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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

OAKLAND DIVISION

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

Plaintiffs,

v.

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

Defendants.

Case No. _____

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

TO THE HONORABLE UNITED STATES DISTRICT JUDGE:

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

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

1. On April 20, 2016, plaintiffs Jerry Dunson, Joseph Gieber, Cheryl Grech, Robert Flanagan and Carol Flanagan filed a complaint ("Compl.") against Cordis Corporation and Does 1 through 100 in the Superior Court of the State of California for the County of Alameda, Civil Action No. RG16812476 ("*Dunson*").

2. On May 3, 2016, plaintiffs Heather Quinn, Brian Quinn, Kathrynn Kirby, Allison Brauer, Edward Brown, Patricia Brown, Michael Hickson, William Schenk, and Christina Jones filed a complaint against Cordis Corporation; Johnson & Johnson; and Does 1 through 50 in the Superior Court of the State of California for the County of Alameda, Civil Action No. RG16814166 ("*Quinn*").

3. On May 13, 2016, plaintiffs in *Quinn* filed a First Amended Complaint ("FAC"), adding as plaintiffs Nancy Folz, Edward Chizek and Andrew Chapman. Plaintiffs' FAC does not assert claims against Johnson & Johnson.

4. On May 5, 2016, plaintiffs Walter Herbert, Russell Anderson, Martha Graham, Frank Graham, Tamarra Grayson, Timothy Howard, Ted Michael Martinez, Cynthia Martinez, Judy Shaffer and John Shaffer, Jr. filed a complaint against Cordis Corporation; Johnson & Johnson; and Does 1 through 50 in the Superior Court of the State of California for the County of Alameda, Civil Action No. RG16814569 ("*Herbert*").

5. On May 13, 2016, plaintiffs in *Herbert* filed a FAC, adding as plaintiffs Clarice Stepp and Allison Fisher. Plaintiffs' FAC does not assert claims against Johnson & Johnson.

6. On May 6, 2016, 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 filed a complaint against Cordis Corporation; Johnson & Johnson; and Does 1 through 50, in the Superior Court of the State of California for the County of Alameda, Civil Action No. RG16814688 ("*Grant*").

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

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

9. On May 20, 2016, 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, Venesia Johnson, Darnell Kilgore, Joseph Hershberger, Russell Zukrigil and Brian Zukrigil filed a complaint against Cordis Corporation; Johnson & Johnson; 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. RG16816487 ("*Barber*").

10. On May 20, 2016, plaintiffs Lisa Oehring, Luther Leatham, Sonji Hutchinson, Sandra Sutter, Lynda Smith, Alan Goldberg, Benito Brown, Lupe Brown, Patricia Bunker, Carmen Burgess, Travis Burkhart, Kimberly Burkhart, 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 filed a complaint against Cordis Corporation; Johnson & Johnson; 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, 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, 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

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

32. While plaintiffs suggest that they "are not requesting a consolidation of Related Actions for purposes of a single trial to determine the outcome for all plaintiffs," Mem. at 7, this rhetoric rings hollow given what in fact they propose. Plaintiffs do not limit their consolidation request to pretrial proceedings. They do not limit their request to achieving efficiency goals. And they propose not merely a bellwether trial, but an entire "process" and "protocol" for bellwether trials. In like circumstances, courts look beyond rhetoric, focus on the substance of the request, and find the joint trial element satisfied. *Corber*, 771 F.3d at 1225; *Allen*, 2015 WL 846792, at *4; *see also Atwell*, 740 F.3d at 1166; *In re Abbott Labs.*, 698 F.3d at 573.[1]

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

B. The Parties Are Minimally Diverse

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

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

[1] Seeking bellwether trials is not inconsistent with a proposal to try cases jointly. "[A] joint trial can take different forms so long as the plaintiffs' claims are being determined jointly." *In re 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, Kathrynn 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.

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[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; *Resovsk*y Compl. ¶¶ 1-2. They contend that their injuries have caused or will cause them to "continue to suffer significant medical expenses,"

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

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

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

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

June 6, 2016

CROWELL & MORING LLP

By: /*s*/ Kevin C. Mayer

Attorneys for Defendant Cordis Corporation

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 — **Attorneys for Plaintiffs**
BRENES LAW GROUP
16 A Journey, Suite 200
Aliso Viejo, CA 92656
Telephone: 949.397.9360
Facsimile: 949.607.4192

☒ 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.

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

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

Jennifer S. Tai

EXHIBIT A Part 1

CT Corporation

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
	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

CT Corporation

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)

Email Notification, Cindy Fricke cindy.fricke@cardinalhealth.com

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

SIGNED: C T Corporation System
ADDRESS: 1300 East 9th Street
Suite 1010
Cleveland, OH 44114
TELEPHONE: 216-802-2121

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C003

CARDINAL HEALTH, INC.
C/O CT CORPORATION
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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,

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

The parties named in *Jerry Dunson, et al. vs. Cordis Corporation, et al.*, Case No. RG16812476 are Plaintiffs Jerry Dunson, Joseph Gieber, Cheryl Grech, Robert Flanagan, and Carol Flanagan.[1] 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 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 *Heather Quinn, et al. vs. Cordis Corporation, et al.*, Case No. RG16814166 are Plaintiffs Heather Quinn, Brian Quinn, Kathrynn Kirby, Allison Brauer, Edward Brown, Patricia Brown, Michael Hickson, William Schenk, and Christina Jones.[2] 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.[3] 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 *Walter Herbert, et al. vs. Cordis Corporation, et al.*, Case No. RG16814569 are Plaintiffs Walter Herbert, Russell Anderson, Martha Graham, Frank Graham, Tamarra

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

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

[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

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[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 Burkhart, Kimberly Burkhart, 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,

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[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.*

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

The parties named in *Wanda Holden, et al. vs. Cordis Corporation, et al.*, Case No. RG16816600 are 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, Cheryl Wright, Evelyn Wright, and Plaintiff Thomas Yaudas, Sr. Defendants are Cordis Corporation, Confluent Medical Technologies, Inc., 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 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 motion should be granted on the grounds that all of the Related Actions arise out of the same set of operative facts; specifically, all Plaintiffs (or Decedent) were implanted with Defendants' Inferior Vena Cava ("IVC") filter medical devices— the TrapEase™ Permanent Vena Cava Filter or the OptEase™ Vena Cava Filter—and suffered injury and/or death due to a malfunction of the Defendants' IVC filter. Both devices are nearly identical in manufacture, design, warnings provided, and marketing claims made. Moreover, the Related Actions each contain common issues such that the oral and written discovery sought from Defendants in each Related Action will be the same; the majority of the expert discovery in each Related Action will also be the same. Consolidation of all of the Related Actions for purposes of pretrial discovery proceedings and creation of a bellwether-trial process will avoid unnecessary duplication of evidence and procedures, 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.

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

Dated: May 27, 2016

Respectfully submitted,

LOPEZ McHUGH LLP

By: /s/ Matthew R. Lopez
Ramon Rossi Lopez
Matthew R. Lopez
Amorina P. Lopez

Attorneys for Plaintiffs

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.

____ **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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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.*;

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

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

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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I.

INTRODUCTION

The Related Actions are product liability cases being asserted against Cordis Corporation, as the primary Defendant[1], 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

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[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.

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

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

II.

JURISDICTION AND VENUE IS PROPER FOR CONSOLIDATION

Defendant Cordis Corporation ("Cordis") is a multi-national corporation which is incorporated under the laws of Florida with its principal place of business located at 6500 Paseo Padre Pkwy., Fremont, California, 94555, which is within Alameda County. Defendant Cordis Corporation was a wholly-owned subsidiary of Defendant Johnson & Johnson's ("J&J") and part of the J&J family of companies until October 2015. On October 4, 2015, Defendant Cardinal Health ("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.

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 27, 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 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

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

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 symmetric filter. The filter has proximal and distal anchoring barbs located on each connecting strut for fixation of the filter to the vena cava wall to prevent movement after placement.

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

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

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

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

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

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

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

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

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

IV.

PENDING ACTIONS

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

V.

LEGAL ARGUMENT

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.

Code of Civil Procedure § 1048(a) states that, "when the actions involving a common question 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

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

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

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

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

Consolidation of the Related Actions for purposes of pretrial discovery and proceedings, and 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.

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.

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

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

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

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

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

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

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

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

VI.

CONCLUSION

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

Dated: May 27, 2016

Respectfully submitted,

LOPEZ McHUGH LLP

By: /Matthew R. Lopez/

Ramon Rossi Lopez
Matthew R. Lopez
Amorina P. Lopez

Attorneys for Plaintiffs

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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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

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)

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

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

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

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

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

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

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

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

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

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

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

v. Complaint filed on May 6, 2016 in *David Resovsky, et al. vs. Cordis Corporation, 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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SUPERIOR COURT OF CALIFORNIA, COUNTY OF ALAMEDA
RENE C. DAVIDSON ALAMEDA COUNTY COURTHOUSE

JERRY DUNSON, JOSEPH GIEBER, CHERYL GRECH, ROBERT FLANAGAN and CAROL FLANAGAN,

Plaintiff(s),

vs.

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

Defendant(s).

Case No.: RG16812476

COMPLAINT FOR DAMAGES

DEMAND FOR JURY TRIAL

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

PARTIES

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

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

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

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

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

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

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

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

California, 94555. Cordis at all times relevant to this action, designed, set specifications for, manufactured, prepared, compounded, assembled, processed, marketed, distributed, and sold the TrapEase™ Permanent Vena Cava Filter ("TrapEase filter") and OptEase™ Permanent Vena Cava Filter ("OptEase filter") to be implanted in patients throughout the United States, including California. 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.

8. The true names and/or capacities, whether individual, corporate, partnership, associate, governmental, or otherwise, of Defendant DOES 1 through 100, 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.

9. Plaintiffs are informed and believe, and thereon allege, that at all times herein mentioned, the Defendant 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.

10. Plaintiffs are informed and believe, and thereon allege, that at all times mentioned herein, Defendant and DOES 1 through 100, 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, fabricating, designing, developing, labeling, assembling, distributing, supplying, leasing, buying, offering for sale, selling, inspecting, servicing, contracting others for marketing, warranting, rebranding, manufacturing for others, packaging, and advertising the device.

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

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

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

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

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

16. "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

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

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

BACKGROUND

INFERIOR VENA CAVA FILTERS GENERALLY

19. 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.

20. 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.

21. 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.

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

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

23. 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, however, an explosion in off-label use began with the introduction of IVC filters that were cleared for both permanent placement and optional removal. Most of this market expansion came from uses such as prophylactic prevention of pulmonary embolism without a prior history of pulmonary embolism.

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

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

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

27. Comparing the results of over 30,000 trauma patients who had not received IVC filters 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.

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 Adminstration'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.

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

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

> If the FDA concludes on the basis of the [manufacturer's] § 510(k) notification that the device is 'substantially equivalent' to a pre-existing device, it can be marketed without further regulatory analysis.... The § 510(k) notification process is by no means 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 on commentator noted: "The attraction of substantial equivalence to manufacturers is clear. Section 510(k) notification required little information, rarely elicits a negative response form the FDA, and gets processed quickly.

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

34. Pursuant to *Wyeth v. Levine*, 555 U.S. 555 (2009), once a product is cleared "the manufacturer remains under an obligation to investigate and report any adverse associated with 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.

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

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

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

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

38. 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 has anchoring barbs for fixation of the filter only on the superior end of each of the six straight struts and has a hook at the inferior end of the basket to allow retrieval with a snare.

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

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

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

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

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

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

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

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

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

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

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

a. Death;

b. Hemorrhage;

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.

49. 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.

50. 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.

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

52. 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.

53. 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.

54. 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.

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

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

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

> dissection force in addition to laser tissue ablation to achieve removal. A possible 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."

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

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

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

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

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

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

63. Given the unreasonably high failure and injury rates associated with Defendants 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.

ESTOPPEL FROM PLEADING STATUTES OF LIMITATIONS OR REPOSE

64. Plaintiffs incorporate by reference all prior allegations.

65. 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 Defendants' IVC filters.

66. Plaintiffs' ignorance of the defective and unreasonably dangers nature of Defendants' IVC filters, and the causal connection between these defects and Plaintiffs' 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.

67. 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.

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

69. Defendants had a duty to disclose the fact that Defendants' 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 the above described risks.

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.

77. 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.

78. As a direct and proximate result of the defective and unreasonably dangerous condition of the TrapEase and 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

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

80. 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 TrapEase and OptEase filters.

81. The TrapEase and 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.

82. Defendants knew or it was knowable at the time they distributed the devices implanted in Plaintiffs that the TrapEase and 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.

83. Defendants' TrapEase and 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 used in an intended and reasonably foreseeable way. Such ordinary consumers, including Plaintiffs and their prescribing physician(s), would not and could not have recognized or discovered the potential risks and side effects of the device, as set forth herein.

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

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

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

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

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

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

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

89. 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.

90. 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.

91. 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.

92. 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

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. 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 TrapEase and OptEase filters so as to avoid exposing others to foreseeable and unreasonable risks of harm.

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

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

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.

98. 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.

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

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

a. 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 burden of taking safety measures to reduce or avoid harm;

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 likelihood of potential harm from other devices and treatment options available for the same purpose;

c. Failing to use reasonable care in manufacturing the product and producing a product that differed from their design or specifications or from other typical units from the same production line;

d. 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;

e. 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 and adequate post-market surveillance program;

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

102. 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

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

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.

118. 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.

119. 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.

120. 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

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

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

123. 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

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

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

125. The Defendants are and were under a continuing duty to disclose the true character, 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.

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

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

128. 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

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

130. 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.

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

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.

132. 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.

133. 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.

134. 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

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

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

137. 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.

138. 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.

139. 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;

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 Carol Flanagan

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

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

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 Carol Flanagan suffered the loss of support, service, love, companionship, affection, society, intimate relations, and other elements of consortium, all to Plaintiff's general damage, in an amount in excess of the jurisdictional minimum of this Court.

WHEREFORE, Plaintiff Carol Flanagan demand judgment against the Defendants as hereinafter set forth.

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

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.

Respectfully Submitted,

DATED: April 21, 2016

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

JERRY DUNSON, JOSEPH GIEBER, CHERYL GRECH, ROBERT FLANAGAN, CAROL FLANAGAN, MARY ELDEB, DAYNA CURRIE AND HARLOWE CURRIE

Plaintiffs,

vs.

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

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

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

PARTIES

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

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

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

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

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

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

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

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

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

10. Defendant Cordis Corporation ("Cordis") is a corporation organized under the laws of the State of Florida, with its principal place of business at 6500 Paseo Padre Pkwy, Fremont, California, 94555. Cordis at all times relevant to this action, designed, set specifications for, manufactured, prepared, compounded, assembled, processed, marketed, distributed, and sold the TrapEase™ Permanent Vena Cava Filter ("TrapEase filter") and OptEase™ Permanent Vena Cava Filter ("OptEase filter") to be implanted in patients throughout the United States, including California. 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.

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

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

13. The true names and/or capacities, whether individual, corporate, partnership, associate, governmental, or otherwise, of Defendant DOES 1 through 100, 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.

14. Plaintiffs are informed and believe, and thereon allege, that at all times herein mentioned, 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.

15. Plaintiffs are informed and believe, and thereon allege, that at all times mentioned herein, Defendants and DOES 1 through 100, 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, fabricating, designing, developing, labeling, assembling, distributing, supplying, leasing, buying, offering for sale, selling, inspecting, servicing, contracting others for marketing, warranting, rebranding, manufacturing for others, packaging, and advertising the device.

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

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

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

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

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

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

21. "Cordis," "Confluent" 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, Confluent, as well as DOE Defendants 1 through 100, and each of them.

JURISDICTION AND VENUE

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

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

BACKGROUND

INFERIOR VENA CAVA FILTERS GENERALLY

24. 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.

25. 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.

26. 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.

27. 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 manage their conditions with medications, physicians may recommend surgically implanting an IVC filter to prevent thromboembolitic events.

28. 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, however, an explosion in off-label use began with the introduction of IVC filters that were cleared for both permanent placement and optional removal. Most of this market expansion came from uses such as prophylactic prevention of pulmonary embolism without a prior history of pulmonary embolism.

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

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

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

32. Comparing the results of over 30,000 trauma patients who had not received IVC filters 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.

33. 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.

34. 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.

35. 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

36. On January 10, 2001, Defendants bypassed the more onerous Food and Drug Adminstration'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.

37. 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.

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

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

> If the FDA concludes on the basis of the [manufacturer's] § 510(k) notification that the device is 'substantially equivalent' to a pre-existing device, it can be marketed without further regulatory analysis.... The § 510(k) notification process is by no means 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 on commentator noted: "The attraction of substantial equivalence to manufacturers is clear. Section 510(k) notification required little information, rarely elicits a negative response form the FDA, and gets processed quickly.

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

39. Pursuant to *Wyeth v. Levine*, 555 U.S. 555 (2009), once a product is cleared "the manufacturer remains under an obligation to investigate and report any adverse associated with 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.

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

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

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

43. 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 has anchoring barbs for fixation of the filter only on the superior end of each of the six straight struts and has a hook at the inferior end of the basket to allow retrieval with a snare.

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

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

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

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

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

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

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

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

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

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

a. Death;

b. Hemorrhage;

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.

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

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

> "...we thought the OPTEASE and TRAPEASE filter types were subjectively among the most difficult to remove in our study, often requiring aggressive blunt dissection force in addition to laser tissue ablation to achieve removal. A possible 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."

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

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

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

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

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

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

68. Given the unreasonably high failure and injury rates associated with Defendants 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.

ESTOPPEL FROM PLEADING STATUTES OF LIMITATIONS OR REPOSE

69. Plaintiffs incorporate by reference all prior allegations.

70. 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 Defendants' IVC filters.

71. Plaintiffs' ignorance of the defective and unreasonably dangers nature of Defendants' IVC filters, and the causal connection between these defects and Plaintiffs' 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.

72. 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.

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

74. Defendants had a duty to disclose the fact that Defendants' 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 the above described risks.

COUNT I:
STRICT PRODUCTS LIABILITY- DESIGN DEFECT
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. 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.

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

78. 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.

79. 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.

80. 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.

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

82. 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.

83. As a direct and proximate result of the defective and unreasonably dangerous condition of the TrapEase and 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

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

85. 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 TrapEase and OptEase filters.

86. The TrapEase and 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.

87. Defendants knew or it was knowable at the time they distributed the devices implanted in Plaintiffs that the TrapEase and 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.

88. Defendants' TrapEase and 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 used in an intended and reasonably foreseeable way. Such ordinary consumers, including Plaintiffs and their prescribing physician(s), would not and could not have recognized or discovered the potential risks and side effects of the device, as set forth herein.

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

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

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

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

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.

100. 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 TrapEase and OptEase filters so as to avoid exposing others to foreseeable and unreasonable risks of harm.

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

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

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.

103. 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.

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

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

a. 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 burden of taking safety measures to reduce or avoid harm;

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 likelihood of potential harm from other devices and treatment options available for the same purpose;

c. Failing to use reasonable care in manufacturing the product and producing a product that differed from their design or specifications or from other typical units from the same production line;

d. 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;

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 and adequate post-market surveillance program;

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

107. 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

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

109. 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.

110. 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.

111. 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.

112. 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

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

114. 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.

115. 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.

116. 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.

117. 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.

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

119. 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.

120. 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.

121. 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.

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

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

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

130. The Defendants are and were under a continuing duty to disclose the true character, 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.

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

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

133. 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

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

135. 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.

136. 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.

137. 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.

138. 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.

139. 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

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

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

142. 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.

143. 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.

144. 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;

145. 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 Carol Flanagan

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

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

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

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

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

PUNITIVE DAMAGES ALLEGATIONS

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

151. 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.

152. 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.

153. 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.

154. 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 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, Confluent Medical Technologies, Inc., 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.

Respectfully Submitted,

DATED: May 24, 2016

BRENES LAW GROUP

/s/ Troy A. Brenes
Troy A. Brenes
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ENDORSED
FILED
ALAMEDA COUNTY
MAY - 3 2016
CLERK OF THE SUPERIOR COURT
By MARGARET J. DOWNI Deputy

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.: RG16814166

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:

BY FAX

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 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' TrapEase Vena Cava Filter on or about March 19, 2001, in California. The filter subsequently malfunctioned and caused injury and damages to Plaintiff HEATHER QUINN, including, but not limited to, fracture, tilt, migration and perforation. As a direct and proximate result of these malfunctions, Plaintiff HEATHER QUINN suffered life-threatening injuries and damages, and required

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

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

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

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

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

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

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

15. Plaintiff WILLIAM SCHENK at all times relevant to this action was and is a citizen and resident of the State of Illinois. Plaintiff WILLIAM SCHENK underwent placement of Defendants' OptEase Vena Cava Filter on or about December 28, 2004. The filter subsequently malfunctioned and caused injury and damages to Plaintiff WILLIAM SCHENK, including, but not limited to, tilt, 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 WILLIAM SCHENK suffered life-threatening injuries and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff WILLIAM SCHENK has suffered and will continue to suffer significant medical expenses, and pain and suffering, and other damages.

16. Plaintiff CHRISTINA JONES at all times relevant to this action was and is a citizen and resident of the State of Kentucky. Plaintiff CHRISTINA JONES underwent placement of Defendants' OptEase Vena Cava Filter on or about December 9, 2010. The filter subsequently malfunctioned and caused injury and damages to Plaintiff CHRISTINA JONES, including, but not limited to, tilt, 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 CHRISTINA JONES suffered life-threatening injuries and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff CHRISTINA JONES has suffered and will continue to suffer significant medical expenses, and pain and suffering, and other damages.

17. Defendant CORDIS CORPORATION ("Cordis"), including its department, division, and subsidiary, Cordis Endovascular, is a corporation or business entity organized and existing under the laws of the State of California with its headquarters located at 6500 Paseo Padre Pkwy., Fremont, California, 94555. 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.

18. Defendant CORDIS COPORATION 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.

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

28. 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 thromboembolitic events.

29. 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.

30. 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.

31. Defendants Cordis and J&J 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.

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

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

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

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

36. Comparing the results of over 30,000 trauma patients who had not received IVC filters 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 Defendants Cordis and J&J told the FDA, physicians, and the public that its IVC filters were designed to prevent.

37. This *Annals of Surgery* study – and many others referenced by it – 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

38. 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.

39. 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).

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

> If the FDA concludes on the basis of the [manufacturer's] § 510(k) notification that the device is "substantially equivalent" to a pre-existing device, it can be marketed without further regulatory analysis. . . . The § 510(k) notification process is by no means 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."

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

41. Pursuant to *Wyeth v. Levine*, 555 U.S. 555 (2009), once a product is cleared "the manufacturer remains under an obligation to investigate and report any adverse events associated with 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.

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

43. 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 symmetric filter. The filter has proximal and distal anchoring barbs located on each connecting strut for fixation of the filter to the vena cava wall to prevent movement after placement.

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

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

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

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

48. 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 has anchoring barbs for fixation of the filter only on the superior end of each of the six straight struts and has a hook at the inferior end of the basket to allow retrieval with a snare.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

a. Death;

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; and

f. Perforations of tissue, vessels and organs.

63. 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*.

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

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

66. 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

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

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

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

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

72. 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.

73. 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.

74. In 2010, Dr. Gred Usoh 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* Usoh, *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.

75. 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 was detected inside the filter in two cases. Based on these results, Dr. Sano criticized previous studies that had found the TrapEase filter to be safe as being conducted over too short a period of time and concluded that "patients undergoing permanent TrapEase IVCF insertion are at extremely high risk of strut fractures as early as two to three years after IVCF placement."

76. On May 6, 2014, the FDA issued another Safety Alert involving IVC filters. In this safety communication, the FDA wrote that it had received adverse event reports concerning "device 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.

82. 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.

83. 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)

84. Plaintiffs incorporate by reference all prior allegations.

85. 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.

86. 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.

87. 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.

88. 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.

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,

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.

98. 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.

99. 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.

100. 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.

101. 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.

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.

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

116. 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

g. 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.

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

118. 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.

119. 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.

120. 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.

121. 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.

122. 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.

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

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

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

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

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

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

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

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

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

FIFTH CAUSE OF ACTION

NEGLIGENT MISREPRESENTATION

(By All Plaintiffs, As to All Defendants)

132. Plaintiffs incorporate by reference all prior allegations.

133. 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.

134. These representations were untrue.

135. 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.

136. 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.

137. 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.

138. 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.

139. 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.

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

141. 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.

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.

147. 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.

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

149. The foregoing representations and omissions by Defendants were false.

150. Defendants' IVC filters are not safe, fit, and effective for human use in their intended and reasonably foreseeable manner.

151. Further, the use of Cordis IVC filters is hazardous to the users' health, and Cordis IVC filters have a serious propensity to cause users to suffer serious injuries, including without limitation the injuries Plaintiffs suffered.

152. Finally, Defendants' IVC filters have a statistically significant higher rate of failure and injury than do other comparable IVC filters.

153. 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.

154. 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.

155. 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.

156. 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.

157. 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)

158. Plaintiffs incorporate by reference all prior allegations.

159. In marketing and selling Cordis IVC filters (the TrapEase filters and the OptEase filters), Defendants concealed material facts from Plaintiffs and their healthcare providers.

160. 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.

161. Plaintiffs and their health care providers were not aware of these and other facts concealed by Defendants.

162. In concealing these and other facts, Defendants intended to deceive Plaintiffs and their health care providers.

163. 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.

164. 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)

165. Plaintiffs incorporate by reference all prior allegations.

166. Plaintiffs, through their medical providers, purchased a Cordis IVC filter from Defendants.

167. At all relevant times, Defendants were merchants of goods of the kind including medical devices and vena cava filters (i.e., Cordis IVC filters).

168. 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.

169. 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.

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

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)

180. Plaintiffs incorporate by reference all prior allegations.

181. 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.

182. At all times material hereto, Defendants attempted to misrepresent and did knowingly misrepresent facts concerning the safety of Cordis IVC filters.

183. 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.

184. 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.

185. 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.

186. Notwithstanding the foregoing, Defendants continued to market Cordis IVC filters aggressively to consumers, including Plaintiffs, without disclosing the aforesaid side effects.

187. 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.

188. 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.

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: Matthew R. Lopez

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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

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'

TrapEase Vena Cava Filter on or about March 19, 2001, in California. The filter subsequently malfunctioned and caused injury and damages to Plaintiff HEATHER QUINN, including, but not limited to, fracture, tilt, migration and perforation. As a direct and proximate result of these malfunctions, Plaintiff HEATHER QUINN suffered life-threatening injuries and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff HEATHER QUINN has suffered and will continue to suffer significant medical expenses, and pain and suffering, and other damages.

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

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

11. Plaintiff ALLISON BRAUER at all times relevant to this action was and is a citizen and resident of the State of Tennessee. Plaintiff ALLISON BRAUER underwent placement of Defendants' OptEase Vena Cava Filter on or about May 1, 2013. The filter subsequently malfunctioned and caused injury and damages to Plaintiff ALLISON BRAUER, including, but not limited to, tilt, filter embedded in wall of the IVC, and filter unable to be retrieved. As a direct and proximate result of these malfunctions, Plaintiff ALLISON BRAUER suffered life-threatening injuries and damages, and required

extensive medical care and treatment. As a further proximate result, Plaintiff ALLISON BRAUER has suffered and will continue to suffer significant medical expenses, and pain and suffering, and other damages.

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

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

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

15. Plaintiff WILLIAM SCHENK at all times relevant to this action was and is a citizen and resident of the State of Illinois. Plaintiff WILLIAM SCHENK underwent placement of Defendants' OptEase Vena Cava Filter on or about December 28, 2004. The filter subsequently malfunctioned and caused injury and damages to Plaintiff WILLIAM SCHENK, including, but not limited to, tilt, 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 WILLIAM SCHENK suffered life-threatening injuries and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff WILLIAM SCHENK has suffered and will continue to suffer significant medical expenses, and pain and suffering, and other damages.

16. Plaintiff CHRISTINA JONES at all times relevant to this action was and is a citizen and resident of the State of Kentucky. Plaintiff CHRISTINA JONES underwent placement of Defendants' OptEase Vena Cava Filter on or about December 9, 2010. The filter subsequently malfunctioned and caused injury and damages to Plaintiff CHRISTINA JONES, including, but not limited to, tilt, 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 CHRISTINA JONES suffered life-threatening injuries and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff CHRISTINA JONES has suffered and will continue to suffer significant medical expenses, and pain and suffering, and other damages.

17. Plaintiff NANCY FOLZ at all times relevant to this action was a citizen and resident of the State of Ohio. Plaintiff NANCY FOLZ underwent placement of Defendants' OptEase Vena Cava Filter on or about August 22, 2007. The filter subsequently malfunctioned and caused injury and damages to Plaintiff NANCY FOLZ, including, but not limited to, tilt, filter embedded in wall of the IVC, and filter unable to be retrieved. As a direct and proximate result of these malfunctions, Plaintiff NANCY FOLZ suffered life-threatening injuries and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff NANCY FOLZ has suffered and will continue to suffer significant medical expenses, and pain and suffering, and other damages.

18. Plaintiff EDWARD CHIZEK at all times relevant to this action was and is a citizen and resident of the State of Ohio. Plaintiff EDWARD CHIZEK underwent placement of Defendants'

TrapEase Vena Cava Filter on or about November 16, 2005. The filter subsequently malfunctioned and caused injury and damages to Plaintiff EDWARD CHIZEK, including, but not limited to, tilt, filter embedded in wall of the IVC, filter unable to be retrieved, blood clots, clotting and occlusion of IVC filter. As a direct and proximate result of these malfunctions, Plaintiff EDWARD CHIZEK suffered life-threatening injuries and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff EDWARD CHIZEK has suffered and will continue to suffer significant medical expenses, and pain and suffering, and other damages.

19. Plaintiff ANDREW CHAPMAN at all times relevant to this action was and is a citizen and resident of the State of Florida. Plaintiff ANDREW CHAPMAN underwent placement of Defendants' TrapEase Vena Cava Filter on or about May 30, 2010. The filter subsequently malfunctioned and caused injury and damages to Plaintiff ANDREW CHAPMAN, including, but not limited to, migration of the IVC filter. As a direct and proximate result of these malfunctions, Plaintiff ANDREW CHAPMAN suffered life-threatening injuries and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff ANDREW CHAPMAN has suffered and will continue to suffer significant medical expenses, and pain and suffering, and other damages.

20. Defendant CORDIS CORPORATION ("Cordis"), including its department, division, and subsidiary, Cordis Endovascular, is a corporation or business entity organized and existing under the laws of the State of Florida with its headquarters located at 6500 Paseo Padre Pkwy., Fremont, California, 94555.

21. 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.

22. 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.

23. Plaintiffs are informed and believe, and thereon allege, that at all times herein mentioned, the Defendant 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.

24. Plaintiffs are informed and believe, and thereon allege, that at all times mentioned herein, Defendant 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, fabricating, designing, developing, labeling, assembling, distributing, supplying, leasing, buying, offering for sale, selling, inspecting, servicing, contracting others for marketing, warranting, rebranding, manufacturing for others, packaging, and advertising the device.

25. Defendant and DOES 1 through 50, and each of them, are liable for the acts, omissions and tortious conduct of its successors and/or predecessors in interest/business/product line/or a portion thereof, assigns, parent, subsidiary, affiliate, partner, co-venturer, merged company, alter ego, agent, equitable trustee, fiduciary and/or its alternate entities in that Defendant and DOES 1 through 50, and each of them, enjoy the goodwill originally attached to each such alternate entity, acquired the assets or product line (or a portion thereof), and in that there has been a virtual destruction of Plaintiffs' remedy against each such alternate entity, and that each such Defendant has the ability to assume the risk-spreading role of each such alternate entity.

26. Plaintiffs are informed and believe, and thereon allege that, at all times herein mentioned, DOES 1 through 50, and each of them, were and are corporations organized and existing under the laws of the State of California or the laws of some state or foreign jurisdiction; that each of the said DOE

defendants were and are authorized to do and are doing business in the State of California and regularly conducted business in the State of California.

27. Upon information and belief, Defendants at all relevant times were engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce and into the State of California, either directly or indirectly through third parties or related entities, its products, including the TrapEase and OptEase IVC filters, and derived substantial income from doing business in California.

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, selling, marketing, and/or introducing into interstate commerce in the state of California, either directly or indirectly, its products, including Cordis IVC filters.

34. 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 California. Therefore, the claims of California-plaintiffs *and* out-of-state plaintiffs relate to and arise from Defendants' explicit contacts and purposeful avail of the State of California. Further and independently, Cordis consented to jurisdiction in the State of California by appointing an agent for service of process in this State and by conducting substantial systematic business in this State.

35. The instant First Amended Complaint for Damages does not confer diversity jurisdiction upon the federal courts pursuant to 28 U.S.C. § 1332. Likewise, federal question subject matter jurisdiction pursuant to 28 U.S.C. § 1331 is not invoked by the instant Complaint, as it sets forth herein exclusively state law claims against the Defendants. Nowhere do Plaintiffs plead, expressly or implicitly, any cause of action or request any remedy that arises under or is founded upon federal law, and any alleged federal rights or remedies are expressly disavowed. The issues presented by Plaintiffs do not implicate substantial federal questions, do not turn on the necessary interpretation of federal law, and do not affect the federal system as a whole. The assertion of federal jurisdiction over claims made herein would improperly disturb the congressionally approved balance of federal and state responsibilities.

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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 thromboembolitic 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.

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

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

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

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

47. Comparing the results of over 30,000 trauma patients who had not received IVC filters 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.

48. 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.

49. 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[tm] AND OPTEASE[tm] IVC FILTERS

50. 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.

51. 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).

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

> If the FDA concludes on the basis of the [manufacturer's] § 510(k) notification that the device is "substantially equivalent" to a pre-existing device, it can be marketed without further regulatory analysis. . . . The § 510(k) notification process is by no means 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."

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

53. Pursuant to *Wyeth v. Levine*, 555 U.S. 555 (2009), once a product is cleared "the manufacturer remains under an obligation to investigate and report any adverse events associated with 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.

55. 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 symmetric filter. The filter has proximal and distal anchoring barbs located on each connecting strut for fixation of the filter to the vena cava wall to prevent movement after placement.

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

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

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

59. In or around September 2002, Defendants sought clearance through the 510(k) process to market the OptEase Vena Cava Filter for the same indicated uses as the TrapEase filter. Defendants

represented that the OptEase filter contained the same fundamental technology and was substantially equivalent in terms of safety and efficacy as the predicate devices already available on the market.

60. 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 has anchoring barbs for fixation of the filter only on the superior end of each of the six straight struts and has a hook at the inferior end of the basket to allow retrieval with a snare.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

a. Death;

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,

Defendants represented that their filters were safe and effective – more safe and effective than other available IVC filters. 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.

81. 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.

82. Defendants also marketed the OptEase filter as being "easy" to remove. However, it is one of the most difficult filters to remove. 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. 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.

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

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

85. Cordis' labeling was additionally defective in that it directed physicians to implant the OptEase filter upside down. When the OptEase filter was placed as directed by the labeling, the hooks designed to ensure stability were facing in the wrong direction, rendering an already inadequate anchoring system even further defective. As Cordis now explain in its labeling, implanting the device in

this fashion "can result in life threatening or serious injury including, but not limited to dissection, vessel perforation, migration of the filter with secondary damage to cardiac structures, ineffective pulmonary embolism prevention or death."

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

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

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

89. 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.

90. 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

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.

99. 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.

100. The devices implanted in Plaintiffs were in an unreasonably dangerous condition at the 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.

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.

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

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.

136. 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.

137. 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.

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

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

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

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

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

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

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

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

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

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.

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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.

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

165. The foregoing representations and omissions by Defendants were false.

166. Defendants' IVC filters are not safe, fit, and effective for human use in their intended and reasonably foreseeable manner.

167. Further, the use of Cordis IVC filters is hazardous to the users' health, and Cordis IVC filters have a serious propensity to cause users to suffer serious injuries, including without limitation the injuries Plaintiffs suffered.

168. Finally, Defendants' IVC filters have a statistically significant higher rate of failure and injury than do other comparable IVC filters.

169. 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.

170. 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.

171. 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.

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.

204. 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.

205. 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.

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.

207. 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.

DEMAND FOR JURY TRIAL

Plaintiffs hereby demand a trial by jury on all triable issues.

Dated: May 13, 2016

Respectfully submitted,

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By: _____

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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, indivdually 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

malfunctioned and caused injury and damages to Plaintiff WALTER HERBERT, including, but not limited to, tilt, 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 WALTER HERBERT suffered life-threatening injuries and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff WALTER HERBERT has suffered and will continue to suffer significant medical expenses, and pain and suffering, and other damages.

9. Plaintiff RUSSELL ANDERSON at all times relevant to this action was and is a citizen and resident of the State of Arizona. Plaintiff RUSSELL ANDERSON underwent placement of Defendants' OptEase Vena Cava Filter on or about January 29, 2008. The filter subsequently malfunctioned and caused injury and damages to Plaintiff RUSSELL ANDERSON, including, but not limited to, tilt, 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 RUSSELL ANDERSON suffered life-threatening injuries and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff RUSSELL ANDERSON has suffered and will continue to suffer significant medical expenses, and pain and suffering, and other damages.

10. Plaintiff MARTHA GRAHAM at all times relevant to this action was and is a citizen and resident of the State of Maryland. Plaintiff MARTHA GRAHAM underwent placement of Defendants' OptEase Vena Cava Filter on or about June 2, 2006. The filter subsequently malfunctioned and caused injury and damages to Plaintiff MARTHA GRAHAM, including, but not limited to, tilt, 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 MARTHA GRAHAM suffered life-threatening injuries and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff MARTHA GRAHAM has suffered and will continue to suffer significant medical expenses, and pain and suffering, and other damages.

11. Plaintiff FRANK GRAHAM at all times relevant to this action was and is a citizen and resident of the State of Arizona. Plaintiffs MARTHA GRAHAM and FRANK GRAHAM were and are, at all times relevant to this action, legally married as wife and husband. Plaintiff FRANK GRAHAM

brings this action for, *inter alia*, the loss of consortium, comfort, and society he suffered due to the personal injuries suffered by his wife, MARTHA GRAHAM.

12. Plaintiff TAMARRA GRAYSON at all times relevant to this action was and is a citizen and resident of the State of Oklahoma. Plaintiff TAMARRA GRAYSON underwent placement of Defendants' OptEase Vena Cava Filter on or about September 10, 2009. The filter subsequently malfunctioned and caused injury and damages to Plaintiff TAMARRA GRAYSON, including, but not limited to, tilt, 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 TAMARRA GRAYSON suffered life-threatening injuries and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff TAMARRA GRAYSON has suffered and will continue to suffer significant medical expenses, and pain and suffering, and other damages.

13. Plaintiff TIMOTHY HOWARD at all times relevant to this action was and is a citizen and resident of the State of Tennessee. Plaintiff TIMOTHY HOWARD underwent placement of Defendants' TrapEase Vena Cava Filter on or about November 6, 2014. The filter subsequently malfunctioned and caused injury and damages to Plaintiff TIMOTHY HOWARD, including, but not limited to, migration of the filter. As a direct and proximate result of these malfunctions, Plaintiff TIMOTHY HOWARD suffered life-threatening injuries and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff TIMOTHY HOWARD has suffered and will continue to suffer significant medical expenses, and pain and suffering, and other damages.

14. Plaintiff TED MICHAEL MARTINEZ at all times relevant to this action was and is a citizen and resident of the State of Nevada. Plaintiff TED MICHAEL MARTINEZ underwent placement of Defendants' TrapEase Vena Cava Filter on or about June 25, 2006. The filter subsequently malfunctioned and caused injury and damages to Plaintiff TED MICHAEL MARTINEZ, including, but not limited to, migration of the filter. As a direct and proximate result of these malfunctions, Plaintiff TED MICHAEL MARTINEZ suffered life-threatening injuries and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff TED MICHAEL MARTINEZ has suffered and will continue to suffer significant medical expenses, and pain and suffering, and other damages.

15. Plaintiff CYNTHIA MARTINEZ at all times relevant to this action was and is a citizen and resident of the State of Nevada. Plaintiffs TED MICHAEL MARTINEZ and CYNTHIA MARTINEZ were and are, at all times relevant to this action, legally married as husband and wife. Plaintiff CYNTHIA MARTINEZ brings this action for, *inter alia*, the loss of consortium, comfort, and society he suffered due to the personal injuries suffered by her husband, TED MICHAEL MARTINEZ.

16. Plaintiff JUDY SHAFFER at all times relevant to this action was a citizen and resident of the State of Maryland. Plaintiff JUDY SHAFFER underwent placement of Defendants' OptEase Vena Cava Filter on or about February 3, 2015. The filter subsequently malfunctioned and caused injury and damages to Plaintiff JUDY SHAFFER, including, but not limited to, tilt, 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 JUDY SHAFFER suffered life-threatening injuries and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff JUDY SHAFFER has suffered and will continue to suffer significant medical expenses, and pain and suffering, and other damages.

17. Plaintiff JOHN SHAFFER, JR. at all times relevant to this action was a citizen and resident of the State of Maryland. Plaintiffs JUDY SHAFFER and JOHN SHAFFER, JR. were and are, at all times relevant to this action, legally married as wife and husband. Plaintiff JOHN SHAFFER, JR. brings this action for, *inter alia*, the loss of consortium, comfort, and society he suffered due to the personal injuries suffered by his wife, JUDY SHAFFER.

18. Defendant CORDIS CORPORATION ("Cordis"), including its department, division, and subsidiary, Cordis Endovascular, is a corporation or business entity organized and existing under the laws of the State of Florida with its headquarters located at 6500 Paseo Padre Pkwy., Fremont, California, 94555. 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.

19. Defendant CORDIS COPORATION 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.

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

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

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

23. 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

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.

25. 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

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.

28. 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.

29. 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 thromboembolitic events.

30. 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.

31. 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.

32. Defendants Cordis and J&J 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.

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

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

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

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

37. Comparing the results of over 30,000 trauma patients who had not received IVC filters 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 Defendants Cordis and J&J told the FDA, physicians, and the public that its IVC filters were designed to prevent.

38. This *Annals of Surgery* study – and many others referenced by it – 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

39. 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.

40. 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).

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

> If the FDA concludes on the basis of the [manufacturer's] § 510(k) notification that the device is "substantially equivalent" to a pre-existing device, it can be marketed without further regulatory analysis. . . . The § 510(k) notification process is by no means 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."

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

42. Pursuant to *Wyeth v. Levine*, 555 U.S. 555 (2009), once a product is cleared "the manufacturer remains under an obligation to investigate and report any adverse events associated with 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.

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

symmetric filter. The filter has proximal and distal anchoring barbs located on each connecting strut for fixation of the filter to the vena cava wall to prevent movement after placement.

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

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

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

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

49. 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 has anchoring barbs for fixation of the filter only on the superior end of each of the six straight struts and has a hook at the inferior end of the basket to allow retrieval with a snare.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

a. Death;

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; and

f. Perforations of tissue, vessels and organs.

64. 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*.

65. Defendants failed to identify or acknowledge these device failures or determine their causes.

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

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

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

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

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 Usoh 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* Usoh, *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

was detected inside the filter in two cases. Based on these results, Dr. Sano criticized previous studies that had found the TrapEase filter to be safe as being conducted over too short a period of time and concluded that "patients undergoing permanent TrapEase IVCF insertion are at extremely high risk of strut fractures as early as two to three years after IVCF placement."

77. On May 6, 2014, the FDA issued another Safety Alert involving IVC filters. In this safety communication, the FDA wrote that it had received adverse event reports concerning "device 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.

78. 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

79. Plaintiffs incorporate by reference all prior allegations.

80. 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.

81. 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.

82. 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.

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.

FIRST CAUSE OF ACTION

STRICT PRODUCTS LIABILITY – DESIGN DEFECT

(By All Plaintiffs, As to All Defendants)

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.

88. 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.

89. 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.

90. 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.

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

92. 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.

93. 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.

94. 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.

95. 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)

96. Plaintiffs incorporate by reference all prior allegations.

97. 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.

98. 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.

99. 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.

100. 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.

101. 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.

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

g. 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.

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

119. 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.

120. 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.

121. 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.

122. 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.

123. 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.

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

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

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

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

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

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

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

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

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

FIFTH CAUSE OF ACTION

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,

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.

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

142. 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.

143. 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)

144. Plaintiffs incorporate by reference all prior allegations.

145. 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.

146. 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.

147. 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.

148. 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.

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

150. The foregoing representations and omissions by Defendants were false.

151. Defendants' IVC filters are not safe, fit, and effective for human use in their intended and reasonably foreseeable manner.

152. Further, the use of Cordis IVC filters is hazardous to the users' health, and Cordis IVC filters have a serious propensity to cause users to suffer serious injuries, including without limitation the injuries Plaintiffs suffered.

153. Finally, Defendants' IVC filters have a statistically significant higher rate of failure and injury than do other comparable IVC filters.

154. 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.

155. 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.

156. 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.

157. 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.

158. 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)

159. Plaintiffs incorporate by reference all prior allegations.

160. In marketing and selling Cordis IVC filters (the TrapEase filters and the OptEase filters), Defendants concealed material facts from Plaintiffs and their healthcare providers.

161. 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.

162. Plaintiffs and their health care providers were not aware of these and other facts concealed by Defendants.

163. In concealing these and other facts, Defendants intended to deceive Plaintiffs and their health care providers.

164. 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.

165. 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)

166. Plaintiffs incorporate by reference all prior allegations.

167. Plaintiffs, through their medical providers, purchased a Cordis IVC filter from Defendants.

168. At all relevant times, Defendants were merchants of goods of the kind including medical devices and vena cava filters (i.e., Cordis IVC filters).

169. 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.

170. 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.

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

related to the care, treatment, medications, and hospitalization of their respective Plaintiff spouses due to their injuries.

180. Plaintiffs FRANK GRAHAM, CYNTHIA MARTINEZ and JOHN SHAFFER, JR. 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 FRANK GRAHAM, CYNTHIA MARTINEZ and JOHN SHAFFER, JR. 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 FRANK GRAHAM, CYNTHIA MARTINEZ and JOHN SHAFFER, JR.

PUNITIVE DAMAGES ALLEGATIONS

(By All Plaintiffs, As to All Defendants)

181. Plaintiffs incorporate by reference all prior allegations.

182. 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.

183. At all times material hereto, Defendants attempted to misrepresent and did knowingly misrepresent facts concerning the safety of Cordis IVC filters.

184. 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.

185. 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.

186. 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.

187. Notwithstanding the foregoing, Defendants continued to market Cordis IVC filters aggressively to consumers, including Plaintiffs, without disclosing the aforesaid side effects.

188. 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.

189. 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.

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.

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.

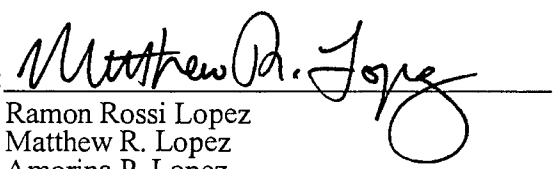
DEMAND FOR JURY TRIAL

Plaintiffs hereby demand a trial by jury on all triable issues.

Dated: May 5, 2016

Respectfully submitted,

LOPEZ McHUGH LLP

By: 

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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, indivdually 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'

OptEase Vena Cava Filter on or about October 25, 2005, in California. The filter subsequently malfunctioned and caused injury and damages to Plaintiff WALTER HERBERT, including, but not limited to, tilt, 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 WALTER HERBERT suffered life-threatening injuries and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff WALTER HERBERT has suffered and will continue to suffer significant medical expenses, and pain and suffering, and other damages.

9. Plaintiff RUSSELL ANDERSON at all times relevant to this action was and is a citizen and resident of the State of Arizona. Plaintiff RUSSELL ANDERSON underwent placement of Defendants' OptEase Vena Cava Filter on or about January 29, 2008. The filter subsequently malfunctioned and caused injury and damages to Plaintiff RUSSELL ANDERSON, including, but not limited to, tilt, 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 RUSSELL ANDERSON suffered life-threatening injuries and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff RUSSELL ANDERSON has suffered and will continue to suffer significant medical expenses, and pain and suffering, and other damages.

10. Plaintiff MARTHA GRAHAM at all times relevant to this action was and is a citizen and resident of the State of Maryland. Plaintiff MARTHA GRAHAM underwent placement of Defendants' OptEase Vena Cava Filter on or about June 2, 2006. The filter subsequently malfunctioned and caused injury and damages to Plaintiff MARTHA GRAHAM, including, but not limited to, tilt, 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 MARTHA GRAHAM suffered life-threatening injuries and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff MARTHA GRAHAM has suffered and will continue to suffer significant medical expenses, and pain and suffering, and other damages.

11. Plaintiff FRANK GRAHAM at all times relevant to this action was and is a citizen and resident of the State of Arizona. Plaintiffs MARTHA GRAHAM and FRANK GRAHAM were and are, at all times relevant to this action, legally married as wife and husband. Plaintiff FRANK GRAHAM

brings this action for, inter alia, the loss of consortium, comfort, and society he suffered due to the personal injuries suffered by his wife, MARTHA GRAHAM.

12. Plaintiff TAMARRA GRAYSON at all times relevant to this action was and is a citizen and resident of the State of Oklahoma. Plaintiff TAMARRA GRAYSON underwent placement of Defendants' OptEase Vena Cava Filter on or about September 10, 2009. The filter subsequently malfunctioned and caused injury and damages to Plaintiff TAMARRA GRAYSON, including, but not limited to, tilt, 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 TAMARRA GRAYSON suffered life-threatening injuries and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff TAMARRA GRAYSON has suffered and will continue to suffer significant medical expenses, and pain and suffering, and other damages.

13. Plaintiff TIMOTHY HOWARD at all times relevant to this action was and is a citizen and resident of the State of Tennessee. Plaintiff TIMOTHY HOWARD underwent placement of Defendants' TrapEase Vena Cava Filter on or about November 6, 2014. The filter subsequently malfunctioned and caused injury and damages to Plaintiff TIMOTHY HOWARD, including, but not limited to, migration of the filter. As a direct and proximate result of these malfunctions, Plaintiff TIMOTHY HOWARD suffered life-threatening injuries and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff TIMOTHY HOWARD has suffered and will continue to suffer significant medical expenses, and pain and suffering, and other damages.

14. Plaintiff TED MICHAEL MARTINEZ at all times relevant to this action was and is a citizen and resident of the State of Nevada. Plaintiff TED MICHAEL MARTINEZ underwent placement of Defendants' TrapEase Vena Cava Filter on or about June 25, 2006. The filter subsequently malfunctioned and caused injury and damages to Plaintiff TED MICHAEL MARTINEZ, including, but not limited to, migration of the filter. As a direct and proximate result of these malfunctions, Plaintiff TED MICHAEL MARTINEZ suffered life-threatening injuries and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff TED MICHAEL MARTINEZ has suffered and will continue to suffer significant medical expenses, and pain and suffering, and other damages.

15. Plaintiff CYNTHIA MARTINEZ at all times relevant to this action was and is a citizen and resident of the State of Nevada. Plaintiffs TED MICHAEL MARTINEZ and CYNTHIA MARTINEZ were and are, at all times relevant to this action, legally married as husband and wife. Plaintiff CYNTHIA MARTINEZ brings this action for, inter alia, the loss of consortium, comfort, and society he suffered due to the personal injuries suffered by her husband, TED MICHAEL MARTINEZ.

16. Plaintiff JUDY SHAFFER at all times relevant to this action was a citizen and resident of the State of Maryland. Plaintiff JUDY SHAFFER underwent placement of Defendants' OptEase Vena Cava Filter on or about February 3, 2015. The filter subsequently malfunctioned and caused injury and damages to Plaintiff JUDY SHAFFER, including, but not limited to, tilt, 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 JUDY SHAFFER suffered life-threatening injuries and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff JUDY SHAFFER has suffered and will continue to suffer significant medical expenses, and pain and suffering, and other damages.

17. Plaintiff JOHN SHAFFER, JR. at all times relevant to this action was a citizen and resident of the State of Maryland. Plaintiffs JUDY SHAFFER and JOHN SHAFFER, JR. were and are, at all times relevant to this action, legally married as wife and husband. Plaintiff JOHN SHAFFER, JR. brings this action for, inter alia, the loss of consortium, comfort, and society he suffered due to the personal injuries suffered by his wife, JUDY SHAFFER.

18. Plaintiff CLARICE STEPP at all times relevant to this action was and is a citizen and resident of the State of Ohio. Plaintiff CLARICE STEPP underwent placement of Defendants' TrapEase Vena Cava Filter on or about December 14, 2005. The filter subsequently malfunctioned and caused injury and damages to Plaintiff CLARICE STEPP, including, but not limited to, blood clots, clotting and occlusion of IVC filter. As a direct and proximate result of these malfunctions, Plaintiff CLARICE STEPP suffered life-threatening injuries and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff CLARICE STEPP has suffered and will continue to suffer significant medical expenses, and pain and suffering, and other damages.

19. Plaintiff ALLISON FISHER at all times relevant to this action was and is a citizen and resident of the State of North Carolina. Plaintiff ALLISON FISHER underwent placement of Defendants' OptEase Vena Cava Filter on or about August 24, 2009. The filter subsequently malfunctioned and caused injury and damages to Plaintiff ALLISON FISHER, including, but not limited to, filter embedded in wall of the IVC, filter unable to be retrieved, blood clots, clotting and occlusion of IVC filter. As a direct and proximate result of these malfunctions, Plaintiff ALLISON FISHER suffered life-threatening injuries and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff ALLISON FISHER has suffered and will continue to suffer significant medical expenses, and pain and suffering, and other damages.

20. Defendant CORDIS CORPORATION ("Cordis"), including its department, division, and subsidiary, Cordis Endovascular, is a corporation or business entity organized and existing under the laws of the State of Florida with its headquarters located at 6500 Paseo Padre Pkwy., Fremont, California, 94555.

21. 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.

22. 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.

23. Plaintiffs are informed and believe, and thereon allege, that at all times herein mentioned, the Defendant 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.

24. Plaintiffs are informed and believe, and thereon allege, that at all times mentioned herein, Defendant 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, fabricating, designing, developing, labeling, assembling, distributing, supplying, leasing, buying, offering for sale, selling, inspecting, servicing, contracting others for marketing, warranting, rebranding, manufacturing for others, packaging, and advertising the device.

25. Defendant and DOES 1 through 50, and each of them, are liable for the acts, omissions and tortious conduct of its successors and/or predecessors in interest/business/product line/or a portion thereof, assigns, parent, subsidiary, affiliate, partner, co-venturer, merged company, alter ego, agent, equitable trustee, fiduciary and/or its alternate entities in that Defendant and DOES 1 through 50, and each of them, enjoy the goodwill originally attached to each such alternate entity, acquired the assets or product line (or a portion thereof), and in that there has been a virtual destruction of Plaintiffs' remedy against each such alternate entity, and that each such Defendant has the ability to assume the risk-spreading role of each such alternate entity.

26. Plaintiffs are informed and believe, and thereon allege that, at all times herein mentioned, DOES 1 through 50, and each of them, were and are corporations organized and existing under the laws of the State of California or the laws of some state or foreign jurisdiction; that each of the said DOE defendants were and are authorized to do and are doing business in the State of California and regularly conducted business in the State of California.

27. Upon information and belief, Defendants at all relevant times were engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce and into the State of California, either directly or indirectly through third parties or related entities, its products, including the TrapEase and OptEase IVC filters, and derived substantial income from doing business in California.

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,

selling, marketing, and/or introducing into interstate commerce in the state of California, either directly or indirectly, its products, including Cordis IVC filters.

34. 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 California. Therefore, the claims of California-plaintiffs *and* out-of-state plaintiffs relate to and arise from Defendants' explicit contacts and purposeful avail of the State of California. Further and independently, Cordis consented to jurisdiction in the State of California by appointing an agent for service of process in this State and by conducting substantial systematic business in this State.

35. The instant First Amended Complaint for Damages does not confer diversity jurisdiction upon the federal courts pursuant to 28 U.S.C. § 1332. Likewise, federal question subject matter jurisdiction pursuant to 28 U.S.C. § 1331 is not invoked by the instant Complaint, as it sets forth herein exclusively state law claims against the Defendants. Nowhere do Plaintiffs plead, expressly or implicitly, any cause of action or request any remedy that arises under or is founded upon federal law, and any alleged federal rights or remedies are expressly disavowed. The issues presented by Plaintiffs do not implicate substantial federal questions, do not turn on the necessary interpretation of federal law, and do not affect the federal system as a whole. The assertion of federal jurisdiction over claims made herein would improperly disturb the congressionally approved balance of federal and state responsibilities.

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 thromboembolitic 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.

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

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

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

46. Years after the implantation of retrievable filters into the bodies of patients, scientists began to study the effectiveness of the retrievable filters. As recently as October 2015, an expansive

article published in the *Annals of Surgery* concerning trauma patients inserted with IVC filters concluded that IVC filters were not effective in preventing pulmonary emboli, and instead actually caused thrombi to occur.

47. Comparing the results of over 30,000 trauma patients who had not received IVC filters 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.

48. 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.

49. 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[tm] AND OPTEASE[tm] IVC FILTERS

50. 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.

51. 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).

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

> If the FDA concludes on the basis of the [manufacturer's] § 510(k) notification that the device is "substantially equivalent" to a pre-existing device, it can be marketed without further regulatory analysis. . . . The § 510(k) notification process is by no means 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."

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

53. Pursuant to *Wyeth v. Levine*, 555 U.S. 555 (2009), once a product is cleared "the manufacturer remains under an obligation to investigate and report any adverse events associated with 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.

55. 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 symmetric filter. The filter has proximal and distal anchoring barbs located on each connecting strut for fixation of the filter to the vena cava wall to prevent movement after placement.

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

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

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

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

60. 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 has anchoring barbs for fixation of the filter only on the superior end of each of the six straight struts and has a hook at the inferior end of the basket to allow retrieval with a snare.

61. Both designs for the TrapEase filter and OptEase filter suffer flaws making them defective and unreasonably dangerous. Defendants' IVC filters are designed in such a way that when exposed to expected and reasonably foreseeable *in-vivo* conditions, the devices will fracture, migrate,

tilt, perforate internal organs and vasculature, and lead to the formation of thromboembolism and pulmonary embolism.

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

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

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

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

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

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

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

69. Prior to bringing a product to market, a manufacturer must also conduct sufficient testing under real world or simulated use conditions to ensure that the device will meet user needs even when

exposed to reasonably foreseeable worst-case conditions. Defendants failed to adequately establish and maintain such policies, procedures or protocols with respect to their IVC filters.

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

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

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

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

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

a. Death;

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, Defendants represented that their filters were safe and effective – more safe and effective than other available IVC filters. 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.

81. 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.

82. Defendants also marketed the OptEase filter as being "easy" to remove. However, it is one of the most difficult filters to remove. 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. 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.

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

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

85. Cordis' labeling was additionally defective in that it directed physicians to implant the OptEase filter upside down. When the OptEase filter was placed as directed by the labeling, the hooks designed to ensure stability were facing in the wrong direction, rendering an already inadequate anchoring system even further defective. As Cordis now explain in its labeling, implanting the device in this fashion "can result in life threatening or serious injury including, but not limited to dissection, vessel perforation, migration of the filter with secondary damage to cardiac structures, ineffective pulmonary embolism prevention or death."

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

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

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

89. 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.

90. 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

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.

99. 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.

100. The devices implanted in Plaintiffs were in an unreasonably dangerous condition at the 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.

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.

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

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.

136. 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.

137. 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.

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

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

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

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

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

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

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

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

146. As a direct and proximate result of Defendants' negligent conduct described herein, 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.

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.

164. Defendants' intent and purpose in making these misrepresentations was to deceive and defraud the public and the medical community, including Plaintiffs' health care providers; to gain the confidence of the public and the medical community, including Plaintiffs' health care providers; to falsely assure the public and the medical community of the quality of Cordis IVC filters and their fitness for use; and to induce the public and the medical community, including Plaintiffs' health care providers

to request, recommend, prescribe, implant, purchase, and continue to use Cordis IVC filters, all in reliance on Defendants' misrepresentations.

165. The foregoing representations and omissions by Defendants were false.

166. Defendants' IVC filters are not safe, fit, and effective for human use in their intended and reasonably foreseeable manner.

167. Further, the use of Cordis IVC filters is hazardous to the users' health, and Cordis IVC filters have a serious propensity to cause users to suffer serious injuries, including without limitation the injuries Plaintiffs suffered.

168. Finally, Defendants' IVC filters have a statistically significant higher rate of failure and injury than do other comparable IVC filters.

169. 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.

170. 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.

171. 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.

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.

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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.

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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.

196. Plaintiffs FRANK GRAHAM, CYNTHIA MARTINEZ and JOHN SHAFFER, JR. 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 FRANK GRAHAM, CYNTHIA MARTINEZ and JOHN SHAFFER, JR. 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 FRANK GRAHAM, CYNTHIA MARTINEZ and JOHN SHAFFER, JR.

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.

204. 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.

205. 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.

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.

207. 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.

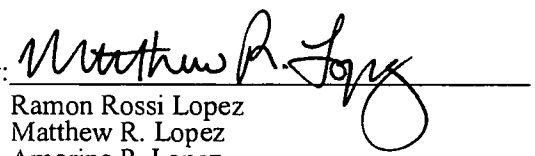
DEMAND FOR JURY TRIAL

Plaintiffs hereby demand a trial by jury on all triable issues.

Dated: May 13, 2016

Respectfully submitted,

LOPEZ McHUGH LLP

By: 

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Matthew R. Lopez
Amorina P. Lopez

-And-

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-And-

Howard Nations (for *pro hac vice* consideration)
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EXHIBIT A Part 2

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Attorneys for Plaintiffs

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;

Plaintiffs,

vs.

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

Defendants.

Case No.: RG16814688

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, 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

caused injury and damages to Plaintiff GEANICE GRANT, including, but not limited to, severe and constant chest pains and compromised respiratory system. As a direct and proximate result of these malfunctions, Plaintiff GEANICE GRANT suffered serious injuries and damages, and will require extensive medical care and treatment. As a further proximate result, Plaintiff GEANICE GRANT has suffered and will continue to suffer significant medical expenses, and pain and suffering, and other damages.

9. Plaintiff VIOLET ELAINE KERN at all times relevant to this action was and is a citizen and resident of the State of Texas. Plaintiff VIOLET ELAINE KERN underwent placement of Defendants' OptEase Vena Cava Filter on or about March 28, 2012. The filter subsequently malfunctioned and caused injury and damages to Plaintiff VIOLET ELAINE KERN, including, but not limited to, 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 VIOLET ELAINE KERN suffered life-threatening injuries and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff VIOLET ELAINE KERN has suffered and will continue to suffer significant medical expenses, and pain and suffering, and other damages.

10. Plaintiff RUSSELL HOPKINS at all times relevant to this action was and is a citizen and resident of the State of Texas. Plaintiff RUSSELL HOPKINS underwent placement of Defendants' OptEase Vena Cava Filter on or about April 27, 2011. The filter subsequently malfunctioned and caused injury and damages to Plaintiff RUSSELL HOPKINS, including, but not limited to, filter embedded in wall of the IVC and unable to be retrieved. As a direct and proximate result of these malfunctions, Plaintiff RUSSELL HOPKINS suffered life-threatening injuries and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff RUSSELL HOPKINS has suffered and will continue to suffer significant medical expenses, and pain and suffering, and other damages.

11. Plaintiff ANTHONY BURBINE at all times relevant to this action was and is a citizen and resident of the State of Massachusetts. Plaintiff ANTHONY BURBINE underwent placement of Defendants' OptEase Vena Cava Filter on or about April 11, 2012. The filter subsequently malfunctioned and caused injury and damages to Plaintiff ANTHONY BURBINE, including, but not

limited to, filter embedded in wall of the IVC and unable to be retrieved. As a direct and proximate result of these malfunctions, Plaintiff ANTHONY BURBINE suffered life-threatening injuries and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff ANTHONY BURBINE has suffered and will continue to suffer significant medical expenses, and pain and suffering, and other damages.

12. Plaintiff COURTNEY COMER at all times relevant to this action was a citizen and resident of the State of Maryland and, subsequently, became a citizen and resident of the State of Texas. Plaintiff COURTNEY COMER underwent placement of Defendants' TrapEase Vena Cava Filter on or about May 5, 2005. The filter subsequently malfunctioned and caused injury and damages to Plaintiff COURTNEY COMER, including, but not limited to, fracture of the filter. As a direct and proximate result of these malfunctions, Plaintiff COURTNEY COMER suffered life-threatening injuries and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff COURTNEY COMER has suffered and will continue to suffer significant medical expenses, and pain and suffering, and other damages.

13. Plaintiff WILLIAM GOUGE at all times relevant to this action was and is a citizen and resident of the State of Maryland. Plaintiff WILLIAM GOUGE underwent placement of Defendants' TrapEase Vena Cava Filter on or about August 13, 2010. The filter subsequently malfunctioned and caused injury and damages to Plaintiff WILLIAM GOUGE, including, but not limited to, migration of the filter to heart requiring emergency open-heart surgery. As a direct and proximate result of these malfunctions, Plaintiff WILLIAM GOUGE suffered life-threatening injuries and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff WILLIAM GOUGE has suffered and will continue to suffer significant medical expenses, and pain and suffering, and other damages.

14. Plaintiff RHONDA GAIL SCHENK at all times relevant to this action was a citizen and resident of the State of Maryland. Plaintiff RHONDA GAIL SCHENK underwent placement of Defendants' OptEase Vena Cava Filter on or about March 1, 2010. The filter subsequently malfunctioned and caused injury and damages to Plaintiff RHONDA GAIL SCHENK, including, but not limited to, filter embedded in wall of the IVC and unable to be retrieved, and recurrent DVTs. As a

direct and proximate result of these malfunctions, Plaintiff RHONDA GAIL SCHENK suffered life-threatening injuries and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff RHONDA GAIL SCHENK has suffered and will continue to suffer significant medical expenses, and pain and suffering, and other damages.

15. Plaintiff JENNIFER ALLISON at all times relevant to this action was and is a citizen and resident of the State of Maryland. Plaintiff JENNIFER ALLISON underwent placement of Defendants' OptEase Vena Cava Filter on or about January 14, 2011. The filter subsequently malfunctioned and caused injury and damages to Plaintiff JENNIFER ALLISON, including, but not limited to, tilt, migration, 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 JENNIFER ALLISON suffered life-threatening injuries and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff JENNIFER ALLISON has suffered and will continue to suffer significant medical expenses, and pain and suffering, and other damages.

16. Plaintiff BOBBY FULLER at all times relevant to this action was and is a citizen and resident of the State of North Carolina. Plaintiff BOBBY FULLER underwent placement of Defendants' OptEase Vena Cava Filter on or about May 18, 2006. The filter subsequently malfunctioned and caused injury and damages to Plaintiff BOBBY FULLER, including, but not limited to, filter embedded in wall of the IVC. As a direct and proximate result of these malfunctions, Plaintiff BOBBY FULLER suffered life-threatening injuries and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff BOBBY FULLER has suffered and will continue to suffer significant medical expenses, and pain and suffering, and other damages.

17. Plaintiff ROBERT EDWARD BECKER at all times relevant to this action was and is a citizen and resident of the State of Wisconsin. Plaintiff ROBERT EDWARD BECKER underwent placement of Defendants' TrapEase Vena Cava Filter on or about June 21, 2010. The filter subsequently malfunctioned and caused injury and damages to Plaintiff ROBERT EDWARD BECKER, including, but not limited to, hematoma and recurrent pulmonary embolisms. As a direct and proximate result of these malfunctions, Plaintiff ROBERT EDWARD BECKER suffered life-threatening injuries and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff

ROBERT EDWARD BECKER has suffered and will continue to suffer significant medical expenses, and pain and suffering, and other damages.

18. Plaintiff TERRY ANN FOUNTAIN at all times relevant to this action was and is a citizen and resident of the State of Georgia. Plaintiff TERRY ANN FOUNTAIN underwent placement of Defendants' TrapEase Vena Cava Filter on or about June 2, 2007. The filter subsequently malfunctioned and caused injury and damages to Plaintiff TERRY ANN FOUNTAIN, including, but not limited to, blood clots, clotting and occlusion of IVC filter. As a direct and proximate result of these malfunctions, Plaintiff TERRY ANN FOUNTAIN suffered life-threatening injuries and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff TERRY ANN FOUNTAIN has suffered and will continue to suffer significant medical expenses, and pain and suffering, and other damages.

19. Plaintiff MARGUERITE NORTON at all times relevant to this action was and is a citizen and resident of the State of Pennsylvania. Plaintiff MARGUERITE NORTON underwent placement of Defendants' OptEase Vena Cava Filter on or about April 15, 2010. The filter subsequently malfunctioned and caused injury and damages to Plaintiff MARGUERITE NORTON, including, but not limited to, fracture of the filter. As a direct and proximate result of these malfunctions, Plaintiff MARGUERITE NORTON suffered life-threatening injuries and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff MARGUERITE NORTON has suffered and will continue to suffer significant medical expenses, and pain and suffering, and other damages.

20. Plaintiff JAMES FRANKLIN WILLIAMS, SR. at all times relevant to this action was and is a citizen and resident of the State of Maryland. Plaintiff JAMES FRANKLIN WILLIAMS, SR. underwent placement of Defendants' TrapEase Vena Cava Filter on or about June 27, 2013. The filter subsequently malfunctioned and caused injury and damages to Plaintiff JAMES FRANKLIN WILLIAMS, SR., including, but not limited to, DVT. As a direct and proximate result of these malfunctions, Plaintiff JAMES FRANKLIN WILLIAMS, SR. suffered life-threatening injuries and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff

JAMES FRANKLIN WILLIAMS, SR. has suffered and will continue to suffer significant medical expenses, and pain and suffering, and other damages.

21. Plaintiff BETTY REED at all times relevant to this action was and is a citizen and resident of the State of West Virginia. Plaintiff BETTY REED underwent placement of Defendants' TrapEase Vena Cava Filter on or about October 14, 2014. The filter subsequently malfunctioned and caused injury and damages to Plaintiff BETTY REED, including, but not limited to, migration of the filter. As a direct and proximate result of these malfunctions, Plaintiff BETTY REED suffered life-threatening injuries and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff BETTY REED has suffered and will continue to suffer significant medical expenses, and pain and suffering, and other damages.

22. Plaintiff CLINT HURTADO at all times relevant to this action was and is a citizen and resident of the State of Wyoming. Plaintiff CLINT HURTADO underwent placement of Defendants' OptEase Vena Cava Filter on or about August 19, 2010. The filter subsequently malfunctioned and caused injury and damages to Plaintiff CLINT HURTADO, including, but not limited to, fracture of the filter. As a direct and proximate result of these malfunctions, Plaintiff CLINT HURTADO suffered life-threatening injuries and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff CLINT HURTADO has suffered and will continue to suffer significant medical expenses, and pain and suffering, and other damages.

23. Plaintiff MARK WEHMEIER at all times relevant to this action was and is a citizen and resident of the State of Wisconsin. Plaintiff MARK WEHMEIER underwent placement of Defendants' TrapEase Vena Cava Filter on or about October 20, 2012. The filter subsequently malfunctioned and caused injury and damages to Plaintiff MARK WEHMEIER, including, but not limited to, 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 MARK WEHMEIER suffered life-threatening injuries and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff MARK WEHMEIER has suffered and will continue to suffer significant medical expenses, and pain and suffering, and other damages.

24. Plaintiff JENNIFER SCHOCK at all times relevant to this action was and is a citizen and resident of the State of Wisconsin. Plaintiff JENNIFER SCHOCK underwent placement of Defendants' TrapEase Vena Cava Filter on or about November 16, 2005. The filter subsequently malfunctioned and caused injury and damages to Plaintiff JENNIFER SCHOCK, including, but not limited to, fracture of the filter and perforation of filter struts into vena cava. As a direct and proximate result of these malfunctions, Plaintiff JENNIFER SCHOCK suffered life-threatening injuries and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff JENNIFER SCHOCK has suffered and will continue to suffer significant medical expenses, and pain and suffering, and other damages.

25. Plaintiff JORDAN DEED at all times relevant to this action was and is a citizen and resident of the State of Wisconsin. Plaintiff JORDAN DEED underwent placement of Defendants' OptEase Vena Cava Filter on or about November 28, 2010. The filter subsequently malfunctioned and caused injury and damages to Plaintiff JORDAN DEED, including, but not limited to, severe pain and swelling of lower extremity, blood clots, clotting and occlusion of IVC filter, requiring emergency surgery to remove the filter. As a direct and proximate result of these malfunctions, Plaintiff JORDAN DEED suffered life-threatening injuries and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff JORDAN DEED has suffered and will continue to suffer significant medical expenses, and pain and suffering, and other damages.

26. Defendant CORDIS CORPORATION ("Cordis"), including its department, division, and subsidiary, Cordis Endovascular, is a corporation or business entity organized and existing under the laws of the State of Florida with its headquarters located at 6500 Paseo Padre Pkwy., Fremont, California, 94555. 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.

27. Defendant CORDIS COPORATION 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.

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

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

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

31. 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

32. 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.

33. 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

34. 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.

35. 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.

36. 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.

37. 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 thromboembolitic events.

38. 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.

39. 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.

40. Defendants Cordis and J&J 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.

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

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

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

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

45. Comparing the results of over 30,000 trauma patients who had not received IVC filters 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 Defendants Cordis and J&J told the FDA, physicians, and the public that its IVC filters were designed to prevent.

46. This *Annals of Surgery* study – and many others referenced by it – 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

47. 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.

48. 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).

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

> If the FDA concludes on the basis of the [manufacturer's] § 510(k) notification that the device is "substantially equivalent" to a pre-existing device, it can be marketed without further regulatory analysis. . . . The § 510(k) notification process is by no means 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."

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

50. Pursuant to *Wyeth v. Levine*, 555 U.S. 555 (2009), once a product is cleared "the manufacturer remains under an obligation to investigate and report any adverse events associated with 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.

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

symmetric filter. The filter has proximal and distal anchoring barbs located on each connecting strut for fixation of the filter to the vena cava wall to prevent movement after placement.

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

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

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

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

57. 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 has anchoring barbs for fixation of the filter only on the superior end of each of the six straight struts and has a hook at the inferior end of the basket to allow retrieval with a snare.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

a. Death;

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; and

f. Perforations of tissue, vessels and organs.

72. 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*.

73. Defendants failed to identify or acknowledge these device failures or determine their causes.

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

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

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

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

81. 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.

82. 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.

83. In 2010, Dr. Gred Usoh 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* Usoh, *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.

84. 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

was detected inside the filter in two cases. Based on these results, Dr. Sano criticized previous studies that had found the TrapEase filter to be safe as being conducted over too short a period of time and concluded that "patients undergoing permanent TrapEase IVCF insertion are at extremely high risk of strut fractures as early as two to three years after IVCF placement."

85. On May 6, 2014, the FDA issued another Safety Alert involving IVC filters. In this safety communication, the FDA wrote that it had received adverse event reports concerning "device 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.

86. 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

87. Plaintiffs incorporate by reference all prior allegations.

88. 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.

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.

96. 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.

97. 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.

98. 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.

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

100. 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.

101. 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.

102. 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.

103. 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)

104. Plaintiffs incorporate by reference all prior allegations.

105. 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.

106. 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.

107. 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.

108. 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.

109. 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.

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.

117. 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.

118. 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.

119. 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.

120. 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)

121. Plaintiffs incorporate by reference all prior allegations.

122. 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.

123. 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.

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

g. 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.

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

127. 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.

128. 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.

129. 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.

130. 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.

131. 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.

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

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

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

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

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

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

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

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

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

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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

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.

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

150. 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.

151. 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)

152. Plaintiffs incorporate by reference all prior allegations.

153. 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.

154. 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.

155. 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.

156. 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.

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

158. The foregoing representations and omissions by Defendants were false.

159. Defendants' IVC filters are not safe, fit, and effective for human use in their intended and reasonably foreseeable manner.

160. Further, the use of Cordis IVC filters is hazardous to the users' health, and Cordis IVC filters have a serious propensity to cause users to suffer serious injuries, including without limitation the injuries Plaintiffs suffered.

161. Finally, Defendants' IVC filters have a statistically significant higher rate of failure and injury than do other comparable IVC filters.

162. 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.

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

d. That Cordis IVC filters were not adequately tested to withstand normal placement within the human body.

170. Plaintiffs and their health care providers were not aware of these and other facts concealed by Defendants.

171. In concealing these and other facts, Defendants intended to deceive Plaintiffs and their health care providers.

172. 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.

173. 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)

174. Plaintiffs incorporate by reference all prior allegations.

175. Plaintiffs, through their medical providers, purchased a Cordis IVC filter from Defendants.

176. At all relevant times, Defendants were merchants of goods of the kind including medical devices and vena cava filters (i.e., Cordis IVC filters).

177. 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.

178. 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.

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;

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.

DEMAND FOR JURY TRIAL

Plaintiffs hereby demand a trial by jury on all triable issues.

Dated: May 6, 2016

Respectfully submitted,

LOPEZ McHUGH LLP

By: _____

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Matthew R. Lopez
Amorina P. Lopez

-And-

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Attorneys for Plaintiffs

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

Vena Cava Filter on or August 13, 2014, in California. The filter subsequently malfunctioned and caused injury and damages to Plaintiff GEANICE GRANT, including, but not limited to, severe and constant chest pains and compromised respiratory system. As a direct and proximate result of these malfunctions, Plaintiff GEANICE GRANT suffered serious injuries and damages, and will require extensive medical care and treatment. As a further proximate result, Plaintiff GEANICE GRANT has suffered and will continue to suffer significant medical expenses, and pain and suffering, and other damages.

9. Plaintiff VIOLET ELAINE KERN at all times relevant to this action was and is a citizen and resident of the State of Texas. Plaintiff VIOLET ELAINE KERN underwent placement of Defendants' OptEase Vena Cava Filter on or about March 28, 2012. The filter subsequently malfunctioned and caused injury and damages to Plaintiff VIOLET ELAINE KERN, including, but not limited to, 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 VIOLET ELAINE KERN suffered life-threatening injuries and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff VIOLET ELAINE KERN has suffered and will continue to suffer significant medical expenses, and pain and suffering, and other damages.

10. Plaintiff RUSSELL HOPKINS at all times relevant to this action was and is a citizen and resident of the State of Texas. Plaintiff RUSSELL HOPKINS underwent placement of Defendants' OptEase Vena Cava Filter on or about April 27, 2011. The filter subsequently malfunctioned and caused injury and damages to Plaintiff RUSSELL HOPKINS, including, but not limited to, filter embedded in wall of the IVC and unable to be retrieved. As a direct and proximate result of these malfunctions, Plaintiff RUSSELL HOPKINS suffered life-threatening injuries and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff RUSSELL HOPKINS has suffered and will continue to suffer significant medical expenses, and pain and suffering, and other damages.

11. Plaintiff ANTHONY BURBINE at all times relevant to this action was and is a citizen and resident of the State of Massachusetts. Plaintiff ANTHONY BURBINE underwent placement of Defendants' OptEase Vena Cava Filter on or about April 11, 2012. The filter subsequently

malfunctioned and caused injury and damages to Plaintiff ANTHONY BURBINE, including, but not limited to, filter embedded in wall of the IVC and unable to be retrieved. As a direct and proximate result of these malfunctions, Plaintiff ANTHONY BURBINE suffered life-threatening injuries and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff ANTHONY BURBINE has suffered and will continue to suffer significant medical expenses, and pain and suffering, and other damages.

12. Plaintiff COURTNEY COMER at all times relevant to this action was a citizen and resident of the State of Maryland and, subsequently, became a citizen and resident of the State of Texas. Plaintiff COURTNEY COMER underwent placement of Defendants' TrapEase Vena Cava Filter on or about May 5, 2005. The filter subsequently malfunctioned and caused injury and damages to Plaintiff COURTNEY COMER, including, but not limited to, fracture of the filter. As a direct and proximate result of these malfunctions, Plaintiff COURTNEY COMER suffered life-threatening injuries and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff COURTNEY COMER has suffered and will continue to suffer significant medical expenses, and pain and suffering, and other damages.

13. Plaintiff WILLIAM GOUGE at all times relevant to this action was and is a citizen and resident of the State of Maryland. Plaintiff WILLIAM GOUGE underwent placement of Defendants' TrapEase Vena Cava Filter on or about August 13, 2010. The filter subsequently malfunctioned and caused injury and damages to Plaintiff WILLIAM GOUGE, including, but not limited to, migration of the filter to heart requiring emergency open-heart surgery. As a direct and proximate result of these malfunctions, Plaintiff WILLIAM GOUGE suffered life-threatening injuries and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff WILLIAM GOUGE has suffered and will continue to suffer significant medical expenses, and pain and suffering, and other damages.

14. Plaintiff RHONDA GAIL SCHENK at all times relevant to this action was a citizen and resident of the State of Maryland. Plaintiff RHONDA GAIL SCHENK underwent placement of Defendants' OptEase Vena Cava Filter on or about March 1, 2010. The filter subsequently malfunctioned and caused injury and damages to Plaintiff RHONDA GAIL SCHENK, including, but

not limited to, filter embedded in wall of the IVC and unable to be retrieved, and recurrent DVTs. As a direct and proximate result of these malfunctions, Plaintiff RHONDA GAIL SCHENK suffered life-threatening injuries and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff RHONDA GAIL SCHENK has suffered and will continue to suffer significant medical expenses, and pain and suffering, and other damages.

15. Plaintiff JENNIFER ALLISON at all times relevant to this action was and is a citizen and resident of the State of Maryland. Plaintiff JENNIFER ALLISON underwent placement of Defendants' OptEase Vena Cava Filter on or about January 14, 2011. The filter subsequently malfunctioned and caused injury and damages to Plaintiff JENNIFER ALLISON, including, but not limited to, tilt, migration, 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 JENNIFER ALLISON suffered life-threatening injuries and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff JENNIFER ALLISON has suffered and will continue to suffer significant medical expenses, and pain and suffering, and other damages.

16. Plaintiff BOBBY FULLER at all times relevant to this action was and is a citizen and resident of the State of North Carolina. Plaintiff BOBBY FULLER underwent placement of Defendants' OptEase Vena Cava Filter on or about May 18, 2006. The filter subsequently malfunctioned and caused injury and damages to Plaintiff BOBBY FULLER, including, but not limited to, filter embedded in wall of the IVC. As a direct and proximate result of these malfunctions, Plaintiff BOBBY FULLER suffered life-threatening injuries and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff BOBBY FULLER has suffered and will continue to suffer significant medical expenses, and pain and suffering, and other damages.

17. Plaintiff ROBERT EDWARD BECKER at all times relevant to this action was and is a citizen and resident of the State of Wisconsin. Plaintiff ROBERT EDWARD BECKER underwent placement of Defendants' TrapEase Vena Cava Filter on or about June 21, 2010. The filter subsequently malfunctioned and caused injury and damages to Plaintiff ROBERT EDWARD BECKER, including, but not limited to, hematoma and recurrent pulmonary embolisms. As a direct and proximate result of these malfunctions, Plaintiff ROBERT EDWARD BECKER suffered life-threatening injuries

and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff ROBERT EDWARD BECKER has suffered and will continue to suffer significant medical expenses, and pain and suffering, and other damages.

18. Plaintiff TERRY ANN FOUNTAIN at all times relevant to this action was and is a citizen and resident of the State of Georgia. Plaintiff TERRY ANN FOUNTAIN underwent placement of Defendants' TrapEase Vena Cava Filter on or about June 2, 2007. The filter subsequently malfunctioned and caused injury and damages to Plaintiff TERRY ANN FOUNTAIN, including, but not limited to, blood clots, clotting and occlusion of IVC filter. As a direct and proximate result of these malfunctions, Plaintiff TERRY ANN FOUNTAIN suffered life-threatening injuries and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff TERRY ANN FOUNTAIN has suffered and will continue to suffer significant medical expenses, and pain and suffering, and other damages.

19. Plaintiff MARGUERITE NORTON at all times relevant to this action was and is a citizen and resident of the State of Pennsylvania. Plaintiff MARGUERITE NORTON underwent placement of Defendants' OptEase Vena Cava Filter on or about April 15, 2010. The filter subsequently malfunctioned and caused injury and damages to Plaintiff MARGUERITE NORTON, including, but not limited to, fracture of the filter. As a direct and proximate result of these malfunctions, Plaintiff MARGUERITE NORTON suffered life-threatening injuries and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff MARGUERITE NORTON has suffered and will continue to suffer significant medical expenses, and pain and suffering, and other damages.

20. Plaintiff JAMES FRANKLIN WILLIAMS, SR. at all times relevant to this action was and is a citizen and resident of the State of Maryland. Plaintiff JAMES FRANKLIN WILLIAMS, SR. underwent placement of Defendants' TrapEase Vena Cava Filter on or about June 27, 2013. The filter subsequently malfunctioned and caused injury and damages to Plaintiff JAMES FRANKLIN WILLIAMS, SR., including, but not limited to, DVT. As a direct and proximate result of these malfunctions, Plaintiff JAMES FRANKLIN WILLIAMS, SR. suffered life-threatening injuries and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff

JAMES FRANKLIN WILLIAMS, SR. has suffered and will continue to suffer significant medical expenses, and pain and suffering, and other damages.

21. Plaintiff BETTY REED at all times relevant to this action was and is a citizen and resident of the State of West Virginia. Plaintiff BETTY REED underwent placement of Defendants' TrapEase Vena Cava Filter on or about October 14, 2014. The filter subsequently malfunctioned and caused injury and damages to Plaintiff BETTY REED, including, but not limited to, migration of the filter. As a direct and proximate result of these malfunctions, Plaintiff BETTY REED suffered life-threatening injuries and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff BETTY REED has suffered and will continue to suffer significant medical expenses, and pain and suffering, and other damages.

22. Plaintiff CLINT HURTADO at all times relevant to this action was and is a citizen and resident of the State of Wyoming. Plaintiff CLINT HURTADO underwent placement of Defendants' OptEase Vena Cava Filter on or about August 19, 2010. The filter subsequently malfunctioned and caused injury and damages to Plaintiff CLINT HURTADO, including, but not limited to, fracture of the filter. As a direct and proximate result of these malfunctions, Plaintiff CLINT HURTADO suffered life-threatening injuries and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff CLINT HURTADO has suffered and will continue to suffer significant medical expenses, and pain and suffering, and other damages.

23. Plaintiff MARK WEHMEIER at all times relevant to this action was and is a citizen and resident of the State of Wisconsin. Plaintiff MARK WEHMEIER underwent placement of Defendants' TrapEase Vena Cava Filter on or about October 20, 2012. The filter subsequently malfunctioned and caused injury and damages to Plaintiff MARK WEHMEIER, including, but not limited to, 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 MARK WEHMEIER suffered life-threatening injuries and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff MARK WEHMEIER has suffered and will continue to suffer significant medical expenses, and pain and suffering, and other damages.

24. Plaintiff JENNIFER SCHOCK at all times relevant to this action was and is a citizen and resident of the State of Wisconsin. Plaintiff JENNIFER SCHOCK underwent placement of Defendants' TrapEase Vena Cava Filter on or about November 16, 2005. The filter subsequently malfunctioned and caused injury and damages to Plaintiff JENNIFER SCHOCK, including, but not limited to, fracture of the filter and perforation of filter struts into vena cava. As a direct and proximate result of these malfunctions, Plaintiff JENNIFER SCHOCK suffered life-threatening injuries and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff JENNIFER SCHOCK has suffered and will continue to suffer significant medical expenses, and pain and suffering, and other damages.

25. Plaintiff JORDAN DEED at all times relevant to this action was and is a citizen and resident of the State of Wisconsin. Plaintiff JORDAN DEED underwent placement of Defendants' OptEase Vena Cava Filter on or about November 28, 2010. The filter subsequently malfunctioned and caused injury and damages to Plaintiff JORDAN DEED, including, but not limited to, severe pain and swelling of lower extremity, blood clots, clotting and occlusion of IVC filter, requiring emergency surgery to remove the filter. As a direct and proximate result of these malfunctions, Plaintiff JORDAN DEED suffered life-threatening injuries and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff JORDAN DEED has suffered and will continue to suffer significant medical expenses, and pain and suffering, and other damages.

26. Plaintiff MICHELLE YOUNG at all times relevant to this action was a citizen and resident of the State of Ohio. Plaintiff MICHELLE YOUNG underwent placement of Defendants' TrapEase Vena Cava Filter on or about February 10, 2011. The filter subsequently malfunctioned and caused injury and damages to Plaintiff MICHELLE YOUNG, including, but not limited to, severe and constant chest pains and pulmonary embolisms. As a direct and proximate result of these malfunctions, Plaintiff MICHELLE YOUNG suffered serious injuries and damages, and will require extensive medical care and treatment. As a further proximate result, Plaintiff MICHELLE YOUNG has suffered and will continue to suffer significant medical expenses, and pain and suffering, and other damages.

27. Plaintiff VICTOR BLAIR at all times relevant to this action was and is a citizen and resident of the State of Ohio. Plaintiff VICTOR BLAIR underwent placement of Defendants' TrapEase

Vena Cava Filter on or about August 17, 2005. The filter subsequently malfunctioned and caused injury and damages to Plaintiff VICTOR BLAIR, including, but not limited to, severe and constant chest pains and compromised respiratory system. As a direct and proximate result of these malfunctions, Plaintiff VICTOR BLAIR suffered life-threatening injuries and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff VICTOR BLAIR has suffered and will continue to suffer significant medical expenses, and pain and suffering, and other damages.

28. Defendant CORDIS CORPORATION ("Cordis"), including its department, division, and subsidiary, Cordis Endovascular, is a corporation or business entity organized and existing under the laws of the State of Florida with its headquarters located at 6500 Paseo Padre Pkwy., Fremont, California, 94555.

29. 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.

30. 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.

31. Plaintiffs are informed and believe, and thereon allege, that at all times herein mentioned, the Defendant 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.

32. Plaintiffs are informed and believe, and thereon allege, that at all times mentioned herein, Defendant 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, fabricating, designing, developing, labeling, assembling, distributing, supplying, leasing, buying, offering for sale, selling, inspecting, servicing, contracting others for marketing, warranting, rebranding, manufacturing for others, packaging, and advertising the device.

33. Defendant and DOES 1 through 50, and each of them, are liable for the acts, omissions and tortious conduct of its successors and/or predecessors in interest/business/product line/or a portion thereof, assigns, parent, subsidiary, affiliate, partner, co-venturer, merged company, alter ego, agent, equitable trustee, fiduciary and/or its alternate entities in that Defendant and DOES 1 through 50, and each of them, enjoy the goodwill originally attached to each such alternate entity, acquired the assets or product line (or a portion thereof), and in that there has been a virtual destruction of Plaintiffs' remedy against each such alternate entity, and that each such Defendant has the ability to assume the risk-spreading role of each such alternate entity.

34. Plaintiffs are informed and believe, and thereon allege that, at all times herein mentioned, DOES 1 through 50, and each of them, were and are corporations organized and existing under the laws of the State of California or the laws of some state or foreign jurisdiction; that each of the said DOE defendants were and are authorized to do and are doing business in the State of California and regularly conducted business in the State of California.

35. Upon information and belief, Defendants at all relevant times were engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce and into the State of California, either directly or indirectly through third parties or related entities, its products, including the TrapEase and OptEase IVC filters, and derived substantial income from doing business in California.

36. "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.

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,

manufacturing and/or distributing Cordis IVC filters took place, in whole or in part, in the State of California. Therefore, the claims of California-plaintiffs *and* out-of-state plaintiffs relate to and arise from Defendants' explicit contacts and purposeful avail of the State of California. Further and independently, Cordis consented to jurisdiction in the State of California by appointing an agent for service of process in this State and by conducting substantial systematic business in this State.

43. The instant First Amended Complaint for Damages does not confer diversity jurisdiction upon the federal courts pursuant to 28 U.S.C. § 1332. Likewise, federal question subject matter jurisdiction pursuant to 28 U.S.C. § 1331 is not invoked by the instant Complaint, as it sets forth herein exclusively state law claims against the Defendants. Nowhere do Plaintiffs plead, expressly or implicitly, any cause of action or request any remedy that arises under or is founded upon federal law, and any alleged federal rights or remedies are expressly disavowed. The issues presented by Plaintiffs do not implicate substantial federal questions, do not turn on the necessary interpretation of federal law, and do not affect the federal system as a whole. The assertion of federal jurisdiction over claims made herein would improperly disturb the congressionally approved balance of federal and state responsibilities.

BACKGROUND

INFERIOR VENA CAVA FILTERS GENERALLY

44. 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.

45. 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.

46. 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.

47. 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 thromboembolitic events.

48. 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.

49. 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.

50. 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.

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

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

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

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

55. Comparing the results of over 30,000 trauma patients who had not received IVC filters 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.

56. 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.

57. 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

58. 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.

59. 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).

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

> If the FDA concludes on the basis of the [manufacturer's] § 510(k) notification that the device is "substantially equivalent" to a pre-existing device, it can be marketed without further regulatory analysis. . . . The § 510(k) notification process is by no means 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."

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

61. Pursuant to *Wyeth v. Levine*, 555 U.S. 555 (2009), once a product is cleared "the manufacturer remains under an obligation to investigate and report any adverse events associated with 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.

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

symmetric filter. The filter has proximal and distal anchoring barbs located on each connecting strut for fixation of the filter to the vena cava wall to prevent movement after placement.

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

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

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

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

68. 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 has anchoring barbs for fixation of the filter only on the superior end of each of the six straight struts and has a hook at the inferior end of the basket to allow retrieval with a snare.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

a. Death;

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.

83. 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*.

84. 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.

85. 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.

86. Defendants failed to identify or acknowledge these device failures or determine their causes.

87. Defendants failed to take timely and adequate remedial measures to correct known design and manufacturing defects with the Cordis IVC filters.

88. 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, Defendants represented that their filters were safe and effective – more safe and effective than other available IVC filters. 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.

89. 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.

90. Defendants also marketed the OptEase filter as being "easy" to remove. However, it is one of the most difficult filters to remove. 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. 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.

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

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

93. Cordis' labeling was additionally defective in that it directed physicians to implant the OptEase filter upside down. When the OptEase filter was placed as directed by the labeling, the hooks designed to ensure stability were facing in the wrong direction, rendering an already inadequate anchoring system even further defective. As Cordis now explain in its labeling, implanting the device in this fashion "can result in life threatening or serious injury including, but not limited to dissection, vessel perforation, migration of the filter with secondary damage to cardiac structures, ineffective pulmonary embolism prevention or death."

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

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

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

97. 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.

98. 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

99. Plaintiffs incorporate by reference all prior allegations.

100. 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.

101. 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.

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

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.

119. 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.

120. 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.

121. 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.

122. 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 wamings 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.

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.

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

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

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

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

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

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

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

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

f. The ability to retrieve the device at any time over a person's life.

169. 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.

170. 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.

171. 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.

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

173. The foregoing representations and omissions by Defendants were false.

174. Defendants' IVC filters are not safe, fit, and effective for human use in their intended and reasonably foreseeable manner.

175. Further, the use of Cordis IVC filters is hazardous to the users' health, and Cordis IVC filters have a serious propensity to cause users to suffer serious injuries, including without limitation the injuries Plaintiffs suffered.

176. Finally, Defendants' IVC filters have a statistically significant higher rate of failure and 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;

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.

185. Plaintiffs and their health care providers were not aware of these and other facts concealed by Defendants.

186. In concealing these and other facts, Defendants intended to deceive Plaintiffs and their health care providers.

187. 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.

188. 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)

189. Plaintiffs incorporate by reference all prior allegations.

190. Plaintiffs, through their medical providers, purchased a Cordis IVC filter from Defendants.

191. At all relevant times, Defendants were merchants of goods of the kind including medical devices and vena cava filters (i.e.. Cordis IVC filters).

192. 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.

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.

202. At all times material hereto, Defendants attempted to misrepresent and did knowingly misrepresent facts concerning the safety of Cordis IVC filters.

203. 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.

204. 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.

205. 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.

206. Notwithstanding the foregoing, Defendants continued to market Cordis IVC filters aggressively to consumers, including Plaintiffs, without disclosing the aforesaid side effects.

207. 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.

208. 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.

209. 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.

210. 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 13, 2016

Respectfully submitted,

LOPEZ McHUGH LLP

By: Matthew R. Lopez

Ramon Rossi Lopez
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-And-

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

DAVID RESOVSKY, GEORGE TODD, DAVID BROWN, GWEN KRAMER

Plaintiff(s),

vs.

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

Defendant(s).

Case No. RG16814745

COMPLAINT FOR DAMAGES

DEMAND FOR JURY TRIAL

Plaintiffs DAVID RESOVSKY, GEORGE TODD, DAVID BROWN, AND GWEN KRAMER hereby sue defendants CORDIS CORPORATION 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. As a result of the malfunction, Mr. Resovsky has suffered life-threatening injuries and damages and required extensive medical care and treatment. Plaintiff has suffered and will continue to suffer

significant medical expenses, extreme pain and suffering, loss of enjoyment of life, disability, and other losses.

2. Plaintiff George Todd was implanted with an OptEase™ filter in October 2006 at Aventura Hospital & Medical Center in Florida. The device subsequently tilted and perforated the vena cava. As a result, he suffered, *inter alia*, bilateral pulmonary emboli and the device cannot be removed. Plaintiff has suffered and will continue to suffer significant medical expenses, extreme pain and suffering, loss of enjoyment of life, disability, and other losses.

3. Plaintiff David Brown was implanted with an OptEase™ filter on November 4, 2014 at Hannibal Regional Hospital in Missouri. On February 5, 2015 he underwent a procedure to remove the device. The attempt failed secondary to the device having tilted and migrated after placement. Plaintiff has suffered medical expenses, pain and suffering, loss of enjoyment of life, and other losses.

4. Plaintiff Gwen Kramer underwent implantation of two OptEase™ filters on October 28, 2013. The first filter immediately migrated to the "origin of the left iliac vein." This filter was removed percutaneously. Another OptEase™ filter was then placed and this filter also migrated proximally with the distal portion of the filter being proximal to the renal veins. This filter was left in place. Given the migration of the second filter, Ms. Kramer is at increased risk of fracture, perforation and the device will be less effective at stopping clots. Plaintiff has suffered and will continue to suffer significant medical expenses, extreme pain and suffering, loss of enjoyment of life, disability, and other losses.

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

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

California, 94555. Cordis at all times relevant to this action, designed, set specifications for, manufactured, prepared, compounded, assembled, processed, marketed, distributed, and sold the OptEase™ Vena Cava Filter ("OptEase filter") to be implanted in patients throughout the United States, including California. 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.

7. The true names and/or capacities, whether individual, corporate, partnership, associate, governmental, or otherwise, of Defendant DOES 1 through 100, 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.

8. Plaintiffs are informed and believe, and thereon allege, that at all times herein mentioned, the Defendant 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.

9. Plaintiffs are informed and believe, and thereon allege, that at all times mentioned herein, Defendant and DOES 1 through 100, 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, fabricating, designing, developing, labeling, assembling, distributing, supplying, leasing, buying, offering for sale, selling, inspecting, servicing, contracting others for marketing, warranting, rebranding, manufacturing for others, packaging, and advertising the device.

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

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

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

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

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

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 it 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

clotting factor of the blood. In some people who are at high risk for DVT/PE, or who cannot manage their conditions with medications, physicians may recommend surgically implanting an IVC filter to prevent thromboembolitic events.

22. 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, however, an explosion in off-label use began with the introduction of IVC filters that were cleared for both permanent placement and optional removal. Most of this market expansion came from uses such as prophylactic prevention of pulmonary embolism without a prior history of pulmonary embolism.

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

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

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

26. Comparing the results of over 30,000 trauma patients who had not received IVC filters 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 Defendants represented to the FDA, physicians, and the public that its IVC filters would prevent.

27. 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.

28. 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

29. 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.

30. 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.

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

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

> If the FDA concludes on the basis of the [manufacturer's] § 510(k) notification that the device is 'substantially equivalent' to a pre-existing device, it can be marketed without further regulatory analysis.... The § 510(k) notification process is by no means 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 on commentator noted: "The attraction of substantial equivalence to manufacturers is clear. Section 510(k) notification required little information, rarely elicits a negative response form the FDA, and gets processed quickly.

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

32. Pursuant to *Wyeth v. Levine*, 555 U.S. 555 (2009), once a product is cleared "the manufacturer remains under an obligation to investigate and report any adverse associated with 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.

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

has anchoring barbs for fixation of the filter only on the superior end of each of the six straight struts and has a hook at the inferior end of the basket to allow retrieval with a snare.

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

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

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

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

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

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

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

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

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

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

a. Death;

b. Hemorrhage;

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.

45. 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.

46. 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.

47. Defendants, however, failed to take timely and adequate action to correct known design and manufacturing defects with the OptEase filter.

48. 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.

49. 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.

50. 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.

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

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

> "...we thought the OPTEASE and TRAPEASE filter types were subjectively among the most difficult to remove in our study, often requiring aggressive blunt dissection force in addition to laser tissue ablation to achieve removal. A possible 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."

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

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

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

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

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

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

59. Given the unreasonably high failure and injury rates associated with Defendants 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.

ESTOPPEL FROM PLEADING STATUTES OF LIMITATIONS OR REPOSE

60. Plaintiffs incorporate by reference all prior allegations.

61. 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 Defendants' IVC filters.

62. Plaintiffs' ignorance of the defective and unreasonably dangers nature of Defendants' IVC filters, and the causal connection between these defects and Plaintiffs' 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.

63. 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.

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

65. Defendants had a duty to disclose the fact that Defendants' 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 the above described risks.

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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

used in an intended and reasonably foreseeable way. Such ordinary consumers, including Plaintiffs and their prescribing physician(s), would not and could not have recognized or discovered the potential risks and side effects of the device, as set forth herein.

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

81. The labeling also failed to provide adequate directions on how to appropriately use the product.

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

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

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

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

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

85. 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.

86. 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.

87. 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.

88. 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

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. 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.

92. Defendants knew or reasonably should have known that the OptEase filters were dangerous or were likely to be dangerous when used in an intended or reasonably foreseeable manner.

93. At the time of manufacture and sale of the OptEase filters, Defendants knew or should have known that the OptEase filters:

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 to 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:

a. 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 burden of taking safety measures to reduce or avoid harm;

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 likelihood of potential harm from other devices and treatment options available for the same purpose;

c. Failing to use reasonable care in manufacturing the product and producing a product that differed from their design or specifications or from other typical units from the same production line;

d. 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 OptEase filters' substantially dangerous condition or about facts making the products likely to be dangerous;

e. 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 OptEase filters;

h. Advertising, marketing and recommending the use of the 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 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 and 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.

107. 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.

108. 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, impiant, purchase, and continue to use the device, all in reliance on Defendants' misrepresentations.

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

110. 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.

111. 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.

112. 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.

113. Defendants had sole access to material facts concerning the defective nature of the 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.

114. 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.

115. 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.

116. 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

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

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

119. 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

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

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

121. The Defendants are and were under a continuing duty to disclose the true character, 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.

129. 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 OptEase 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.

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

COUNT IX
BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY
By all Plaintiffs

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

132. Defendants sold the OptEase filters for Plaintiffs' ultimate use.

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.

134. 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.

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:

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;

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,
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ALAMEDA COUNTY
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THE SUPERIOR COURT
By Amrit Khan, Deputy
CASE NUMBER:
RG16814745

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.

As a result of the malfunction, Mr. Resovsky has suffered life-threatening injuries and damages and required extensive medical care and treatment. Plaintiff has suffered and will continue to suffer significant medical expenses, extreme pain and suffering, loss of enjoyment of life, disability, and other losses.

2. Plaintiff George Todd was implanted with an OptEase™ filter in October 2006 at Aventura Hospital & Medical Center in Florida. The device subsequently tilted and perforated the vena cava. As a result, he suffered, *inter alia*, bilateral pulmonary emboli and the device cannot be removed. Plaintiff has suffered and will continue to suffer significant medical expenses, extreme pain and suffering, loss of enjoyment of life, disability, and other losses.

3. Plaintiff David Brown was implanted with an OptEase™ filter on November 4, 2014 at Hannibal Regional Hospital in Missouri. On February 5, 2015 he underwent a procedure to remove the device. The attempt failed secondary to the device having tilted and migrated after placement. Plaintiff has suffered medical expenses, pain and suffering, loss of enjoyment of life, and other losses.

4. Plaintiff Gwen Kramer underwent implantation of two OptEase™ filters on October 28, 2013. The first filter immediately migrated to the "origin of the left iliac vein." This filter was removed percutaneously. Another OptEase™ filter was then placed and this filter also migrated proximally with the distal portion of the filter being proximal to the renal veins. This filter was left in place. Given the migration of the second filter, Ms. Kramer is at increased risk of fracture, perforation and the device will be less effective at stopping clots. Plaintiff has suffered and will continue to suffer significant medical expenses, extreme pain and suffering, loss of enjoyment of life, disability, and other losses.

5. Plaintiff Richard Longston underwent placement of an OptEase™ filter on March 13, 2015 in the State of Florida. At the time of placement, Mr. Longston was and still is a resident of the State of Florida. The device subsequently suffered a malfunction in its anchoring system

resulting in severe tilt, embedment, perforation and inability to remove. Plaintiff has suffered and will continue to suffer medical expenses, pain and suffering, loss of enjoyment of life, and other losses.

6. Plaintiff Ronald Mareski underwent placement of an OptEase™ filter on August 15, 2006. The device subsequently malfunctioned and migrated to his heart, which required open heart surgery. Plaintiff has suffered and will continue to suffer significant medical expenses, extreme pain and suffering, loss of enjoyment of life, disability, and other losses.

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

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

9. Defendant Cordis Corporation ("Cordis") is a corporation organized under the laws of the State of Florida, with its principal place of business at 6500 Paseo Padre Pkwy, Fremont, California, 94555. Cordis at all times relevant to this action, designed, set specifications for, manufactured, prepared, compounded, assembled, processed, marketed, distributed, and sold the OptEase™ Vena Cava Filter ("OptEase filter") to be implanted in patients throughout the United States, including California. 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.

10. Defendant Confluent Medical Technologies, Inc. (Hereinafter "Confluent") is a corporation organized under the laws of the State of Delaware, with its principal place of business at 47533 Westinghouse Drive, Fremont, California 94539. Confluent manufactured, prepared, processed and helped design the OptEase and TrapEase filters implanted in the above-named

plaintiffs, whether under its current name or as the successor in interest to Nitinol Development Corporation. Confluent may be served with process by serving its registered agent, CT Corporation System, at 818 West Seventh Street Suite 930, Los Angeles, California 90017.

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

12. The true names and/or capacities, whether individual, corporate, partnership, associate, governmental, or otherwise, of Defendant DOES 1 through 100, 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.

13. Plaintiffs are informed and believe, and thereon allege, that at all times herein mentioned, 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.

14. Plaintiffs are informed and believe, and thereon allege, that at all times mentioned herein, Defendants and DOES 1 through 100, 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, fabricating, designing, developing, labeling, assembling, distributing, supplying, leasing, buying, offering for sale, selling, inspecting, servicing, contracting others for marketing, warranting, rebranding, manufacturing for others, packaging, and advertising the device.

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

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

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

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

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

20. "Cordis," "Confluent" 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, Confluent, as well as DOE Defendants 1 through 100, and each of them.

JURISDICTION AND VENUE

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

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

BACKGROUND

INFERIOR VENA CAVA FILTERS GENERALLY

23. 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.

24. 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.

25. 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.

26. 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 manage their conditions with medications, physicians may recommend surgically implanting an IVC filter to prevent thromboembolitic events.

27. 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, however, an explosion in off-label use began with the introduction of IVC filters that were cleared for both permanent placement and optional removal. Most of this market expansion came from uses such as prophylactic prevention of pulmonary embolism without a prior history of pulmonary embolism.

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

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

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

31. Comparing the results of over 30,000 trauma patients who had not received IVC filters 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 Defendants represented to the FDA, physicians, and the public that its IVC filters would prevent.

32. 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.

33. 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

34. 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.

35. 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.

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

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

> If the FDA concludes on the basis of the [manufacturer's] § 510(k) notification that the device is 'substantially equivalent' to a pre-existing device, it can be marketed without further regulatory analysis.... The § 510(k) notification process is by no means 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 on commentator noted: "The attraction of substantial equivalence to manufacturers is clear. Section 510(k) notification required little information, rarely elicits a negative response form the FDA, and gets processed quickly.

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

37. Pursuant to *Wyeth v. Levine*, 555 U.S. 555 (2009), once a product is cleared "the manufacturer remains under an obligation to investigate and report any adverse associated with 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.

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

39. 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 has anchoring barbs for fixation of the filter only on the superior end of each of the six straight struts and has a hook at the inferior end of the basket to allow retrieval with a snare.

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

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

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

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

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

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

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

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

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

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

a. Death;

b. Hemorrhage;

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.

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

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

> "...we thought the OPTEASE and TRAPEASE filter types were subjectively among the most difficult to remove in our study, often requiring aggressive blunt dissection force in addition to laser tissue ablation to achieve removal. A possible 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."

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

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

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

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

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

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

64. Given the unreasonably high failure and injury rates associated with Defendants 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.

ESTOPPEL FROM PLEADING STATUTES OF LIMITATIONS OR REPOSE

65. Plaintiffs incorporate by reference all prior allegations.

66. 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 Defendants' IVC filters.

67. Plaintiffs' ignorance of the defective and unreasonably dangers nature of Defendants' IVC filters, and the causal connection between these defects and Plaintiffs' 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.

68. 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.

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

70. Defendants had a duty to disclose the fact that Defendants' 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 the above described risks.

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

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

72. 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.

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

74. 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.

75. 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.

76. 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.

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

78. 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.

79. 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

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

81. 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.

82. 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.

83. 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.

84. 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 used in an intended and reasonably foreseeable way. Such ordinary consumers, including Plaintiffs and their prescribing physician(s), would not and could not have recognized or discovered the potential risks and side effects of the device, as set forth herein.

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

86. The labeling also failed to provide adequate directions on how to appropriately use the product.

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

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

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

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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.

97. Defendants knew or reasonably should have known that the OptEase filters were dangerous or were likely to be dangerous when used in an intended or reasonably foreseeable manner.

98. At the time of manufacture and sale of the OptEase filters, Defendants knew or should have known that the OptEase filters:

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.

99. 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.

100. 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.

101. Defendants breached their to 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:

a. 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 burden of taking safety measures to reduce or avoid harm;

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 likelihood of potential harm from other devices and treatment options available for the same purpose;

c. Failing to use reasonable care in manufacturing the product and producing a product that differed from their design or specifications or from other typical units from the same production line;

d. 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 OptEase filters' substantially dangerous condition or about facts making the products likely to be dangerous;

e. 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 OptEase filters;

h. Advertising, marketing and recommending the use of the 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 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 and adequate post-market surveillance program;

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

102. 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

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

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 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.

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 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.

118. 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.

119. 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.

120. 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

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

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

123. 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

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

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

125. The Defendants are and were under a continuing duty to disclose the true character, 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.

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

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

128. 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

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

130. 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.

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 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.

132. 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.

133. 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 OptEase filters' inability to conform to these express warranties.

134. 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

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

136. Defendants sold the OptEase filters for Plaintiffs' ultimate use.

137. 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.

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

consortium, all to her general damage, in an amount in excess of the jurisdictional minimum of this Court.

WHEREFORE, Plaintiff Linda Mareski demand judgment against the Defendants as hereinafter set forth.

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 OptEase filters were defective and unreasonably dangerous and were causing injury and death to patients.

146. 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.

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 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 OptEase filters, Defendants consciously disregarded the known risks and continued to actively market and offer for sale the OptEase filters.

149. 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, Confluent Medical Technologies, Inc., 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.

Respectfully Submitted,

DATED: May 24, 2016

BRENES LAW GROUP

/s/ Troy A. Brenes
Troy A. Brenes
Attorney for Plaintiffs

Exhibit 11

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ENDORSED
FILED
ALAMEDA COUNTY

MAY 20 2016

CLERK OF THE SUPERIOR COURT
By Samuel Mena
Deputy

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

husband;

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 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 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 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

malfunctioned and caused injury and damages to Plaintiff JACQUELYN HANSON, including, but not limited to, tilt, filter embedded in wall of the IVC, defect of the IVC, and trauma to her IVC. As a direct and proximate result of these malfunctions, Plaintiff JACQUELYN HANSON suffered life-threatening injuries and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff JACQUELYN HANSON has suffered and will continue to suffer significant medical expenses, and pain and suffering, and other damages.

11. Plaintiff DONALD HERNANDEZ, SR. at all times relevant to this action was and is a citizen and resident of the State of Texas. Plaintiff DONALD HERNANDEZ, SR. underwent placement of Defendants' OptEase Vena Cava Filter on or about April 25, 2012. The filter subsequently malfunctioned and caused injury and damages to Plaintiff DONALD HERNANDEZ, SR., including, but not limited to, filter embedded in wall of the IVC and unable to be retrieved. As a direct and proximate result of these malfunctions, Plaintiff DONALD HERNANDEZ, SR. suffered life-threatening injuries and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff DONALD HERNANDEZ, SR. has suffered and will continue to suffer significant medical expenses, and pain and suffering, and other damages.

12. Plaintiff RHONDA HERNANDEZ at all times relevant to this action was and is a citizen and resident of the State of Texas. Plaintiffs DONALD HERNANDEZ, SR. and RHONDA HERNANDEZ were and are, at all times relevant to this action, legally married as husband and wife. Plaintiff RHONDA HERNANDEZ brings this action for, *inter alia*, the loss of consortium, comfort, and society she suffered due to the personal injuries suffered by her husband, DONALD HERNANDEZ, SR.

13. Plaintiff JAMES LEWIS at all times relevant to this action was and is a citizen and resident of the State of Ohio. Plaintiff JAMES LEWIS underwent placement of Defendants' TrapEase Vena Cava Filter on or about July 29, 2008. The filter subsequently malfunctioned and caused injury and damages to Plaintiff JAMES LEWIS, including, but not limited to, tilt, filter embedded in wall of the IVC, and filter unable to be retrieved. As a direct and proximate result of these malfunctions, Plaintiff JAMES LEWIS suffered life-threatening injuries and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff JAMES LEWIS has suffered and will continue to suffer significant medical expenses, and pain and suffering, and other damages.

14. Plaintiff CONNIE PATTERSON at all times relevant to this action was and is a citizen and resident of the State of Ohio. Plaintiff CONNIE PATTERSON underwent placement of Defendants' TrapEase Vena Cava Filter on or about July 15, 2005. The filter subsequently malfunctioned and caused injury and damages to Plaintiff CONNIE PATTERSON, including, but not limited to, migration of the filter. As a direct and proximate result of these malfunctions, Plaintiff CONNIE PATTERSON suffered life-threatening injuries and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff CONNIE PATTERSON has suffered and will continue to suffer significant medical expenses, and pain and suffering, and other damages.

15. Plaintiff CAROLYN SIMMONS at all times relevant to this action was and is a citizen and resident of the State of Florida. Plaintiff CAROLYN SIMMONS underwent placement of Defendants' TrapEase Vena Cava Filter on or about February 27, 2015. The filter subsequently malfunctioned and caused injury and damages to Plaintiff CAROLYN SIMMONS, including, but not limited to, pain at filter site. As a direct and proximate result of these malfunctions, Plaintiff CAROLYN SIMMONS suffered life-threatening injuries and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff CAROLYN SIMMONS has suffered and will continue to suffer significant medical expenses, and pain and suffering, and other damages.

16. Plaintiff WALTER SIMMONS at all times relevant to this action was and is a citizen and resident of the State of Florida. Plaintiffs CAROLYN SIMMONS and WALTER SIMMONS were and are, at all times relevant to this action, legally married as wife and husband. Plaintiff WALTER SIMMONS brings this action for, *inter alia*, the loss of consortium, comfort, and society he suffered due to the personal injuries suffered by his wife, CAROLYN SIMMONS.

17. Plaintiff MICHAEL DONLIN at all times relevant to this action was and is a citizen and resident of the State of New York. Plaintiff MICHAEL DONLIN underwent placement of Defendants' TrapEase Vena Cava Filter on or about May 30, 2010. The filter subsequently malfunctioned and caused injury and damages to Plaintiff MICHAEL DONLIN, including, but not limited to, filter embedded in wall of the IVC and unable to be retrieved. As a direct and proximate result of these malfunctions, Plaintiff MICHAEL DONLIN suffered life-threatening injuries and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff MICHAEL

DONLIN has suffered and will continue to suffer significant medical expenses, and pain and suffering, and other damages.

18. Plaintiff DAVID HAMILTON at all times relevant to this action was and is a citizen and resident of the State of Georgia. Plaintiff DAVID HAMILTON underwent placement of Defendants' OptEase Vena Cava Filter on or about January 30, 2011. The filter subsequently malfunctioned and caused injury and damages to Plaintiff DAVID HAMILTON, including, but not limited to, pain at filter site. As a direct and proximate result of these malfunctions, Plaintiff DAVID HAMILTON suffered life-threatening injuries and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff DAVID HAMILTON has suffered and will continue to suffer significant medical expenses, and pain and suffering, and other damages.

19. Plaintiff STEPHEN VANDALL at all times relevant to this action was and is a citizen and resident of the State of West Virginia. Plaintiff STEPHEN VANDALL underwent placement of Defendants' TrapEase Vena Cava Filter on or about October 10, 2008. The filter subsequently malfunctioned and caused injury and damages to Plaintiff STEPHEN VANDALL, including, but not limited to, filter embedded in wall of the IVC and unable to be retrieved. As a direct and proximate result of these malfunctions, Plaintiff STEPHEN VANDALL suffered life-threatening injuries and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff STEPHEN VANDALL has suffered and will continue to suffer significant medical expenses, and pain and suffering, and other damages.

20. Plaintiff HEATHER VANDALL at all times relevant to this action was and is a citizen and resident of the State of Texas. Plaintiffs STEPHEN VANDALL and HEATHER VANDALL were and are, at all times relevant to this action, legally married as husband and wife. Plaintiff HEATHER VANDALL brings this action for, *inter alia*, the loss of consortium, comfort, and society she suffered due to the personal injuries suffered by her husband, STEPHEN VANDALL.

21. Plaintiff DOROTHY MILLS at all times relevant to this action was a citizen and resident of the State of West Virginia and, subsequently, became a citizen and resident of the State of Oklahoma. Plaintiff DOROTHY MILLS underwent placement of Defendants' TrapEase Vena Cava Filter on or about May 23, 2005. The filter subsequently malfunctioned and caused injury and damages to Plaintiff

DOROTHY MILLS, including, but not limited to, tilt, pain at filter site. As a direct and proximate result of these malfunctions, Plaintiff DOROTHY MILLS suffered life-threatening injuries and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff DOROTHY MILLS has suffered and will continue to suffer significant medical expenses, and pain and suffering, and other damages.

22. Plaintiff LAKISHA HOOKS at all times relevant to this action was and is a citizen and resident of the State of Texas. Plaintiff LAKISHA HOOKS underwent placement of Defendants' OptEase Vena Cava Filter on or about May 1, 2014. The filter subsequently malfunctioned and caused injury and damages to Plaintiff LAKISHA HOOKS, including, but not limited to, blood clots, clotting and occlusion of IVC filter. As a direct and proximate result of these malfunctions, Plaintiff LAKISHA HOOKS suffered life-threatening injuries and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff LAKISHA HOOKS has suffered and will continue to suffer significant medical expenses, and pain and suffering, and other damages.

23. Plaintiff DEBORAH JARVIS at all times relevant to this action was and is a citizen and resident of the State of Pennsylvania. Plaintiff DEBORAH JARVIS underwent placement of Defendants' TrapEase Vena Cava Filter on or about September 25, 2007. The filter subsequently malfunctioned and caused injury and damages to Plaintiff DEBORAH JARVIS, including, but not limited to, pain at filter site. As a direct and proximate result of these malfunctions, Plaintiff DEBORAH JARVIS suffered life-threatening injuries and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff DEBORAH JARVIS has suffered and will continue to suffer significant medical expenses, and pain and suffering, and other damages.

24. Plaintiff CAROLINE CARR at all times relevant to this action was and is a citizen and resident of the State of Pennsylvania. Plaintiff CAROLINE CARR underwent placement of Defendants' TrapEase Vena Cava Filter on or about May 13, 2011. The filter subsequently malfunctioned and caused injury and damages to Plaintiff CAROLINE CARR, including, but not limited to, blood clots, clotting and occlusion of IVC filter. As a direct and proximate result of these malfunctions, Plaintiff CAROLINE CARR suffered life-threatening injuries and damages, and required extensive medical care

and treatment. As a further proximate result, Plaintiff CAROLINE CARR has suffered and will continue to suffer significant medical expenses, and pain and suffering, and other damages.

25. Plaintiff GERALDINE CLARK at all times relevant to this action was and is a citizen and resident of the State of Tennessee. Plaintiff GERALDINE CLARK underwent placement of Defendants' TrapEase Vena Cava Filter on or about January 9, 2015. The filter subsequently malfunctioned and caused injury and damages to Plaintiff GERALDINE CLARK, including, but not limited to, blood clots, clotting and occlusion of IVC filter. As a direct and proximate result of these malfunctions, Plaintiff GERALDINE CLARK suffered life-threatening injuries and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff GERALDINE CLARK has suffered and will continue to suffer significant medical expenses, and pain and suffering, and other damages.

26. Plaintiff ROBERT SPISHAK at all times relevant to this action was and is a citizen and resident of the State of Ohio. Plaintiff ROBERT SPISHAK underwent placement of Defendants' TrapEase Vena Cava Filter on or about April 8, 2009. The filter subsequently malfunctioned and caused injury and damages to Plaintiff ROBERT SPISHAK, including, but not limited to, severe shortness of breath, dizziness, and pain at filter site. As a direct and proximate result of these malfunctions, Plaintiff ROBERT SPISHAK suffered life-threatening injuries and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff ROBERT SPISHAK has suffered and will continue to suffer significant medical expenses, and pain and suffering, and other damages.

27. Plaintiff BARBARA SPISHAK at all times relevant to this action was and is a citizen and resident of the State of Ohio. Plaintiffs ROBERT SPISHAK and BARBARA SPISHAK were and are, at all times relevant to this action, legally married as husband and wife. Plaintiff BARBARA SPISHAK brings this action for, *inter alia*, the loss of consortium, comfort, and society she suffered due to the personal injuries suffered by her husband, ROBERT SPISHAK.

28. Plaintiff REINA JONES at all times relevant to this action was and is a citizen and resident of the State of New York. Plaintiff REINA JONES underwent placement of Defendants' OptEase Vena Cava Filter on or about August 14, 2006. The filter subsequently malfunctioned and caused injury and damages to Plaintiff REINA JONES, including, but not limited to, blood clots,

clotting and occlusion of the IVC filter. As a direct and proximate result of these malfunctions, Plaintiff REINA JONES suffered life-threatening injuries and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff REINA JONES has suffered and will continue to suffer significant medical expenses, and pain and suffering, and other damages.

29. Plaintiff VANESIA JOHNSON at all times relevant to this action was and is a citizen and resident of the State of Texas. Plaintiff VANESIA JOHNSON underwent placement of Defendants' OptEase Vena Cava Filter on or about February 23, 2009. The filter subsequently malfunctioned and caused injury and damages to Plaintiff VANESIA JOHNSON, including, but not limited to, filter embedded to wall of IVC and cannot be retrieved. As a direct and proximate result of these malfunctions, Plaintiff VANESIA JOHNSON suffered life-threatening injuries and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff VANESIA JOHNSON has suffered and will continue to suffer significant medical expenses, and pain and suffering, and other damages.

30. Plaintiff DARNELL KILGORE at all times relevant to this action was and is a citizen and resident of the State of South Carolina. Plaintiff DARNELL KILGORE underwent placement of Defendants' OptEase Vena Cava Filter on or about February 10, 2009. The filter subsequently malfunctioned and caused injury and damages to Plaintiff DARNELL KILGORE, including, but not limited to, blood clots, clotting and occlusion of the IVC filter. As a direct and proximate result of these malfunctions, Plaintiff DARNELL KILGORE suffered life-threatening injuries and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff DARNELL KILGORE has suffered and will continue to suffer significant medical expenses, and pain and suffering, and other damages.

31. Plaintiff JOSEPH HERSHBERGER at all times relevant to this action was a citizen and resident of the State of Arizona and, subsequently, became a citizen and resident of the State of Colorado. Plaintiff JOSEPH HERSHBERGER underwent placement of Defendants' OptEase Vena Cava Filter on or about July 14, 2013. The filter subsequently malfunctioned and caused injury and damages to Plaintiff JOSEPH HERSHBERGER, including, but not limited to, perforation of the IVC and blood clots. As a direct and proximate result of these malfunctions, Plaintiff JOSEPH

HERSHBERGER suffered life-threatening injuries and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff JOSEPH HERSHBERGER has suffered and will continue to suffer significant medical expenses, and pain and suffering, and other damages.

32. Plaintiff RUSSELL ZUKRIGIL at all times relevant to this action was and is a citizen and resident of the State of New York. Plaintiff RUSSELL ZUKRIGIL underwent placement of Defendants' TrapEase Vena Cava Filter on or about March 2, 2007. The filter subsequently malfunctioned and caused injury and damages to Plaintiff RUSSELL ZUKRIGIL, including, but not limited to, perforation of the IVC. As a direct and proximate result of these malfunctions, Plaintiff RUSSELL ZUKRIGIL suffered life-threatening injuries and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff RUSSELL ZUKRIGIL has suffered and will continue to suffer significant medical expenses, and pain and suffering, and other damages.

33. Plaintiff BRIAN ZUKRIGIL at all times relevant to this action was and is a citizen and resident of the State of New York. Plaintiffs RUSSELL ZUKRIGIL and BRIAN ZUKRIGIL were and are, at all times relevant to this action, legally married. Plaintiff BRIAN ZUKRIGIL brings this action for, *inter alia*, the loss of consortium, comfort, and society he suffered due to the personal injuries suffered by his husband, RUSSELL ZUKRIGIL.

34. Defendant CORDIS CORPORATION ("Cordis"), including its department, division, and subsidiary, Cordis Endovascular, is a corporation or business entity organized and existing under the laws of the State of Florida with its headquarters located at 6500 Paseo Padre Pkwy., Fremont, California, 94555.

35. 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.

36. 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.

37. 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.

38. 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.

39. 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.

40. 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, fabricating, designing, developing, labeling, assembling, distributing, supplying, leasing, buying, offering for sale, selling, inspecting, servicing, contracting others for marketing, warranting, rebranding, manufacturing for others, packaging, and advertising the device.

41. Defendants and DOES 1 through 50, and each of them, are liable for the acts, omissions and tortious conduct of its successors and/or predecessors in interest/business/product line/or a portion thereof, assigns, parent, subsidiary, affiliate, partner, co-venturer, merged company, alter ego, agent,

equitable trustee, fiduciary and/or its alternate entities in that Defendants and DOES 1 through 50, and each of them, enjoy the goodwill originally attached to each such alternate entity, acquired the assets or product line (or a portion thereof), and in that there has been a virtual destruction of Plaintiffs' remedy against each such alternate entity, and that each such Defendant has the ability to assume the risk-spreading role of each such alternate entity.

42. Plaintiffs are informed and believe, and thereon allege that, at all times herein mentioned, DOES 1 through 50, and each of them, were and are corporations organized and existing under the laws of the State of California or the laws of some state or foreign jurisdiction; that each of the said DOE defendants were and are authorized to do and are doing business in the State of California and regularly conducted business in the State of California.

43. Upon information and belief, Defendants at all relevant times were engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce and into the State of California, either directly or indirectly through third parties or related entities, its products, including the TrapEase and OptEase IVC filters, and derived substantial income from doing business in California.

44. "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, J&J, Cardinal, as well as DOE Defendants 1 through 50, and each of them.

45. Joinder of Plaintiffs in this Complaint for Damages is proper pursuant to *Code of Civil Procedure* § 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

46. 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.

47. 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.

48. 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.

49. 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.

50. 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 California. Therefore, the claims of California-plaintiffs *and* out-of-state plaintiffs relate to and arise from Defendants' explicit contacts and purposeful avail of the State of California. Further and independently, Cordis consented to jurisdiction in the State of California by appointing an agent for service of process in this State and by conducting substantial systematic business in this State.

51. The instant Complaint for Damages does not confer diversity jurisdiction upon the federal courts pursuant to 28 U.S.C. § 1332. Likewise, federal question subject matter jurisdiction pursuant to 28 U.S.C. § 1331 is not invoked by the instant Complaint, as it sets forth herein exclusively state law claims against the Defendants. Nowhere do Plaintiffs plead, expressly or implicitly, any cause of action or request any remedy that arises under or is founded upon federal law, and any alleged federal

rights or remedies are expressly disavowed. The issues presented by Plaintiffs do not implicate substantial federal questions, do not turn on the necessary interpretation of federal law, and do not affect the federal system as a whole. The assertion of federal jurisdiction over claims made herein would improperly disturb the congressionally approved balance of federal and state responsibilities.

BACKGROUND

INFERIOR VENA CAVA FILTERS GENERALLY

52. 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.

53. 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.

54. 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.

55. 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 thromboembolitic events.

56. 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.

57. 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.

58. 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.

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

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

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

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

63. Comparing the results of over 30,000 trauma patients who had not received IVC filters 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.

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^{tm} AND OPTEASE^{tm} 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:

> If the FDA concludes on the basis of the [manufacturer's] § 510(k) notification that the device is "substantially equivalent" to a pre-existing device, it can be marketed without further regulatory analysis. . . . The § 510(k) notification process is by no means 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."

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

69. Pursuant to *Wyeth v. Levine*, 555 U.S. 555 (2009), once a product is cleared "the manufacturer remains under an obligation to investigate and report any adverse events associated with 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.

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

71. 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 symmetric filter. The filter has proximal and distal anchoring barbs located on each connecting strut for fixation of the filter to the vena cava wall to prevent movement after placement.

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

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

74. Electro-polishing is a manner of removing surface blemishes, "draw marking" and circumferential grinding markings on the exterior of the surface of the Nitinol material. The existence

of these surface blemishes, "draw markings" and "circumferential grind-markings" causes/results in the weakening of the structural integrity of the end product, whether it is an IVC filter or other medical device.

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

76. 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 has anchoring barbs for fixation of the filter only on the superior end of each of the six straight struts and has a hook at the inferior end of the basket to allow retrieval with a snare.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

a. Death;

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.

91. 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*.

92. 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.

93. 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.

94. Defendants failed to identify or acknowledge these device failures or determine their causes.

95. Defendants failed to take timely and adequate remedial measures to correct known design and manufacturing defects with the Cordis IVC filters.

96. 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, Defendants represented that their filters were safe and effective – more safe and effective than other available IVC filters. 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.

97. 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.

98. Defendants also marketed the OptEase filter as being "easy" to remove. However, it is one of the most difficult filters to remove. 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. 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.

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

100. Defendants also failed to adequately disclose the risks of these filters, such as migration, fracture, perforation, tilt, thrombosis, the prothrombotic nature of the devices, that the devices may not

be retrievable, or that these failures were known to be causing severe injuries and death or the rate at which these events were occurring.

101. Cordis' labeling was additionally defective in that it directed physicians to implant the OptEase filter upside down. When the OptEase filter was placed as directed by the labeling, the hooks designed to ensure stability were facing in the wrong direction, rendering an already inadequate anchoring system even further defective. As Cordis now explain in its labeling, implanting the device in this fashion "can result in life threatening or serious injury including, but not limited to dissection, vessel perforation, migration of the filter with secondary damage to cardiac structures, ineffective pulmonary embolism prevention or death."

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

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

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

105. 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.

106. 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

107. Plaintiffs incorporate by reference all prior allegations.

108. 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.

109. 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.

110. 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.

111. 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.

112. 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.

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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.

128. 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.

129. 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.

130. 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.

131. 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.

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

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.

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

147. 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.

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

d. Failing to establish an adequate quality assurance program used in the manufacturing of their IVC filters.

150. 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.

151. 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.

152. 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.

153. 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.

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

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

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

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

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

159. Reasonable manufacturers and reasonable distributors, under the same or similar circumstances as those of Defendants prior to, on, and after the date of Plaintiffs' use of a Cordis IVC

filter, would have warned of the dangers presented by Cordis IVC filters, or instructed on the safe use of Cordis IVC filters.

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

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

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

FIFTH CAUSE OF ACTION

NEGLIGENT MISREPRESENTATION

(By All Plaintiffs, As to All Defendants)

163. Plaintiffs incorporate by reference all prior allegations.

164. 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,

165. 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.

166. 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.

167. 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.

168. 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.

169. 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.

170. 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.

171. 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.

172. Defendants had a duty to promptly correct material misstatements Defendants' knew 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

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.

179. 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.

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

181. The foregoing representations and omissions by Defendants were false.

182. Defendants' IVC filters are not safe, fit, and effective for human use in their intended and reasonably foreseeable manner.

183. Further, the use of Cordis IVC filters is hazardous to the users' health, and Cordis IVC filters have a serious propensity to cause users to suffer serious injuries, including without limitation the injuries Plaintiffs suffered.

184. Finally, Defendants' IVC filters have a statistically significant higher rate of failure and injury than do other comparable IVC filters.

185. 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.

186. 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.

187. 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.

188. 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.

189. 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)

190. Plaintiffs incorporate by reference all prior allegations.

191. In marketing and selling Cordis IVC filters (the TrapEase filters and the OptEase filters), Defendants concealed material facts from Plaintiffs and their healthcare providers.

192. 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.

193. Plaintiffs and their health care providers were not aware of these and other facts concealed by Defendants.

194. In concealing these and other facts, Defendants intended to deceive Plaintiffs and their 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

f. Impliedly representing that its filters would be effective in the prevention of pulmonary emboli.

206. 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;

207. 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 RHONDA HERNANDEZ, WALTER SIMMONS, HEATHER VANDALL, BARBARA SPISHAK, and BRIAN ZUKRIGIL ("LOC Plaintiffs"), As to All Defendants)

208. Plaintiffs incorporate by reference all prior allegations

209. As a proximate result of the personal injuries suffered by Plaintiffs DONALD HERNANDEZ, SR., CAROLYN SIMMONS, STEPHEN VANDALL, ROBERT SPISHAK and RUSSELL ZUKRIGIL, as described in this Complaint, LOC Plaintiffs have been deprived of the benefits of their marriage including love, affection, society, and consortium, and other spousal duties and actions. LOC Plaintiffs 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.

210. LOC Plaintiffs 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.

211. LOC Plaintiffs 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. LOC Plaintiffs 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.

212. 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.

PUNITIVE DAMAGES ALLEGATIONS

(By All Plaintiffs, As to All Defendants)

213. Plaintiffs incorporate by reference all prior allegations.

214. 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.

215. At all times material hereto, Defendants attempted to misrepresent and did knowingly misrepresent facts concerning the safety of Cordis IVC filters.

216. 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.

217. 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.

218. 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.

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

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.

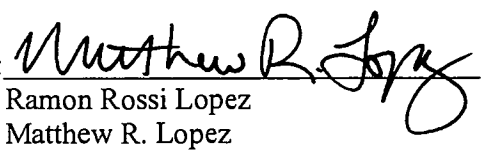
DEMAND FOR JURY TRIAL

Plaintiffs hereby demand a trial by jury on all triable issues.

Dated: May 19, 2016

Respectfully submitted,

LOPEZ McHUGH LLP

By: 

Ramon Rossi Lopez
Matthew R. Lopez
Amorina P. Lopez

-And-

Turner W. Branch (for *pro hac vice* consideration)
Margaret M. Branch (for *pro hac vice* consideration)
Adam T. Funk (for *pro hac vice* consideration)
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Attorneys for Plaintiffs

ENDORSED
FILED
ALAMEDA COUNTY

MAY 20 2016

CLERK OF THE SUPERIOR COURT
By Sammi Mancuso
Deputy

SUPERIOR COURT OF THE STATE OF CALIFORNIA

FOR THE COUNTY OF ALAMEDA

LISA OEHRING, an individual; LUTHER LEATHAM, an individual; SONJI HUTCHINSON, an individual; SANDRA SUTTER, an individual; LYNDA SMITH, an individual; ALAN GOLDBERG, an individual; BENITO BROWN and LUPE BROWN, 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

BY FAX

DEMAND FOR JURY TRIAL

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.

10. Plaintiff SONJI HUTCHINSON at all times relevant to this action was and is a citizen and resident of the State of Florida. Plaintiff SONJI HUTCHINSON underwent placement of Defendants' TrapEase Vena Cava Filter on or about June 1, 2013. The filter subsequently malfunctioned and caused injury and damages to Plaintiff SONJI HUTCHINSON, including, but not limited to, recurrent DVT. As a direct and proximate result of these malfunctions, Plaintiff SONJI HUTCHINSON suffered life-threatening injuries and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff SONJI HUTCHINSON has suffered and will continue to suffer significant medical expenses, and pain and suffering, and other damages.

11. Plaintiff SANDRA SUTTER at all times relevant to this action was and is a citizen and resident of the State of Florida. Plaintiff SANDRA SUTTER underwent placement of Defendants' TrapEase Vena Cava Filter on or about November 13, 2009. The filter subsequently malfunctioned and caused injury and damages to Plaintiff SANDRA SUTTER, including, but not limited to, blood clots, clotting, occlusion of the IVC filter, and recurrent DVT. As a direct and proximate result of these malfunctions, Plaintiff SANDRA SUTTER suffered life-threatening injuries and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff SANDRA SUTTER has suffered and will continue to suffer significant medical expenses, and pain and suffering, and other damages.

12. Plaintiff LYNDA SMITH at all times relevant to this action was and is a citizen and resident of the State of New Jersey. Plaintiff LYNDA SMITH underwent placement of Defendants' TrapEase Vena Cava Filter on or about December 20, 2010. The filter subsequently malfunctioned and caused injury and damages to Plaintiff LYNDA SMITH, including, filter embedded in wall of the IVC and ensuing pain. As a direct and proximate result of these malfunctions, Plaintiff LYNDA SMITH suffered life-threatening injuries and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff LYNDA SMITH has suffered and will continue to suffer significant medical expenses, and pain and suffering, and other damages.

13. Plaintiff ALAN GOLDBERG at all times relevant to this action was a citizen and resident of the State of Pennsylvania and, subsequently, became a citizen and resident of the State of New Jersey. Plaintiff ALAN GOLDBERG underwent placement of Defendants' OptEase Vena Cava

Filter on or about March 26, 2010. The filter subsequently malfunctioned and caused injury and damages to Plaintiff ALAN GOLDBERG, including, but not limited to, perforation, filter embedded in wall of the IVC, and unsuccessful removal attempt. As a direct and proximate result of these malfunctions, Plaintiff ALAN GOLDBERG suffered life-threatening injuries and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff ALAN GOLDBERG has suffered and will continue to suffer significant medical expenses, and pain and suffering, and other damages.

14. Plaintiff BENITO BROWN at all times relevant to this action was and is a citizen and resident of the State of Colorado. Plaintiff BENITO BROWN underwent placement of Defendants' OptEase Vena Cava Filter on or about March 10, 2011. The filter subsequently malfunctioned and caused injury and damages to Plaintiff BENITO BROWN, including, but not limited to, filter embedded in wall of the IVC. As a direct and proximate result of these malfunctions, Plaintiff BENITO BROWN suffered life-threatening injuries and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff BENITO BROWN has suffered and will continue to suffer significant medical expenses, and pain and suffering, and other damages.

15. Plaintiff LUPE BROWN at all times relevant to this action was and is a citizen and resident of the State of Colorado. Plaintiffs BENITO BROWN and LUPE BROWN were and are, at all times relevant to this action, legally married as husband and wife. Plaintiff LUPE BROWN brings this action for, *inter alia*, the loss of consortium, comfort, and society she suffered due to the personal injuries suffered by her husband, BENITO BROWN.

16. Plaintiff PATRICIA BUNKER at all times relevant to this action was and is a citizen and resident of the State of Massachusetts. Plaintiff PATRICIA BUNKER underwent placement of Defendants' OptEase Vena Cava Filter on or about November 13, 2008. The filter subsequently malfunctioned and caused injury and damages to Plaintiff PATRICIA BUNKER, including, but not limited to, tilt, migration, and filter embedded in wall of the IVC. As a direct and proximate result of these malfunctions, Plaintiff PATRICIA BUNKER suffered life-threatening injuries and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff PATRICIA

BUNKER has suffered and will continue to suffer significant medical expenses, and pain and suffering, and other damages.

17. Plaintiff CARMEN BURGESS at all times relevant to this action was and is a citizen and resident of the State of South Carolina. Plaintiff CARMEN BURGESS underwent placement of Defendants' OptEase Vena Cava Filter on or about February 7, 2006. The filter subsequently malfunctioned and caused injury and damages to Plaintiff CARMEN BURGESS, including, but not limited to, fracture of the IVC filer, perforation, and filter embedded in wall of the IVC. As a direct and proximate result of these malfunctions, Plaintiff CARMEN BURGESS suffered life-threatening injuries and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff CARMEN BURGESS has suffered and will continue to suffer significant medical expenses, and pain and suffering, and other damages.

18. Plaintiff TRAVIS BURKHART at all times relevant to this action was and is a citizen and resident of the State of Indiana. Plaintiff TRAVIS BURKHART underwent placement of Defendants' OptEase Vena Cava Filter on or about February 21, 2008. The filter subsequently malfunctioned and caused injury and damages to Plaintiff TRAVIS BURKHART, including, but not limited to, thrombosis and DVT. As a direct and proximate result of these malfunctions, Plaintiff TRAVIS BURKHART suffered life-threatening injuries and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff TRAVIS BURKHART has suffered and will continue to suffer significant medical expenses, and pain and suffering, and other damages.

19. Plaintiff KIMBERLY BURKHART at all times relevant to this action was and is a citizen and resident of the State of Indiana. Plaintiffs TRAVIS BURKHART and KIMBERLY BURKHART were and are, at all times relevant to this action, legally married as husband and wife. Plaintiff KIMBERLY BURKHART brings this action for, *inter alia*, the loss of consortium, comfort, and society she suffered due to the personal injuries suffered by her husband, TRAVIS BURKHART.

20. Plaintiff PHILIP FACIANA at all times relevant to this action was a citizen and resident of the State of Minnesota and, subsequently, became a citizen and resident of the State of Ohio. Plaintiff PHILIP FACIANA underwent placement of Defendants' OptEase Vena Cava Filter on or about September 15, 2010. The filter subsequently malfunctioned and caused injury and damages to Plaintiff

PHILIP FACIANA, including, but not limited to, tilt, caval thrombosis, and DVT. As a direct and proximate result of these malfunctions, Plaintiff PHILIP FACIANA suffered life-threatening injuries and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff PHILIP FACIANA has suffered and will continue to suffer significant medical expenses, and pain and suffering, and other damages.

21. Plaintiff LOUISE HILL at all times relevant to this action was and is a citizen and resident of the State of Wyoming. Plaintiff LOUISE HILL underwent placement of Defendants' OptEase Vena Cava Filter on or about August 19, 2014. The filter subsequently malfunctioned and caused injury and damages to Plaintiff LOUISE HILL, including, but not limited to, migration, perforation, and DVT. As a direct and proximate result of these malfunctions, Plaintiff LOUISE HILL suffered life-threatening injuries and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff LOUISE HILL has suffered and will continue to suffer significant medical expenses, and pain and suffering, and other damages.

22. Plaintiff KEITH HUNTER at all times relevant to this action was and is a citizen and resident of the State of Pennsylvania. Plaintiff KEITH HUNTER underwent placement of Defendants' OptEase Vena Cava Filter on or about May 18, 2011. The filter subsequently malfunctioned and caused injury and damages to Plaintiff KEITH HUNTER, including, but not limited to, filter embedded in wall of the IVC. As a direct and proximate result of these malfunctions, Plaintiff KEITH HUNTER suffered life-threatening injuries and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff KEITH HUNTER has suffered and will continue to suffer significant medical expenses, and pain and suffering, and other damages.

23. Plaintiff ELLEN JUVERA-SAIZ at all times relevant to this action was and is a citizen and resident of the State of Colorado. Plaintiff ELLEN JUVERA-SAIZ underwent placement of Defendants' OptEase Vena Cava Filter on or about December 26, 2006. The filter subsequently malfunctioned and caused injury and damages to Plaintiff ELLEN JUVERA-SAIZ, including, but not limited to, fracture of the IVC filter. As a direct and proximate result of these malfunctions, Plaintiff ELLEN JUVERA-SAIZ suffered life-threatening injuries and damages, and required extensive medical

care and treatment. As a further proximate result, Plaintiff ELLEN JUVERA-SAIZ has suffered and will continue to suffer significant medical expenses, and pain and suffering, and other damages.

24. Plaintiff BRANDI KIRK at all times relevant to this action was and is a citizen and resident of the State of Arizona. Plaintiff BRANDI KIRK underwent placement of Defendants' OptEase Vena Cava Filter on or about December 15, 2011. The filter subsequently malfunctioned and caused injury and damages to Plaintiff BRANDI KIRK, including, but not limited to, tilt of the IVC filter. As a direct and proximate result of these malfunctions, Plaintiff BRANDI KIRK suffered life-threatening injuries and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff BRANDI KIRK has suffered and will continue to suffer significant medical expenses, and pain and suffering, and other damages.

25. Plaintiff LISA KUMBIER at all times relevant to this action was and is a citizen and resident of the State of Wisconsin. Plaintiff LISA KUMBIER underwent placement of Defendants' OptEase Vena Cava Filter on or about February 28, 2014. The filter subsequently malfunctioned and caused injury and damages to Plaintiff LISA KUMBIER, including, but not limited to, filter embedded in wall of the IVC. As a direct and proximate result of these malfunctions, Plaintiff LISA KUMBIER suffered life-threatening injuries and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff LISA KUMBIER has suffered and will continue to suffer significant medical expenses, and pain and suffering, and other damages.

26. Plaintiff JESSICA LARIMORE at all times relevant to this action was and is a citizen and resident of the State of South Carolina. Plaintiff JESSICA LARIMORE underwent placement of Defendants' OptEase Vena Cava Filter on or about February 28, 2014. The filter subsequently malfunctioned and caused injury and damages to Plaintiff JESSICA LARIMORE, including, but not limited to, fracture of the IVC filter, migration, and filter embedded in wall of the IVC. As a direct and proximate result of these malfunctions, Plaintiff JESSICA LARIMORE suffered life-threatening injuries and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff JESSICA LARIMORE has suffered and will continue to suffer significant medical expenses, and pain and suffering, and other damages.

27. Plaintiff HERMAN MALONE at all times relevant to this action was and is a citizen and resident of the State of Texas. Plaintiff HERMAN MALONE underwent placement of Defendants' OptEase Vena Cava Filter on or about April 30, 2014. The filter subsequently malfunctioned and caused injury and damages to Plaintiff HERMAN MALONE, including, but not limited to, migration of the IVC filter. As a direct and proximate result of these malfunctions, Plaintiff HERMAN MALONE suffered life-threatening injuries and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff HERMAN MALONE has suffered and will continue to suffer significant medical expenses, and pain and suffering, and other damages.

28. Plaintiff DOROTHY MAY at all times relevant to this action was and is a citizen and resident of the State of Arkansas. Plaintiff DOROTHY MAY underwent placement of Defendants' OptEase Vena Cava Filter on or about April 29, 2008. The filter subsequently malfunctioned and caused injury and damages to Plaintiff DOROTHY MAY, including, but not limited to, filter embedded in wall of the IVC. As a direct and proximate result of these malfunctions, Plaintiff DOROTHY MAY suffered life-threatening injuries and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff DOROTHY MAY has suffered and will continue to suffer significant medical expenses, and pain and suffering, and other damages.

29. Plaintiff DUSTIN MERRITT at all times relevant to this action was and is a citizen and resident of the State of Oklahoma. Plaintiff DUSTIN MERRITT underwent placement of Defendants' OptEase Vena Cava Filter on or about July 14, 2005. The filter subsequently malfunctioned and caused injury and damages to Plaintiff DUSTIN MERRITT, including, but not limited to, tilt, perforation, filter embedded in wall of the IVC, DVT, and retroperitoneal hematoma. As a direct and proximate result of these malfunctions, Plaintiff DUSTIN MERRITT suffered life-threatening injuries and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff DUSTIN MERRITT has suffered and will continue to suffer significant medical expenses, and pain and suffering, and other damages.

30. Plaintiff CINDY SEYMORE at all times relevant to this action was and is a citizen and resident of the State of Maryland. Plaintiff CINDY SEYMORE underwent placement of Defendants' OptEase Vena Cava Filter on or about November 14, 2012. The filter subsequently malfunctioned and

caused injury and damages to Plaintiff CINDY SEYMORE, including, but not limited to, tilt of the IVC filter and filter embedded in wall of the IVC. As a direct and proximate result of these malfunctions, Plaintiff CINDY SEYMORE suffered life-threatening injuries and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff CINDY SEYMORE has suffered and will continue to suffer significant medical expenses, and pain and suffering, and other damages.

31. Plaintiff FREDDIE WILSON at all times relevant to this action was and is a citizen and resident of Washington D.C. Plaintiff FREDDIE WILSON underwent placement of Defendants' TrapEase Vena Cava Filter on or about May 21, 2012. The filter subsequently malfunctioned and caused injury and damages to Plaintiff FREDDIE WILSON, including, but not limited to, filter embedded in wall of the IVC. As a direct and proximate result of these malfunctions, Plaintiff FREDDIE WILSON suffered life-threatening injuries and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff FREDDIE WILSON has suffered and will continue to suffer significant medical expenses, and pain and suffering, and other damages.

32. Plaintiff DONALD HOLLAND at all times relevant to this action was and is a citizen and resident of Texas. Plaintiff DONALD HOLLAND underwent placement of Defendants' TrapEase Vena Cava Filter on or about May 11, 2006. The filter subsequently malfunctioned and caused injury and damages to Plaintiff DONALD HOLLAND, including, but not limited to, fracture of the IVC filter. As a direct and proximate result of these malfunctions, Plaintiff DONALD HOLLAND suffered life-threatening injuries and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff DONALD HOLLAND has suffered and will continue to suffer significant medical expenses, and pain and suffering, and other damages.

33. Plaintiff JAMES MCCORD at all times relevant to this action was and is a citizen and resident of Arizona. Plaintiff JAMES MCCORD underwent placement of Defendants' OptEase Vena Cava Filter on or about April 1, 2013. The filter subsequently malfunctioned and caused injury and damages to Plaintiff JAMES MCCORD, including, but not limited to, migration and fracture of the IVC filter, emergency open-heart surgery to remove the filter, and subsequent surgery to remove remaining pieces of the filter from Plaintiff's heart. As a direct and proximate result of these malfunctions, Plaintiff JAMES MCCORD suffered life-threatening injuries and damages, and required extensive

medical care and treatment. As a further proximate result, Plaintiff JAMES MCCORD has suffered and will continue to suffer significant medical expenses, and pain and suffering, and other damages.

34. Plaintiff BILLY RICHARD at all times relevant to this action was and is a citizen and resident of the State of Texas. Plaintiff BILLY RICHARD underwent placement of Defendants' OptEase Vena Cava Filter on or about January 13, 2014. The filter subsequently malfunctioned and caused injury and damages to Plaintiff BILLY RICHARD, including, but not limited to, fracture of the IVC filter, caval thrombosis, DVT, and post-thrombotic syndrome. As a direct and proximate result of these malfunctions, Plaintiff BILLY RICHARD suffered life-threatening injuries and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff BILLY RICHARD has suffered and will continue to suffer significant medical expenses, and pain and suffering, and other damages.

35. Plaintiff MELANIE RICHARD at all times relevant to this action was and is a citizen and resident of the State of Texas. Plaintiffs BILLY RICHARD and MELANIE RICHARD were and are, at all times relevant to this action, legally married as husband and wife. Plaintiff MELANIE RICHARD brings this action for, *inter alia*, the loss of consortium, comfort, and society she suffered due to the personal injuries suffered by her husband, BILLY RICHARD.

36. Plaintiff JOHN ROGERS at all times relevant to this action was and is a citizen and resident of Illinois. Plaintiff JOHN ROGERS underwent placement of Defendants' TrapEase Vena Cava Filter on or about June 14, 2007. The filter subsequently malfunctioned and caused injury and damages to Plaintiff JOHN ROGERS, including, but not limited to, filter embedded in wall of the IVC and recurring PE. As a direct and proximate result of these malfunctions, Plaintiff JOHN ROGERS suffered life-threatening injuries and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff JOHN ROGERS has suffered and will continue to suffer significant medical expenses, and pain and suffering, and other damages.

37. Plaintiff SEAN MAGUIRE at all times relevant to this action was and is a citizen and resident of Missouri. Plaintiff SEAN MAGUIRE underwent placement of Defendants' TrapEase Vena Cava Filter on or about August 12, 2003. The filter subsequently malfunctioned and caused injury and damages to Plaintiff SEAN MAGUIRE, including, but not limited to, internal bleeding, blood clots,

clotting and occlusion of the IVC filter, filter embedded in wall of the IVC and cannot be retrieved. As a direct and proximate result of these malfunctions, Plaintiff SEAN MAGUIRE suffered life-threatening injuries and damages, and required extensive medical care and treatment. As a further proximate result, Plaintiff SEAN MAGUIRE has suffered and will continue to suffer significant medical expenses, and pain and suffering, and other damages.

38. Plaintiff LAURA MAGUIRE at all times relevant to this action was and is a citizen and resident of the State of Missouri. Plaintiffs SEAN MAGUIRE and LAURA MAGUIRE were and are, at all times relevant to this action, legally married as husband and wife. Plaintiff LAURA MAGUIRE brings this action for, *inter alia*, the loss of consortium, comfort, and society she suffered due to the personal injuries suffered by her husband, SEAN MAGUIRE.

39. Plaintiffs GILDA SOUTHERLAND, VINCENT SOUTHERLAND and CHAD SOUTHERLAND (collectively, "Southerland Plaintiffs"), are the surviving wife and children, respectively, of DUKE SOUTHERLAND (or, "Plaintiffs' Decedent") and at all times relevant to this action were and are citizens and residents of the State of Connecticut. Plaintiffs bring this case in their individual capacities and as the legal heirs to DUKE SOUTHERLAND.

40. Southerland Plaintiffs' Decedent, DUKE SOUTHERLAND, at all times relevant to this action was a citizen and resident of the State of Connecticut. DUKE SOUTHERLAND underwent placement of Defendants' OptEase Vena Cava Filter on or about April 14, 2008. The filter subsequently malfunctioned and caused great bodily harm to DUKE SOUTHERLAND, including, but not limited to, caval thrombosis, PE, and DVT. As direct and proximate results of these filter malfunctions, DUKE SOUTHERLAND suffered fatal injuries, damages, and untimely death on or about July 5, 2014. As a further proximate result, Plaintiffs GILDA SOUTHERLAND, VINCENT SOUTHERLAND and CHAD SOUTHERLAND have suffered and will continue to suffer the wrongful and premature death of their beloved husband and father, respectively.

41. Defendant CORDIS CORPORATION ("Cordis"), including its department, division, and subsidiary, Cordis Endovascular, is a corporation or business entity organized and existing under the laws of the State of Florida with its headquarters located at 6500 Paseo Padre Pkwy., Fremont, 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,

fabricating, designing, developing, labeling, assembling, distributing, supplying, leasing, buying, offering for sale, selling, inspecting, servicing, contracting others for marketing, warranting, rebranding, manufacturing for others, packaging, and advertising the device.

48. Defendants and DOES 1 through 50, and each of them, are liable for the acts, omissions and tortious conduct of its successors and/or predecessors in interest/business/product line/or a portion thereof, assigns, parent, subsidiary, affiliate, partner, co-venturer, merged company, alter ego, agent, equitable trustee, fiduciary and/or its alternate entities in that Defendant and DOES 1 through 50, and each of them, enjoy the goodwill originally attached to each such alternate entity, acquired the assets or product line (or a portion thereof), and in that there has been a virtual destruction of Plaintiffs' remedy against each such alternate entity, and that each such Defendant has the ability to assume the risk-spreading role of each such alternate entity.

49. Plaintiffs are informed and believe, and thereon allege that, at all times herein mentioned, DOES 1 through 50, and each of them, were and are corporations organized and existing under the laws of the State of California or the laws of some state or foreign jurisdiction; that each of the said DOE defendants were and are authorized to do and are doing business in the State of California and regularly conducted business in the State of California.

50. Upon information and belief, Defendants at all relevant times were engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce and into the State of California, either directly or indirectly through third parties or related entities, its products, including the TrapEase and OptEase IVC filters, and derived substantial income from doing business in California.

51. "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, J&J, Cardinal, as well as DOE Defendants 1 through 50, and each of them.

52. Joinder of Plaintiffs in this Complaint for Damages is proper pursuant to *Code of Civil Procedure* § 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

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

California. Therefore, the claims of California-plaintiffs *and* out-of-state plaintiffs relate to and arise from Defendants' explicit contacts and purposeful avail of the State of California. Further and independently, Cordis consented to jurisdiction in the State of California by appointing an agent for service of process in this State and by conducting substantial systematic business in this State.

58. The instant Complaint for Damages does not confer diversity jurisdiction upon the federal courts pursuant to 28 U.S.C. § 1332. Likewise, federal question subject matter jurisdiction pursuant to 28 U.S.C. § 1331 is not invoked by the instant Complaint, as it sets forth herein exclusively state law claims against the Defendants. Nowhere do Plaintiffs plead, expressly or implicitly, any cause of action or request any remedy that arises under or is founded upon federal law, and any alleged federal rights or remedies are expressly disavowed. The issues presented by Plaintiffs do not implicate substantial federal questions, do not turn on the necessary interpretation of federal law, and do not affect the federal system as a whole. The assertion of federal jurisdiction over claims made herein would improperly disturb the congressionally approved balance of federal and state responsibilities.

BACKGROUND

INFERIOR VENA CAVA FILTERS GENERALLY

59. 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.

60. 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.

61. 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.

62. 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 thromboembolitic events.

63. 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.

64. 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.

65. 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.

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

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

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

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

70. Comparing the results of over 30,000 trauma patients who had not received IVC filters 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^{tm} AND OPTEASE^{tm} 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

> 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).

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

> If the FDA concludes on the basis of the [manufacturer's] § 510(k) notification that the device is "substantially equivalent" to a pre-existing device, it can be marketed without further regulatory analysis. . . . The § 510(k) notification process is by no means 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."

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

76. Pursuant to *Wyeth v. Levine*, 555 U.S. 555 (2009), once a product is cleared "the manufacturer remains under an obligation to investigate and report any adverse events associated with 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.

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

78. 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 symmetric filter. The filter has proximal and distal anchoring barbs located on each connecting strut for fixation of the filter to the vena cava wall to prevent movement after placement.

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

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

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

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

83. 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 has anchoring barbs for fixation of the filter only on the superior end of each of the six straight struts and has a hook at the inferior end of the basket to allow retrieval with a snare.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

a. Death;

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.

98. 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*.

99. 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.

100. 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.

101. Defendants failed to identify or acknowledge these device failures or determine their causes.

102. Defendants failed to take timely and adequate remedial measures to correct known design and manufacturing defects with the Cordis IVC filters.

103. 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, Defendants represented that their filters were safe and effective – more safe and effective than other available IVC filters. 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.

104. 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.

105. Defendants also marketed the OptEase filter as being "easy" to remove. However, it is one of the most difficult filters to remove. 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. 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.

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

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

108. Cordis' labeling was additionally defective in that it directed physicians to implant the OptEase filter upside down. When the OptEase filter was placed as directed by the labeling, the hooks designed to ensure stability were facing in the wrong direction, rendering an already inadequate anchoring system even further defective. As Cordis now explain in its labeling, implanting the device in this fashion "can result in life threatening or serious injury including, but not limited to dissection, vessel perforation, migration of the filter with secondary damage to cardiac structures, ineffective pulmonary embolism prevention or death."

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

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

111. Defendants have admitted that any patients implanted with one of these recalled units should receive medical monitoring. Specifically, these patients should undergo imaging to ascertain 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

use of Cordis IVC filters, and the devices were more dangerous than the ordinary customer would expect.

126. 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.

127. Plaintiffs (or their Decedent) received and utilized Defendants' IVC filters in a foreseeable manner as normally intended, recommended, promoted, and marketed by Defendants.

128. 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.

129. These alternative designs would have prevented the harm resulting in each Plaintiff's (or their Decedent's) Injuries and Damages, and/or Death, without substantially impairing the reasonably anticipated or intended function of Cordis IVC filters.

130. Neither Plaintiffs, Plaintiffs' Decedent, 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.

131. As a direct and proximate result of the defective and unreasonably dangerous condition of Cordis IVC filters, Plaintiffs and Plaintiffs' Decedent suffered Injuries and Damages, and/or Death.

SECOND CAUSE OF ACTION

STRICT PRODUCTS LIABILITY – INADEQUATE WARNING

(By All Plaintiffs, As to All Defendants)

132. Plaintiffs incorporate by reference all prior allegations.

133. 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 (or their Decedent) who would become implanted with them.

134. Defendants did, in fact, test, develop, design, manufacture, package, label, market and/or promote, sell and/or distribute their Cordis IVC filters to Plaintiffs, Plaintiffs' Decedent, 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, Plaintiffs' Decedent, and their prescribing health care professionals, without any substantial change in the condition of the product from when it was initially distributed by Defendants.

135. 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.

136. 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.

137. Defendants placed into the stream of commerce for ultimate use by users like Plaintiffs, Plaintiffs' Decedent, 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.

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.

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

156. 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.

157. 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.

158. Prior to, on, and after the date of Plaintiffs' and Plaintiffs' Decedent's 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.

159. Prior to, on, and after the date of Plaintiffs' and Plaintiffs' Decedent's 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 and Plaintiffs' Decedent suffered.

160. 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 and Plaintiffs' Decedent.

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

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

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

164. Such danger included the propensity of Cordis IVC filters to cause injuries similar to those suffered by Plaintiffs and Plaintiffs' Decedent.

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

166. Reasonable manufacturers and reasonable distributors, under the same or similar circumstances as those of Defendants prior to, on, and after the date of each Plaintiff's and Plaintiffs' Decedent's use of a Cordis IVC filter, would have warned of the dangers presented by Cordis IVC filters, or instructed on the safe use of Cordis IVC filters.

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

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

169. As a direct and proximate result of Defendants' negligent conduct described herein, 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

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.

176. 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.

177. 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 and Plaintiffs' Decedent.

178. 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.

179. Defendants had a duty to promptly correct material misstatements Defendants' knew others were relying upon in making healthcare decisions.

180. Defendants failed in each of these duties by misrepresenting to Plaintiffs, Plaintiffs' Decedent, and the medical community the safety and efficacy of Cordis IVC filters and failing to correct known misstatements and misrepresentations.

181. As a direct and proximate result of Defendants' negligent misrepresentations, Plaintiffs 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.

187. Defendants' intent and purpose in making these misrepresentations was to deceive and defraud the public and the medical community, including Plaintiffs' and Plaintiffs' Decedent's health care providers; to gain the confidence of the public and the medical community, including Plaintiffs' and Plaintiffs' Decedent's health care providers; to falsely assure the public and the medical community of the quality of Cordis IVC filters and their fitness for use; and to induce the public and the medical community, including Plaintiffs' and Plaintiffs' Decedent's health care providers to request, recommend, prescribe, implant, purchase, and continue to use Cordis IVC filters, all in reliance on Defendants' misrepresentations.

188. The foregoing representations and omissions by Defendants were false.

189. Defendants' IVC filters are not safe, fit, and effective for human use in their intended and reasonably foreseeable manner.

190. Further, the use of Cordis IVC filters is hazardous to the users' health, and Cordis IVC filters have a serious propensity to cause users to suffer serious injuries, including without limitation the injuries and/or death Plaintiffs and Plaintiffs' Decedent suffered.

191. Finally, Defendants' IVC filters have a statistically significant higher rate of failure and injury than do other comparable IVC filters.

192. 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 and Plaintiffs' Decedent to sustain severe and permanent personal injuries, and/or death.

193. Defendants knew and had reason to know that Plaintiffs, Plaintiffs' Decedent, 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.

194. 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.

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.

213. At the time Plaintiffs, Plaintiffs' Decedent, 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;

214. As a direct and proximate result of Defendants' breach of its implied warranty, Plaintiffs and Plaintiffs' Decedent suffered Injuries and Damages, and/or Death.

TENTH CAUSE OF ACTION

LOSS OF CONSORTIUM

(By Plaintiffs LUPE BROWN, KIMBERLY BURKHART, MELANIE RICHARD, and LAURA MAGUIRE ("LOC Plaintiffs"), As to All Defendants)

215. LOC Plaintiffs incorporate by reference all prior allegations

216. As a proximate result of the personal injuries suffered by Plaintiffs BENITO BROWN, TRAVIS BURKHART, BILLY RICHARD and SEAN MAGUIRE, as described in this Complaint, LOC Plaintiffs have been deprived of the benefits of their marriage including love, affection, society, and consortium, and other spousal duties and actions. LOC Plaintiffs 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.

217. LOC Plaintiffs 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.

218. LOC Plaintiffs 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. LOC Plaintiffs 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.

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.

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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

sales and profits at the expense of the health and safety of the public, including Plaintiffs and Plaintiffs' Decedent, in conscious disregard of the foreseeable harm caused by Cordis IVC filters.

234. Defendants' intentional and/or reckless failure to disclose information deprived Plaintiffs' and Plaintiffs' Decedent's physicians of necessary information to enable them to weigh the true risks of using Cordis IVC filters against its benefits.

235. 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 and Plaintiffs' Decedent.

236. 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.

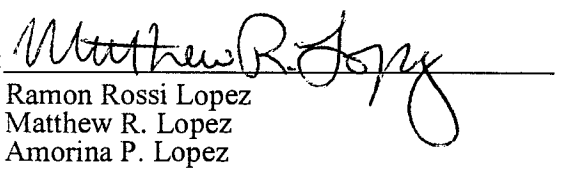
DEMAND FOR JURY TRIAL

Plaintiffs hereby demand a trial by jury on all triable issues.

Dated: May 19, 2016

Respectfully submitted,

LOPEZ McHUGH LLP

By: 

Ramon Rossi Lopez
Matthew R. Lopez
Amorina P. Lopez

-And-

David P. Matthews (for *pro hac vice* consideration)
MATTHEWS & ASSOCIATES

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Richard A. Freese (for *pro hac vice* consideration)
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Attorney for Plaintiffs

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

By Fax

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:

PARTIES

1. Plaintiff Wanda Holden (hereinafter "Plaintiff Holden") is a citizen and resident of the State of California, Los Angeles County. Plaintiff underwent placement of a TrapEase™ Permanent Vena Cava Filter (referred to as "TrapEase filter," "device" or "product" hereinafter) at Brotman Medical Center located in Culver City, California. The extent of the device failure has not been fully documented by Plaintiff's treating medical provider(s). As a result of the malfunction, Plaintiff has or may suffer life-threatening injuries and damages and require extensive medical care and treatment. Plaintiff has or may suffer and will continue to suffer significant medical expenses, extreme pain and suffering, loss of enjoyment of life, disability, and other losses.

2. Plaintiff Tambra Shifflet (hereinafter "Plaintiff Shifflet") is a citizen and resident of the State of Ohio, Athens County. Plaintiff underwent placement of a TrapEase™ Permanent Vena Cava Filter (referred to as "TrapEase filter," "device" or "product" hereinafter) at Holzer Medical Center located in Gallipolis, Ohio. The extent of the device failure has not been fully documented by Plaintiff's treating medical provider(s). As a result of the malfunction, Plaintiff has or may suffer life-threatening injuries and damages and require extensive medical care and treatment. Plaintiff has or may suffer and will continue to suffer significant medical expenses, extreme pain and suffering, loss of enjoyment of life, disability, and other losses.

3. Plaintiff LaNora Barrett (hereinafter "Plaintiff Barrett") is a citizen and resident of the State of Florida, Polk County. Plaintiff underwent placement of a TrapEase™ Permanent Vena Cava Filter (referred to as "TrapEase filter," "device" or "product" hereinafter) at Heart of Florida Regional Medical Center located in Davenport, Florida. The extent of the device failure has not been fully documented by Plaintiff's treating medical provider(s). As a result of the malfunction, Plaintiff has or may suffer life-threatening injuries and damages and require extensive medical care and treatment. Plaintiff has or may suffer and will continue to suffer significant medical expenses, extreme pain and suffering, loss of enjoyment of life, disability, and other losses.

4. Plaintiff Marcelo Coogan (hereinafter "Plaintiff Coogan") is a citizen and resident of the State of Texas, Harris County. Plaintiff underwent placement of an OptEase™ Retrievable Vena Cava Filter (referred to as "OptEase filter," "device" or "product" hereinafter) at Memorial Herman

Hospital located in Houston, TX. The device, *inter* alia, caused thrombosis of the vena cava and filter. As a result of the malfunction, Plaintiff has suffered life-threatening injuries and damages and require extensive medical care and treatment. Plaintiff has suffered and will continue to suffer significant medical expenses, extreme pain and suffering, loss of enjoyment of life, disability, and other losses.

5. Plaintiff Willie Cook (hereinafter "Plaintiff Cook") is a citizen and resident of the State of Texas, Hill County. Plaintiff underwent placement of an OptEase™ Retrievable Vena Cava Filter (referred to as "OptEase filter," "device" or "product" hereinafter) at Plaza Medical center located in Irving, Texas. The extent of the device failure has not been fully documented by Plaintiff's treating medical provider(s). As a result of the malfunction, Plaintiff has or may suffer life-threatening injuries and damages and require extensive medical care and treatment. Plaintiff has or may suffer and will continue to suffer significant medical expenses, extreme pain and suffering, loss of enjoyment of life, disability, and other losses.

6. Plaintiff John Dawson (hereinafter "Plaintiff Dawson") is a citizen and resident of the State of Louisiana, Bossier County. Plaintiff underwent placement of an OptEase™ Retrievable Vena Cava Filter (referred to as "OptEase filter," "device" or "product" hereinafter) at Willis-Knighton Health System located in Bossier City, Louisiana. The extent of the device failure has not been fully documented by Plaintiff's treating medical provider(s). As a result of the malfunction, Plaintiff has or may suffer life-threatening injuries and damages and require extensive medical care and treatment. Plaintiff has or may suffer and will continue to suffer significant medical expenses, extreme pain and suffering, loss of enjoyment of life, disability, and other losses.

7. Plaintiff Fredderick Hall (hereinafter "Plaintiff Hall") is a citizen and resident of the State of Pennsylvania, Harrisburg County. Plaintiff underwent placement of a TrapEase™ Permanent Vena Cava Filter (referred to as "TrapEase filter," "device" or "product" hereinafter) at Pinnacle Health/Harrisburg Hospital located in Harrisburg, Pennsylvania. The extent of the device failure has not been fully documented by Plaintiff's treating medical provider(s). As a result of the malfunction, Plaintiff has or may suffer life-threatening injuries and damages and require extensive

medical care and treatment. Plaintiff has or may suffer and will continue to suffer significant medical expenses, extreme pain and suffering, loss of enjoyment of life, disability, and other losses.

8. Plaintiff Thomas Husted (hereinafter "Plaintiff Husted") is a citizen and resident of the State of South Carolina, Spartanburg County. Plaintiff underwent placement of an OptEase™ Retrievable Vena Cava Filter (referred to as "OptEase filter," "device" or "product" hereinafter) at Spartanburg Regional Medical Center located in Spartanburg, South Carolina. The extent of the device failure has not been fully documented by Plaintiff's treating medical provider(s). As a result of the malfunction, Plaintiff has or may suffer life-threatening injuries and damages and require extensive medical care and treatment. Plaintiff has or may suffer and will continue to suffer significant medical expenses, extreme pain and suffering, loss of enjoyment of life, disability, and other losses.

9. Plaintiff Sabrina Jackson (hereinafter "Plaintiff Jackson") is a citizen and resident of the State of New Jersey, Passaic County. Plaintiff underwent placement of a TrapEase™ Permanent Vena Cava Filter (referred to as "TrapEase filter," "device" or "product" hereinafter) at St. Joseph's Wayne Hospital located in Wayne, New Jersey. The device, *inter* alia, caused severe and persistent chest and back pain. As a result of the malfunction, Plaintiff has suffered life-threatening injuries and damages and require extensive medical care and treatment. Plaintiff has suffered and will continue to suffer significant medical expenses, extreme pain and suffering, loss of enjoyment of life, disability, and other losses.

10. Plaintiff Juan Jeanes (hereinafter "Plaintiff Jeanes") is a citizen and resident of the State of Oklahoma, McCurtain County. Plaintiff underwent placement of a TrapEase™ Permanent Vena Cava Filter (referred to as "TrapEase filter," "device" or "product" hereinafter) at Wadley Regional Medical Center located in Texarkana, Texas. The extent of the device failure has not been fully documented by Plaintiff's treating medical provider(s). As a result of the malfunction, Plaintiff has or may suffer life-threatening injuries and damages and require extensive medical care and treatment. Plaintiff has or may suffer and will continue to suffer significant medical expenses, extreme pain and suffering, loss of enjoyment of life, disability, and other losses.

11. Plaintiff Steven Johnson (hereinafter "Plaintiff Johnson") is a citizen and resident of the State of Louisiana, Orleans County. Plaintiff underwent placement of an OptEase™ Retrievable Vena Cava Filter (referred to as "OptEase filter," "device" or "product" hereinafter) at West Jefferson Medical Center located in Marrero, Louisiana. The device, *inter* alia, caused severe and persistent chest pain and shortness of breath. As a result of the malfunction, Plaintiff has suffered life-threatening injuries and damages and requires extensive medical care and treatment. Plaintiff has suffered and will continue to suffer significant medical expenses, extreme pain and suffering, loss of enjoyment of life, disability, and other losses.

12. Plaintiff Kendall McCoy (hereinafter "Plaintiff McCoy") is a citizen and resident of the State of Georgia, Dekalb County. Plaintiff underwent placement of an OptEase™ Retrievable Vena Cava Filter (referred to as "OptEase filter," "device" or "product" hereinafter) at Emory University Hospital located in Atlanta, Georgia. The extent of the device failure has not been fully documented by Plaintiff's treating medical provider(s). As a result of the malfunction, Plaintiff has or may suffer life-threatening injuries and damages and require extensive medical care and treatment. Plaintiff has or may suffer and will continue to suffer significant medical expenses, extreme pain and suffering, loss of enjoyment of life, disability, and other losses.

13. Plaintiff Michelle Montoya (hereinafter "Plaintiff Montoya") is a citizen and resident of the State of Colorado, Rio Grande County. Plaintiff underwent placement of an OptEase™ Retrievable Vena Cava Filter (referred to as "OptEase filter," "device" or "product" hereinafter) at Penrose-St. Francis Hospital located in Colorado Springs, Colorado. The device, *inter* alia, caused a large thrombus of the vena cava and filter and is irretrievable. As a result of the malfunction, Plaintiff has suffered life-threatening injuries and damages and requires extensive medical care and treatment. Plaintiff has suffered and will continue to suffer significant medical expenses, extreme pain and suffering, loss of enjoyment of life, disability, and other losses.

14. Plaintiff Karen Neal (hereinafter "Plaintiff McCoy") is a citizen and resident of the State of Tennessee, Davidson County. Plaintiff underwent placement of a TrapEase™ Permanent Vena Cava Filter (referred to as "TrapEase filter," "device" or "product" hereinafter) at Centennial Hospital located in Nashville, Tennessee. The extent of the device failure has not been fully

documented by Plaintiff's treating medical provider(s). As a result of the malfunction, Plaintiff has or may suffer life-threatening injuries and damages and require extensive medical care and treatment. Plaintiff has or may suffer and will continue to suffer significant medical expenses, extreme pain and suffering, loss of enjoyment of life, disability, and other losses.

15. Plaintiff Debra Porter (hereinafter "Plaintiff D. Porter") is a citizen and resident of the State of North Carolina, Wake County. Plaintiff underwent placement of an OptEase™ Retrievable Vena Cava Filter (referred to as "OptEase filter," "device" or "product" hereinafter) at Union Hospital located in Dover, Ohio. The extent of the device failure has not been fully documented by Plaintiff's treating medical provider(s). As a result of the malfunction, Plaintiff has or may suffer life-threatening injuries and damages and require extensive medical care and treatment. Plaintiff has or may suffer and will continue to suffer significant medical expenses, extreme pain and suffering, loss of enjoyment of life, disability, and other losses.

16. Plaintiff Tommy Porter (hereinafter "Plaintiff T. Porter") is a citizen and resident of the State of Illinois, Cook County. Plaintiff underwent placement of an OptEase™ Retrievable Vena Cava Filter (referred to as "OptEase filter," "device" or "product" hereinafter) at Our Lady of the Resurrection Medical Center located in Chicago, Illinois. The extent of the device failure has not been fully documented by Plaintiff's treating medical provider(s). As a result of the malfunction, Plaintiff has or may suffer life-threatening injuries and damages and require extensive medical care and treatment. Plaintiff has or may suffer and will continue to suffer significant medical expenses, extreme pain and suffering, loss of enjoyment of life, disability, and other losses.

17. Plaintiff Carl Rexing (hereinafter "Plaintiff Rexing") is a citizen and resident of the State of Illinois, Hamilton County. Plaintiff underwent placement of an OptEase™ Retrievable Vena Cava Filter (referred to as "OptEase filter," "device" or "product" hereinafter) at Deaconess Hospital located in Evansville, Indiana. The device, *inter* alia, caused leg aches and shortness of breath. As a result of the malfunction, Plaintiff has suffered life-threatening injuries and damages and requires extensive medical care and treatment. Plaintiff has suffered and will continue to suffer significant medical expenses, extreme pain and suffering, loss of enjoyment of life, disability, and other losses.

18. Plaintiff Hazel Webb (hereinafter "Plaintiff Webb") is a citizen and resident of the State of Tennessee, Weakley County. Plaintiff underwent placement of an OptEase™ Retrievable Vena Cava Filter (referred to as "OptEase filter," "device" or "product" hereinafter) at Regional Hospital located in Jackson, Tennessee. The extent of the device failure has not been fully documented by Plaintiff's treating medical provider(s). As a result of the malfunction, Plaintiff has or may suffer life-threatening injuries and damages and require extensive medical care and treatment. Plaintiff has or may suffer and will continue to suffer significant medical expenses, extreme pain and suffering, loss of enjoyment of life, disability, and other losses.

19. Plaintiff Cheryl Wright (hereinafter "Plaintiff C. Wright") is a citizen and resident of the State of Maryland, Anne Arundel County. Plaintiff underwent placement of an OptEase™ Retrievable Vena Cava Filter (referred to as "OptEase filter," "device" or "product" hereinafter) at Harbor Hospital Center located in Baltimore, Maryland. The extent of the device failure has not been fully documented by Plaintiff's treating medical provider(s). As a result of the malfunction, Plaintiff has or may suffer life-threatening injuries and damages and require extensive medical care and treatment. Plaintiff has or may suffer and will continue to suffer significant medical expenses, extreme pain and suffering, loss of enjoyment of life, disability, and other losses.

20. Plaintiff Evelyn Wright (hereinafter "Plaintiff E. Wright") is a citizen and resident of the State of Florida, Marion County. Plaintiff underwent placement of an OptEase™ Retrievable Vena Cava Filter (referred to as "OptEase filter," "device" or "product" hereinafter) at Munroe Regional Medical Center located in Ocaba, Florida. The device, *inter* alia, caused severe and persistent chest pain. As a result of the malfunction, Plaintiff has suffered life-threatening injuries and damages and requires extensive medical care and treatment. Plaintiff has suffered and will continue to suffer significant medical expenses, extreme pain and suffering, loss of enjoyment of life, disability, and other losses.

21. Plaintiff Thomas Yaudas, Sr. (hereinafter "Plaintiff Yaudas") is a citizen and resident of the State of Texas, Montgomery County. Plaintiff underwent placement of a TrapEase™ Permanent Vena Cava Filter (referred to as "TrapEase filter," "device" or "product" hereinafter) at Tomball Regional Medical Center located in Tomball, TX. The extent of the device failure has not

been fully documented by Plaintiff's treating medical provider(s). As a result of the malfunction, Plaintiff has or may suffer life-threatening injuries and damages and require extensive medical care and treatment. Plaintiff has or may suffer and will continue to suffer significant medical expenses, extreme pain and suffering, loss of enjoyment of life, disability, and other losses.

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

23. Defendant Cordis Corporation ("Cordis") is a corporation organized under the laws of the State of Florida, with its principal place of business at 6500 Paseo Padre Pkwy, Fremont, California, 94555. Cordis at all times relevant to this action, designed, set specifications for, manufactured, prepared, compounded, assembled, processed, marketed, distributed, and sold the TrapEase™ Permanent Vena Cava Filter ("TrapEase filter") and OptEase™ Retrievable Vena Cava Filter ("OptEase filter") to be implanted in patients throughout the United States, including California. 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.

24. Defendant Confluent Medical Technologies, Inc. (Hereinafter "Confluent") is a corporation organized under the laws of the State of Delaware, with its principal place of business at 47533 Westinghouse Drive, Fremont, California 94539. Confluent manufactured, prepared, processed and helped design the OptEase and TrapEase filters implanted in the above-named plaintiffs, whether under its current name or as the successor in interest to Nitinol Development Corporation.

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

26. The true names and/or capacities, whether individual, corporate, partnership, associate, governmental, or otherwise, of Defendant DOES 1 through 100, 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.

27. Plaintiffs are informed and believe, and thereon allege, that at all times herein mentioned, 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.

28. Plaintiffs are informed and believe, and thereon allege, that at all times mentioned herein, Defendants and DOES 1 through 100, 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, fabricating, designing, developing, labeling, assembling, distributing, supplying, leasing, buying, offering for sale, selling, inspecting, servicing, contracting others for marketing, warranting, rebranding, manufacturing for others, packaging, and advertising the device.

29. Defendants and DOES 1 through 100, and each of them, are liable for the acts, omissions and tortious conduct of its successors and/or predecessors in interest/business/product line/or a portion thereof, assigns, parent, subsidiary, affiliate, partner, co-venturer, merged company, alter ego, agent, equitable trustee, fiduciary and/or its alternate entities in that Defendants and DOES 1 through 100, and each of them, enjoy the goodwill originally attached to each such alternate entity, acquired the assets or product line (or a portion thereof), and in that there has been a

virtual destruction of Plaintiffs' remedy against each such alternate entity, and that each such Defendant has the ability to assume the risk-spreading role of each such alternate entity.

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

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

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

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

34. "Cordis," "Confluent" 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, Confluent, as well as DOE Defendants 1 through 100, and each of them.

JURISDICTION AND VENUE

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

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

BACKGROUND

INFERIOR VENA CAVA FILTERS GENERALLY

37. 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.

38. 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.

39. 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.

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

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,

however, an explosion in off-label use began with the introduction of IVC filters that were cleared for both permanent placement and optional removal. Most of this market expansion came from uses such as prophylactic prevention of pulmonary embolism without a prior history of pulmonary embolism.

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

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

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

45. Comparing the results of over 30,000 trauma patients who had not received IVC filters 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.

46. 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.

47. 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.

48. 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

49. 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.

50. 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.

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

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

> If the FDA concludes on the basis of the [manufacturer's] § 510(k) notification that the device is 'substantially equivalent' to a pre-existing device, it can be marketed without further regulatory analysis.... The § 510(k) notification process is by no means 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 on commentator noted: "The attraction of substantial equivalence to manufacturers is clear. Section 510(k) notification required little information, rarely elicits a negative response form the FDA, and gets processed quickly.

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

52. Pursuant to *Wyeth v. Levine*, 555 U.S. 555 (2009), once a product is cleared "the manufacturer remains under an obligation to investigate and report any adverse associated with 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.

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

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

55. On September 18, 2002, Defendants sought clearance through the 510(k) process to market the Cordis OptEase™ Retrievable 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 predicate devices (TrapEase Filter, Gunther Tulip filter, and the Vena Tech LGM Vena Cava Filter).

56. 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

has anchoring barbs for fixation of the filter only on the superior end of each of the six straight struts and has a hook at the inferior end of the basket to allow retrieval with a snare.

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

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

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

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

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

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

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

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

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

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

a. Death;

b. Hemorrhage;

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.

67. 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.

68. 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.

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

70. 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.

71. 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.

72. 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.

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

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

> "...we thought the OPTEASE and TRAPEASE filter types were subjectively among the most difficult to remove in our study, often requiring aggressive blunt dissection force in addition to laser tissue ablation to achieve removal. A possible 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."

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

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

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

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

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

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

81. Given the unreasonably high failure and injury rates associated with Defendants 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.

ESTOPPEL FROM PLEADING STATUTES OF LIMITATIONS OR REPOSE

82. Plaintiffs incorporate by reference all prior allegations.

83. 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 Defendants' IVC filters.

84. Plaintiffs' ignorance of the defective and unreasonably dangers nature of Defendants' IVC filters, and the causal connection between these defects and Plaintiffs' 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.

85. 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.

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

87. Defendants had a duty to disclose the fact that Defendants' 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 the above described risks.

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

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

89. 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.

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

91. 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.

92. 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.

93. 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.

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

95. 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.

96. As a direct and proximate result of the defective and unreasonably dangerous condition of the TrapEase and 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

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

98. 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 TrapEase and OptEase filters.

99. The TrapEase and 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.

100. Defendants knew or it was knowable at the time they distributed the devices implanted in Plaintiffs that the TrapEase and 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.

101. Defendants' TrapEase and 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 used in an intended and reasonably foreseeable way. Such ordinary consumers, including Plaintiffs and their prescribing physician(s), would not and could not have recognized or discovered the potential risks and side effects of the device, as set forth herein.

102. The warnings and directions Defendants provided with its TrapEase and OptEase filters, including the devices implanted in Plaintiffs, failed to adequately warn of the above-

described risks and side-effects, whether as to existence of the risk, its likelihood, severity, or the comparative risk to other products.

103. The labeling also failed to provide adequate directions on how to appropriately use the product.

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

105. Defendants' lack of sufficient instructions or warnings prior to, on, and after the date Plaintiffs 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 III:
STRICT PRODUCTS LIABILITY — MANUFACTURING DEFECT
By all Plaintiffs

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

107. 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.

108. 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.

109. 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.

110. 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

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

112. 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.

113. 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 TrapEase and OptEase filters so as to avoid exposing others to foreseeable and unreasonable risks of harm.

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

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

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.

116. 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.

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

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

a. 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 burden of taking safety measures to reduce or avoid harm;

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

likelihood of potential harm from other devices and treatment options available for the same purpose;

c. Failing to use reasonable care in manufacturing the product and producing a product that differed from their design or specifications or from other typical units from the same production line;

d. 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;

e. 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 and adequate post-market surveillance program;

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

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

COUNT V:
NEGLIGENT MISREPRESENTATION
By all Plaintiffs

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

122. 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 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:

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.

128. 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.

129. 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.

130. 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.

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

132. 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.

133. 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.

134. 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.

135. 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.

136. 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.

137. 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.

138. 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

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

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

141. 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

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

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

143. The Defendants are and were under a continuing duty to disclose the true character, 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.

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

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

146. 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

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.

160. 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.

161. 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.

162. 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 Plaintiffs. 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.

163. 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 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, Confluent Medical Technologies, Inc. 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.

Respectfully Submitted,

DATED: May 20, 2016

BRENES LAW GROUP

/s/ Troy A. Brenes
Troy A. Brenes
Attorney for Plaintiffs

CM-015

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 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: 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: 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. DEFENDANT/RESPONDENT: Cordis Corporation et al.	CASE NUMBER: 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)

▶ Matthew R. Lopez
(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)

SHORT TITLE:	CASE NUMBER:
Heather Quinn et al. v. Cordis Corporation, et al.	RG16814166

ATTACHMENT *(Number):* 4

(This Attachment may be used with any Judicial Council form.)

a. Title: Geanice Grant et al v. Cordis Corporation et al.
b. Case Number: RG16814688
c. Court: Same as above
d. Department: 30
e. Case type: unlimited civil
f. Filing date: May 6, 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.

i. Status of case: pending

a. Title: David Resovsky et al. v. Cordis Corporation et al.
b. Case Number: RG16814745
c. Court: Same as above
d. Department:
e. Case type: unlimited civil
f. Filing date: May 6, 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.)

(Add pages as required)

MC-025

SHORT TITLE:	CASE NUMBER:
Heather Quinn et al. v. Cordis Corporation et al.	RG16814166

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.)

(Add pages as required)

MC-025

SHORT TITLE:	CASE NUMBER:
Heather Quinn et al. v. Cordis Corporation et al.	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 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.)

(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

__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
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16A Journey Suite 200
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One Johnson & Johnson Plaza
New Brunswick, NJ 08933

Cardinal Health, Inc.
CT Corporation
1300 East Ninth Street
Cleveland, OH 44111

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

DEFENDANTS

Ramon Rossi Lopez, Bar No. 86361
Matthew Ramon Lopez, Bar No. 263134
Amorina Patrice Lopez, Bar No. 278002
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Telephone: (949) 737-1501
Facsimile: (949) 737-1504
rlopez@lopezmchugh.com
mlopez@lopezmchugh.com
alopez@lopezmchugh.com

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

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

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

that the document is "Related to ALL Cases." If brought by the parties, it shall be filed and docketed in the Master File under Master File No. _____. Documents intended to apply only to a particular case shall indicate in the caption the Case Number of the case to which the documents apply.

IT IS FURTHER ORDERED THAT _____

_____

_____

_____

_____

Dated: _____

_____
Honorable Brad Seligman
JUDGE OF THE SUPERIOR COURT

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.

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[ ] 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
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Facsimile: 202-628-5116

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New Brunswick, NJ 08933

Cardinal Health, Inc.
CT Corporation

1300 East Ninth Street
Cleveland, OH 44111

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

DEFENDANTS

EXHIBIT B

CT Corporation

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

CT Corporation

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)

NOTICE TO DEFENDANT:
(AVISO AL DEMANDADO):

CORDIS CORPORATION, et al.

COPY

YOU ARE BEING SUED BY PLAINTIFF:
(LO ESTÁ DEMANDANDO EL DEMANDANTE):

David Resovsky, George Todd, David Brown, Gwen Kramer

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

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 ó 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:
(Número del caso): RG16814745

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 Pesko , Deputy *(Adjunto)*

(For proof of service of this summons, use Proof of Service of Summons *(form POS-010).)*
(Para prueba de entrega de esta citatión 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)
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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 Sue Pesko
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

JUDGE:
DEPT:

CIVIL CASE COVER SHEET

☑ Unlimited (Amount demanded exceeds $25,000) ☐ Limited (Amount demanded is $25,000 or less)

Complex Case Designation

☐ Counter ☐ Joinder

Filed with first appearance by defendant (Cal. Rules of Court, rule 3.402)

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
- ☐ Auto (22)
- ☐ Uninsured motorist (46)

Other PI/PD/WD (Personal Injury/Property Damage/Wrongful Death) Tort
- ☐ Asbestos (04)
- ☐ Product liability (24)
- ☐ Medical malpractice (45)
- ☐ Other PI/PD/WD (23)

Non-PI/PD/WD (Other) Tort
- ☐ Business tort/unfair business practice (07)
- ☐ Civil rights (08)
- ☐ Defamation (13)
- ☐ Fraud (16)
- ☐ Intellectual property (19)
- ☐ Professional negligence (25)
- ☐ Other non-PI/PD/WD tort (35)

Employment
- ☐ Wrongful termination (36)
- ☐ Other employment (15)

Contract
- ☐ Breach of contract/warranty (06)
- ☐ Rule 3.740 collections (09)
- ☐ Other collections (09)
- ☐ Insurance coverage (18)
- ☐ Other contract (37)

Real Property
- ☐ Eminent domain/Inverse condemnation (14)
- ☐ Wrongful eviction (33)
- ☐ Other real property (26)

Unlawful Detainer
- ☐ Commercial (31)
- ☐ Residential (32)
- ☐ Drugs (38)

Judicial Review
- ☐ Asset forfeiture (05)
- ☐ Petition re: arbitration award (11)
- ☐ Writ of mandate (02)
- ☐ Other judicial review (39)

Provisionally Complex Civil Litigation (Cal. Rules of Court, rules 3.400–3.403)
- ☐ Antitrust/Trade regulation (03)
- ☐ Construction defect (10)
- ☑ Mass tort (40)
- ☐ Securities litigation (28)
- ☐ Environmental/Toxic tort (30)
- ☐ Insurance coverage claims arising from the above listed provisionally complex case types (41)

Enforcement of Judgment
- ☐ Enforcement of judgment (20)

Miscellaneous Civil Complaint
- ☐ RICO (27)
- ☐ Other complaint *(not specified above)* (42)

Miscellaneous Civil Petition
- ☐ Partnership and corporate governance (21)
- ☐ 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. ☐ Large number of separately represented parties
   b. ☑ Extensive motion practice raising difficult or novel issues that will be time-consuming to resolve
   c. ☑ Substantial amount of documentary evidence
   d. ☑ Large number of witnesses
   e. ☑ Coordination with related actions pending in one or more courts in other counties, states, or countries, or in a federal court
   f. ☐ 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.

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 PI/PD/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 PI/PD/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 PI/PD/WD

Non-PI/PD/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-PI/PD/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

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ENDORSED
FILED
ALAMEDA COUNTY
MAY 06 2016
CLERK OF THE SUPERIOR COURT
By Sue Resko Deputy

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

DAVID RESOVSKY, GEORGE TODD, DAVID BROWN, GWEN KRAMER

Plaintiff(s),

vs.

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

Defendant(s).

Case No.: RG16814745

COMPLAINT FOR DAMAGES

DEMAND FOR JURY TRIAL

Plaintiffs DAVID RESOVSKY, GEORGE TODD, DAVID BROWN, AND GWEN KRAMER hereby sue defendants CORDIS CORPORATION 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. As a result of the malfunction, Mr. Resovsky has suffered life-threatening injuries and damages and required extensive medical care and treatment. Plaintiff has suffered and will continue to suffer

significant medical expenses, extreme pain and suffering, loss of enjoyment of life, disability, and other losses.

2. Plaintiff George Todd was implanted with an OptEase™ filter in October 2006 at Aventura Hospital & Medical Center in Florida. The device subsequently tilted and perforated the vena cava. As a result, he suffered, *inter alia*, bilateral pulmonary emboli and the device cannot be removed. Plaintiff has suffered and will continue to suffer significant medical expenses, extreme pain and suffering, loss of enjoyment of life, disability, and other losses.

3. Plaintiff David Brown was implanted with an OptEase™ filter on November 4, 2014 at Hannibal Regional Hospital in Missouri. On February 5, 2015 he underwent a procedure to remove the device. The attempt failed secondary to the device having tilted and migrated after placement. Plaintiff has suffered medical expenses, pain and suffering, loss of enjoyment of life, and other losses.

4. Plaintiff Gwen Kramer underwent implantation of two OptEase™ filters on October 28, 2013. The first filter immediately migrated to the "origin of the left iliac vein." This filter was removed percutaneously. Another OptEase™ filter was then placed and this filter also migrated proximally with the distal portion of the filter being proximal to the renal veins. This filter was left in place. Given the migration of the second filter, Ms. Kramer is at increased risk of fracture, perforation and the device will be less effective at stopping clots. Plaintiff has suffered and will continue to suffer significant medical expenses, extreme pain and suffering, loss of enjoyment of life, disability, and other losses.

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

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

California, 94555. Cordis at all times relevant to this action, designed, set specifications for, manufactured, prepared, compounded, assembled, processed, marketed, distributed, and sold the OptEase™ Vena Cava Filter ("OptEase filter") to be implanted in patients throughout the United States, including California. 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.

7. The true names and/or capacities, whether individual, corporate, partnership, associate, governmental, or otherwise, of Defendant DOES 1 through 100, 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.

8. Plaintiffs are informed and believe, and thereon allege, that at all times herein mentioned, the Defendant 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.

9. Plaintiffs are informed and believe, and thereon allege, that at all times mentioned herein, Defendant and DOES 1 through 100, 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, fabricating, designing, developing, labeling, assembling, distributing, supplying, leasing, buying, offering for sale, selling, inspecting, servicing, contracting others for marketing, warranting, rebranding, manufacturing for others, packaging, and advertising the device.

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

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

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

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

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

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 it 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

clotting factor of the blood. In some people who are at high risk for DVT/PE, or who cannot manage their conditions with medications, physicians may recommend surgically implanting an IVC filter to prevent thromboembolitic events.

22. 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, however, an explosion in off-label use began with the introduction of IVC filters that were cleared for both permanent placement and optional removal. Most of this market expansion came from uses such as prophylactic prevention of pulmonary embolism without a prior history of pulmonary embolism.

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

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

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

26. Comparing the results of over 30,000 trauma patients who had not received IVC filters 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 Defendants represented to the FDA, physicians, and the public that its IVC filters would prevent.

27. 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.

28. 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

29. 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.

30. 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.

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

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

> If the FDA concludes on the basis of the [manufacturer's] § 510(k) notification that the device is 'substantially equivalent' to a pre-existing device, it can be marketed without further regulatory analysis.... The § 510(k) notification process is by no means 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 on commentator noted: "The attraction of substantial equivalence to manufacturers is clear. Section 510(k) notification required little information, rarely elicits a negative response form the FDA, and gets processed quickly.

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

32. Pursuant to *Wyeth v. Levine*, 555 U.S. 555 (2009), once a product is cleared "the manufacturer remains under an obligation to investigate and report any adverse associated with 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.

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

has anchoring barbs for fixation of the filter only on the superior end of each of the six straight struts and has a hook at the inferior end of the basket to allow retrieval with a snare.

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

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

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

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

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

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

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

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

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

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

a. Death;

b. Hemorrhage;

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.

45. 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.

46. 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.

47. Defendants, however, failed to take timely and adequate action to correct known design and manufacturing defects with the OptEase filter.

48. 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.

49. 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.

50. 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.

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

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

> "...we thought the OPTEASE and TRAPEASE filter types were subjectively among the most difficult to remove in our study, often requiring aggressive blunt dissection force in addition to laser tissue ablation to achieve removal. A possible 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."

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

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

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

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

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

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

59. Given the unreasonably high failure and injury rates associated with Defendants 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.

ESTOPPEL FROM PLEADING STATUTES OF LIMITATIONS OR REPOSE

60. Plaintiffs incorporate by reference all prior allegations.

61. 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 Defendants' IVC filters.

62. Plaintiffs' ignorance of the defective and unreasonably dangers nature of Defendants' IVC filters, and the causal connection between these defects and Plaintiffs' 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.

63. 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.

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

65. Defendants had a duty to disclose the fact that Defendants' 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 the above described risks.

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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

used in an intended and reasonably foreseeable way. Such ordinary consumers, including Plaintiffs and their prescribing physician(s), would not and could not have recognized or discovered the potential risks and side effects of the device, as set forth herein.

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

81. The labeling also failed to provide adequate directions on how to appropriately use the product.

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

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

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

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

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

85. 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.

86. 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.

87. 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.

88. 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

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. 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.

92. Defendants knew or reasonably should have known that the OptEase filters were dangerous or were likely to be dangerous when used in an intended or reasonably foreseeable manner.

93. At the time of manufacture and sale of the OptEase filters, Defendants knew or should have known that the OptEase filters:

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 to 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:

a. 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 burden of taking safety measures to reduce or avoid harm;

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 likelihood of potential harm from other devices and treatment options available for the same purpose;

c. Failing to use reasonable care in manufacturing the product and producing a product that differed from their design or specifications or from other typical units from the same production line;

d. 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 OptEase filters' substantially dangerous condition or about facts making the products likely to be dangerous;

e. 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 OptEase filters;

h. Advertising, marketing and recommending the use of the 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 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 and 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.

107. 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.

108. 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.

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

110. 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.

111. 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.

112. 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.

113. Defendants had sole access to material facts concerning the defective nature of the 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.

114. 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.

115. 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.

116. 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

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

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

119. 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

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

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

121. The Defendants are and were under a continuing duty to disclose the true character, 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.

129. 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 OptEase 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.

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

COUNT IX
BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY
By all Plaintiffs

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

132. Defendants sold the OptEase filters for Plaintiffs' ultimate use.

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.

134. 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.

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:

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;

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

CT Corporation

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

CT Corporation

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)

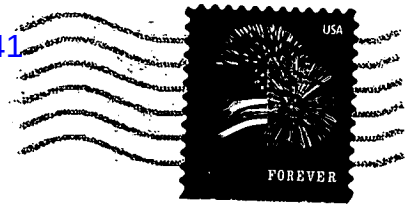
SIGNED: C T Corporation System
ADDRESS: 818 West Seventh Street
Los Angeles, CA 90017
TELEPHONE: 213-337-4615

BRENES
LAW GROUP

16A Journey, Suite 200
Aliso Viejo, CA 92656

SANTA ANA CA 926

09 MAY 2016 PM 5 L



C T Corporation System
Cordis Corporation
818 W. 7th St., Suite 930
Los Angeles, CA 90017

9001734763O

CM-015

ATTORNEY OR PARTY WITHOUT ATTORNEY (Name, State Bar number, and address):	FOR COURT USE ONLY
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	
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. DEFENDANT/RESPONDENT: Cordis Corporation et al.	CASE NUMBER:

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. DEFENDANT/RESPONDENT: Cordis Corporation et al.	CASE NUMBER:

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)

JS 44 (Rev. 12/12)
Cand rev (1/15/13)

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)
CROWELL & MORING LLP
275 Battery Street, 23rd Floor
San Francisco, CA 94111
Phone: 415.986.2800; Fax: 415.986.2827
Email: kmayer@crowell.com

Andrew D. Kaplan (*pro hac vice* application to be filed)
Rebecca B. Chaney (*pro hac vice* application to be filed)
CROWELL & MORING LLP
1001 Pennsylvania Ave., NW, Washington DC 20004
Phone: 202.624.2500; Fax: 202.628.5116
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)*

(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☐ 1	☐ 1	Incorporated *or* Principal Place of Business In This State	☐ 4	☐ 4
Citizen of Another State	☒ 2	☐ 2	Incorporated *and* Principal Place of Business In Another State	☐ 5	☒ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

IV. NATURE OF SUIT *(Place an "X" in One Box Only)*

CONTRACT
- ☐ 110 Insurance
- ☐ 120 Marine
- ☐ 130 Miller Act
- ☐ 140 Negotiable Instrument
- ☐ 150 Recovery of Overpayment & Enforcement of Judgment
- ☐ 151 Medicare Act
- ☐ 152 Recovery of Defaulted Student Loans (Excludes Veterans)
- ☐ 153 Recovery of Overpayment of Veteran's Benefits
- ☐ 160 Stockholders' Suits
- ☐ 190 Other Contract
- ☐ 195 Contract Product Liability
- ☐ 196 Franchise

REAL PROPERTY
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

TORTS

PERSONAL INJURY
- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers' Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury
- ☐ 362 Personal Injury - Medical Malpractice

PERSONAL INJURY
- ☒ 365 Personal Injury - Product Liability
- ☐ 367 Health Care/ Pharmaceutical Personal Injury Product Liability
- ☐ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

CIVIL RIGHTS
- ☐ 440 Other Civil Rights
- ☐ 441 Voting
- ☐ 442 Employment
- ☐ 443 Housing/ Accommodations
- ☐ 445 Amer. w/Disabilities Employment
- ☐ 446 Amer. w/Disabilities Other
- ☐ 448 Education

PRISONER PETITIONS

Habeas Corpus:
- ☐ 463 Alien Detainee
- ☐ 510 Motions to Vacate Sentence
- ☐ 530 General
- ☐ 535 Death Penalty

Other:
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Condition
- ☐ 560 Civil Detainee - Conditions of Confinement

FORFEITURE/PENALTY
- ☐ 625 Drug Related Seizure of Property 21 USC 881
- ☐ 690 Other

LABOR
- ☐ 710 Fair Labor Standards Act
- ☐ 720 Labor/Management Relations
- ☐ 740 Railway Labor Act
- ☐ 751 Family and Medical Leave Act
- ☐ 790 Other Labor Litigation
- ☐ 791 Employee Retirement Income Security Act

IMMIGRATION
- ☐ 462 Naturalization Application
- ☐ 465 Other Immigration Actions

BANKRUPTCY
- ☐ 422 Appeal 28 USC 158
- ☐ 423 Withdrawal 28 USC 157

PROPERTY RIGHTS
- ☐ 820 Copyrights
- ☐ 830 Patent
- ☐ 840 Trademark

SOCIAL SECURITY
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

FEDERAL TAX SUITS
- ☐ 870 Taxes (U.S. Plaintiff or Defendant)
- ☐ 871 IRS—Third Party 26 USC 7609

OTHER STATUTES
- ☐ 375 False Claims Act
- ☐ 400 State Reapportionment
- ☐ 410 Antitrust
- ☐ 430 Banks and Banking
- ☐ 450 Commerce
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced and Corrupt Organizations
- ☐ 480 Consumer Credit
- ☐ 490 Cable/Sat TV
- ☐ 850 Securities/Commodities/ Exchange
- ☐ 890 Other Statutory Actions
- ☐ 891 Agricultural Acts
- ☐ 893 Environmental Matters
- ☐ 895 Freedom of Information Act
- ☐ 896 Arbitration
- ☐ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ☐ 950 Constitutionality of State Statutes

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

VI. CAUSE OF ACTION

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

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.