UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

CATHERINE ROWDEN, individually and on behalf of the estate of Johnny Rowden, Plaintiff, vs. C.R. BARD, INC., a foreign corporation, and BARD PERIPHERAL VASCULAR, INC., an Arizona corporation, Defendants.	)	Case No.: **JURY TRIAL DEMANDED**

COMPLAINT FOR DAMAGES

Comes Now Plaintiff Catherine Rowden, individually and on behalf of the Estate of Johnny Rowden and other qualified survivors, by and through her undersigned attorneys, and hereby sues Defendants C.R. BARD, INC. and BARD PERIPHERAL VASCULAR, INC. (collectively "Bard"), and alleges as follows:

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PARTIES

Plaintiff

1. Plaintiffs are individuals, or the duly authorized representatives of individuals and/or the estates of a deceased individuals, who were injured as a result of their use of the G2® Filter System ("G2 Filter)" or Recovery Cone and/or because of their spouse's, child's, decedent's or ward's use of these devices. Plaintiffs bring these civil actions for damages caused as a direct result of the use of the G2 Filter and Recovery Cone. In addition, Plaintiffs assert derivative claims including, but not limited to, loss of consortium and survivorship.

2. Plaintiff Catherine Rowden brings this suit as an individual and as the personal representative of the estate of Johnny Rowden. Ms. Rowden was the wife of decedent Johnny Rowden. At all time relevant to this lawsuit, she resided and continues to reside in St. Louis, Missouri. Mr. Rowden was implanted with a G2 Filter on November 16, 2006 in St. Louis, Missouri. The G2 Filter subsequently tilted and perforated his vena cava substantially reducing its ability to prevent pulmonary embolisms. On September 28, 2012, Plaintiff died as a result of the defective G2 Filter failing to perform its intended function of preventing clots from moving to the heart or lungs.

Defendants

3. Defendant C.R. Bard, Inc., ("Bard") is a corporation formed under the laws of Delaware with its principal place of business in New Jersey. Bard is authorized to do business in St. Louis, Missouri and said Defendant was doing business in St. Louis, Missouri. Bard at all times relevant to this action, designed, set specifications, manufactured, prepared, compounded, assembled, processed, marketed, distributed, and sold the G2 Filter and Recovery Cone to be used in patients such as the Plaintiff throughout the United States, including Missouri.

4. Defendant Bard Peripheral Vascular, Inc. ("BPV") is a wholly owned subsidiary corporation of Defendant C.R. Bard, Inc., and is a foreign corporation with its principal place of business in Arizona. BPV is authorized to do business in Missouri and said Defendant was doing business in St. Louis, Missouri. BPV, at all times relevant to this action, designed, set specifications, manufactured, prepared, compounded, assembled, processed, marketed, distributed, and sold the G2 Filter and Recovery Cone to be used in patients such as the Plaintiff throughout the United States, including Missouri.

5. All references to "Bard" or "Defendants" hereafter shall refer to Defendants Bard and BPV.

JURISDICTION AND VENUE

6. Jurisdiction is proper in this Court under 28 U.S.C. § 1332(a) (1) because the Plaintiff and the Defendants are citizens of different states, and the amount in controversy exceeds seventy-five thousand dollars ($75,000.00), excluding interest and costs.

7. Venue is proper in this Court, as the facts and circumstances leading to injuries occurred in St. Louis County, Missouri and the Plaintiff currently resides in St. Louis County, Missouri. Further, the G2 Filter and Recovery Cone that are the subject of this action were sold and purchased in St. Louis County, Missouri. Furthermore, the Defendant's herein were authorized to conduct business in the State of Missouri and did conduct business in St. Louis County, Missouri.

GENERAL FACTUAL ALLEGATIONS

A. INFERIOR VENA CAVA FILTERS GENERALLY

8. Inferior vena cava ("IVC") filters first came onto the market in the

1960's. Over the years, medical device manufacturers have introduced several different designs of IVC filters.

9. 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.

10. 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.

11. These devices have only been cleared by the FDA to prevent recurrent pulmonary embolism where anticoagulants are contraindicated or have failed. Thus, any use in a patient without a history of pulmonary embolism, is an off-label use.

12. Of note, Bard's internal documents as well as recent medical literature establish that there is no proven benefit to these devices.

13. Those people at risk for DVT/PE can undergo medical treatment to manage the risk. For example, a doctor may prescribe anticoagulation medications such as 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 are not candidates for anticoagulation medications may require the permanent or temporary implantation of an IVC filter to prevent thromboembolic events.

14. As indicated above, IVC filters have been on the market for decades. The first

IVC filters marketed were permanent filters. These devices were designed to be implanted into the IVC permanently. These permanent filters have long-term follow-up data (of up to 20 years and longer) regarding their use. Beginning in 2003, manufacturers also began marketing what are known as optional or retrievable filters. These filters are marketed as being designed to be left in permanently or having the option to retrieve once the risk of pulmonary embolism has passed.

B. THE RECOVERY FILTER®

i. Simon Nitinol Filter and Bard's Reasoning For Retrievable Filters

15. Bard has distributed and marketed the Simon Nitinol Filter in the United States since 1992. The Simon Nitinol Filter is a permanent IVC filter, which is substantially safer than Bard's optional filters and is still sold by Bard today. Bard modified the design of the Simon Nitinol Filter in order to make a device that was supposed to be equally safe to leave in permanently and/or could be retrieved once the risk of pulmonary embolism had passed. The modified device was ultimately marketed as the Recovery® Filter System ("Recovery Filter").

16. Bard's stated purpose in designing the Recovery Filter was to increase the overall size of the market for these devices through off-label promotion and to increase Bard's percentage of that market. Specifically, Bard marketed the device for patients that were at risk for DVT and PE but that had not actually ever had a pulmonary embolism as required by the FDA label. These included patients who were immobilized for periods of time, e,g, orthopedic patients; bariatric patients, and cancer patients.

17. Of note, prior to the Recovery filter being cleared for use by the FDA, Bard was losing market share in an IVC Filter market that was reported to be worth $100,000,000 in sales. In July 2001, Bard's overall market share was 16-17%. By March 2003, Bard's market share was down to 11-12%.

18. Bard's marketing Manager, Janet Hudson, explained Bard's marketing plan for the Recovery Filter in a March 28, 2003 Market Appraisal Memorandum. She wrote, "Users can be swayed by ease of use, low profile and aggressive marketing even in the absence of solid clinical history and in spite of negative clinical experience."

ii. FDA Clearance

19. In 2002, Bard and BPV submitted a notification to market the Recovery Filter System for the prevention of recurrent pulmonary embolism by placement in the inferior vena cava.[1] On November 27, 2002, the FDA cleared the device for sale and use in the prevention of recurrent pulmonary embolism via *permanent* placement in the vena cava.

20. In April 2003, Bard submitted a notification of intent to market and sell the Recovery Filter for the additional intended use of *optional retrieval* and Bard received FDA clearance to begin marketing the Recovery Filter as both a permanent and retrievable filter on or about July 25, 2003.

21. Kay Fuller, the ex-BPV employee responsible for submitting materials to the FDA regarding Defendants' application to market the Recovery Filter has testified that she raised safety concerns regarding the device prior to FDA clearance to her bosses at BPV. She further testifies that her concerns were ignored and that she was threatened with retaliation if she did not drop those safety concerns. She further testified that Rob Carr, project manager for the Recovery

[1] Bard and BPV 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.

Filter at BPV, created a culture that was all about rushing the product to market and would not tolerate anything that could slow that process down. Ms. Fuller quit her job when her safety concerns were ignored. Defendants then forged her signature on the FDA application to market the device, in order to get it cleared for marketing.

22. Ultimately, Bard's plan to promote its retrievable devices for off-label uses and for unproven benefits succeeded. By 2009, the overall market share for IVC filters had tripled; moreover, Bard's percentage of that market share has increased from 11-12% to 42%.

23. Bard's marketing claims made to all physicians, included, that the Recovery Filter was safer than all previously available filters, including the Simon Nitinol Filter. As will be discussed below, this claim was false.

iii. The Design Recovery Filter

24. The Recovery Filter is conical in shape and it consists of two (2) levels of six (6) radially distributed 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/apex 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 from "normal respiratory movement" or even massive pulmonary emboli.

25. The Recovery filter is inserted percutaneously by a deployment 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.

26. The Recovery Filter included several design changes from the Simon Nitinol Filter including, but not limited to, the following:

a. decreasing the leg span of the device;

b. decreasing the hook diameter of each hook on the leg struts;

c. decreasing the radial force of the struts; and

d. changing the closed petal arm strut design to an open arm strut design.

iv. Bard's Design Efforts Were Inadequate

27. Each of the design changes referenced above had the unintended consequence of substantially reducing the Recovery Filter's stability, i.e. tendency to move whether it being tilting or migration completely out of the area of placement, and structural integrity and increasing it propensity to perforate the vena cava.

28. However, because Bard failed to conduct adequate testing and research to understand the anatomy of where the device would be placed and what forces it would be exposed to when used in a reasonably foreseeable manner, Defendants failed to realize that these design changes would result in the device not being reasonably safe for user needs.

29. In a 2009 Bard IVC Filter franchise review, Bard's Filter Franchise Team admits that Bard's weakness have been a:

a. Lack of thorough understanding dynamics of caval anatomy – impacting testing methods;

b. We have a historical reactive/evolution design mindset;

c. Product complications – forcing focus on reactive designing;

d. Limited understanding of user needs.

30. Due to Bard's lack of understanding of caval anatomy and the forces the device would be exposed to once implanted, Bard set design specifications that were not clinically relevant and did not account for the forces these devices would actually see when implanted in the human body. For instance, Bard's decision to set the minimum safety standard regarding migration resistance at 50 mmHg reflected a complete lack of understanding of the forces this device could be exposed to once implanted.

31. Bard also failed to test the device under reasonably foreseeable conditions that the device could be exposed to when used in an intended and expected manner. Among other things, Bard knew that these devices could be placed in appropriately sized vena cavas that subsequently expanded beyond 28 mm in diameter. Bard knew that this decreased migration resistance if the device was challenged by a clot and could lead to migration if the vena cava expanded beyond the leg span of the filter, such that the hooks were no longer in touch with the vena cava walls. Yet Bard chose not to test the device to simulate how it would perform if caval distension were to occur. Bard also failed to test the device to determine how it would perform if tilted, fractured, or perforating the vena cava in respect to stability and structural integrity.

v. Pre-Market Expectations

32. Prior to introducing the Recovery Filter and later the G2 and Eclipse Filters to market, Bard and consumer expected that a properly placed filter would remain stable, maintain structural integrity and would not perforate through the vena cava when used in a reasonably foreseeable manner. Bard's internal documents repeatedly support this point:

a. Bard filed patents for its retrievable filters, which state "An elastic hook is formed on the free end of an appendage to pierce the vessel wall and insure that the filter does not

migrate in response to normal respiratory functions or in the event of a massive pulmonary embolism."

b. Bard's Product Performance Specifications for its retrievable filters provide specifications that are to ensure the following "user needs", that the devices must not migrate, fracture or perforate the vena cava.

c. Bard's premarket testing, which failed to account for real world conditions, predicated that there would be no fractures, migration, or perforation failures.

d. Bard's pre-market design and testing documents state that if a clot challenges a filter "pressure below the filter increases significantly and tends to drive the filter toward the heart" and that "the device must not migrate in response to such a challenge."

e. In a June 2004 Health Hazard Evaluation, Bard's Medical Director states that clot induced migrations are a malfunction of the device and a failure to carry out its intended function.

f. Bard's own quality engineers working on the retrievable filter projects admit that if one of its filters is driven into the heart by a clot challenge, then the device failed to perform as intended.

g. In 2004, Bard conducted a physician focus group regarding what were the expected complications from IVC filters. The physicians reported that an IVC Filter must not migrate no matter how big a clot is.

h. Bard also marketed its retrievable filters as being "self-centering" meaning that they would not tilt in the vena cava.

33. Bard and physicians further expected that Bard's retrievable filters would perform at least as safely and effectively as Bard's permanent filter. For example:

a. BPV's Vice-President of Quality Assurance, Doug Uelmen and C.R. Bard, Inc.'s Medical director, Dr. Ciavarella, both admit that a device that fails to perform as safely and effectively as a predicate device is adulterated and misbranded under federal law and company must stop selling it.

b. Bard marketed the Recovery, G2, and the Eclipse Filter as being substantially safer than all previous IVC filters, including the Simon Nitinol Filter.

c. In 2004, Bard conducted a physician focus group regarding what were the expected complications from IVC filters. The physicians reported that "A retrievable filter is expected to perform just as well as a permanent filter."

vi. Bard's Post-Market Surveillance Revealed Recovery Filter Did Not Perform as Expected.

34. Once the Recovery Filter was released to market, Bard became aware from reported complaints, its own investigations and epidemiological studies that the design changes made from the Simon Nitinol Filter to its Recovery Filter had the unintended result of substantially reducing the stability, structural integrity, and perforation resistance of the device.

35. Thus, even when properly placed, the Recovery Filter would move, fracture, and or perforate the vena cava when exposed to normal and expected in vivo forces.

36. These failures often caused severe patient injuries such as:

i. death;

ii. hemorrhage;

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

iv. cardiac arrhythmia and other symptoms similar to myocardial infarction;

v. severe and persistent pain;

vi. and perforations of tissue, vessels and organs.

37. Moreover, Bard was aware that these failures and resulting injuries were far more likely to occur with the Recovery Filter versus other available IVC Filters. For instance:

a. Multiple studies have reported Bard's Recovery Filter to have a fracture and migration rate ranging from 21% to 31.7%.

b. In February 2004, Bard's Marketing Manager, Janet Hudnall, sent an email admitting that the Recovery Filter is being reported to have tilted at significantly high rate even though it was initially properly placed. She further requested that this high rate of failure be downplayed to consumers.

c. In June 2004, Bard's divisional head of Quality Assurance, Doug Uelmen, admitted: "Bard has been in the permanent filter market for 10 years (SNF). We have had a great deal of experience with a traditional patient base, experiencing a very low and unremarkable adverse event rate. We have now moved into the optional filter market with RNF and have experienced increased failures."

d. By July 2004, Bard's own was aware that the Recovery Filter has a reported fracture rate that was 28 times higher than all other available IVC Filters.

e. In December 2004, Bard performed a risk assessment of the Recovery Filter, which analyzed reported failure rates, and concluded: "Reports of death, filter migration (movement), IVC perforation, and filter fracture associated with Recovery filter were seen in the MAUDE database at reporting rates that were 4.6, 4.4, 4.1, and 5.3 higher, respectively, than reporting rate for all other filters. These differences were all statistically significant, Recovery's reporting rates for all adverse events, filter fracture,

filter migration, and filter migration deaths were found to be significantly higher than those for other removable filters." Dr. Ciavarella, Bard's Medical Director, concluded that this risk (substantially higher reported failure rates) was not known or obvious to consumers, and that Bard should consider providing a warning regarding the increased reporting rate.

f. By December 2004, BPV's Vice President of Quality Assurance, Doug Uelmen, admits that according to Bard's own policy and procedure for when devices should be recalled, the Recovery filter was considered unreasonably dangerous for human health and required product correction.

38. 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*.

39. In addition to design defects, the Recovery Filter suffers from manufacturing defects. These manufacturing defects include, but are not limited to, the absence of electropolishing and 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.

vii. Bard's Design Review Regarding Migration Failures

40. In late 2003, as migrations failures for the Recovery Filter continued to mount, Bard convened a group to reexamine the adequacy of the design of the Recovery Filter as it relates to its ability to remain stable after implantation. The group established a number of action items, including the following: an investigation into what the minimum migration resistance specification of 50 mmHg had been based on, testing comparing the migration resistance of the Recovery Filter to other available filters, and testing comparing radial force difference between the range of available devices.

41. This design review revealed that the minimum safety migration resistance specification was unsupported and had been set artificially low. Bard developed this critical safety standard based on undocumented informal estimates obtained from unidentified physicians regarding the highest pressure below a filter that could be seen in the vena cava (35 mmHg). Bard then tested the device in three (3) sheep and claimed that the test results confirmed that that 35 mmHg was the highest pressure that could ever be seen in the vena cava under worst case conditions. Bard then added a safety factor of 15 mmHg, and concluded that its filters would never migrate. However, the test results from the sheep testing actually show pressure levels well above 50 mmHg.

42. Further, Bard's own investigations concluded that multiple properly placed Recovery Filters migrated and caused death because the filters lacked adequate strength to resist clot challenges and/or lacked an adequate margin of safety to accommodate post-placement distention of the vena cava. Thus, further confirming that the safety specification of 50 mmHg was inadequate and that it's testing, which predicted no migration failures, did not accurately reflect real world conditions.

43. As part of its design review in early 2004, Bard also spoke with its two long time physician consultants, Drs. Venbrux and Kaufman. They warned Bard that their input on the migration resistance specification had just be an "estimate" and that Bard needed to consider revising the

migration resistance specification from 50 mmHg to 140 mmHg. They further warned Bard that the Recovery Filter was a "wimpy" filter and its radial force also needed to be increased to ensure stability.

44. The design review also revealed that the Recovery Filter had migration resistance values that were far below most other filters, including the Simon Nitinol Filter. Bard's internal records reveal that this was a known contributing factor to why Bard anchoring mechanism was insufficient to assure stability.

45. Bard knew that caval distension (expansion of the vena cava diameter beyond the size at placement) could occur from multiple factors. These factors included: anesthesia, hydration following medical procedure such as bariatric procedures, exertion from exercise, coughing, straining during bowel movements. However, Bard to date has failed to make any efforts to determine the size of vena cava distension that can occur.

viii. Bard's Investigation Regarding Fractures

46. In 2004, Bard also investigated what was causing the Recovery Filter to fracture. Among other things, Bard believed that movement, whether it be tilting or migration of more than 2 cm, substantially increased the risk of fracture. Bard also determined that perforation of struts through the wall of the vena cava was causing fractures. Bard also discovered that tilt also led to the inability to retrieve the device and/or could lead to fractures during retrievals. Bard was also aware of other factors causing fractures:

a. On June 18, 2003, BPV engineer, Robert Carr, sent an email noting that chamfering the edge of cap would reduce the likelihood of fracture;

b. On March 16, 2004, a BPV engineer sent an email admitting that the surface damage, as seen on the Recovery® Filter from the manufacturing

process, decreases fatigue resistance and that electropolishing increases fatigue resistance;

c. On May 5, 2004, a BPV engineer sent an email stating that adding a "chamfer" to filter will "address the arm fracture issue."

d. On May 26, 2004, a BPV engineer sent an email stating that a proposed modified Recovery® Filter design with a large chamfer lasted 50 bending cycles before breaking, whereas another proposed modified Recovery® Filter with a small chamfer broke after 10 bending cycles.

ix. Bard Conducts Silent Recall of Recovery Filter

47. In or around April 2004 Bard, without notifying consumers of the design and manufacturing flaws inherent in the Recovery Filter, began redesigning the Recovery Filter in an attempt to correct its design flaws. The redesigned filter is known as the G2 Filter, which stands for second generation Recovery Filter. Once Bard began marketing and selling the redesigned product in approximately August 2005, Bard quietly stopped selling the Recovery Filter. Of note, however, Bard continued to market the Recovery Filter as being safer and more effective than all prior filters up until the day the Recovery Filter was removed from the market. Moreover, Bard never issued a recall for the Recovery Filter, which had a three (3) year shelf-life.

C. THE G2® FILTER SYSTEM

48. On August 29, 2005, Bard obtained clearance to market the G2 Filter through the 510k process by having represented to the FDA that the G2 Filter was substantially equivalent in respect to safety and efficacy as the Recovery Filter.

49. Bard represented that the differences between the Recovery Filter and the G2 Filter were primarily dimensional and no material changes or additional components were added.

The G2 Filter was only cleared for permanent implantation until January 15, 2008. Thus, between September 2005 through all of 2007, Bard sold two filters, the Simon Nitinol Filter and G2 Filter, with the exact same indications for use.

50. Bard marketed the G2 Filter as having "enhanced fracture resistance," "improved centering," and "increased migration resistance" over all of its previous filters. Bard's marketing brochure states that supporting data was "on file." Yet, Bard refused to share this allegedly supporting evidence with consumers when it was asked for it. In reality, Bard knew these claims were false and misleading. Bard knew that the Simon Nitinol Filter was far less likely to fracture, migrate, tilt, or perforate the vena cava.

51. Further, Bard again failed to conduct adequate testing for long term safety and efficacy and failed to conduct adequate bench testing and animal studies, to ensure that the device would perform safely and effectively once implanted in the human body and subjected to reasonably foreseeable *in vivo* stresses. Furthermore, Bard still did not have a thorough and/or adequate understanding of vena caval dynamics. Not surprisingly, the G2 Filter's design still lacked adequate structural integrity, stability and perforation resistance to withstand normal *in vivo* body stresses within the human without failing.

52. For instance, the new minimum safety migration resistance design requirement for the G2 Filter was that its migration resistance had to be "statistically greater" than of the predicate Simon Nitinol Filter. Bard's testing established that the G2 Filter failed this requirement. However, instead of going back and modifying the device further to ensure this safety requirement was met, Bard changed the minimum safety requirement to be that it just had to be better than the Recovery Filter, which was the device it was removing from the market because it migrated when challenged by large clots.

53. Compounding this utter lack of concern for patient safety, Bard also decided that G2 filters could be reworked or reloaded on the jig used to form the filters up to five times in order to save money despite knowing that this would significantly decrease the migrations resistance of such devices. To allow for this, Bard readopted the same minimum safety migration resistance specification that had been adopted and proven to be utterly unsupported for the Recovery Filter, e.g. 50 mmHg.

54. Thus, knowing that the specification and migration resistance of the Recovery Filter had been inadequate and was resulting in patient death, Bard's premarket design requirements was the device had to be at least as good as the Simon Nitinol Filter regarding migration resistance. When the G2 Filter failed that requirement, Bard simply changed the design requirement to the G2 Filter just having to be at least as good as the device that was known to be inadequate and causing patient death.

55. The Redesigned G2 Filter also still had substantially less radial force than did the Simon Nitinol Filter.

56. Bard also again failed to account for how movement (tilt/migration), perforation, and fracture would affect device performance despite knowing that these failures had occurred with the Recovery Filter.

57. Also, like its predecessor, in addition to design defects, the G2 Filter suffers from manufacturing defects. These manufacturing defects include, but are not limited to, the absence of electropolishing and 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 Filter while *in vivo*. In particular, the G2 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 G2 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 fatigue failure and migration.

58. Within months of being released to market post-market safety data revealed to Bard that the safety problems introduced with the Recovery Filter had not been corrected. Some representative examples of this knowledge include the following:

a. Bard again received large numbers of adverse event reports reporting that properly placed G2 Filter were, *inter alia*, fracturing, migrating, tilting, and perforating the vena cava often resulting in serious injuries and death.

b. By November 2005, Bard was aware of a "safety signal" regarding the high rate of reported perforation and movement failures.

c. In a December 25, 2005 email, Bard's Medical Director, Dr. David Ciavarella, questioned why Bard was even selling the G2 filter given the numerous reported failures when the Simon Nitinol Filter had virtually no reported adverse events.

d. By no later than February 2006, internal safety investigations revealed that the G2 Filter's design continued to fail to ensure adequate stability as the device continued to tilt and migrate at unreasonably high rates. Indeed, within months of being on the market, the G2 filter was found to migrate at rates that violated Bard's own safety threshold. The G2 Filter also exhibited a previously unseen failure mode, in that it would migrate downwards as well as upwards and side to side in the vena cava.

e. As with the Recovery Filter, Bard knew that movement, whether it be tilt or migration, increased the risk fracture and strut perforation through the vena cava as well making the device irretrievable. For example in a February 2006, Health

Hazard Evaluation regarding G2 Failures, Bard's Medical Director acknowledges that tilt increases the risk of fracture and perforation and that events can cause serious injury and death. Similarly, a 2009 PowerPoint Presentation prepared by Bard's engineers, movement causes tilt and that "[T]ilted filter elements are more likely to penetrate IVC and adjacent structures due to change in the angle between the elements and the IVC." The PowerPoint states that tilting and perforation or penetration leads to fracture.

f. Bard's investigations into comparative failure risks between the different available devices continually showed that the G2 filters posed a substantially higher risk of migration, tilt, perforation and fracture.

g. By 2008, physicians were reporting that they believe there were fundamental design flaws with the G2 filter that was causing it to move, fracture and perforate and requesting evidence as to what the reported complication rates were for the device. Bard's corporate policy was to refuse to disclose such failure rate data.

h. In a document dated April 1, 2010, senior Bard employees admit that there were known quality problems with the G2 line of filters, that Bard's own sales force had lost faith with the product, and that doctors were refusing to use it do to the numerous reported failures. The document evidences Bard's plan to reduce the risk of tiling, perforation, fracture and migration by improving the anchoring system on the G2 line of filters. This became the Meridian filter, which was cleared through the 510(k) process on October 24, 2011.

i. Recent medical studies report that the G2 will suffer a 38 to 40 percent fracture rate at four to five years.

59. As with the Recovery Filter, these failures often caused 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.

60. Despite being aware from February 2006 that the G2 Filer was not safe for its intended use and was substantially more likely to fail and cause patient injuries than all other available IVC Filters devices, Bard continued to sell the device into 2010 and even continued to market it as being safer than Bard's permanent filter, the Simon Nitinol Filter.

D. The G2 Express® and Eclipse® Filter

61. On July 30, 2008, Bard obtained clearance to begin marketing the G2 Express® Filter (G2 Express) via the 510k process. The filter is the identical in design to the G2 Filter except that it has a hook at the top of the device, which allows it to be retrieved by snares, as well as Bard's Recovery Cone. The G2 Express Filter contained no design fixes to alleviate the stability, structural integrity and perforation problems that Bard knew to exist with the G2 Filter.

62. On January 14, 2010, Bard obtained clearance to begin marketing the Eclipse® Filter ("Eclipse Filter") via the 510k process. Bard obtained clearance by representing that the Eclipse Filter was substantially equivalent to the G2 Express Filter in respect to safety and efficacy and that the only change "was an improvement of the surface finish of the filter raw

material wire by electropolishing the wire prior to forming the filter." Adding electropolishing to the manufacturing process was intended to improve structural integrity by removing manufacturing defects caused by the manufacturing process, which were believed to be increasing the risk of fracture. This device did not incorporate any design changes to address the known stability, perforation and structural integrity design problems experienced by the device.

63. Both devices continued to experience the unacceptably high failure modes and patient injuries originally introduced with the design changed in the Recovery Filter.

E. The Meridian® Filter

64. By March 2006, Bard opened the project to redesign the G2 Filter to correct its defective anchoring system so as to prevent it from moving/tilting once placed, which Bard knew to be causing perforations, fractures, and the inability to retrieve these devices. The redesigned filter is became known as the Meridian® Filter ("Meridian Filter") and was cleared by the FDA via the 510k process on August 24, 2011.

65. The Meridian Filter contained multiple design changes to prevent movement and tilt which was known to lead to perforation, fracture, reduced efficacy and inability to retrieve the device. The stated purpose and expectations of these design changes is that the device would not migrate, tilt, perforate the vena cava, or fracture.

66. Thus, as discussed above, Bard knew from March 2006 that its G2, G2 Express, and Eclipse filters were defectively designed and needed to be fixed to prevent movement/tilt once placed, which was leading to perforations, fractures, and inability to retrieve. Yet, from March 2006 through August 2011, Bard continued to market these devices and even falsely marketed them as being safer than the available permanent devices.

67. Even after Bard released the Meridian Filter, it failed to recall the older generation devices and/or to warn consumers about the increased risk posed by these devices. Instead, Bard conducted another silent recall. It stopped manufacturing the older device, sold remaining units, and allowed hospitals to use up units already on their shelves.

68. As a result, Plaintiff was implanted with known defective device, when Bard knew there was a safer alternative design available.

F. The Denali® Filter

69. At the same time Bard was working to fix design defects in the G2 Filter in what became the Meridian Filter, it was also working on the Denali® Filter ("Denali Filter") as another means to correct these design flaws. Bard obtained 510k clearance to begin marketing the Denali Filter on April 5, 2013 by claiming it was substantially similar to the Eclipse Filter in respect to safety and efficacy.

70. The Denali Filter incorporated design changes to fix design defects in the G2, G2 Express and Express Filters regarding the devices' inadequate stability, structural integrity and propensity to perforate the vena cava. These design changes included, *inter alia*, an improved anchoring system and "penetration limiters." The stated purpose and expectations of these design changes is that the device would not migrate, tilt, perforate the vena cava, or fracture.

71. Even after Bard released the Denali Filter, it failed to recall the older generation devices and/or to warn consumers about the increased risk posed by these devices. Instead, Bard conducted another silent recall. It stopped manufacturing the older device, sold remaining units, and allowed hospitals to use up units already on their shelves.

72. As a result, Plaintiff was implanted with known defective device, when Bard knew there was a safer alternative design available.

73. Plaintiff further alleges that Bard acted in willful, wanton, gross and total disregard for the health and safety of the users or consumers of Eclipse Filter, acted to serve their own financial 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.

G. THE RECOVERY CONE REMOVAL SYSTEM

74. Bard marketed a medical device known as the Recovery Cone Removal System to be used with the Recovery Filter and G2 Filter. Specifically, Bard's labeling instructed doctors that the Recovery Cone Removal System was the only method to safely remove the Recovery Filter and G2 Filter. Defendants internal documents specifically warn that use of any device other than the Recovery Cone to retrieve a Recovery or G2 Filter, would lead to "malfunctions and serious patient complications such as perforation, migration, fracture, tilting and pulmonary emboli."

75. However, Bard never sought nor obtained clearance via the premarket notification process (510k) or approval through the more stringent pre-market approval process to market this device. Thus, Bard was illegally marketing the Recovery Cone device and there has never been, nor is there currently a device cleared by the FDA as safe and effective for retrieving the Recovery Filter or G2 Filter. This was first disclosed to the public on July 13, 2015.

76. There have been numerous reports of the Recovery Cone Removal System failing, such as breaking during use or causing the filters themselves to break and/or not being able retrieved.

77. As these devices were never cleared for marketing, Bard has subjected all patient who have undergone removal of a Recovery or G2 Filter, which includes Plaintiff, to an illegal research trial without the safeguards and oversight of an approved clinical trial and/or without their informed consent.

78. Further, consumers who used the Recovery and G2 Filters with the understanding and expectation they could be safely retrieved, were knowingly mislead by Defendants and now have no safe way to retrieve these deadly IVC Filters.

H. FDA WARNING LETTER

79. On July 13, 2015, the FDA issued a warning letter notifying Bard that its IVC Filters are adulterated and misbranded under federal law.

80. The FDA noted that the Recovery Cone Removal Systems are adulterated pursuant to 501(f)(1)(B) of 21 U.S.C. § 351(f)(1)(B) and misbranded pursuant to section 21 U.S.C. 352(o) because these devices have never been cleared or approved for use in humans. Thus, the FDA demanded that Bard immediately cease commercial distribution of its Recovery Cone Removal Systems.

81. The FDA notified Bard that its IVC Filters are adulterated and misbranded because the methods used in, or the facilities or controls used for, their manufacture, packing, storage, or installation are not in conformity with the current good manufacturing practice requirements of the Quality System regulation found at Title 21, Code of Federal Regulations (CFR), Section 820, and that Bard failed to comply with adverse event reporting requirements of 21 C.F.R. 803.

82. The FDA cites numerous specific violations, including the failure to establish and maintain procedures to ensure that product complaints are adequately investigated and reported,

and a consistent pattern of Bard underreporting the severity of injuries caused by device failures and failing to report device malfunctions all together. For instance, the FDA cites numerous examples of Bard reporting G2, and G2 Express and Eclipse Filter failures resulting in death and other serious injuries as if there was no patient injury involved. Other examples of Bard's failures include the FDA finding Bard failed to establish and maintain a procedure to ensure that the toxic acids and chemicals used in the manufacture of its filters were reduced to acceptable levels prior to distribution.

SPECIFIC FACTUAL ALLEGATIONS AS TO JOHNNY ROWDEN

83. On November 16, 2006, Plaintiff underwent placement of G2 Filter. The anchoring system of the G2 Filter subsequently failed leading it to tilt and perforate the vena cava. As a result the ability of the device to prevent pulmonary embolisms was substantially reduced. On September 28, 2012, Plaintiff died as a result of the defective G2 Filter failing to perform its intended function of preventing clots from moving to the heart or lungs.

84. Plaintiff suffered significant medical expenses, pain and suffering, loss of enjoyment of life, and other losses.

FRUADULENT CONCEALMENT

85. Any applicable statutes of limitation have been tolled by the knowing and active concealment and denial of material facts known by Bard when they had a duty to disclose those facts. They have kept Plaintiff and his physicians 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 his causes of action. Bard's fraudulent concealment did result in such delay.

86. Bard is estopped from relying on the statute of limitations defense because Bard failed to timely disclose, among other things, facts evidencing the defective and unreasonably dangerous nature of the G2 Filter and the Recovery Cone.

87. Bard has failed to ever issue a recall for the G2 Filter, has never admitted is exposed consumers to increased risks, that it knew the G2 Filter had substantially higher reported failure rates, and/or that it redesigned the device because of design defects that were known to exist as early as 2006.

88. Bard was under a continuing duty to disclose the true character, quality and nature of the device that was implanted in the Plaintiff, but instead they concealed them. Bard's conduct, as described in this Complaint, amounts to conduct purposely committed, which Bard must have realized was dangerous, needlessly reckless, without regard to the consequences or the rights and safety of Plaintiff.

CORPORATE/VICARIOUS LIABILITY

89. At all times herein mentioned, the Bard Defendants were the agents, servants, partners, co-conspirators and/or joint venturers of each of the other and were 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, knowing that their collective conduct constituted a breach of duty owed to the Plaintiff.

90. There exists and, at all times herein mentioned, there existed a unity of interest in ownership between the Bard Defendants such that any individuality and separateness between these Bard Defendants has ceased and these Defendants are the alter ego of the other and exerted control over one another. Adherence to the fiction of the separate existence of the Bard

Defendants as entities distinct from each other will permit an abuse of the corporate privilege and would sanction a fraud and/or would promote injustice.

91. At all times herein mentioned, the Bard 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 Bard Defendant is individually, as well as jointly and severally, liable to the Plaintiff for Plaintiff's damages.

92. At all times herein mentioned, the officers and/or directors of the Bard 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 the Recovery Filter and G2 Filter, and thereby actively participated in the tortious conduct that resulted in the injuries suffered by the Plaintiff.

FIRST CAUSE OF ACTION
NEGLIGENCE
(Against all Defendants)

93. Plaintiff re-alleges and incorporates by reference each and every allegation contained in paragraphs 1-92 as though fully set forth herein.

94. At all times relevant to this cause of action, the Bard Defendants were in the business of designing, developing, setting specifications, manufacturing, marketing, selling, and distributing the G2 Filter.

95. Bard designed, manufactured, marketed, inspected, labeled, promoted, distributed and sold the G2 Filter that was implanted in Plaintiff.

96. Bard 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.

97. Bard knew or reasonably should have known that the G2 Filter was defective in condition unreasonably dangerous or was likely to be unreasonably dangerous when used in its intended or in a reasonably foreseeable manner.

98. At the time of manufacture and sale of the G2 Filter, Bard knew or should have known that the G2 Filter was designed and manufactured in such way that it was defective in condition and unreasonably dangerous because it lacked adequate stability and structural integrity and posed an excessively high risk of perforation, all of which were known to substantially decrease its effectiveness.

99. At the time of manufacture and sale of the G2 Filter, Bard knew or should have known that using the G2 Filter as intended or in a reasonably foreseeable manner created a significant risk of a patient suffering and severe health side effects including, but not limited to: hemorrhage; pulmonary embolism; 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.

100. Bard 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.

101. Bard breached their to 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 it 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 and/or outweighed the benefits of the device;

b. Designing and distributing a product in which it 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 G2 Filter's unreasonably 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 the use of G2 filter;

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

i. Continuing to manufacture and sell the G2 Filter with the knowledge that said products were unreasonably dangerous and not reasonably safe, and failing to comply with 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 these filter systems;

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 and maintain adequate policies and procedures in the used in the design, manufacture and post-market surveillance of the G2 Filter so as to ensure that the device would be safe for its intended and reasonably foreseeable uses.

m. Failing to remove the G2 Filter from the market despite knowing that the device lacked adequate stability and structural integrity and safer alternative devices were available.

102. As a direct and proximate result of the foregoing negligent acts and omissions by the Bard Defendants, Johnny Rowden suffered physical injuries, including death, and economic damages in an amount to be determined at trial.

SECOND CAUSE OF ACTION
STRICT PRODUCTS LIABILITY – FAILURE TO WARN
(Against all Defendants)

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

104. Bard 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 devices to consumers or persons responsible for consumers.

105. At the time Bard designed, manufactured, prepared, compounded, assembled, processed, marketed, labeled, distributed, and sold the G2 Filter into the stream of commerce, Bard knew or should have known the device was defective and unreasonably dangerous when used as intended or in a reasonably foreseeable manner as Bard failed to provide adequate warnings of the known or knowable risks in light of the generally recognized prevailing scientific and technical knowledge available at the time of manufacture and distribution.

106. Specifically, Bard knew or should have known at the time it manufactured, labeled, and distributed and sold the G2 Filter, which was implanted in Plaintiff, that the G2 Filter, *inter alia*, lacked sufficient stability and structural integrity to perform safely when used

as intended or in a reasonably foreseeable manner and posed an excessive risk of perforating the vena cava. As result the device suffered a high rate of failure, substantially reducing its ability to prevent pulmonary embolisms and was known to be directly causing serious patient injuries, including death.

107. Bard was further aware that the G2 Filter was substantially more likely to fracture, migrate, tilt and perforate the vena cava causing serious injuries than was any other available IVC Filter, including other filters marketed by Bard.

108. Bard was further aware that there were safer alternative designs at the time Plaintiff's G2 Filter was distributed, including Bard's own Simon Nitinol Filter.

109. Bard was also aware or should have been aware that the G2 Filter was adulterated and misbranded under federal law because the it had failed to comply with numerous federal safety laws and regulations designed to ensure that only safe medical devices are distributed to the public.

110. This contradicted Bard's own marketing campaigns that marketed the G2, G2 Express, and Eclipse Filter as being safer than the available permanent filters.

111. Despite this awareness, Bard failed to adequately warn Plaintiff or his health care providers of any of these material facts. Indeed, Bard actively and falsely marketed the G2, G2 Express and Eclipse Filters as being safer than the available permanent filters.

112. Upon information and belief, Mr. Rowden's prescribing physician reviewed the labeling provided by Bard that was included with the G2 Filter. He further relied on the warnings and representations made in the labeling in deciding to use the filter and as to what warnings to pass on to Mr. Rowden.

113. Neither Mr. Rowden, nor his prescribing physician would have used the G2 Filter had the above-described information been provided.

114. 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.

115. Mr. Rowden and his 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.

116. Therefore, the G2 Filter implanted in Mr. Rowden 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.

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

118. As a direct and proximate result of Bard's failure to provide adequate warning and instructions for safe use, Mr. Rowden suffered serious physical injuries, including death, and economic damages in an amount to be determined at trial.

THIRD CAUSE OF ACTION
STRICT PRODUCT LIABILITY – DESIGN DEFECT
(Against all Defendants)

119. Plaintiff re-alleges and incorporates by reference each and every allegation contained in paragraphs 1-118, as though fully set forth herein.

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

121. 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 Bard's possession.

122. The G2 Filter implanted in the Mr. Rowden was in a defective 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 the Defendant's possession.

123. The G2 Filter implanted in the Mr. Rowden was defective in design because its risk exceed any alleged benefit of the design. Bard own internal documents as well as the medical literature establish that there is no proven benefit to the use of IVC Filters. Moreover, Bard itself was marketing alternative safer designs at the time Mr. Rowden was implanted with the G2 Filter, which would have substantially reduced the risk of failure. There were also additional design enhancements that Bard should and could have instituted, such as were later introduced with the Meridian and Denali Filters.

124. Mr. Rowden and Plaintiff's health care providers used the G2 Filter in a manner that was reasonably foreseeable to Bard.

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

126. As a direct and proximate result of the Eclipse Filter's defective design, Mr. Rowden suffered serious physical injuries, including death, and economic damages in an amount to be determined at trial.

FOURTH CAUSE OF ACTION
STRICT PRODUCT LIABILITY – MANUFACTURING DEFECT
(Against all Defendants)

127. Plaintiff re-alleges and incorporates by reference each and every allegation contained in paragraphs 1-26 as though fully set forth herein.

128. Bard designed, set specifications, manufactured, prepared, compounded, assembled, processed, marketed, labeled, distributed, and sold the G2 Filter that was implanted into Mr. Rowden. The G2 Filter was unreasonably dangerous because of a manufacturing defect in that it was different from its intended design or specifications and/or differed from other manufactured units.

129. The G2 Filter implanted in Mr. Rowden was in a defective condition unreasonably dangerous and the filter was expected to and did reach the Mr. Rowden and/or his physicians without substantial change affecting the filter.

130. Mr. Rowden and his health care providers used the device in a manner that was reasonably foreseeable to Bard.

131. As a direct and proximate result of the Eclipse Filter's manufacturing defect, Mr. Rowden suffered serious physical injuries, including death, and economic damages in an amount to be determined at trial.

FIFTH CAUSE OF ACTION
BREACH OF EXPRESS WARRANTY
(Against all Defendants)

132. Plaintiff re-alleges and incorporates by reference each and every allegation contained in paragraphs 1-131 as though fully set forth herein.

133. At all times relevant to this action, Bard 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.

134. At the time and place of the sale, distribution, and supply of the G2 Filter to Plaintiff by way of Mr. Rowden prescribing physician, through sales representatives, consultants, printed materials and other advertising and marketing efforts expressly represented and warranted that the G2 Filter System was safe and effective for its intended and reasonably foreseeable uses.

135. The G2 Filter did not conform to the express representations made by Defendants through sales representatives, consultants, printed materials, and other advertising and marketing efforts. The Mr. Rowden and his prescribing physician relied on these express representations in the purchase, use and implantation of the G2 Filter in Mr. Rowden.

136. Bard 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 Mr. Rowden, and warranted the product to be of merchantable quality, and safe and fit for its intended use.

137. Bard represented and warranted to the healthcare community, Mr. Rowden and his 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.

138. The representations and warranties made by Bard were false, misleading, and inaccurate because the G2 Filter was defective and unreasonably dangerous and the device was not of merchantable quality when used in its intended and/or reasonably foreseeable manner.

139. Mr. Rowden and his health care providers reasonably relied on the superior skill and judgment of Bard 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 warranty of merchantability and fitness for the particular use and purpose for which the G2 Filter was manufactured and sold.

140. Bard 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 Mr. Rowden without substantial change in the condition in which the G2 Filter was manufactured and sold.

141. Bard breached their warranty because their G2 Filter was not fit for its intended use and purpose.

142. As a proximate result of the Bard Defendants breaching of their express warranties, Mr. Rowden suffered serious physical injuries, including death, and economic damages in an amount to be determined at trial.

SIXTH CAUSE OF ACTION
BREACH OF IMPLIED WARRANTY
(Against All Defendants)

143. Plaintiff re-alleges and incorporates by reference each and every allegation contained in paragraphs 1-141 as though fully set forth herein.

144. 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 retrievable 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.

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

146. 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 Mr. Rowden, and impliedly warranted the product to be of merchantable quality and safe and fit for its intended use. Defendants impliedly represented and warranted to the healthcare community, Mr. Rowden and his health care providers, that the G2 Filter was of merchantable quality and fit for their ordinary purposes for which the product was intended and marketed.

147. The representations and implied warranties made by Defendants were false, misleading, and inaccurate because the G2 Filter was defective and unreasonably dangerous, and not of merchantable quality when used in its intended and/or reasonably foreseeable manner. Specifically, at the time of Mr. Rowden's purchase of the products from Defendants, through his 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 high incidence of failure, including fracture, migration, excessive tilting, and perforation of the inferior vena cava, and loss of effectiveness;

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 reduced effectiveness; 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.

148. Mr. Rowden and his 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 G2 Filters were manufactured and sold.

149. 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 Mr. Rowden without substantial change in the condition in which the G2 Filter was manufactured and sold.

150. Defendants breached their implied warranty because the G2 Filter is not fit for its intended or/or reasonably foreseeable uses.

151. As a proximate result of Defendants breach of their implied warranties, Mr. Rowden suffered serious physical injuries, including death, and economic damages in an amount to be determined at trial.

SEVENTH CAUSE OF ACTION
FRAUD AND CONCEALMENT
(Against all Defendants)

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

153. At all times relevant to this cause, and as detailed *supra,* Defendants fraudulently concealed material information concerning the G2 Filter from Mr. Rowden, his prescribing physician relating to the safety and efficacy of the G2 Filter.

154. Defendants marketed the G2 Filter as being safer and less likely to fracture, migrate, or tilt than other devices, including the Simon Nitinol Filter. Yet, Defendants concealed that they were aware of information suggesting that the G2 Filter was substantially more likely to fracture, migrate, tilt, or perforate the vena cava and was less than were other available IVC Filters.

155. Defendants were also were aware and concealed from Mr. Rowden and his prescribing physician that that there were known design problems with the G2 Filter that led to it have inadequate stability, structural integrity, perforation resistance, and insufficient effectiveness.

156. Defendants were aware and concealed from Mr. Rowden and his prescribing physician that there safer alternative devices had been designed and were being marketed expressly to address the known safety problems posed by the Eclipse Filter.

157. Defendants were also aware that numerous deaths and serious injuries had been confirmed to have been caused by failures of G2 filters. Yet, Defendants concealed this information from Mr. Rowden and his physicians. Instead, Defendants only warned that people with filters had been reported to die and suffer serious injuries but not that any of these events were confirmed to have been caused by Bard's filters.

158. Mr. Rowden and his prescribing physician could not reasonably have discovered the claims made herein until at the earliest when the device was discovered to have failed and caused his death on September 28, 2012.

159. Defendants are and were under a continuing duty to disclose the true character, quality and nature of the device that was implanted in Mr. Rowden, 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 Mr. Rowden.

160. As a proximate result of Defendants fraudulent concealment, Mr. Rowden has suffered Mr. Rowden suffered serious physical injuries, including death, and economic damages in an amount to be determined at trial.

EIGHTH CAUSE OF ACTION
WRONGFUL DEATH
(Against all Defendants)

161. Plaintiff re-alleges and incorporates by reference each and every allegation contained in paragraphs 1-160 as though fully set forth herein.

162. Plaintiff, Catherine Rowden, bring this wrongful death action as the spouse of decedent.

163. As the direct and proximate result of the Defendants' wrongful conduct, Johnny Rowden died, and Catherine Rowden, as the spouse of Mr. Rowden, suffered grief, sorrow, loss of love, advice and guidance, society, comfort, and companionship in an amount to be determined at trial.

NINTH CAUSE OF ACTION
SURVIVAL ACTION
(Against all Defendants)

164. Plaintiff re-alleges and incorporates by reference each and every allegation contained in paragraphs 1-163 as though fully set forth herein.

165. Plaintiff brings this cause of action as the personal representative of the estate for Johnny Rowden.

166. As a direct and proximate results of Defendants' wrongful conduct, Johnny Rowden endured pain, suffering and emotional distress, as well as medical expenses up to the time of his untimely death.

PUNITIVE DAMAGES AS TO BARD DEFENDANTS

167. 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.

168. Plaintiff is entitled to an award of punitive and exemplary damages based upon Bard's intentional, willful, knowing, fraudulent, malicious acts, omissions, and conduct, and their complete and total reckless disregard for the public safety and welfare.

169. Bard 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, Bard 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

170. Bard 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.

171. As a direct, proximate, and legal result of Bard's acts and omissions a described herein, and Mr. Rowden suffered serious injury, and death.

JURY DEMAND

168. Plaintiffs demand that all issues of fact in this case be tried to a properly empaneled jury.

VI.

CONCLUSION AND PRAYER

169. WHEREFORE, Plaintiff request trial by jury and that the Court grant them the following relief against Defendants, jointly and severally, on all counts of this Complaint, including:

(A) Money Damages representing fair, just and reasonable compensation for his common law and statutory claims in excess of $75,000.00;

(B) Lost Wages;

(C) Punitive and/or Treble Damages pursuant to state law;

(D) Disgorgement of profits and restitution of all costs;

(E) Attorneys' fees pursuant to state law;

(F) Pre-judgment and post-judgment interests as authorized by law on the judgments which enter on Plaintiffs' behalf;

(G) Costs of suit;

(H) Delay Damages; and

(I) Such other relief as is deemed just and appropriate.

Respectfully Submitted,

THE DRISCOLL FIRM, P.C.

By: */s/ John J. Driscoll*

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JS 44 (Rev. 12/12)

CIVIL COVER SHEET

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
CATHERINE ROWDEN, individually and on behalf of the estate of Johnny Rowden

(b) County of Residence of First Listed Plaintiff St. Louis County, Missouri
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
John J. Driscoll, 211 N. Broadway, St. Louis, MO 63102
(314)932-3232

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

County of Residence of First Listed Defendant Union County, New Jersey
(IN U.S. PLAINTIFF CASES ONLY)
NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

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)

	PTF	DEF		PTF	DEF
Citizen of This State	☒ 1	☐ 1	Incorporated *or* Principal Place of Business In This State	☐ 4	☐ 4
Citizen of Another State	☐ 2	☒ 2	Incorporated *and* Principal Place of Business In Another State	☐ 5	☒ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

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

CONTRACT
- ☐ 110 Insurance
- ☐ 120 Marine
- ☐ 130 Miller Act
- ☐ 140 Negotiable Instrument
- ☐ 150 Recovery of Overpayment & Enforcement of Judgment
- ☐ 151 Medicare Act
- ☐ 152 Recovery of Defaulted Student Loans (Excludes Veterans)
- ☐ 153 Recovery of Overpayment of Veteran's Benefits
- ☐ 160 Stockholders' Suits
- ☐ 190 Other Contract
- ☐ 195 Contract Product Liability
- ☐ 196 Franchise

REAL PROPERTY
- ☐ 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
- ☐ 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

PERSONAL INJURY
- ☐ 365 Personal Injury - Product Liability
- ☒ 367 Health Care/ Pharmaceutical Personal Injury Product Liability
- ☐ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

CIVIL RIGHTS
- ☐ 440 Other Civil Rights
- ☐ 441 Voting
- ☐ 442 Employment
- ☐ 443 Housing/ Accommodations
- ☐ 445 Amer. w/Disabilities - Employment
- ☐ 446 Amer. w/Disabilities - Other
- ☐ 448 Education

PRISONER PETITIONS

Habeas Corpus:
- ☐ 463 Alien Detainee
- ☐ 510 Motions to Vacate Sentence
- ☐ 530 General
- ☐ 535 Death Penalty

Other:
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Condition
- ☐ 560 Civil Detainee - Conditions of Confinement

FORFEITURE/PENALTY
- ☐ 625 Drug Related Seizure of Property 21 USC 881
- ☐ 690 Other

LABOR
- ☐ 710 Fair Labor Standards Act
- ☐ 720 Labor/Management Relations
- ☐ 740 Railway Labor Act
- ☐ 751 Family and Medical Leave Act
- ☐ 790 Other Labor Litigation
- ☐ 791 Employee Retirement Income Security Act

IMMIGRATION
- ☐ 462 Naturalization Application
- ☐ 465 Other Immigration Actions

BANKRUPTCY
- ☐ 422 Appeal 28 USC 158
- ☐ 423 Withdrawal 28 USC 157

PROPERTY RIGHTS
- ☐ 820 Copyrights
- ☐ 830 Patent
- ☐ 840 Trademark

SOCIAL SECURITY
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

FEDERAL TAX SUITS
- ☐ 870 Taxes (U.S. Plaintiff or Defendant)
- ☐ 871 IRS—Third Party 26 USC 7609

OTHER STATUTES
- ☐ 375 False Claims Act
- ☐ 400 State Reapportionment
- ☐ 410 Antitrust
- ☐ 430 Banks and Banking
- ☐ 450 Commerce
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced and Corrupt Organizations
- ☐ 480 Consumer Credit
- ☐ 490 Cable/Sat TV
- ☐ 850 Securities/Commodities/ Exchange
- ☐ 890 Other Statutory Actions
- ☐ 891 Agricultural Acts
- ☐ 893 Environmental Matters
- ☐ 895 Freedom of Information Act
- ☐ 896 Arbitration
- ☐ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ☐ 950 Constitutionality of State 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 *(specify)* ☐ 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 USC 1332(a)(1)
Brief description of cause:
pharmaceutical personal injury / product liability action regarding inferior vena cava ("IVC") filter.

VII. REQUESTED IN COMPLAINT:
☐ CHECK IF THIS IS A CLASS ACTION UNDER RULE 23, F.R.Cv.P.
DEMAND $ 75,000.00
CHECK YES only if demanded in complaint:
JURY DEMAND: ☒ Yes ☐ No

VIII. RELATED CASE(S) IF ANY *(See instructions)*:
JUDGE _____ DOCKET NUMBER _____

DATE 09/28/2015
SIGNATURE OF ATTORNEY OF RECORD /s/John J. Driscoll

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____

AO 440 (Rev. 12/09) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

Eastern District of Missouri

CATHERINE ROWDEN, individually and on behalf of the estate of Johnny Rowden,

Plaintiff

v.

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

Defendant

Civil Action No.

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* C.R. BARD, INC.
730 Central Ave.
Murray Hill, NJ 07974

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are:

John J. Driscoll, #54729MO
The Driscoll Firm, P.C.
211 N. Broadway, 40th Floor
St. Louis, MO 63102

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

Civil Action No.

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

This summons for *(name of individual and title, if any)* _____

was received by me on *(date)* _____ .

☐ I personally served the summons on the individual at *(place)* _____

_____ on *(date)* _____ ; or

☐ I left the summons at the individual's residence or usual place of abode with *(name)* _____

_____ , a person of suitable age and discretion who resides there,

on *(date)* _____ , and mailed a copy to the individual's last known address; or

☐ I served the summons on *(name of individual)* _____ , who is

designated by law to accept service of process on behalf of *(name of organization)* _____

_____ on *(date)* _____ ; or

☐ I returned the summons unexecuted because _____ ; or

☐ Other *(specify):*

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____

Server's signature

_____

Printed name and title

_____

Server's address

Additional information regarding attempted service, etc:

AO 440 (Rev. 12/09) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

Eastern District of Missouri

CATHERINE ROWDEN, individually and on behalf of the estate of Johnny Rowden, *Plaintiff* v. C.R. BARD, INC., a foreign corporation, and BARD PERIPHERAL VASCULAR, INC. an AZ corporation, *Defendant*	)	Civil Action No.

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* BARD PERIPHERAL VASCULAR, INC.
Registered Agent: CT Corporation System
3800 N. Central Ave., Suite 460
Phoenix, AZ 85012

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are:

John J. Driscoll, #54729MO
The Driscoll Firm, P.C.
211 N. Broadway, 40th Floor
St. Louis, MO 63102

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

Civil Action No.

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

This summons for *(name of individual and title, if any)* _____

was received by me on *(date)* _____.

☐ I personally served the summons on the individual at *(place)* _____

_____ on *(date)* _____ ; or

☐ I left the summons at the individual's residence or usual place of abode with *(name)* _____

_____, a person of suitable age and discretion who resides there,

on *(date)* _____, and mailed a copy to the individual's last known address; or

☐ I served the summons on *(name of individual)* _____, who is

designated by law to accept service of process on behalf of *(name of organization)* _____

_____ on *(date)* _____ ; or

☐ I returned the summons unexecuted because _____ ; or

☐ Other *(specify)*:

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____

Server's signature

_____

Printed name and title

_____

Server's address

Additional information regarding attempted service, etc: