begun to awaken to the fact that despite
13 marketing claims by Defendants, there is no reliable evidence that any IVC filter offers a benefit
14 and that these products expose patients to substantial safety hazards. For example, an October 2015
15 article published in the Annals of Surgery concerning trauma patients inserted with IVC filters
16 concluded that IVC filters were not effective in preventing pulmonary emboli, and instead actually
17 caused thrombi to occur.

18 45. Comparing the results of over 30,000 trauma patients who had not received IVC
19 filters with those who had received them, the Annals of Surgery study published its alarming
20 results:

- 21 a. Almost twice the percentage of patients with IVC filters in the study died compared
22 to those that had not received them.
- 23 b. Over five times the relative number of patients with IVC filters developed DVTs.
- 24 c. Over four times the relative percentage of patients with filters developed
25 thromboemboli.

26 46. Over twice the percentage of patients developed a pulmonary embolus – the very
27 condition Defendants represented to the FDA, physicians, and the public that its IVC filters would
28 prevent.

1 47. Other studies have also revealed that these devices suffer common failure modes
 2 such as migration, perforation, thrombosis, fracture all of which can cause serious injury or death.
 3 For example, recent studies for Defendants IVC Filters have revealed fracture rates as high as 50%
 4 and recommend medical monitoring and/or removal.

5 48. These studies, including the *Annals of Surgery* study, have now shown that not only
 6 is there no reliable evidence establishing that IVC filters are efficacious but that they also pose
 7 substantial health hazards.

8 THE TRAPEASE™ AND OPTEASE™ IVC FILTERS

9 49. On January 10, 2001, Defendants bypassed the more onerous Food and Drug
 10 Administration's ("FDA's") approval process for new devices and obtained "clearance" under
 11 Section 510(k) of the Medical Device Amendments to the Food, Drug, and Cosmetic Act to market
 12 the Trap Ease™ Permanent Vena Cava Filter and Introduction Kit ("TrapEase filter") as a
 13 permanent filter by claiming it was substantially equivalent in respect to safety, efficacy, design,
 14 and materials as the then already available IVC filters.

15 50. Section 510(k) permits the marketing of medical devices if the device is
 16 substantially equivalent to other legally marketed predicate devices without formal review for the
 17 safety or efficacy of the device. The FDA explained the difference between the 510(k) process and
 18 the more rigorous "premarket approval" ("PMA") process in its amicus brief filed with the Third
 19 Circuit in *Horn v. Thoratec Corp.*, which the court quoted from:

20 A manufacture can obtain an FDA findings of 'substantial equivalence' by
 21 submitting a premarket notification to the agency in accordance with section
 22 510(k) of the [Food Drug and Cosmetic Act.] 21 U.S.C. § 360(k). A device found
 23 to be 'substantially equivalent' to a predicate device is said to be 'cleared' by the
 24 FDA (as opposed to "approved" by the agency under a PMA).

25 376. F.3d 163, 167 (3d. Cir. 2004). A pre-market notification submitted under 510(k) is thus
 26 entirely different from a PMA, which must include data sufficient to demonstrate that the produce
 27 involved is safe and effective.

28 51. In *Medtronic, Inc. v. Lohr*, the U.S. Supreme Court similarly described the 510(k)
 process, observing:

1 If the FDA concludes on the basis of the [manufacturer's] § 510(k) notification
2 that the device is 'substantially equivalent' to a pre-existing device, it can be
3 marketed without further regulatory analysis.... The § 510(k) notification process
4 is by no means comparable to the PMA process; in contrast to the 1,200 hours
5 necessary to complete a PMA review, the § 510(k) review is completed in average
6 of 20 hours As on commentator noted: "The attraction of substantial
equivalence to manufacturers is clear. Section 510(k) notification required little
information, rarely elicits a negative response from the FDA, and gets processed
quickly."

7 518 U.S. 470, 478-79 (1996).

8 52. Pursuant to *Wyeth v. Levine*, 555 U.S. 555 (2009), once a product is cleared "the
9 manufacturer remains under an obligation to investigate and report any adverse associated with the
10 drug...and must periodically submit any new information that may affect the FDA's previous
11 conclusions about the safety, effectiveness, or labeling" This obligation extends to post-market
12 monitoring of adverse events/complaints.

13 53. On July 7, 2000, Defendants obtained clearance through this 510(k) process to begin
14 marketing the Trap Ease filter as a permanent filter.

15 54. The TrapEase filter is made of NITINOL (a nickel titanium alloy whose full name is
16 Nickel Titanium Naval Ordnance Laboratory) and has a symmetrical double-basket design with six
17 straight struts connecting the proximal and distal baskets. The device has proximal and distal
18 anchoring barbs located on each connecting strut for fixation of the filter to the vena cava wall to
19 prevent movement after placement.

20 55. On September 18, 2002, Defendants sought clearance through the 510(k) process to
21 market the Cordis OptEase™ Retrieable Vena Cava Filter ("OptEase filter") for the same
22 indicated uses as the TrapEase Filter. Defendants represented that the OptEase filter had the same
23 basic fundamental technology and was substantially equivalent in respect to safety and efficacy as
24 the predicate devices (TrapEase Filter, Gunther Tulip filter, and the Vena Tech LGM Vena Cava
25 Filter).

26 56. Defendants have further represented that the OptEase filter has the same design as
27 TrapEase filter except that unlike the TrapEase filter, which has proximal and distal anchoring barbs
28 located on each connecting strut for fixation of the filter to the vena cava wall, the OptEase filter

1 has anchoring barbs for fixation of the filter only on the superior end of each of the six straight
2 struts and has a hook at the inferior end of the basket to allow retrieval with a snare.

3 57. Both designs suffer similar design flaws rendering them defective and unreasonably
4 dangerous. Defendants filters are designed in such way that when exposed to expected and
5 reasonably foreseeable *in-vivo* conditions the devices will fracture, migrate, tilt, perforate internal
6 organs and vasculature, and lead to the formation of thromboembolism and pulmonary embolism.

7 58. For instance, Defendants chose not to electropolish their filters. The manufacturing
8 process used to manufacture NITINOL medical devices leads to surface blemishes, draw marking,
9 pitting, gouges and cracks, which can act as stress concentrators leading to fatigue failure.
10 Electropolishing removes these conditions, which substantially increase fatigue and corrosion
11 resistance. Electropolishing has been industry standard for implanted NITINOL medical devices
12 since at least the 1990's.

13 59. The anchoring mechanism of Defendants' filters is also insufficient to prevent tilting
14 and migration post-placement.

15 60. The configuration of Defendants' filters also renders them prothrombotic. This
16 means that these filters actually lead to the formation of blood clots and pulmonary embolism – the
17 exact condition that devices are meant to prevent.

18 61. That Defendants allowed these devices to proceed to market indicates that they failed
19 to establish and maintain an appropriate Quality System in respect to design and risk analysis.

20 62. At a minimum, a manufacturer must undertake sufficient research and testing to
21 understand the anatomy of where a medical device will be implanted so as to understand what
22 forces the device may be exposed to once implanted in the human body. This design input must
23 then be used to determine the minimum safety requirements or attributes the device must have to
24 meet user needs. In the case of an IVC filter, user needs include: a device that will capture DVTs of
25 sufficient size to cause harmful consequences and that will not fracture, migrate, tilt, perforate the
26 vena cava or be prothrombotic.

1 63. Prior to bringing a product to market, a manufacturer must also conduct sufficient
2 testing under real world or simulated use conditions to ensure that the device will meet user needs
3 even when exposed to reasonably foreseeable worst case conditions.

4 64. Defendants failed to adequately establish and maintain such policies and procedures
5 in respect to their IVC filter devices.

6 65. Once brought to market, Defendants' post-market surveillance system should have
7 revealed that the TrapEase and OptEase filters were unreasonably dangerous and substantially more
8 prone to failing and causing injury than other available treatment options.

9 66. For instance soon after market release, Defendants began receiving large numbers of
10 adverse event reports ("AERs") from health care providers reporting that the TrapEase and OptEase
11 filters were fracturing post-implantation and that fractured pieces and/or the entire device was
12 migrating throughout the human body, including the heart and lungs. Defendants also received
13 large numbers of AERs reporting that the TrapEase and OptEase filters were found to have
14 excessively tilted, perforated the inferior vena cava, or caused thrombosis or stenosis of the vena
15 cava post-implantation. These device malfunctions were often associated with reports of inability to
16 retrieve the device and/or severe patient injuries such as:

- 17 a. Death;
- 18 b. Hemorrhage;
- 19 c. Cardiac/pericardial tamponade;
- 20 d. Cardiac arrhythmia and other symptoms similar to myocardial infarction;
- 21 e. Severe and persistent pain;
- 22 f. Perforation of tissue, vessels and organs;
- 23 g. Compartment syndrome.

24 67. Recent medical studies have confirmed what Defendants have known or should have
25 known since shortly after the release of each of these filters - not only do TrapEase and OptEase
26 filters fail at alarming rates, but they also fail at rates substantially higher than other available IVC
27 Filters. For instance, a recent large medical study found that OptEase and TrapEase filters suffer
28 fracture rates of 37.5% and 23.1%, respectively, when left implanted a minimum of 46 months.

1 Another recent study found that the TrapEase filter had a 64% fracture rate when left in more than
2 four (4) years. Another study found a statistically significant increased rate of caval thrombosis with
3 the OptEase filter compared to Gunther Tulip and Recovery Filters.

4 68. As a minimum safety requirement, manufacturers must establish and maintain post-
5 market procedures to timely identify the cause of device failures and other quality problems and to
6 take adequate corrective action to prevent the recurrence of these problems.

7 69. Defendants, however, failed to take timely and adequate action to correct known
8 design and manufacturing defects with the OptEase and TrapEase filters.

9 70. Defendants also misrepresented and concealed the risks and benefits of the TrapEase
10 and OptEase filters in labeling and marketing distributed to the FDA, physicians and the public.

11 71. For instance, Defendants represented that these devices were safe and effective. As
12 discussed above, however, there is no reliable evidence establishing that these devices actually
13 improve patient outcomes.

14 72. Defendants also represented that the design of these devices would eliminate the risk
15 that pieces of the devices could perforate the vena cava, that the devices could tilt, or that fractures
16 could occur and migrate throughout the body. The medical literature and AERS have proven these
17 claims to be false.

18 73. Defendants also represented that these devices were more effective and safer than
19 other available IVC filters. As discussed above, there is no reliable basis for such claims and the
20 evidence indicates otherwise.

21 74. Defendants also marketed the OptEase filter as being "easy" to remove. However,
22 the OptEase filter is one of the most difficult filters to remove after implantation and quite often
23 cannot be removed at all. As Dr. William T. Kuo, one of the leading authors on IVC filters, recently
24 explained in the *Journal of Vascular Interventional Radiology*:

25 "...we thought the OPTEASE and TRAPEASE filter types were subjectively
26 among the most difficult to remove in our study, often requiring aggressive blunt
27 dissection force in addition to laser tissue ablation to achieve removal. A possible
28 explanation is the relatively large amount of contact these filters make with the
underlying vena cava and the possible induction of greater reactive tissue
formation."

1 75. This is particularly concerning because having an IVC filter for a prolonged period
2 of time increases the risk of developing chronic deep venous thrombosis, PE, IVC occlusion, post-
3 thrombotic syndrome, filter fracture, and caval perforation with pain and organ injury. Many
4 patients with IVC filters are now routinely managed with lifelong anticoagulation solely to reduce
5 the risk of having the filter in place, subjecting patients to the risks and inconvenience of
6 anticoagulation.

7 76. Defendants also failed to adequately disclose the risks of these filters, such as
8 migration, fracture, perforation, tilt, thrombosis, the prothrombotic nature of the devices, that the
9 devices may not be retrievable, or that these failures were known to be causing severe injuries and
10 death or the rate at which these events were occurring.

11 77. Defendants labeling was additionally defective in that it directed physicians to
12 implant the OptEase filter upside down. When the OptEase was placed as directed by the labeling,
13 the hooks designed to ensure stability were facing in the wrong direction, rendering an already
14 inadequate anchoring system even further defective. As Defendants' now explain in their labeling,
15 implanting the device in this fashion "can result in life threatening or serious injury including, but
16 not limited to dissection, vessel perforation, migration of the filter with secondary damage to
17 cardiac structures, ineffective pulmonary embolism prevention or death."

18 78. Defendants began a series of recalls on March 29, 2013 relating to its labeling, which
19 instructed physicians to implant the devices upside down. These recalls were not timely, nor did
20 they fully correct the defects in Defendants' labeling. Further, Defendants downplayed the danger
21 patients were exposed to and failed to take adequate steps to ensure patients actually received notice
22 of the recall.

23 79. The FDA classified the initial recall as a Class I recall, which are the most serious
24 type of recall and involve situations in which the FDA has determined there is a reasonable
25 probability that use of these products will cause serious adverse health consequences or death.

26 80. Defendants have admitted that any patients implanted with one of these recalled
27 units should receive medical monitoring. Specifically, these patients should undergo imaging to
28 ascertain whether or not the device was properly deployed and, if not, be assessed for removal.

1 81. Given the unreasonably high failure and injury rates associated with Defendants
2 filters when left implanted long-term, Defendants should be required to pay for medical monitoring
3 to assess the condition of these devices and whether or not retrieval should be undertaken.

4 **ESTOPPEL FROM PLEADING STATUTES OF LIMITATIONS OR REPOSE**

5 82. Plaintiffs incorporate by reference all prior allegations.

6 83. Plaintiffs are within the applicable statute of limitations for their claims because
7 Plaintiffs (and their healthcare professionals) did not discover, and could not reasonably discover,
8 the defects and unreasonably dangerous condition of Defendants' IVC filters.

9 84. Plaintiffs' ignorance of the defective and unreasonably dangers nature of
10 Defendants' IVC filters, and the causal connection between these defects and Plaintiffs' injuries and
11 damages, is due in large part to Defendants' acts and omissions in fraudulently concealing
12 information from the public and misrepresenting and/or downplaying the serious threat to public
13 safety its products present.

14 85. In addition, Defendants are estopped from relying on any statutes of limitation or
15 repose by virtue of its unclean hands, acts of fraudulent concealment, affirmative misrepresentations
16 and omissions.

17 86. Such conduct includes intentional concealment from Plaintiffs, Plaintiffs' prescribing
18 health care professionals, the general consuming public and the FDA of material information that
19 Defendants' filters had not been demonstrated to be safe or effective, and carried with them the
20 risks and dangerous defects described above.

21 87. Defendants had a duty to disclose the fact that Defendants' filters are not safe or
22 effective, not as safe as other filters on the market, defective, and unreasonably dangerous, and that
23 their implantation and use carried the above described risks.

24 **COUNT I:**
25 **STRICT PRODUCTS LIABILITY- DESIGN DEFECT**
26 **By all Plaintiffs**

27 88. Plaintiffs re-allege and incorporate by reference each and every allegation contained
28 in the foregoing paragraphs as though fully set forth herein.

1 89. At all times relevant to this action, Defendants developed, tested, designed,
2 manufactured, inspected, labeled, promoted, distributed and sold into the stream of commerce the
3 TrapEase and OptEase filters, including the devices implanted in Plaintiffs.

4 90. The devices implanted in plaintiffs were in a condition unreasonably dangerous at
5 the time they left Defendants' control.

6 91. The devices implanted in Plaintiffs were expected to, and did, reach their intended
7 consumers without substantial change in the condition in which they were in when they left
8 Defendants' possession. In the alternative, any changes that were made to the devices implanted in
9 Plaintiffs were reasonably foreseeable to Defendants.

10 92. The TrapEase and OptEase filters, including the devices implanted in Plaintiffs, were
11 defective in design and unreasonably dangerous at the time they left Defendants' possession
12 because they failed to perform as safely as an ordinary consumer would expect when used as
13 intended or in a manner reasonably foreseeable by the Defendants, and because the foreseeable risks
14 of these devices exceeded the alleged benefits associated with their use.

15 93. At the time Defendants placed their TrapEase and OptEase filters, including the
16 device implanted in Plaintiffs, into the stream of commerce, safer alternative designs were
17 commercially, technologically, and scientifically attainable and feasible.

18 94. Plaintiffs and their health care providers used the devices in a manner that was
19 reasonably foreseeable to Defendants.

20 95. Neither Plaintiffs, nor their health care providers, could have by the exercise of
21 reasonable care discovered the defective condition or perceived the unreasonable dangers with these
22 devices prior to Plaintiffs' implantation with the devices.

23 96. As a direct and proximate result of the defective and unreasonably dangerous
24 condition of the TrapEase and OptEase filters, Plaintiffs suffered injuries and damages.
25
26
27
28

1 WHEREFORE, Plaintiffs demand judgment against Defendants as hereinafter set forth.

2 **COUNT II:**
3 **STRICT PRODUCTS LIABILITY — INADEQUATE WARNING**

4 **By all Plaintiffs**

5 97. Plaintiffs re-allege and incorporate by reference each and every allegation contained
6 in the foregoing paragraphs as though fully set forth herein.

7 98. Prior to, on, and after the dates during which the device were implanted in Plaintiffs,
8 and at all relevant times, Defendants manufactured, designed, marketed, distributed, and sold the
9 TrapEase and OptEase filters.

10 99. The TrapEase and OptEase filters had potential risks and side effects that were
11 known or knowable to Defendants by the use of scientific knowledge available before, at, and after
12 the manufacture, distribution, and sale of the devices implanted in Plaintiffs.

13 100. Defendants knew or it was knowable at the time they distributed the devices
14 implanted in Plaintiffs that the TrapEase and OptEase filters posed a significant and higher risk of
15 failure than other similar IVC filters, including for fracture, migration, tilting, thrombosis,
16 migration, tilt, inability to retrieve and pulmonary embolism and that these failures were resulting in
17 serious patient injuries and death. Defendants also knew or it was knowable that these devices were
18 actually prothrombotic, that use of these filters did not improve patient outcomes, and the longer
19 these filters were left implanted increased the likelihood of a device failure.

20 101. Defendants' TrapEase and OptEase filters were in a defective condition that was
21 unreasonably and substantially dangerous to any user or consumer implanted with the filters, such
22 as Plaintiffs, when used in an intended and reasonably foreseeable way. Such ordinary consumers,
23 including Plaintiffs and their prescribing physician(s), would not and could not have recognized or
24 discovered the potential risks and side effects of the device, as set forth herein.

25 102. The warnings and directions Defendants provided with its TrapEase and OptEase
26 filters, including the devices implanted in Plaintiffs, failed to adequately warn of the above-

1 described risks and side-effects, whether as to existence of the risk, its likelihood, severity, or the
2 comparative risk to other products.

3 103. The labeling also failed to provide adequate directions on how to appropriately use
4 the product.

5 104. The devices were expected to and did reach Plaintiffs without substantial change in
6 its condition, labeling, or warnings as manufactured, distributed, and sold by Defendants.
7 Additionally, Plaintiffs and their prescribing physicians used the devices in the manner in which
8 they were intended to be used, making such use reasonably foreseeable to Defendants.

9 105. Defendants' lack of sufficient instructions or warnings prior to, on, and after the date
10 Plaintiffs used the devices was a substantial factor in causing Plaintiffs' injuries and damages, as
11 described herein.

12 WHEREFORE, Plaintiffs demand judgment against Defendants as hereinafter set forth.

13 **COUNT III:**
14 **STRICT PRODUCTS LIABILITY — MANUFACTURING DEFECT**
15 **By all Plaintiffs**

16 106. Plaintiffs re-allege and incorporate by reference each and every allegation contained
17 in the foregoing paragraphs as though fully set forth herein.

18 107. Prior to, on, and after the date the devices were implanted in Plaintiffs, and at all
19 relevant times, Defendants designed, distributed, manufactured, sold, and marketed the TrapEase
20 and OptEase filters for use in the United States.

21 108. At all times herein mentioned, Defendants designed, distributed, manufactured,
22 marketed, and sold the devices such that they were dangerous, unsafe, and defective in manufacture,
23 and contained a manufacturing defect when it left defendants' possession.

24 109. Plaintiffs are informed and believe, and on that basis allege, that the TrapEase and
25 OptEase filters, including the devices implanted in them, contained manufacturing defects, in that
26 they differed from Defendants' design or specifications, or from other typical units of the same
27 product line.

1 110. As a direct and proximate result of Defendants' defective manufacture and sale of
2 the TrapEase and OptEase filters prior to, on, and after the date Plaintiffs used the devices, Plaintiffs
3 suffered the injuries and damages herein described.

4 WHEREFORE, Plaintiffs demand judgment against Defendants as hereinafter set forth.

5 **COUNT IV:**
6 **NEGLIGENCE**
7 **By all Plaintiffs**

8 111. Plaintiffs re-allege and incorporate by reference each and every allegation contained
9 in the foregoing paragraphs as though fully set forth herein.

10 112. Prior to, on, and after the date the devices were implanted in Plaintiffs, and at all
11 relevant times, Defendants designed, distributed, manufactured, sold, and marketed the TrapEase
12 and OptEase filters for use in the United States.

13 113. Defendants had a duty to exercise reasonable and prudent care in the development,
14 testing, design, manufacture, inspection, marketing, labeling, promotion, distribution and sale of the
15 TrapEase and OptEase filters so as to avoid exposing others to foreseeable and unreasonable risks
16 of harm.

17 114. Defendants knew or reasonably should have known that the TrapEase and OptEase
18 filters were dangerous or were likely to be dangerous when used in an intended or reasonably
19 foreseeable manner.

20 115. At the time of manufacture and sale of the TrapEase and OptEase filters, Defendants
21 knew or should have known that the TrapEase and OptEase filters:

- 22 a. Were designed and manufactured in such a manner as to lack sufficient structural
23 integrity (fatigue resistance) and stability (tilt/migration) to meet user needs when
24 used in an intended and reasonably foreseeable manner.
25
26 b. Were designed and manufactured so as to present an unreasonable risk of the devices
27 perforating the vena cava wall and/or in the case of the OptEase filter becoming
28 irretrievable;

1 c. Being designed and manufactured in such a manner as to be prothrombotic.

2 116. At the time of manufacture and sale of the TrapEase and OptEase filters, including
3 the ones implanted in Plaintiffs, Defendants knew or should have known that using the TrapEase
4 and OptEase filters as intended or in a reasonably foreseeable manner created a significant risk of
5 patients suffering severe health side effects including, but not limited to: hemorrhage;
6 cardiac/pericardial tamponade; cardiac arrhythmia and other symptoms similar to myocardial
7 infarction; perforations of tissue, vessels and organs; chronic deep vein thrombosis; pulmonary
8 embolism; thrombosis; compartment syndrome; and other severe personal injuries and diseases,
9 which are permanent in nature, including, but not limited to, death, physical pain and mental
10 anguish, scarring and disfigurement, diminished enjoyment of life, continued medical care and
11 treatment due to chronic injuries/illness proximately caused by the device; and the continued risk of
12 requiring additional medical and surgical procedures including general anesthesia, with attendant
13 risk of life threatening complications.
14

15
16 117. Defendants knew or reasonably should have known that consumers of the TrapEase
17 and OptEase filters, including Plaintiffs' prescribing physicians, would not realize the danger
18 associated with using the devices for their intended or reasonably foreseeable use.

19
20 118. Defendants breached their duty to exercise reasonable and prudent care in the
21 development, testing, design, manufacture, inspection, marketing, labeling, promotion, distribution
22 and sale of the TrapEase and OptEase filters in, among other ways, the following acts and
23 omissions:

- 24 a. Designing and distributing a product in which they knew or should have known that
25 the likelihood and severity of potential harm from the product exceeded the burden
26 of taking safety measures to reduce or avoid harm;
27
28 b. Designing and distributing a product in which they knew or should have known that
the likelihood and severity of potential harm from the product exceeded the

1 likelihood of potential harm from other devices and treatment options available for
2 the same purpose;

3 c. Failing to use reasonable care in manufacturing the product and producing a product
4 that differed from their design or specifications or from other typical units from the
5 same production line;

6
7 d. Failing to use reasonable care to warn or instruct, including pre and post-sale,
8 Plaintiffs, their prescribing physicians, or the general health care community about
9 the TrapEase and OptEase filters' substantially dangerous condition or about facts
10 making the products likely to be dangerous;

11 e. Failing to recall, retrofit, or provide adequate notice of such actions to Plaintiffs or
12 their health providers.

13
14 f. Failing to perform reasonable pre and post-market testing of the TrapEase and
15 OptEase filters to determine whether or not the products were safe for their intended
16 use;

17 g. Failing to provide adequate instructions, guidelines, and safety precautions,
18 including pre and post-sale, to those persons to whom it was reasonably foreseeable
19 would prescribe, use, and implant the TrapEase and OptEase filters;

20 h. Advertising, marketing and recommending the use of the TrapEase and OptEase
21 filters, while concealing and failing to disclose or warn of the dangers known by
22 Defendants to be connected with and inherent in the use of these filter systems;

23
24 i. Representing that the TrapEase and OptEase filters were safe for their intended use
25 when, in fact, Defendants knew and should have known the products were not safe
26 for their intended uses;

1 j. Continuing to manufacture and sell the TrapEase and OptEase filters with the
2 knowledge that said products were dangerous and not reasonably safe, and failing to
3 comply with good manufacturing regulations;

4 k. Failing to use reasonable and prudent care in the design, research, manufacture, and
5 development of the TrapEase and OptEase filters so as to avoid the risk of serious
6 harm associated with the use of these filter systems;

7 l. Advertising, marketing, promoting and selling TrapEase and OptEase filters for uses
8 other than as approved and indicated in the product's label;

9 m. Failing to establish an adequate quality assurance program used in the design and
10 manufacture of the TrapEase and OptEase filters.

11 n. Failing to establish and maintain an adequate post-market surveillance program;

12 119. A reasonable manufacturer, distributor, or seller under the same or similar
13 circumstances would not have engaged in the before-mentioned acts and omissions.

14 120. Defendants' negligence prior to, on, and after the date of implantation of the devices
15 in Plaintiffs was a substantial factor in causing Plaintiffs' injuries and damages, as described herein.

16 WHEREFORE, Plaintiffs demand judgment against Defendants as hereinafter set forth.

17 **COUNT V:**
18 **NEGLIGENT MISREPRESENTATION**
19 **By all Plaintiffs**

20 121. Plaintiffs re-allege and incorporate by reference each and every allegation contained
21 in the foregoing paragraphs as though fully set forth herein.

22 122. Prior to, on, and after the date the devices were implanted in Plaintiffs, and at all
23 relevant times, Defendants negligently and carelessly represented to Plaintiffs, their health care
24 providers, and the general public that certain material facts were true. The representations include,
25 *inter alia*, the following:
26
27
28

- a. That the TrapEase and OptEase filters were safe, fit, and effective for use.
- b. That the design of the TrapEase and OptEase filters eliminated the risk that pieces of the device could perforate the vena cava, that the devices could tilt, or that fractures could occur and migrate throughout the body.
- c. That the TrapEase and OptEase filters were safer and more effective than other available IVC filters.
- d. That the OptEase filter was "easy" to remove.

123. Prior to, on, and after the dates during which Plaintiffs and their physicians purchased and used the device, said representations were not true, and there was no reasonable ground for believing said representations to be true at the times said representations were made.

124. Prior to, on, and after the dates during which Plaintiffs and their physicians purchased and used the device, Defendants intended that Plaintiffs, their physicians, and the general public would rely on said representations, which did in fact occur.

125. Defendants' negligent misrepresentations prior to, on, and after the date when Plaintiffs and their physicians purchased and used the devices were a substantial factors in causing Plaintiff's injuries and damages, as described herein.

WHEREFORE, Plaintiffs demand judgment against Defendants as hereinafter set forth.

COUNT VI:
FRAUD - MISREPRESENTATION
By all Plaintiffs

126. Plaintiffs re-allege and incorporate by reference each and every allegation contained in the foregoing paragraphs as though fully set forth herein.

127. At all times relevant to this cause, and as detailed above, Defendants intentionally provided Plaintiffs, their physicians, the medical community and the FDA with false or inaccurate information, and/or omitted material information concerning the Device, including, but not limited to, misrepresentations regarding the following topics:

- 1 a. The safety of the device;
- 2 b. The efficacy of the device;
- 3 c. The rate of failure of the device;
- 4 d. The pre-market testing of the device; and
- 5 e. The approved uses of the device.

6 128. The information distributed by Defendants to the public, the medical community,
7 Plaintiffs and their physicians was in the form of reports, press releases, advertising campaigns,
8 labeling materials, print advertisements, commercial media containing material representations, and
9 instructions for use, as well as through their officers, directors, agents, and representatives. These
10 materials contained false and misleading material representations, which included:

- 11 a. That the device was safe, fit, and effective when used for its intended purpose or in a
12 reasonably foreseeable manner;
- 13 b. That it did not pose dangerous health risks in excess of those associated with the use
14 of other similar devices;
- 15 c. That the design of the device would eliminate the risk that pieces of the device could
16 perforate the vena cava, that the devices could tilt, or that fractures could occur and
17 migrate throughout the body;
- 18 d. That the device was safer and more effective than other available IVC filters; and
- 19 e. That the OptEase filter was "easy" to remove.

20 129. Defendants made the foregoing misrepresentations knowing that they were false.
21 These materials included instructions for use and a warning document that was included in the
22 package of the devices implanted in Plaintiffs.

23 130. Defendants' intent and purpose in making these misrepresentations was to deceive
24 and defraud Plaintiffs and their health care providers; to gain the confidence of Plaintiffs and their
25 health care providers; to falsely assure them of the quality of the device and its fitness for use; and
26 to induce the public and the medical community, including Plaintiffs' healthcare providers to
27 request, recommend, prescribe, implant, purchase, and continue to use the device, all in reliance on
28 Defendants' misrepresentations.

1 131. The foregoing representations and omissions by Defendants were in fact false.

2 132. Defendants acted to serve their own interests and having reasons to know
3 consciously disregarded the substantial risk that the device could kill or significantly harm patients.

4 133. In reliance upon the false representations made by Defendants, Plaintiffs and their
5 health care providers were induced to, and did use the device, thereby causing Plaintiffs to sustain
6 the injuries described herein.

7 134. Defendants knew and had reason to know that Plaintiffs, their health care providers,
8 or the general medical community did not have the ability to determine the true facts intentionally
9 concealed and misrepresented by Defendants, and would not have prescribed and implanted same, if
10 the true facts regarding the device had not been concealed and misrepresented by Defendants.

11 135. Defendants had sole access to material facts concerning the defective nature of the
12 TrapEase and OptEase filters and their propensity to cause serious side effects in the form of
13 dangerous injuries and damages to persons who are implanted with the device.

14 136. At the time Defendants failed to disclose and intentionally misrepresented the
15 foregoing facts, and at the time Plaintiffs' health care providers purchased and used these devices,
16 Plaintiffs' health care providers were unaware of Defendants' misrepresentations.

17 137. Plaintiffs' health care providers reasonably relied upon misrepresentations made by
18 Defendants where the concealed and misrepresented facts were critical to understanding the true
19 dangers inherent in the use of the device.

20 138. Defendants' fraudulent misrepresentations prior to, on, and after the date Plaintiffs
21 and their physicians purchased and used the devices were a substantial factor in causing Plaintiffs'
22 injuries and damages, as described herein.

23 WHEREFORE, Plaintiffs demand judgment against defendants as hereinafter set forth.

24
25 **COUNT VII:**
FRAUDULENT CONCEALMENT
26 **By all Plaintiffs**

27 139. Plaintiffs re-allege and incorporate by reference each and every allegation contained
28 in the foregoing paragraphs as though fully set forth herein.

1 140. In marketing and selling the device, defendants concealed material facts from
2 Plaintiffs and their health care providers.

3 141. Defendants' concealed material facts including, but not limited to, the following:

- 4 a. That the device was unsafe and not fit when used for its intended purpose or
5 in a reasonably foreseeable manner;
- 6 b. That the device posed dangerous health risks in excess of those associated
7 with the use of other similar devices;
- 8 c. That there were additional side effects related to implantation and use of the
9 device that were not accurately and completely reflected in the warnings
10 associated with the device;
- 11 d. That the device was not adequately tested to withstand normal placement
12 within the human body; and
- 13 e. That Defendants were aware at the time Plaintiffs' filters were distributed
14 that electropolishing reduced the risk of fracture and was industry standard
15 for NITINOL medical devices.

16 142. Plaintiffs and their healthcare providers were not aware of these and other facts
17 concealed by Defendants.

18 143. The Defendants are and were under a continuing duty to disclose the true character,
19 quality and nature of the device that was implanted in Plaintiff, but instead they concealed them.
20 Defendants' conduct, as described in this complaint, amounts to conduct purposely committed,
21 which Defendants must have realized was dangerous, heedless and reckless, without regard to the
22 consequences or the rights and safety of Plaintiff.

23 144. In concealing these and other facts, Defendants intended to deceive Plaintiffs and
24 their health care providers by concealing said facts.

25 145. Plaintiffs and their healthcare providers reasonably and justifiably relied on
26 Defendants' concealment and deception.

27 146. Defendants' concealment prior to, on, and after the date Plaintiffs and their
28 healthcare providers purchased and used the devices implanted in Plaintiffs was a substantial factor
in causing Plaintiffs' injuries and damages, as described herein.

WHEREFORE, Plaintiffs demand judgment against defendants as hereinafter set forth.

COUNT VIII
EXPRESS WARRANTY
By all Plaintiffs

147. Plaintiffs re-allege and incorporate by reference each and every allegation contained in the foregoing paragraphs as though fully set forth herein.

148. Prior to, on, and after the dates during which Plaintiffs were implanted with these devices, and at all relevant times, Defendants, and each of them, had knowledge of the purpose for which the devices were to be used, and represented the devices to be in all respects safe, effective, and proper for such purpose. Said warranties and representations were made to Plaintiffs and their treating physicians. Plaintiffs and their treating physicians relied on said warranties and representations in deciding to use the device.

149. Defendants used packaging inserts and media advertisements to represent to the medical community and consumers, including plaintiffs and their health care providers, that the TrapEase and OptEase filters: were safe for their intended use; did not pose serious health hazards when used appropriately; were safer and more effective than alternative IVC filters; had been adequately tested for their intended use; would not perforate the vena cava, tilt, or fracture and migrate throughout the body after placement; and that the OptEase filter was "easy" to remove.

150. Defendants, and each of them, breached the above-described express warranties and representations in that the TrapEase and OptEase filters did not conform to these express warranties and representations.

151. Prior to, on, and after the dates during which Plaintiffs and their physicians purchased and used these devices, Defendants, and each of them, were put on notice of the TrapEase and OptEase filters' inability to conform to these express warranties.

152. Defendants' breach of said express warranties and representations prior to, on, and after the date Plaintiffs and their physicians purchased and used the devices was a substantial factor in causing Plaintiffs' injuries and damages, as described herein.

WHEREFORE, Plaintiffs demand judgment against Defendants as hereinafter set forth.

COUNT IX:
BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY

By all Plaintiffs

153. Plaintiffs re-allege and incorporate by reference each and every allegation contained in the foregoing paragraphs as though fully set forth herein.

154. Defendants sold the TrapEase and OptEase filters for Plaintiffs' ultimate use.

155. At all times hereinafter mentioned, Defendants were in the business of developing, designing, licensing, manufacturing, selling, distributing and/or marketing the TrapEase and OptEase filters, including the one implanted in Plaintiffs.

156. Defendants impliedly warranted to Plaintiffs and their physicians that the TrapEase and OptEase filters were safe and of merchantable quality and for the ordinary purpose for which they product was intended and marketed to be used.

157. The representations and implied warranties made by Defendants were false, misleading, and inaccurate because the TrapEase and OptEase filters were defective, unsafe, unreasonably dangerous, and not of merchantable quality, when used as they were marketed and intended to be used. Specifically, at the time Plaintiffs and their physicians purchased and used the devices, the products were not in a merchantable condition in that:

- a. They offered no benefit to patient outcomes,
- b. They suffered an unreasonably high failure and injury rates, and
- c. The surface of the devices were manufactured and designed in such a way that they were distributed with surface damage that substantially increased the risk of fracture.
- d. They were prothrombotic;

158. Defendants' breach of said implied warranties and representations prior to, on, and after the date Plaintiffs and their physicians purchased and used the devices was a substantial factor in causing Plaintiffs' injuries and damages, as described herein.

WHEREFORE, Plaintiffs demand judgment against Defendants as hereinafter set forth.

COUNT X:
GROSS NEGLIGENCE/PUNITIVE DAMAGES ALLEGATIONS

By all Plaintiffs

159. Plaintiffs re-allege and incorporate by reference each and every allegation contained in the foregoing paragraphs as though fully set forth herein.

1 160. Upon information and belief, Plaintiffs allege that as early as 2003, Defendants were
2 aware and had knowledge of the fact that the TrapEase and OptEase filters were defective and
3 unreasonably dangerous and were causing injury and death to patients.

4 161. Data establishes that the failure rates of the TrapEase and OptEase filters are and
5 were much higher than what Defendants have in the past and currently continue to publish to the
6 medical community and members of the public. Further, Defendants were aware or should have
7 been aware that the TrapEase and OptEase filters had substantially higher failure rates than other
8 similar products on the market and are actually prothrombotic. Defendants were also aware that
9 there was no reliable evidence indicating its devices actually improved patient outcomes. Despite
10 these facts, Defendants continued to sell an unreasonably dangerous product while concealing and
11 misrepresenting its risks and benefits to the public, plaintiffs, plaintiffs' health care providers, and
12 the FDA.

13 162. The conduct of Defendants as alleged in this Complaint constitutes willful, wanton,
14 gross, and outrageous corporate conduct that demonstrates a conscious disregard for the safety of
15 Plaintiffs. Defendants had actual knowledge of the dangers presented by TrapEase and OptEase
16 filters, yet consciously failed to act reasonably to:

- 17 a. Inform or warn Plaintiffs, Plaintiffs' physicians, or the public at large of these
18 dangers; and
19 b. Establish and maintain an adequate quality and post-market surveillance
20 system.

21 163. Despite having knowledge as early as 2003 of the unreasonably dangerous and
22 defective nature of the TrapEase and OptEase filters, Defendants consciously disregarded the
23 known risks and continued to actively market and offer for sale the TrapEase and OptEase filters.
24 Plaintiffs further allege that Defendants acted in willful, wanton, gross, and total disregard for the
25 health and safety of the users or consumers of their TrapEase and OptEase filters, acted to serve
26 their own interests, and consciously disregarded the substantial risk that their product might kill or
27 significantly harm patients, or significantly injure the rights of others. Despite this knowledge,
28

1 Defendants consciously pursued a course of conduct knowing that such conduct created a
2 substantial risk of significant harm to other persons.

3 **PRAYER FOR DAMAGES**

4 **WHEREFORE**, Plaintiffs pray for relief against Defendants Cordis Corporation, Confluent
5 Medical Technologies, Inc. and Does 1 through 100, inclusive, on the entire complaint, as follows:

- 6 a. General damages according to proof at the time of trial;
7
8 b. Special (economic) damages, including without limitation, past and future medical
9 expenses and past and future lost wages according to proof at time of trial.
10 c. Pre-judgment and post-judgment interest pursuant to the laws of the State of
11 California;
12 d. Costs of suit incurred herein;
13 e. Punitive damages in an amount sufficient to punish Defendants and deter similar
14 conduct in the future;
15 f. For such further and other relief as this Court deems necessary, just and proper.

17 **DEMAND FOR JURY TRIAL**

18 Plaintiffs hereby demand trial by jury on all issues.

21 DATED: May 20, 2016

20 Respectfully Submitted,

BRENES LAW GROUP

22 /s/ Troy A. Brenes

23 Troy A. Brenes
24 Attorney for Plaintiffs
25
26
27
28

ATTORNEY OR PARTY WITHOUT ATTORNEY (Name, State Bar number, and address): Ramon Rossi Lopez, Bar No. 86361, Matthew Ramon Lopez, Bar No. 263134, Amorina Patrice Lopez, Bar No. 278002 Lopez McHugh LLP, 100 Bayview Circle, Suite 5600, Newport Beach, CA 92660 TELEPHONE NO.: 949-737-1501 FAX NO. (Optional): 949-737-1504 E-MAIL ADDRESS (Optional): ATTORNEY FOR (Name): Plaintiffs		FILED BY FAX CM-015 ALAMEDA COUNTY May 24, 2016 CLERK OF THE SUPERIOR COURT By Lynn Wiley, Deputy CASE NUMBER: RG16814166
SUPERIOR COURT OF CALIFORNIA, COUNTY OF Alameda STREET ADDRESS: 1225 Fallon Street MAILING ADDRESS: CITY AND ZIP CODE: Oakland 94612 BRANCH NAME: Rene C. Davidson Courthouse		
PLAINTIFF/PETITIONER: Heather Quinn et al. DEFENDANT/RESPONDENT: Cordis Corporation et al.		CASE NUMBER: RG16814166
		JUDICIAL OFFICER: Hon. Brad Seligman
NOTICE OF RELATED CASE		DEPT.: 30

Identify, in chronological order according to date of filing, all cases related to the case referenced above.

1. a. Title: **Dcanna Cottrell v. Cordis Corporation et al.**
 b. Case number: **RG16810157**
 c. Court: ☒ same as above
☐ other state or federal court (name and address):
 d. Department:
 e. Case type: ☐ limited civil ☒ unlimited civil ☐ probate ☐ family law ☐ other (specify):
 f. Filing date: **April 5, 2016**
 g. Has this case been designated or determined as "complex?" ☐ Yes ☒ No
 h. Relationship of this case to the case referenced above (check all that apply):
☒ involves the same parties and is based on the same or similar claims.
☒ arises from the same or substantially identical transactions, incidents, or events requiring the determination of the same or substantially identical questions of law or fact.
☐ involves claims against, title to, possession of, or damages to the same property.
☒ is likely for other reasons to require substantial duplication of judicial resources if heard by different judges.
☐ Additional explanation is attached in attachment 1h
 i. Status of case:
☒ pending
☐ dismissed ☐ with ☐ without prejudice
☐ disposed of by judgment
2. a. Title: **Jerry Dunson et al. v. Cordis Corporation et al.**
 b. Case number: **RG16812476**
 c. Court: ☒ same as above
☐ other state or federal court (name and address):
 d. Department:

CM-015

PLAINTIFF/PETITIONER: Heather Quinn et al.	CASE NUMBER:
DEFENDANT/RESPONDENT: Cordis Corporation et al.	RG16814166

2. (continued)

- e. Case type: ☐ limited civil ☒ unlimited civil ☐ probate ☐ family law ☐ other (specify):
- f. Filing date: April 20, 2016
- g. Has this case been designated or determined as "complex?" ☐ Yes ☒ No
- h. Relationship of this case to the case referenced above (check all that apply):
- ☒ involves the same parties and is based on the same or similar claims.
- ☒ arises from the same or substantially identical transactions, incidents, or events requiring the determination of the same or substantially identical questions of law or fact.
- ☐ involves claims against, title to, possession of, or damages to the same property.
- ☒ is likely for other reasons to require substantial duplication of judicial resources if heard by different judges.
- ☐ Additional explanation is attached in attachment 2h
- i. Status of case:
- ☒ pending
- ☐ dismissed ☐ with ☐ without prejudice
- ☐ disposed of by judgment

3. a. Title: Walter Herbert et al. v. Cordis Corporation et al.

b. Case number: RG16814569

- c. Court: ☒ same as above
☐ other state or federal court (name and address):

d. Department: 30

- e. Case type: ☐ limited civil ☒ unlimited civil ☐ probate ☐ family law ☐ other (specify):
- f. Filing date: May 5, 2016
- g. Has this case been designated or determined as "complex?" ☐ Yes ☒ No
- h. Relationship of this case to the case referenced above (check all that apply):
- ☒ involves the same parties and is based on the same or similar claims.
- ☒ arises from the same or substantially identical transactions, incidents, or events requiring the determination of the same or substantially identical questions of law or fact.
- ☐ involves claims against, title to, possession of, or damages to the same property.
- ☒ is likely for other reasons to require substantial duplication of judicial resources if heard by different judges.
- ☐ Additional explanation is attached in attachment 3h
- i. Status of case:
- ☒ pending
- ☐ dismissed ☐ with ☐ without prejudice
- ☐ disposed of by judgment

4. ☒ Additional related cases are described in Attachment 4. Number of pages attached: 3

Date: May 24, 2016

Matthew R. Lopez

(TYPE OR PRINT NAME OF PARTY OR ATTORNEY)



(SIGNATURE OF PARTY OR ATTORNEY)

CM-015

PLAINTIFF/PETITIONER: Heather Quinn et al.	CASE NUMBER:
DEFENDANT/RESPONDENT: Cordis Corporation et al.	RG16814166

**PROOF OF SERVICE BY FIRST-CLASS MAIL
NOTICE OF RELATED CASE**

(NOTE: You cannot serve the Notice of Related Case if you are a party in the action. The person who served the notice must complete this proof of service. The notice must be served on all known parties in each related action or proceeding.)

1. I am at least 18 years old and **not a party to this action**. I am a resident of or employed in the county where the mailing took place, and my residence or business address is (*specify*):

100 Bayview Circle, Suite 5600, Newport Beach, CA 92660

2. I served a copy of the *Notice of Related Case* by enclosing it in a sealed envelope with first-class postage fully prepaid and (*check one*):
- a. ☒ deposited the sealed envelope with the United States Postal Service.
 - b. ☐ placed the sealed envelope for collection and processing for mailing, following this business's usual practices, with which I am readily familiar. On the same day correspondence is placed for collection and mailing, it is deposited in the ordinary course of business with the United States Postal Service.

3. The *Notice of Related Case* was mailed:
- a. on (*date*): May 19, 2016
 - b. from (*city and state*): Newport Beach, CA

4. The envelope was addressed and mailed as follows:

a. Name of person served:
Cordis Corporation/CT Corporation
Street address: 818 W. 7th St., Suite 930
City: Los Angeles
State and zip code: CA, 90017

c. Name of person served:
Troy Brenes / Brenes Law Group
Street address: 16A Journey, Ste 200
City: Aliso Viejo
State and zip code: CA, 92656

b. Name of person served:
Bonny E. Sweeney / Hausfeld LLP
Street address: 600 Montgomery St. Ste 3200
City: San Francisco
State and zip code: CA, 94111

d. Name of person served:
Cardinal Health, Inc./ CT Corporation
Street address: 1300 East Ninth Street
City: Cleveland
State and zip code: OH, 44111

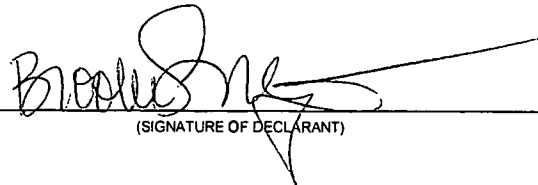
☒ Names and addresses of additional persons served are attached. (*You may use form POS-030(P).*)

I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct.

Date: May 24, 2016

Brooke Meyers

(TYPE OR PRINT NAME OF DECLARANT)

► 

(SIGNATURE OF DECLARANT)

MC-025

SHORT TITLE: Heather Quinn et al. v. Cordis Corporation, et al.	CASE NUMBER: RG16814166
--	----------------------------

ATTACHMENT (Number): 4

(This Attachment may be used with any Judicial Council form.)

<p>a. Title: Geanice Grant et al v. Cordis Corporation et al.</p> <p>b. Case Number: RG16814688</p> <p>c. Court: Same as above</p> <p>d. Department: 30</p> <p>e. Case type: unlimited civil</p> <p>f. Filing date: May 6, 2016</p> <p>g. Has this case been designated or determined as "complex?" No</p> <p>h. Relationship of this case to the case referenced above:</p> <ul style="list-style-type: none"> - involves the same parties and is based on the same or similar claims - arises from the same of substantially identical transactions, incidents, or events requiring the determination of the same or substantially identical questions of law or fact. <p>i. Status of case: pending</p> <p>a. Title: David Resovsky et al. v. Cordis Corporation et al.</p> <p>b. Case Number: RG16814745</p> <p>c. Court: Same as above</p> <p>d. Department:</p> <p>e. Case type: unlimited civil</p> <p>f. Filing date: May 6, 2016</p> <p>g. Has this case been designated or determined as "complex?" No</p> <p>h. Relationship of this case to the case referenced above:</p> <ul style="list-style-type: none"> - involves the same parties and is based on the same or similar claims - arises from the same of substantially identical transactions, incidents, or events requiring the determination of the same or substantially identical questions of law or fact. - is likely for other reasons to require substantial duplication of judicial resources if heard by different judges. <p>i. Status of case: pending</p>

(If the item that this Attachment concerns is made under penalty of perjury, all statements in this Attachment are made under penalty of perjury.)

Page 4 of 6

(Add pages as required)

MC-025

SHORT TITLE: Heather Quinn et al. v. Cordis Corporation et al.	CASE NUMBER: RG16814166
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ATTACHMENT (Number): 5

(This Attachment may be used with any Judicial Council form.)

- a. Title: Michael Barber et al. v. Cordis Corporation et al.
b. Case Number: RG16814687
c. Court: Same as above
d. Department:
e. Case type: unlimited civil
f. Filing date: May 20, 2016
g. Has this case been designated or determined as "complex?" No
h. Relationship of this case to the case referenced above:
- involves the same parties and is based on the same or similar claims
- arises from the same of substantially identical transactions, incidents, or events requiring the determination of the same or substantially identical questions of law or fact.
- is likely for other reasons to require substantial duplication of judicial resources if heard by different judges.
i. Status of case: pending

- a. Title: Lisa Oehring et al. v. Cordis Corporation et al.
b. Case Number: RG16816490
c. Court: Same as above
d. Department:
e. Case type: unlimited civil
f. Filing date: May 20, 2016
g. Has this case been designated or determined as "complex?" No
h. Relationship of this case to the case referenced above:
- involves the same parties and is based on the same or similar claims
- arises from the same of substantially identical transactions, incidents, or events requiring the determination of the same or substantially identical questions of law or fact.
- is likely for other reasons to require substantial duplication of judicial resources if heard by different judges.
i. Status of case: pending

(If the item that this Attachment concerns is made under penalty of perjury, all statements in this Attachment are made under penalty of perjury.)

Page 5 of 6

(Add pages as required)

MC-025

SHORT TITLE: Heather Quinn et al. v. Cordis Corporation et al.	CASE NUMBER: RG16814166
---	----------------------------

ATTACHMENT (Number): 6

(This Attachment may be used with any Judicial Council form.)

- a. Title: Wanda Holden et al. v. Cordis Corporation et al.
- b. Case Number: RG16816600
- c. Court: Same as above
- d. Department:
- e. Case type: unlimited civil
- f. Filing date: May 20, 2016
- g. Has this case been designated or determined as "complex?" No
- h. Relationship of this case to the case referenced above:
 - involves the same parties and is based on the same or similar claims
 - arises from the same or substantially identical transactions, incidents, or events requiring the determination of the same or substantially identical questions of law or fact.
 - is likely for other reasons to require substantial duplication of judicial resources if heard by different judges.
- i. Status of case: pending

(If the item that this Attachment concerns is made under penalty of perjury, all statements in this Attachment are made under penalty of perjury.)

Page 6 of 6

(Add pages as required)

PROOF OF SERVICE
STATE OF CALIFORNIA, COUNTY OF ORANGE

I am a resident of the county aforesaid: I am over the age of eighteen years and not a party to the within entitled action: my business address is 100 Bayview Circle, Suite 5600, Newport Beach, California 92660.

On May 27, 2016 I served the within **DECLARATION OF MATTHEW R. LOPEZ IN SUPPORT OF MOTION FOR CONSOLIDATION OF CASES** on interested parties in said action, by placing a true copy thereof enclosed in a sealed envelope with postage thereon fully prepaid, in the United States mail in Newport Beach, California addressed as follows: SEE ATTACHED SERVICE LIST

☒ **BY REGULAR MAIL:** I am readily familiar with the firm's practice of collection and processing correspondence for mailing. Under that practice it would be deposited with US Postal Service on that same day with postage thereon fully prepaid at Newport Beach, California in the ordinary course of business. I am aware that on motion of the party served, service is presumed invalid if postal cancellation date or postage meter date is more than one day after date of deposit for mailing in affidavit.

☐ **BY FEDERAL EXPRESS/UPS OVERNIGHT DELIVERY SERVICE:** Said documents were delivered to an authorized courier or driver authorized by the express service carrier to receive documents with delivery fees paid or provided for.

☐ **BY FACSIMILE:** Said documents were transmitted by facsimile transmission and the transmission was reported as complete and without error.

☐ **BY E-MAIL:** Said documents were transmitted by electronic mail transmission and the transmission was reported as complete and without error.

☐ **BY PERSONAL SERVICE:** Said documents were personally delivered by:

☐ leaving copies at the attorney's office, in an envelope or package clearly labeled to identify the attorney being served;

☐ with a receptionist or, with a person having charge thereof;

☐ in a conspicuous place in the office between the hours of 9 a.m. and 5 p.m.

☐ by leaving copies at the individual's residence with some person of not less than 18 years of age;

☐ in a conspicuous place in between the hours of 8 in the morning and 6 p.m.

I declare, under penalty of perjury under the laws of the State of California that the foregoing is true and correct. Executed on **May 27, 2016** at Newport Beach, California.


 Brooke Meyers

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24 818 West Seventh Street, Suite 930
25 Los Angeles, CA 90017

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Attorneys for Plaintiffs

**SUPERIOR COURT OF THE STATE OF CALIFORNIA
 FOR THE COUNTY OF ALAMEDA**

JERRY DUNSON, *et al.*;

Plaintiffs,

vs.

CORDIS CORPORATION, a corporation, and
 DOES 1 through 100, inclusive,

Defendants.

Case No.: RG16812476

**[PROPOSED] ORDER CONSOLIDATING
 CASES**

Date: June 28, 2016
 Time: 3:00 p.m.
 Dept.: 30
 Reservation No.: R-1743489

Judge: Hon. Brad Seligman

Trial Date: None
 Action Filed: April 20, 2016

*(Filed concurrently with Notice of Motion;
 Memorandum of Points and Authorities In Support
 of Motion; and Declaration of Matthew R. Lopez)*

HEATHER QUINN, *et al.*;

Plaintiffs,

vs.

CORDIS CORPORATION; JOHNSON &
 JOHNSON; and DOES 1 through 50;

Case No. RG16814166

Judge: Hon. Brad Seligman

Trial Date: None
 Action Filed: May 3, 2016

1 Defendants.

2
3 WALTER HERBERT, *et al.*;

Case No.: RG16814569

4 Plaintiffs,

Judge: Hon. Brad Seligman

5 vs.

Trial Date: None

6 CORDIS CORPORATION; JOHNSON &
7 JOHNSON; and DOES 1 through 50;

Action Filed: May 5, 2016

8 Defendants.

9
10 GEANICE GRANT, *et al.*;

Case No.: RG16814688

11 Plaintiffs,

Judge: Hon. Brad Seligman

12 vs.

Trial Date: None

13 CORDIS CORPORATION; JOHNSON &
14 JOHNSON; and DOES 1 through 50;

Action Filed: May 6, 2016

15 Defendants.

16 DAVID RESOVSKY, *et al.*;

Case No.: RG16814745

17 Plaintiffs,

Judge: Hon. Brad Seligman

18 vs.

Trial Date: None

19 CORDIS CORPORATION, a corporation, and
20 DOES 1 through 100, inclusive,

Action Filed: May 6, 2016

21 Defendants.

22
23 MICHAEL BARBER, *et al.*;

Case No.: RG16816487

24 Plaintiffs,

Judge: Hon. Brad Seligman

25 vs.

Trial Date: None

26 CORDIS CORPORATION, a corporation;
27 JOHNSON & JOHNSON, a corporation;
28 CARDINAL HEALTH, INC., a corporation;
and DOES 1 through 50;

Action Filed: May 20, 2016

Defendants.

LISA OEHRING, *et al.*;

Plaintiffs,

vs.

CORDIS CORPORATION, a corporation;
JOHNSON & JOHNSON, a corporation;
CARDINAL HEALTH, INC., a corporation;
and DOES 1 through 50;

Defendants.

Case No.: RG16816490

Judge: Hon. Brad Seligman

Trial Date: None

Action Filed: May 20, 2016

WANDA HOLDEN, *et al.*;

Plaintiffs,

vs.

CORDIS CORPORATION, a corporation,
CONFLUENT MEDICAL TECHNOLOGIES,
INC., a corporation; and DOES 1 through 100,
inclusive,

Defendants.

Case No.: RG16816600

Judge: Hon. Brad Seligman

Trial Date: None

Action Filed: May 20, 2016

Having read the motion, the memoranda and declarations filed by all the parties, and having heard argument of counsel, the Court finds that the issues of law and fact underlying each Related Action are common to each case such that consolidation for purposes of pretrial proceedings and discovery, and the implementation of a bellwether-trial process, will avoid unnecessary duplication of evidence and procedures, will avoid the risk of inconsistent adjudications, will avoid many of the same witnesses testifying on common issues in all actions, will promote judicial economy and convenience, will not be unduly burdensome and not adversely affect the rights of any party.

THEREFORE, IT IS ORDERED THAT the Motion for Consolidation of Cases is **GRANTED**.

IT IS FURTHER ORDERED THAT, to the extent a pleading, motion, order or other document brought by or before the Court is applicable to all Consolidated Actions, it shall include in the caption

1 that the document is "Related to ALL Cases." If brought by the parties, it shall be filed and docketed in
2 the Master File under Master File No. _____.

3 Documents intended to apply only to a particular case shall indicate in the caption the Case Number of
4 the case to which the documents apply.

5 IT IS FURTHER ORDERED THAT _____
6 _____
7 _____
8 _____
9 _____

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11 Dated: _____
12

13 _____
14 Honorable Brad Seligman
15 JUDGE OF THE SUPERIOR COURT
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PROOF OF SERVICE
STATE OF CALIFORNIA, COUNTY OF ORANGE

I am a resident of the county aforesaid: I am over the age of eighteen years and not a party to the within entitled action: my business address is 100 Bayview Circle, Suite 5600, Newport Beach, California 92660.

On May 27, 2016 I served the within **PROPOSED ORDER CONSOLIDATING CASES** on interested parties in said action, by placing a true copy thereof enclosed in a sealed envelope with postage thereon fully prepaid, in the United States mail in Newport Beach, California addressed as follows: SEE ATTACHED SERVICE LIST

 X **BY REGULAR MAIL:** I am readily familiar with the firm's practice of collection and processing correspondence for mailing. Under that practice it would be deposited with US Postal Service on that same day with postage thereon fully prepaid at Newport Beach, California in the ordinary course of business. I am aware that on motion of the party served, service is presumed invalid if postal cancellation date or postage meter date is more than one day after date of deposit for mailing in affidavit.

 BY FEDERAL EXPRESS/UPS OVERNIGHT DELIVERY SERVICE: Said documents were delivered to an authorized courier or driver authorized by the express service carrier to receive documents with delivery fees paid or provided for.

 BY FACSIMILE: Said documents were transmitted by facsimile transmission and the transmission was reported as complete and without error.

 BY E-MAIL: Said documents were transmitted by electronic mail transmission and the transmission was reported as complete and without error.

 BY PERSONAL SERVICE: Said documents were personally delivered by:

[] leaving copies at the attorney's office, in an envelope or package clearly labeled to identify the attorney being served;

[] with a receptionist or, with a person having charge thereof;

[] in a conspicuous place in the office between the hours of 9 a.m. and 5 p.m.

[] by leaving copies at the individual's residence with some person of not less than 18 years of age;

[] in a conspicuous place in between the hours of 8 in the morning and 6 p.m.

I declare, under penalty of perjury under the laws of the State of California that the foregoing is true and correct. Executed on **May 27, 2016** at Newport Beach, California.



 Brooke Meyers

SERVICE LIST

Troy Brenes
BRENES LAW GROUP
16A Journey Suite 200
Aliso Viejo, CA 92656
Telephone: 949-397-9360
Facsimile: 949-607-4192

Bonny E. Sweeney
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Gregory David Rueb
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1401 Willow Pass Road, Suite 880
Concord, CA 94520
Telephone: (925) 602-3400
Facsimile: (925) 602-0622

ATTORNEYS FOR PLAINTIFFS

Andrew D. Kaplan
Rebecca B. Chaney
Crowell & Moring LLP
1001 Pennsylvania Avenue, NW
Washington, DC 20004
Telephone: 202-624-2500
Facsimile: 202-628-5116

ATTORNEYS FOR DEFENDANT CORDIS CORPORATION

Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933

Cardinal Health, Inc.
CT Corporation

1 1300 East Ninth Street
2 Cleveland, OH 44111

3 Confluent Medical Technologies
4 CT Corporation
5 818 West Seventh Street, Suite 930
6 Los Angeles, CA 90017

6 ***DEFENDANTS***

EXHIBIT B



**Service of Process
Transmittal**

05/10/2016

CT Log Number 529144599

TO: Magdalene Riley
Cardinal Health, Inc.
7000 Cardinal Pl
Dublin, OH 43017-1091

RE: Process Served in California

FOR: Cordis Corporation (Domestic State: FL)

ENCLOSED ARE COPIES OF LEGAL PROCESS RECEIVED BY THE STATUTORY AGENT OF THE ABOVE COMPANY AS FOLLOWS:

TITLE OF ACTION: DAVID RESOVSKY, et al., Pltfs. vs. Cordis Corporation, etc., et al., Dfts.

DOCUMENT(S) SERVED: Summons, Cover Sheet, Instructions, Complaint

COURT/AGENCY: Alameda County - Superior Court - Oakland, CA
Case # RG16814745

NATURE OF ACTION: Product Liability Litigation - Manufacturing Defect - Personal Injury - OptEase
Permanent Vena Cava Filter

ON WHOM PROCESS WAS SERVED: C T Corporation System, Los Angeles, CA

DATE AND HOUR OF SERVICE: By Process Server on 05/10/2016 at 13:25

JURISDICTION SERVED : California

APPEARANCE OR ANSWER DUE: Within 30 days after this summons and legal papers are served on you

ATTORNEY(S) / SENDER(S): Troy A. Brenes
Brenes Law Group
16A Journey, Ste. 200
Aliso Viejo, CA 92656
(949)-397-9360

ACTION ITEMS: CT has retained the current log, Retain Date: 05/11/2016, Expected Purge Date:
05/16/2016

Image SOP

Email Notification, Laura Garza laura.garza@cardinalhealth.com

Email Notification, David Orensten david.orensten@cardinalhealth.com

Email Notification, Corey Goldsand corey.goldsand@cardinalhealth.com

Email Notification, Brenda Cleveland brenda.cleveland@cardinalhealth.com

Email Notification, Magdalene Riley magdalene.riley@cardinalhealth.com

Email Notification, Amanda Pashi amanda.pashi@cardinalhealth.com

Email Notification, Cindy Fricke cindy.fricke@cardinalhealth.com



**Service of Process
Transmittal**

05/10/2016

CT Log Number 529144599

TO: Magdalene Riley
Cardinal Health, Inc.
7000 Cardinal Pl
Dublin, OH 43017-1091

RE: Process Served in California

FOR: Cordis Corporation (Domestic State: FL)

Email Notification, Joshua Stine joshua.stine@cardinalhealth.com

SIGNED: C T Corporation System
ADDRESS: 818 West Seventh Street
Los Angeles, CA 90017
TELEPHONE: 213-337-4615

1:25

SUM-100

SUMMONS (CITACION JUDICIAL)

FOR COURT USE ONLY
(SOLO PARA USO DE LA CORTE)

ENDORSED
FILED
ALAMEDA COUNTY

MAY 06 2016

CLERK OF THE SUPERIOR COURT

By Sue Pesko

Deputy

COPY

NOTICE TO DEFENDANT:
(AVISO AL DEMANDADO):

CORDIS CORPORATION, et al.

YOU ARE BEING SUED BY PLAINTIFF:
(LO ESTÁ DEMANDANDO EL DEMANDANTE):

David Resovsky, George Todd, David Brown, Gwen Kramer

NOTICE! You have been sued. The court may decide against you without your being heard unless you respond within 30 days. Read the information below.

You have 30 CALENDAR DAYS after this summons and legal papers are served on you to file a written response at this court and have a copy served on the plaintiff. A letter or phone call will not protect you. Your written response must be in proper legal form if you want the court to hear your case. There may be a court form that you can use for your response. You can find these court forms and more information at the California Courts Online Self-Help Center (www.courtinfo.ca.gov/selfhelp), your county law library, or the courthouse nearest you. If you cannot pay the filing fee, ask the court clerk for a fee waiver form. If you do not file your response on time, you may lose the case by default, and your wages, money, and property may be taken without further warning from the court.

There are other legal requirements. You may want to call an attorney right away. If you do not know an attorney, you may want to call an attorney referral service. If you cannot afford an attorney, you may be eligible for free legal services from a nonprofit legal services program. You can locate these nonprofit groups at the California Legal Services Web site (www.lawhelpcalifornia.org), the California Courts Online Self-Help Center (www.courtinfo.ca.gov/selfhelp), or by contacting your local court or county bar association. **NOTE:** The court has a statutory lien for waived fees and costs on any settlement or arbitration award of \$10,000 or more in a civil case. The court's lien must be paid before the court will dismiss the case. **¡AVISO!** Lo han demandado. Si no responde dentro de 30 días, la corte puede decidir en su contra sin escuchar su versión. Lea la información a continuación.

Tiene 30 DÍAS DE CALENDARIO después de que le entreguen esta citación y papeles legales para presentar una respuesta por escrito en esta corte y hacer que se entregue una copia al demandante. Una carta o una llamada telefónica no lo protegen. Su respuesta por escrito tiene que estar en formato legal correcto si desea que procesen su caso en la corte. Es posible que haya un formulario que usted pueda usar para su respuesta. Puede encontrar estos formularios de la corte y más información en el Centro de Ayuda de las Cortes de California (www.sucorte.ca.gov), en la biblioteca de leyes de su condado o en la corte que le quede más cerca. Si no puede pagar la cuota de presentación, pida al secretario de la corte que le dé un formulario de exención de pago de cuotas. Si no presenta su respuesta a tiempo, puede perder el caso por incumplimiento y la corte le podrá quitar su sueldo, dinero y bienes sin más advertencia.

Hay otros requisitos legales. Es recomendable que llame a un abogado inmediatamente. Si no conoce a un abogado, puede llamar a un servicio de remisión a abogados. Si no puede pagar a un abogado, es posible que cumpla con los requisitos para obtener servicios legales gratuitos de un programa de servicios legales sin fines de lucro. Puede encontrar estos grupos sin fines de lucro en el sitio web de California Legal Services, (www.lawhelpcalifornia.org), en el Centro de Ayuda de las Cortes de California, (www.sucorte.ca.gov) o poniéndose en contacto con la corte o el colegio de abogados locales. **AVISO:** Por ley, la corte tiene derecho a reclamar las cuotas y los costos exentos por imponer un gravamen sobre cualquier recuperación de \$10,000 o más de valor recibida mediante un acuerdo o una concesión de arbitraje en un caso de derecho civil. Tiene que pagar el gravamen de la corte antes de que la corte pueda desechar el caso.

The name and address of the court is:

(El nombre y dirección de la corte es): Alameda County Superior Court

1225 Fallon Street
Oakland, California 94612

CASE NUMBER **1616814745**
(Número del caso)

The name, address, and telephone number of plaintiff's attorney, or plaintiff without an attorney, is:

(El nombre, la dirección y el número de teléfono del abogado del demandante, o del demandante que no tiene abogado, es):

Troy A. Brenes, 16A Journey, Suite 200, Aliso Viejo, CA 92656 (949)-397-9360

DATE: May 6, 2016

(Fecha)

Chad Finke

Clerk, by
(Secretario)Sue PeskoDeputy
(Adjunto)

(For proof of service of this summons, use Proof of Service of Summons (form POS-010).)

(Para prueba de entrega de esta citación use el formulario Proof of Service of Summons, (POS-010)).

[SEAL]

NOTICE TO THE PERSON SERVED: You are served

1. ☐ as an individual defendant.
2. ☐ as the person sued under the fictitious name of (specify):

3. ☒ on behalf of (specify): CORDIS CORPORATION

- under: ☒ CCP 416.10 (corporation) ☐ CCP 416.60 (minor)
☐ CCP 416.20 (defunct corporation) ☐ CCP 416.70 (conservatee)
☐ CCP 416.40 (association or partnership) ☐ CCP 416.90 (authorized person)
☐ other (specify):

4. ☐ by personal delivery on (date):

CM-010

COPY

ATTORNEY OR PARTY WITHOUT ATTORNEY (Name, State Bar number, and address): Troy A. Brenes (CA Bar No. 249776) Brenes Law Group 16A Journey, Ste. 200 Aliso Viejo, CA 92656 TELEPHONE NO.: (949)-397-9360 FAX NO.: (949)-607-4192 ATTORNEY FOR (Name):		FOR COURT USE ONLY ENDORSED FILED ALAMEDA COUNTY MAY 06 2016 CLERK OF THE SUPERIOR COURT By <u>Sue Pesko</u> Deputy
SUPERIOR COURT OF CALIFORNIA, COUNTY OF Alameda STREET ADDRESS: 1225 Fallon Street MAILING ADDRESS: CITY AND ZIP CODE: Oakland, CA 94612 BRANCH NAME: Oakland - Rene C. Davidson Courthouse		
CASE NAME: David Resovsky v. Cordis Corporation, et al.		CASE NUMBER: RG16814745
CIVIL CASE COVER SHEET <input checked="" type="checkbox"/> Unlimited (Amount demanded exceeds \$25,000) <input type="checkbox"/> Limited (Amount demanded is \$25,000 or less)		Complex Case Designation <input type="checkbox"/> Counter <input type="checkbox"/> Joinder Filed with first appearance by defendant (Cal. Rules of Court, rule 3.402)
		JUDGE: DEPT:

Items 1-6 below must be completed (see instructions on page 2).

1. Check one box below for the case type that best describes this case:

Auto Tort <input type="checkbox"/> Auto (22) <input type="checkbox"/> Uninsured motorist (46) Other PI/PD/WD (Personal Injury/Property Damage/Wrongful Death) Tort <input type="checkbox"/> Asbestos (04) <input type="checkbox"/> Product liability (24) <input type="checkbox"/> Medical malpractice (45) <input type="checkbox"/> Other PI/PD/WD (23) Non-PI/PD/WD (Other) Tort <input type="checkbox"/> Business tort/unfair business practice (07) <input type="checkbox"/> Civil rights (08) <input type="checkbox"/> Defamation (13) <input type="checkbox"/> Fraud (16) <input type="checkbox"/> Intellectual property (19) <input type="checkbox"/> Professional negligence (25) <input type="checkbox"/> Other non-PI/PD/WD tort (35) Employment <input type="checkbox"/> Wrongful termination (36) <input type="checkbox"/> Other employment (15)	Contract <input type="checkbox"/> Breach of contract/warranty (06) <input type="checkbox"/> Rule 3.740 collections (09) <input type="checkbox"/> Other collections (09) <input type="checkbox"/> Insurance coverage (18) <input type="checkbox"/> Other contract (37) Real Property <input type="checkbox"/> Eminent domain/Inverse condemnation (14) <input type="checkbox"/> Wrongful eviction (33) <input type="checkbox"/> Other real property (26) Unlawful Detainer <input type="checkbox"/> Commercial (31) <input type="checkbox"/> Residential (32) <input type="checkbox"/> Drugs (38) Judicial Review <input type="checkbox"/> Asset forfeiture (05) <input type="checkbox"/> Petition re: arbitration award (11) <input type="checkbox"/> Writ of mandate (02) <input type="checkbox"/> Other judicial review (39)	Provisionally Complex Civil Litigation (Cal. Rules of Court, rules 3.400-3.403) <input type="checkbox"/> Antitrust/Trade regulation (03) <input type="checkbox"/> Construction defect (10) <input checked="" type="checkbox"/> Mass tort (40) <input type="checkbox"/> Securities litigation (28) <input type="checkbox"/> Environmental/Toxic tort (30) <input type="checkbox"/> Insurance coverage claims arising from the above listed provisionally complex case types (41) Enforcement of Judgment <input type="checkbox"/> Enforcement of judgment (20) Miscellaneous Civil Complaint <input type="checkbox"/> RICO (27) <input type="checkbox"/> Other complaint (not specified above) (42) Miscellaneous Civil Petition <input type="checkbox"/> Partnership and corporate governance (21) <input type="checkbox"/> Other petition (not specified above) (43)
--	--	--

2. This case ☒ is ☐ is not complex under rule 3.400 of the California Rules of Court. If the case is complex, mark the factors requiring exceptional judicial management:
- | | |
|---|---|
| a. <input type="checkbox"/> Large number of separately represented parties | d. <input checked="" type="checkbox"/> Large number of witnesses |
| b. <input checked="" type="checkbox"/> Extensive motion practice raising difficult or novel issues that will be time-consuming to resolve | e. <input checked="" type="checkbox"/> Coordination with related actions pending in one or more courts in other counties, states, or countries, or in a federal court |
| c. <input checked="" type="checkbox"/> Substantial amount of documentary evidence | f. <input type="checkbox"/> Substantial postjudgment judicial supervision |
3. Remedies sought (check all that apply): a. ☒ monetary b. ☐ nonmonetary; declaratory or injunctive relief c. ☒ punitive
4. Number of causes of action (specify): 9
5. This case ☐ is ☒ is not a class action suit.
6. If there are any known related cases, file and serve a notice of related case. (You may use form CM-015.)

Date: May 6, 2016

Troy A. Brenes

(TYPE OR PRINT NAME)

(SIGNATURE OF PARTY OR ATTORNEY FOR PARTY)

NOTICE

- Plaintiff must file this cover sheet with the first paper filed in the action or proceeding (except small claims cases or cases filed under the Probate Code, Family Code, or Welfare and Institutions Code). (Cal. Rules of Court, rule 3.220.) Failure to file may result in sanctions.
- File this cover sheet in addition to any cover sheet required by local court rule.
- If this case is complex under rule 3.400 et seq. of the California Rules of Court, you must serve a copy of this cover sheet on all other parties to the action or proceeding.
- Unless this is a collections case under rule 3.740 or a complex case, this cover sheet will be used for statistical purposes only.

Page 1 of 2

CM-010

INSTRUCTIONS ON HOW TO COMPLETE THE COVER SHEET

To Plaintiffs and Others Filing First Papers. If you are filing a first paper (for example, a complaint) in a civil case, you **must** complete and file, along with your first paper, the *Civil Case Cover Sheet* contained on page 1. This information will be used to compile statistics about the types and numbers of cases filed. You must complete items 1 through 6 on the sheet. In item 1, you must check **one** box for the case type that best describes the case. If the case fits both a general and a more specific type of case listed in item 1, check the more specific one. If the case has multiple causes of action, check the box that best indicates the **primary** cause of action. To assist you in completing the sheet, examples of the cases that belong under each case type in item 1 are provided below. A cover sheet must be filed only with your initial paper. Failure to file a cover sheet with the first paper filed in a civil case may subject a party, its counsel, or both to sanctions under rules 2.30 and 3.220 of the California Rules of Court.

To Parties in Rule 3.740 Collections Cases. A "collections case" under rule 3.740 is defined as an action for recovery of money owed in a sum stated to be certain that is not more than \$25,000, exclusive of interest and attorney's fees, arising from a transaction in which property, services, or money was acquired on credit. A collections case does not include an action seeking the following: (1) tort damages, (2) punitive damages, (3) recovery of real property, (4) recovery of personal property, or (5) a prejudgment writ of attachment. The identification of a case as a rule 3.740 collections case on this form means that it will be exempt from the general time-for-service requirements and case management rules, unless a defendant files a responsive pleading. A rule 3.740 collections case will be subject to the requirements for service and obtaining a judgment in rule 3.740.

To Parties in Complex Cases. In complex cases only, parties must also use the *Civil Case Cover Sheet* to designate whether the case is complex. If a plaintiff believes the case is complex under rule 3.400 of the California Rules of Court, this must be indicated by completing the appropriate boxes in items 1 and 2. If a plaintiff designates a case as complex, the cover sheet must be served with the complaint on all parties to the action. A defendant may file and serve no later than the time of its first appearance a joinder in the plaintiff's designation, a counter-designation that the case is not complex, or, if the plaintiff has made no designation, a designation that the case is complex.

CASE TYPES AND EXAMPLES**Auto Tort**

Auto (22)—Personal Injury/Property Damage/Wrongful Death
Uninsured Motorist (46) (*if the case involves an uninsured motorist claim subject to arbitration, check this item instead of Auto*)

Other P/DPD/WD (Personal Injury/Property Damage/Wrongful Death) Tort

Asbestos (04)
Asbestos Property Damage
Asbestos Personal Injury/Wrongful Death
Product Liability (*not asbestos or toxic/environmental*) (24)
Medical Malpractice (45)
Medical Malpractice—Physicians & Surgeons
Other Professional Health Care Malpractice
Other P/DPD/WD (23)
Premises Liability (e.g., slip and fall)
Intentional Bodily Injury/PD/WD (e.g., assault, vandalism)
Intentional Infliction of Emotional Distress
Negligent Infliction of Emotional Distress
Other P/DPD/WD

Non-P/DPD/WD (Other) Tort

Business Tort/Unfair Business Practice (07)
Civil Rights (e.g., discrimination, false arrest) (*not civil harassment*) (08)
Defamation (e.g., slander, libel) (13)
Fraud (16)
Intellectual Property (19)
Professional Negligence (25)
Legal Malpractice
Other Professional Malpractice (*not medical or legal*)
Other Non-P/DPD/WD Tort (35)

Employment

Wrongful Termination (36)
Other Employment (15)

Contract

Breach of Contract/Warranty (06)
Breach of Rental/Lease
Contract (*not unlawful detainer or wrongful eviction*)
Contract/Warranty Breach—Seller
Plaintiff (*not fraud or negligence*)
Negligent Breach of Contract/Warranty
Other Breach of Contract/Warranty
Collections (e.g., money owed, open book accounts) (09)
Collection Case—Seller Plaintiff
Other Promissory Note/Collections Case
Insurance Coverage (*not provisionally complex*) (18)
Auto Subrogation
Other Coverage
Other Contract (37)
Contractual Fraud
Other Contract Dispute

Real Property

Eminent Domain/Inverse Condemnation (14)
Wrongful Eviction (33)
Other Real Property (e.g., quiet title) (26)
Writ of Possession of Real Property
Mortgage Foreclosure
Quiet Title
Other Real Property (*not eminent domain, landlord/tenant, or foreclosure*)

Unlawful Detainer

Commercial (31)
Residential (32)
Drugs (38) (*if the case involves illegal drugs, check this item; otherwise, report as Commercial or Residential*)

Judicial Review

Asset Forfeiture (05)
Petition Re: Arbitration Award (11)
Writ of Mandate (02)
Writ—Administrative Mandamus
Writ—Mandamus on Limited Court Case Matter
Writ—Other Limited Court Case Review
Other Judicial Review (39)
Review of Health Officer Order
Notice of Appeal—Labor
Commissioner Appeals

Provisionally Complex Civil Litigation (Cal. Rules of Court Rules 3.400–3.403)

Antitrust/Trade Regulation (03)
Construction Defect (10)
Claims Involving Mass Tort (40)
Securities Litigation (28)
Environmental/Toxic Tort (30)
Insurance Coverage Claims (*arising from provisionally complex case type listed above*) (41)

Enforcement of Judgment

Enforcement of Judgment (20)
Abstract of Judgment (Out of County)
Confession of Judgment (*non-domestic relations*)
Sister State Judgment
Administrative Agency Award (*not unpaid taxes*)
Petition/Certification of Entry of Judgment on Unpaid Taxes
Other Enforcement of Judgment Case

Miscellaneous Civil Complaint

RICO (27)
Other Complaint (*not specified above*) (42)
Declaratory Relief Only
Injunctive Relief Only (*non-harassment*)
Mechanics Lien
Other Commercial Complaint Case (*non-tort/non-complex*)
Other Civil Complaint (*non-tort/non-complex*)

Miscellaneous Civil Petition

Partnership and Corporate Governance (21)
Other Petition (*not specified above*) (43)
Civil Harassment
Workplace Violence
Elder/Dependent Adult Abuse
Election Contest
Petition for Name Change
Petition for Relief From Late Claim
Other Civil Petition

COPY

1 Troy A. Brenes, SBN 249776
 2 BRÉNES LAW GROUP
 16 A Journey, Suite 200
 3 Aliso Viejo, CA 92656
 tbrenes@breneslawgroup.com
 4 Telephone: (949) 397-9360
 Facsimile: (949) 607-4192
 Attorney for Plaintiffs

ENDORSED
 FILED
 ALAMEDA COUNTY

MAY 06 2016

CLERK OF THE SUPERIOR COURT
 By Sue Resko Deputy

6
 7 SUPERIOR COURT OF CALIFORNIA, COUNTY OF ALAMEDA
 8 RENE C. DAVIDSON ALAMEDA COUNTY COURTHOUSE

9 DAVID RESOVSKY, GEORGE TODD, DAVID)
 BROWN, GWEN KRAMER)

Case No.: **RG 1681 4745**

Plaintiff(s),

COMPLAINT FOR DAMAGES

vs.

DEMAND FOR JURY TRIAL

12
 13 CORDIS CORPORATION, a corporation,
 and DOES 1 through 100, inclusive,

Defendant(s).

18 Plaintiffs DAVID RESOVSKY, GEORGE TODD, DAVID BROWN, AND GWEN
 19 KRAMER hereby sue defendants CORDIS CORPORATION and DOES 1 through 100 and allege
 20 as follows:

21 **PARTIES**

22 1. Plaintiff David Resovsky underwent placement of an OptEase™ Permanent Vena
 23 Cava Filter (referred to as "filter," "device" or "product" hereinafter) at Cleveland Clinic in Ohio.
 24 The device subsequently malfunctioned and caused, *inter alia*, thrombosis of the inferior vena cava.
 25 As a result of the malfunction, Mr. Resovsky has suffered life-threatening injuries and damages and
 26 required extensive medical care and treatment. Plaintiff has suffered and will continue to suffer
 27
 28

1 significant medical expenses, extreme pain and suffering, loss of enjoyment of life, disability, and
2 other losses.

3 2. Plaintiff George Todd was implanted with an OptEase™ filter in October 2006 at
4 Aventura Hospital & Medical Center in Florida. The device subsequently tilted and perforated the
5 vena cava. As a result, he suffered, *inter alia*, bilateral pulmonary emboli and the device cannot be
6 removed. Plaintiff has suffered and will continue to suffer significant medical expenses, extreme
7 pain and suffering, loss of enjoyment of life, disability, and other losses.

8 3. Plaintiff David Brown was implanted with an OptEase™ filter on November 4, 2014
9 at Hannibal Regional Hospital in Missouri. On February 5, 2015 he underwent a procedure to
10 remove the device. The attempt failed secondary to the device having tilted and migrated after
11 placement. Plaintiff has suffered medical expenses, pain and suffering, loss of enjoyment of life,
12 and other losses.

13 4. Plaintiff Gwen Kramer underwent implantation of two OptEase™ filters on October
14 28, 2013. The first filter immediately migrated to the "origin of the left iliac vein." This filter was
15 removed percutaneously. Another OptEase™ filter was then placed and this filter also migrated
16 proximally with the distal portion of the filter being proximal to the renal veins. This filter was left
17 in place. Given the migration of the second filter, Ms. Kramer is at increased risk of fracture,
18 perforation and the device will be less effective at stopping clots. Plaintiff has suffered and will
19 continue to suffer significant medical expenses, extreme pain and suffering, loss of enjoyment of
20 life, disability, and other losses.

21 5. All of the above plaintiffs underwent placement in, and were residents of, the United
22 States at the time these devices were implanted and when the devices subsequently failed and
23 caused injury.

24 6. Defendant Cordis Corporation ("Cordis") is a corporation organized under the laws of
25 the State of Florida, with its principal place of business at 6500 Paseo Padre Pkwy, Fremont,
26
27
28

1 California, 94555. Cordis at all times relevant to this action, designed, set specifications for,
2 manufactured, prepared, compounded, assembled, processed, marketed, distributed, and sold the
3 OptEase™ Vena Cava Filter ("OptEase filter") to be implanted in patients throughout the United
4 States, including California. Cordis may be served with process by serving its registered agent, CT
5 Corporation System, at 818 West Seventh Street Suite 930, Los Angeles, California 90017.

6
7 7. The true names and/or capacities, whether individual, corporate, partnership,
8 associate, governmental, or otherwise, of Defendant DOES 1 through 100, inclusive, are unknown
9 to Plaintiffs at this time, who therefore sue said Defendants by such fictitious names. Plaintiffs are
10 informed and believe, and thereon allege, that each Defendant designated herein as a DOE caused
11 injuries and damages proximately thereby to Plaintiffs as is hereinafter alleged, and that each DOE
12 defendant is liable to Plaintiffs for the acts and omissions alleged herein below and the injuries and
13 damages resulting therefrom. Plaintiffs seek leave to amend this Complaint to allege the true names
14 and capacities of said DOE defendants when the same are ascertained.

15 8. Plaintiffs are informed and believe, and thereon allege, that at all times herein
16 mentioned, the Defendant and each of the DOE defendants were the agent, servant, employee
17 and/or joint venturer of the other co-defendants, and each of them, and at all said times each
18 Defendant, including DOE defendants, were acting in the full course, scope, and authority of said
19 agency, service, employment and/or joint venture.

20 9. Plaintiffs are informed and believe, and thereon allege, that at all times mentioned
21 herein, Defendant and DOES 1 through 100, and each of them, were also known as, formerly
22 known as, and/or were the successors and/or predecessors in interest/business/product line/or a
23 portion thereof, assigns, a parent, a subsidiary (wholly or partially owned by, or the whole or partial
24 owner), affiliate, partner, co-venturer, merged company, alter egos, agents, equitable trustees and/or
25 fiduciaries of and/or were members in an entity or entities engaged in the funding, researching,
26 studying, manufacturing, fabricating, designing, developing, labeling, assembling, distributing,
27 supplying, leasing, buying, offering for sale, selling, inspecting, servicing, contracting others for
28 marketing, warranting, rebranding, manufacturing for others, packaging, and advertising the device.

1 10. Defendant and DOES 1 through 100, and each of them, are liable for the acts,
2 omissions and tortious conduct of its successors and/or predecessors in interest/business/product
3 line/or a portion thereof, assigns, parent, subsidiary, affiliate, partner, co-venturer, merged
4 company, alter ego, agent, equitable trustee, fiduciary and/or its alternate entities in that Defendant
5 and DOES 1 through 100, and each of them, enjoy the goodwill originally attached to each such
6 alternate entity, acquired the assets or product line (or a portion thereof), and in that there has been a
7 virtual destruction of Plaintiffs' remedy against each such alternate entity, and that each such
8 Defendant has the ability to assume the risk-spreading role of each such alternate entity.

9 11. Plaintiffs are informed and believe, and thereon allege that, at all times herein
10 mentioned, DOES 1 through 100, and each of them, were and are corporations organized and
11 existing under the laws of the State of California or the laws of some state or foreign jurisdiction;
12 that each of the said DOE defendants were and are authorized to do and are doing business in the
13 State of California and regularly conducted business in the State of California.

14 12. Upon information and belief, at all relevant times, DOES 1 through 100, and each of
15 them, were engaged in the business of researching, developing, designing, licensing, manufacturing,
16 distributing, selling, marketing, and/or introducing into interstate commerce and into the State of
17 California, either directly or indirectly through third parties or related entities, its products,
18 including the TrapEase and OptEase inferior vena cava filters.

19 13. At all relevant times, DOES 1 through 100, and each of them, conducted regular and
20 sustained business and engaged in substantial commerce and business activity in the State of
21 California, which included but was not limited to researching, developing, selling, marketing, and
22 distributing their products, including the TrapEase and OptEase inferior vena cava filters, in the
23 State of California.

24 14. Upon information and belief, at all relevant times, DOES 1 through 100, and each of
25 them, expected or should have expected that their acts would have consequences within the United
26 States including in the State of California, and said Defendants derived and continue to derive
27 substantial revenue therefrom.
28

15. "Cordis" and "Defendants" where used hereinafter, shall refer to all subsidiaries, affiliates, divisions, franchises, partners, joint venturers, organizational units of any kind, predecessors, successors, assigns, officers, directors, employees, agents and representatives of Cordis Corporation; as well as DOE Defendants 1 through 100, and each of them.

JURISDICTION AND VENUE

16. This Court has jurisdiction over all causes of action alleged in this Complaint pursuant to the California Constitution, Article VI, § 10.

17. Venue is proper in this Court, pursuant to *Code of Civil Procedure*, as Defendant Cordis has its principal place of business in Alameda County.

BACKGROUND

INFERIOR VENA CAVA FILTERS GENERALLY

18. Inferior vena cava ("IVC") filters first came on to the medical market in the 1960's. Over the years, medical device manufacturers have introduced several different designs of IVC filters.

19. An IVC filter is a device that is designed to filter or "catch" blood clots that travel from the lower portions of the body to the heart and lungs. IVC filters are designed to be implanted, either permanently or temporarily, in the inferior vena cava.

20. The inferior vena cava is a vein that returns deoxygenated blood to the heart from the lower portions of the body. In certain people, for various reasons, blood clots travel from the vessels in the legs and pelvis, through the vena cava and into the lungs. Oftentimes, these blood clots develop in the deep leg veins, a condition called "deep vein thrombosis" or "DVT." Once blood clots reach the lungs, they are considered "pulmonary emboli" or "PE." Pulmonary emboli present risks to human health.

21. People at risk for DVT/PE can undergo medical treatment to manage the risk. For example, a doctor may prescribe medications like Heparin, Warfarin, or Lovenox to regulate the

1 clotting factor of the blood. In some people who are at high risk for DVT/PE, or who cannot
2 manage their conditions with medications, physicians may recommend surgically implanting an
3 IVC filter to prevent thromboembolic events.

4 22. As stated above, IVC filters have been on the market for decades. All IVC filters are
5 only cleared for use by the FDA for prevention of recurrent pulmonary embolism in patients at risk
6 for pulmonary embolism and where anticoagulation has failed or is contraindicated. In 2003,
7 however, an explosion in off-label use began with the introduction of IVC filters that were cleared
8 for both permanent placement and optional removal. Most of this market expansion came from
9 uses such as prophylactic prevention of pulmonary embolism without a prior history of pulmonary
10 embolism.

11 23. Indeed, from 2000 through 2003 there was a race between manufactures to bring the
12 first IVC filter to market with the added indication of optional retrieval. In 2003, the FDA cleared
13 the first three (3) IVC filters for a retrieval indication. These were the OptEase filter (Cordis &
14 J&J), the Recovery Filter (C.R. Bard, Inc.) and the Gunther Tulip Filter (Cook Medical).

15 24. Upon information and belief, Plaintiffs allege that this market expansion and off-
16 label use was driven by baseless marketing campaigns made by Defendants targeting bariatric,
17 trauma, orthopedic and cancer patient populations.

18 25. The medical community has just recently begun to awaken to the fact that despite
19 marketing claims by Defendants, there is no reliable evidence that any IVC filter offers a benefit
20 and that these products expose patients to substantial safety hazards. For example, an October 2015
21 article published in the Annals of Surgery concerning trauma patients inserted with IVC filters
22 concluded that IVC filters were not effective in preventing pulmonary emboli, and instead actually
23 caused thrombi to occur.

24 26. Comparing the results of over 30,000 trauma patients who had not received IVC
25 filters with those who had received them, the Annals of Surgery study published its alarming
26 results: a) Almost twice the percentage of patients with IVC filters in the study died compared to
27 those that had not received them; b) Over five times the relative number of patients with IVC filters
28 developed DVTs. c) Over four times the relative percentage of patients with filters developed

1 thromboemboli. d) Over twice the percentage of patients developed a pulmonary embolus – the very
 2 condition Defendants represented to the FDA, physicians, and the public that its IVC filters would
 3 prevent.

4 27. Other studies have also revealed that these devices suffer common failure modes
 5 such as migration, perforation, thrombosis, fracture all of which can cause serious injury or death.
 6 For example, recent studies for Defendants IVC Filters have revealed fracture rates as high as 50%
 7 and recommend medical monitoring and/or removal.

8 28. These studies, including the *Annals of Surgery* study, have now shown that not only
 9 is there no reliable evidence establishing that IVC filters are efficacious but that they also pose
 10 substantial health hazards.

11 THE TRAPEASE™ AND OPTEASE™ IVC FILTERS

12
 13 29. On January 10, 2001, Defendants bypassed the more onerous Food and Drug
 14 Administration's ("FDA's") approval process for new devices and obtained "clearance" under
 15 Section 510(k) of the Medical Device Amendments to the Food, Drug, and Cosmetic Act to market
 16 the Trap Ease™ Permanent Vena Cava Filter and Introduction Kit ("TrapEase filter") as a
 17 permanent filter by claiming it was substantially equivalent in respect to safety, efficacy, design,
 18 and materials as the then already available IVC filters.

19 30. Section 510(k) permits the marketing of medical devices if the device is
 20 substantially equivalent to other legally marketed predicate devices without formal review for the
 21 safety or efficacy of the device. The FDA explained the difference between the 510(k) process and
 22 the more rigorous "premarket approval" ("PMA") process in its amicus brief filed with the Third
 23 Circuit in *Horn v. Thoratec Corp.*, which the court quoted from:

24 A manufacture can obtain an FDA findings of 'substantial equivalence' by
 25 submitting a premarket notification to the agency in accordance with section
 26 510(k) of the [Food Drug and Cosmetic Act.] 21 U.S.C. § 360(k). A device found
 27 to be 'substantially equivalent' to a predicate device is said to be 'cleared' by the
 28 FDA (as opposed to "approved" by the agency under a PMA).

1 376 F.3d 163, 167 (3d. Cir. 2004). A pre-market notification submitted under 510(k) is thus
2 entirely different from a PMA, which must include data sufficient to demonstrate that the produce
3 involved is safe and effective.

4 31. In *Medtronic, Inc. v. Lohr*, the U.S. Supreme Court similarly described the 510(k)
5 process, observing:

6
7 If the FDA concludes on the basis of the [manufacturer's] § 510(k) notification
8 that the device is 'substantially equivalent' to a pre-existing device, it can be
9 marketed without further regulatory analysis.... The § 510(k) notification process
10 is by no means comparable to the PMA process; in contrast to the 1,200 hours
11 necessary to complete a PMA review, the § 510(k) review is completed in average
12 of 20 hours As on commentator noted: "The attraction of substantial
13 equivalence to manufacturers is clear. Section 510(k) notification required little
14 information, rarely elicits a negative response from the FDA, and gets processed
15 quickly.

16
17 518 U.S. 470, 478-79 (1996).

18 32. Pursuant to *Wyeth v. Levine*, 555 U.S. 555 (2009), once a product is cleared "the
19 manufacturer remains under an obligation to investigate and report any adverse associated with the
20 drug...and must periodically submit any new information that may affect the FDA's previous
21 conclusions about the safety, effectiveness, or labeling" This obligation extends to post-market
22 monitoring of adverse events/complaints.

23 33. On September 18, 2002, Defendants sought clearance through the 510(k) process to
24 market the Cordis OptEase™ Permanent Vena Cava Filter ("OptEase filter") for the same indicated
25 uses as the TrapEase Filter. Defendants represented that the OptEase filter had the same basic
26 fundamental technology and was substantially equivalent in respect to safety and efficacy as the
27 predicate devices (TrapEase Filter, Gunther Tulip filter, and the Vena Tech LGM Vena Cava
28 Filter).

34. Defendants have further represented that the OptEase filter has the same design as
TrapEase filter except that unlike the TrapEase filter, which has proximal and distal anchoring barbs
located on each connecting strut for fixation of the filter to the vena cava wall, the OptEase filter

1 has anchoring barbs for fixation of the filter only on the superior end of each of the six straight
2 struts and has a hook at the inferior end of the basket to allow retrieval with a snare.

3 35. Both designs suffer similar design flaws rendering them defective and unreasonably
4 dangerous. Defendants filters are designed in such way that when exposed to expected and
5 reasonably foreseeable *in-vivo* conditions the devices will fracture, migrate, tilt, perforate internal
6 organs and vasculature, and lead to the formation of thromboembolism and pulmonary embolism.

7 36. For instance, Defendants chose not to electropolish their filters. The manufacturing
8 process used to manufacture NITINOL medical devices leads to surface blemishes, draw marking,
9 pitting, gouges and cracks, which can act as stress concentrators leading to fatigue failure.
10 Electropolishing removes these conditions, which substantially increase fatigue and corrosion
11 resistance. Electropolishing has been industry standard for implanted NITINOL medical devices
12 since at least the 1990's.

13 37. The anchoring mechanism of Defendants' filters is also insufficient to prevent tilting
14 and migration post-placement.

15 38. The configuration of Defendants' filters also renders them prothrombotic. This
16 means that these filters actually lead to the formation of blood clots and pulmonary embolism – the
17 exact condition that devices are meant to prevent.

18 39. That Defendants allowed these devices to proceed to market indicates that they failed
19 to establish and maintain an appropriate Quality System in respect to design and risk analysis.

20 40. At a minimum, a manufacturer must undertake sufficient research and testing to
21 understand the anatomy of where a medical device will be implanted so as to understand what
22 forces the device may be exposed to once implanted in the human body. This design input must
23 then be used to determine the minimum safety requirements or attributes the device must have to
24 meet user needs. In the case of an IVC filter, user needs include: a device that will capture DVTs of
25 sufficient size to cause harmful consequences and that will not fracture, migrate, tilt, perforate the
26 vena cava or be prothrombotic.

1 41. Prior to bringing a product to market, a manufacturer must also conduct sufficient
2 testing under real world or simulated use conditions to ensure that the device will meet user needs
3 even when exposed to reasonably foreseeable worst case conditions.

4 42. Defendants failed to adequately establish and maintain such policies and procedures
5 in respect to their IVC filter devices.

6 43. Once brought to market, Defendants' post-market surveillance system should have
7 revealed that the OptEase filters were unreasonably dangerous and substantially more prone to
8 failing and causing injury than other available treatment options.

9 44. For instance soon after market release, Defendants began receiving large numbers of
10 adverse event reports ("AERs") from health care providers reporting that the OptEase filters were
11 fracturing post-implantation and that fractured pieces and/or the entire device was migrating
12 throughout the human body, including the heart and lungs. Defendants also received large numbers
13 of AERs reporting that the OptEase filters were found to have excessively tilted, perforated the
14 inferior vena cava, or caused thrombosis or stenosis of the vena cava post-implantation. These
15 device malfunctions were often associated with reports of inability to retrieve the device and/or
16 severe patient injuries such as:

- 17 a. Death;
- 18 b. Hemorrhage;
- 19 c. Cardiac/pericardial tamponade;
- 20 d. Cardiac arrhythmia and other symptoms similar to myocardial infarction;
- 21 e. Severe and persistent pain;
- 22 f. Perforation of tissue, vessels and organs;
- 23 g. compartment syndrome.

24 45. Recent medical studies have confirmed what Defendants have known or should have
25 known since shortly after the release of each of these filters - not only do OptEase filters fail at
26 alarming rates, but they also fail at rates substantially higher than other available IVC Filters. For
27 instance, a recent large medical study found that OptEase and TrapEase filters suffer fracture rates
28 of 37.5% and 23.1%, respectively, when left implanted a minimum of 46 months. Another recent

1 study found that the TrapEase filter had a 64% fracture rate when left in more than four (4) years.
2 Another study found a statistically significant increased rate of caval thrombosis with the OptEase
3 filter compared to Gunther Tulip and Recovery Filters.

4 46. As a minimum safety requirement, manufacturers must establish and maintain post-
5 market procedures to timely identify the cause of device failures and other quality problems and to
6 take adequate corrective action to prevent the recurrence of these problems.

7 47. Defendants, however, failed to take timely and adequate action to correct known
8 design and manufacturing defects with the OptEase filter.

9 48. Defendants also misrepresented and concealed the risks and benefits of the OptEase
10 filters in labeling and marketing distributed to the FDA, physicians and the public.

11 49. For instance, Defendants represented that these devices were safe and effective. As
12 discussed above, however, there is no reliable evidence establishing that these devices actually
13 improve patient outcomes.

14 50. Defendants also represented that the design of these devices would eliminate the risk
15 that pieces of the devices could perforate the vena cava, that the devices could tilt, or that fractures
16 could occur and migrate throughout the body. The medical literature and AERS have proven these
17 claims to be false.

18 51. Defendants also represented that these devices were more effective and safer than
19 other available IVC filters. As discussed above, there is no reliable basis for such claims and the
20 evidence indicates otherwise.

21 52. Defendants also marketed the OptEase filter as being "easy" to remove. However,
22 the OptEase filter is one of the most difficult filters to remove after implantation and quite often
23 cannot be removed at all. As Dr. William T. Kuo, one of the leading authors on IVC filters, recently
24 explained in *the Journal of Vascular Interventional Radiology*:

25 "...we thought the OPTEASE and TRAPEASE filter types were subjectively
26 among the most difficult to remove in our study, often requiring aggressive blunt
27 dissection force in addition to laser tissue ablation to achieve removal. A possible
28 explanation is the relatively large amount of contact these filters make with the
underlying vena cava and the possible induction of greater reactive tissue
formation."

1 53. This is particularly concerning because having an IVC filter for a prolonged period
2 of time increases the risk of developing chronic deep venous thrombosis, PE, IVC occlusion, post-
3 thrombotic syndrome, filter fracture, and caval perforation with pain and organ injury. Many
4 patients with IVC filters are now routinely managed with lifelong anticoagulation solely to reduce
5 the risk of having the filter in place, subjecting patients to the risks and inconvenience of
6 anticoagulation.

7 54. Defendants also failed to adequately disclose the risks of these filters, such as
8 migration, fracture, perforation, tilt, thrombosis, the prothrombotic nature of the devices, that the
9 devices may not be retrievable, or that these failures were known to be causing severe injuries and
10 death or the rate at which these events were occurring.

11 55. Defendants labeling was additionally defective in that it directed physicians to
12 implant the OptEase filter upside down. When the OptEase was placed as directed by the labeling,
13 the hooks designed to ensure stability were facing in the wrong direction, rendering an already
14 inadequate anchoring system even further defective. As Defendants' now explain in their labeling,
15 implanting the device in this fashion "can result in life threatening or serious injury including, but
16 not limited to dissection, vessel perforation, migration of the filter with secondary damage to
17 cardiac structures, ineffective pulmonary embolism prevention or death."

18 56. Defendants began a series of recalls on March 29, 2013 relating to its labeling, which
19 instructed physicians to implant the devices upside down. These recalls were not timely, nor did
20 they fully correct the defects in Defendants' labeling. Further, Defendants downplayed the danger
21 patients were exposed to and failed to take adequate steps to ensure patients actually received notice
22 of the recall.

23 57. The FDA classified the initial recall as a Class I recall, which are the most serious
24 type of recall and involve situations in which the FDA has determined there is a reasonable
25 probability that use of these products will cause serious adverse health consequences or death.

26 58. Defendants have admitted that any patients implanted with one of these recalled
27 units should receive medical monitoring. Specifically, these patients should undergo imaging to
28 ascertain whether or not the device was properly deployed and, if not, be assessed for removal.

1 59. Given the unreasonably high failure and injury rates associated with Defendants
2 filters when left implanted long-term, Defendants should be required to pay for medical monitoring
3 to assess the condition of these devices and whether or not retrieval should be undertaken.

4
5 **ESTOPPEL FROM PLEADING STATUTES OF LIMITATIONS OR REPOSE**

6 60. Plaintiffs incorporate by reference all prior allegations.

7 61. Plaintiffs are within the applicable statute of limitations for their claims because
8 Plaintiffs (and their healthcare professionals) did not discover, and could not reasonably discover,
9 the defects and unreasonably dangerous condition of Defendants' IVC filters.

10 62. Plaintiffs' ignorance of the defective and unreasonably dangers nature of
11 Defendants' IVC filters, and the causal connection between these defects and Plaintiffs' injuries and
12 damages, is due in large part to Defendants' acts and omissions in fraudulently concealing
13 information from the public and misrepresenting and/or downplaying the serious threat to public
14 safety its products present.

15 63. In addition, Defendants are estopped from relying on any statutes of limitation or
16 repose by virtue of its unclean hands, acts of fraudulent concealment, affirmative misrepresentations
17 and omissions.

18 64. Such conduct includes intentional concealment from Plaintiffs, Plaintiffs' prescribing
19 health care professionals, the general consuming public and the FDA of material information that
20 Defendants' filters had not been demonstrated to be safe or effective, and carried with them the
21 risks and dangerous defects described above.

22 65. Defendants had a duty to disclose the fact that Defendants' filters are not safe or
23 effective, not as safe as other filters on the market, defective, and unreasonably dangerous, and that
24 their implantation and use carried the above described risks.

25 ///

26 ///

27 ///

28 ///

COUNT I:
STRICT PRODUCTS LIABILITY- DESIGN DEFECT
By all Plaintiffs

66. Plaintiffs re-allege and incorporate by reference each and every allegation contained in the foregoing paragraphs as though fully set forth herein.

67. At all times relevant to this action, Defendants developed, tested, designed, manufactured, inspected, labeled, promoted, distributed and sold into the stream of commerce the OptEase filters, including the devices implanted in Plaintiffs.

68. The devices implanted in plaintiffs were in a condition unreasonably dangerous at the time they left Defendants' control.

69. The devices implanted in Plaintiffs were expected to, and did, reach their intended consumers without substantial change in the condition in which they were in when they left Defendants' possession. In the alternative, any changes that were made to the devices implanted in Plaintiffs were reasonably foreseeable to Defendants.

70. The OptEase filters, including the devices implanted in Plaintiffs, were defective in design and unreasonably dangerous at the time they left Defendants' possession because they failed to perform as safely as an ordinary consumer would expect when used as intended or in a manner reasonably foreseeable by the Defendants, and because the foreseeable risks of these devices exceeded the alleged benefits associated with their use.

71. At the time Defendants placed their OptEase filters, including the device implanted in Plaintiffs, into the stream of commerce, safer alternative designs were commercially, technologically, and scientifically attainable and feasible.

72. Plaintiffs and their health care providers used the devices in a manner that was reasonably foreseeable to Defendants.

1 73. Neither Plaintiffs, nor their health care providers, could have by the exercise of
2 reasonable care discovered the defective condition or perceived the unreasonable dangers with these
3 devices prior to Plaintiffs' implantation with the devices.

4 74. As a direct and proximate result of the defective and unreasonably dangerous
5 condition of the OptEase filters, Plaintiffs suffered injuries and damages.

6
7 WHEREFORE, Plaintiffs demand judgment against Defendants as hereinafter set forth.

8
9 **COUNT II:**
10 **STRICT PRODUCTS LIABILITY — INADEQUATE WARNING**
11 **By all Plaintiffs**

12 75. Plaintiffs re-allege and incorporate by reference each and every allegation contained
13 in the foregoing paragraphs as though fully set forth herein.

14 76. Prior to, on, and after the dates during which the device were implanted in Plaintiffs,
15 and at all relevant times, Defendants manufactured, designed, marketed, distributed, and sold the
16 OptEase filters.

17 77. The OptEase filters had potential risks and side effects that were known or knowable
18 to Defendants by the use of scientific knowledge available before, at, and after the manufacture,
19 distribution, and sale of the devices implanted in Plaintiffs.

20 78. Defendants knew or it was knowable at the time they distributed the devices
21 implanted in Plaintiffs that the OptEase filters posed a significant and higher risk of failure than
22 other similar IVC filters, including for fracture, migration, tilting, thrombosis, migration, tilt,
23 inability to retrieve and pulmonary embolism and that these failures were resulting in serious patient
24 injuries and death. Defendants also knew or it was knowable that these devices were actually
25 prothrombotic, that use of these filters did not improve patient outcomes, and the longer these filters
26 were left implanted increased the likelihood of a device failure.

27 79. Defendants' OptEase filters were in a defective condition that was unreasonably and
28 substantially dangerous to any user or consumer implanted with the filters, such as Plaintiffs, when

1 used in an intended and reasonably foreseeable way. Such ordinary consumers, including Plaintiffs
 2 and their prescribing physician(s), would not and could not have recognized or discovered the
 3 potential risks and side effects of the device, as set forth herein.

4 80. The warnings and directions Defendants provided with its OptEase filters, including
 5 the devices implanted in Plaintiffs, failed to adequately warn of the above-described risks and side-
 6 effects, whether as to existence of the risk, its likelihood, severity, or the comparative risk to other
 7 products.

8 81. The labeling also failed to provide adequate directions on how to appropriately use
 9 the product.

11 82. The devices were expected to and did reach Plaintiffs without substantial change in
 12 its condition, labeling, or warnings as manufactured, distributed, and sold by Defendants.
 13 Additionally, Plaintiffs and their prescribing physicians used the devices in the manner in which
 14 they were intended to be used, making such use reasonably foreseeable to Defendants.

15 83. Defendants' lack of sufficient instructions or warnings prior to, on, and after the date
 16 Plaintiffs used the devices was a substantial factor in causing Plaintiffs' injuries and damages, as
 17 described herein.

18 WHEREFORE, Plaintiff demands judgment against Defendants as hereinafter set forth.

19
 20 **COUNT III:**
 21 **STRICT PRODUCTS LIABILITY — MANUFACTURING DEFECT**
 22 **By all Plaintiffs**

23 84. Plaintiffs re-allege and incorporate by reference each and every allegation contained
 24 in the foregoing paragraphs as though fully set forth herein.

25 85. Prior to, on, and after the date the devices were implanted in Plaintiffs, and at all
 26 relevant times, Defendants designed, distributed, manufactured, sold, and marketed the OptEase
 27 filters for use in the United States.

1 86. At all times herein mentioned, Defendants designed, distributed, manufactured,
2 marketed, and sold the devices such that they were dangerous, unsafe, and defective in manufacture,
3 and contained a manufacturing defect when it left defendants' possession.

4 87. Plaintiffs are informed and believe, and on that basis allege, that the OptEase filters,
5 including the devices implanted in them, contained manufacturing defects, in that they differed from
6 Defendants' design or specifications, or from other typical units of the same product line.

7 88. As a direct and proximate result of Defendants' defective manufacture and sale of
8 the OptEase filters prior to, on, and after the date Plaintiffs used the devices, Plaintiffs suffered the
9 injuries and damages herein described.

10 WHEREFORE, Plaintiffs demand judgment against Defendants as hereinafter set forth.

11
12 **COUNT IV:**
13 **NEGLIGENCE**
 By all Plaintiffs

14 89. Plaintiffs re-allege and incorporate by reference each and every allegation contained
15 in the foregoing paragraphs as though fully set forth herein.

16 90. Prior to, on, and after the date the devices were implanted in Plaintiffs, and at all
17 relevant times, Defendants designed, distributed, manufactured, sold, and marketed the OptEase
18 filters for use in the United States.

19 91. Defendants had a duty to exercise reasonable and prudent care in the development,
20 testing, design, manufacture, inspection, marketing, labeling, promotion, distribution and sale of the
21 OptEase filters so as to avoid exposing others to foreseeable and unreasonable risks of harm.

22 92. Defendants knew or reasonably should have known that the OptEase filters were
23 dangerous or were likely to be dangerous when used in an intended or reasonably foreseeable
24 manner.

25 93. At the time of manufacture and sale of the OptEase filters, Defendants knew or
26 should have known that the OptEase filters:
27
28

1 a. Were designed and manufactured in such a manner as to lack sufficient
2 structural integrity (fatigue resistance) and stability (tilt/migration) to meet user
3 needs when used in an intended and reasonably foreseeable manner.

4 b. Were designed and manufactured so as to present an unreasonable risk of the
5 devices perforating the vena cava wall and/or in the case of the OptEase filter
6 becoming irretrievable;

7 c. Being designed and manufactured in such a manner as to be prothrombotic.
8

9 94. At the time of manufacture and sale of the OptEase filters, including the ones
10 implanted in Plaintiffs, Defendants knew or should have known that using the OptEase filters as
11 intended or in a reasonably foreseeable manner created a significant risk of patients suffering severe
12 health side effects including, but not limited to: hemorrhage; cardiac/pericardial tamponade; cardiac
13 arrhythmia and other symptoms similar to myocardial infarction; perforations of tissue, vessels and
14 organs; chronic deep vein thrombosis; pulmonary embolism; thrombosis; compartment syndrome;
15 and other severe personal injuries and diseases, which are permanent in nature, including, but not
16 limited to, death, physical pain and mental anguish, scarring and disfigurement, diminished
17 enjoyment of life, continued medical care and treatment due to chronic injuries/illness proximately
18 caused by the device; and the continued risk of requiring additional medical and surgical procedures
19 including general anesthesia, with attendant risk of life threatening complications.
20

21 95. Defendants knew or reasonably should have known that consumers of the OptEase
22 filters, including Plaintiffs' prescribing physicians, would not realize the danger associated with
23 using the devices for their intended or reasonably foreseeable use.
24

25 96. Defendants breached their to duty to exercise reasonable and prudent care in the
26 development, testing, design, manufacture, inspection, marketing, labeling, promotion, distribution
27 and sale of the OptEase filters in, among other ways, the following acts and omissions:
28

- 1 a. Designing and distributing a product in which they knew or should have known
2 that the likelihood and severity of potential harm from the product exceeded the
3 burden of taking safety measures to reduce or avoid harm;
- 4 b. Designing and distributing a product in which they knew or should have known
5 that the likelihood and severity of potential harm from the product exceeded the
6 likelihood of potential harm from other devices and treatment options available
7 for the same purpose;
- 8 c. Failing to use reasonable care in manufacturing the product and producing a
9 product that differed from their design or specifications or from other typical
10 units from the same production line;
- 11 d. Failing to use reasonable care to warn or instruct, including pre and post-sale,
12 Plaintiffs, their prescribing physicians, or the general health care community
13 about the OptEase filters' substantially dangerous condition or about facts
14 making the products likely to be dangerous;
- 15 e. Failing to recall, retrofit, or provide adequate notice of such actions to Plaintiffs
16 or their health providers.
- 17 f. Failing to perform reasonable pre and post-market testing of the TrapEase and
18 OptEase filters to determine whether or not the products were safe for their
19 intended use;
- 20 g. Failing to provide adequate instructions, guidelines, and safety precautions,
21 including pre and post-sale, to those persons to whom it was reasonably
22 foreseeable would prescribe, use, and implant the OptEase filters;
- 23 h. Advertising, marketing and recommending the use of the OptEase filters, while
24 concealing and failing to disclose or warn of the dangers known by Defendants
25 to be connected with and inherent in the use of these filter systems;
- 26
27
28

- i. Representing that the OptEase filters were safe for their intended use when, in fact, Defendants knew and should have known the products were not safe for their intended uses;
- j. Continuing to manufacture and sell the OptEase filters with the knowledge that said products were dangerous and not reasonably safe, and failing to comply with good manufacturing regulations;
- k. Failing to use reasonable and prudent care in the design, research, manufacture, and development of the OptEase filters so as to avoid the risk of serious harm associated with the use of these filter systems;
- l. Advertising, marketing, promoting and selling OptEase filters for uses other than as approved and indicated in the product's label;
- m. Failing to establish an adequate quality assurance program used in the design and manufacture of the OptEase filters.
- n. Failing to establish and maintain an adequate post-market surveillance program;

97. A reasonable manufacturer, distributor, or seller under the same or similar circumstances would not have engaged in the before-mentioned acts and omissions.

98. Defendants' negligence prior to, on, and after the date of implantation of the devices in Plaintiffs was a substantial factor in causing Plaintiffs' injuries and damages, as described herein.

WHEREFORE, Plaintiff demands judgment against Defendants as hereinafter set forth.

COUNT V:
NEGLIGENT MISREPRESENTATION
By all Plaintiffs

99. Plaintiffs re-allege and incorporate by reference each and every allegation contained in the foregoing paragraphs as though fully set forth herein.

1 100. Prior to, on, and after the date the devices were implanted in Plaintiffs, and at all
2 relevant times, Defendants negligently and carelessly represented to Plaintiffs, their health care
3 providers, and the general public that certain material facts were true. The representations include,
4 *inter alia*, the following:

- 5 a. That the OptEase filters were safe, fit, and effective for use.
6 b. that the design of the OptEase filters eliminated the risk that pieces of the
7 device could perforate the vena cava, that the devices could tilt, or that
8 fractures could occur and migrate throughout the body.
9 c. That the OptEase filters were safer and more effective than other available
10 IVC filters.
11 d. That the OptEase filter was “easy” to remove.

12 101. Prior to, on, and after the dates during which Plaintiffs and their physicians
13 purchased and used the device, said representations were not true, and there was no reasonable
14 ground for believing said representations to be true at the times said representations were made.
15

16 102. Prior to, on, and after the dates during which Plaintiffs and their physicians
17 purchased and used the device, Defendants intended that Plaintiffs, their physicians, and the general
18 public would rely on said representations, which did in fact occur.
19

20 103. Defendants’ negligent misrepresentations prior to, on, and after the date when
21 Plaintiffs and their physicians purchased and used the devices were a substantial factors in causing
22 Plaintiff’s injuries and damages, as described herein.

23 WHEREFORE, Plaintiff demands judgment against Defendants as hereinafter set forth.
24

25 ///

26 ///

27 ///

COUNT VI
FRAUD - MISREPRESENTATION
By all Plaintiffs

104. Plaintiffs re-allege and incorporate by reference each and every allegation contained in the foregoing paragraphs as though fully set forth herein.

105. At all times relevant to this cause, and as detailed above, Defendants intentionally provided Plaintiffs, their physicians, the medical community and the FDA with false or inaccurate information, and/or omitted material information concerning the Device, including, but not limited to, misrepresentations regarding the following topics:

- a. The safety of the device;
- b. The efficacy of the device;
- c. The rate of failure of the device;
- d. The pre-market testing of the device; and
- e. The approved uses of the device.

106. The information distributed by Defendants to the public, the medical community, Plaintiffs and their physicians was in the form of reports, press releases, advertising campaigns, labeling materials, print advertisements, commercial media containing material representations, and instructions for use, as well as through their officers, directors, agents, and representatives. These materials contained false and misleading material representations, which included:

- a. That the device was safe, fit, and effective when used for its intended purpose or in a reasonably foreseeable manner;
- b. that it did not pose dangerous health risks in excess of those associated with the use of other similar devices;
- c. That the design of the device would eliminate the risk that pieces of the device could perforate the vena cava, that the devices could tilt, or that fractures could occur and migrate throughout the body;
- d. That the device was safer and more effective than other available IVC filters; and
- e. That the OptEase filter was "easy" to remove.

1 107. Defendants made the foregoing misrepresentations knowing that they were false.
2 These materials included instructions for use and a warning document that was included in the
3 package of the devices implanted in Plaintiffs.

4 108. Defendants' intent and purpose in making these misrepresentations was to deceive
5 and defraud Plaintiffs and their health care providers; to gain the confidence of Plaintiffs and their
6 health care providers; to falsely assure them of the quality of the device and its fitness for use; and
7 to induce the public and the medical community, including Plaintiffs' healthcare providers to
8 request, recommend, prescribe, implant, purchase, and continue to use the device, all in reliance on
9 Defendants' misrepresentations.

10 109. The foregoing representations and omissions by Defendants were in fact false.

11 110. Defendants acted to serve their own interests and having reasons to know
12 consciously disregarded the substantial risk that the device could kill or significantly harm patients.

13 111. In reliance upon the false representations made by Defendants, Plaintiffs and their
14 health care providers were induced to, and did use the device, thereby causing Plaintiffs to sustain
15 the injuries described herein.

16 112. Defendants knew and had reason to know that Plaintiffs, their health care providers,
17 or the general medical community did not have the ability to determine the true facts intentionally
18 concealed and misrepresented by Defendants, and would not have prescribed and implanted same, if
19 the true facts regarding the device had not been concealed and misrepresented by Defendants.

20 113. Defendants had sole access to material facts concerning the defective nature of the
21 OptEase filters and their propensity to cause serious side effects in the form of dangerous injuries
22 and damages to persons who are implanted with the device.

23 114. At the time Defendants failed to disclose and intentionally misrepresented the
24 foregoing facts, and at the time Plaintiffs' health care providers purchased and used these devices,
25 Plaintiffs' health care providers were unaware of Defendants' misrepresentations.

26 115. Plaintiffs' health care providers reasonably relied upon misrepresentations made by
27 Defendants where the concealed and misrepresented facts were critical to understanding the true
28 dangers inherent in the use of the device.

1 116. Defendants' fraudulent misrepresentations prior to, on, and after the date Plaintiffs
2 and their physicians purchased and used the devices were a substantial factor in causing Plaintiff's
3 injuries and damages, as described herein.

4 WHEREFORE, Plaintiffs demand judgment against defendants as hereinafter set forth.

5
6 **COUNT VII**
FRAUDULENT CONCEALMENT
7 **By all Plaintiffs**

8 117. Plaintiffs re-allege and incorporate by reference each and every allegation contained
9 in the foregoing paragraphs as though fully set forth herein.

10 118. In marketing and selling the device, defendants concealed material facts from
11 Plaintiffs and their health care providers.

12 119. Defendants' concealed material facts including, but not limited to, the following:

- 13 a. That the device was unsafe and not fit when used for its intended purpose or
14 in a reasonably foreseeable manner;
- 15 b. That the device posed dangerous health risks in excess of those associated
16 with the use of other similar devices;
- 17 c. That there were additional side effects related to implantation and use of the
18 device that were not accurately and completely reflected in the warnings
19 associated with the device;
- 20 d. That the device was not adequately tested to withstand normal placement
21 within the human body; and
- 22 e. That Defendants were aware at the time Plaintiffs' filters were distributed
23 that electropolishing reduced the risk of fracture and was industry standard
24 for NITINOL medical devices.

25 120. Plaintiffs and their healthcare providers were not aware of these and other facts
26 concealed by Defendants.

27 121. The Defendants are and were under a continuing duty to disclose the true character,
28 quality and nature of the device that was implanted in Plaintiff, but instead they concealed them.
Defendants' conduct, as described in this complaint, amounts to conduct purposely committed,
which Defendants must have realized was dangerous, heedless and reckless, without regard to the
consequences or the rights and safety of Plaintiff.

122. In concealing these and other facts, Defendants intended to deceive Plaintiffs and their health care providers by concealing said facts.

123. Plaintiffs and their healthcare providers reasonably and justifiably relied on Defendants' concealment and deception.

124. Defendants' concealment prior to, on, and after the date Plaintiffs and their healthcare providers purchased and used the devices implanted in Plaintiffs was a substantial factor in causing Plaintiffs' injuries and damages, as described herein.

WHEREFORE, Plaintiffs demand judgment against defendants as hereinafter set forth.

COUNT VIII
EXPRESS WARRANTY
By all Plaintiffs

125. Plaintiffs re-allege and incorporate by reference each and every allegation contained in the foregoing paragraphs as though fully set forth herein.

126. Prior to, on, and after the dates during which Plaintiffs were implanted with these devices, and at all relevant times, Defendants, and each of them, had knowledge of the purpose for which the devices were to be used, and represented the devices to be in all respects safe, effective, and proper for such purpose. Said warranties and representations were made to Plaintiffs and their treating physicians. Plaintiffs and their treating physicians relied on said warranties and representations in deciding to use the device.

127. Defendants used packaging inserts and media advertisements to represent to the medical community and consumers, including plaintiffs and their health care providers, that the OptEase filters: were safe for their intended use; did not pose serious health hazards when used appropriately; were safer and more effective than alternative IVC filters; had been adequately tested for their intended use; would not perforate the vena cava, tilt, or fracture and migrate throughout the body after placement; and that the OptEase filter was "easy" to remove.

128. Defendants, and each of them, breached the above-described express warranties and representations in that the OptEase filters did not conform to these express warranties and representations.

WHEREFORE, Plaintiffs demand judgment against Defendants as hereinafter set forth.

131. Plaintiffs re-allege and incorporate by reference each and every allegation contained in the foregoing paragraphs as though fully set forth herein.

133. At all times hereinafter mentioned, Defendants were in the business of developing, designing, licensing, manufacturing, selling, distributing and/or marketing the TrapEase and OptEase filters, including the one implanted in Plaintiffs.

135. The representations and implied warranties made by Defendants were false, misleading, and inaccurate because the OptEase filters were defective, unsafe, unreasonably dangerous, and not of merchantable quality, when used as they were marketed and intended to be used. Specifically, at the time Plaintiffs and their physicians purchased and used the devices, the products were not in a merchantable condition in that:

- ## COMPLAINT FOR DAMAGES

c. The surface of the devices were manufactured and designed in such a way that they were distributed with surface damage that substantially increased the risk of fracture.

d. They were prothrombotic;

136. Defendants' breach of said implied warranties and representations prior to, on, and after the date Plaintiffs and their physicians purchased and used the devices was a substantial factor in causing Plaintiffs' injuries and damages, as described herein.

WHEREFORE, Plaintiffs demand judgment against Defendants as hereinafter set forth.

PUNITIVE DAMAGES ALLEGATIONS

137. Plaintiff re-alleges and incorporates by reference each and every allegation contained in the foregoing paragraphs as though fully set forth herein.

138. Upon information and belief, Plaintiffs allege that as early as 2003, Defendants were aware and had knowledge of the fact that the OptEase filters were defective and unreasonably dangerous and were causing injury and death to patients.

139. Data establishes that the failure rates of the OptEase filters are and were much higher than what Defendants have in the past and currently continue to publish to the medical community and members of the public. Further, Defendants were aware or should have been aware that the OptEase filters had substantially higher failure rates than other similar products on the market and are actually prothrombotic. Defendants were also aware that there was no reliable evidence indicating its devices actually improved patient outcomes. Despite these facts, Defendants continued to sell an unreasonably dangerous product while concealing and misrepresenting its risks and benefits to the public, plaintiffs, plaintiffs' health care providers, and the FDA.

140. The conduct of Defendants as alleged in this Complaint constitutes willful, wanton, gross, and outrageous corporate conduct that demonstrates a conscious disregard for the safety of Plaintiff. Defendants had actual knowledge of the dangers presented by OptEase filters, yet consciously failed to act reasonably to:

- a. Inform or warn Plaintiffs, Plaintiffs' physicians, or the public at large of these dangers; and
- b. Establish and maintain an adequate quality and post-market surveillance system.

141. Despite having knowledge as early as 2003 of the unreasonably dangerous and defective nature of the OptEase filters, Defendants consciously disregarded the known risks and continued to actively market and offer for sale the OptEase filters. Plaintiffs further allege that Defendants acted in willful, wanton, gross, and total disregard for the health and safety of the users or consumers of their OptEase filters, acted to serve their own interests, and consciously disregarded the substantial risk that their product might kill or significantly harm patients, or significantly injure the rights of others. Despite this knowledge, Defendants consciously pursued a course of conduct knowing that such conduct created a substantial risk of significant harm to other persons.

PRAYER FOR DAMAGES

WHEREFORE, Plaintiffs pray for relief against Defendants Cordis Corporation and Does 1 through 100, inclusive, on the entire complaint, as follows:

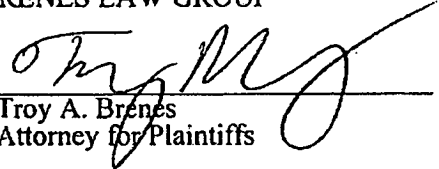
- a. General damages according to proof at the time of trial;
- b. Special (economic) damages, including without limitation, past and future medical expenses and past and future lost wages according to proof at time of trial.
- c. Pre-judgment and post-judgment interest pursuant to the laws of the State of California;
- d. Costs of suit incurred herein;
- e. Punitive damages in an amount sufficient to punish Defendants and deter similar conduct in the future;
- f. For such further and other relief as this Court deems necessary, just and proper.

DEMAND FOR JURY TRIAL

Plaintiffs hereby demand trial by jury on all issues.

DATED: May 6, 2016

Respectfully Submitted,
BRENES LAW GROUP



Troy A. Brenes
Attorney for Plaintiffs



**Service of Process
Transmittal**

05/11/2016

CT Log Number 529150285

TO: Magdalene Riley
Cardinal Health, Inc.
7000 Cardinal Pl
Dublin, OH 43017-1091

RE: Process Served in California

FOR: Cordis Corporation (Domestic State: FL)

ENCLOSED ARE COPIES OF LEGAL PROCESS RECEIVED BY THE STATUTORY AGENT OF THE ABOVE COMPANY AS FOLLOWS:

TITLE OF ACTION: DAVID RESOVSKY, et al., Pltfs. vs. Cordis Corporation, etc., et al., Dfts.

DOCUMENT(S) SERVED: Notice, Proof of Service

COURT/AGENCY: Alameda County - Superior Court - Oakland, CA
Case # None Specified

NATURE OF ACTION: Notice of Related Case

ON WHOM PROCESS WAS SERVED: C T Corporation System, Los Angeles, CA

DATE AND HOUR OF SERVICE: By Regular Mail on 05/11/2016 postmarked: "Not Post Marked"

JURISDICTION SERVED : California

APPEARANCE OR ANSWER DUE: None Specified

ATTORNEY(S) / SENDER(S): Troy A. Brenes
Brenes Law Group
16A Journey, Ste. 200
Aliso Viejo, CA 92656
(949)-397-9360

ACTION ITEMS: CT has retained the current log, Retain Date: 05/12/2016, Expected Purge Date: 05/17/2016

Image SOP

Email Notification, Laura Garza laura.garza@cardinalhealth.com

Email Notification, David Orensten david.orensten@cardinalhealth.com

Email Notification, Corey Goldsand corey.goldsand@cardinalhealth.com

Email Notification, Brenda Cleveland brenda.cleveland@cardinalhealth.com

Email Notification, Magdalene Riley magdalene.riley@cardinalhealth.com

Email Notification, Amanda Pashi amanda.pashi@cardinalhealth.com

Email Notification, Cindy Fricke cindy.fricke@cardinalhealth.com

Email Notification, Joshua Stine joshua.stine@cardinalhealth.com



**Service of Process
Transmittal**

05/11/2016

CT Log Number 529150285

TO: Magdalene Riley
Cardinal Health, Inc.
7000 Cardinal Pl
Dublin, OH 43017-1091

RE: Process Served in California

FOR: Cordis Corporation (Domestic State: FL)

SIGNED:
ADDRESS:
TELEPHONE:

C T Corporation System
818 West Seventh Street
Los Angeles, CA 90017
213-337-4615

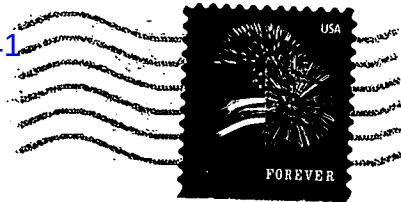


BRENES
LAW GROUP

16A Journey, Suite 200
Aliso Viejo, CA 92656

Case 4:16-cv-03082-KAW Document 1-3 Filed 06/06/16 Page 38 of 41

09 MAY 2016 PM 5 L



C T Corporation System
Cordis Corporation
818 W. 7th St., Suite 930
Los Angeles, CA 90017

90017347630



ATTORNEY OR PARTY WITHOUT ATTORNEY (Name, State Bar number, and address): Troy A. Brenes Brenes Law Group 16A Journey, Ste. 200 Aliso Viejo, CA 92656 TELEPHONE NO.: 949-397-9360 FAX NO. (Optional): 949-607-4192 E-MAIL ADDRESS (Optional): tbrenes@breneslawgroup.com ATTORNEY FOR (Name): Plaintiffs	FOR COURT USE ONLY
SUPERIOR COURT OF CALIFORNIA, COUNTY OF Alameda STREET ADDRESS: 1225 Fallon Street MAILING ADDRESS: CITY AND ZIP CODE: Oakland, CA 94612 BRANCH NAME: Oakland - Rene C. Davidson Courthouse	
PLAINTIFF/PETITIONER: David Resovsky et al. DEFENDANT/RESPONDENT: Cordis Corporation et al.	CASE NUMBER: JUDICIAL OFFICER:
NOTICE OF RELATED CASE	DEPT.:

Identify, in chronological order according to date of filing, all cases related to the case referenced above.

1. a. Title: **Deanna Cottrell v. Cordis Corporation et al.**
 b. Case number: **RG16810157**
 c. Court: ☒ same as above
☐ other state or federal court (name and address):
 d. Department:
 e. Case type: ☐ limited civil ☒ unlimited civil ☐ probate ☐ family law ☐ other (specify):
 f. Filing date: **April 5, 2016**
 g. Has this case been designated or determined as "complex?" ☐ Yes ☒ No
 h. Relationship of this case to the case referenced above (check all that apply):
☒ involves the same parties and is based on the same or similar claims.
☐ arises from the same or substantially identical transactions, incidents, or events requiring the determination of the same or substantially identical questions of law or fact.
☐ involves claims against, title to, possession of, or damages to the same property.
☒ is likely for other reasons to require substantial duplication of judicial resources if heard by different judges.
☐ Additional explanation is attached in attachment 1h
 i. Status of case:
☒ pending
☐ dismissed ☐ with ☐ without prejudice
☐ disposed of by judgment
2. a. Title: **Heather Quinn et al. v. Cordis Corporation et al.**
 b. Case number: **RG16814166**
 c. Court: ☒ same as above
☐ other state or federal court (name and address):
 d. Department:

CM-015

PLAINTIFF/PETITIONER: David Resovsky et al.	CASE NUMBER:
DEFENDANT/RESPONDENT: Cordis Corporation et al.	

2. (continued)

- e. Case type: ☐ limited civil ☒ unlimited civil ☐ probate ☐ family law ☐ other (specify):
- f. Filing date: May 3, 2016
- g. Has this case been designated or determined as "complex?" ☐ Yes ☒ No
- h. Relationship of this case to the case referenced above (check all that apply):
- ☒ involves the same parties and is based on the same or similar claims.
- ☒ arises from the same or substantially identical transactions, incidents, or events requiring the determination of the same or substantially identical questions of law or fact.
- ☐ involves claims against, title to, possession of, or damages to the same property.
- ☒ is likely for other reasons to require substantial duplication of judicial resources if heard by different judges.
- ☐ Additional explanation is attached in attachment 2h
- i. Status of case:
- ☒ pending
- ☐ dismissed ☐ with ☐ without prejudice
- ☐ disposed of by judgment

3. a. Title: Dehart et al. v. Cordis Corporation

b. Case number:

- c. Court: ☒ same as above
- ☐ other state or federal court (name and address):

d. Department:

e. Case type: ☐ limited civil ☒ unlimited civil ☐ probate ☐ family law ☐ other (specify):

f. Filing date: May 3, 2016

g. Has this case been designated or determined as "complex?" ☐ Yes ☒ No

h. Relationship of this case to the case referenced above (check all that apply):

- ☒ involves the same parties and is based on the same or similar claims.
- ☒ arises from the same or substantially identical transactions, incidents, or events requiring the determination of the same or substantially identical questions of law or fact.
- ☐ involves claims against, title to, possession of, or damages to the same property.
- ☒ is likely for other reasons to require substantial duplication of judicial resources if heard by different judges.
- ☐ Additional explanation is attached in attachment 3h

i. Status of case:

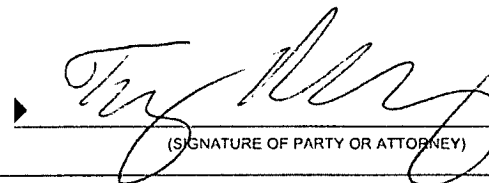
- ☒ pending
- ☐ dismissed ☐ with ☐ without prejudice
- ☐ disposed of by judgment

4. ☐ Additional related cases are described in Attachment 4. Number of pages attached: _____

Date: 5/9/2016

Troy A. Brenes

(TYPE OR PRINT NAME OF PARTY OR ATTORNEY)



(SIGNATURE OF PARTY OR ATTORNEY)

CM-015

PLAINTIFF/PETITIONER: David Resovsky et al.	CASE NUMBER:
DEFENDANT/RESPONDENT: Cordis Corporation et al.	

**PROOF OF SERVICE BY FIRST-CLASS MAIL
NOTICE OF RELATED CASE**

(NOTE: You cannot serve the Notice of Related Case if you are a party in the action. The person who served the notice must complete this proof of service. The notice must be served on all known parties in each related action or proceeding.)

1. I am at least 18 years old and not a party to this action. I am a resident of or employed in the county where the mailing took place, and my residence or business address is *(specify)*:
16A Journey, Ste. 200, Aliso Viejo, CA 92656

2. I served a copy of the *Notice of Related Case* by enclosing it in a sealed envelope with first-class postage fully prepaid and *(check one)*:
 - a. ☒ deposited the sealed envelope with the United States Postal Service.
 - b. ☐ placed the sealed envelope for collection and processing for mailing, following this business's usual practices, with which I am readily familiar. On the same day correspondence is placed for collection and mailing, it is deposited in the ordinary course of business with the United States Postal Service.

3. The *Notice of Related Case* was mailed:
 - a. on *(date)*: May 9, 2016
 - b. from *(city and state)*: Aliso Viejo, CA

4. The envelope was addressed and mailed as follows:

a. Name of person served: Cordis Corporation/ CT Corporation Street address: 818 W. 7th St., Suite 930 City: Los Angeles State and zip code: CA, 90017	c. Name of person served: Matthew Lopez/ LopezMcHugh, LLP Street address: 100 Bayview Circle, Ste. 5600 City: Newport Beach State and zip code: CA, 92660
b. Name of person served: Bonnie E. Sweeney/ Hausfield LLP Street address: 600 Montgomery St. Ste. 3200 City: San Francisco State and zip code: CA, 94111	d. Name of person served: Street address: City: State and zip code:

☐ Names and addresses of additional persons served are attached. *(You may use form POS-030(P).)*

I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct.

Date: 5/9/2016

Justin A. Sabol

(TYPE OR PRINT NAME OF DECLARANT)


 (SIGNATURE OF DECLARANT)

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)

I. (a) PLAINTIFFS

David Resovsky, et al.

(b) County of Residence of First Listed Plaintiff Unknown
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys (Firm Name, Address, and Telephone Number)
Troy A. Brenes (CSB No. 249776)
BRENES LAW GROUP
16 A Journey, Suite 200
Aliso Viejo, CA 92656
Phone: 949.397.9360; Fax: 949.607.4192
Email: tbrenes@breneslawgroup.com

DEFENDANTS

Cordis Corporation

County of Residence of First Listed Defendant Franklin County, Ohio
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys (If Known)
Kevin C. Mayer (CSB No. 118177) Andrew D. Kaplan (pro hac vice application to be filed)
CROWELL & MORING LLP Rebecca B. Chaney (pro hac vice application to be filed)
275 Battery Street, 23rd Floor CROWELL & MORING LLP
San Francisco, CA 94111 1001 Pennsylvania Ave., NW, Washington DC 20004
Phone: 415.986.2800; Fax: 415.986.2827 Phone: 202.624.2500; Fax: 202.628.5116
Email: kmayer@crowell.com Email: akaplan@crowell.com; rchaney@crowell.com

II. BASIS OF JURISDICTION (Place an "X" in One Box Only)

- ☐ 1 U.S. Government Plaintiff ☐ 3 Federal Question (U.S. Government Not a Party)
- ☐ 2 U.S. Government Defendant ☒ 4 Diversity (Indicate Citizenship of Parties in Item III)

III. CITIZENSHIP OF PRINCIPAL PARTIES (Place an "X" in One Box for Plaintiff and One Box for Defendant)

- | | PTF | DEF | | PTF | DEF |
|---|---------------------------------------|----------------------------|---|----------------------------|---------------------------------------|
| Citizen of This State | <input type="checkbox"/> 1 | <input type="checkbox"/> 1 | Incorporated or Principal Place of Business In This State | <input type="checkbox"/> 4 | <input type="checkbox"/> 4 |
| Citizen of Another State | <input checked="" type="checkbox"/> 2 | <input type="checkbox"/> 2 | Incorporated and Principal Place of Business In Another State | <input type="checkbox"/> 5 | <input checked="" type="checkbox"/> 5 |
| Citizen or Subject of a Foreign Country | <input type="checkbox"/> 3 | <input type="checkbox"/> 3 | Foreign Nation | <input type="checkbox"/> 6 | <input type="checkbox"/> 6 |

IV. NATURE OF SUIT (Place an "X" in One Box Only)

CONTRACT	TORTS		FORFEITURE/PENALTY	BANKRUPTCY	OTHER STATUTES
<input type="checkbox"/> 110 Insurance <input type="checkbox"/> 120 Marine <input type="checkbox"/> 130 Miller Act <input type="checkbox"/> 140 Negotiable Instrument <input type="checkbox"/> 150 Recovery of Overpayment & Enforcement of Judgment <input type="checkbox"/> 151 Medicare Act <input type="checkbox"/> 152 Recovery of Defaulted Student Loans (Excludes Veterans) <input type="checkbox"/> 153 Recovery of Overpayment of Veteran's Benefits <input type="checkbox"/> 160 Stockholders' Suits <input type="checkbox"/> 190 Other Contract <input type="checkbox"/> 195 Contract Product Liability <input type="checkbox"/> 196 Franchise	PERSONAL INJURY <input type="checkbox"/> 310 Airplane <input type="checkbox"/> 315 Airplane Product Liability <input type="checkbox"/> 320 Assault, Libel & Slander <input type="checkbox"/> 330 Federal Employers' Liability <input type="checkbox"/> 340 Marine <input type="checkbox"/> 345 Marine Product Liability <input type="checkbox"/> 350 Motor Vehicle <input type="checkbox"/> 355 Motor Vehicle Product Liability <input type="checkbox"/> 360 Other Personal Injury <input type="checkbox"/> 362 Personal Injury - Medical Malpractice	PERSONAL INJURY <input checked="" type="checkbox"/> 365 Personal Injury - Product Liability <input type="checkbox"/> 367 Health Care/Pharmaceutical Personal Injury Product Liability <input type="checkbox"/> 368 Asbestos Personal Injury Product Liability PERSONAL PROPERTY <input type="checkbox"/> 370 Other Fraud <input type="checkbox"/> 371 Truth in Lending <input type="checkbox"/> 380 Other Personal Property Damage <input type="checkbox"/> 385 Property Damage Product Liability	<input type="checkbox"/> 625 Drug Related Seizure of Property 21 USC 881 <input type="checkbox"/> 690 Other LABOR <input type="checkbox"/> 710 Fair Labor Standards Act <input type="checkbox"/> 720 Labor/Management Relations <input type="checkbox"/> 740 Railway Labor Act <input type="checkbox"/> 751 Family and Medical Leave Act <input type="checkbox"/> 790 Other Labor Litigation <input type="checkbox"/> 791 Employee Retirement Income Security Act IMMIGRATION <input type="checkbox"/> 462 Naturalization Application <input type="checkbox"/> 465 Other Immigration Actions	<input type="checkbox"/> 422 Appeal 28 USC 158 <input type="checkbox"/> 423 Withdrawal 28 USC 157 PROPERTY RIGHTS <input type="checkbox"/> 820 Copyrights <input type="checkbox"/> 830 Patent <input type="checkbox"/> 840 Trademark SOCIAL SECURITY <input type="checkbox"/> 861 HIA (1395ff) <input type="checkbox"/> 862 Black Lung (923) <input type="checkbox"/> 863 DIWC/DIWW (405(g)) <input type="checkbox"/> 864 SSID Title XVI <input type="checkbox"/> 865 RSI (405(g)) FEDERAL TAX SUITS <input type="checkbox"/> 870 Taxes (U.S. Plaintiff or Defendant) <input type="checkbox"/> 871 IRS—Third Party 26 USC 7609	<input type="checkbox"/> 375 False Claims Act <input type="checkbox"/> 400 State Reapportionment <input type="checkbox"/> 410 Antitrust <input type="checkbox"/> 430 Banks and Banking <input type="checkbox"/> 450 Commerce <input type="checkbox"/> 460 Deportation <input type="checkbox"/> 470 Racketeer Influenced and Corrupt Organizations <input type="checkbox"/> 480 Consumer Credit <input type="checkbox"/> 490 Cable/Sat TV <input type="checkbox"/> 850 Securities/Commodities/Exchange <input type="checkbox"/> 890 Other Statutory Actions <input type="checkbox"/> 891 Agricultural Acts <input type="checkbox"/> 893 Environmental Matters <input type="checkbox"/> 895 Freedom of Information Act <input type="checkbox"/> 896 Arbitration <input type="checkbox"/> 899 Administrative Procedure Act/Review or Appeal of Agency Decision <input type="checkbox"/> 950 Constitutionality of State Statutes
REAL PROPERTY <input type="checkbox"/> 210 Land Condemnation <input type="checkbox"/> 220 Foreclosure <input type="checkbox"/> 230 Rent Lease & Ejectment <input type="checkbox"/> 240 Torts to Land <input type="checkbox"/> 245 Tort Product Liability <input type="checkbox"/> 290 All Other Real Property	CIVIL RIGHTS <input type="checkbox"/> 440 Other Civil Rights <input type="checkbox"/> 441 Voting <input type="checkbox"/> 442 Employment <input type="checkbox"/> 443 Housing/Accommodations <input type="checkbox"/> 445 Amer. w/Disabilities Employment <input type="checkbox"/> 446 Amer. w/Disabilities Other <input type="checkbox"/> 448 Education	PRISONER PETITIONS Habeas Corpus: <input type="checkbox"/> 463 Alien Detainee <input type="checkbox"/> 510 Motions to Vacate Sentence <input type="checkbox"/> 530 General <input type="checkbox"/> 535 Death Penalty Other: <input type="checkbox"/> 540 Mandamus & Other <input type="checkbox"/> 550 Civil Rights <input type="checkbox"/> 555 Prison Condition <input type="checkbox"/> 560 Civil Detainee - Conditions of Confinement			

V. ORIGIN (Place an "X" in One Box Only)

- ☐ 1 Original Proceeding ☒ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from Another District (specify) ☐ 6 Multidistrict Litigation

Cite the U.S. Civil Statute under which you are filing (Do not cite jurisdictional statutes unless diversity):
28 U.S.C. §§ 1332, 1441, 1446 and 1453

VI. CAUSE OF ACTION

Brief description of cause: This matter is being removed under the Class Action Fairness Act, 28 U.S.C. § 1332(d), as a mass action in which monetary relief claims of more than 100 persons are proposed to be tried jointly on the ground that plaintiffs' claims involve common questions of law or facts; the parties are of at least minimal diversity; and the amount in controversy requirement is met.

VII. REQUESTED IN COMPLAINT:

☐ CHECK IF THIS IS A CLASS ACTION UNDER RULE 23, F.R.Cv.P. DEMAND \$ CHECK YES only if demanded in complaint:
JURY DEMAND: ☒ Yes ☐ No

VIII. RELATED CASE(S) IF ANY

(See instructions):

JUDGE

DOCKET NUMBER

IX. DIVISIONAL ASSIGNMENT (Civil L.R. 3-2)

(Place an "X" in One Box Only)

(X) SAN FRANCISCO/OAKLAND () SAN JOSE () EUREKA

DATE

SIGNATURE OF ATTORNEY OF RECORD

June 6, 2016

/s/ Kevin C. Mayer

INSTRUCTIONS FOR ATTORNEYS COMPLETING CIVIL COVER SHEET FORM JS 44

Authority For Civil Cover Sheet

The JS 44 civil cover sheet and the information contained herein neither replaces nor supplements the filings and service of pleading or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. Consequently, a civil cover sheet is submitted to the Clerk of Court for each civil complaint filed. The attorney filing a case should complete the form as follows:

- I. (a) **Plaintiffs-Defendants.** Enter names (last, first, middle initial) of plaintiff and defendant. If the plaintiff or defendant is a government agency, use only the full name or standard abbreviations. If the plaintiff or defendant is an official within a government agency, identify first the agency and then the official, giving both name and title.
 - (b) **County of Residence.** For each civil case filed, except U.S. plaintiff cases, enter the name of the county where the first listed plaintiff resides at the time of filing. In U.S. plaintiff cases, enter the name of the county in which the first listed defendant resides at the time of filing. (NOTE: In land condemnation cases, the county of residence of the "defendant" is the location of the tract of land involved.)
 - (c) **Attorneys.** Enter the firm name, address, telephone number, and attorney of record. If there are several attorneys, list them on an attachment, noting in this section "(see attachment)".
- II. **Jurisdiction.** The basis of jurisdiction is set forth under Rule 8(a), F.R.Cv.P., which requires that jurisdictions be shown in pleadings. Place an "X" in one of the boxes. If there is more than one basis of jurisdiction, precedence is given in the order shown below.
- United States plaintiff. (1) Jurisdiction based on 28 U.S.C. 1345 and 1348. Suits by agencies and officers of the United States are included here.
- United States defendant. (2) When the plaintiff is suing the United States, its officers or agencies, place an "X" in this box.
- Federal question. (3) This refers to suits under 28 U.S.C. 1331, where jurisdiction arises under the Constitution of the United States, an amendment to the Constitution, an act of Congress or a treaty of the United States. In cases where the U.S. is a party, the U.S. plaintiff or defendant code takes precedence, and box 1 or 2 should be marked.
- Diversity of citizenship. (4) This refers to suits under 28 U.S.C. 1332, where parties are citizens of different states. When Box 4 is checked, the citizenship of the different parties must be checked. (See Section III below; **NOTE: federal question actions take precedence over diversity cases.**)
- III. **Residence (citizenship) of Principal Parties.** This section of the JS 44 is to be completed if diversity of citizenship was indicated above. Mark this section for each principal party.
- IV. **Nature of Suit.** Place an "X" in the appropriate box. If the nature of suit cannot be determined, be sure the cause of action, in Section VI below, is sufficient to enable the deputy clerk or the statistical clerk(s) in the Administrative Office to determine the nature of suit. If the cause fits more than one nature of suit, select the most definitive.
- V. **Origin.** Place an "X" in one of the six boxes.
- Original Proceedings. (1) Cases which originate in the United States district courts.
- Removed from State Court. (2) Proceedings initiated in state courts may be removed to the district courts under Title 28 U.S.C., Section 1441. When the petition for removal is granted, check this box.
- Remanded from Appellate Court. (3) Check this box for cases remanded to the district court for further action. Use the date of remand as the filing date.
- Reinstated or Reopened. (4) Check this box for cases reinstated or reopened in the district court. Use the reopening date as the filing date.
- Transferred from Another District. (5) For cases transferred under Title 28 U.S.C. Section 1404(a). Do not use this for within district transfers or multidistrict litigation transfers.
- Multidistrict Litigation. (6) Check this box when a multidistrict case is transferred into the district under authority of Title 28 U.S.C. Section 1407. When this box is checked, do not check (5) above.
- VI. **Cause of Action.** Report the civil statute directly related to the cause of action and give a brief description of the cause. **Do not cite jurisdictional statutes unless diversity.** Example: U.S. Civil Statute: 47 USC 553 Brief Description: Unauthorized reception of cable service
- VII. **Requested in Complaint.** Class Action. Place an "X" in this box if you are filing a class action under Rule 23, F.R.Cv.P.
- Demand. In this space enter the actual dollar amount being demanded or indicate other demand, such as a preliminary injunction.
- Jury Demand. Check the appropriate box to indicate whether or not a jury is being demanded.
- VIII. **Related Cases.** This section of the JS 44 is used to reference related pending cases, if any. If there are related pending cases, insert the docket numbers and the corresponding judge names for such cases.

Date and Attorney Signature. Date and sign the civil cover sheet.