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SUPERIOR COURT OF CALIFORNIA
COUNTY OF LOS ANGELES

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Attorneys for Plaintiffs
DAVID DELEON AND RICHARD GONZALEZ, on their own behalf, and on behalf of all other persons similarly situated

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BY FAX

SUPERIOR COURT OF THE STATE OF CALIFORNIA

FOR THE COUNTY OF LOS ANGELES - CENTRAL DISTRICT

DAVID DELEON and RICHARD GONZALEZ On behalf of themselves and the Class of all others similarly Situated,

Plaintiffs,

vs.

C.R. BARD, INC., a corporation of The State of New Jersey and BARD PERIPHERAL VASCULAR, INC., A Corporation of the State of Arizona And DOE DEFENDANTS 1 through 100, INCLUSIVE;

Defendants.

CASE NO: BC490020
Assigned to:

CLASS ACTION

COMPLAINT FOR MEDICAL MONITORING BASED UPON CAUSES OF ACTION FOR:
(1) NEGLIGENCE
(2) STRICT LIABILITY MANUFACTURING DEFECT
(3) STRICT LIABILITY-WARNING DEFECT
(4) FRAUDULENT CONCEALMENT
(5) BREACH OF IMPLIED WARRANTIES
(6) NEGLINGENT BREACH OF DUTY TO PROVIDE POST SALE WARNING
(7) STRICT LIABILITY- DESIGN DEFECT

DEMAND FOR TRIAL BY JURY [MADE PURSUANT C.C.P. § 600 AND F.R.C.P. IF THIS ACTION IS EVER REMOVED TO FEDERAL COURT]

Plaintiffs, DAVID DELEON AND RICHARD GONZALEZ, on their own behalf and on behalf of all other persons similarly situated, hereby allege:

THE PARTIES

Plaintiffs

1. At all material times hereto, Plaintiff, DAVID DELEON, has been residing in the State of California. As further stated in more detail infra, this action is brought by Plaintiff, DAVID DELEON, in his individual capacity and on behalf of others similarly situated, hereinafter and referred to infra as the FILTER IMPLANT CLASS.

2. At all material times hereto, Plaintiff, RICHARD GONZALEZ, has been residing in the State of California. As further stated in more detail infra, this action is brought by Plaintiff, RICHARD GONZALEZ, in his individual capacity and on behalf of others similarly situated, hereinafter and referred to infra as the FILTER IMPLANT CLASS.

Defendants

3. Plaintiffs are informed and believe and thereon allege that Defendant, C.R. BARD, Inc., is a New Jersey corporation, which at all material times hereto, was doing business in the County of Los Angeles, State of California. Further, Plaintiffs are informed and believe and thereon allege that Defendant, BARD PERIPHERAL VASCULAR, INC., is an Arizona corporation, which at all material times hereto, was doing business in the County of Los Angeles, State of California.

4. Defendants, C.R. BARD, INC., and BARD PERIPHERAL VASCULAR, INC. are manufacturers of medical devices designed and manufactured to be implanted in the human body. With specific regard to this Complaint, the medical device at issue is an "inferior vena cava filter" (also called an "IVC filter").

5. The true names and capacities of Defendants Does 1 through 100 are unknown to Plaintiffs, who therefore sue said defendants by such fictitious names. Plaintiffs will amend this

complaint to state the true names and capacities of said fictitious defendants when they have been ascertained.

6. Plaintiffs are informed and believe and thereon allege that Defendants Does 1 through 100 are in some manner responsible for the occurrences herein alleged, and that Plaintiffs' damages and the damages of those similarly situated as herein alleged were proximately caused by their conduct.

7. Plaintiffs are informed and believe and based thereon allege that, at all times material hereto, each of the Defendants, including the fictitiously named Defendants, was acting in an individual, corporate, partnership, associate, parent-subsidiary, successor-predecessor, conspiratorial or other capacity or as the agent, employee, co-conspirator, and/or alter ego of its co-defendants, and in doing the acts herein alleged, was acting within the course and scope of its authority as such parent, successor, partner, associate, agent, employee, co-conspirator, or alter ego, and with the permission, consent, knowledge, authorization, ratification and direction of its co-defendants, including all fictitiously named defendants.

STATEMENT OF JURISDICTION AND NON-REMOVABILITY

8. Jurisdiction is proper in this matter in the Superior Court of the State of California, because Plaintiffs are all citizens of and domiciled in California and because Defendants' IVC filters were implanted into Plaintiffs' bodies in the State of California.

9. Although the parties are of diverse citizenship, this action is nevertheless not removable to federal court, because it does not allege a "case or controversy" within the meaning of Article III of the United States Constitution.

10. Specifically, this action does not allege that either the class representatives or the class members have suffered any injury to their person or property. Indeed, this action expressly alleges that Plaintiffs have no present injury, but rather seek medical monitoring to hopefully prevent or at least detect the onset of future injuries, because Plaintiffs are at a substantially increased risk of developing

such injuries in the future due to Defendants' defective IVC filters that have been implanted in their bodies and likely to fracture, migrate, or otherwise fail and cause future injuries due to their defective design and manufacture.

11. A complaint alleging that the plaintiff has no present injury to person or property, but rather seeks medical monitoring to prevent or detect the onset of future injury does not satisfy the minimum requirement of an "injury in fact" which the U.S. Supreme Court has established is the "irreducible constitutional minimum" for Article III standing. See, *Toxic Injuries Corp. v. Safety-Kleen Corp.* (C.D. Cal. 1999) 57 F.Supp.2d 947. Thus, this action may not be removed to federal court notwithstanding diversity of citizenship.

CLASS ALLEGATIONS

12. This action is brought by Plaintiffs, DAVID DELEON AND RICHARD GONZALEZ, as a Class Action, on their own behalf and on behalf of all other persons similarly situated, under the provisions of *California Code of Civil Procedure* § 382, for medical monitoring and other available relief other than damages.

13. The Class represented by Plaintiffs, DAVID DELEON AND RICHARD GONZALEZ, consists of all persons who have had implantation of IVC filter(s) designed, manufactured, distributed and sold by the Defendants, C.R. BARD, INC., and BARD PERIPHERAL VASCULAR, INC., and who have the device(s) remaining within their anatomy. The trade names for these IVC Filters are "Recovery®", "G2®", and/or the "G2 Express®" vena cava filters. These devices are described in detail in the paragraphs contained infra. This class of Plaintiffs will hereinafter be referred to as the "FILTER IMPLANT CLASS."

14. On information and belief, the proposed FILTER IMPLANT CLASS consists of thousands of members located throughout the State of California. The members of the FILTER IMPLANT CLASS are so numerous that joinder of individual members herein is not practical.

15. Common questions of law and fact predominate in this action that relate to and affect the rights of each member of the FILTER IMPLANT CLASS and the relief sought, for example, and not by way of limitation, that Plaintiffs have had one of the aforementioned IVC filters implanted within their anatomy, are exposed to a risk of injury from the existence of said device within their anatomy, and require regular, frequent and necessary medical monitoring to ensure that the device has not fractured, migrated or otherwise failed, so as to cause grave, life threatening injury to the Plaintiffs.

16. The claims of DAVID DELEON AND RICHARD GONZALEZ are typical of the claims of the FILTER IMPLANT CLASS in that the claims of all members of the FILTER IMPLANT CLASS, including Plaintiffs, depend on a showing of the acts and omissions of Defendants upon which liability is based.

17. The representative Plaintiffs, DAVID DELEON AND RICHARD GONZALEZ, can and will fairly and adequately protect the interests of the FILTER IMPLANT CLASS.

18. The questions of law and fact common to the members of the class predominate over questions affecting individual class members. A class action is superior to other available methods for the fair and efficient adjudication of this controversy. Moreover, in order for Plaintiffs to proceed against Defendants in an economical manner, and to prevent the massive duplication of discovery and other similar proceedings which would occur if there were a multiplicity of actions, Plaintiffs seek the benefits of *California Code of Civil Procedure* § 382.

TOLLING OF THE STATUTE OF LIMITATIONS

No Injury

19. When Plaintiffs and members of the FILTER IMPLANT CLASS were implanted with the Recovery®, G2®, and/or G2 Express® filters, they experienced no injury or trauma and were unaware

of any problems associated with the implantation of these filters. It was not until the FDA first issued a public communication in August 2010, indicating that adverse events and increased health risks were associated with Defendants' filters, members of the FILTER IMPLANT CLASS reasonably could have known that they have increased health risks from Defendants' filters or that they may have a cause of action arising from Defendants' conduct.

Fraudulent Concealment of Health Hazards by Defendants

20. At all material times hereto, Defendants fraudulently concealed from Plaintiffs, members of the FILTER IMPLANT CLASS, the public at large, and the medical community, material facts concerning the nature of their Recovery®, G2®, and/or G2 Express® filters that were implanted in Plaintiffs and members of the FILTER IMPLANT CLASS.

21. At all material times hereto, Defendants fraudulently concealed the hazards of their Recovery®, G2®, and/or G2 Express® filters that exist as a result of the manufacturing process of these filters, to wit, significant risk that the filters will fail and/or fracture, which may lead to death, hemorrhage, cardiac/pericardial tamponade, severe and persistent pain, and perforation of tissue, vessels, and organs.

22. Defendants' concealment was sufficiently complete that Plaintiffs and all members of the FILTER IMPLANT CLASS did not know, nor in the exercise of reasonable care could have known earlier than August 2010 of Defendants' culpability, or that Plaintiffs had causes of action arising from Defendants' concealment.

23. In August 2010, the FDA first issued a public communication concerning adverse events and health risks associated with Defendants' filters, which is the earliest time that members of the FILTER IMPLANT CLASS could have been aware of any problems with the implants and their substantially increased risk of future injury.

Discovery of Defect of the Implanted IVC Filters

24. Plaintiff, DAVID DELEON, learned in about October or November 2010 that the IVC Filter implanted within his anatomy, to wit, the G2® filter, was fraught with the problems mentioned in this paragraph and in more detail infra. Plaintiff was blamelessly ignorant of the defective and dangerous condition of the G2® filter until these times. His G2® filter still cannot be removed safely and remains at risk for additional fractures.

25. Plaintiff, RICHARD GONZALEZ, learned in mid-2011 that the IVC Filter implanted within his anatomy, to wit, the G2® filter, was fraught with the problems mentioned in this paragraph and in more detail infra. Plaintiff was blamelessly ignorant of the defective and dangerous condition of the G2® filter until these times. His G2® filter still cannot be removed safely and remains at risk for additional fractures.

Fraudulent Concealment of the Hazards and Defects of the Recovery®, G2® and G2 Express® by Defendants

26. At all material times hereto, Defendants C.R. BARD, INC., and BARD PERIPHERAL VASCULAR, INC., fraudulently concealed from Plaintiffs, the medical community, the public at large and others material facts concerning the nature of the Recovery®, G2® and G2 Express® vena cava filters to which Plaintiffs, DAVID DELEON AND RICHARD GONZALEZ, and members of the FILTER IMPLANT CLASS had implanted in their bodies.

27. Defendants C.R. BARD, INC., and BARD PERIPHERAL VASCULAR, INC.'s fraudulent concealment was sufficiently complete that Plaintiffs, the medical community, the public at large and others, did not know, nor in the exercise of reasonable care could have known, earlier than August 2010, of Defendants' culpability and that Plaintiffs had a cause of action, at least for medical monitoring, against Defendants.

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GENERAL ALLEGATIONS

IVC Filters Generally

28. IVC filters first came on the medical market decades ago. Over the years, several different medical device manufacturers have introduced several different designs of IVC filters.

29. An IVC filter is a device that is designed to filter or blood clots (called "thrombi") that travel from the lower portions of the body to the heart and lungs. IVC filters may be designed to be implanted, either permanently or temporarily, in the human body, more specifically, within the inferior vena cava.

30. The inferior vena cava is a vein that returns blood to the heart from the lower portions of the body. In certain people, for various reasons, thrombi travel from the vessels in the legs and pelvis, through the vena cava and into the lungs. Often times, these thrombi develop in the deep leg veins. These thrombi are called a deep vein thrombosis or "DVT". Once thrombi reach the lungs, they are considered "pulmonary emboli" or "PE". Pulmonary emboli present grave risks to human health. They can, and often do, result in death.

31. Certain people are at increased risk for the development of DVT or PE. For instance, someone who undergoes knee or hip joint replacement surgery is at risk for developing DVT/PE. Obese patients are also at increased risk for DVT/PE. So too are people who have vascular diseases or whom have experienced previous strokes. A number of other conditions predispose people to develop DVT/PE.

32. Those 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. For some 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.

33. The first IVC filter was introduced in the late 1960's. Since then, the market has been supplemented with all types and designs of filters offered by many different manufacturers.

34. Over the years, a concern developed within the medical community (and was shared by IVC filter manufacturers) that an IVC filter should be designed and manufactured so that is able to be retrieved from the human body. Ultimately, retrievable IVC filter designs were offered in the market. However, these IVC filter designs were not intended to remain within the human body for indeterminate periods of time. In other words, the initial designs of retrievable IVC filters were intended to remain implanted for a finite period of time. The Recovery Filter System[1] was introduced to the market in late 2002 as an IVC filter that could be retrieved after an indeterminate time of placement within the human body.

35. The IVC filters at issue in this case bear the trademark name "Recovery®", "G2®" or "G2 Express®" vena cava filter. Each is discussed in turn, infra. Each of the devices was designed, manufactured, marketed, and sold by Defendants C.R. Bard, Inc. and/ or Bard Peripheral Vascular, Inc. from 2002 until the present.

The Recovery® Filter System

36. In 2002, the Defendants C.R. Bard, Inc. and/or Bard Peripheral Vascular, Inc., applied to the United States Food and Drug Administration ("FDA") for approval of an IVC filter called the Recovery® Filter System.[2] In 2002, the Recovery® Filter System was approved by the FDA for permanent placement. It was subsequently approved by the FDA as a "retrievable" device. That is, it was intended that the device could be explanted by a physician at a time into the future following initial placement.

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[1] The Recovery® Filter System is the predecessor device to the G2® and G2 Express® Filters.

[2] Defendant C.R. Bard, Inc. applied for marketing approval of the Recovery® Filter System under Section 510(k) of the United States Food, Drug and Cosmetic Act (21 U.S.C. § 360). In so doing, defendant C.R. Bard, Inc. represented to the FDA that the Recovery® Filter System was substantially equivalent to a predecessor device, the Simon Nitinol IVC filter. As such, the Recovery® Filter System did not undergo pre-market approval scrutiny.

37. The Recovery® Filter System is constructed of a nickel titanium alloy (also called "Nitinol"). This composite material is unique. Nitinol is actually an acronym that stands for Nickel Titanium Naval Ordnance Laboratory. Nitinol was developed by Navy scientists in 1962 as a material to be used in ordnance. Nitinol is also unique as it possesses "shape memory." That is, Nitinol will change shape according to change in temperature, and then, retake its prior shape after returning to its initial temperature. This quality makes Nitinol appealing for use in certain medical devices, including IVC filters.

38. The Recovery® Filter System was first marketed for sale by the Defendants C.R. Bard, Inc. and/or Bard Peripheral Vascular, Inc. on or about April 2003. On or about October 15, 2003, defendant C.R. Bard, Inc. executive John H. Weiland[3] was quoted as stating "We are taking a very measured approach with our rollout of the Recovery® in order to position ourselves well for long-term success with this exciting new product." Despite Mr. Weiland's comments to company shareholders, the Recovery® Filter System was pulled from the market in about August 2005, just a little over two years after its introduction to the market and the comments made by C.R. Bard Inc.'s President and Chief Operating Officer.

39. Although a rough or crude analogy, the Recovery® Filter System resembles an "upside down umbrella" with the fabric removed. It consists of twelve "struts" or legs. There are six long struts and six shorter struts. The shorter struts are positioned above the longer struts. All of the struts are held together by a Nitinol "cap" located at the top of the device. The shorter struts were designed to be "centering" or "positioning" struts to assist in the proper centering of the filter when placed within the vena cava.

40. The Recovery® Filter System is inserted into the human body in endovascular fashion.

[3] Mr. Weiland was defendant C.R. Bard, Inc.'s President and Chief Operating Officer.

That is, the Recovery® is inserted via catheter that is guided by a physician[4] through a blood vessel into the inferior vena cava. The Recovery® Filter was designed to be retrieved in a somewhat similar fashion.

41. Following endovascular placement of the Recovery®, the physician typically uses imaging studies (like "vena cava grams" or CT scans) to confirm successful placement and positioning of the device within the vena cava.

Post Implant Failure of the Recovery® Filter

42. There is documented medical evidence of the fact that the Recovery® Filter System is prone to failure following placement within the human body. Since its introduction in 2003, several reports of studies have been published in medical journals and other written works which address the efficacy and safety of the Recovery® Filter System. These medical studies and reports indicate that the Recovery® Filter System is prone to failure by fracture of the device. That is, it breaks apart.

43. The aforementioned studies report that the Recovery® Filter System's "struts" are prone to fracture, and then, migrate to locations within the human body. Most typically, the fractured struts migrate to the heart and lungs of the victim. These studies report a fracture rate of the Recovery® Filter System struts ranging between 21% and 31.7%.[5]

44. Other medical research studies indicate that the Recovery® Filter is predisposed to a high incidence of penetration of the walls of the vena cava.[6] Specifically, the distal (end) points of the

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[4] Typically, although not universally, an IVC filter is placed by an interventional radiologist. The procedure is called an "endovascular" medical procedure.

[5] In 2005, the New England Society for Vascular Surgery reported a 31.7% fracture rate of the Recovery® Filter. This report followed the Society's examination of the FDA "MAUDE" database which records adverse patient-product events, like failure of an IVC filter. In 2008, the Journal of Vascular and Interventional Radiology published an article by Robertson and Hull (Bard Recovery Filter: Evaluation and Management of Vena Cava Limb Perforation, Fracture, and Migration, Journal of Vascular and Interventional Radiology, November 2008) indicating a 21% device fracture rate in the Recovery Filter System.

[6] See, Recovery J Vena Cava Filter: Experience in 96 Patients, Kalva, et al, Journal of Cardiovascular and Interventional Radiology, (2006) 29: 559-564- showing a 27.4% vena cava penetration rate with the Recovery® Filter System. This same study called for "additional studies to determine the long term safety of the device."

Recovery® Filter's struts have been observed to perforate the walls of the vena cava. When this occurs, the perforating strut becomes fixed in its position and resists flexion or movement. The fixed struts then become subjected to a high frequency of bending stress due to the vena cava wall's movement during normal respiration and cardiac cycles. Researchers have discovered that this leads to metal fatigue in the strut, at a point just below the Recovery® Filter's cap.[7] Metallurgical analysis also confirms the Recovery® Filter's proneness to bending, metal fatigue, and fracture. The metal fatigue causes the strut to bend, and then, fracture.

45. Additional studies have revealed that the Recovery® Filter System is also prone to "tilt" following placement within the vena cava and/or improper deployment.[8]

46. Furthermore, the FDA's MAUDE" (Manufacturer and User Facility Device Experience) database includes several reports of the failure, fracture and migration of the Recovery® Filter System.

47. The Recovery® Filter was pulled from the market by the Defendants C.R. Bard, Inc. and/or Bard Peripheral Vascular, Inc. in 2005. It is no longer commercially available. It was replaced by the G2® Filter, also manufactured by Defendants C.R. Bard, Inc. and/or Bard Peripheral Vascular, Inc. Like the Recovery®, the G2® was initially approved by the FDA only as a permanent implant device, and was later approved for retrievable use. Defendants used the 510(k) process for approval of the G2® as they had for the Recovery®.

48. The G2® filter was advertised by Defendants C.R. Bard, Inc. and/or Bard Peripheral Vascular, Inc. to have "enhanced fracture resistance," "improved centering," and "increased migration

[7] Retrieval of the Recovery Filter after Arm Perforation, Fracture, and Migration to the Right Ventricle, Hull et al, J. Vasc. Interv. Radiol. 2008; 19:1110. In this study, Dr. Hull compares this bending stress to that of bending a paper clip back and forth until it breaks.

[8] See, Retrieval of the Recovery Filter after Arm Perforation, Fracture, and Migration to the Right Ventricle, Hull et al, J. Vasc. Interv. Radiol. 2008; 19:1107-1111.

resistance." Defendant Bard Peripheral Vascular's website[9] indicates that "data is on file" with respect to these product enhancements.

Sales of the Recovery® Filter System

49. The Recovery® Filter was on the market from on or about April 2003 until August 2005, a total of less than two and one-half years. The Defendants sold at least approximately 35,000 of the Recovery® Filters during the time the device was on the market.

The G2® Filter - the Successor to Recovery®

50. The G2® Filter is the successor device to the Recovery® filter. It was introduced to the market by the Defendants in August 2005. Like the Recovery® Filter, it is constructed of Nitinol and is designed to filter blood clots (thrombi) from the human circulatory system.

51. The design of the G2® Filter is similar to that of the Recovery® filter. The only differences in design of the G2, as compared to the Recovery® are dimensional and angular. For all other purposes, the G2® Filter is similar to its predecessor.

52. As stated supra, the Recovery® Filter was the predecessor/predicate device for the G2® Filter. Soon after introduction of the Recovery® to the market, reports were made by doctors and patients to the Defendants that portions of the device were fracturing and migrating to the anatomy and vital organs of the patients in whom it was implanted. These reports continued to surface and were made to healthcare providers, the FDA, and, to the Defendants. In fact, as early as 2003, Defendants were made aware that the Recovery® Filter was flawed and was causing injury and death to patients other than Plaintiffs who had Defendants' filters implanted in their bodies.

53. As mentioned supra, the Recovery® Filter was plagued with manufacturing and design defects which caused Recovery® to experience a significant rate of fracture and migration of the device.

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[9] www.bardpv.com/ vascular/product.php?p 83

These rates of fracture have been studies by medical researchers and have been documented to range from 21% in one study, to 25% in another, to over 31% in yet another.[10]

54. The failure of the Recovery® Filter, as aforesaid, was attributable, in part, to the fact that the Recovery® Filter was designed so as to be unable to withstand the normal anatomical and physiological loading cycles exerted in vivo.[11]

55. On or about late 2004, the Defendants made a decision to introduce a substitute vena cava filter for the Recovery® Filter. This substitute vena cava filter was meant to replace the Recovery® Filter in the United States. It was to be called the "G2®". G2® stands for "second generation" of the Recovery® Filter.

56. In 2005, the Defendants submitted an application to the FDA for introduction of the G2 Filter to the global market. The application was submitted under Section 510(k) of the United States Food, Drug and Cosmetic Act ("Act") of 1976 (21 U.S.C. 321 *et. seq.*). Under Section 510(k), a medical device manufacturer may represent that the device which is offered for approval is "substantially similar" to a "predicate device." With regard to the G2®, the Defendants represented to the FDA that it was substantially similar to the Recovery® (the predicate device).

57. The Defendants first received approval from the FDA in 2005 to market the G2® Filter as a permanent placement vena cava filter. Like the Recovery®, the G2® was not initially approved for retrievable use. The Defendants began selling the G2® in about August 2005. Later, in 2008, the G2® Filter was approved by the FDA as a retrievable (optional) IVC filter.

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[10] See, respectively, Retrieval of the Recovery Filter after Arm Perforation, Fracture, and Migration to the Right Ventricle, Hull et. al., J. Vasc. Interv. Radiol. 2008; 19:1107-1111; Prevalence of Fracture and Fragment Embolization of Bard Retrievable Vena Cave Filters and Clinical Implications Including Cardiac Perforation and Tamponade, August 9, 2010 Arch. Intern. Med. (Online Publication 8/9/2010). In 2005, the New England Society for Vascular Surgery reported a 31.7% fracture rate of the Recovery® Filter. This report followed the Society's examination of the FDA "MAUDE" database which records adverse patient-product events, like failure of an IVC filter.

[11] The Recovery Filter System was plagued with manufacturing defects, namely lack of preparation of the exterior surface of the device so as to eliminate gouges in the Nitinol struts of the device. These gouges caused or contributed to cause the Recovery Filter System to fail/ fracture. The G2® Filter continues to have manufacturing defects in the form of Adrawing marks" on the exterior of the device.

The G2 Express® Filter

58. In 2008, the Defendants introduced another "version" of the G2® Filter. This was called the "G2 Express®". The sole difference between the G2 Express® and the G2® Filter is that the G2 Express® has a "snare" or "hook" at the top of the filter to allow an explanting physician an optional way to attempt to snare or hook the top of the device to retrieve the filter- if possible.

Sales of the G2® and G2® Express Filters

59. Upon information and belief, the Defendants sold at least approximately 65,000 of the G2® and G2 Express® filters nationwide during the time the devices were on the market.[12]

A Comparison of the Recovery®

G2® and G2 Express® Filter Systems

60. Recovery®, G2® and G2 Express® Filters bear strong resemblances in a number of different respects. First, they look strikingly similar in appearance and have the same design for filtration. That is, the Recovery®, G2® Filter and G2 Express® have six upper struts used for device positioning and filtering, and, six lower struts used for anchoring and filtering.

61. In addition, the G2® and G2 Express® Filters are made of the same alloy material as the Recovery® Filter. They are all manufactured of Nitinol alloy, discussed supra.

62. Like the Recovery® Filter, the G2/G2 Express® filters are inserted via catheter that is guided by a physician (typically an interventional radiologist) through a blood vessel into the inferior vena cava. Both filters were designed to be retrieved in similar fashion. And, like Recovery®, following implant of the G2® and G2 Express®, physicians use imaging studies to confirm placement and location of the device.

63. Unfortunately, the G2® and G2 Express® filters also share some of the defects of the

[12] See, Medical Devices and the FDA Approval Process: Balancing Safety and Innovation, August 9, 2010, Rita Redberg, M.D.; Dept. of Medicine, Univ. of California San Francisco: published online Archives of Internal Medicine; August 9, 2010. The G2® and G2 Express® devices have been "replaced" by yet another iteration of the device- called the "eclipse®" filter.

Recovery® Filter. The G2® and G2 Express® filters are of insufficient integrity and strength to withstand normal placement within the human body. The global stressors of the respiratory and cardiac cycles of the human body cause the G2® and G2 Express® to develop stress or "fatigue" fractures of the Nitinol surface of the device. This results in fracture of one or more of the struts of the device. The struts will then become imbedded in the anatomy, piercing tissue and organs.

64. Also, like their predecessor, the G2® and G2 Express® suffer from manufacturing defects. These manufacturing defects primarily include the existence of Adraw markings" and circumferential grinding markings on the Nitinol exterior of the surface of the device. The presence of these draw markings and/or circumferential grinding markings compromises the structural integrity of the G2® and G2 Express® while in vivo. In particular, the G2® and G2 Express® are prone to fail at or near the location of draw markings/circumferential grinding markings on the struts of the device. Put simply, the G2® and G2 Express® are not of sufficient strength to withstand normal placement within the human body because of cracks, flaws and gouges in the alloy which makes up the device. The presence of the aforementioned exterior defects makes the device more significantly susceptible to fatigue, failure and resulting fracture.

65. Defendants claim publicly that the G2® and G2 'Express® filters are superior to the Recovery® in that they have enhanced fatigue and migration resistance". However, despite the Defendants' claims concerning the safety and efficacy of the G2® and G2 Express®, the FDA's "MAUDE" (Manufacturer and User Facility Device Experience) database includes several reports of the failure, fracture and migration of the G2® and G2 Express®.

66. Defendants represent the fracture rate of the G2® to be 1.2%. Based upon a review of the data available in the public domain (including the FDA MAUDE database statistics), and the relevant medical literature that has been published, this representation does not accurately reflect the true incidence of device fracture for the G2® and G2 Express®. Rather, the true fracture rate is much higher

than 1.2%- specifically 12%.

67. A review of the MAUDE database from the years 2004-2008 reveals data to establish that the Defendants' vena cava filters (including the G2® Filter) are responsible for a significant percentage of the reported adverse patient events involving vena cava filters. Specifically, the G2® Filter and the Recovery® Filter combine to account for the following statistics:

a. 50% of all "adverse events";

b. 64% of all occurrences of migration of the device;

c. 69% of all occurrences of vena cava wall perforation;

d. 70% of all occurrences of filter fracture.

What Happens When the Recovery®, G2® or G2 Express® Filter Fails?

68. The failure (fracture and/or migration) of these devices leads to a number of different, and potentially fatal, complications. These complications include, but are not limited to:

a. Death;

b. Hemorrhage;

c. Cardiac/pericardial tamponade (pressure caused by a collection of blood in the area around the heart);

d. Severe and persistent pain; and

e. Perforation of tissue, vessels and organs.

69. The person who experiences failure (fracture and/or migration of fractured components) of these devices typically experiences an acute onset of chest pain and shortness of breath. This typically results in the person presenting to an emergency room, hospital, and/or physician for evaluation. The symptoms often resemble a myocardial infarction ("heart attack").

Electro-Polishing - Rather, the Lack Thereof

70. 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 Recovery®, G2® and G2 Express®, and other brands, of IVC filters.

71. 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.

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

73. For years, it has been known by manufacturers of 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.

74. The exterior surfaces of the Recovery®, G2® and G2 Express® were not electro-polished prior to completion of the manufacturing process. This is a manufacturing defect that exists in the Recovery®, G2® and G2 Express® vena cava filters which causes these filters to be structurally weak and susceptible to a significant risk of failure/fracture.

75. In 2010, the Defendants, C.R. BARD, INC., and BARD PERIPHERAL VASCULAR, INC. began marketing a "new" vena cava filter called the "Eclipse®" vena cava filter. The Eclipse® filter is identical to the G2 Express® except for one important difference- the surface of the Eclipse® filter is electro-polished.[13]

76. Defendants, C.R. BARD, INC., and BARD PERIPHERAL VASCULAR, INC.

[13] It too was approved via a 510(k) application to the FDA in which the Defendants again represented that the device was substantially similar to the predicate device- the G2®.

introduced the Eclipse® filter because:

a. The Recovery®, G2® and G2 Express® filters were not electro-polished;

b. It is standard within the industry, and has been for years, to electro-polish Nitinol medical devices including vena cava filters;

c. The Recovery®, G2® and G2 Express® filters were experiencing significantly increased rates of failure/fracture due to the fact that they were not electro-polished.

Retrievability of the Recovery®, G2® and G2 Express®

77. As stated supra, the Recovery®, G2® and G2 Express® filters were/are marketed as "retrievable" or "optional" vena cava filters. However, in a significant number of cases, the device is unable to be removed or safely removed from the human body. In these instances, the device has either perforated tissue or has otherwise become unable to be removed from the vessel, as originally intended by the Defendants. In these instances, the device becomes a "permanent" device, that is, it cannot be removed from the body. Such is the case with the FILTER IMPLANT CLASS Plaintiffs in this case.

78. Each of the Recovery®, G2® and G2 Express® filters implanted in Plaintiffs and the members of the FILTER IMPLANT CLASS are defective and have malfunctioned as they cannot be safely removed from their bodies as intended and marketed by Defendants, and now are "permanent" devices.

THE CASE FOR MEDICAL MONITORING

79. Plaintiffs, DAVID DELEON and RICHARD GONZALEZ, and the FILTER IMPLANT CLASS require medical monitoring to ensure that the Recovery®, G2® and G2 Express® filters implanted within their bodies have not failed/fractured.

80. In order to determine whether failure of a Recovery®, G2® and G2 Express® filter has occurred, imaging studies must be performed. Typically, these imaging studies will include computed tomography scan (CT Scan) or flouroscopy so that the filter may be visualized. CT Scan imaging

produces an image of the filter and is able to reveal whether the filter has failed.

81. Those people requiring medical monitoring, like Plaintiffs, DAVID DELEON and RICHARD GONZALEZ, and the members of the FILTER IMPLANT CLASS, are recommended[14] to undergo regular and frequent imaging studies of the device or portions of the device at least once or twice annually. As long as the device remains within the body of the patient, the potential for future device failure exists. Consequently, these people require regular and frequent medical monitoring for the duration of time the device remains within their bodies.

82. Those eligible for medical monitoring of the Recovery®, G2® and G2 Express® filters need not have experienced past failure of the device. As stated supra, patients who have undergone implant of these devices frequently learn that the devices cannot be removed due to the fact that the device has "grown into" tissue or has become occluded by thrombi, but, that failure/fracture of the device has not yet occurred. As a result of the inability to remove the device, the device must remain permanently implanted in the patient, for the patient's lifetime. Although these patients may not yet have experienced device failure, they are at a significant risk for future device failure and require regular and frequent monitoring to evaluate the integrity of the device.

83. In addition to the aforementioned imaging studies, endovascular intervention (typically cardiac catheterization) may also be used by medical professionals to diagnose or discover whether

[14] In August 2010, the FDA issued a pronouncement concerning the safety of indwelling retrievable vena cava filters. This includes the Recovery®, G2® and G2 Express® devices. The FDA warns physicians about the consequences of long term implant of retrievable IVC filters. These consequences include fracture and migration of devices. Also, medical research studies performed in 2008 and 2010 call for the need of regular and frequent medical monitoring for a patient who had the Recovery vena cava filter implanted in their body. The 2008 research study performed by Jeffrey Hull, M.D. recommends regular and frequent monitoring of patients in whom the Recovery Filter System remains implanted. (Retrieval of the Recovery Filter after Arm Perforation, Fracture, and Migration to the Right Ventricle, Hull et. al., J. Vasc. Interv. Radiol. 2008; 19:1107-1111). Dr. Hull specifically recommends "imaging with unenhanced abdominal CT to look for arm perforation, fracture, or migration to further evaluate the scope and risk posed by this [the Recovery®] filter." The 2010 study, performed by William Nicholson, M.D., Prevalence of Fracture and Fragment Embolization of Bard Retrievable Vena Cave Filters and Clinical Implications Including Cardiac Perforation and Tamponade, August 9, 2010- Arch. Intern. Med. (Online Publication 8/9/2010) demonstrated a high rate of fracture with the Bard G2® and Recovery® devices- 12% and 25% respectively. Dr. Nicholson, et al reported that the rate of fracture for the G2® may not be accurate, and actually, may be higher given the time that the G2® filter may be implanted in the human body.

fractured portions of the device have migrated to the heart or lungs or other organs. Furthermore, endovascular surgery may assess the nature and extent of the damage resulting from failure of the device.

84. The need for medical monitoring of the FILTER IMPLANT CLASS Plaintiffs in this case is a reasonably certain consequence of the placement of the Recovery®, G2® and G2 Express® filters inside their bodies. Each of them is at a significant risk of device failure/fracture in the future- this is a risk to which they would not be exposed but for the conduct of the Defendants as alleged in this Complaint and the implant of the device within their bodies. The seriousness of the complications that can result from device failure encompasses a spectrum of conditions, up to and including sudden death from cardiac hemorrhage. And, there is clear clinical value through well-established medical means, to early detection and diagnosis of device failure.

85. The forms of medical monitoring that will provide early detection and diagnosis of device failure include, but may not be limited to the following medical procedures:

a. CT Scanning;

b. Flouroscopy;

c. "Vena Cava Grams:"

d. Other appropriate imaging studies;

e. Regular physicians' visits and examinations.

DEFENDANTS' KNOWLEDGE OF THE FAILURE OF, AND DANGERS ASSOCIATED WITH, THE RECOVERY® G2® AND G2® EXPRESS FILTERS

86. As early as 2003, the Defendants C.R. Bard, Inc. and Bard Peripheral Vascular, Inc., knew that the Recovery® Filter was defective and was failing/fracturing and causing injury and death to patients other than Plaintiffs in which the device was implanted. Still, despite this knowledge, the Defendants C.R. Bard, Inc. and Bard Peripheral Vascular, Inc., failed to voluntarily recall the

Recovery® Filter, advise the medical community or public of the dangers associated with failure/fracture of the device or otherwise remove the device from the market. Rather, the Defendants C.R. Bard, Inc. and Bard Peripheral Vascular, Inc., kept the device on the market, for sale, for a profit, until such time the G2® Filter was designed, manufactured and ready for sale in August 2005.

87. Upon information and belief, Plaintiffs allege that as early as 2005, Defendants C.R. Bard, Inc. and Bard Peripheral Vascular, Inc., were aware and had knowledge of the fact that the G2® Filter and G2 Express® were also defective and unreasonably dangerous and were causing injury and death to patients who had received the G2® Filter System.

88. Reliable scientific and medical researchers have established that the failure rate of the Recovery®, G2® and G2 Express® filters was/is exceedingly higher than the rate the Defendants have in the past, and currently continue to publish to the medical community and members of the public.

89. Upon information and belief, from the time the Recovery®, G2® and G2 Express® each became available on the market, the Defendants C.R. Bard, Inc. and Bard Peripheral Vascular, Inc., had embarked on an aggressive campaign of "off label marketing" concerning these devices. This included representations made to physicians, healthcare professionals, and other members of the medical community that the devices were safe and effective for retrievable use prior to the FDA approving the devices for retrievable use.

90. Furthermore, once the "Eclipse®" filter was introduced in 2010, the Defendants C.R. Bard, Inc. and Bard Peripheral Vascular, Inc., engaged in a pattern of significantly raising the prices of the G2® and G2 Express® filters in order to motivate their customers to buy the new "Eclipse®" filter and to aggressively phase out by cannibalizing the G2® and G2 Express®. At no time did the Defendants advise the medical community or the public that the reason they were phasing out the G2® and G2 Express® because of failure/fracture concerns due to lack of electro-polishing of the devices. Rather, the Defendants C.R. Bard, Inc., and Bard Peripheral Vascular, Inc., vaguely told customers that

the new device was because of continued product improvements.

91. Further, the Defendants C.R. Bard, Inc., and Bard Peripheral Vascular, Inc., engaged in conduct in marketing the Recovery®, G2® and G2 Express® devices which included offering payments or "kickbacks" to physicians chosen by the Defendants to "promote" these devices. These payments and kickbacks included "honoraria", all expenses paid trips to luxury resorts, pre-paid golf trips at exclusive courses, private jet charters and country clubs and other complimentary leisure activities. Once the regulations changed for device manufacturers in about 2006, the Defendants C.R. Bard, Inc. and Bard Peripheral Vascular, Inc., retained a third party to engage in the process of wooing doctors to become promoters of these devices in order to circumvent the regulations prohibiting such conduct.

92. The conduct of the Defendants C.R. Bard, Inc., and Bard Peripheral Vascular, Inc., as alleged in this Complaint, constituted, outrageous corporate conduct that demonstrates a conscious disregard for the safety of the Plaintiffs. The Defendants C.R. Bard, Inc., and Bard Peripheral Vascular, Inc., had actual knowledge of dangers to the life and limb of the Plaintiffs presented by the Recovery®, G2® and G2 Express® filters, yet consciously failed to act reasonably to:

a. Inform or warn the Plaintiffs, their physicians, or the public at large of the dangers; and

b. Recall the Recovery®, G2® and G2 Express® filters from the market in a timely and safe fashion;

93. Despite having knowledge of the defective and dangerous condition of the Recovery®, G2® and G2 Express® filters as early as 2003 and 2005 and 2008, respectively, the Defendants C.R. Bard, Inc., and Bard Peripheral Vascular, Inc. consciously disregarded the known risks and continued to actively market and offer for sale the Recovery®, G2® and G2 Express® filters.

94. The Plaintiffs further allege that the Defendants C.R. Bard, Inc. and Bard Peripheral Vascular, Inc. acted to serve their own interests and having reason to know and consciously disregarding

the substantial risk that their product might kill or significantly harm patients, or significantly injure the rights of others, and consciously pursued a course of conduct knowing that such conduct created a substantial risk of significant harm to other persons.

FIRST CAUSE OF ACTION

(NEGLIGENCE)

(By Plaintiffs, DAVID DELEON AND RICHARD GONZALEZ on their own behalf and on behalf of the FILTER IMPLANT CLASS Against Defendants C.R. BARD, INC. and BARD PERIPHERAL VASCULAR, INC.)

95. Plaintiffs refer to paragraphs 1 through 94, and, by this reference, incorporate said paragraphs herein as though set forth in full.

96. At all times relevant to this cause of action, the Defendants C.R. Bard, Inc. and Bard Peripheral Vascular, Inc. were in the business of designing, developing, manufacturing, marketing, and selling sophisticated medical devices, including the Recovery®, G2® and G2 Express® filters.

97. At all times relevant to this cause of action, the Defendants C.R. Bard, Inc. and Bard Peripheral Vascular, Inc., were under a duty to act reasonably to design, develop, manufacture, market, and sell a product that did not present a risk of harm or injury to the Plaintiffs and to those people receiving the Recovery®, G2® and G2 Express® filters.

98. At the time of manufacture and sale of the Recovery®, G2® and G2 Express® filters (2003 until present), the Defendants C.R. Bard, Inc. and Bard Peripheral Vascular, Inc., knew or should have known that the Recovery®, G2® and G2 Express® filters:

a. Were designed and manufactured in such a manner so as to present an unreasonable risk of fracture of portions of the device;

b. Were substandard and dangerous in that they were not electro-polished;

c. Were designed and manufactured so as to present a unreasonable risk of migration of the device and/or portions of the device; and/or

d. Were designed and manufactured to have unreasonable and insufficient strength or structural integrity to withstand normal placement within the human body.

99. Despite the aforementioned duty on the part of the Defendants C.R. Bard, Inc. and Bard Peripheral Vascular, Inc., they committed one or more breaches of the duty of reasonable care and were negligent in:

a. Unreasonably and carelessly failing to properly warn of the dangers and risks of harm associated with the Recovery®, G2® and G2 Express® filters, to wit, the incidence of failure of the Recovery®, G2® and G2 Express® filters and/or the likelihood that these filters could not be safely removed;

b. Unreasonably and carelessly manufacturing a product, to wit, Recovery®, G2® and G2 Express® filters, that was insufficient in strength or structural integrity to withstand the foreseeable use of normal placement within the human body;

c. Unreasonably and carelessly designing a product, to wit, Recovery®, G2® and G2 Express® filters, that was insufficient in strength or structural integrity to withstand the foreseeable use of normal placement within the human body; and

d. Unreasonably and carelessly designing a product, to wit, Recovery®, G2® and G2 Express® filters, that presented a risk of harm to the Plaintiffs and others similarly situated in that it was prone to failure.

100. As a direct and a proximate result of the foregoing negligence by Defendants C.R. Bard, Inc., and Bard Peripheral Vascular, Inc., Plaintiffs and members of the FILTER IMPLANT CLASS, have been harmed as they are at a substantially increased risk that their filters will fail and/or fracture, resulting in hemorrhage, cardiac/pericardial tamponade, severe and persistent pain, perforation of tissue, vessels, and organs, and even causing death.

101. As a further direct and proximate result of the foregoing negligence by Defendants C.R.

Bard, Inc., and Bard Peripheral Vascular, Inc., Plaintiffs and members of the FILTER IMPLANT CLASS, have been harmed as the risks posed to their health by Defendants' filters are so significant that they each require regular and frequent medical monitoring for the duration of time that Defendants' filters remain within their bodies. Plaintiffs and members of the FILTER IMPLANT CLASS will be required to expend money and incur obligations for medical and related expenses as a result of this medical monitoring.

102. Plaintiffs further allege that in committing the foregoing negligent acts, Defendants C.R. Bard, Inc. and Bard Peripheral Vascular, Inc. acted in willful, wanton, gross and in total disregard for the health and safety of the user or consumer of their Recovery®, G2® and G2 Express® filters to serve their own interests and having reason to know and consciously disregarding the substantial risk that their product might kill or significantly harm patients, or significantly injure the rights of others, consciously pursued a course of conduct knowing that such conduct created a substantial risk of significant harm to other persons. Defendants C.R. Bard, Inc., and Bard Peripheral Vascular, Inc., therefore, should be required to respond to the FILTER IMPLANT CLASS in the form of a punitive or exemplary damage award.

SECOND CAUSE OF ACTION

(STRICT LIABILITY BASED ON DEFECTIVE PRODUCT MANUFACTURE)

(By Plaintiffs, DAVID DELEON AND RICHARD GONZALEZ on their own behalf and on behalf of the FILTER IMPLANT CLASS Against Defendants C.R. BARD, INC. and BARD PERIPHERAL VASCULAR, INC.)

103. Plaintiffs adopt and incorporate by reference all relevant preceding paragraphs from paragraphs 1-102 supra as paragraphs of this Second Cause of Action.

104. When the Recovery®, G2® and G2 Express® filters were manufactured, and sold by the Defendants C.R. Bard, Inc. and Bard Peripheral Vascular, Inc, they were in a defective and unreasonably

dangerous condition in one or more of the following respects:

a. They were manufactured so as to be insufficient to withstand the foreseeable use of placement in the human body; and

b. They were manufactured defectively inasmuch as the exterior surface of the Recovery®, G2® and G2 Express® filters were inadequately, improperly, and inappropriately prepared and/or finished causing the device to weaken and fail.

105. As a direct and a proximate result of the foregoing defective and unreasonably dangerous condition of the products of Defendants C.R. Bard, Inc., and Bard Peripheral Vascular, Inc., Plaintiffs and members of the FILTER IMPLANT CLASS, have been harmed as they are at a substantially increased risk that their filters will fail and/or fracture, resulting in hemorrhage, cardiac/pericardial tamponade, severe and persistent pain, perforation of tissue, vessels, and organs, and even causing death.

106. As a further direct and a proximate result of the foregoing defective and unreasonably dangerous condition of the products of Defendants C.R. Bard, Inc., and Bard Peripheral Vascular, Inc., Plaintiffs and members of the FILTER IMPLANT CLASS, have been harmed as the risks posed to their health by Defendants' filters are so significant that they each require regular and frequent medical monitoring for the duration of time that Defendants' filters remain within their bodies. Plaintiffs and members of the FILTER IMPLANT CLASS will be required to expend money and incur obligations for medical and related expenses as a result of this medical monitoring.

107. Plaintiffs further allege that the Defendants C.R. Bard, Inc., and Bard Peripheral Vascular, Inc. acted to serve their own interests and having reason to know and consciously disregarding the substantial risk that their product might kill or significantly harm patients, or significantly injure the rights of others, consciously pursued a course of conduct knowing that such conduct created a substantial risk of significant harm to other persons. Defendants C.R. Bard, Inc., and Bard Peripheral Vascular, Inc., therefore, should be required to respond to the FILTER IMPLANT CLASS in the form of a

punitive or exemplary damage award.

THIRD CAUSE OF ACTION

(STRICT LIABILITY BASED ON DEFECTIVE PRODUCT DESIGN)

(By Plaintiffs, DAVID DELEON AND RICHARD GONZALEZ on their own behalf and on behalf of the FILTER IMPLANT CLASS Against Defendants C.R. BARD, INC. and BARD PERIPHERAL VASCULAR, INC.)

108. Plaintiffs adopt and incorporate by reference all relevant preceding paragraphs from paragraphs 1-107 supra as paragraphs of this Third Cause of Action.

109. When the Recovery®, G2® and G2 Express® filters were designed, manufactured, and sold by the Defendants C.R. Bard, Inc., and Bard Peripheral Vascular, Inc., they were in a defective and unreasonably dangerous condition because the exterior surface of the Recovery®, G2® and G2 Express® filters were inadequately, improperly, and inappropriately prepared and/or finished, causing the device to be at substantial risk of weakening and failure. The risk of failure and resultant injury from the IVC filters is of a different nature and kind than other implants and presents risks to Plaintiffs above and beyond the usual foreign body reaction and rejection risks of other implants. The substantially increased risks of injury to Plaintiffs derives from Defendants' defective design of the implants which design does not include electro-polishing as part of the implants' design, subjecting them to substantially increased risks of fracture and failure that are absent in other implants.

110. As a direct and a proximate result of the defective design of the products of Defendants C.R. Bard, Inc., and Bard Peripheral Vascular, Inc., Plaintiffs and members of the FILTER IMPLANT CLASS, have been harmed as they are at a substantially increased risk that their filters will fail and/or fracture, resulting in hemorrhage, cardiac/pericardial tamponade, severe and persistent pain, perforation of tissue, vessels, and organs, and even causing death.

111. As a further direct and a proximate result of the defective design of the products of

Defendants C.R. Bard, Inc., and Bard Peripheral Vascular, Inc., Plaintiffs and members of the FILTER IMPLANT CLASS, have been harmed as the risks posed to their health by Defendants' filters are so significant that they each require regular and frequent medical monitoring for the duration of time that Defendants' filters remain within their bodies. Plaintiffs and members of the FILTER IMPLANT CLASS will be required to expend money and incur obligations for medical and related expenses as a result of this medical monitoring.

112. Plaintiffs further allege that the Defendants C.R. Bard, Inc., and Bard Peripheral Vascular, Inc. acted to serve their own interests and having reason to know and consciously disregarding the substantial risk that their product might kill or significantly harm patients, or significantly injure the rights of others, consciously pursued a course of conduct knowing that such conduct created a substantial risk of significant harm to other persons. Defendants C.R. Bard, Inc., and Bard Peripheral Vascular, Inc., therefore, should be required to respond to the FILTER IMPLANT CLASS in the form of a punitive or exemplary damage award.

FOURTH CAUSE OF ACTION

(STRICT LIABILITY - WARNING DEFECT)

(By Plaintiffs, DAVID DELEON AND RICHARD GONZALEZ on their own behalf and on behalf of the FILTER IMPLANT CLASS Against Defendants C.R. BARD, INC. and BARD PERIPHERAL VASCULAR, INC.)

113. Plaintiffs adopt and incorporate by reference all relevant preceding paragraphs from paragraphs 1-112 supra as paragraphs of this Fourth Cause of Action.

114. At all times material herein, Defendants C.R. Bard, Inc. and Bard Peripheral Vascular, Inc. were in the business of designing, developing, manufacturing, marketing, and selling sophisticated medical devices, including the Recovery®, G2® and G2 Express® filters.

115. Defendants' Recovery®, G2® and G2 Express® filters were defective, because they

lacked warnings adequate to apprise Plaintiffs, members of the FILTER IMPLANT CLASS, and members of the medical community of the substantial hazards posed by these filters, including the significant and actual risk that their filters would fail and/or fracture, resulting in hemorrhage, cardiac/pericardial tamponade, severe and persistent pain, perforation of tissue, vessels, and organs, and even death.

116. Defendants' Recovery®, G2® and G2 Express® filters also were defective, because they lacked warnings adequate to apprise Plaintiffs, members of the FILTER IMPLANT CLASS, and members of the medical community of the actual incidence of failure of the Recovery®, G2® and G2 Express® filters.

117. Defendants' Recovery®, G2® and G2 Express® filters also were defective, because they lacked warnings adequate to apprise Plaintiffs, members of the FILTER IMPLANT CLASS, and members of the medical community of the substantial risk that these filters could not be safely removed from the human body as intended and would have to remain permanent devices.

118. Defendants' Recovery®, G2® and G2 Express® filters further were defective, because they lacked warnings adequate to apprise Plaintiffs, members of the FILTER IMPLANT CLASS, and members of the medical community of the fact that these Nitinol devices were not electro-polished, as was standard in the industry.

119. Plaintiffs and members of the FILTER IMPLANT CLASS each were implanted with one of Defendants' Recovery®, G2® and G2 Express® filters, and these filters remain in their bodies.

120. As a direct and proximate result of the defective warnings of Defendants' Recovery®, G2® and G2 Express® filters, Plaintiffs and members of the FILTER IMPLANT CLASS, have been harmed as they are at a substantially increased risk that their filters will fail and/or fracture, resulting in hemorrhage, cardiac/pericardial tamponade, severe and persistent pain, perforation of tissue, vessels, and organs, and even causing death.

121. As a further direct and proximate result of the defective warnings of Defendants' Recovery®, G2® and G2 Express® filters, Plaintiffs and members of the FILTER IMPLANT CLASS, have been harmed as the risks posed to their health by Defendants' filters are so significant that they each require regular and frequent medical monitoring for the duration of time that Defendants' filters remain within their bodies. Plaintiffs and members of the FILTER IMPLANT CLASS will be required to expend money and incur obligations for medical and related expenses as a result of this medical monitoring.

122. Plaintiffs further allege that the Defendants C.R. Bard, Inc., and Bard Peripheral Vascular, Inc. acted to serve their own interests and having reason to know and consciously disregarding the substantial risk that their product might kill or significantly harm patients, or significantly injure the rights of others, consciously pursued a course of conduct knowing that such conduct created a substantial risk of significant harm to other persons. Defendants C.R. Bard, Inc., and Bard Peripheral Vascular, Inc., therefore, should be required to respond to the FILTER IMPLANT CLASS in the form of a punitive or exemplary damage award.

FIFTH CAUSE OF ACTION

(FRAUDULENT CONCEALMENT)

(By Plaintiffs, DAVID DELEON AND RICHARD GONZALEZ on their own behalf and on behalf of the FILTER IMPLANT CLASS Against Defendants C.R. BARD, INC. and BARD PERIPHERAL VASCULAR, INC.)

123. Plaintiffs adopt and incorporate by reference all relevant preceding paragraphs from paragraphs 1–122 supra as paragraphs of this Fifth Cause of Action.

124. At all times relevant to this cause of action, Defendants were in the business of designing, developing, manufacturing, marketing, selling, and distributing sophisticated medical devices, including the Recovery®, G2® and G2 Express® filters.

125. Defendants' Recovery®, G2® and G2 Express® filters were defectively manufactured and designed, such that they pose a substantial risk of failure and/or fracture and serious adverse health risks, including but not limited to, death, hemorrhage, cardiac/pericardial tamponade, severe and persistent pain, and perforation of tissue, vessels, and organs.

126. Defendants were aware of the defective nature of their Recovery®, G2® and G2 Express® filters, and the risks associated therewith.

127. As the manufacturers, distributors, marketers, and sellers of sophisticated medical devices, including the Recovery®, G2® and G2 Express® filters, Defendants were under a legal duty to fully disclose the hazards of their products to Plaintiffs and other members of the FILTER IMPLANT CLASS, the public at large, and the medical community.

128. Defendants also owed a duty to disclose the hazardous nature of their Recovery®, G2® and G2 Express® filters to Plaintiffs and members of the FILTER IMPLANT CLASS, the public at large, and the medical community, because Defendants alone had knowledge of material facts, to wit, the hazardous nature of their Recovery®, G2® and G2 Express® filters, which were not accessible to Plaintiffs and members of the FILTER IMPLANT CLASS, the public at large, and the medical community.

129. Defendants also owed a duty to disclose the hazardous nature of their Recovery®, G2® and G2 Express® filters to Plaintiffs and members of the FILTER IMPLANT CLASS, the public at large, and the medical community, because Defendants made representations regarding their Recovery®, G2® and G2 Express® filters, but failed to disclose additional facts which materially qualify the facts disclosed, and/or which rendered the disclosures made likely to mislead Plaintiffs, the public at large, and the medical community.

130. Notwithstanding their knowledge of the hazardous nature of their Recovery®, G2® and G2 Express® filters, at all material times hereto, Defendants concealed said hazards from Plaintiffs and

members of the FILTER IMPLANT CLASS, the public at large, and the medical community, so that these groups or individuals would use or authorize use of Defendants' Recovery®, G2® and G2 Express® filters.

131. Plaintiffs and members of the FILTER IMPLANT CLASS, the public at large, and the medical community were unaware of the hazards of Defendants' Recovery®, G2® and G2 Express® filters and would not have acted as they did had they known of said hazards.

132. As a direct and proximate result of Defendants' fraudulent concealment of the hazards of their Recovery®, G2® and G2 Express® filters, from Plaintiffs and members of the FILTER IMPLANT CLASS, the public at large, and the medical community, Defendants' Recovery®, G2® and G2 Express® filters were implanted in Plaintiffs and members of the FILTER IMPLANT CLASS.

133. As a further direct and proximate result of Defendants' fraudulent concealment of the hazards of their Recovery®, G2® and G2 Express® filters, from Plaintiffs and members of the FILTER IMPLANT CLASS, the public at large, and the medical community, Plaintiffs and members of the FILTER IMPLANT CLASS have been harmed as they are at a substantially increased risk of hemorrhage, cardiac/pericardial tamponade, severe and persistent pain, and perforation of tissue, vessels, and organs, and even of death.

134. As a further direct and proximate result of Defendants' fraudulent concealment of the hazards of their Recovery®, G2® and G2 Express® filters, from Plaintiffs and members of the FILTER IMPLANT CLASS, the public at large, and the medical community, Plaintiffs and members of the FILTER IMPLANT CLASS, have been harmed as the risks posed to their health by Defendants' filters are so significant that they each require regular and frequent medical monitoring for the duration of time that Defendants' filters remain within their bodies. Plaintiffs and members of the FILTER IMPLANT CLASS will be required to expend money and incur obligations for medical and related expenses as a result of this medical monitoring.

135. Plaintiffs further allege that Defendants, C.R. Bard, Inc., and Bard Peripheral Vascular, Inc., acted in willful, wanton, gross and in total disregard for the health and safety of the user or consumer of their Recovery®, G2® and G2 Express® filters to serve their own interests and having reason to know and consciously disregarding the substantial risk that their product might kill or significantly harm patients, or significantly injure the rights of others, and consciously pursued a course of conduct knowing that such conduct created a substantial risk of significant harm to other persons. Defendants, C.R. Bard, Inc., and Bard Peripheral Vascular, Inc., therefore, should be required to respond to the Plaintiffs in the form of a punitive or exemplary damage award.

SIXTH CAUSE OF ACTION

(BREACH OF IMPLIED WARRANTIES)

(By Plaintiffs, DAVID DELEON AND RICHARD GONZALEZ on their own behalf and on behalf of the FILTER IMPLANT CLASS Against Defendants C.R. BARD, INC. and BARD PERIPHERAL VASCULAR, INC.)

136. Plaintiffs adopt and incorporate by reference all relevant preceding paragraphs from paragraphs 1-135 supra as paragraphs of this Sixth Cause of Action.

137. At all times relevant to this cause of action, Defendants were in the business of designing, developing, manufacturing, marketing, selling, and distributing sophisticated medical devices, including the Recovery®, G2® and G2 Express® filters.

138. Each of the respective Plaintiffs in this case purchased the Recovery®, G2® or G2 Express® vena cava filters from the Defendants C.R. Bard, Inc., and Bard Peripheral Vascular, Inc.

139. At the time of Plaintiffs' purchase of the Recovery®, G2® or G2 Express® from the Defendants, they were not in a merchantable condition, because they were manufactured in such a manner so that the exterior surface of the G2® or G2 Express® was inadequately, improperly and inappropriately prepared and/or finished, thereby subjecting the device to weakening and failure.

140. Defendants' Recovery®, G2® and G2 Express® filters that were implanted in Plaintiffs and members of the FILTER IMPLANT CLASS are hazardous, inasmuch as they are accordingly at a significant risk of failure and/or fracture.

141. By selling their Recovery®, G2® and G2 Express® filters to Plaintiffs, Defendants impliedly warranted that their filters were reasonably fit for their intended uses, that their filters were of merchantable quality, that they were not defective, that they would function as safely as ordinary users would expect when used in an intended or reasonably foreseeable manner, and that they would not cause serious harm or death.

142. Defendants, and each of them, breached said implied warranties, because their Recovery®, G2® and G2 Express® filters were not reasonably fit for their intended uses, were not of merchantable quality, were defective, failed to function as safely as an ordinary user would expect when used in an intended or reasonably foreseeable manner, and because they present a substantially increased risk of failure and or fracture, and likely consequent future injury to Plaintiffs and members of the FILTER IMPLANT CLASS.

143. As a direct and proximate result of Defendants' breaches of the foregoing implied warranties, Plaintiffs and members of the FILTER IMPLANT CLASS, have been harmed as they are at a substantially increased risk of hemorrhage, cardiac/pericardial tamponade, severe and persistent pain, perforation of tissue, vessels, and organs, and even death.

144. As a further direct and proximate result of Defendants' breaches of the foregoing implied warranties, Plaintiffs and members of the FILTER IMPLANT CLASS, have been harmed as the risks posed to their health by Defendants' filters are so significant that they each require regular and frequent medical monitoring for the duration of time that Defendants' filters remain within their bodies. Plaintiffs and members of the FILTER IMPLANT CLASS will be required to expend money and incur obligations for medical and related expenses as a result of this medical monitoring.

145. Plaintiffs further allege that the Defendants C.R. Bard, Inc., and Bard Peripheral Vascular, Inc. acted to serve their own interests and having reason to know and consciously disregarding the substantial risk that their product might kill or significantly harm patients, or significantly injure the rights of others, consciously pursued a course of conduct knowing that such conduct created a substantial risk of significant harm to other persons.

SEVENTH CAUSE OF ACTION

(NEGLIGENT BREACH OF DUTY TO WARN POST-SALE OF DEVICE FAILURE)

(By Plaintiffs, DAVID DELEON AND RICHARD GONZALEZ on their own behalf and on behalf of the FILTER IMPLANT CLASS Against Defendants C.R. BARD, INC. and BARD PERIPHERAL VASCULAR, INC.)

146. Plaintiffs adopt and incorporate by reference all relevant preceding paragraphs from paragraphs 1-145 supra as paragraphs of this Seventh Cause of Action.

147. A product manufacturer, such as Defendants, C.R. Bard, Inc., and Bard Peripheral Vascular, Inc., has a duty to provide adequate, effective warning to foreseeable users of the product.

148. The duty to warn imposed on a product manufacturer, such as Defendants, C.R. Bard, Inc., and Bard Peripheral Vascular, Inc., is a continuing duty that extends past the time of sale and includes an obligation to warn of dangers the manufacturer discovers after sale.

149. Since the time the Recovery®, G2® or G2 Express® was/were introduced to the market, Defendants, C.R. Bard, Inc., and Bard Peripheral Vascular, Inc., became aware of various injuries and life threatening consequences resulting from the manufacture, and sale of their Recovery®, G2® or G2 Express® as implanted in patients across the country other than Plaintiffs herein.

150. Once the Defendants, C.R. Bard, Inc. and Bard Peripheral Vascular, Inc., became aware of or gained knowledge of the fact that the Recovery®, G2® or G2 Express® were defective and failing, as stated supra, the Defendants were under a duty to warn the Plaintiffs, the Plaintiffs' medical providers

and the public at large of the dangers and risks associated with these devices.

151. Upon information and belief, the Defendants, C.R. Bard, Inc., and Bard Peripheral Vascular, Inc., maintained records of sales to indicate (a) the point of sale of each of the devices/ products it sold, and (b) to whom the device/product was sold.

152. Despite such knowledge, as aforesaid, the Defendants, C.R. Bard, Inc., and Bard Peripheral Vascular, Inc., failed to notify or warn the medical professionals or end users/purchasers of the dangers and risk associated with the Recovery®, G2® or G2 Express® filters so as to permit them to monitor the device's integrity, and remove the device if appropriate before injury occurred.

153. In failing to notify or warn, as set forth supra, the Defendants, C.R. Bard, Inc., and Bard Peripheral Vascular, Inc., breached their duty of care and were negligent.

154. As a direct and proximate result of Defendants' negligent failure to provide post-sale warnings of the hazards and risks of implant failure and fracture, Plaintiffs and members of the FILTER IMPLANT CLASS have been harmed as they are at a substantially increased risk of hemorrhage, cardiac/pericardial tamponade, severe and persistent pain, and perforation of tissue, vessels, and organs, and even of death.

155. As a direct and proximate result of the conduct of the Defendants, C.R. Bard, Inc., and Bard Peripheral Vascular, Inc., as aforesaid, Plaintiffs and members of the FILTER IMPLANT CLASS, have had implanted within their bodies a device which is significantly prone to failure, and, which may fracture at any time. Plaintiffs and the members FILTER IMPLANT CLASS have been harmed as they will be required to undergo any number of defined medical procedures into the future to ensure that the device implanted within their bodies (the Recovery®, G2® or G2 Express® filters) has not failed/fractured. Of course, to obtain these procedures, Plaintiffs and the members of the FILTER IMPLANT CLASS will be required to incur future expense.

PRAYER FOR JUDGMENT AND RELIEF

WHEREFORE, Plaintiffs, DAVID DELEON AND RICHARD GONZALEZ, and the FILTER IMPLANT CLASS Plaintiffs pray for judgment against Defendants, including Defendants, C.R. Bard, Inc., and Bard Peripheral Vascular, Inc., for:

Class Certification

1. For certification of this cause as a class action suit pursuant to California Code of Civil Procedure § 382 and for definition of the class as follows: "All persons who received implant of a non-electro-polished inferior vena cava filter designed, manufactured and sold by the Defendants, C.R. Bard, Inc. and/or Bard Peripheral Vascular, Inc., to wit, the Recovery®, G2® and/or G2 Express® vena cava filters, and who continue to have said device(s) implanted within their bodies."

Medical Monitoring

2. For medical monitoring, to provide Plaintiffs and the FILTER IMPLANT CLASS with periodic medical examinations and such other medical procedures as are reasonably necessary and designed to facilitate early detection and treatment of conditions related to the fracture of the Recovery®, G2® and G2 Express® vena cava filters.

3. For medical monitoring, to provide for a Court supervised medical monitoring program to gather and forward to treating physicians of Plaintiffs and the FILTER IMPLANT CLASS information relating to the prevention, detection, and treatment of conditions related to fracture of the Recovery®, G2® or G2 Express® vena cava filters.

Punitive Damages

4. For punitive and exemplary damages, sufficient to punish Defendants and deter others from engaging in conduct which is so despicable, fraudulent, malicious, oppressive and perpetrated in violation of patients' rights to health and safety

Costs of Suit

5. For Plaintiffs' costs of suit incurred herein.

Attorney's Fees and Costs

6. For Plaintiffs' reasonable attorney's fees, pursuant to *California Code of Civil Procedure* § 1021.5.

Other Relief

7. For such other and further relief as the Court deems just and proper.

Dated this 9th day of August, 2012

LOPEZ McHUGH LLP

By: _____

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Attorneys for Plaintiffs, DAVID DELEON AND RICHARD GONZALEZ , on behalf of themselves and the class of all others similarly situated

DEMAND FOR JURY TRIAL

Pursuant to *California Code of Civil Procedure* § 600 et seq. (and Rule 38 of the *Federal Rules of Civil Procedure* should this case ever be removed to federal court), Plaintiffs hereby demand trial by jury of all issues which may be tried to a jury.

Dated this 9th day of August, 2012

LOPEZ McHUGH LLP

By: _____
Ramon Rossi Lopez
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