IN THE UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

MARY DUFFIE and JAMES DUFFIE, *Plaintiffs*, vs. C.R. BARD, INC., a New Jersey corporation, BARD PERIPHERAL VASCULAR, INC., (a subsidiary and/or division of defendant C.R. BARD, INC.) an Arizona corporation, *Defendants*.	**Case No.** **COMPLAINT FOR DAMAGES** **DEMAND FOR A JURY TRIAL**

COMPLAINT

Plaintiffs, MARY and JAMES DUFFIE, by and through undersigned attorneys, hereby sue defendants C.R. BARD, INC.; BARD PERIPHERAL VASCULAR, INC., a subsidiary corporation and/or division of C.R. BARD, INC., (collectively, the "Defendants") and allege as follows:

1. This is an action for damages relating to Defendants' development, testing, assembling, manufacturing, packaging, labeling, preparing, distribution,

marketing, supplying, and/or selling the defective product sold under the name "inferior vena cava filter" (hereinafter "IVC filter").

PARTIES

2. Mary Duffie and James Duffie ("Plaintiffs") at all times relevant to this action resided in, continue to reside in, and are citizens of Atlanta, Georgia, which is located in DeKalb County, Georgia.

3. Defendant C.R. Bard, Inc. ("Bard") is a corporation duly organized and existing under the laws of the state of Delaware and has its principal place of business at 730 Central Avenue in Murray Hill, New Jersey. Bard at all times relevant to this action, designed, set specifications, manufactured, prepared, compounded, assembled, processed, marketed, distributed, and sold the G2® Filter system to be implanted in patients throughout the United States, including Georgia.[1] At all times relevant hereto, Defendant Bard was or has been engaged in business in Georgia, and has conducted substantial business activity in Georgia. Defendant has also carried on solicitations or service activities in the State of Georgia. Service of Process can be had on Defendant C.R. Bard, Inc. by serving

[1] "G2 Filter" is meant to include the G2, and the "G2 Express" filter manufactured by Bard. The G2 Express is the G2 filter with a modified cap to include a hook on the top of the device to allow clinicians the ability to attempt to snare the filter during retrieval.

its registered agent, CT Corporation System, at 1999 Bryan Street, Suite 900, Dallas, Texas 75201-3136.

4. Defendant Bard Peripheral Vascular, Inc. ("BPV") is a wholly owned subsidiary corporation of defendant Bard, with its principal place of business at 1625 West 3rd Street, Tempe, Arizona. BPV at all times relevant to this action, designed, set specifications, manufactured, prepared, compounded, assembled, processed, marketed, distributed, and sold the G2® Filter System to be implanted in patients throughout the United States, including Georgia. At all times relevant hereto, Defendant BPV was or has been engaged in business in Georgia, and has conducted substantial business activity in Georgia. Defendant has also carried on solicitations or service activities in the State of Georgia. Service of Process can be had on Defendant Bard Peripheral Vascular, Inc. by serving its registered agent, CT Corporation System, at 3800 North Central Avenue, Suite 460, Phoenix, Arizona 85012.

JURISDICTION AND VENUE

5. Jurisdiction is proper in this Court under 28 U.S.C. § 1332(a) (1) because the plaintiffs and the defendants are citizens of different states, and the amount in controversy exceeds $75,000, excluding interest and costs.

6. On August 17, 2015, The United States Judicial Panel on Multidistrict Litigation transferred civil actions to the United States District Court for the District of Arizona for coordinated or consolidated pretrial proceedings under 28 U.S.C. § 1407, assigned to the Honorable David G. Campbell under MDL No. 2641.

GENERAL FACTUAL ALLEGATIONS

7. Plaintiffs bring this case for serious injuries suffered as a result of a surgically implanted medical device, known as a G2 Filter System (hereafter G2, G2 Filter, or G2 Filter System), causing serious and ongoing physical, emotional, and economic damages.

8. The G2 Filter was designed, manufactured, prepared, compounded, assembled, processed, labeled, marketed, distributed, and sold by Defendants from approximately September 2005 to the present for prevention of blood clots (thrombi) from traveling from the lower portions of the body to the heart and lungs.

9. Prior to Plaintiff Mary Duffie being implanted with a G2 filter on or about February 13, 2008, Defendants knew and should have known that the device was defective and unreasonably dangerous for, *inter alia*, the following reasons:

a. Defendants failed to conduct any clinical testing, such as animal studies, to determine how the device would function once permanently implanted in the human body.

b. Defendants knew and/or should have known that the Recovery Filter and G2 filter system had a high rate of fracture, migration, and excessive tilting and perforation of the vena cava wall once implanted in the human body. Defendants know and/or should have known that such failures exposed patients to serious injuries, including: death; hemorrhage; cardiac/pericardial tamponade; cardiac arrhythmia and other symptoms similar to myocardial infarction; severe and persistent pain; perforations of tissue, vessels, and organs; and inability to remove the device. Upon information and belief, Defendants also knew or should have known that certain conditions or post-implant procedures, such as morbid obesity or open abdominal procedures, could affect the safety and integrity of the device. Further, Defendants knew and should have known that these risks for the Recovery device and the G2

filter were and are substantially higher than other similar devices.

c. Further, Defendants knew and/or should have known that the Recovery Device and G2 filter contained conditions, which Defendants did not intend, which resulted in the device not performing as safely as the ordinary customer would expect.

d. Despite being aware of these risks, Defendants misrepresented, omitted, and/or failed to provide adequate warnings of these risks or instructions for safe use.

e. Even when Defendants designed and began marketing what they alleged to be a device that specifically reduced these risks, they still failed to issue a recall or notify consumers that a safer device was available.

INFERIOR VENA CAVA FILTERS GENERALLY

10. The IVC filter at issue in this case bears the trademark name "G2" filter or "G2 Filter System". The G2 Filter System (hereafter "G2" or "G2 Filter") was manufactured, marketed, and sold by Defendants, C.R. Bard, Inc. and/or Bard Peripheral Vascular, Inc., from September 2005 until approximately 2015. The

Defendants have now ceased manufacturing and selling the G2 throughout the United States of America and abroad.

11. 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.

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

13. The inferior vena cava is a vein that returns blood to the heart from the lower portions of the body. In certain people, for various reasons, thrombi travel from the vessels in the legs and pelvis, through the vena cava and into the lungs. Oftentimes, these thrombi develop in the deep leg veins. 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.

14. Certain people are at increased risk for the development of DVT or PE. For instance someone who undergoes knee or hip joint replacement is at risk for developing DVT/PE. Obese patients are also at increased risk for DVT/PE. So

too are people who have vascular diseases or whom have experienced previous strokes. A number of other conditions predispose people to develop DVT/PE.

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

16. As stated in this Complaint, IVC filters have been on the market for decades. The first IVC filter was introduced in the later 1960's. Since then, the market has been supplemented with all types and designs of filters offered by many different manufacturers.

17. Over the years, a concern developed within the medical community, which was shared with IVC filter manufacturers, that an IVC filter should be designed and manufactured so that it is able to be retrieved from the human body. Ultimately, retrievable IVC filter designs were offered in the market. However, these IVC filter designs were not intended to remain within the human body for indeterminate periods of time. In other words, the initial designs of retrievable IVC filters were intended to remain implanted for a finite period of time. The Recovery

Filter System[2] (discussed in more detail *infra*) was introduced to the market in late 2002 or 2003 (and subsequently removed from the market in late 2005) as an IVC filter that was able to be retrieved after an indeterminate time of placement within the human body.

THE G2 FILTER

18. The G2 Filter System is a medical device constructed of a nickel-titanium alloy (also called "Nitinol") designed to filter blood clots (thrombi) from the human circulatory system. Nitinol material is unique. Nitinol is actually an acronym that stands for Nickel Titanium Naval Ordnance Laboratory. Nitinol is also unique as it possesses "shape memory." That is, Nitinol will change shape according to change in temperature, and then, retake its prior shape after returning to its initial temperature. This quality makes Nitinol appealing for use in certain medical devices, including IVC filters.

19. The design of the G2 Filter System finds its roots in a predecessor device, also designed, manufactured and sold by the Defendants. The predecessor device was called the Recovery Filter System (hereafter "Recovery" or "Recovery Filter").

[2] The Recovery Filter System is the predecessor device to the G2 Filter System.

20. As stated *supra,* the Recovery Filter System was indeed the predecessor/predicate device for the G2 Filter System. Soon after its introduction to the market, reports were made 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 F.D.A., and to the Defendants. In fact, as early as 2003, the Defendants were made aware that the Recovery Filter System was flawed and was causing injury and death to patients who had the filter implanted in their bodies.

21. The Recovery Filter System was plagued with manufacturing and design defects which caused the Recovery Filter System to experience a significant rate of fracture and migration of the device. Studies performed in the medical and scientific communities established that the Recovery Filter had a 21% to 31.7% rate of fracture.

22. The failure of the Recovery Filter System, as aforesaid, was attributable, in part, to the fact that the Recovery Filter System was designed so as to be unable to withstand the normal anatomical and physiological loading cycles exerted *in vivo*.[3]

[3] 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

23. Sometime after 2003, the Defendants made a decision to introduce a substitute vena cava filter for Bard Peripheral Vascular's vena cava filter product line. This substitute vena cava filter was meant to replace the Recovery Filter System. It was to be called the "G2 Filter". G2 stands for "second generation".

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

25. The Defendants first received clearance from the F.D.A. to market the G2 Filter System as a permanent placement vena cava filter. That is, the G2 Filter System was not initially cleared for retrievable use. The Defendants began selling the G2 Filter System in September of 2005. Later, in 2008, the G2 Filter was cleared by the F.D.A. as a retrievable (option) IVC filter.

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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 "draw marks" on the exterior of the device.

A COMPARISON OF THE RECOVERY FILTER SYSTEM AND THE G2FILTER SYSTEM

26. The Recovery Filter System and the G2 Filter System bear a strong resemblance in a number of respects. First, they look strikingly similar in appearance and have the same design for filtration. That is, the G2 Filter System has six upper struts used for device positioning and filtering, and, six lower struts used for anchoring and filtering-just like the Recovery Filter.

27. In addition, the G2 Filter System is made of the same alloy material as the Recovery Filter System. They both were manufactured of Nitinol, discussed *supra*.

28. Like the Recovery Filter, the G2 Filter System is inserted *via* catheter that is guided by a physician (typically an interventional radiologist) through a blood vessel into the inferior vena cava. Both filters are designed to be retrieved in a somewhat similar fashion.

29. Following endovascular placement of the G2 Filter System, a physician typically uses imaging studies (such as x-rays, "vena cava grams" or CT scans) to confirm successful placement and positioning of the device within the vena cava.

30. Unfortunately, the G2 Filter System also shares some of the defects of its ancestor. The G2 Filter System design causes it to be of insufficient integrity

and strength to withstand normal placement within the human body. The global stressors of the respiratory and cardiac cycles of the human body cause the G2 Filter System to develop stress or "fatigue" fractures of the Nitinol surface of the device.

31. Also, like its predecessor, in addition to design defects, the G2 Filter System suffers from manufacturing defects. These manufacturing defects primarily include the existence of "draw marking" and circumferential grinding markings on the exterior of the surface of the device. The presence of these draw markings and/or circumferential grinding markings further compromises the structural integrity of the G2 Filter System while *in vivo.* In particular, the G2 Filter System is prone to fail at or near the location of draw markings/circumferential grinding markings on the struts of the device. Put simply, the G2 Filter System is not of sufficient strength to withstand normal placement within the human body. The presence of the aforementioned exterior manufacturing defects makes the device more susceptible to fatigue failure.

32. The G2 Filter System is 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[4] indicates that "data is on file" with respect to these product enhancements.

33. Despite the Defendants' claims concerning the safety and efficacy of the G2 Filter System, the F.D.A.'s "MAUDE" (Manufacturer and User Facility Device Experience) database includes several reports of the failure, fracture and migration of the G2 Filter System.

34. Defendants represent the fracture rate of the G2 Filter System to be 1.2%. Based upon a review of the data available in the public domain (including the F.D.A. MAUDE database statistics), this representation does not accurately reflect the true incidence of device fracture.

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

a. 50% of all "adverse events";

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

[4] *See* **www.bardpv.com/** vascular/product.php?p+83 (as available on October 21, 2009).

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

d. 70% of all occurrences of filter fracture.

WHAT HAPPENS WHEN THE G2 FILTER SYSTEM FAILS?

36. The failure (fracture and/or migration) of the G2 Filter System 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.

37. The person who experiences failure (fracture and/or migration) of the G2 Filter System 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 CASE FOR MEDICAL MONITORING

38. In certain cases, medical monitoring is required to evaluate whether a G2 Filter System (or portions of the G2 Filter) has fractured, tilted and/or migrated

(collectively referred to herein as "device failure" or "failure"). In order to determine whether failure of the G2 Filter System has occurred, imaging studies must be performed. Typically, these imaging studies will include un-enhanced computed tomography scan (CT scan) 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 fractured or migrated.

39. Patients requiring medical monitoring are recommended[5] 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, or portions of the device, remains within the body of the patient, the potential for future device failure exists. Consequently, these patients require regular and frequent medical monitoring for the duration of time the device, or portions of the device, remain within their bodies.

[5] Research studies performed in 2008 call for the need of regular and frequent medical monitoring for a patient who had the Recovery vena cava filter implanted in their body. This 2008 research study performed by Jeffrey Hull, M.D. recommends regular and frequent monitoring of patients in whom the Recovery Filter System remains implanted. (*Retrieval of the Recovery Filter after Arm Perforation, Fracture, and Migration to the Right Ventricle*, Hull *et. al.*, J. Vasc. Intern. Radiol. 2008; 19:1107.1111). Dr. Hull specifically recommends "imaging with un-enhanced abdominal CT to look for arm perforation, fracture, or migration to further evaluate the scope and risk posed by this [the Recovery] filter."

40. Patients eligible for medical monitoring for the G2 Filter System or portions of the device need not have experienced past failure of the G2 Filter System. For example, patients who have undergone implant of the G2 Filter System frequently learn that the G2 Filter System cannot be removed due to the fact that it has "grown into" tissue, but, the fracture, tilt or migration of the device may not yet have occurred. As a result of the inability to remove the G2 Filter System, 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 risk for future device failure and require regular and frequent monitoring to evaluate the integrity of the G2 Filter System. 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 G2 Filter System have migrated to the heart or lungs. Furthermore, endovascular surgery may assess the nature and extent of the damage resulting from failure of the G2 Filter System.

41. In those instances where device fracture has occurred, and depending on the circumstances particular to the patient, a person may be required to undergo one or all of the following medical procedures:

a. CT scanning or other imaging studies;

b. Cardiac catheterization;

c. Open heart surgery; and/or,

d. Removal of the G2 Filter System from the vena cava.

42. The G2 Express Filter System was placed in Plaintiff Mary Duffie's body on or about February 13, 2008. Plaintiff learned on January 2, 2014 that a "leg" from her G2 Filter System had perforated a muscle in the heart and open-heart surgery was required to remove the piece of broken filter. The substantial remaining portion of the filter was then removed on January 8, 2014; however, another missing "leg" was never retrieved and assumed to still be in her body. The Plaintiff did not and could not have discovered her injury, the cause of her injury, nor the Defendants part in the cause of her injury until January 2, 2014 at the earliest. Plaintiff has incurred significant medical expenses and has endured extreme pain and suffering, loss of enjoyment of life, and other losses, some of which are permanent in nature. As a result of the failure of the G2 Filter System, Plaintiff has become impaired and her ability to earn wages has been diminished, and will remain so in the future.

43. As a direct and proximate result of the conduct and defective product of the Defendants, C.R. Bard, Inc. and Bard Peripheral Vascular, Inc., as alleged in her Complaint, Plaintiff has suffered permanent and continuing injury, loss of

enjoyment of life, pain, suffering, and impairment. Plaintiff has suffered emotional trauma, harm and injuries. Plaintiff's ability to carry on the affairs of her daily life has been impacted and diminished, and will continue to diminish in the future.

44. As a direct and proximate result of the conduct and defective product of the Defendants, C.R. Bard, Inc. and Bard Peripheral Vascular, Inc., as alleged in this Complaint, the Plaintiff has incurred substantial medical expenses, and will continue to incur substantial medical expenses into the future.

THE NECESSITY FOR MEDICAL MONITORING

45. As a direct and proximate result of the conduct and defective product of the Defendants, C.R. Bard, Inc. and Bard Peripheral Vascular, Inc., as alleged in this Complaint, medical monitoring is necessary for Plaintiff. Medical monitoring includes:

a. Regularly scheduled CT scans or other appropriate imaging studies; and/or,

b. Potential cardiac catheterization or other endovascular procedure to detect the presence of migrated pieces of the G2 Filter System; and/or physicians' visits and examinations.

THE DEFENDANTS' KNOWLEDGE OF THE FAILURE OF THE G2 FILTER SYSTEM AND THE DANGERS ASSOCIATED WITH THE DEVICE

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

47. Data established that the failure rate of the G2 Filter System was/is exceedingly higher than the rates the Defendants have published in the past, and currently continue to publish to the medical community, members of the public, and the F.D.A.

48. Over 921 adverse events were identified by the FDA through a warning issued in August of 2010 regarding risks associated with IVC filter complications.

49. Upon information and belief, from the time the G2 Filter System became available on the market, the Defendants, C.R. Bard, Inc. and Bard Peripheral Vascular, Inc., embarked on an aggressive campaign of "off-label marketing" concerning the G2 Filter System. This included representations made to physicians, healthcare professionals, and other members of the medical

community that the G2 Filter System was safe and effective for retrievable use prior to the F.D.A. clearing the G2 Filter System retrievable use in 2008.

50. The conduct of the Defendants C.R. Bard, Inc. and Bard Peripheral Vascular, Inc. as alleged in this Complaint, constituted, willful, wanton, gross, and outrageous corporate conduct that demonstrates a conscious disregard for the safety of Plaintiff Mary Duffie. The Defendants C.R. Bard, Inc. and Bard Peripheral Vascular Inc. had actual knowledge of dangers to the life and limb of the Plaintiff presented by the G2 Filter System, yet consciously failed to act reasonably to:

a. Inform or warn the Plaintiff, her physicians, or the public at large of the dangers; and

b. Recall the G2 Filter System from the market in a timely and safe fashion.

51. Despite having knowledge as early as 2005 of the unreasonably dangerous and defective nature of the product, 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 G2 Filter System.

52. Plaintiffs further allege that the Defendants C.R. Bard, Inc. and Bard Peripheral Vascular, Inc. acted in willful, wanton, gross manner, and in total

disregard for the health and safety of the users or consumers of its G2 Filter System, including Plaintiff Mary Duffie, and acted to serve their own interests and having reason to know and consciously pursued a course of conduct knowing that such conduct created a substantial risk of significant harm to other persons. Therefore, Defendants C.R. Bard, Inc. and Bard Peripheral Vascular, Inc. should be required to respond to the Plaintiffs in the form of a punitive or exemplary damage award.

THE FEDERAL REQUIREMENTS

53. Federal regulation states that "recall means a firm's removal or correction of a marketed product that the Food and Drug Administration considers to be in violation of the laws it administers and against which the agency would initiate legal action, e.g. seizure." See 21 CFR §7.3(g).

54. Federal regulation states that "recall classification means the numerical designation, i.e., I, II or III, assigned by the Food and Drug Administration to a particular product recall to indicate the relative degree of health hazard presented by the product being recalled." See 21 CFR §7.3(m).

55. Federal regulation states that "class II is a situation in which use of, or exposure to, a violative product may cause temporary or medically reversible

adverse health consequences or where the probability of serious adverse health consequences is remote." See 21 CFR §7.3(m).

56. The classification of the product withdrawals and corrections of the Defendants' devices (described above) as Class II Recalls by the F.D.A confirms by definition that the devices were in violation of federal law and that initiation of legal action or seizure would be indicated for these devices.

57. Pursuant to federal law, a device is deemed to be adulterated if, among other things, it fails to meet established performance standards, or if the methods, facilities or controls used for its manufacture, packing, storage or installation are not in conformity with federal requirements. See 21 U.S.C. §351.

58. Pursuant to federal law, a device is deemed to be misbranded if, among other things, its labeling is false or misleading in any particular manner, or if it is dangerous to health when used in the manner prescribed, recommended or suggested in the labeling thereof. See 21 U.S.C. §352.

59. Pursuant to federal law, manufacturers are required to comply with F.D.A. regulation of medical devices, including F.D.A. requirements for records and reports, in order to prohibit introduction of medical devices that are adulterated or misbranded, and to assure the safety and effectiveness of medical devices. In particular, manufacturers must keep records and make reports if any medical

device that may have caused or contributed to death or serious injury, or if the device has malfunctioned in a manner likely to cause or contribute to death or serious injury. Federal law also mandates that the F.D.A. establish regulations requiring a manufacturer of a medical device to report promptly to F.D.A. any correction or removal of a device undertaken to reduce a risk to health posed by the device, or to remedy a violation of federal law by which a device may present a risk to health. See 21 U.S.C. §360(i).

60. Pursuant to federal law, the Secretary of Health and Human Services may prescribe regulations requiring that the methods used in, and that facilities and controls used for, the manufacture, pre-production design validation (including a process to assess the performance of a device but not including an evaluation of the safety or effectiveness of a device), packaging, storage, and installation of a device conform to current good manufacturing proactive, as prescribed in such regulations, to assure that the device will be safe and effective and otherwise in compliance with federal law. See 21. U.S.C §360j (f).

61. Pursuant to F.D.A. regulation, adverse events associated with a medical device must be reported to F.D.A. within 30 days after the manufacturer becomes aware that a device may have caused or contributed to death or serious injury, or that a device has malfunctioned and would be likely to cause or

contribute to death or serious injury if the malfunction was to recur. Such reports must contain all information reasonably known to the manufacturer, including any information that can be obtained by analysis, testing, or other evaluation of the device, and any information in the manufacturer's possession. In addition, manufacturers are responsible for conducting an investigation of each adverse event, and must evaluate the cause of the adverse event. See 21 CFR §803.50.

62. Pursuant to federal regulation, manufacturers of medical devices must also describe in every individual adverse event report whether remedial action was taken in regard to the adverse event, and whether the remedial action was reported to F.D.A. as a removal or correction of the device. See 21 CFR §803.52.

63. Pursuant to federal regulation, manufacturers must report to F.D.A. within five (5) business days after becoming aware of any reportable MDR event or events, including a trend analysis that necessitates remedial action to prevent an unreasonable risk of substantial harm to the public health. See 21 CFR §803.53.

64. Pursuant to federal regulation, device manufacturers must report promptly to F.D.A. any device corrections and removals, and maintain records of device corrections and removals. F.D.A. regulations require submission of a written report within ten (10) working days of any correction or removal of a device initiated by the manufacturer to reduce a risk to health posed by the device,

or to remedy a violation of the Act caused by the device, which may present a risk to health. The written submission must contain, among other things, a description of the event giving rise to the information reported and the corrective or removal actions taken, and any illness or injuries that have occurred with use of the device, including reference to any device report numbers. Manufacturers must also indicate the total number of devices manufactured or distributed which are subject to the correction or removal, and provide a copy of all communications regarding the correction or removal. See 21 CFR §806.

65. Pursuant to federal regulation, manufacturers must comply with specific quality system requirements promulgated by F.D.A. These regulations require manufacturers to meet design control requirements, including but not limited to, conducting design validation to ensure that devices conform to defined user needs and intended uses. Manufacturers must also meet quality standards in manufacture and production. Manufacturers must establish and maintain procedures for implementing corrective actions and preventive actions, and investigate the cause of nonconforming products and take corrective action to prevent recurrence. Manufacturers are also required to review and evaluate all complaints and determine whether an investigation is necessary. Manufacturers are

also required to use statistical techniques where necessary to evaluate product performance. See 21 CFR §820.

66. The regulations requiring conformance to good manufacturing practices are set forth in 21 CFR §820 *et seq*. As explained in the Federal Register, because the Current Good Manufacturing Practice (CGMP) regulations must apply to a variety of medical devices, the regulations do not prescribe the details for how a manufacturer must produce a device. Rather, the quality system regulations provide a framework of basic requirements for each manufacturer to use in establishing a quality system appropriate to the devices designed and manufactured, and the manufacturing processes employed. Manufacturers must adopt current and effective methods and procedures for each device they design and manufacture to comply with and implement the basic requirements set forth in the quality system regulations.

67. Pursuant to 21 CFR §820.1(c), the failure to comply with any applicable provision in Part 820 renders a device adulterated under section 501(h) of the Federal Food Drug & Cosmetic Act ("the Act") (21 U.S.C. § 351).

68. Pursuant to 21 CFR §820.5, each manufacturer shall establish and maintain a quality system that is appropriate for the specific medical device designed or manufactured. "Quality system" means the organizations structure,

responsibilities, procedures, processes, and resources for implementing quality management. See 21 CFR §820.3(v).

69. Pursuant to 21 CFR §820.22, each manufacturer shall establish procedures for quality audits and conduct such audits to assure that the quality system is in compliance with the established quality system requirements and to determine the effectiveness of the quality system.

70. Pursuant to 21 CFR §820.30(a), each manufacturer shall establish and maintain procedures to control the design of the device in order to ensure that specified design requirements are met.

71. Pursuant to 21 CFR §820.30(d), each manufacturer shall establish and maintain procedures for defining and documenting design output in terms that allow an adequate evaluation of conformance to design input requirements.

72. Pursuant to 21 CFR §820.30(e), each manufacturer shall establish and maintain procedures to ensure that formal documented reviews of the design results are planned and conducted at appropriate stages of the device's design development.

73. Pursuant to 21 CFR §820.30(f), each manufacturer shall establish and maintain procedures for verifying the device design to confirm that the device design output meets the design input requirements.

74. Pursuant to 21 CFR §820.30(g), each manufacturer shall establish and maintain procedures for validating the device design. Design validation shall be performed under defined operating conditions on initial production units, lots, or batches, or their equivalents. Design validations shall ensure that devices conform to defined user needs and intended uses and shall include testing of production units under actual or simulated use conditions.

75. Pursuant to 21 CFR §820.30(h), each manufacturer shall establish and maintain procedures to ensure that the device design is correctly translated into production specifications.

76. Pursuant to 21 CFR §820.30(i), each manufacturer shall establish and maintain procedures for the identification, documentation, validation or where appropriate verification, review, and approval of design changes before their implementation.

77. Pursuant to 21 CFR §820.70(a), each manufacturer shall develop, conduct, control, and monitor production processes to ensure that a device conforms to its specifications. Where deviations from device specifications could occur as a result of the manufacturing process, the manufacturer shall establish and maintain process control procedures that describe any process controls necessary to ensure conformance to specifications. Such process controls shall include:

a. Documented instructions, standard operating procedures (SOP's), and methods that define and control the manner of production;

b. Monitoring and control of process parameters and component and device characteristics during production;

c. Compliance with specified reference standards or codes;

d. The approval of processes and process equipment; and

e. Criteria for workmanship which shall be expressed in documented standards or by means of identified and approved representative samples.

78. Pursuant to 21 CFR §820.70(b), each manufacturer shall establish and maintain procedures for changes to a specification, method, process, or procedure.

79. Pursuant to 21 CFR §820.70(c), each manufacturer shall establish and maintain procedures to adequately control environmental conditions that could reasonably be expected to have an adverse effect on product quality, including periodic inspection of environmental control system(s) to verify that the system, including necessary equipment, is adequate and functioning properly.

80. Pursuant to 21 CFR §820.70(e), each manufacturer shall establish and maintain procedures to prevent contamination of equipment or product by

substances that could reasonably be expected to have an adverse effect on product quality.

81. Pursuant to 21 CFR §820.70(g), each manufacturer shall ensure that all equipment used in the manufacturing process meets specified requirement and is appropriately designed, constructed, placed, and installed to facilitate maintenance, adjustment, cleaning and use.

82. Pursuant to 21 CFR §820.70(h), each manufacturer shall establish and maintain procedures for the use and removal of manufacturing material which could reasonably be expected to have an adverse effect on product quality to ensure that it is removed or limited to an amount that does not adversely affect the device's quality.

83. Pursuant to 21 CFR §820.70(i), when computers or automated data processing systems are used as part of production or the quality system, the manufacturer shall validate computer software for its intended use according to an established protocol.

84. Pursuant to 21 CFR §820.72, each manufacturer shall ensure that all inspection, measuring, and test equipment, including mechanical, automated, or electronic inspection and test equipment, is suitable for its intended purposes and is capable of producing valid results. Each manufacturer shall establish and maintain

procedures to ensure that equipment is routinely calibrated, inspected, checked, and maintained.

85. Pursuant to 21 CFR §820.75(a), where the results of a process cannot be fully verified by subsequent inspection and test, the process shall be validated with a high degree of assurance and approved according to established procedures. "Process validation" means establishing by objective evidence that a process consistently produces a result or product meeting its predetermined specifications. See 21 CFR §820.3(z) (1).

86. Pursuant to 21 CFR §820.75(b), each manufacturer shall establish and maintain procedures for monitoring and control of process parameters for validated processes to ensure that the specified requirements continue to be met. Each manufacturer shall ensure that validated processes are performed by qualified individuals.

87. Pursuant to 21 CFR §820.90, each manufacturer shall establish and maintain procedures to control product that does not conform to specified requirements.

88. Pursuant to 21 CFR §820.100, each manufacturer shall establish and maintain procedures for implementing corrective and preventive action. The procedures shall include requirements for:

a. Analyzing processes, work operations, concessions, quality audit reports, quality records, service records, complaints, returned product, and other sources of quality data to identify existing and potential causes of nonconforming product, or other quality problem,

b. Investigating the cause of nonconformities relating to product, processes and the quality system;

c. Identifying the action(s) needed to correct and prevent recurrence of nonconforming product and other quality problems;

d. Verifying or validating the corrective and preventative action to ensure that such action is effective and does not adversely affect the finished device;

e. Implementing and recording changes in methods and procedures needed to correct and prevent identified quality problems;

f. Ensuring that information related to quality problems or nonconforming product is disseminated to those directly

responsible for assuring the quality of such product or the prevention of such problems; and

g. Submitting relevant information on identified quality problems, as well as corrective and preventative actions, for management review.

DEFENDANTS' G2 FILTER SYSTEM IS A 510(k) APPROVED MEDICAL DEVICE

89. Defendants submitted a §510(k) premarket notification and obtained marketing clearance for its G2 Filter System from the F.D.A. under Section 510(k) of the Act. *See* 21 U.S.C. §360 *et seq.*

90. Under the §510(k) approval process, the F.D.A. determined that Defendants' G2 Filter System was "substantially equivalent" to devices that have been reclassified in accordance with the provisions of the Act and did not require F.D.A. approval of a pre-market approval application (PMA).

91. Upon information and belief, Defendants' G2 Filter System is adulterated pursuant to 21 U.S.C. §351 because, among other things, it failed to meet established performance standards, and/or the methods, facilities, or controls used for its manufacture, packing, storage or installation are not in conformity with federal requirements. *See* 21 U.S.C. §351.

92. Upon information and belief, Defendants' G2 Filter System is

misbranded because, among other things, it is dangerous to health when used in the manner prescribed, recommended or suggested in the labeling thereof. *See* 21 U.S.C. §352.

93. Upon information and belief, Defendants' G2 Filter System is adulterated pursuant to 21 U.S.C. §351 because Defendants failed to establish and maintain CGMP for their G2 Filter System in accordance with 21 CFR §820 *et seq.*, as set forth above.

94. Upon information and belief, Defendants failed to establish and maintain CGMP with respect to the quality audits, quality testing and process validation for their G2 Filter System.

95. As a result of Defendants' failure to establish and maintain CGMP as set forth above, Defendants' G2 Filter System was defective and failed, resulting in injuries to the Plaintiff.

96. If Defendants had complied with the federal requirements regarding CGMP, Defendants' G2 Filter System would have been manufactured properly such that it would not have resulted in injuries to the Plaintiff.

FRUADULENT CONCEALMENT

97. Any applicable statutes of limitation have been tolled by the knowing and active concealment and denial of material facts known by Defendants when

they had a duty to disclose those facts. They have kept Plaintiff ignorant of vital information essential to the pursuit of her claims, without any fault or lack of diligence on Plaintiff's part, for the purpose of obtaining delay on Plaintiff's part in filing on their causes of action. Defendants' fraudulent concealment did result in such delay.

98. Defendants are estopped from relying on the statute of limitations defense because Defendants failed to timely disclose, among other things, facts evidencing the defective and unreasonably dangerous nature of the Recovery® and G2® Filter Systems.

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

CORPORATE/VICARIOUS LIABILITY

100. At all times herein mentioned, each of the Defendants was the agent, servant, partner, aider and abettor, co-conspirator and/or joint venturer of each of the other Defendants herein and was at all times operating and acting within the

purpose and scope of said agency, service, employment, partnership, conspiracy and/or joint venture and rendered substantial assistance and encouragement to the other Defendants, knowing that their collective conduct constituted a breach of duty owed to the Plaintiff.

101. There exists and, at all times herein mentioned, there existed a unity of interest in ownership between certain Defendants and other certain Defendants such that any individuality and separateness between the certain Defendants has ceased and these Defendants are the alter ego of the other certain Defendants and exerted control over those Defendants. Adherence to the fiction of the separate existence of these certain Defendants as entities distinct from other certain Defendants will permit an abuse of the corporate privilege and would sanction a fraud and/or would promote injustice.

102. At all times herein mentioned, each Defendant was engaged in the business of, or were successors in interest to, entities engaged in the business of researching, designing, formulating, compounding, testing, manufacturing, producing, processing, assembling, inspecting, distributing, marketing, labeling, promoting, packaging, prescribing and/or advertising for sale, and selling products for use by the Plaintiff. As such, each Defendant is individually, as well as jointly and severally, liable to the Plaintiff for Plaintiff's damages.

103. At all times herein mentioned, the officers and/or directors of the Defendants named herein participated in, authorized and/or directed the production and promotion of the aforementioned products when they knew, or with the exercise of reasonable care and diligence should have known, of the hazards and dangerous propensities of said products, and thereby actively participated in the tortious conduct that resulted in the injuries suffered by the Plaintiff.

FIRST CAUSE OF ACTION
NEGLIGENCE

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

105. At all times relevant to this cause of action, the Defendants Bard and BPV were in the business of designing, developing, setting specifications, manufacturing, marketing, selling, and distributing the Recovery® and G2® Filters.

106. Defendants designed, manufactured, marketed, inspected, labeled, promoted, distributed and sold the G2 Filter that was implanted in Plaintiff Mary Duffie.

107. Defendants had a duty to exercise reasonable and prudent care in the development, testing, design, manufacture, inspection, marketing, labeling,

promotion, distribution and sale of the G2 Filter so as to avoid exposing others to foreseeable and unreasonable risks of harm.

108. Defendants knew or reasonably should have known that the G2 Filter was dangerous or was likely to be dangerous when used in its intended or reasonably foreseeable manner.

109. At the time of manufacture and sale of the G2 Filter (September 2005 until present), Defendants knew or should have known that the G2 Filter:

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

b. Was designed and manufactured so as to present an unreasonable risk of migration of the device and/or portions of the device;

c. Was designed and manufactured so as to present an unreasonable risk of the device tilting and/or perforating the vena cava wall; and/or,

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

110. At the time of manufacture and sale of the G2 Filter (September 2005 until present), Defendants knew or should have known that using the G2 Filter in its intended use or in a reasonably foreseeable manner created a significant risk of a patient suffering severe health side effects, including, but not limited to: hemorrhage; cardiac/pericardial tamponade; cardiac arrhythmia and other symptoms similar to myocardial infarction; perforations of tissue, vessels and organs; and other severe personal injuries and diseases, which are permanent in nature, including, but not limited to, death, physical pain and mental anguish, scarring and disfigurement, diminished enjoyment of life, continued medical care and treatment due to chronic injuries/illness proximately caused by the device; and the continued risk of requiring additional medical and surgical procedures including general anesthesia, with attendant risk of life threatening complications.

111. Defendants knew or reasonably should have known that consumers of the G2 Filter would not realize the danger associated with using the device in its intended use and/or in a reasonably foreseeable manner.

112. Defendants breached their duty to exercise reasonable and prudent care in the development, testing, design, manufacture, inspection, marketing, labeling, promotion, distribution and sale of the G2 Filter in, among other ways, the following acts and omissions:

a. Designing and distributing a product in which they knew or should have known that the likelihood and severity of potential harm from the product exceeded the burden of taking safety measures to reduce or avoid harm;

b. Designing and distributing a product in which they knew or should have known that the likelihood and severity of potential harm from the product exceeded the likelihood of potential harm from other device available for the same purpose;

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

d. Failing to use reasonable care to warn or instruct, including pre- and post-sale, Plaintiff Mary Duffie, Plaintiff's physicians, or the general health care community about the G2 Filter's substantially dangerous condition or about facts making the product likely to be dangerous;

e. Failing to perform reasonable pre- and post-market testing of the G2 Filter to determine whether or not the product was safe for its intended use;

f. Failing to provide adequate instructions, guidelines, and safety precautions, including pre- and post-sale, to those persons to whom it was reasonably foreseeable would prescribe, use, and implant the G2 Filter;

g. Advertising, marketing and recommending the use of the G2 Filter, while concealing and failing to disclose or warn of the dangers known by Defendants to be connected with and inherent in the use of the G2 Filter;

h. Representing that the G2 Filter was safe for its intended use when in fact, Defendants knew and should have known the product was not safe for its intended purpose;

i. Continuing manufacture and sale of the G2 Filter with the knowledge that said product was dangerous and not reasonably safe, and failing to comply with FDA good manufacturing regulations;

j. Failing to use reasonable and prudent care in the design, research, manufacture, and development of the G2 Filter so as to avoid the risk of serious harm associated with the use of the G2 Filter;

k. Advertising, marketing, promoting and selling G2 Filter for uses other than as approved and indicated in the product's label;

l. Failing to establish an adequate quality assurance program used in the manufacturing of the G2 Filter; and,

m. Failing to establish and maintain an adequate post-market surveillance program.

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

114. As a direct and proximate result of the foregoing negligent acts and omissions by Defendants, Plaintiff has suffered and will continue to suffer serious physical injuries, economic loss, loss of enjoyment of life, disability, and other losses, in an amount to be determined at trial.

SECOND CAUSE OF ACTION
STRICT PRODUCTS LIABILITY - FAILURE TO WARN

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

116. Defendants designed, set specifications, manufactured, prepared, compounded, assembled, processed, marketed, labeled, distributed, and sold the G2 Filter, including the one implanted into Plaintiff Mary Duffie, into the stream of commerce and in the course of same, directly advertised and marketed the device to consumers or persons responsible for consumers.

117. At the time Defendants designed, manufactured, prepared, compounded, assembled, processed, marketed, labeled, distributed, and sold the device into the stream of commerce, Defendants knew or should have known the device presented an unreasonable danger to users of the product when put to its intended and reasonably anticipated use. Specifically, Defendants knew or should have known at the time they manufactured, labeled, distributed and sold the G2 Filter, which was implanted in Plaintiff Mary Duffie, that the G2 Filter, *inter alia*, posed a significant and higher risk than other similar devices of device failure (fracture, migration, tilting, and perforation of the vena cava wall) and resulting serious injuries. Upon information and belief, Defendants also knew or should have known that certain conditions or post-implant procedures, such as morbid

obesity or open abdominal procedures, could affect the safety and integrity of the device.

118. Therefore, Defendants had a duty to warn of the risk of harm associated with the use of the device and to provide adequate instructions on the safe and proper use of the device. Defendants further had a duty to warn of dangers and proper safety instructions that it became aware of even after the device was distributed and implanted in Plaintiff Mary Duffie.

119. Despite this duty, Defendants failed to adequately warn of material facts regarding the safety and efficacy of the G2 Filter, and further failed to adequately provide instructions on the safe and proper use of the device.

120. No health care provider, including Plaintiff's, or patient would have used the device in the manner directed, had those facts been made known to the prescribing healthcare providers and/or ultimate users of the device.

121. The health risks associated with the device as described herein are of such a nature that ordinary consumers would not have readily recognized the potential harm.

122. Plaintiff and Plaintiff's health care providers used the device in a normal, customary, intended, and foreseeable manner, namely as a surgically implanted device used to prevent pulmonary embolisms.

123. Therefore, the G2 Filter implanted in Plaintiff was defective and unreasonably dangerous at the time of release into the stream of commerce due to inadequate warnings, labeling and/or instructions accompanying the product.

124. The G2 Filter implanted in Plaintiff was in the same condition as when it was manufactured, inspected, marketed, labeled, promoted, distributed and sold by Defendants.

125. As a direct and proximate result of Defendants' lack of sufficient warning and/or instructions, Plaintiff has suffered and will continue to suffer serious physical injuries, economic loss, loss of enjoyment of life, disability, and other losses, in an amount to be determined at trial.

THIRD CAUSE OF ACTION
STRICT PRODUCTS LIABILITY – DESIGN DEFECTS

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

127. At all times relevant to this action, Defendants developed, tested, designed, manufactured, inspected, labeled, promoted, distributed and sold into the stream of commerce the G2 Filter, including the one implanted in Plaintiff.

128. The G2 Filter was expected to, and did, reach its intended consumers without substantial change in the condition in which it was in when it left

Defendants' possession. In the alternative, any changes that were made to G2 Filter implanted in Plaintiff were reasonably foreseeable to Defendants.

129. The G2 Filter implanted in Plaintiff was defective in design because it failed to perform as safely as persons who ordinarily use the product would have expected at the time of use.

130. The G2 Filter implanted in Plaintiff was defective in design, in that its risks of harm exceeded its claimed benefits.

131. Plaintiff and Plaintiff's health care providers used the G2 Filter in a manner that was reasonably foreseeable to Defendants.

132. Neither Plaintiff, nor Plaintiff's health care providers could have, by the exercise of reasonable care, discovered the devices defective condition or perceived its unreasonable dangers prior to Plaintiff's implantation with the device.

133. As a direct and proximate result of the G2 Filter's defective design, Plaintiff has suffered and will continue to suffer serious physical injuries, economic loss, loss of enjoyment of life, disability, and other losses, in an amount to be determined at trial.

FOURTH CAUSE OF ACTION
STRICT PRODUCTS LIABILITY – MANUFACTURING DEFECT

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

135. Defendants designed, set specifications, manufactured, prepared, compounded, assembled, processed, marketed, labeled, distributed, and sold the G2 Filter that was implanted into Plaintiff.

136. The G2 Filter implanted in Plaintiff contained a condition, which Defendants did not intend, at the time it left Defendants' control and possession.

137. Plaintiff and Plaintiff's health care providers used the device in a manner that was reasonably foreseeable to Defendants.

138. As a result of this condition, the product injured Plaintiff and failed to perform as safely as the ordinary consumer would expect when used in a reasonably foreseeable manner.

139. As a direct and proximate result of the G2 Filter's manufacturing defect, Plaintiff has suffered and will continue to suffer serious physical injuries, economic loss, loss of enjoyment of life, disability, and other losses, in an amount to be determined at trial.

FIFTH CAUSE OF ACTION
BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY

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

141. At all times relevant to this action, Defendants designed, researched, developed, manufactured, tested, labeled, inspected, advertised, promoted,

marketed, sold, and distributed into the stream of commerce the G2 Filter for use as a surgically implanted device used to prevent pulmonary embolisms and for uses other than as approved and indicated in the product's instructions, warnings, and labels.

142. At the time and place of the sale, distribution, and supply of the Defendants' G2 Filter System to Plaintiff by way of Plaintiff's health care providers and medical facilities, Defendants expressly represented and warranted, by labeling materials submitted with the product, that the G2 Filter System was safe and effective for its intended and reasonably foreseeable use.

143. Defendants knew of the intended and reasonably foreseeable use of the G2 Filter, at the time they marketed, sold, and distributed the product for use by Plaintiff, and impliedly warranted the product to be of merchantable quality, and safe and fit for its intended use.

144. Defendants impliedly represented and warranted to the healthcare community, Plaintiff and Plaintiff's health care providers, that the G2 Filter was safe and of merchantable quality and fit for the ordinary purpose for which the product was intended and marketed to be used.

145. The representations and implied warranties made by Defendants were false, misleading, and inaccurate because the G2 Filter was defective, unsafe,

unreasonably dangerous, and not of merchantable quality, when used in its intended and/or reasonably foreseeable manner. Specifically, at the time of Plaintiff's purchase of the G2 Filter from the Defendants, through Plaintiff's physicians and medical facilities, it was not in a merchantable condition in that:

a. It was designed in such a manner so as to be prone to a statistically high incidence of failure, including fracture, migration, excessive tilting, and perforation of the inferior vena cava;

b. It was designed in such a manner so as to result in a statistically significant incidence of injury to the organs and anatomy; and,

c. It was manufactured in such a manner so that the exterior surface of the G2 Filter System was inadequately, improperly and inappropriately prepared and/or finished causing the device to weaken and fail.

146. Plaintiff and Plaintiff's health care providers reasonably relied on the superior skill and judgment of Defendants as the designers, researchers and manufacturers of the product, as to whether the G2 Filter was of merchantable quality and safe and fit for its intended use, and also relied on the implied warranty

of merchantability and fitness for the particular use and purpose for which the G2 Filter was manufactured and sold.

147. Defendants placed the G2 Filter into the stream of commerce in a defective, unsafe, and unreasonably dangerous condition, and the product was expected to and did reach Plaintiff without substantial change in the condition in which the G2 Filter was manufactured and sold.

148. Defendants breached their implied warranty because their G2 Filter was not fit for its intended use and purpose.

149. As a proximate result of Defendants breaching their implied warranties, Plaintiff has suffered and will continue to suffer serious physical injuries, economic loss, loss of enjoyment of life, disability, and other losses, in an amount to be determined at trial.

SIXTH CAUSE OF ACTION
NEGLIGENT MISREPRESENTATION

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

151. At all times relevant to this cause, and as detailed *supra*, Defendants negligently provided Plaintiff, Plaintiff's health care providers, and the general medical community with false or incorrect information, or omitted or failed to

disclose material information concerning the G2 Filter, including, but not limited to, misrepresentations relating to the following subject areas:

a. The safety of the G2 Filter;

b. The efficacy of the G2 Filter;

c. The rate of failure of the G2 Filter; and

d. The approved uses of the G2 Filter.

152. The information distributed by Defendants to the public, the medical community and Plaintiff's health care providers was in the form of reports, press releases, advertising campaigns, labeling materials, print advertisements, commercial media containing material representations, which were false and misleading, and contained omissions and concealment of the truth about the dangers of the use of the G2 Filter. Defendants made the foregoing misrepresentations knowing that they were false or without reasonable basis. These materials included instructions for use and warning document that was included in the package of the G2 Filter that was implanted in Plaintiff.

153. Defendants' intent and purpose in making these misrepresentations was to deceive and defraud the public and the medical community, including Plaintiff's health care providers; to gain the confidence of the public and the medical community, including Plaintiff's health care providers; to falsely assure

them of the quality of the G2 Filter and its fitness for use; and to induce the public and the medical community, including Plaintiff's healthcare providers to request, recommend, prescribe, implant, purchase, and continue to use the G2 Filter.

154. The foregoing representations and omissions by Defendants were in fact false. The G2 Filter is not safe, fit, and effective for human use in its intended and reasonably foreseeable manner. The use of the G2 Filter is hazardous to the user's health, and said device has a serious propensity to cause users to suffer serious injuries, including without limitation, the injuries Plaintiff suffered. Further, the device has a significantly higher rate of failure and injury than do other comparable devices.

155. In reliance upon the false and negligent misrepresentations and omissions made by Defendants, Plaintiff and Plaintiff's health care providers were induced to, and did use the G2 Filter, thereby causing Plaintiff to sustain severe and permanent personal injuries.

156. Defendants knew and had reason to know that Plaintiff, Plaintiff's health care providers, and the general medical community did not have the ability to determine the true facts intentionally and/or negligently concealed and misrepresented by Defendants, and would not have prescribed and implanted same,

if the true facts regarding the device had not been concealed and misrepresented by Defendants.

157. Defendants had sole access to material facts concerning the defective nature of the product and its propensity to cause serious and dangerous side effects in the form of dangerous injuries and damages to persons who are implanted with the G2 Filter.

158. At the time Defendants failed to disclose and misrepresented the foregoing facts, and at the time Plaintiff used the G2 Filter, Plaintiff and Plaintiff's health care providers were unaware of said Defendants' negligent misrepresentations and omissions.

159. Plaintiff, Plaintiff's health care providers and general medical community reasonably relied upon misrepresentations and omissions made by Defendants where the concealed and misrepresented facts were critical to understanding the true dangers inherent in the use of the G2 Filter.

160. Plaintiff and Plaintiff's health care provider's reliance on the foregoing misrepresentations and omissions by Defendants' were the direct and proximate cause of Plaintiff's injuries as described herein.

LOSS OF CONSORTIUM CLAIM

161. Plaintiffs re-allege and incorporate each and every allegation in this Complaint, as if fully set forth herein.

162. At all relevant times hereto, Mary and James Duffie have been lawfully married.

163. As a direct and proximate result of Defendants' conduct, James Duffie has been deprived of and/or suffered a loss of his wife's love, companionship, society, solace, moral support and services and has otherwise suffered losses, the extent of which will be more fully adduced at the trial of this matter.

PUNITIVE DAMAGES ALLEGATIONS

164. Plaintiffs re-allege and incorporate each and every allegation in this Complaint, as if fully set forth herein.

165. Plaintiffs are entitled to an award of punitive and exemplary damages based upon Defendants' intentional, willful, knowing, fraudulent, malicious acts, omissions, and conduct, and their complete and total reckless disregard for the public safety and welfare.

166. Defendants had knowledge of, and were in possession of evidence demonstrating that, the G2 Filter was defective and unreasonably dangerous and

had a substantially higher failure rate than did other similar devices on the market. Yet, Defendants failed to:

a. Inform or warn Plaintiff or her health care providers of the dangers;

b. To establish and maintain an adequate quality and post-market surveillance system; and,

c. Recall the G2 Filter from the market.

167. Defendants acted to serve their own interests and having reasons to know and consciously disregard the substantial risk that their product might kill or significantly harm patients, or significantly injure the rights of others, and consciously pursue a course of conduct knowing that such conduct created a substantial risk of significant harm to other persons.

168. As a direct, proximate, and legal result of Defendants' acts and omissions described herein, Plaintiff has suffered and will continue to suffer serious physical injuries, economic loss, loss of enjoyment of life, disability, and other losses, in an amount to be determined at trial.

PRAYER FOR DAMAGES

WHEREFORE, Plaintiffs pray for relief on the entire complaint, as follows:

a. Judgment to be entered against all defendants on all causes of action of this Complaint, including but not limited to:

1. Physical pain and suffering in the past and which, in reasonable probability, Plaintiff will continue to suffer in the future;

2. Physical impairment and incapacity in the past and which, in reasonable probability, Plaintiff will continue to suffer in the future;

3. Pain, suffering and mental anguish in the past and which, in reasonable probability, Plaintiff will sustain in the future;

4. Reasonable and necessary medical expenses for treatment received in the past and, based upon reasonable medical probability, the reasonable medical expenses Plaintiff will need in the future;

5. Loss of earning capacity in the past and future; and

6. Punitive damages.

b. Plaintiffs be awarded full, fair, and complete recovery for all claims and causes of action relevant to this action;

c. Plaintiffs be awarded all appropriate costs, fees, expenses, and pre-judgment and post judgment interest pursuant to the laws of the State of Georgia as authorized by law on the judgments entered in Plaintiffs' behalf; and,

d. Such other relief the court deems just and proper.

DEMAND FOR JURY TRIAL

Plaintiffs hereby demand trial by jury on all issues.

/s/: M. Brandon Smith
M. Brandon Smith
Georgia Bar No: 141418
CHILDERS, SCHLUETER & SMITH, LLC
1932 North Druid Hills Road, Suite 100
Atlanta, GA 30319
(404) 419-9500 – telephone
(404) 419-9501 – facsimile
bsmith@cssfirm.com

/s/: Stephen "Buck" Daniel
Stephen "Buck" Daniel
Georgia Bar No. 777514
THE NATIONS LAW FIRM
1932 North Druid Hills Road, Suite 250
Atlanta, GA 30319
(404) 692-4378 – telephone
(713) 807-8423 – facsimile
buck@howardnations.com

JS44 (Rev. 1/13 NDGA)

CIVIL COVER SHEET

The JS44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form is required for the use of the Clerk of Court for the purpose of initiating the civil docket record. (SEE INSTRUCTIONS ATTACHED)

I. (a) PLAINTIFF(S)

Mary Duffie and James Duffie

(b) COUNTY OF RESIDENCE OF FIRST LISTED PLAINTIFF DEKALB
(EXCEPT IN U.S. PLAINTIFF CASES)

DEFENDANT(S)

C.R. Bard, Inc.; and,
Bard Peripheral Vascular, Inc.

COUNTY OF RESIDENCE OF FIRST LISTED DEFENDANT _____
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED

(c) ATTORNEYS (FIRM NAME, ADDRESS, TELEPHONE NUMBER, AND E-MAIL ADDRESS)

Stephen "Buck" Daniel
The Nations Law Firm
3131 Briarpark Drive, Suite 208
Houston, TX 77042

ATTORNEYS (IF KNOWN)

II. BASIS OF JURISDICTION
(PLACE AN "X" IN ONE BOX ONLY)

- ☐ 1 U.S. GOVERNMENT PLAINTIFF
- ☐ 3 FEDERAL QUESTION (U.S. GOVERNMENT NOT A PARTY)
- ☐ 2 U.S. GOVERNMENT DEFENDANT
- ■ 4 DIVERSITY (INDICATE CITIZENSHIP OF PARTIES IN ITEM III)

III. CITIZENSHIP OF PRINCIPAL PARTIES
(PLACE AN "X" IN ONE BOX FOR PLAINTIFF AND ONE BOX FOR DEFENDANT)
(FOR DIVERSITY CASES ONLY)

PLF	DEF		PLF	DEF	
■ 1	☐ 1	CITIZEN OF THIS STATE	☐ 4	☐ 4	INCORPORATED OR PRINCIPAL PLACE OF BUSINESS IN THIS STATE
☐ 2	☐ 2	CITIZEN OF ANOTHER STATE	☐ 5	■ 5	INCORPORATED AND PRINCIPAL PLACE OF BUSINESS IN ANOTHER STATE
☐ 3	☐ 3	CITIZEN OR SUBJECT OF A FOREIGN COUNTRY	☐ 6	☐ 6	FOREIGN NATION

IV. ORIGIN (PLACE AN "X "IN ONE BOX ONLY)

■ 1 ORIGINAL PROCEEDING ☐ 2 REMOVED FROM STATE COURT ☐ 3 REMANDED FROM APPELLATE COURT ☐ 4 REINSTATED OR REOPENED ☐ 5 TRANSFERRED FROM ANOTHER DISTRICT (Specify District) ☐ 6 MULTIDISTRICT LITIGATION ☐ 7 APPEAL TO DISTRICT JUDGE FROM MAGISTRATE JUDGE JUDGMENT

V. CAUSE OF ACTION (CITE THE U.S. CIVIL STATUTE UNDER WHICH YOU ARE FILING AND WRITE A BRIEF STATEMENT OF CAUSE - DO NOT CITE JURISDICTIONAL STATUTES UNLESS DIVERSITY)

28:1332 - Diversity, Product Litigation

(IF COMPLEX, CHECK REASON BELOW)

- ☐ 1. Unusually large number of parties.
- ☐ 2. Unusually large number of claims or defenses.
- ☐ 3. Factual issues are exceptionally complex
- ☐ 4. Greater than normal volume of evidence.
- ☐ 5. Extended discovery period is needed.
- ☐ 6. Problems locating or preserving evidence
- ☐ 7. Pending parallel investigations or actions by government.
- ☐ 8. Multiple use of experts.
- ☐ 9. Need for discovery outside United States boundaries.
- ☐ 10. Existence of highly technical issues and proof.

CONTINUED ON REVERSE

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT $_____ APPLYING IFP _____ MAG. JUDGE (IFP)_____

JUDGE_____ MAG. JUDGE_____ (Referral) NATURE OF SUIT _____ CAUSE OF ACTION_____

VI. NATURE OF SUIT (PLACE AN "X" IN ONE BOX ONLY)

CONTRACT - "0" MONTHS DISCOVERY TRACK
- ☐ 150 RECOVERY OF OVERPAYMENT & ENFORCEMENT OF JUDGMENT
- ☐ 152 RECOVERY OF DEFAULTED STUDENT LOANS (Excl. Veterans)
- ☐ 153 RECOVERY OF OVERPAYMENT OF VETERAN'S BENEFITS

CONTRACT - "4" MONTHS DISCOVERY TRACK
- ☐ 110 INSURANCE
- ☐ 120 MARINE
- ☐ 130 MILLER ACT
- ☐ 140 NEGOTIABLE INSTRUMENT
- ☐ 151 MEDICARE ACT
- ☐ 160 STOCKHOLDERS' SUITS
- ☐ 190 OTHER CONTRACT
- ☐ 195 CONTRACT PRODUCT LIABILITY
- ☐ 196 FRANCHISE

REAL PROPERTY - "4" MONTHS DISCOVERY TRACK
- ☐ 210 LAND CONDEMNATION
- ☐ 220 FORECLOSURE
- ☐ 230 RENT LEASE & EJECTMENT
- ☐ 240 TORTS TO LAND
- ☐ 245 TORT PRODUCT LIABILITY
- ☐ 290 ALL OTHER REAL PROPERTY

TORTS - PERSONAL INJURY - "4" MONTHS DISCOVERY TRACK
- ☐ 310 AIRPLANE
- ☐ 315 AIRPLANE PRODUCT LIABILITY
- ☐ 320 ASSAULT, LIBEL & SLANDER
- ☐ 330 FEDERAL EMPLOYERS' LIABILITY
- ☐ 340 MARINE
- ☐ 345 MARINE PRODUCT LIABILITY
- ☐ 350 MOTOR VEHICLE
- ☐ 355 MOTOR VEHICLE PRODUCT LIABILITY
- ☐ 360 OTHER PERSONAL INJURY
- ☐ 362 PERSONAL INJURY - MEDICAL MALPRACTICE
- ☐ 365 PERSONAL INJURY - PRODUCT LIABILITY
- ☑ 367 PERSONAL INJURY - HEALTH CARE/ PHARMACEUTICAL PRODUCT LIABILITY
- ☐ 368 ASBESTOS PERSONAL INJURY PRODUCT LIABILITY

TORTS - PERSONAL PROPERTY - "4" MONTHS DISCOVERY TRACK
- ☐ 370 OTHER FRAUD
- ☐ 371 TRUTH IN LENDING
- ☐ 380 OTHER PERSONAL PROPERTY DAMAGE
- ☐ 385 PROPERTY DAMAGE PRODUCT LIABILITY

BANKRUPTCY - "0" MONTHS DISCOVERY TRACK
- ☐ 422 APPEAL 28 USC 158
- ☐ 423 WITHDRAWAL 28 USC 157

CIVIL RIGHTS - "4" MONTHS DISCOVERY TRACK
- ☐ 441 VOTING
- ☐ 442 EMPLOYMENT
- ☐ 443 HOUSING/ ACCOMMODATIONS
- ☐ 444 WELFARE
- ☐ 440 OTHER CIVIL RIGHTS
- ☐ 445 AMERICANS with DISABILITIES - Employment
- ☐ 446 AMERICANS with DISABILITIES - Other
- ☐ 448 EDUCATION

IMMIGRATION - "0" MONTHS DISCOVERY TRACK
- ☐ 462 NATURALIZATION APPLICATION
- ☐ 465 OTHER IMMIGRATION ACTIONS

PRISONER PETITIONS - "0" MONTHS DISCOVERY TRACK
- ☐ 463 HABEAS CORPUS- Alien Detainee
- ☐ 510 MOTIONS TO VACATE SENTENCE
- ☐ 530 HABEAS CORPUS
- ☐ 535 HABEAS CORPUS DEATH PENALTY
- ☐ 540 MANDAMUS & OTHER
- ☐ 550 CIVIL RIGHTS - Filed Pro se
- ☐ 555 PRISON CONDITION(S) - Filed Pro se
- ☐ 560 CIVIL DETAINEE: CONDITIONS OF CONFINEMENT

PRISONER PETITIONS - "4" MONTHS DISCOVERY TRACK
- ☐ 550 CIVIL RIGHTS - Filed by Counsel
- ☐ 555 PRISON CONDITION(S) - Filed by Counsel

FORFEITURE/PENALTY - "4" MONTHS DISCOVERY TRACK
- ☐ 625 DRUG RELATED SEIZURE OF PROPERTY 21 USC 881
- ☐ 690 OTHER

LABOR - "4" MONTHS DISCOVERY TRACK
- ☐ 710 FAIR LABOR STANDARDS ACT
- ☐ 720 LABOR/MGMT. RELATIONS
- ☐ 740 RAILWAY LABOR ACT
- ☐ 751 FAMILY and MEDICAL LEAVE ACT
- ☐ 790 OTHER LABOR LITIGATION
- ☐ 791 EMPL. RET. INC. SECURITY ACT

PROPERTY RIGHTS - "4" MONTHS DISCOVERY TRACK
- ☐ 820 COPYRIGHTS
- ☐ 840 TRADEMARK

PROPERTY RIGHTS - "8" MONTHS DISCOVERY TRACK
- ☐ 830 PATENT

SOCIAL SECURITY - "0" MONTHS DISCOVERY TRACK
- ☐ 861 HIA (1395ff)
- ☐ 862 BLACK LUNG (923)
- ☐ 863 DIWC (405(g))
- ☐ 863 DIWW (405(g))
- ☐ 864 SSID TITLE XVI
- ☐ 865 RSI (405(g))

FEDERAL TAX SUITS - "4" MONTHS DISCOVERY TRACK
- ☐ 870 TAXES (U.S. Plaintiff or Defendant)
- ☐ 871 IRS - THIRD PARTY 26 USC 7609

OTHER STATUTES - "4" MONTHS DISCOVERY TRACK
- ☐ 375 FALSE CLAIMS ACT
- ☐ 400 STATE REAPPORTIONMENT
- ☐ 430 BANKS AND BANKING
- ☐ 450 COMMERCE/ICC RATES/ETC.
- ☐ 460 DEPORTATION
- ☐ 470 RACKETEER INFLUENCED AND CORRUPT ORGANIZATIONS
- ☐ 480 CONSUMER CREDIT
- ☐ 490 CABLE/SATELLITE TV
- ☐ 891 AGRICULTURAL ACTS
- ☐ 893 ENVIRONMENTAL MATTERS
- ☐ 895 FREEDOM OF INFORMATION ACT
- ☐ 950 CONSTITUTIONALITY OF STATE STATUTES
- ☐ 890 OTHER STATUTORY ACTIONS
- ☐ 899 ADMINISTRATIVE PROCEDURES ACT / REVIEW OR APPEAL OF AGENCY DECISION

OTHER STATUTES - "8" MONTHS DISCOVERY TRACK
- ☐ 410 ANTITRUST
- ☐ 850 SECURITIES / COMMODITIES / EXCHANGE

OTHER STATUTES - "0" MONTHS DISCOVERY TRACK
- ☐ 896 ARBITRATION (Confirm / Vacate / Order / Modify)

*** PLEASE NOTE DISCOVERY TRACK FOR EACH CASE TYPE. SEE LOCAL RULE 26.3**

VII. REQUESTED IN COMPLAINT:

☐ **CHECK IF CLASS ACTION UNDER F.R.Civ.P. 23** **DEMAND $**_____

JURY DEMAND ■ **YES** ☐ **NO** **(CHECK YES ONLY IF DEMANDED IN COMPLAINT)**

VIII. RELATED/REFILED CASE(S) IF ANY

JUDGE_____ **DOCKET NO.**_____

CIVIL CASES ARE DEEMED RELATED IF THE PENDING CASE INVOLVES: (CHECK APPROPRIATE BOX)

- ☐ **1. PROPERTY INCLUDED IN AN EARLIER NUMBERED PENDING SUIT.**
- ☐ **2. SAME ISSUE OF FACT OR ARISES OUT OF THE SAME EVENT OR TRANSACTION INCLUDED IN AN EARLIER NUMBERED PENDING SUIT.**
- ☐ **3. VALIDITY OR INFRINGEMENT OF THE SAME PATENT, COPYRIGHT OR TRADEMARK INCLUDED IN AN EARLIER NUMBERED PENDING SUIT.**
- ☐ **4. APPEALS ARISING OUT OF THE SAME BANKRUPTCY CASE AND ANY CASE RELATED THERETO WHICH HAVE BEEN DECIDED BY THE SAME BANKRUPTCY JUDGE.**
- ☐ **5. REPETITIVE CASES FILED BY PRO SE LITIGANTS.**
- ☐ **6. COMPANION OR RELATED CASE TO CASE(S) BEING SIMULTANEOUSLY FILED (INCLUDE ABBREVIATED STYLE OF OTHER CASE(S)):**
- ☐ **7. EITHER SAME OR ALL OF THE PARTIES AND ISSUES IN THIS CASE WERE PREVIOUSLY INVOLVED IN CASE NO.** **, WHICH WAS DISMISSED. This case** ☐ **IS** ☐ **IS NOT (check one box) SUBSTANTIALLY THE SAME CASE.**

/s/ Stephen "Buck" Daniel 9/2/2015

SIGNATURE OF ATTORNEY OF RECORD **DATE**