



UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF MISSISSIPPI  
NORTHERN DIVISION

CLIFFORD GETER,

*Plaintiff,*

vs.

C.R. BARD, INC., a foreign corporation,  
BARD PERIPHERAL VASCULAR, INC.,  
an Arizona corporation,

*Defendants.*

) Case No. 3:15cv403 CWR-FKB

) **COMPLAINT FOR DAMAGES**

- ) 1. NEGLIGENCE
- ) 2. NEGLIGENT FAILURE TO WARN
- ) 3. STRICT LIABILITY FAILURE TO WARN
- ) 4. STRICT LIABILITY DESIGN DEFECT
- ) 5. STRICT LIABILITY MANUFACTURING DEFECT
- ) 6. BREACH OF EXPRESS WARRANTY
- ) 7. BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY
- ) 8. BREACH OF IMPLIED WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE
- ) 9. FRAUDULENT CONCEALMENT
- ) 10. NEGLIGENT MISREPRESENTATION
- ) 11. FRAUDULENT MISREPRESENTATION

) **DEMAND FOR A JURY TRIAL**

**COMPLAINT FOR DAMAGES**

Plaintiff, Clifford Geter, by and through his undersigned attorneys, hereby sues Defendants, C.R. Bard, Inc.; and Bard Peripheral Vascular, Inc.; (collectively, the "Defendants") and allege as follows:

**PARTIES**

**Plaintiff**

- 1. Plaintiff, Clifford Geter, at all times relevant to this action is and was a

citizen of Mississippi and resided in and continues to reside in Warren County, Mississippi. On or about October 13, 2008, Plaintiff underwent placement of a Bard G2® Inferior Vena Cava Filter (“G2® IVC Filter”). On or about June 2, 2012, the filter tilted and the struts of the Bard G2® IVC Filter penetrated the wall of the IVC with at least one strut adjacent to the common iliac artery, another strut in the right paraspinal region, another strut fractured and within a hepatic vein and attempts at removing the Bard G2® IVC filter and fragment(s) were unsuccessful causing injury and damage. Plaintiff was caused to undergo extensive medical treatment and care, including unsuccessful surgery to remove the G2® IVC Filter as a result of the failure of the filter manufactured by Defendants. Plaintiff has suffered and will continue to suffer significant medical expenses, extreme pain and suffering, mental anguish, loss of enjoyment of life, disability, and other losses proximately caused by the device. Plaintiff will have continued risk of requiring additional medical and surgical procedures, including risk of life threatening complications and ongoing medical care to monitor the G2® IVC Filter to ensure that it does not cause additional or further injury.

2. Plaintiff was caused to undergo extensive medical care as a result of the failure of the G2® IVC Filter manufactured by the Bard Defendants. Plaintiff has suffered and will continue to suffer significant medical expenses, extreme pain and suffering, mental anguish, loss of enjoyment of life, disability, and other losses proximately caused by the device. Plaintiff will have continued risk of requiring additional medical and surgical procedures, including risk of life threatening complications and ongoing medical care to monitor the G2® IVC Filter to ensure that it does not cause additional or further injury.

**Defendants**

3. Defendant, C.R. Bard, Inc. (“Bard”), is a foreign corporation authorized to do business in Mississippi and said Defendant was doing business in Warren County, Mississippi. Bard at all times relevant to this action, designed, set specifications, manufactured, prepared, compounded, assembled, processed, marketed, distributed, and sold the RECOVERY®, the G2®, and the G2® IVC Filter Systems to be implanted in patients throughout the United States, including Florida.

4. Defendant, Bard Peripheral Vascular, Inc. (“BPV”), is a wholly owned subsidiary corporation of defendant Bard, foreign corporation authorized to do business in Mississippi and said Defendant was doing business in Warren County, Mississippi. BPV, at all times relevant to this action, designed, set specifications, manufactured, prepared, compounded, assembled, processed, marketed, distributed, and sold the RECOVERY®, the G2®, and the G2® X IVC Filter Systems to be implanted in patients throughout the United States, including Mississippi.

5. All references to “Defendants” hereafter shall refer to Defendants Bard and BPV.

#### **JURISDICTION AND VENUE**

6. Plaintiff has suffered damages in an amount that exceeds the jurisdictional minimum of this Court. 28 U.S.C. § 1332. Furthermore, as alleged in Paragraphs 1, 2, 3, and 4 above the citizenship of the parties to this action is diverse.

7. Venue is proper in this Court, as the facts and circumstances leading to injuries occurred in Warren County, Mississippi, and the G2® IVC Filter System that is the subject of this action was marketed, sold, purchased and implanted into the Plaintiff’s body and the failures of defective Bard G2® IVC Filter System and resulting injuries and damages suffered by the Plaintiff occurred in Warren County, Mississippi. Furthermore, the Defendants herein were authorized to conduct business in the State of Mississippi and did conduct business in Warren County, Mississippi.

#### **GENERAL FACTUAL ALLEGATIONS**

8. Plaintiff brings this case for serious personal injuries Plaintiff suffered as result of a surgically implanted medical device, known as a G2® IVC Filter System (hereafter “G2® Filter”), failing and perforating within Plaintiff’s body and causing serious and ongoing physical, emotional, and economic damages, including pain and suffering, mental anguish, loss of enjoyment of life, disability, risk of requiring additional medical and surgical procedures, ongoing medical monitoring, and other losses proximately caused by the G2® Filter.

9. The G2® Filter was designed, manufactured, prepared, compounded, assembled,

processed, labeled, marketed, distributed, and sold by Defendants in October, 2008, to prevent blood clots (thrombi) from travelling from the lower portions of the body to the heart and lungs.

10. Prior to Plaintiff being implanted with a G2® Filter in October, 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 appropriate 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®, the G2®, and the G2® X Filters had high rate of perforation, fracture, migration, and excessive tilting in the vena cava once implanted in the human body. Defendants knew 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 or should have known that these risks for the RECOVERY®, the G2®, and the G2® X Filters were and are substantially higher than other similar devices.

c. Further, Defendants knew and/or should have known that the RECOVERY®, G2®, and the G2® X Filters are used to treat conditions which Defendants did not intend and which resulted in the device not performing as safely as the ordinary consumer 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 the above described risks, they still failed to issue a recall or notify consumers that a safer device was available.

**A. INFERIOR VENA CAVA FILTERS GENERALLY**

11. Inferior vena cava (“IVC”) filters first came on to the medical market in the 1960’s. Over the years, medical device manufacturers have introduced several different designs of IVC filters.

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. Often times, 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 significant 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, an individual who undergoes knee or hip joint replacement surgery is at risk for developing DVT/PE. Obese patients are also at increased risk for DVT/PE. So too are people who have vascular diseases or who have experienced previous strokes. A number of other conditions predispose people to develop DVT/PE, including “coagulopathies” and clotting disorders.

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 recommend surgically implanting an IVC filter to prevent thromboembolic.

16. As stated above, IVC filters have been on the market for decades. The first IVC filters marketed were permanent filters. These devices were designed to be left in a patient’s IVC permanently and have long-term follow-up data (of up to 20 years and longer) supporting their use and efficacy. Beginning in 2003, manufacturers also began marketing what are known as

optional or retrievable filters. These filters are designed so that they can be surgically removed from a patient after the risk of PE has subsided. These IVC filter designs, however, 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 and the subsequent G2® and G2® X Filters manufactured by Defendants are examples of retrievable filters.

**B. THE RECOVERY® FILTER®**

**i. FDA Clearance and Intended Use**

17. In 2002, Defendants submitted a notification to market the “RECOVERY® Filter System” (hereafter “RECOVERY®” or “RECOVERY® Filter”) for the prevention of recurrent pulmonary embolism by placement in the inferior vena cava.<sup>1</sup> On November 27, 2002, the RECOVERY® Filter was available for sale and use in the prevention of recurrent in the prevention of recurrent pulmonary embolism via *permanent* placement in the vena cava.

18. In April 2003, Defendants submitted a notification of intent to market and sell the RECOVERY® Filter for the additional intended use of *optional retrieval* and Bard began to market and sell the RECOVERY® Filter as both permanent and retrievable filter on or about on July 25, 2003.

19. Defendants began actually marketing the device in April 2003, but did not begin full market release until 2004. Defendants were aware that the RECOVERY® filter was also used extensively off-label, including for purely prophylactic reasons for trauma patients or patients with upcoming surgeries such as bariatric procedures.

**ii. Design of the RECOVERY® Filter**

20. The RECOVERY® Filter consists of two (2) levels of six (6) radially distributed

---

<sup>1</sup> Defendants submitted the notification under Section 510(k) of the United States Food, Drug and Cosmetic Act (“Act”) of 1976 (21 U.S.C. 321 *et seq*). The 510(k) review process requires any entity engaged in the design, manufacture, distribution or marketing of a device intended for human use to notify the FDA 90 days before it intends to market the device and to establish that the device is substantially equivalent to a legally marketed predicate device. (21 C.F.R. §§ 807.81, 807.92(a)(3)). Substantial equivalence means that the new device has the same intended use and technological characteristics as the predicate device. This approval process allows a manufacturer to bypass the rigorous safety scrutiny required by the pre-market approval process

NITINOL struts that are designed to anchor the filter into the inferior vena cava and to catch any embolizing clots. There are six short struts, which are commonly referred to as the arms, and six long struts, which are commonly referred to as the legs. Each strut is held together by a single connection to a cap located at the top of the device. According to the patent filed for this device, the short struts are primarily for “centering” or “positioning” within the vena cava, and the long struts with attached hooks are designed to primarily prevent the device from migrating in response to “normal respiratory movement” or “pulmonary embolism.”

21. As noted above, the RECOVERY® Filter is constructed with NITINOL, which is an acronym that stands for Nickel Titanium Naval Ordnance Laboratory. NITINOL 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. When placed in saline, therefore, the NITINOL struts become soft and can be straightened to allow delivery through a small diameter catheter. The metal struts then reassume their original shape when warmed to body temperature in the vena cava.

22. The RECOVERY® Filter is inserted by a catheter that is guided by a physician through a blood vessel into the inferior vena cava. The RECOVERY® Filter is designed to be retrieved in a similar fashion.

**iii. Inherent Risks of the RECOVERY® Filter**

23. The RECOVERY® Filter is prone to an unreasonably high risk of failure and patient injury following placement in the human body. Multiple studies have reported Bard’s RECOVERY® Filter to have a fracture and migration rate ranging from 21% to 31.7%. When such failures occur, shards of the device or the entire device can travel to the heart, where it can cause cardiac tamponade, perforation of the atrial wall, myocardial infarction and death. These fractured shards may also become too embedded in tissue or migrate to other organ systems and vasculature, such as the renal veins, heart and lungs, such that they are too dangerous to remove. These patients are exposed to a lifetime of future risk.

24. The RECOVERY® Filter similarly poses a high risk of tilting and penetrating and

perforating the vena cava walls. When such failures occur, the device can perforate the duodenum, small bowel, ureter, which may lead to retroperitoneal hematomas, small-bowel obstructions, extended periods of severe pain, and/or death. Further, given the risks of injury in attempting to remove devices that have penetrated or perforated the vena cava, the device may be irremovable. These patients are faced with a lifetime of future risk.

25. The RECOVERY® Filter failures described above occur at a substantially higher rate than with other IVC filters.

26. The adverse event reports (AERs) associated with IVC filter devices demonstrates that Bard's IVC Filters to include the RECOVERY® Filter are far more prone to device failure than are other similar devices.

27. These failures are attributable, in part, to the fact that the RECOVERY® Filter was designed so as to be unable to withstand the normal anatomical and physiological loading cycles exerted *in vivo*.

28. In addition to design defects, the RECOVERY® Filter suffers from manufacturing defects. These manufacturing defects include, but are not limited to, the existence of "draw markings" 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 device while *in vivo*. In particular, the RECOVERY® Filter is prone to fail at or near the location of draw markings/circumferential grinding markings on the struts of the device. Put simply, the RECOVERY® Filter 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 failure.

**iv. What Defendants Knew or Should Have Known**

29. Defendants knew that no clinical testing, bench testing, animal studies or adequate testing was conducted to determine whether the RECOVERY® Filter would perform safely or effectively for short-term and/or long-term use once implanted in the human body and subjected to normal *in vivo* stresses.

30. Soon after the RECOVERY® Filter's introduction to the market in 2003, Defendants



began receiving large numbers of adverse event reports (“AERs”) from health care providers reporting that the RECOVERY® Filter was fracturing or migrating post-implantation and that fractured pieces and/or the entire device were migrating throughout the human body, including to other vessels, the heart and lungs. Defendants also received large numbers of AERs reporting that the RECOVERY® Filter was found to have excessively tilted, migrated and/or perforated the inferior vena cava post-implantation. These failures were often associated with reports of severe patient injuries such as:

- a. death;
- b. hemorrhage;
- c. cardiac/pericardial tamponade (pressure caused by a collection of blood in the area around the heart);
- d. cardiac arrhythmia and other symptoms similar to myocardial infarction;
- e. severe and persistent pain;
- f. and perforations of tissue, vessels and organs.

31. Defendants received AERs reporting that the RECOVERY® Filter had fractured *in vivo* and that the entire device had migrated *in vivo* some of which were reported to have been associated with patient death.

32. From 2003 through September 2005, Defendants received ever growing numbers of AERs reporting the above described failures and patient injuries. Defendants knew or should have known that the failure rates associated with the RECOVERY® Filter were substantially higher than other similar products on the market.

**v. Market Withdrawal, but no Recall**

33. In late 2004 or early 2005 Defendants, without notifying consumers of the design and manufacturing flaws inherent in the RECOVERY® Filter, began redesigning the RECOVERY® Filter in an attempt to correct those flaws. The redesigned filter is known as the G2® Filter,

which stands for second generation RECOVERY® Filter. Once Defendants began marketing and selling the redesigned product in or around August 2005, Defendants quietly stopped marketing the RECOVERY® Filter. Defendants failed, however, to make any effort to notify consumers of the risk inherent in the use of the RECOVERY® Filter.

**C. THE G2® AND G2® X FILTER SYSTEM**

34. On August 10, 2005, Defendants stated that the G2® Filter was as safe as or better than the RECOVERY® Filter and was, therefore, substantially equivalent to the RECOVERY® Filter. Defendants stated that the differences between the RECOVERY® Filter and the G2® Filter were primarily dimensional and no material changes or additional components were added. On August 29, 2005, Defendants began selling and marketing the G2® Filter for the same intended uses as the RECOVERY® Filter, except that it was not sold as a retrievable device.

35. On July 2, 2008, Defendants stated that the G2® X Filter was as safe as or better than the G2® Filter and was, therefore, substantially equivalent the G2® Filter. Defendants stated that the differences between the G2® Filter and the G2® X Filter were the addition of a snare (a hook) to the tip of the filter and minor dimensional modifications were made to the delivery system to accommodate the snare tip, no other material changes or components were added. On July 30, 2008, Defendants began selling and marketing the G2®X Filter for the same intended uses as the RECOVERY® Filter and the G2® Filter.

36. On October 31, 2008, G2® X Filter was indicated for retrievable use.

37. Defendants expound that the single difference between the G2® Filter and G2® X Filter is that the G2® X Filter includes a modified apical hook which enables the ease of device retrieval. For all other purposes, the G2® Filter and the G2® X Filter are identical.

38. Defendants falsely marketed the G2® and the G2®X Filters as having “enhanced fracture resistance,” “improved centering,” and “increased migration resistance.” However, Defendants again failed to conduct adequate clinical testing, bench testing or animal studies, to ensure that the device would perform safely and effectively for short-term or long-term use once implanted in the human body and subjected to *in vivo* stresses. Not surprisingly, the G2® and the

G2® X Filters' defective design causes these filters to be of insufficient integrity and strength to withstand normal *in vivo* body stresses within the human body so as to resist perforation of the inferior vena cava, fracturing, migrating, and/or tilting within the inferior vena cava.

39. Also, like its predecessor, in addition to design defects, the G2® and the G2® X Filters suffer from manufacturing defects. These manufacturing defects include, but are not limited to, the existence of "draw markings" 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® and the G2® X Filter while *in vivo*. In particular, the G2® and the G2® X Filters are prone to fail at or near the location of draw markings/circumferential grinding markings on the struts of the device. Put simply, the G2® and the G2® X Filters are 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 and migration.

40. Thus, the G2® and the G2® X Filters shares similar defects and health risks as its predicate device.

41. As with the RECOVERY® Filter, Defendants immediately began receiving large and excessive numbers of AERs reporting that the G2® and G2® X Filters were, *inter alia*, perforating the IVC, fracturing, migrating, tilting in the IVC once implanted and could not be removed percutaneously. These failures were again often associated with reports of severe patient injuries such as:

- a. death;
- b. hemorrhage;
- c. cardiac/pericardial tamponade (pressure caused by a collection of blood in the area around the heart);
- d. cardiac arrhythmia and other symptoms similar to myocardial infarction;
- e. severe and persistent pain;
- f. and perforations of tissue, vessels and organs.

42. Defendants represent the fracture rate of the G2® and the G2® X Filters to be 1.2%.

Based upon a review of the data available in the public domain (including the FDA MAUDE database statistics and the published medical literature), this representation does not accurately reflect the true incidence of device fracture for the G2® and the G2® X Filters.

43. A review of the MAUDE database from the years 2004-2008 reveals data to establish that the Defendants' vena cava filters are responsible for the majority of all reported adverse events related to inferior vena cava filters.

**D. DEFENDANTS'S KNOWLEDGE OF THE RISK OF FAILURE AND RESULTING DANGERS**

44. Upon information and belief, Plaintiff alleges that as early as 2003, Defendants were aware and had knowledge or should have had knowledge of the fact that the RECOVERY® Filter was defective and unreasonably dangerous and was causing injury and death to patients who had received it. Similarly, Defendants were aware as early as 2005 that the G2® Filter System (identical to the G2® X Filter) was defective and unreasonably dangerous and was causing injury and death to patients who had received it. The RECOVERY Filter, the G2 Filter and the G2 X Filter failed to perform as safely as an ordinary consumer would expect when used as intended or in a manner reasonably foreseeably by the Defendant's and/or the risk associated with these filter systems outweigh any benefit of the filters.

45. Data establishes that the failure rates of the RECOVERY® Filter, the G2® Filter and the G2® X Filter are/were exceedingly higher than the rate that Defendants have in the past, and currently continue to publish to the medical community, members of the public. Further, Defendants were aware or should have been aware that the RECOVERY® Filter, the G2® Filter and G2® X Filter have substantially higher failure rates than do other similar products on the market, yet Defendants have failed to warn consumers of this fact.

46. Upon information and belief, from the time the RECOVERY® Filter and G2® Filter became available on the market, the Defendants embarked on an aggressive campaign of "off label marketing" concerning the RECOVERY® Filter and G2® Filter. This included representations made to physicians, healthcare professionals, and other members of the medical

community that the RECOVERY® Filter and G2® Filter Systems were safe and effective for retrievable use prior to its availability for retrievable use.

47. The conduct of Defendants as alleged in this Complaint constitutes willful, wanton, gross, and outrageous corporate conduct that demonstrates a conscious disregard for the safety of Plaintiff. Defendants had actual knowledge of the dangers presented by the RECOVERY Filter®, the G2® Filter, and G2® X Filter, yet consciously failed to act reasonably to:

- a. Inform or warn Plaintiff, Plaintiff's physicians, or the public at large of these dangers;
- b. Establish and maintain an adequate quality and post-market surveillance system; and
- c. Recall the RECOVERY® Filter, the G2® Filter and G2® X Filter from the market.

48. Despite having knowledge as early as 2003 of the unreasonably dangerous and defective nature of the RECOVERY® Filter, Defendants consciously disregarded the known risks and continued to actively market and offer for sale the RECOVERY® and, subsequently, the G2® and G2® X Filter Systems. As a result of the allegations set-forth in paragraphs 19 through 61, the G2 Filter was unreasonably dangerous because the design of the device failed to perform as safely as an ordinary consumer would expect when used as intended or when used in a manner reasonably foreseeably by Bard.

49. Plaintiff further alleges that the Defendants acted in willful, wanton, gross and total disregard for the health and safety of the users or consumers of their RECOVERY® Filter, the G2® Filter, and G2® X Filter, 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.

#### **SPECIFIC FACTUAL ALLEGATIONS AS TO PLAINTIFF**

50. On October 13, 2008, Plaintiff underwent surgical placement of a G2® Filter.

51. This G2® Filter device was designed, manufactured, prepared, compounded, assembled, processed, marketed, distributed, and sold by Defendants.

52. The G2® Filter subsequently failed and struts of the device perforated Plaintiff's

vena cava wall, fractured and caused severe complications with the involvement of organs/anatomical structures. Plaintiff was caused to undergo extensive medical treatment and care, including surgery on or about June 21, 2012, in an attempt to remove the filter; that attempt was unsuccessful. Plaintiff has suffered and will continue to suffer significant medical expenses, extreme pain and suffering, mental anguish, loss of enjoyment of life, disability, and other losses proximately caused by the device. Plaintiff will have continued risk of requiring additional medical and surgical procedures, including risk of life threatening complications and ongoing medical care to monitor the G2® Filter to ensure that it does not cause additional or further injury.

**DISCOVERY RULE AND FRAUDULENT CONCEALMENT**

53. Plaintiff pleads that the discovery rule should be applied to toll the running of the statute of limitations until Plaintiff knew, or through the exercise of reasonable care and diligence should have known, of facts indicating that Plaintiff had been injured, the cause of the injury, and the tortious nature of the wrongdoing that caused the injury.

54. Despite diligent investigation by Plaintiff into the cause of her injuries, including consultations with Plaintiff's medical providers, the nature of Plaintiff's injuries and damages and their relationship to the G2® Filter System and Defendants' wrongful conduct was not discovered, and through reasonable care and due diligence could not have been discovered, until a date within the applicable statute of limitations for filing Plaintiff's claims. Therefore, under appropriate application of the discovery rule, Plaintiff's suit was filed well within the applicable statutory limitations period.

55. 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 their 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 cause of action. Defendants' fraudulent concealment did result in such delay.

56. 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®, G2® and G2® X Filter System.

57. Plaintiff's and Plaintiff's health care providers could not reasonably have discovered the claims made herein until at the earliest the device was discovered to have migrated and learned of his health care provider's inability to remove the filter.

58. 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 to this complaint, amounts to conduct purposely committed, which Defendants must realize was dangerous, heedless and reckless, without regard to the consequences or the rights and safety of Plaintiff.

#### **CORPORATE/VICARIOUS LIABILITY**

59. At all times herein mentioned, each of the Defendants was the agent, servant, partner, co-conspirator and/or joint venture 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.

60. 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.

61. At all times herein mentioned, Defendants, and each of them, were 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.

60. 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**

61. Plaintiff re-alleges and incorporates by reference each and every allegation contained in paragraphs 1 through 60 as though fully set forth herein.

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

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

64. 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 RECOVERY®, G2® and G2® X Filters and to timely withdraw/remove/recall these filters from the market so as to avoid exposing others to foreseeable and unreasonable risks of harm.

65. Defendants knew or reasonably should have known that the RECOVERY®, G2® and G2® X Filters were dangerous or were likely to be dangerous when used in its intended or reasonably foreseeable manner.

66. At the time of manufacture and sale of the RECOVERY® Filter, G2® Filter and G2® X Filter, Defendants knew or should have known that the RECOVERY® Filter, G2® Filter and the G2® X Filter:

- a. Were defectively designed and manufactured so as to present a unreasonable risk of the device perforating the vena cava wall;



- b. Were defectively designed and manufactured in such a manner so as to present an unreasonable risk of fracture of portions of the device;
- c. Were defectively designed and manufactured so as to present a unreasonable risk of migration of the device and/or portions of the device;
- d. Were defectively designed and manufactured so as to present a unreasonable risk of the device tilting in the vena cava wall;
- e. Were defectively designed and manufactured to have unreasonable and insufficient strength or structural integrity to withstand normal placement within the human body; and.
- f. Were defectively designed and manufactured so as to present a unreasonable risk in that the device cannot be removed, cannot be removed utilizing a minimally invasive percutaneous technique and/or can only be removed through an open vascular surgical procedure.

67. At the time of manufacture and sale of RECOVERY® Filter, the G2® Filter, and the G2® X Filter, Defendants knew or should have known that using RECOVERY® Filter, the G2® Filter and the G2® X 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.

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

69. 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 RECOVERY® Filter, the G2® Filter and the G2® X 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, Plaintiff's physicians, or the general health care community about the RECOVERY® Filter, the G2® Filter and the G2® X 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 RECOVERY® Filter, the G2® Filter, and the G2® X 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 RECOVERY® Filter, the G2® Filter the G2® X Filter;
- g. Advertising, marketing and recommending the use of the RECOVERY® Filter, the G2® Filter, and the G2® X 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 RECOVERY® Filter, the G2® Filter, and the G2® X Filter;
- h. Representing that the RECOVERY® Filter, the G2® Filter, and the G2® X Filter were 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 RECOVERY® Filter, the G2® Filter, and the G2® X Filter with the knowledge that said product was dangerous and not reasonably safe, and failing to comply with the good manufacturing regulations;

- j. Failing to use reasonable and prudent care in the design, research, manufacture, and development of the RECOVERY® Filter, the G2® Filter, and the G2® X Filter so as to avoid the risk of serious harm associated with the use;
- k. Advertising, marketing, promoting and selling the RECOVERY® Filter, the G2® Filter, and G2® X 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 RECOVERY® Filter, the G2® Filter, and the G2® X Filter;
- m. Failing to establish and maintain an adequate post-market surveillance program.

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

71. As a direct and proximate result of the foregoing negligent acts and omissions by Defendants, Plaintiff has suffered and will continue to suffer significant medical expenses, extreme pain and suffering, mental anguish, loss of enjoyment of life, disability, and other losses proximately caused by the device. Plaintiff will have continued risk of requiring additional medical and surgical procedures, including risk of life threatening complications and ongoing medical care to monitor the G2® Filter to ensure that it does not cause additional or further injury, in an amount to be determined at trial.

**SECOND CAUSE OF ACTION**  
**NEGLIGENT FAILURE TO WARN**

72. Plaintiff re-alleges and incorporates by reference each and every allegation contained in paragraphs 1 through 71 as though fully set forth herein.

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

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

75. Defendants had a duty to exercise reasonable and prudent care to give appropriate warnings about particular risks of the G2® Filter which the Defendant's knew or should have known are involved in the reasonably foreseeable uses of the G2® Filter.

76. Defendants knew or reasonably should have known that the RECOVERY®, G2® and G2® X Filters were dangerous or were likely to be dangerous when used in its intended or reasonably foreseeable manner.

77. At the time of manufacture and sale of the RECOVERY® Filter, G2® Filter and G2® X Filter, Defendants knew or should have known that the RECOVERY® Filter, G2® Filter and the G2® X Filter:

- a. Were defectively designed and manufactured so as to present a unreasonable risk of the device perforating the vena cava wall;
- b. Were defectively designed and manufactured in such a manner so as to present an unreasonable risk of fracture of portions of the device;
- c. Were defectively designed and manufactured so as to present a unreasonable risk of migration of the device and/or portions of the device;
- d. Were defectively designed and manufactured so as to present a unreasonable risk of the device tilting in the vena cava wall;
- e. Were defectively designed and manufactured to have unreasonable and insufficient strength or structural integrity to withstand normal placement within the human body; and.
- f. Were defectively designed and manufactured so as to present a unreasonable risk in that the device cannot be removed, cannot be removed utilizing a minimally invasive percutaneous technique and/or can only be removed through an open vascular surgical procedure.

78. At the time of manufacture and sale of RECOVERY® Filter, the G2® Filter, and the G2® X Filter, Defendants knew or should have known that using RECOVERY® Filter, the G2® Filter and the G2® X 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.

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

80. Defendants breached their to duty to exercise reasonable and prudent care in failing to give appropriate warnings about the particular risks of the G2® Filter as described in paragraph 77 (a)-(f), 78, and further failed to disclose that the safety profile of the G2® Filter was worse than competitor filters and that the safety profile of the G2® Filter was not as good as or better than the Defendant's own SNF.

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

82. As a direct and proximate result of the foregoing negligent acts and omissions by Defendants, Plaintiff has suffered and will continue to suffer significant medical expenses, extreme pain and suffering, mental anguish, loss of enjoyment of life, disability, and other losses proximately caused by the device. Plaintiff will have continued risk of requiring additional medical and surgical procedures, including risk of life threatening complications and ongoing medical care to monitor the G2® Filter to ensure that it does not cause additional or further injury, in an amount to be determined at trial.

**THIRD CAUSE OF ACTION**  
**STRICT LIABILITY FAILURE TO WARN**

83. Plaintiff re-alleges and incorporates by reference each and every allegation contained in paragraphs 1 through 71 as though fully set forth herein.

84. Defendants designed, set specifications, manufactured, prepared, compounded,

assembled, processed, marketed, labeled, distributed, and sold the G2® Filter, including the one implanted into Plaintiff, into the stream of commerce and in the course of same, directly advertised and marketed the device to consumers or persons responsible for consumers.

85. 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, 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.

86. 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.

87. Despite this duty, Defendants failed to adequately warn of material facts regarding the safety and efficacy of RECOVERY® Filter, the G2® Filter, the G2® X Filter, and further failed to adequately provide instructions on the safe and proper use of the device. Furthermore, the foreseeable risks of harm from the G2® Filter could have been reduced or avoided by providing reasonable instructions and/or warnings and the failure to provide those instructions or warnings makes the G2® Filter unreasonably dangerous and renders the device defective.

88. 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.

89. 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.

90. 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.

91. 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.

92. 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.

93. As a direct and proximate result of Defendants' lack of sufficient warning and/or instructions, Plaintiff has suffered and will continue to suffer significant medical expenses, extreme pain and suffering, mental anguish, loss of enjoyment of life, disability, and other losses proximately caused by the device. Plaintiff will have continued risk of requiring additional medical and surgical procedures, including risk of life threatening complications and ongoing medical care to monitor the G2® Filter to ensure that it does not cause additional or further injury, in an amount to be determined at trial.

**FOURTH CAUSE OF ACTION**  
**STRICT LIABILITY DESIGN DEFECTS**

94. Plaintiff re-alleges and incorporates by reference each and every allegation contained in paragraphs 1 through 71 as though fully set forth herein.

95. 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.

96. The G2® Filter was in a condition unreasonably dangerous and 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.

97. The G2® Filter implanted in Plaintiff was defective in design because it failed to perform as safely as an ordinary consumer would expect when used as intended or when uses in a manner reasonably foreseeable by Bard and/or the risk of danger in the design outweighed the benefits of the filter.

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

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

100. 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.

101. As a direct and proximate result of the RECOVERY®, G2® and the G2® X Filter's defective design, Plaintiff has suffered and will continue to suffer significant medical expenses, extreme pain and suffering, mental anguish, loss of enjoyment of life, disability, and other losses proximately caused by the device. Plaintiff will have continued risk of requiring additional medical and surgical procedures, including risk of life threatening complications and ongoing medical care to monitor the G2® Filter to ensure that it does not cause additional or further injury, in an amount to be determined at trial.

**FIFTH CAUSE OF ACTION**  
**STRICT LIABILITY MANUFACTURING DEFECT**

102. Plaintiff re-alleges and incorporates by reference each and every allegation contained in paragraphs 1 through 71 as though fully set forth herein.

103. Defendants designed, set specifications, manufactured, prepared, compounded, assembled, processed, marketed, labeled, distributed, and sold the G2® Filter that was implanted into Plaintiff. The G2® filter was unreasonably dangerous because of a manufacturing defect in that it was different from its intended design and failed to perform as safely as the intended design would have performed.

104. The G2® Filter implanted in Plaintiff was in a condition unreasonably



dangerous and the filter was expected to and did reach the Plaintiff and/or her physicians without substantial change affecting that condition.

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

106. 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.

107. As a direct and proximate result of the RECOVERY®, G2® and G2® X Filter's manufacturing defect, Plaintiff has suffered and will continue to suffer significant medical expenses, extreme pain and suffering, mental anguish, loss of enjoyment of life, disability, and other losses proximately caused by the device. Plaintiff will have continued risk of requiring additional medical and surgical procedures, including risk of life threatening complications and ongoing medical care to monitor the G2® Filter to ensure that it does not cause additional or further injury, in an amount to be determined at trial.

**SIXTH CAUSE OF ACTION**  
**BREACH OF EXPRESS WARRANTY**

108. Plaintiff hereby re-alleges and incorporates by reference all of the allegations and statements contained in Paragraphs 1 through 71, inclusive, as though fully set forth herein.

109. Through sales representatives, consultants, printed materials and other advertising and marketing efforts, Defendants made express representations to healthcare providers and patients, including Plaintiff and Plaintiff's healthcare providers, about the safety and efficacy of the RECOVERY®, G2®, and the G2® X Filter Systems.

110. The RECOVERY®, G2®, and the G2® X Filter Systems do not conform to the express representations of fact made by Defendants through sales representatives, consultants, printed materials, and other advertising and marketing efforts and the Plaintiff and/or her physicians relied on these express representations in the purchase, use and implantation of the G2 Filter in the Plaintiff..

111. Defendants' conduct in this manner was a contributing cause of injuries and damages suffered by Plaintiff.

112. As a direct and proximate result of the RECOVERY®, and G2® and G2® X Filter's breach of express warranty defect, Plaintiff has suffered and will continue to suffer significant medical expenses, extreme pain and suffering, mental anguish, loss of enjoyment of life, disability, and other losses proximately caused by the device. Plaintiff will have continued risk of requiring additional medical and surgical procedures, including risk of life threatening complications and ongoing medical care to monitor the G2® Filter to ensure that it does not cause additional or further injury, in an amount to be determined at trial.

**SEVENTH CAUSE OF ACTION**  
**BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY**

113. Plaintiff re-alleges and incorporates by reference each and every allegation contained in paragraphs 1 through 71 as though fully set forth herein.

114. 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 RECOVERY®, G2®, and the G2® X Filters 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.

115. 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.

116. 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.

117. 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.

118. 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® X Filter System was inadequately, improperly and inappropriately prepared and/or finished causing the device to weaken and fail.

119. 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 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 RECOVERY®, G2® and the G2® X Filters were manufactured and sold.

120. Defendants placed the RECOVERY®, the G2® and the G2® X Filters 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.

121. Defendants breached their implied warranty because the RECOVERY®, the G2® and the G2® X Filters are not fit for their intended use(s) and/or the use(s) reasonably foreseeably by the Defendant.

122. As a proximate result of Defendants breaching their implied warranties, Plaintiff has suffered and will continue to suffer significant medical expenses, extreme pain and suffering, mental anguish, loss of enjoyment of life, disability, and other losses proximately caused by the device. Plaintiff will have continued risk of requiring additional medical and surgical procedures, including risk of life threatening complications and ongoing medical care to monitor the G2® Filter to ensure that it does not cause additional or further injury, in an amount to be determined at trial.

**EIGHTH CAUSE OF ACTION**  
**BREACH OF IMPLIED WARRANTY OF**  
**FITNESS FOR A PARTICULAR PURPOSE**

123. Plaintiff re-alleges and incorporates by reference each and every allegation contained in paragraphs 1 through 71 as though fully set forth herein.

124. 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 RECOVERY®, G2®, and the G2® X Filters 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.

125. 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.

126. 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.

127. Defendants knowingly 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.

128. The representations and 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.

129. 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 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 RECOVERY®, G2® and the G2® X Filters were manufactured and sold.

130. Defendants placed the RECOVERY®, the G2® and the G2® X Filters 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.

131. Defendants breached their warranty of fitness for a particular purpose because the

RECOVERY®, the G2® and the G2® X Filters are not fit for the specific purpose for which the Defendants' knowingly sold the filters and for which, in reliance on the judgment of the Defendants, the Plaintiff and/or her physicians bought and implanted the filter.

132. As a proximate result of Defendants breaching their implied warranties, Plaintiff has suffered and will continue to suffer significant medical expenses, extreme pain and suffering, mental anguish, loss of enjoyment of life, disability, and other losses proximately caused by the device. Plaintiff will have continued risk of requiring additional medical and surgical procedures, including risk of life threatening complications and ongoing medical care to monitor the G2® Filter to ensure that it does not cause additional or further injury, in an amount to be determined at trial.

**NINTH CAUSE OF ACTION**  
**FRAUDULMENT CONCEALMENT**

133. Plaintiff re-alleges and incorporates by reference each and every allegation contained in paragraphs 1 through 71 as though fully set forth herein.

134. At all times relevant to this cause, and as detailed *supra*, Defendants fraudulently concealed material information concerning the G2® Filter from Plaintiff, Plaintiff's health care providers, and the general medical community relating to the safety of the RECOVERY®, the G2® and the G2® X Filters, the efficacy of RECOVERY®, the G2® and the G2® X Filter and the rate of failure of the RECOVERY®, the G2® and the G2® X Filter;

135. 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 their 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

136. 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®, the G2®, and G2® X Filter Systems.

137. Plaintiff and Plaintiff's health care providers could not reasonably have discovered the claims made herein until at the earliest the device was discovered to have perforated Plaintiff's vena cava wall and learned of her health care providers' inability to remove the filter.

138. 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.

139. As a proximate result of Defendants' fraudulent concealment, Plaintiff has suffered and will continue to suffer significant medical expenses, extreme pain and suffering, mental anguish, loss of enjoyment of life, disability, and other losses proximately caused by the device. Plaintiff will have continued risk of requiring additional medical and surgical procedures, including risk of life threatening complications and ongoing medical care to monitor the G2® Filter to ensure that it does not cause additional or further injury, in an amount to be determined at trial.

**TENTH CAUSE OF ACTION**  
**NEGLIGENT MISREPRESENTATION**

140. Plaintiff re-alleges and incorporates by reference each and every allegation contained in paragraphs 1 through 71 as though fully set forth herein.

141. 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, misleading or incorrect information, or omitted or failed to disclose material information/facts/facts concerning the G2® Filter that the Defendant's knew or should have known was in fact false and misleading, the Defendants' made these false and misleading statements intending that the statements would be relied on by the Plaintiff, the Plaintiff's health care providers and the general medical community and the Plaintiff and her health care providers

justifiably relied upon the Defendant's false and misleading statements. The Defendant's false and misleading statements concerned the following material facts and subjects::

- a. The safety of the RECOVERY®, the G2® and the G2® X Filters;
- b. The efficacy of the RECOVERY®, the G2® and the G2® X Filters;
- c. The rates of failure of the RECOVERY®, the G2® and the G2® X Filters; and
- d. The approved uses of the RECOVERY®, the G2® and the G2® X Filters.

142. The false and misleading 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 RECOVERY®, the G2® and the G2® X Filters. 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.

143. 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 RECOVERY®, the G2® and the G2® X Filters 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 RECOVERY®, the G2® and the G2® X Filters.

144. The foregoing representations and omissions by Defendants were in fact false. The RECOVERY®, the G2® and the G2® X Filters are not safe, fit, and effective for human use in its intended and reasonably foreseeable manner. The use of the RECOVERY®, the G2® and the G2® X Filters are 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.



145. 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.

146. 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.

147. 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 RECOVERY®, the G2® and the G2® X Filters.

148. 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.

149. 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 RECOVERY®, the G2® and the G2® X Filters.

150. Plaintiff and Plaintiff's health care provider's relied on the foregoing negligent misrepresentations and omissions by Defendants and, as a result, Plaintiff has suffered and will continue to suffer significant medical expenses, extreme pain and suffering, mental anguish, loss of enjoyment of life, disability, and other losses proximately caused by the device. Plaintiff will have continued risk of requiring additional medical and surgical procedures, including risk of life threatening complications and ongoing medical care to monitor the G2® Filter to ensure that it does not cause additional or further injury, in an amount to be determined at trial.

**ELEVENTH CAUSE OF ACTION**  
**FRAUDULENT MISREPRESENTATION**

151. Plaintiff re-alleges and incorporates by reference each and every allegation contained in paragraphs 1 through 71 as though fully set forth herein.

152. At all times relevant to this cause, and as detailed *supra*, Defendants intentionally made false statements of material fact to the Plaintiff, Plaintiff's health care providers, and the general medical community or intentionally omitted or intentionally failed to disclose material information concerning the G2® Filter that the Defendants knew the statements were in fact false and misleading or made the statements knowing they did not know whether the statements were true or false, the Defendants' made these false and misleading statements intending that the statements would be relied on by the Plaintiff, the Plaintiff's health care providers and the general medical community and the Plaintiff and her health care providers relied upon the Defendants' false and misleading statements. The Defendants' false and misleading statements concerned the following material facts and subjects::

- a. The safety of the RECOVERY®, the G2® and the G2® X Filters;
- b. The efficacy of the RECOVERY®, the G2® and the G2® X Filters;
- c. The rates of failure of the RECOVERY®, the G2® and the G2® X Filters; and
- d. The approved uses of the RECOVERY®, the G2® and the G2® X Filters.

153. The false and misleading 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 RECOVERY®, the G2® and the G2® X Filters. 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.

154. 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 RECOVERY®, the G2® and the G2® X Filters 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 RECOVERY®, the G2® and the G2® X Filters.

155. The foregoing representations and omissions by Defendants were in fact false. The RECOVERY®, the G2® and the G2® X Filters are not safe, fit, and effective for human use in its intended and reasonably foreseeable manner. The use of the RECOVERY®, the G2® and the G2® X Filters are 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.

156. 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.

157. 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.

158. 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 RECOVERY®, the G2® and the G2® X Filters.

159. 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.

160. 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 RECOVERY®, the G2® and the G2® X Filters.

161. Plaintiff and Plaintiff's health care provider's relied on the foregoing fraudulent misrepresentations and omissions by Defendants and as a result, Plaintiff has suffered and will continue to suffer significant medical expenses, extreme pain and suffering, mental anguish, loss of enjoyment of life, disability, and other losses proximately caused by the device. Plaintiff will have continued risk of requiring additional medical and surgical procedures, including risk of life threatening complications and ongoing medical care to monitor the G2® Filter to ensure that it does not cause additional or further injury, in an amount to be determined at trial.

#### **PUNITIVE DAMAGES ALLEGATIONS**

162. Plaintiff re-alleges each and every allegation in this Complaint and incorporates each allegation into this Count, as if set forth at length, in its entirety.

163. Plaintiff is 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.

164. Defendants had knowledge of, and were in possession of evidence demonstrating that, the RECOVERY®, the G2® and the G2® X Filters were 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 RECOVERY®, the G2® and the G2® X Filters from the market

165. Defendants acted to serve their own interests and having reasons 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.

166. As a direct, proximate, and legal result of Defendants' acts and omissions as described herein, and Plaintiff's implantation with Defendants' defective product, Plaintiff has suffered and will continue to suffer significant medical expenses, extreme pain and suffering, mental anguish, loss of enjoyment of life, disability, and other losses proximately caused by the device. Plaintiff will have continued risk of requiring additional medical and surgical procedures, including risk of life-threatening complications and ongoing medical care to monitor the G2® Filter to ensure that it does not cause additional or further injury, in an amount to be determined at trial.

**PRAYER FOR DAMAGES**

**WHEREFORE**, Plaintiff, Clifford Geter, prays 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, she will continue to suffer in the future;
  2. Physical impairment and incapacity in the past and which, in reasonable probability, she will continue to suffer in the future;
  3. Mental anguish in the past and which, in reasonable probability, she 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 she will need in the future;
  5. Disfigurement in the past and which, in reasonable probability, she will continue to suffer in the future;
  6. Loss of earning capacity in the past and future; and
  7. Punitive damages.

- b. Plaintiff be awarded full, fair, and complete recovery for all claims and causes of action relevant to this action;
- c. Plaintiff be awarded all appropriate costs, fees, expenses, and pre-judgment and post judgment interest pursuant to the laws of the State of Mississippi as authorized by law on the judgments entered in Plaintiff's behalf; and,
- d. Such other relief the court deems just and proper.

**DEMAND FOR JURY TRIAL**

Plaintiff hereby demands trial by jury on all issues.

Respectfully submitted, on this, the 2nd day of June 2015, by:



Nathan C. VanDerVeer  
Mississippi Bar No: 102742  
Richard A. Freese  
Mississippi Bar No.: 99885  
**FRESE & GOSS, PLLC**  
1901 Sixth Ave. North, STE 3120  
Birmingham, AL 35209  
Telephone: (205) 871-4144  
Facsimile: (205) 871-4104 Fax  
nathan@freeseandgoss.com  
rich@freeseandgoss.com

Joseph R. Johnson  
Florida Bar No.: 372250  
**BABBITT & JOHNSON, P.A.**  
1641 Worthington Road, STE 100  
P.O. Box 4426  
West Palm Beach, FL 33402-4426  
Telephone: (561) 684-2500  
Facsimile: (561) 684-6308  
jjohnson@babbitt-johnson.com

*Attorneys for the Plaintiff,  
Clifford Geter*

CIVIL COVER SHEET

3:15cv403 CWR-FKB

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)

I. (a) PLAINTIFFS
CLIFFORD GETER

SOUTHERN DISTRICT OF MISSISSIPPI
FILED
JUN -2 2015
ARTHUR JOHNSTON
NOTE DEPUTY
BY

DEFENDANTS
D. R. BARD, INC., a foreign corporation, and BARD PERIPHERAL
VASCULAR, INC., an Arizona corporation,

(b) County of Residence of First Listed Plaintiff Warren
County of Residence of First Listed Defendant Union

(c) Attorneys (Firm Name, Address, and Telephone Number)
Nate C. VanDerVeer, Freese & Goss, PLLC, 1901 6th Avenue North,
Suite 3120, Birmingham, AL 35203

Attorneys (If Known)

II. BASIS OF JURISDICTION (Place an "X" in One Box Only)

- 1 U.S. Government Plaintiff
2 U.S. Government Defendant
3 Federal Question
4 Diversity

III. CITIZENSHIP OF PRINCIPAL PARTIES (Place an "X" in One Box for Plaintiff and One Box for Defendant)

- Citizen of This State
Citizen of Another State
Citizen or Subject of a Foreign Country
PTF DEF
Incorporated or Principal Place of Business In This State
Incorporated and Principal Place of Business In Another State
Foreign Nation

IV. NATURE OF SUIT (Place an "X" in One Box Only)

Table with 5 columns: CONTRACT, REAL PROPERTY, TORTS, CIVIL RIGHTS, PRISONER PETITIONS, FORFEITURE/PENALTY, LABOR, IMMIGRATION, BANKRUPTCY, SOCIAL SECURITY, FEDERAL TAX SUITS, OTHER STATUTES.

V. ORIGIN (Place an "X" in One Box Only)

- 1 Original Proceeding
2 Removed from State Court
3 Remanded from Appellate Court
4 Reinstated or Reopened
5 Transferred from Another District
6 Multidistrict Litigation

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing (Do not cite jurisdictional statutes unless diversity):
28 U.S.C. Section 1332
Brief description of cause product liability

VII. REQUESTED IN COMPLAINT:

CHECK IF THIS IS A CLASS ACTION UNDER RULE 23, F.R.Cv.P. DEMAND \$ CHECK YES only if demanded in complaint: JURY DEMAND: Yes No

VIII. RELATED CASE(S) IF ANY

(See instructions): JUDGE DOCKET NUMBER

DATE 06/02/2015 SIGNATURE OF ATTORNEY OF RECORD /s/ Nathan C. VanDerVeer, Esq.

FOR OFFICE USE ONLY

RECEIPT # AMOUNT APPLYING IFP JUDGE MAG. JUDGE

#8463033586