



against Defendants, C.R. BARD, INC., a New Jersey Corporation, and BARD PERIPHERAL VASCULAR, INC., an Arizona corporation, (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 Plaintiffs as a Class Action on their behalf and on behalf of all other persons similarly situated, under the provisions of Rules 1701 et seq., 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, GOLDIE BROWN has been a citizen and resident of the Commonwealth of Pennsylvania, residing therein at 1519 Logan Way, Chester, PA 19013. On August 3, 2005, GOLDIE BROWN was implanted with a Recovery<sup>®</sup> IVC Filter manufactured by Defendants named herein. To date, the Recovery<sup>®</sup> IVC Filter manufactured by Defendants implanted in GOLDIE BROWN has not yet fractured, migrated or otherwise failed and she has suffered no injury therefrom.

4. At all material times hereto SHANTEL BROWN has been a citizen and resident of the Commonwealth of Pennsylvania, residing therein at 37 State Road Apt. A5, Media, PA 19063. On November 25, 2008, SHANTEL BROWN was implanted with a G2<sup>®</sup> IVC Filter manufactured by Defendants named herein. To date, the G2<sup>®</sup> IVC Filter manufactured by defendants implanted in SHANTEL BROWN has not yet fractured, migrated or otherwise failed and she has suffered no injury therefrom.

### **Defendants**

5. Defendant C.R. BARD, INC. is a New Jersey corporation with its corporate offices at 730 Central Avenue, Murray Hill, New Jersey 07974. At all material times hereto, Defendant was doing business in the County of Philadelphia, where it sold and distributed the subject IVC filters. Defendant acted through its agents, servants, and employees engaged in the business of designing, testing, manufacturing, labeling, licensing, marketing, advertising, distributing, promoting and/or selling, either directly or indirectly through third parties, the products more specifically identified herein.

a. Defendant is, and was at all relevant times, duly authorized to conduct business in the Commonwealth of Pennsylvania, and possesses offices and operations within the Commonwealth.

b. At all times relevant hereto, Defendant regularly conducted and solicited business within the Commonwealth of Pennsylvania, and specifically Philadelphia County, and continues to do so.

c. Defendant, either directly or through its agents, servants, and employees, does business in the Commonwealth of Pennsylvania, including in Philadelphia County, and at

all relevant times, has sold and distributed its IVC filters in the Commonwealth of Pennsylvania, including Philadelphia County.

d. Defendant derives substantial revenue from goods used or consumed in the Commonwealth of Pennsylvania, including Philadelphia County.

e. Defendant reasonably expected, or should have reasonably expected, that its actions could or would have consequences within the Commonwealth of Pennsylvania, including Philadelphia County.

f. It is believed and therefore averred that Defendant has advertised IVC filters to patients in Philadelphia, doctors in Philadelphia, and Philadelphia hospitals and/or other medical facilities located within Philadelphia County.

g. It is believed and therefore averred that Defendant, both in the past and presently, takes advantage of the entire Commonwealth of Pennsylvania, including Philadelphia County, infrastructure including, without limitation, roads, highways and airports.

h. It is believed and therefore averred that Defendant advertises or otherwise promotes its business in the Commonwealth of Pennsylvania, including in Philadelphia County.

i. It is believed and therefore averred that Defendant extensively uses the Pennsylvania and, more specifically, the Philadelphia County medical community and its physicians to purchase, dispense and/or promote the use of Defendants' products to residents in the Commonwealth of Pennsylvania and in Philadelphia County.

j. It is believed and therefore averred that Defendant enters into contracts with Pennsylvania individuals, companies, hospitals, healthcare facilities, physicians and/or healthcare providers to purchase a variety of goods and perform a variety of services.

6. Defendant BARD PERIPHERAL VASCULAR, INC., is an Arizona corporation with its corporate offices at 1625 West 3rd Street, Tempe, AZ 85281. At all material times hereto, Defendant was doing business in the County of Philadelphia, where it sold and distributed the subject IVC filters. Defendant acted through its agents, servants, and employees engaged in the business of designing, testing, manufacturing, labeling, licensing, marketing, advertising, distributing, promoting and/or selling, either directly or indirectly through third parties, the products more specifically identified herein.

a. Defendant is, and was at all relevant times, duly authorized to conduct business in the Commonwealth of Pennsylvania, and possesses offices and operations within the Commonwealth.

b. At all times relevant hereto, Defendant regularly conducted and solicited business within the Commonwealth of Pennsylvania, and specifically Philadelphia County, and continues to do so.

c. Defendant, either directly or through its agents, servants, and employees, does business in the Commonwealth of Pennsylvania, including in Philadelphia County, and at all relevant times, has sold and distributed its IVC filters in the Commonwealth of Pennsylvania, including Philadelphia County.

d. Defendant derives substantial revenue from goods used or consumed in the Commonwealth of Pennsylvania, including Philadelphia County.

e. Defendant reasonably expected, or should have reasonably expected, that its actions could or would have consequences within the Commonwealth of Pennsylvania, including Philadelphia County.

f. It is believed and therefore averred that Defendant has advertised IVC filters to patients in Philadelphia, doctors in Philadelphia, and Philadelphia hospitals and/or other medical facilities located within Philadelphia County.

g. It is believed and therefore averred that Defendant, both in the past and presently, takes advantage of the entire Commonwealth of Pennsylvania, including Philadelphia County, infrastructure including, without limitation, roads, highways and airports.

h. It is believed and therefore averred that Defendant advertises or otherwise promotes its business in the Commonwealth of Pennsylvania, including in Philadelphia County.

i. It is believed and therefore averred that Defendant extensively uses the Pennsylvania and, more specifically, the Philadelphia County medical community and its physicians to purchase, dispense and/or promote the use of Defendants' products to residents in the Commonwealth of Pennsylvania and in Philadelphia County.

j. It is believed and therefore averred that Defendant enters into contracts with Pennsylvania individuals, companies, hospitals, healthcare facilities, physicians and/or healthcare providers to purchase a variety of goods and perform a variety of services.

7. Defendants 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".

8. Each Defendant has been the parent, subsidiary, alter ego, agent, apparent agent, joint venturer, or employee of the other defendant, and/or unnamed corporate entities involved in the manufacture, sale, distribution, and marketing of Defendants' IVC filters, 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**

9. This is an action for a medical monitoring fund that exceeds Fifty Thousand Dollars (\$50,000) exclusive of costs, interest, attorneys fees, and as such, pursuant to 42 Pa.C.S. §7361, subject matter jurisdiction is properly exercised over this action.

10. All Plaintiffs and the putative class are all citizens of the Commonwealth of Pennsylvania and all received their IVC filters while residing in the Commonwealth of Pennsylvania.

11. At all times relevant to this Complaint, the Defendants operated, conducted, engaged in, or carried on business in Pennsylvania or had offices or agents in Pennsylvania, and IVC Filters were distributed throughout the Commonwealth of Pennsylvania, including Philadelphia County, in a defective state. Therefore, personal jurisdiction is properly exercised over each of the Defendants to this action pursuant to 42 Pa.C.S. §5322 and §5301.

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

13. 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: Plaintiffs are at a substantially increased risk of developing 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.

14. 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 despite diversity of citizenship.

#### **CLASS ALLEGATIONS**

15. This action is brought pursuant to Pa.R.C.P. 1701 et seq. by Plaintiffs GOLDIE BROWN and SHANTEL BROWN 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."

16. The class represented by Plaintiffs consists of all persons who have had implantation of IVC filter(s) designed, manufactured, distributed and sold by the defendants C.R. BARD, INC., and BARD PERIPHERAL VASCULAR, INC., and who have the device(s) remaining within their anatomy. The trade names for these IVC Filters are "Recovery<sup>®</sup>", "G2<sup>®</sup>" and/or the "G2 Express<sup>®</sup>", vena cava filters. These devices are described in detail in the



paragraphs contained herein. This class of Plaintiffs will hereinafter be referred to as the “FILTER IMPLANT CLASS”.

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

18. 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, each Plaintiff has had one of the aforementioned IVC filters implanted within their anatomy, is exposed to a likely risk of injury from the existence of said device within their anatomy, and requires 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.

19. The claims of GOLDIE BROWN and SHANTEL BROWN are typical of the claims of the FILTER IMPLANT CLASS in that the claims of all members of the FILTER IMPLANT CLASS, including Representative Plaintiffs, depend on a showing of the acts and omissions of Defendants upon which liability is based.

20. The representative Plaintiffs, GOLDIE BROWN and SHANTEL BROWN, can and will fairly and adequately protect the interests of the FILTER IMPLANT CLASS under the criteria set forth in Pa.R.C.P. 1709.

21. Undersigned counsel and firms with which it is associated will adequately represent the interests of the class.

22. Undersigned counsel and firms with which it is associated have adequate financial resources to assure that the interests of the class will not be harmed.

23. Neither of the Representative Plaintiffs would have a conflict of interest in the maintenance of a class action.

24. The questions of law and fact common to the members of the class predominate over questions affecting individual class members.

25. A class action is superior to other available methods for the fair and efficient adjudication of this controversy under the criteria set forth in Pa.R.C.P. 1708 because the prosecution of separate actions by individual members of the class would create a risk of inconsistent or varying adjudications with respect to individual members of the class which would confront the Defendants with incompatible standards of conduct

26. Adjudications with respect to individual members of the class would, as a practical matter, be dispositive of the interests of other members not parties to the adjudications or substantially impair or impede their ability to protect their interests.

27. A class action would permit 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.

28. In view of the complexities of the issues or the expenses of litigation, in the absence of a class action the separate claims of individual class members would be insufficient in amount to support separate actions.

29. The Philadelphia Court of Common Pleas, known for its excellent programs for class action and mass tort litigation, is appropriate for the litigation of the claims of the entire class.

## TOLLING OF THE STATUTE OF LIMITATIONS

### **No Injury in Fact**

30. When Plaintiffs and members of the FILTER IMPLANT CLASS were implanted with the Recovery<sup>®</sup>, G2<sup>®</sup> and/or the G2 Express<sup>®</sup> 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 on August 9, 2010, indicating that adverse events and increased health risks were associated with Defendants’ filters, that members of the FILTER IMPLANT CLASS reasonably could have known that they have increased health risks from Defendants’ filters or that they may have a cause of action arising from Defendants’ conduct. There was no possible way that Plaintiffs and members of the FILTER IMPLANT CLASS could have discovered the defective nature of these filters prior to the date of the FDA advisory warning.

### **Fraudulent Concealment of Health Hazards by Defendants**

31. 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<sup>®</sup>, G2<sup>®</sup> and/or the G2 Express<sup>®</sup> 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.

32. At all material times hereto, Defendants fraudulently concealed the hazards of their Recovery<sup>®</sup>, G2<sup>®</sup> and/or the G2 Express<sup>®</sup> 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.

33. 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 of 2010 of Defendants' culpability, or that Plaintiffs had causes of action for medical monitoring arising from Defendants' concealment.

34. On August 9, 2010, the FDA first issued a public communication concerning adverse events and health risks associated with Defendants' filters. That was 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**

35. Prior to the implantation of the Recovery<sup>®</sup> Filter on August 3, 2005, Plaintiff GOLDIE BROWN did not discover, and could not reasonably have discovered, that the Recovery<sup>®</sup> Filter was fraught with the problems described in detail herein. Plaintiff was blamelessly unaware of the defective and dangerous condition of the Recovery<sup>®</sup> Filter until August 9, 2010 at the earliest, when such information was first released to the general public.

36. Prior to the implantation of the G2<sup>®</sup> Filter on November 25, 2008, Plaintiff SHANTEL BROWN did not discover, and could not reasonably have discovered, that the G2<sup>®</sup> Filter was fraught with the problems described in detail herein. Plaintiff was blamelessly unaware of the defective and dangerous condition of the G2<sup>®</sup> Filter until August 9, 2010 at the earliest, when such information was first released to the general public.

**Fraudulent Concealment of the Hazards and Defects of the  
Recovery<sup>®</sup>, G2<sup>®</sup>, and G2 Express<sup>®</sup> by Defendants.**

37. 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<sup>®</sup>, G2<sup>®</sup>, and G2 Express<sup>®</sup> vena cava filters that the Representative Plaintiffs and members of the FILTER IMPLANT CLASS had implanted in their bodies.

38. Defendants' 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 9, 2010, of Defendants' culpability and that Plaintiffs had a cause of action, at least for medical monitoring, against Defendants.

**GENERAL ALLEGATIONS**

**IVC Filters Generally**

39. 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.

40. 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 are designed to be either permanently or temporarily implanted in the human body, commonly within the inferior vena cava.

41. The inferior vena cava is a vein that returns blood to the heart from the lower portions of the body. For various reasons, thrombi can 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.

42. 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 or 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 or PE.

43. Those people at risk for DVT or 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 or PE, or who cannot manage their conditions with medications, physicians may recommend surgically implanting an IVC filter to prevent thromboembolic events.

44. 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.

45. The Recovery<sup>®</sup> Filter System—the predecessor device to the G2<sup>®</sup> and G2 Express<sup>®</sup> Filters—was introduced to the market in April 2003 as a permanent device, and then an optionally retrievable form of the Recovery IVC filter was introduced shortly thereafter in July 2003.

46. The IVC filters at issue in this case bear the trademark names “Recovery<sup>®</sup>”, “G2<sup>®</sup>”, and “G2 Express<sup>®</sup>” vena cava filter. Each is discussed in turn, *infra*. Each of the devices was designed, manufactured, marketed and sold by Defendants from 2002 (when FDA approval was received) until the present.

## The Recovery<sup>®</sup> Filter System

47. In 2002, the Defendants applied to the United States Food and Drug Administration (“FDA”) for approval of the Recovery<sup>®</sup> Filter System. Defendant C.R. Bard, Inc. applied for marketing approval of the Recovery<sup>®</sup> 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<sup>®</sup> Filter System was substantially equivalent to a predecessor device, the Simon Nitinol IVC filter. As such, the Recovery<sup>®</sup> Filter System did not undergo pre-market approval scrutiny.

48. In 2002, the Recovery<sup>®</sup> Filter System was approved by the FDA for permanent placement. Defendants began marketing the IVC filter in April 2003. Defendants also received FDA approval for an optionally retrievable Recovery<sup>®</sup> Filter System in July 2003. Thus, the Recovery<sup>®</sup> 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).

49. The Recovery<sup>®</sup> Filter System is constructed of a unique nickel-titanium alloy called “Nitinol”. Nitinol is an acronym for Nickel Titanium Naval Ordnance Laboratory. Nitinol was developed by Navy scientists in 1962 as a material to be used in ordnance. Nitinol is also unique in that it possesses “shape memory”; that is, Nitinol will change shape according to changes 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.

50. After receiving FDA approval in 2002, the Recovery<sup>®</sup> Filter System was first marketed for sale by the Defendants on or about April 2003. On or about October 15, 2003, C.R.

Bard, Inc. President and Chief Operating Officer John H. Weiland was quoted as stating "We are taking a very measured approach with our rollout of the Recovery<sup>®</sup> 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<sup>®</sup> Filter System was pulled from the market around 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.

51. Although a rough or crude analogy, the Recovery<sup>®</sup> 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.

52. The Recovery<sup>®</sup> Filter System is inserted into the human body in endovascular fashion. That is, the Recovery<sup>®</sup> is inserted via catheter that is guided by a physician<sup>1</sup> through a blood vessel into the inferior vena cava. The Recovery<sup>®</sup> Filter was designed to be retrieved in a somewhat similar fashion.

53. Following endovascular placement of the Recovery<sup>®</sup>, the physician typically uses imaging studies (such as "venacavagrams" or CT scans) to confirm successful placement and positioning of the device within the vena cava.

### **Post Implant Failure of the Recovery<sup>®</sup> Filter**

54. There is documented medical evidence that the Recovery<sup>®</sup> Filter System is prone to failure following placement within the human body. Since 2003, the time of introduction of

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<sup>1</sup> Typically, although not universally, an IVC filter is placed by an interventional radiologist. The procedure is called an "endovascular" medical procedure.



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<sup>®</sup> Filter System. These medical studies and reports indicate that the Recovery<sup>®</sup> Filter System is prone to failure by fracture of the device. That is, it breaks apart.

55. The aforementioned studies report that the Recovery<sup>®</sup> 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<sup>®</sup> Filter System struts ranging between 21%-31.7%.<sup>2</sup>

56. Other medical research studies indicate that the Recovery<sup>®</sup> Filter is predisposed to a high incidence of penetration of the walls of the vena cava.<sup>3</sup> Specifically, the distal (end) points of the Recovery<sup>®</sup> Filter's struts have been observed to perforate the walls of the vena cava. When this occurs, the perforating strut becomes fixed in its position and resists flexion or movement. The fixed struts then become subjected to a high frequency of bending stress due to the vena cava wall's movement during normal respiration and cardiac cycles. Researchers have discovered that this leads to metal fatigue in the strut, at a point just below the Recovery<sup>®</sup> Filter's cap.<sup>4</sup> Metallurgical analysis also confirms the Recovery<sup>®</sup> Filter's proneness to bending, metal fatigue, and fracture. The metal fatigue causes the strut to bend, and then fracture.

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<sup>2</sup> In 2005, the New England Society for Vascular Surgery reported a 31.7% fracture rate of the Recovery<sup>®</sup> 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.

<sup>3</sup> See, Recovery<sup>™</sup> 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<sup>™</sup> Filter System. This same study called for "additional studies to determine the long term safety of the device."

<sup>4</sup> *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.

57. Additional studies have revealed that the Recovery<sup>®</sup> Filter System is also prone to “tilt” following placement within the vena cava and/or improper deployment.<sup>5</sup>

58. Furthermore, the FDA’s “MAUDE” (Manufacturer and User Facility Device Experience) database includes several reports of the failure, fracture and migration of the Recovery<sup>®</sup> Filter System.

59. The Recovery<sup>®</sup> 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<sup>®</sup> Filter, also manufactured by Defendants C.R. Bard, Inc. and/or Bard Peripheral Vascular, Inc. Like the Recovery<sup>®</sup>, the G2<sup>®</sup> 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<sup>®</sup> as they had for the Recovery<sup>®</sup>.

60. The G2<sup>®</sup> 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<sup>6</sup> indicates that “data is on file” with respect to these product enhancements.

### **Sales of the Recovery<sup>®</sup> Filter System**

61. The permanent and optionally retrievable Recovery<sup>®</sup> 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<sup>®</sup> Filters during the time the device was on the market.

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<sup>5</sup> 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.

<sup>6</sup> [www.bardpv.com/vascular/product.php?p=83](http://www.bardpv.com/vascular/product.php?p=83)

## The G2<sup>®</sup> Filter – the Successor to Recovery<sup>®</sup>

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

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

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

65. As mentioned supra, the Recovery<sup>®</sup> Filter was plagued with manufacturing and design defects which caused Recovery<sup>®</sup> 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.<sup>7</sup>

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<sup>7</sup> 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 Fracture 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<sup>®</sup> 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.

66. The failure of the Recovery<sup>®</sup> Filter as aforesaid was attributable, in part, to the fact that the Recovery<sup>®</sup> Filter was designed so as to be unable to withstand the normal anatomical and physiological loading cycles exerted in vivo.<sup>8</sup>

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

68. In 2005, the Defendants submitted an application to the FDA for introduction of the G2<sup>®</sup> 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<sup>®</sup>, the Defendants represented to the FDA that it was substantially similar to the Recovery<sup>®</sup> Filter (the predicate device).

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

### **The G2<sup>®</sup> Express Filter**

70. In 2008, the Defendants introduced another “version” of the G2<sup>®</sup> Filter. This was called the “G2 Express<sup>®</sup>”. The sole difference between the G2 Express<sup>®</sup> and the G2<sup>®</sup> Filter is

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<sup>8</sup> The Recovery Filter System was plagued with manufacturing defects, namely lack of preparation of the exterior surface of the device so as to eliminate gouges in the Nitinol struts of the device. These gouges caused or contributed to cause the Recovery Filter System to fail/ fracture. The G2 Filter continues to have manufacturing defects in the form of "drawing marks" on the exterior of the device

that the G2 Express<sup>®</sup> 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.

### **Sales of the G2<sup>®</sup> and G2<sup>®</sup> Express Filters**

71. Upon information and belief, the Defendants sold at least approximately 65,000 of the G2<sup>®</sup> and G2 Express<sup>®</sup> filters nationwide during the time the devices were on the market.<sup>9</sup>

### **A Comparison of the Recovery<sup>®</sup>, G2<sup>®</sup> and G2 Express<sup>®</sup> Filter Systems**

72. Recovery<sup>®</sup>, G2<sup>®</sup> and G2 Express<sup>®</sup> 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<sup>®</sup>, G2<sup>®</sup> Filter and G2 Express<sup>®</sup> have six upper struts used for device positioning and filtering, and, six lower struts used for anchoring and filtering.

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

74. Like the Recovery<sup>®</sup> Filter, the G2 and G2 Express<sup>®</sup> 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<sup>®</sup>, following implant of the G2<sup>®</sup> and G2 Express<sup>®</sup>, physicians use imaging studies to confirm placement and location of the device.

75. Unfortunately, the G2<sup>®</sup> and G2 Express<sup>®</sup> filters also share some of the defects of the Recovery<sup>®</sup> Filter. The G2<sup>®</sup> and G2 Express<sup>®</sup> filters are of insufficient integrity and strength to withstand normal placement within the human body. The global stressors of the respiratory-

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<sup>9</sup> 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<sup>®</sup> and G2 Express<sup>®</sup> devices have been "replaced" by yet another iteration of the device- called the "Eclipse<sup>®</sup>" filter.

and cardiac cycles of the human body cause the G2<sup>®</sup> and G2 Express<sup>®</sup> 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.

76. Also, like their predecessor, the G2<sup>®</sup> and G2 Express<sup>®</sup> 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<sup>®</sup> and G2 Express<sup>®</sup> while *in vivo*. In particular, the G2<sup>®</sup> and G2 Express<sup>®</sup> 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<sup>®</sup> and G2 Express<sup>®</sup> 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.

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

78. Defendants represent the fracture rate of the G2<sup>®</sup> 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<sup>®</sup> and G2 Express<sup>®</sup>. Rather, the true fracture rate is much higher than 1.2% -- specifically, 12%.

79. A review of the MAUDE database from the years 2004-2008 reveals data to establish that the Defendants' vena cava filters (including the G2<sup>®</sup> Filter) are responsible for a significant percentage of the reported adverse patient events involving vena cava filters. Specifically, the G2<sup>®</sup> Filter and the Recovery<sup>®</sup> 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<sup>®</sup>, G2<sup>®</sup> or G2 Express<sup>®</sup> Filter Fails?**

80. 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

81. 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**

82. 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<sup>®</sup>, G2<sup>®</sup> and G2 Express<sup>®</sup>, and other brands of IVC filters.

83. 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.

84. 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.

85. 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.

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



87. In 2010, the Defendants began marketing a “new” vena cava filter called the “Eclipse<sup>®</sup>” vena cava filter. The Eclipse<sup>®</sup> filter is identical to the G2 Express<sup>®</sup> except for one important difference: the surface of the Eclipse<sup>®</sup> filter is electro-polished.<sup>10</sup>

88. Defendants introduced the Eclipse<sup>®</sup> filter because:

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

#### **Retrievability of the Recovery<sup>®</sup>, G2<sup>®</sup> and G2 Express<sup>®</sup>**

89. As stated above, the Recovery<sup>®</sup>, G2<sup>®</sup> and G2 Express<sup>®</sup> 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.

90. Each of the Recovery<sup>®</sup>, G2<sup>®</sup> and G2 Express<sup>®</sup> 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**

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<sup>10</sup> 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<sup>®</sup>.

91. Plaintiffs, GOLDIE BROWN and SHANTEL BROWN, and the FILTER IMPLANT CLASS require medical monitoring to ensure that the Recovery<sup>®</sup>, G2<sup>®</sup> and G2 Express<sup>®</sup> filters implanted within their bodies have not yet failed/fractured.

92. In order to determine whether failure of a Recovery<sup>®</sup>, G2<sup>®</sup> and G2 Express<sup>®</sup> 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.

93. Those people requiring medical monitoring, like Plaintiffs, GOLDIE BROWN and SHANTEL BROWN, and the members of the FILTER IMPLANT CLASS, are recommended<sup>11</sup> 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.

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<sup>11</sup> In August 2010, the FDA issued a pronouncement concerning the safety of indwelling retrievable vena cava filters. This included the Recovery<sup>®</sup>, G2<sup>®</sup> and G2 Express<sup>®</sup> devices. The FDA warned physicians about the consequences of long term implant of retrievable IVC filters. These consequences include fracture and migration of devices. The Society of Interventional Radiologists published recommended reporting standards in 2003 in which they stated that “Patients with permanently implanted devices deserve routine follow-up” via “clinical examination and objective testing.” *Recommended Reporting Standards for Vena Cava Filter Placement and Patient Follow-Up*, J Vasc Radiol 2003; 14:S427-432. In addition, 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 recommends regular and frequent monitoring of patients in whom the Recovery Filter System remains implanted. (*Retrieval of the Recovery Filter after Arm Perforation, Fracture, and Migration to the Right Ventricle*, Hull et. al., J. Vasc. Interv. Radiol. 2008; 19:1107-1111). Dr. Hull specifically recommends “imaging with unenhanced abdominal CT to look for arm perforation, fracture, or migration to further evaluate the scope and risk posed by this [the Recovery<sup>TM</sup>7 filter.” The 2010 study (“Prevalence of Fracture and Fragment Embolization of Bard Retrievable Vena Cava 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<sup>®</sup> and Recovery<sup>®</sup> devices: 125 and 259r, respectively. Nicholson, et al reported that the rate of fracture for the G2<sup>®</sup> may actually be higher given the time that the G2<sup>®</sup> filter may be implanted in the human body.

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

95. 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.

96. 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<sup>®</sup>, G2<sup>®</sup> and G2 Express<sup>®</sup> 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.

97. 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. “Venacavagrams”;
- d. Other Appropriate Imaging Studies; and
- e. Regular physicians' visits and examinations.

**DEFENDANTS’ KNOWLEDGE OF THE FAILURE OF, AND DANGERS ASSOCIATED WITH, THE RECOVERY<sup>®</sup> G2<sup>®</sup> AND G2 EXPRESS<sup>®</sup> FILTERS**

98. As early as 2003, the Defendants C.R. Bard, Inc. and Bard Peripheral Vascular, Inc., knew that the Recovery<sup>®</sup> Filter was defective and was failing and causing injury and death to patients other than Plaintiffs in which the device was implanted.

99. Still, despite this knowledge, the Defendants C.R. Bard, Inc. and Bard Peripheral Vascular, Inc., failed to voluntarily recall the Recovery<sup>®</sup> 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<sup>®</sup> Filter was designed, manufactured and ready for sale in August 2005.

100. 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<sup>®</sup> Filter and G2 Express<sup>®</sup> were also defective and unreasonably dangerous due to filter failure and were causing injury and death to patients who had received the G2<sup>®</sup> Filter System.

101. Reliable scientific and medical researchers have established that the filter failure rate of the Recovery<sup>®</sup>, G2<sup>®</sup> and G2 Express<sup>®</sup> 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.

102. Upon information and belief, from the time the Recovery<sup>®</sup>, G2<sup>®</sup> and G2 Express<sup>®</sup> 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.

103. Furthermore, once the "Eclipse<sup>®</sup>" filter was introduced in 2010, the Defendants engaged in a pattern of significantly raising the prices of the G2<sup>®</sup> and G2 Express<sup>®</sup> filters in order to motivate their customers to buy the new "Eclipse<sup>®</sup>" filter and to aggressively phase out by cannibalizing the G2<sup>®</sup> and G2 Express<sup>®</sup>. At no time did the Defendants advise the medical community or the public that the reason they were phasing out the G2<sup>®</sup> and G2 Express<sup>®</sup> because of filter failure due to lack of electro-polishing of the devices. Rather, the Defendants deceptively told customers that the new device was because of continued product improvements.

104. Further, the Defendants engaged in conduct in marketing the Recovery<sup>®</sup>, G2<sup>®</sup> and G2 Express<sup>®</sup> 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 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.

105. The conduct of the Defendants, as alleged in this Complaint, constituted outrageous corporate conduct that demonstrates a conscious disregard for the safety of the Plaintiffs. The Defendants had actual knowledge of dangers to the life and limb of the Plaintiffs presented by the Recovery<sup>®</sup>, G2<sup>®</sup> and G2 Express<sup>®</sup> 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<sup>®</sup>, G2<sup>®</sup> and G2 Express<sup>®</sup> filters from the market in a timely and safe fashion;

106. Despite having knowledge of the defective and dangerous condition of the Recovery<sup>®</sup>, G2<sup>®</sup> and G2 Express<sup>®</sup> 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<sup>®</sup>, G2<sup>®</sup> and G2 Express<sup>®</sup> filters.

107. The Plaintiffs further allege that the Defendants 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**

108. Plaintiffs reallege and incorporate by reference each of the foregoing allegations.

109. 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<sup>®</sup>, G2<sup>®</sup>, and G2 Express<sup>®</sup> filters.

110. C.R. BARD, INC., in designing, developing, manufacturing marketing, labeling, selling, and monitoring 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 its IVC Filters.

111. At the time of the manufacture and sale of the Recovery<sup>®</sup>, G2<sup>®</sup>, and G2 Express<sup>®</sup> filters (2003 until the present), defendant C.R. BARD, INC. knew or should have known that the Recovery<sup>®</sup>, G2<sup>®</sup>, and G2 Express<sup>®</sup> 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.

112. 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<sup>®</sup>, G2<sup>®</sup>, and G2 Express<sup>®</sup> filters, namely, the incidence of filter failure of the Recovery<sup>®</sup>, G2<sup>®</sup>, and G2 Express<sup>®</sup> filters and/or the likelihood that these filters could not be safely removed;
- b. Unreasonably and carelessly manufacturing a product, namely, Recovery<sup>®</sup>, G2<sup>®</sup>, and G2 Express<sup>®</sup> 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<sup>®</sup>, G2<sup>®</sup>, and G2 Express<sup>®</sup> 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<sup>®</sup>, G2<sup>®</sup>, and G2 Express<sup>®</sup> filters that presented the risk of harm to the Plaintiffs and others similarly situated in that it was prone to filter failure.

113. 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.



114. 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 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.

115. 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 users or consumers of their Recovery<sup>®</sup>, G2<sup>®</sup>, and G2 Express<sup>®</sup> 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 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.

WHEREFORE, the Representative Plaintiffs and the FILTER IMPLANT CLASS Plaintiffs pray for judgment against Defendants, including Defendants, C.R. BARD, INC., and BARD PERIPHERAL VASCULAR, INC., for damages for medical monitoring, attorneys costs and fees, and any additional damages the Court deems appropriate.

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

116. Plaintiffs reallege and incorporate by reference each of the foregoing allegations.

117. 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<sup>®</sup>, G2<sup>®</sup>, and G2 Express<sup>®</sup> filters.

118. BARD PERIPHERAL VASCULAR, INC., in designing, developing, manufacturing marketing, labeling, selling, and monitoring 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.

119. At the time of the manufacture and sale of the Recovery<sup>®</sup>, G2<sup>®</sup>, and G2 Express<sup>®</sup> filters (2003 until the present), defendant BARD PERIPHERAL VASCULAR, INC. knew or should have known that the Recovery<sup>®</sup>, G2<sup>®</sup>, and G2 Express<sup>®</sup> 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.

120. 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<sup>®</sup>, G2<sup>®</sup>, and G2 Express<sup>®</sup> filters,

namely, the incidence of filter failure of the Recovery<sup>®</sup>, G2<sup>®</sup>, and G2 Express<sup>®</sup> filters and/or the likelihood that these filters could not be safely removed;

b. Unreasonably and carelessly manufacturing a product, namely, Recovery<sup>®</sup>, G2<sup>®</sup>, and G2 Express<sup>®</sup> 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<sup>®</sup>, G2<sup>®</sup>, and G2 Express<sup>®</sup> 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<sup>®</sup>, G2<sup>®</sup>, and G2 Express<sup>®</sup> filters that presented the risk of harm to the Plaintiffs and others similarly situated in that it was prone to filter failure.

121. 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.

122. 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 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.

123. 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<sup>®</sup>, G2<sup>®</sup>, and G2 Express<sup>®</sup> 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.

WHEREFORE, the Representative Plaintiffs and the FILTER IMPLANT CLASS Plaintiffs pray for judgment against Defendants, including Defendants, C.R. BARD, INC., and BARD PERIPHERAL VASCULAR, INC., for damages for medical monitoring, attorneys costs and fees, and any additional damages the Court deems appropriate.

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

124. Plaintiffs reallege and incorporate by reference each of the foregoing allegations.

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

126. When the Recovery<sup>®</sup>, G2<sup>®</sup>, and G2 Express<sup>®</sup> filters were manufactured and sold by the Defendant C.R. Bard, 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<sup>®</sup>, G2<sup>®</sup>, and G2 Express<sup>®</sup> filters were inadequately, improperly, and inappropriately prepared and/or finished, causing the device to weaken and fail.

127. 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.

128. As a further direct and 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.

129. Plaintiffs further allege that 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.

WHEREFORE, the Representative Plaintiffs and the FILTER IMPLANT CLASS Plaintiffs pray for judgment against Defendants, including Defendants, C.R. BARD, INC., and BARD PERIPHERAL VASCULAR, INC., for damages for medical monitoring, attorneys costs and fees, and any additional damages the Court deems appropriate.

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

130. Plaintiffs reallege and incorporate by reference each of the foregoing allegations.

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

132. When the Recovery<sup>®</sup>, G2<sup>®</sup>, and G2 Express<sup>®</sup> filters were manufactured, and sold by 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<sup>®</sup>, G2<sup>®</sup>, and G2 Express<sup>®</sup> filters were inadequately, improperly, and inappropriately prepared and/or finished, causing the device to weaken and fail.

133. 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.

134. 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 Defendants' filters remain within their bodies. Plaintiffs and members of the FILTER IMPLANT CLASS will be required to expend money and incur obligations for medical and related expenses as a result of this medical monitoring.

135. Plaintiffs further allege that 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. 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.

WHEREFORE, the Representative Plaintiffs and the FILTER IMPLANT CLASS Plaintiffs pray for judgment against Defendants, including Defendants, C.R. BARD, INC., and

BARD PERIPHERAL VASCULAR, INC., for damages for medical monitoring, attorneys costs and fees, and any additional damages the Court deems appropriate.

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

136. Plaintiffs reallege and incorporate by reference each of the foregoing allegations.

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

138. When the Recovery<sup>®</sup>, G2<sup>®</sup>, and G2 Express<sup>®</sup> 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<sup>®</sup>, G2<sup>®</sup>, and G2 Express<sup>®</sup> 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, as electro-polishing was not part of the implants' design, subjecting them to substantially increased risks of fracture and failure that are absent in other implants.

139. 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 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.

140. 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 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.

141. Plaintiffs further allege that 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.

WHEREFORE, the Representative Plaintiffs and the FILTER IMPLANT CLASS Plaintiffs pray for judgment against Defendants, including Defendants, C.R. BARD, INC., and BARD PERIPHERAL VASCULAR, INC., for damages for medical monitoring, attorneys costs and fees, and any additional damages the Court deems appropriate.

**COUNT VI**  
**STRICT LIABILITY – DESIGN DEFECT**  
**PLAINTIFFS vs. BARD PERIPHERAL VASCULAR, INC.**  
**MEDICAL MONITORING**

142. Plaintiffs reallege and incorporate by reference each of the foregoing allegations.

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

144. When the Recovery<sup>®</sup>, G2<sup>®</sup>, and G2 Express<sup>®</sup> 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<sup>®</sup>, G2<sup>®</sup>, and G2 Express<sup>®</sup> filters were inadequately, improperly, and inappropriately prepared and/or finished, causing the device to be at substantial risk of weakening and failure. The risk of failure and resultant injury from the IVC filters is of a different nature and kind than other implants and presents risks to Plaintiffs above and beyond the usual foreign body reaction and rejection risks of other implants. The substantially increased risks of injury to Plaintiffs derives from Defendants' defective design of the implants, as electro-polishing was not part of the implants' design, subjecting them to substantially increased risks of fracture and failure that are absent in other implants.

145. 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.

146. 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 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.

147. Plaintiffs further allege that 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. 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.

WHEREFORE, the Representative Plaintiffs and the FILTER IMPLANT CLASS Plaintiffs pray for judgment against Defendants, including Defendants, C.R. BARD, INC., and BARD PERIPHERAL VASCULAR, INC., for damages for medical monitoring, attorneys costs and fees, and any additional damages the Court deems appropriate.

**COUNT VII**  
**STRICT LIABILITY – WARNING DEFECT**  
**PLAINTIFFS vs. C.R. BARD, INC.**  
**MEDICAL MONITORING**

148. Plaintiffs reallege and incorporate by reference each of the foregoing allegations.

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

150. Defendants' Recovery<sup>®</sup>, G2<sup>®</sup>, and G2 Express<sup>®</sup> 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.

151. Defendants' Recovery<sup>®</sup>, G2<sup>®</sup>, and G2 Express<sup>®</sup> 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<sup>®</sup>, G2<sup>®</sup>, and G2 Express<sup>®</sup> filters.

152. Defendants' Recovery<sup>®</sup>, G2<sup>®</sup>, and G2 Express<sup>®</sup> 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.

153. Defendants' Recovery<sup>®</sup>, G2<sup>®</sup>, and G2 Express<sup>®</sup> 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 fact that these Nitinol devices were not electro-polished, as was standard in the industry.

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

155. As a direct and proximate result of the defective warnings of Defendants' Recovery<sup>®</sup>, G2<sup>®</sup>, and G2 Express<sup>®</sup> 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.

156. As a further direct and proximate result of the defective warnings of Defendants' Recovery<sup>®</sup>, G2<sup>®</sup>, and G2 Express<sup>®</sup> 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.

157. 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.

WHEREFORE, the Representative Plaintiffs and the FILTER IMPLANT CLASS Plaintiffs pray for judgment against Defendants, including Defendants, C.R. BARD, INC., and BARD PERIPHERAL VASCULAR, INC., for damages for medical monitoring, attorneys costs and fees, and any additional damages the Court deems appropriate.

**COUNT VIII**  
**STRICT LIABILITY – WARNING DEFECT**  
**PLAINTIFFS vs. BARD PERIPHERAL VASCULAR, INC.**  
**MEDICAL MONITORING**

158. Plaintiffs reallege and incorporate by reference each of the foregoing allegations.

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

160. Defendants' Recovery<sup>®</sup>, G2<sup>®</sup>, and G2 Express<sup>®</sup> 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.

161. Defendants' Recovery<sup>®</sup>, G2<sup>®</sup>, and G2 Express<sup>®</sup> 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<sup>®</sup>, G2<sup>®</sup>, and G2 Express<sup>®</sup> filters.

162. Defendants' Recovery<sup>®</sup>, G2<sup>®</sup>, and G2 Express<sup>®</sup> 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.

163. Defendants' Recovery<sup>®</sup>, G2<sup>®</sup>, and G2 Express<sup>®</sup> 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 fact that these Nitinol devices were not electro-polished, as was standard in the industry.

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

165. As a direct and proximate result of the defective warnings of Defendants' Recovery<sup>®</sup>, G2<sup>®</sup>, and G2 Express<sup>®</sup> 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.

166. As a further direct and proximate result of the defective warnings of Defendants' Recovery<sup>®</sup>, G2<sup>®</sup>, and G2 Express<sup>®</sup> 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.

167. 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. 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.

WHEREFORE, the Representative Plaintiffs and the FILTER IMPLANT CLASS Plaintiffs pray for judgment against Defendants, including Defendants, C.R. BARD, INC., and BARD PERIPHERAL VASCULAR, INC., for damages for medical monitoring, attorneys costs and fees, and any additional damages the Court deems appropriate.

**COUNT IX**  
**FRAUDULENT CONCEALMENT**  
**PLAINTIFFS vs. C.R. BARD, INC.**  
**MEDICAL MONITORING**

168. Plaintiffs reallege and incorporate by reference each of the foregoing allegations.

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

170. Defendants' Recovery<sup>®</sup>, G2<sup>®</sup>, and G2 Express<sup>®</sup> 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.

171. Defendant was aware of the defective nature of their Recovery<sup>®</sup>, G2<sup>®</sup>, and G2 Express<sup>®</sup> filters, and the risks associated therewith.

172. As the manufacturer, distributor, marketer, and seller of sophisticated medical devices, including the Recovery<sup>®</sup>, G2<sup>®</sup>, and G2 Express<sup>®</sup> filters, Defendant was 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.

173. Defendant also owed a duty to disclose the hazardous nature of their Recovery<sup>®</sup>, G2<sup>®</sup>, and G2 Express<sup>®</sup> 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 which were not accessible to Plaintiffs and members of the FILTER IMPLANT CLASS, the public at large, and the medical community; namely, the hazardous nature of their Recovery<sup>®</sup>, G2<sup>®</sup>, and G2 Express<sup>®</sup> filters.



174. Defendant also owed a duty to disclose the hazardous nature of their Recovery<sup>®</sup>, G2<sup>®</sup>, and G2 Express<sup>®</sup> filters to Plaintiffs and members of the FILTER IMPLANT CLASS, the public at large, and the medical community, because Defendant made representations regarding their Recovery<sup>®</sup>, G2<sup>®</sup>, and G2 Express<sup>®</sup> 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.

175. Notwithstanding their knowledge of the hazardous nature of their Recovery<sup>®</sup>, G2<sup>®</sup>, and G2 Express<sup>®</sup> 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 Defendants' Recovery<sup>®</sup>, G2<sup>®</sup>, and G2 Express<sup>®</sup> filters.

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

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

178. As a further direct and proximate result of Defendants' fraudulent concealment of the hazards of their Recovery<sup>®</sup>, G2<sup>®</sup>, and G2 Express<sup>®</sup> 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.

179. As a further direct and proximate result of Defendants' fraudulent concealment of the hazards of their Recovery<sup>®</sup>, G2<sup>®</sup>, and G2 Express<sup>®</sup> 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 Defendants' 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.

180. 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 users or consumers of their Recovery<sup>®</sup>, G2<sup>®</sup>, and G2 Express<sup>®</sup> filters to serve their own interests and, having reason to know and consciously disregarding the substantial risk that their product might kill or significantly harm patients, or significantly injure the rights of others, consciously pursued a course of conduct knowing that such conduct created a substantial risk of significant harm to other persons. Defendant C.R. BARD, INC., therefore, should be required to respond to the Plaintiffs in the form of a punitive or exemplary damage award.

WHEREFORE, the Representative Plaintiffs and the FILTER IMPLANT CLASS Plaintiffs pray for judgment against Defendants, including Defendants, C.R. BARD, INC., and BARD PERIPHERAL VASCULAR, INC., for damages for medical monitoring, attorneys costs and fees, and any additional damages the Court deems appropriate.

**COUNT X**  
**FRAUDULENT CONCEALMENT**  
**PLAINTIFFS vs. BARD PERIPHERAL VASCULAR, INC.**  
**MEDICAL MONITORING**

181. Plaintiffs reallege and incorporate by reference each of the foregoing allegations.

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

183. Defendants' Recovery<sup>®</sup>, G2<sup>®</sup>, and G2 Express<sup>®</sup> 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.

184. Defendant was aware of the defective nature of their Recovery<sup>®</sup>, G2<sup>®</sup>, and G2 Express<sup>®</sup> filters, and the risks associated therewith.

185. As the manufacturer, distributor, marketer, and seller of sophisticated medical devices, including Recovery<sup>®</sup>, G2<sup>®</sup>, and G2 Express<sup>®</sup>, Defendant was 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.

186. Defendant also owed a duty to disclose the hazardous nature of their Recovery<sup>®</sup>, G2<sup>®</sup>, and G2 Express<sup>®</sup> 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 which were not accessible to Plaintiffs and members of the FILTER IMPLANT CLASS, the public at large, and the medical community; namely, the hazardous nature of their Recovery<sup>®</sup>, G2<sup>®</sup>, and G2 Express<sup>®</sup> filters.

187. Defendant also owed a duty to disclose the hazardous nature of their Recovery<sup>®</sup>, G2<sup>®</sup>, and G2 Express<sup>®</sup> filters to Plaintiffs and members of the FILTER IMPLANT CLASS, the public at large, and the medical community, because Defendant made representations regarding their Recovery<sup>®</sup>, G2<sup>®</sup>, and G2 Express<sup>®</sup> 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.

188. Notwithstanding their knowledge of the hazardous nature of their Recovery<sup>®</sup>, G2<sup>®</sup>, and G2 Express<sup>®</sup> 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 Defendants' Recovery<sup>®</sup>, G2<sup>®</sup>, and G2 Express<sup>®</sup> filters.

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

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

191. As a further direct and proximate result of Defendants' fraudulent concealment of the hazards of their Recovery<sup>®</sup>, G2<sup>®</sup>, and G2 Express<sup>®</sup> 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.

192. a further direct and proximate result of Defendants' fraudulent concealment of the hazards of their Recovery<sup>®</sup>, G2<sup>®</sup>, and G2 Express<sup>®</sup> 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.

193. 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<sup>®</sup>, G2<sup>®</sup>, and G2 Express<sup>®</sup> 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.

WHEREFORE, the Representative Plaintiffs and the FILTER IMPLANT CLASS Plaintiffs pray for judgment against Defendants, including Defendants, C.R. BARD, INC., and BARD PERIPHERAL VASCULAR, INC., for damages for medical monitoring, attorneys costs and fees, and any additional damages the Court deems appropriate.

**COUNT XI**  
**BREACH OF IMPLIED WARRANTIES**  
**PLAINTIFFS vs. C.R. BARD, INC.**  
**MEDICAL MONITORING**

194. Plaintiffs reallege and incorporate by reference each of the foregoing allegations.

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

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

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

198. As set forth hereinabove, Plaintiff and Defendants were in privity of contract.

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

200. Contrary to such implied warranty, Defendant C.R. BARD, INC.'s Recovery<sup>®</sup>, G2<sup>®</sup>, and G2 Express<sup>®</sup> filters were not of merchantable quality, safe or fit for 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.

201. At all times material hereto, the Recovery<sup>®</sup>, G2<sup>®</sup>, and G2 Express<sup>®</sup> 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, Defendant 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.

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

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

204. Defendant 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.

205. Defendant C.R. BARD, INC. sold Recovery<sup>®</sup>, G2<sup>®</sup>, and G2 Express<sup>®</sup> filters to the Plaintiffs and/or their representatives with the knowledge and intent that it would be used for the benefit of the Plaintiffs. Recovery<sup>®</sup>, G2<sup>®</sup>, and G2 Express<sup>®</sup> filters were implanted into Plaintiffs and the FILTER IMPLANT CLASS during surgical procedures, and the Plaintiffs and members of the FILTER IMPLANT CLASS were charged the cost for the Recovery<sup>®</sup>, G2<sup>®</sup>, and G2 Express<sup>®</sup> filters.

206. As a direct and proximate result of Defendants' 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.

207. 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 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.

208. Recovery<sup>®</sup>, G2<sup>®</sup>, and G2 Express<sup>®</sup> filters were not altered by the Plaintiffs, their treating physician or other medical personnel. The Recovery<sup>®</sup>, G2<sup>®</sup>, and G2 Express<sup>®</sup> filters were defective when they left the control of Defendant C.R. BARD, INC., and Defendant knew they would be used without additional testing. Recovery<sup>®</sup>, G2<sup>®</sup>, and G2 Express<sup>®</sup> filters were



unfit for intended purpose for use as described hereinabove, and the Plaintiffs did not receive the Recovery<sup>®</sup>, G2<sup>®</sup>, and G2 Express<sup>®</sup> filters as warranted.

209. Plaintiffs further allege that 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.

WHEREFORE, the Representative Plaintiffs and the FILTER IMPLANT CLASS Plaintiffs pray for judgment against Defendants, including Defendants, C.R. BARD, INC., and BARD PERIPHERAL VASCULAR, INC., for damages for medical monitoring, attorneys costs and fees, and any additional damages the Court deems appropriate.

**COUNT XII**  
**BREACH OF IMPLIED WARRANTIES**  
**PLAINTIFFS vs. BARD PERIPHERAL VASCULAR, INC.**  
**MEDICAL MONITORING**

210. Plaintiffs reallege and incorporate by reference each of the foregoing allegations.

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

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

213. At the time of Plaintiffs' purchase of the Recovery<sup>®</sup>, G2<sup>®</sup>, and G2 Express<sup>®</sup> 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 Recovery<sup>®</sup>, G2<sup>®</sup>, and G2 Express<sup>®</sup> filters was inadequately, improperly and inappropriately prepared and/or finished, thereby subjecting the device to weakening and failure.

214. As set forth hereinabove, Plaintiff and Defendant was in privity of contract.

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

216. Contrary to such implied warranty, Defendant BARD PERIPHERAL VASCULAR, INC.'s Recovery<sup>®</sup>, G2<sup>®</sup>, and G2 Express<sup>®</sup> filters were not of merchantable quality, safe or fit for 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.

217. At all times material hereto, the Recovery<sup>®</sup>, G2<sup>®</sup>, and G2 Express<sup>®</sup> 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, Defendant 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.

218. Defendant BARD PERIPHERAL VASCULAR, INC., as the designer, manufacturer, marketer, packager, distributor or seller, impliedly warranted that Recovery<sup>®</sup>, G2<sup>®</sup>, and G2 Express<sup>®</sup> filters were fit for their intended purpose as described hereinabove.

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

220. Defendant 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 Defendant BARD PERIPHERAL VASCULAR, INC. filters to be merchantable.

221. Defendant sold Recovery<sup>®</sup>, G2<sup>®</sup>, and G2 Express<sup>®</sup> filters to the Plaintiffs and/or their representatives with the knowledge and intent that it would be used for the benefit of the Plaintiffs. Recovery<sup>®</sup>, G2<sup>®</sup>, and G2 Express<sup>®</sup> filters were implanted into Plaintiffs and the FILTER IMPLANT CLASS during surgical procedures, and the Plaintiffs and members of the FILTER IMPLANT CLASS were charged the cost for the Recovery<sup>®</sup>, G2<sup>®</sup>, and G2 Express<sup>®</sup> filters.

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

223. 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.

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

225. Plaintiffs further allege that 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.

WHEREFORE, the Representative Plaintiffs and the FILTER IMPLANT CLASS Plaintiffs pray for judgment against Defendants, including Defendants, C.R. BARD, INC., and BARD PERIPHERAL VASCULAR, INC., for damages for medical monitoring, attorneys costs and fees, and any additional damages the Court deems appropriate.

**COUNT XIII**  
**NEGLIGENCE – FAILURE TO WARN**  
**PLAINTIFFS vs. C.R. BARD, INC.**  
**MEDICAL MONITORING**

226. Plaintiffs reallege and incorporate by reference each of the foregoing allegations.

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

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

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

230. Since the time the Recovery<sup>®</sup>, G2<sup>®</sup>, and G2 Express<sup>®</sup> was/were introduced to the market, Defendant C.R. BARD, INC. became aware of various injuries and life threatening consequences resulting from the manufacture and sale of their Recovery<sup>®</sup>, G2<sup>®</sup>, and G2 Express<sup>®</sup> as implanted in patients across the country other than Plaintiffs herein.

231. Once Defendant C.R. BARD, INC. became aware of or gained knowledge of the fact that the Recovery<sup>®</sup>, G2<sup>®</sup>, and G2 Express<sup>®</sup> were defective and failing, as stated hereinabove, the Defendant was 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.

232. Upon information and belief, Defendant 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 devices/products were sold.

233. Despite such knowledge, Defendant C.R. BARD, INC. failed to notify or warn medical professionals or end users/purchasers of the dangers and risk associated with the Recovery<sup>®</sup>, G2<sup>®</sup>, and G2 Express<sup>®</sup> filters so as to permit them to monitor the devices' integrity, and remove the devices if appropriate before injury occurred.

234. In failing to notify or warn, as set forth hereinabove, Defendant C.R. BARD, INC. breached their duty of care and was negligent.

235. 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.

236. As a direct and proximate result of the conduct of Defendant C.R. BARD, INC., 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 in the future to ensure that the device implanted within their bodies (the Recovery<sup>®</sup>, G2<sup>®</sup>, and G2 Express<sup>®</sup> filters) has not failed/fractured. In order to obtain these procedures, Plaintiffs and the members of the FILTER IMPLANT CLASS will be required to incur future expenses.

WHEREFORE, the Representative Plaintiffs and the FILTER IMPLANT CLASS Plaintiffs pray for judgment against Defendants, including Defendants, C.R. BARD, INC., and BARD PERIPHERAL VASCULAR, INC., for damages for medical monitoring, attorneys costs and fees, and any additional damages the Court deems appropriate.

**COUNT XIV**  
**NEGLIGENCE – FAILURE TO WARN OF POST-MARKETING DEVICE FAILURE**  
**PLAINTIFFS vs. BARD PERIPHERAL VASCULAR, INC.**  
**MEDICAL MONITORING**

237. Plaintiffs reallege and incorporate by reference each of the foregoing allegations.

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

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

240. 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.

241. Since the time the Recovery<sup>®</sup>, G2<sup>®</sup>, and G2 Express<sup>®</sup> 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<sup>®</sup>, G2<sup>®</sup>, and G2 Express<sup>®</sup> as implanted in patients across the country other than Plaintiffs herein.

242. Once Defendant BARD PERIPHERAL VASCULAR, INC. became aware of or gained knowledge of the fact that the Recovery<sup>®</sup>, G2<sup>®</sup>, and G2 Express<sup>®</sup> were defective and failing, as stated hereinabove, the Defendant was 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.

243. Upon information and belief, 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.

244. Despite such knowledge, 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<sup>®</sup>, G2<sup>®</sup>, and G2 Express<sup>®</sup> filters so as to permit them to monitor the devices' integrity, and remove the devices if appropriate before injury occurred.

245. In failing to notify or warn, as set forth hereinabove, Defendant BARD PERIPHERAL VASCULAR, INC. breached its duty of care and was negligent.

246. 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.

247. As a direct and proximate result of the conduct of Defendant BARD PERIPHERAL VASCULAR, INC., 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<sup>®</sup>, G2<sup>®</sup>, and G2



Express<sup>®</sup> filters) has not failed/fractured. In order to obtain these procedures, Plaintiffs and the members of the FILTER IMPLANT CLASS will be required to incur future expenses.

WHEREFORE, the Representative Plaintiffs and the FILTER IMPLANT CLASS Plaintiffs pray for judgment against Defendants, including Defendants, C.R. BARD, INC., and BARD PERIPHERAL VASCULAR, INC., for damages for medical monitoring, attorneys costs and fees, and any additional damages the Court deems appropriate.

### **PRAYER FOR RELIEF**

#### **Class Certification**

1. Plaintiffs request certification of this cause as a class action suit pursuant to the Pennsylvania Rules of Civil Procedure, 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<sup>®</sup>, G2<sup>®</sup>, and G2 Express<sup>®</sup> 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<sup>®</sup>, G2<sup>®</sup>, and G2 Express<sup>®</sup> 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<sup>®</sup>, G2<sup>®</sup> or G2 Express<sup>®</sup> vena cava filters.

5. For Plaintiffs' costs of suit incurred herein;
6. Pre-judgment and post-judgment interest;
7. For Plaintiffs' reasonable attorney's fees; and
8. For such other and further relief as the Court deems just and proper.

WHEREFORE, the Plaintiffs hereby demand trial by jury of all issues pleaded against each Defendant.

Respectfully submitted,

**Lopez McHugh, LLP**



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*Attorneys for Plaintiffs*

Dated: August 9, 2012

**VERIFICATION**

I hereby verify that I am counsel for the plaintiffs and that the statements made in the foregoing Complaint are true and correct to the best of my knowledge, information and belief. The undersigned understands that the statements therein are made subject to the penalties of 18 Pa.C.S. §4904 relating to unsworn falsification to authorities.



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James J. McHugh, Jr., Esquire  
Carrie R. Capouellez, Esquire  
Michael S. Katz, Esquire

DATED: August 9, 2012