IN THE CIRCUIT COURT IN AND FOR
THE FIFTEENTH JUDICIAL CIRCUIT,
PALM BEACH COUNTY, FLORIDA
CASE NO.:

SAMANTHA BOULDRY, EULA HUFF, SANDRA LORENZ, and JANET ROBERTS on behalf of themselves and the class of all others similarly situated,

50 2012 CA 013660 XXXX MB

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 20, INCLUSIVE;

Defendants.
_____/

COPY
RECEIVED FOR FILIN
JUL 26 2012
SHARON R. BOCK
CLERK & COMPTROLLER
CIRCUIT CIVIL DIVISION

CLASS ACTION COMPLAINT FOR MEDICAL MONITORING

COMES NOW the Plaintiffs, SAMANTHA BOULDRY, EULA HUFF, SANDRA LORENZ, JANET ROBERTS (hereinafter referred to as "Plaintiffs"), by and through their undersigned attorneys, bring this action pursuant to Florida Rule of Civil Procedure 1.220(a) and 1.220(b) for themselves and other similarly situated, and sue Defendants, C.R. BARD, INC., a New Jersey Corporation, BARD PERIPHERAL VASCULAR, INC., an Arizona corporation and DOE DEFENDANTS 1 through 20, INCLUSIVE, (hereinafter referred to as

"Defendants"). Plaintiffs seek certification of this matter as a class action. For their complaint against Defendants, Plaintiffs allege as follows:

NATURE OF THE CASE

1. This action is brought by SAMANTHA BOULDRY, EULA HUFF, SANDRA LORENZ, JANET ROBERTS as a Class Action on their behalf and on behalf of all other persons similarly situation, under the provisions of Rule 1.220(a) and 1.220(b)(3) seeking to establish a medical monitoring fund or to otherwise recover the cost of providing medical monitoring to the proposed class of plaintiffs.

2. This Class consists of all persons who have had implantation of "inferior vena cava filters" (hereinafter "IVC filters") designed, manufactured, distributed and sold by the defendants C.R. BARD, INC., a New Jersey Corporation and BARD PERIPHERAL VASCULAR, INC., an Arizona corporation and who have the device(s), or portion thereof, remaining within their anatomy.

THE PARTIES

Plaintiffs

3. At all material times, SAMANTHA BOULDRY has been residing in the state of Florida. In January 2009, SAMANTHA BOULDRY was implanted with a G2® IVC Filter manufactured by Defendants named herein. To date, the G2® IVC Filter manufactured by Defendants implanted in SAMANTHA BOULDRY has not yet fractured, migrated or otherwise failed and she has suffered no injury therefrom.

4. At all material times hereto EULA HUFF has been residing in the state of Florida. In October 2008, EULA HUFF was implanted with a G2® IVC Filter manufactured by Defendants named herein. To date, the G2® IVC Filter manufactured by defendants implanted in EULA HUFF has not yet fractured, migrated or otherwise failed and she has suffered no injury therefrom.

5. At all material times hereto SANDRA LORENZ has been residing in the state of Florida. In May 2010, SANDRA LORENZ was implanted with a G2 Express® IVC Filter manufactured by Defendants named herein. To date, the G2 Express® IVC Filter manufactured by defendants implanted in SANDRA LORENZ has not yet fractured, migrated or otherwise failed and she has suffered no injury therefrom.

6. At all material times hereto JANET ROBERTS has been residing in the state of Florida. In February 2007, JANET ROBERTS was implanted with a G2® IVC Filter manufactured by Defendants named herein. To date, the G2® IVC Filter manufactured by defendants implanted in JANET ROBERTS has not yet fractured, migrated or otherwise failed and she has suffered no injury therefrom.

Defendants

7. Defendant C.R. BARD, INC., is a New Jersey Corporation, which at all material times hereto, was doing business in the County of Palm Beach County where it sold and distributed the subject IVC filters.

8. Defendant BARD PERIPHERAL VASCULAR, INC., is an Arizona corporation which at all material times hereto, was doing business in the County of Palm Beach County where it sold and distributed the subject IVC filters.

9. 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".

10. Plaintiffs do not currently know the names of Does 1-20, inclusive. Plaintiffs allege that each Doe Defendant is legally responsible in some manner for damages sought herein.

11. Each Defendant has been the parent-subsidiary, alter ego, agent, apparent agent, joint venturer, or employee of each of the remaining defendants, and in the conduct alleged herein, each has been acting within the course and scope of said parent-subsidiary relationship, alter ego, agency, employment, or joint venture with the advanced knowledge, acquiescence, or subsequent ratification of each and every remaining Defendant.

STATEMENT OF JURISDICTION, VENUE AND NON-REMOVABILITY

12. This is an action for a medical monitoring fund that exceeds Fifteen Thousand Dollars ($15,000) exclusive of costs, interest, attorneys fees, and as such, pursuant to Fla. Stat. §26.012, subject matter jurisdiction is properly exercised over this action.

13. All Plaintiffs and the putative class are all citizens of the State of Florida and all received their IVC filters while residing in the State of Florida.

14. Each of the Defendants named herein, at all times relevant to this Complaint operated, conducted, engaged in, or carried on a business in Florida

or had an office or agency in Florida, and IVC Filters are distributed throughout the State of Florida including Palm Beach County in a defective state. Florida, personal jurisdiction is properly exercised over each of the defendants to this action pursuant to Fla. Stat §48.193.

15. 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.

16. Specifically, this action does not allege that either the class representative or the class members have suffered any "injury in fact" to their person or property within the meaning of Article III of the United States Constitution. 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 are likely to fracture, perforate, migrate, or otherwise fail and cause future injuries due to their defective design and manufacture.

17. A complaint alleging that the plaintiff has no present injury to a 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.* 57 F.Supp.2d 947 (C.D. Cal. 1999)(citing *Lujan v. Defenders*

of Wildlife, 504 U.S. 555, 560(1992)). This action may not be removed to federal court notwithstanding diversity of citizenship.

CLASS ALLEGATIONS

18. This action is brought pursuant to F.R.C.P. 1.220(a) and 1.220(b)(3) by Plaintiffs SAMANTHA BOULDRY, EULA HUFF, SANDRA LORENZ, JANET ROBERTS on behalf of themselves and others similarly situated to create a medical monitoring fund and/or other available relief other than damages for an "injury in fact."

19. The class represented by Plaintiffs SAMANTHA BOULDRY, EULA HUFF, SANDRA LORENZ, JANET ROBERTS, consists of all persons who have had implantation of IVC filter(s) designed, manufactured, distributed an 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".

20. On information and belief, the proposed FILTER IMPLANT CLASS consists of thousands of members located throughout the State of Florida. The members of the FILTER IMPLANT CLASS are so numerous that joinder of individual members herein is impracticable.

21. 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 likely 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.

22. The claims of SAMANTHA BOULDRY, EULA HUFF, SANDRA LORENZ, JANET ROBERTS 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.

23. The representative Plaintiffs, SAMANTHA BOULDRY, EULA HUFF, SANDRA LORENZ, JANET ROBERTS, can and will fairly and adequately protect the interests of the FILTER IMPLANT CLASS.

24. 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 F.R.C.P. 1.220.

TOLLING OF THE STATUTE OF LIMITATIONS

No Injury

25. When Plaintiffs and members of the FILTER IMPLANT CLASS were implanted with the Recovery®, G2® and/or the G2 Express®, vena cava filters, they experienced no "injury in fact" 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 reasonable 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

26. 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 hazards associated with their Recovery®, G2® and/or the G2 Express® vena cava filters to include migration, fracture and perforation (hereinafter collectively referred to as "filter failure") that were implanted in Plaintiffs and members of the FILTER IMPLANT CLASS.

27. At all material times hereto, Defendants fraudulently concealed the hazards of their Recovery®, G2® and/or the G2 Express® vena cava filters that exist as a result of the manufacturing process of these filters, namely, significant risk that filter failure will occur which may lead to death, hemorrhage, injury to the

lung(s) cardiac/pericardial tamponade, injury to the heart and/or lung(s), severe and persistent pain, and perforation of tissue, vessels and organs.

28. 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 for medical monitoring arising from Defendants' concealment.

29. 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 the likelihood of future injury.

Discovery of Defect of the Implanted IVC Filters

30. Prior to January 2009, Plaintiff SAMANTHA BOULDRY did not discover, and could not reasonably have discovered, that the G2® Filter was fraught with the problems described in detail *infra*. Plaintiff was blamelessly unaware of the defective and dangerous condition of the G2® Filter until these times.

31. Prior to May 2010, Plaintiff SANDRA LORENZ did not discover, and could not reasonably have discovered, that the G2 Express® Filter was fraught with the problems described in detail *infra*. Plaintiff was blamelessly

unaware of the defective and dangerous condition of the G2 Express® Filter until these times.

32. Prior to October 2008, Plaintiff EULA HUFF did not discover, and could not reasonably have discovered, that the G2® Filter was fraught with the problems described in detail *infra*. Plaintiff was blamelessly unaware of the defective and dangerous condition of the G2® Filter until these times.

33. Prior to February 2007, Plaintiff JANET ROBERTS did not discover, and could not reasonably have discovered, that the G2® Filter was fraught with the problems described in detail *infra*. Plaintiff was blamelessly unaware of the defective and dangerous condition of the G2® Filter until these times.

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

34. 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 hazards associated with the Recovery®, G2® , and G2 Express® vena cava filters to which Plaintiffs, SAMANTHA BOULDRY, EULA HUFF, SANDRA LORENZ, JANET ROBERTS, and members of the FILTER IMPLANT CLASS had implanted in their bodies.

35. Defendants C.R. BARD, INC and BARD PERIPHERAL VASCULAR, INC.'s fraudulent concealment was sufficiently complete that the 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.

GENERAL ALLEGATIONS
IVC Filters Generally

36. 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.

37. An IVC filter is a device that is designed to filter or "catch" 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, commonly, within the inferior vena cava.

38. The inferior vena cava is a vein that returns blood to the heart from the lower portions of the body. For various reasons, thrombi travel from the vessels in the legs and pelvis, through the vena cava and into the lungs. These thrombi are called "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.

39. 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. 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.

40. 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.

41. 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.

42. The Recovery® Filter System[1] was introduced to the market April 2003 as a permanent device and then an optionally retrievable form of the Recovery IVC filter was introduced shortly thereafter in July 2003.

43. The IVC filters at issue in this case bear the trademark name "Recovery®", "G2®", and "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 (when FDA approval was received) until the present.

The Recovery® Filter System

44. In 2002, the Defendants C.R. Bard, Inc. and/or Bard Peripheral Vascular, Inc., applied to the United States Food and Drug Administration

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

("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. Defendants began marketing the IVC filter in April 2003. The defendants also received FDA approval for an optionally retrievable Recovery® Filter System in July 2003. Thus, the Recovery® Filter System could be permanently implanted or optionally retrieved by a physician as indicated in the "Instructions for Use" (IFU) for the optionally retrievable version: "Recovery filter may be removed according to the instructions supplied in Section labeled: **Optional Procedure for Filter Removal**." (emphasis in original).

45. 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 Ordinance 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.

46. After receiving FDA approval in 2002, the Recovery® Filter System was first marketed for sale by the Defendants on or about April 2003. On or

[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 doing so, 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.

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.

47. 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.

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

49. 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.

---

[3] Mr. Weiland was defendant C.R. Bard, Inc's President and Chief Operating Officer.
[4] Typically, although not universally, an IVC filter is placed by an interventional radiologist. The procedure is called an "endovascular" medical procedure.

Post Implant Failure of the Recovery® Filter

50. There is documented medical evidence of the fact that the Recovery® Filter System is prone to failure following placement within the human body. Since the introduction in 2003 of permanent and optionally retrievable IVC filters, 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.

51. 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%-31.7%.[5]

52. 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 Recovery® Filter's struts have been observed to perforate the walls of the vena cava. When this occurs, the

[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 ™ *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 Recover™ Filter System. This same study called for "additional studies to determine the long term safety of the device."

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.

53. 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]

54. 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.

55. 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®.

---

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

56. 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 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

57. The permanent and optionally retrievable Recovery® Filters were on the market from on or about April 2003 (July 2003 for optionally retrievable version) 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®

58. The G2® Filter is the successor device to the Recovery® Filter, it is constructed of Nitinol and is designed to filter blood clots (thrombi) from the human circulatory system.

59. 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.

60. 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

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

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.

61. 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. These rates of fracture have been studied 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]

62. 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]

63. On or about late 2004, the Defendants made a decision to introduce a substitute vena cava filter for the Recovery® Filter. This substitute

---

[10] *See*, respectively, *Retrieval of the Recovery Filter after Arm Perforation, Fracture, and Migration to the Right Ventricle, Hull et. al.*, J. Vasco Interv. Radiol. 2008; 19:1107-1111; *Prevalence of Fractre and Fragment Embolization of Bard Retrievable Veba 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

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.

64. 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® Filter (the predicate device).

65. 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.

THE G2® Express Filter

66. 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 tops 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.

---

fail/ fracture. The G2 Filter continues to have manufacturing defects in the form of "drawing

Sales of the G2® and G2® Express Filters

67. 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

68. 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.

69. 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*.

70. 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 have the optional capability 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.

---

marks" on the exterior of the device

[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.

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

72. Also, like their predecessor, the G2® and G2 Express® suffer from manufacturing defects. These manufacturing defects primarily include the existence of "draw 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.

73. 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 reports of the failure, fracture and migration of the G2® and G2 Express®.

74. 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%.

75. 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?

76. The failure (fracture, **perforation** 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

77. The person who experiences failure (fracture, perforation 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 Was Not Performed

78. 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.

79. 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.

80. 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.

81. 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.

82. 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.

83. 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]

84. Defendants, C.R. BARD, INC., and BARD PERIPHERAL VASCULAR, INC. introduced the Eclipse® filter because:

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

[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®.

b. It is standard in 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®

85. As stated *supra*, the Recovery®, G2® and G2 Express® filters were/are marketed as "retrievable" or "optionally" retrievable vena cava filters. However, in a significant number of cases, the device is unable to be removed..

86. 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

87. Plaintiffs, SAMANTHA BOULDRY, EULA HUFF, SANDRA LORENZ, JANET ROBERTS, and the FILTER IMPLANT CLASS require medical monitoring to ensure that the Recovery®, G2®, G2 Express® filters implanted within their bodies have not yet failed/fractured.

88. In order to determine whether failure of a Recovery®, G2® and G2 Express® filter is occurring or 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 or is in the process of failing.

89. Those people requiring medical monitoring, like Plaintiffs, SAMANTHA BOULDRY, EULA HUFF, SANDRA LORENZ, JANET ROBERTS, 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 likely 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.

90. 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

[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 RecoveryTM7 filter." The 2010 study, performed by William Nicholson, M.D., Prevalence of Fractre and Fragment Embolization of Bard Retrievable Veba 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- 125-;, and 259r, respectively. Dr. Nicholson, et al reported that the rate of

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 and likely risk for future device failure and require regular and frequent monitoring to evaluate the integrity of the device.

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

92. 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 and likely risk of device failure in the future and 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 hemorrhage. There is clear clinical value through well-established medical means, to early detection and diagnosis of device failure.

---

fracture for the G2° may not be accurate, and actually, may be higher given the time that the G2®

93. 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; and

e. Regular physicians' visits and examinations.

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

94. 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 and causing injury and death to patients other than Plaintiffs in which the device was implanted.

95. 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 filter failure of the device or otherwise timely 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.

---

filter may be implanted in the human body.

96. 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 due to filter failure and were causing injury and death to patients who had received the G2® Filter System.

97. Reliable scientific and medical researchers have established that the filter 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.

98. 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.

99. 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 filter failure-due to

lack of electro-polishing of the devices. Rather, the Defendants C.R. Bard, Inc., and Bard Peripheral Vascular, Inc., deceptively told customers that the new device was because of continued product improvements.

100. 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.

101. 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;

102. 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.

103. 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.

COUNT I
NEGLIGENCE RE: C.R. BARD, INC.
MEDICAL MONITORING

104. Plaintiff realleges and incorporates by reference each allegation contained in Paragraph 1 through 103 above.

105. At all times relevant to this cause of action, C.R. BARD, INC. was in the business of designing, developing, manufacturing, marketing, and selling sophisticated medical devices, including the Recovery®, G2®, and G2® Express filters.

106. C.R. BARD, INC. in designing, developing, manufacturing marketing, labeling, selling, monitoring and surveiling its products had a duty to act with reasonable care and to warn the Plaintiff and Plaintiff's physicians of the risk, dangers, adverse events involving failures/migrations/fractures and potential failures of the its IVC Filters.

107. At the time of the manufacture and sale of the Recovery®, G2®, and G2® Express filters (2003 until the present), defendant C.R. BARD, 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 filter failure;

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

c. Were designed and manufactured so as to present an unreasonable risk of fracture, perforation of vessels and/organs, 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.

108. C.R. BARD, INC. 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, namely, the incidence of filter 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, namely, 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, namely, 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, namely, Recovery®, G2®, and G2® Express filters that presented the risk of harm to the Plaintiffs and others similarly situated in that it was prone to filter failure.

109. As a direct and a proximate result of the foregoing negligence by Defendants C.R. BARD, Inc., Plaintiffs and members of the FILTER IMPLANT CLASS, are at a substantially increased risk that filter failure will occur, resulting in hemorrhage, cardiac/pericardial tamponade, injury to the heart and/or lung(s), severe and persistent pain, perforation of tissue, vessels, and organs, and even causing death.

110. As a further direct and proximate result of the foregoing negligence by Defendants C.R. BARD, INC., Plaintiffs and members of the FILTER IMPLANT CLASS, 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.

111. Plaintiffs further allege that in committing the foregoing negligent acts, Defendant C.R. BARD, 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 injuring 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., therefore, should be required to respond to the FILTER IMPLANT CLASS in the form of a punitive or exemplary damage award.

COUNT II
NEGLIGENCE RE: BARD PERIPHERAL VASCULAR, INC.
MEDICAL MONITORING

112. Plaintiff realleges and incorporates by reference each allegation contained in Paragraph 1 through 111 above.

113. At all times relevant to this cause of action, BARD PERIPHERAL VASCULAR, INC. was in the business of designing, developing, manufacturing, marketing, and selling sophisticated medical devices, including the Recovery®, G2®, and G2® Express filters.

114. BARD PERIPHERAL VASCULAR, INC. in designing, developing, manufacturing marketing, labeling, selling, monitoring and surveiling its products had a duty to act with reasonable care and to warn the Plaintiffs and Plaintiffs' physicians of the risk, dangers, adverse events involving failures/migrations/fractures and potential failures of the its IVC Filters.

115. At the time of the manufacture and sale of the Recovery®, G2®, and G2® Express filters (2003 until the present), defendant 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 filter fracture;

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

c. Were designed and manufactured so as to present an unreasonable risk of fracture, perforation of vessels and/or organs, 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.

116. BARD PERIPHERAL VASCULAR, INC. 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, namely, the incidence of filter 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, namely, 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, namely, 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, namely, Recovery®, G2®, and G2® Express filters that presented the risk of harm to the Plaintiffs and others similarly situated in that it was prone to filter failure.

117. As a direct and a proximate result of the foregoing negligence by Defendant BARD PERIPHERAL VASCULAR, INC. Plaintiffs and members of the FILTER IMPLANT CLASS, are at a substantially increased risk that filter failure will occur resulting in hemorrhage, cardiac/pericardial tamponade, injury to the heart and/or lung(s), severe and persistent pain, perforation of tissue, vessels, and organs, and even causing death.

118. As a further direct and proximate result of the foregoing negligence by Defendant BARD PERIPHERAL VASCULAR, INC. Plaintiffs and members of the FILTER IMPLANT CLASS, require regular and frequent medical monitoring for the duration of time that Defendant's 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.

119. Plaintiffs further allege that in committing the foregoing negligent acts, Defendant 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 injuring the rights of others, consciously pursued a course of conduct knowing that such conduct created a substantial risk of significant harm to other persons. Defendant 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.

COUNT III
STRICT LIABILITY - MANUFACTURE DEFECT RE: C.R. BARD, INC. MEDICAL MONITORING

120. Plaintiff realleges and incorporates by reference each allegation contained in Paragraph 1 through 119 above.

121. At all times relevant to this cause of action, C.R. BARD, INC. was in the business of designing, developing, manufacturing, marketing, and selling

sophisticated medical devices, including the Recovery®, G2®, and G2® Express filters.

122. When the Recovery®, G2® and G2 Express® filters were manufactured, and sold by the Defendant C.R. Bard, Inc. 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.

123. As a direct and a proximate result of the foregoing defective and unreasonably dangerous condition of the products of Defendant C.R. BARD, INC., Plaintiffs and members of the FILTER IMPLANT CLASS are at a substantially increased risk that their filter failure will occur , resulting in hemorrhage, cardiac/pericardial tamponade, injury to the heart and/or lung(s), severe and persistent pain, perforation of tissue, vessels, and organs, and even causing death.

124. As a further direct and a proximate result of the foregoing defective and unreasonably dangerous condition of the products of Defendant C.R. BARD INC., Plaintiffs and members of the FILTER IMPLANT CLASS 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.

125. Plaintiffs further allege that the Defendant C.R. BARD 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. Defendant C.R. BARD INC., therefore, should be required to respond to the FILTER IMPLANT CLASS in the form of a punitive or exemplary damage award.

COUNT IV
STRICT LIABILITY – MANUFACTURE DEFECT RE: BARD PERIPHERAL VASCULAR, INC.
MEDICAL MONITORING

126. Plaintiff realleges and incorporates by reference each allegation contained in Paragraph 1 through 125 above.

127. At all times relevant to this cause of action, BARD PERIPHERAL VASCULAR, INC. was in the business of designing, developing, manufacturing, marketing, and selling sophisticated medical devices, including the Recovery®, G2®, and G2® Express filters.

128. When the Recovery®, G2® and G2 Express® filters were manufactured, and sold by the Defendant 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.

129. As a direct and a proximate result of the foregoing defective and unreasonably dangerous condition of the products of Defendant BARD PERIPHERAL VASCULAR, INC., Plaintiffs and members of the FILTER IMPLANT CLASS, are at a substantially increased risk that filter failure will occur , resulting in hemorrhage, cardiac/pericardial tamponade, injury to the heart and/or lung(s), severe and persistent pain, perforation of tissue, vessels, and organs, and even causing death.

130. As a further direct and a proximate result of the foregoing defective and unreasonably dangerous condition of the products of Defendant BARD PERIPHERAL VASCULAR, INC., Plaintiffs and members of the FILTER IMPLANT CLASS, require regular and frequent medical monitoring for the duration of time that Defendant's 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.

131. Plaintiffs further allege that the Defendant BARD PERIPHERAL VASCULAR, INC., and 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. Defendant 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.

COUNT V
STRICT LIABILITY – DESIGN DEFECT RE: C.R. BARD, INC.
MEDICAL MONITORING

132. Plaintiff realleges and incorporates by reference each allegation contained in Paragraph 1 through 131 above.

133. At all times relevant to this cause of action, C.R. BARD, INC. was in the business of designing, developing, manufacturing, marketing, and selling sophisticated medical devices, including the Recovery®, G2®, and G2 Express® filters.

134. When the Recovery®, G2® and G2 Express® filters were designed, manufactured, and sold by the Defendants C.R. Bard, 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 potential 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.

135. As a direct and a proximate result of the defective design of the products of Defendant C.R. BARD, INC., Plaintiffs and members of the FILTER IMPLANT CLASS, y are at a substantially increased risk that filter fracture will occur, resulting in hemorrhage, cardiac/pericardial tamponade, injury to the heart and/or lung(s), severe and persistent pain, perforation of tissue, vessels, and organs, and even causing death.

136. As a further direct and a proximate result of the defective design of the products of Defendant C.R. BARD, INC., Plaintiffs and members of the FILTER IMPLANT CLASS, require regular and frequent medical monitoring for the duration of time that Defendant's 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.

137. Plaintiffs further allege that the Defendant C.R. BARD, 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. Defendant C.R. BARD, INC., therefore, should be required to respond to the FILTER IMPLANT CLASS in the form of a punitive or exemplary damage award.

COUNT VI
STRICT LIABILITY – DESIGN DEFECT RE: BARD PERIPHERAL VASCULAR, INC.
MEDICAL MONITORING

138. Plaintiff realleges and incorporates by reference each allegation contained in Paragraph 1 through 137 above.

139. At all times relevant to this cause of action, BARD PERIPHERAL VASCULAR, INC. was in the business of designing, developing, manufacturing, marketing, and selling sophisticated medical devices, including the Recovery®, G2®, and G2 Express® filters.

140. When the Recovery®, G2® and G2 Express® filters were designed, manufactured, and sold by the 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 Defendant's 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.

141. As a direct and a proximate result of the defective design of the products of Defendant BARD PERIPHERAL VASCULAR, INC., Plaintiffs and members of the FILTER IMPLANT CLASS, are at a substantially increased risk that filter fracture will occur resulting in hemorrhage, cardiac/pericardial tamponade, injury to the heart and/or lung(s), severe and persistent pain, perforation of tissue, vessels, and organs, and even causing death.

142. As a further direct and a proximate result of the defective design of the products of Defendant BARD PERIPHERAL VASCULAR, INC., Plaintiffs and members of the FILTER IMPLANT CLASS, require regular and frequent medical monitoring for the duration of time that Defendant's 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.

143. Plaintiffs further allege that the Defendants 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. Defendant 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.

COUNT VII
STRICT LIABILITY – WARNING DEFECT RE: C.R. BARD, INC.
MEDICAL MONITORING

144. Plaintiff realleges and incorporates by reference each allegation contained in Paragraph 1 through 143 above.

145. At all times relevant to this cause of action, C.R. BARD, INC. was in the business of designing, developing, manufacturing, marketing, and selling sophisticated medical devices, including the Recovery®, G2®, and G2 Express® filters.

146. Defendant's 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, injury to the heart and/or lung(s), severe and persistent pain, perforation of tissue, vessels, and organs, and even death.

147. Defendant's' 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.

148. Defendant's 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.

149. Defendant's 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.

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

151. As a direct and proximate result of the defective warnings of Defendant's Recovery®, G2® and G2 Express® filters, Plaintiffs and members of the FILTER IMPLANT CLASS, are at a substantially increased risk that filter failure will occur, resulting in hemorrhage, cardiac/pericardial tamponade, injury to the heart and/or lung(s), severe and persistent pain, perforation of tissue, vessels, and organs, and even causing death.

152. As a further direct and proximate result of the defective warnings of Defendant's Recovery®, G2® and G2 Express® filters, Plaintiffs and members of the FILTER IMPLANT CLASS, 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.

153. Plaintiffs further allege that the Defendant C.R. BARD, 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. Defendant C.R. BARD, INC. therefore, should be required to respond to the FILTER IMPLANT CLASS in the form of a punitive or exemplary damage award.

COUNT VIII
STRICT LIABILITY – WARNING DEFECT RE: BARD PERIPHERAL VASCULAR, INC.
MEDICAL MONITORING

154. Plaintiff realleges and incorporates by reference each allegation contained in Paragraph 1 through 153 above.

155. At all times relevant to this cause of action, BARD PERIPHERAL VASCULAR, INC.. was in the business of designing, developing, manufacturing, marketing, and selling sophisticated medical devices, including the Recovery®, G2®, and G2 Express® filters.

156. Defendant's 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, injury to the heart and/or lung(s), severe and persistent pain, perforation of tissue, vessels, and organs, and even death.

157. Defendant's 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.

158. Defendant's 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.

159. Defendant's 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.

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

161. As a direct and proximate result of the defective warnings of Defendant's Recovery®, G2® and G2 Express® filters, Plaintiffs and members of the FILTER IMPLANT CLASS, are at a substantially increased risk that filter failure will occur resulting in hemorrhage, cardiac/pericardial tamponade, injury to

the heart and/or lung(s), severe and persistent pain, perforation of tissue, vessels, and organs, and even causing death.

162. As a further direct and proximate result of the defective warnings of Defendant's Recovery®, G2® and G2 Express® filters, Plaintiffs and members of the FILTER IMPLANT CLASS, require regular and frequent medical monitoring for the duration of time that Defendant's 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.

163. Plaintiffs further allege that the Defendant 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 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.

COUNT IX
FRAUDULENT CONCEALMENT RE: C.R. BARD, INC.
MEDICAL MONITORING

164. Plaintiff realleges and incorporates by reference each allegation contained in Paragraph 1 through 163 above.

165. At all times relevant to this cause of action, C.R. BARD, INC. was in the business of designing, developing, manufacturing, marketing, and selling sophisticated medical devices, including the Recovery®, G2®, and G2 Express® filters.

166. Defendant's 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, injury to the heart and/or lung(s), severe and persistent pain, and perforation of tissue, vessels, and organs.

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

168. As the manufacturers, distributors, marketers, and sellers of sophisticated medical devices, including the Recovery®, G2® and G2 Express® filters, Defendant 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.

169. Defendant 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 Defendant alone had knowledge of material facts, namely, 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.

170. Defendant 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.

171. Notwithstanding their knowledge of the hazardous nature of their Recovery®, G2® and G2 Express® filters, at all material times hereto, Defendant 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 Defendant's Recovery®, G2® and G2 Express® filters.

172. 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.

173. As a direct and proximate result of Defendant's 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, Defendant's Recovery®, G2® and G2 Express® filters were implanted in Plaintiffs and members of the FILTER IMPLANT CLASS.

174. As a further direct and proximate result of Defendant's 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 are at a substantially increased risk of hemorrhage, cardiac/pericardial tamponade, injury to the heart and/or lung(s), severe and persistent pain, and perforation of tissue, vessels, and organs, and even of death.

175. As a further direct and proximate result of Defendant's 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, face increased risks posed to their health by Defendant's filters that 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.

176. Plaintiffs further allege that Defendant, C.R. BARD 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., therefore, should be required to respond to the Plaintiffs in the form of a punitive or exemplary damage award.

COUNT X
FRAUDULENT CONCEALMENT RE: BARD PERIPHERAL VASCULAR, INC. MEDICAL MONITORING

177. Plaintiff realleges and incorporates by reference each allegation contained in Paragraph 1 through 176 above.

178. At all times relevant to this cause of action, BARD PERIPHERAL VASCULAR, INC. was in the business of designing, developing, manufacturing, marketing, and selling sophisticated medical devices, including the Recovery®, G2®, and G2 Express® filters.

179. Defendant's 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, injury to the heart and/or lung(s), severe and persistent pain, and perforation of tissue, vessels, and organs.

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

181. 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.

182. Defendant 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, namely, 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.

183. Defendant 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.

184. Notwithstanding their knowledge of the hazardous nature of their Recovery®, G2® and G2 Express® filters, at all material times hereto, Defendant 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 Defendant's Recovery®, G2® and G2 Express® filters.

185. 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.

186. As a direct and proximate result of Defendant's 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, Defendant's Recovery®, G2® and G2 Express® filters were implanted in Plaintiffs and members of the FILTER IMPLANT CLASS.

187. 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 are at a substantially increased risk of hemorrhage, cardiac/pericardial tamponade, injury to the heart and/or lung(s), severe and persistent pain, and perforation of tissue, vessels, and organs, and even of death.

188. As a further direct and proximate result of Defendant's 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, 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.

189. Plaintiffs further allege that Defendants, 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. Defendant, BARD PERIPHERAL VASCULAR, INC., therefore, should be required to respond to the Plaintiffs in the form of a punitive or exemplary damage award.

COUNT XI
BREACH OF IMPLIED WARRANTIES RE: C.R. BARD, INC.
MEDICAL MONITORING

190. Plaintiff realleges and incorporates by reference each allegation contained in Paragraph 1 through 189 above.

191. At all times relevant to this cause of action, C.R. BARD, INC. was in the business of designing, developing, manufacturing, marketing, and selling sophisticated medical devices, including the Recovery®, G2®, and G2 Express® filters.

192. At the time Defendant C.R. BARD, INC. designed, manufactured, produced, tested, studied, inspected, labeled, marketed, advertised, sold, promoted, and distributed its Recovery®, G2®, and G2 Express® filters for use by Plaintiffs, they knew of the potential for fracture, migration, or other potential failures.

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

194. As set forth herein, Plaintiff and Defendants were in privity of contract.

195. Defendant C.R. BARD, INC. impliedly warranted its Recovery®, G2®, and G2 Express® filters to be of merchantable quality and safe and fit for its intended use.

196. Contrary to such implied warranty, Defendant C.R. BARD, INC.'s Recovery®, G2®, and G2 Express® filters were not of merchantable quality, safe or fit for its intended use as described hereinabove because they were and are defective, failed to function as safely as an ordinary user would expect when used in an intended and 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.

197. At all times material hereto, the Recovery®, G2®, and G2 Express® filters that were implanted in Plaintiffs and members of the FILTER IMPLANT CLASS were in defective condition in the manner herein alleged, which was unreasonably and inherently dangerous to the Plaintiffs and the FILTER IMPLANT CLASS in that they are accordingly at a significantly increased risk of future injury due to failure and/or fracture. Notwithstanding this knowledge, C.R. BARD, INC. in willful and conscious disregard, failed to give any notice or warning to the Plaintiffs, the FILTER IMPLANT CLASS and/or their physicians, placed and persisted in placing a defective product into the stream of commerce, thus causing it to be used during the surgical procedures performed on the Plaintiffs and the FILTER IMPLANT CLASS.

198. C.R. BARD, INC., as the designer, manufacturer, marketer, packager, distributor or seller, impliedly warranted that Recovery®, G2®, and G2 Express® filters was fit for its intended purpose ass described hereinabove.

199. C.R. BARD, INC. was a merchant with respect to the Recovery®, G2®, and G2 Express® filters stent, which were sold to the Plaintiffs and/or their representatives, and there was an implied warranty that the Recovery®, G2®, and G2 Express® filters stent was merchantable.

200. C.R. BARD, INC. breached the warranty implied in the contract for the sale of goods in that the goods could not pass without objection in the trade under the contract description, the goods were not of fair, average quality within

the description, and the goods were unfit for their intended purpose and use as described hereinabove. Furthermore, such goods did not conform to the promises or affirmations of fact made on the container, packaging and/or label. As a result, the Plaintiffs did not receive the goods as impliedly warranted by C.R. BARD, INC. filters to be merchantable.

201. Recovery®, G2®, and G2 Express® filters were sold to the Plaintiff and/or his representative with the knowledge and intent that it would be used for the benefit of the Plaintiffs. Recovery®, G2®, and G2 Express® filters were placed into Plaintiffs and the those of the FILTER IMPLANT CLASS' bodies during surgical procedures and the Plaintiffs and members of the FILTER IMPLANT CLASS were charged the cost for the Recovery®, G2®, and G2 Express® filters.

202. As a direct and proximate result of Defendant's breaches of the foregoing implied warranties, Plaintiffs and members of the FILTER IMPLANT CLASS, are at a substantially increased risk of hemorrhage, cardiac/pericardial tamponade, injury to the heart and/or lung(s), severe and persistent pain, perforation or tissue, vessels, and organs, and even death.

203. As a further and direct and proximate result of Defendants' breaches of the foregoing implied warranties, Plaintiffs and members of the FILTER IMPLANT CLASS, require regular and frequent medical monitoring for the duration if 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.

204. Recovery®, G2®, and G2 Express® filters were not altered by the Plaintiffs, their treating physician or other medical personnel. The Recovery®, G2®, and G2 Express® filters were defective when they left the control of C.R. BARD, INC. and C.R. BARD, INC. knew they would be used without additional testing. Recovery®, G2®, and G2 Express® filters were unfit for its intended purpose for use as described hereinabove and the Plaintiffs did not receive the Recovery®, G2®, and G2 Express® filters as warranted.

205. Plaintiffs further allege that the Defendant C.R. BARD, 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.

COUNT XII
BREACH OF IMPLIED WARRANTIES RE: BARD PERIPHERAL VASCULAR, INC.
MEDICAL MONITORING

206. Plaintiff realleges and incorporates by reference each allegation contained in Paragraph 1 through 205 above.

207. At all times relevant to this cause of action, BARD PERIPHERAL VASCULAR, INC. was in the business of designing, developing, manufacturing, marketing, and selling sophisticated medical devices, including the Recovery®, G2®, and G2 Express® filters.

208. At the time Defendant BARD PERIPHERAL VASCULAR, INC. designed, manufactured, produced, tested, studied, inspected, labeled, marketed, advertised, sold, promoted, and distributed its Recovery®, G2®, and G2 Express® filters for use by Plaintiffs, they knew of the potential for fracture, migration, or other potential failures.

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

210. As set forth herein, Plaintiff and Defendants were in privity of contract.

211. Defendant BARD PERIPHERAL VASCULAR, INC. impliedly warranted its Recovery®, G2®, and G2 Express® filters to be of merchantable quality and safe and fit for its intended use.

212. Contrary to such implied warranty, Defendant BARD PERIPHERAL VASCULAR, INC.'s Recovery®, G2®, and G2 Express® filters were not of merchantable quality, safe or fit for its intended use as described hereinabove because they were and are defective, failed to function as safely as an ordinary user would expect when used in an intended and reasonably foreseeable manner, and because they present a substantially increased risk of failure, and

likely consequent future injury to Plaintiffs and members of the FILTER IMPLANT CLASS.

213. At all times material hereto, the Recovery®, G2®, and G2 Express® filters that were implanted in Plaintiffs and members of the FILTER IMPLANT CLASS were in defective condition in the manner herein alleged, which was unreasonably and inherently dangerous to the Plaintiffs and the FILTER IMPLANT CLASS in that they are accordingly at a significantly increased risk of future injury due to failure and/or fracture. Notwithstanding this knowledge, BARD PERIPHERAL VASCULAR, INC. in willful and conscious disregard, failed to give any notice or warning to the Plaintiffs, the FILTER IMPLANT CLASS and/or their physicians, placed and persisted in placing a defective product into the stream of commerce, thus causing it to be used during the surgical procedures performed on the Plaintiffs and the FILTER IMPLANT CLASS.

214. BARD PERIPHERAL VASCULAR, INC., as the designer, manufacturer, marketer, packager, distributor or seller, impliedly warranted that Recovery®, G2®, and G2 Express® filters was fit for its intended purpose as described hereinabove.

215. BARD PERIPHERAL VASCULAR, INC. was a merchant with respect to the Recovery®, G2®, and G2 Express® filters stent, which were sold to the Plaintiffs and/or their representatives, and there was an implied warranty that the Recovery®, G2®, and G2 Express® filters stent was merchantable.

216. BARD PERIPHERAL VASCULAR, INC. breached the warranty implied in the contract for the sale of goods in that the goods could not pass

without objection in the trade under the contract description, the goods were not of fair, average quality within the description, and the goods were unfit for their intended purpose and use as described hereinabove. Furthermore, such goods did not conform to the promises or affirmations of fact made on the container, packaging and/or label. As a result, the Plaintiffs did not receive the goods as impliedly warranted by BARD PERIPHERAL VASCULAR, INC. filters to be merchantable.

217. Recovery®, G2®, and G2 Express® filters were sold to the Plaintiff and/or his representative with the knowledge and intent that it would be used for the benefit of the Plaintiffs. Recovery®, G2®, and G2 Express® filters were placed into Plaintiffs' and the those of the FILTER IMPLANT CLASS' bodies during surgical procedures and the Plaintiffs and members of the FILTER IMPLANT CLASS were charged the cost for the Recovery®, G2®, and G2 Express® filters.

218. As a direct and proximate result of Defendant's 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, injury to the heart and/or lung(s), severe and persistent pain, perforation or tissue, vessels, and organs, and even death.

219. As a further and 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.

220. Recovery®, G2®, and G2 Express® filters were not altered by the Plaintiffs, their treating physician or other medical personnel. The Recovery®, G2®, and G2 Express® filters were defective when they left the control of BARD PERIPHERAL VASCULAR, INC. and BARD PERIPHERAL VASCULAR, INC. knew they would be used without additional testing. Recovery®, G2®, and G2 Express® filters were unfit for its intended purpose for use as described hereinabove and the Plaintiffs did not receive the Recovery®, G2®, and G2 Express® filters as warranted.

221. Plaintiffs further allege that the Defendant 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.

COUNT XIII
NEGLIGENCE – DUTY TO WARN OF POST-MARKETING DEVICE FAILURE
RE: C.R. BARD, INC.
MEDICAL MONITORING

222. Plaintiff realleges and incorporates by reference each allegation contained in Paragraph 1 through 221 above.

223. At all times relevant to this cause of action, C.R. BARD, INC. was in the business of designing, developing, manufacturing, marketing, and selling sophisticated medical devices, including the Recovery®, G2®, and G2 Express® filters.

224. A product manufacturer, such as Defendants, C.R. BARD, INC.,has a duty to provide adequate, effective warning to foreseeable users of the product.

225. The duty to warn imposed on a product manufacturer, such as Defendants, C.R. BARD, 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.

226. Since the time the Recovery®, G2® or G2 Express® was/were introduced to the market, Defendants, C.R. Bard, 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.

227. Once the Defendants, C.R. BARD, 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.

228. Upon information and belief, the Defendants, C.R. BARD, 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.

229. Despite such knowledge, as aforesaid, the Defendants, C.R. BARD, 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.

230. In failing to notify or warn, as set forth *supra*, the Defendants, C.R. BARD, INC., breached their duty of care and were negligent.

231. 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 are at a substantially increased risk of hemorrhage, cardiac/pericardial tamponade, injury to the heart and/or lung(s), severe and persistent pain, and perforation of tissue, vessels, and organs, and even of death.

232. As a direct and proximate result of the conduct of the Defendants, C.R. BARD, 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.

COUNT XIV
NEGLIGENCE – DUTY TO WARN OF POST-MARKETING DEVICE FAILURE
RE: BARD PERIPHERAL VASCULAR, INC.
MEDICAL MONITORING

233. Plaintiff realleges and incorporates by reference each allegation contained in Paragraph 1 through 232 above.

234. At all times relevant to this cause of action, BARD PERIPHERAL VASCULAR, INC. was in the business of designing, developing, manufacturing, marketing, and selling sophisticated medical devices, including the Recovery®, G2®, and G2 Express® filters.

235. A product manufacturer, such as Defendant, BARD PERIPHERAL VASCULAR, INC. has a duty to provide adequate, effective warning to foreseeable users of the product.

236. The duty to warn imposed on a product manufacturer, such as Defendant, 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.

237. Since the time the Recovery®, G2® or G2 Express® was/were introduced to the market, Defendant, 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.

238. Once the Defendant, 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.

239. Upon information and belief, the Defendant, 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.

240. Despite such knowledge, as aforesaid, the Defendant 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.

241. In failing to notify or warn, as set forth supra, the Defendant, BARD PERIPHERAL VASCULAR, INC., breached their duty of care and were negligent.

242. 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 are at a substantially increased risk of hemorrhage, cardiac/pericardial tamponade, injury

to the heart and/or lung(s), severe and persistent pain, and perforation of tissue, vessels, and organs, and even of death.

243. As a direct and proximate result of the conduct of the Defendant, 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, SAMANTHA BOULDRY, EULA HUFF, SANDRA LORENZ, JANET ROBERTS, 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 Florida Rules of Civil Procedure §1.220(a) and 1.220(b)(3) 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 filter failure of the Recovery®, G2® and G2 Express® vena cava filters.

3. For medical monitoring, to provide for a Court supervised medical monitoring program/fund 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 filter failure of the Recovery®, G2® or G2 Express® vena cava filters.

Costs of Suit

5. For Plaintiffs' costs of suit incurred herein;

Attorney's Fees and Costs

6. For Plaintiffs' reasonable attorney's fees.

Other Relief

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

WHEREFORE, the SAMANTHA BOULDRY, EULA HUFF, SANDRA

LORENZ, JANET ROBERTS, hereby demand trial by jury of all issues which may be tried to a jury against each Defendant.

DATED: This 26th day of July, 2012.

BABBITT JOHNSON OSBORNE & LECLAINCHE, P.A.
Attorneys for Plaintiffs
1641 Worthington Road, Suite 100 (33409)
P. O. Box 4426
West Palm Beach, FL 33402-4426
(561) 684-2500
(561) 684-6308 (fax)

By _____
JOSEPH R. JOHNSON
Fla. Bar No: 372250