

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF MISSISSIPPI**

ALEC CALDWELL,)	
)	
PLAINTIFF,)	
)	CASE NO. <u>1:15cv208-SA-DAS</u>
V.)	
)	
C.R. BARD, INC., A FOREIGN CORPORATION,)	JURY TRIAL DEMANDED
AND BARD PERIPHERAL VASCULAR, INC.,)	
A FOREIGN CORPORATION,)	
)	
DEFENDANTS.)	

COMPLAINT

Plaintiff Alec Caldwell hereby states as follows for his complaint against defendants:

INTRODUCTORY ALLEGATIONS

1. Plaintiff brings this action for personal injuries he suffered as a direct and proximate result of being implanted with a defective and unreasonably dangerous Inferior Vena Cava (“IVC”) filter medical device manufactured by Bard.
2. The specific IVC filter implanted in plaintiff was the Bard Eclipse® Optional IVC filter (“Eclipse Filter”).
3. The Eclipse is part of Bard’s “retrievable” IVC filter product line that includes the following devices: Recovery®, G2®, G2®X (G2 Express®), Eclipse®, Meridian® and Denali® (for convenience, these devices will be referred to in this complaint under the generic term “Bard IVC Filters”). The term “Bard IVC Filters” also includes Bard’s Recovery® Cone Removal System®.
4. Plaintiff’s claims for damages all relate to Bard’s design, manufacture, sale, testing, marketing, labeling, advertising, promotion, and/or distribution of Bard IVC Filters, including without limitation the Eclipse.

5. The Bard Eclipse IVC Filter at issue reached Plaintiff and his physicians without substantial change in condition from the time it left Bard's possession.

6. Plaintiff and his physicians used the Bard Eclipse IVC Filter at issue in the manner in which it was intended.

7. Bard is solely responsible for any alleged design, manufacture or informational defect Bard IVC Filters, including the subject Eclipse, contain.

8. Bard does not allege that any other person or entity is comparatively at fault for any alleged design, manufacture, or informational defect Bard IVC Filters, including the Eclipse at issue, contain.

PARTIES

9. Plaintiff Alec Caldwell is and was at all times relevant to this complaint a citizen and resident of Tupelo, Lee County, Mississippi.

10. On or about September 29, 2010, plaintiff underwent placement of an Eclipse filter in Lee County, Mississippi.

11. The Eclipse Filter implanted in plaintiff subsequently "grossly tilted" to the point where it was "almost horizontal"; perforated the inferior vena cava to the extent that "at least 5 of the prominence of the filter [were] seen outside of the IVC with 2 of the legs abutting the anterior and posterior wall of the abdominal aorta"; migrating such that the legs of the Eclipse filter now overlap the central end of plaintiff's venous stent; and the filter, which was intended to be retrievable, can no longer be removed, which will ultimately result in the arms and/or legs of the Eclipse filter fracturing and embolizing (if this has not already occurred).

12. As a direct and proximate result of the failure of the Eclipse filter, plaintiff has suffered and will continue to suffer significant medical expenses, pain, suffering, emotional

distress, loss of enjoyment of life, psychological trauma, anxiety, hedonic damages, lost wages, loss of earning capacity, the need for medical monitoring of the Eclipse filter, and any other form of damages under the law of the subject forum.

13. Defendant C.R. Bard, Inc. (“CR Bard”) is a corporation duly organized and existing under the laws of the state of Delaware with its principal place of business in New Jersey.

14. At all times relevant herein, defendant CR Bard was doing business in Lee County, Mississippi.

15. CR Bard, at all times relevant to this action, designed, set specifications for, manufactured, prepared, compounded, assembled, processed, marketed, distributed, and sold the Eclipse Filter to be implanted in patients such as plaintiff throughout the United States, including Mississippi.

16. Defendant Bard Peripheral Vascular, Inc. (“BPV”) is a wholly-owned subsidiary corporation of Defendant C.R. Bard, with its principal place of business at 1625 West Third Street, Tempe, Arizona.

17. At all times relevant herein, defendant BPV was doing business in Lee County, Mississippi.

18. BPV, at all times relevant to this action, designed, set specifications for, manufactured, prepared, compounded, assembled, processed, marketed, distributed, and sold the Eclipse Filter to be implanted in patients such as plaintiff throughout the United States, including Mississippi.

19. There exists, and at all relevant times existed, a unity of interest in ownership between certain defendants and other defendants such that any individuality and separateness

between the certain defendants has ceased and those defendants are the alter ego of the other certain defendants, and exerted control over those defendants.

20. Adherence to the fiction of the separate existence of these certain defendants as any entity distinct from other certain defendants would permit an abuse of the corporate privilege, sanction fraud, and promote injustice.

21. Plaintiff is informed and believes, and thereon alleges, that at all times herein mentioned each of the Defendants were the agent, servant, employee, and/or joint venturer of the other co-defendant, and at all said times each Defendant was acting in the full course, scope, and authority of said agency, service, employment, and/or joint venture.

22. “Bard” or “Defendants” includes CR Bard, BPV, and any and all parent companies, subsidiaries, affiliates, divisions, franchises, partners, joint venturers, and organizational units of any kind; their predecessors, successors, and assigns; their officers, directors, employees, agents, representatives; and any and all other persons acting on their behalf.

23. At all times relevant, Bard was engaged in the business of researching, designing, testing, developing, manufacturing, packaging, labeling, marketing, advertising, distributing, promoting, warranting, and selling in interstate commerce Bard IVC Filters, including the Eclipse Filter, either directly or indirectly through third parties or related entities.

24. Bard develops, manufactures, sells, and distributes medical devices and surgical products throughout the United States, including Mississippi, and around the world, including Bard IVC Filters such as the Eclipse Filter, for use in various medical applications including endovascular cardiology.

25. Upon information and belief, at all relevant times, Defendants expected or should have expected that their acts would have consequences within the United States, including in the

State of Mississippi, and said Defendants derived and continue to derive substantial revenue therefrom.

JURISDICTION AND VENUE

26. This Court has jurisdiction under 28 U.S.C. § 1332 because Plaintiff and Defendants are citizens of different states, and the amount in controversy for each action exceeds seventy-five thousand dollars (\$75,000.00) excluding interest and costs.

27. Venue is proper in this Court, as the facts and circumstances leading to injuries occurred in Lee County, Mississippi; the Plaintiff currently resides in Lee County, Mississippi; the Eclipse filter that is the subject of this action was sold and purchased in Lee County, Mississippi; and, at all relevant times Defendants were conducting business in Lee County, Mississippi.

BACKGROUND

INFERIOR VENA CAVA FILTERS GENERALLY

28. IVC filters were first made commercially available to the medical community in the 1960s. Over the years, medical device manufacturers have introduced several different designs of IVC filters.

29. An IVC filter is a device that is designed to filter or “catch” blood clots that travel from the lower portions of the body to the heart and lungs. IVC filters were originally designed to be permanently implanted in the inferior vena cava (“IVC”).

30. The IVC is a vein that returns blood to the heart from the lower portions of the body. In certain people, for various reasons, blood clots travel from the vessels in the legs and pelvis, through the vena cava and into the lungs. Oftentimes, these blood clots develop in the deep leg veins, a condition called “deep vein thrombosis” or “DVT.” Once blood clots reach the

lungs, they are considered “pulmonary emboli” or “PE.” Pulmonary emboli present risks to human health.

31. People at risk for DVT/PE can undergo medical treatment to manage the risk. For example, a doctor may prescribe anticoagulant therapies such as 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 and who cannot manage their conditions with medications, physicians may recommend surgically implanting an IVC filter to prevent thromboembolic events.

32. As stated above, IVC filters have been on the market for decades and were permanent implants. However, use of these filters was limited primarily to patients who were contraindicated for anticoagulation therapy.

33. In order to increase sales of these devices, Bard sought to expand the market for prophylactic use among nontraditional patient populations that were temporarily at risk of developing blood clots.

34. Specifically, Bard targeted the bariatric, trauma, orthopedic and cancer patient population. Expansion to these new patient groups would triple sales and the first manufacturer to market would capture market share.

35. At the same time, Bard was aware that physicians developed interest in filter devices that could be easily removed after the risk of clotting in these new patient populations subsided. This too was an opportunity to gain market share in the lucrative IVC filter market.

36. Other manufacturers also saw this opportunity; triggering a race to market a device that provided physicians the option to retrieve the filter after the clot risk subsided.

37. Bard was the first medical device manufacturer to obtain FDA clearance for marketing a “retrievable” IVC filter (the Bard Recovery® filter) in July 2003.

38. This “clearance” was obtained despite lack of adequate testimony on the safety and efficacy of the new line of devices.

39. As shown below, Bard’s retrievable IVC filters have been plagued with problems – all created by Bard itself – most notably the absence of any evidence that the products were effective in preventing pulmonary embolism (the very condition the product was indicated to prevent).

40. Years after the implantation of retrievable filters into the bodies of patients, scientists began to study the effectiveness of the retrievable filters – studies that Bard itself had never done before placing the product on the market. As recently as October 2015, an expansive article published in the *Annals of Surgery* concerning trauma patients inserted with IVC filters concluded that IVC filters were not effective in preventing pulmonary emboli, and instead actually caused thrombi to occur.

41. Comparing the results of over 30,000 trauma patients who had not received IVC filters with those who had received them, the *Annals of Surgery* study published its alarming results:

- Almost twice the percentage of patients with IVC filters in the study died compared to those that had not received them.
- Over five times the relative number of patients with IVC filters developed DVTs.
- Over four times the relative percentage of patients with filters developed thromboemboli.
- Over twice the percentage of patients developed a pulmonary embolus – the very condition Bard told the FDA, physicians, and the public that its IVC Filters were designed to prevent.

42. This *Annals of Surgery* study – and many others referenced by it – shows without any question that IVC filters are not only utterly ineffective but that they are themselves a health hazard.

THE RECOVERY® FILTER

A. Development and Regulatory Clearance of the Recovery® Filter

43. Bard has distributed and marketed the Simon Nitinol Filter (“SNF”) device since 1992. The SNF is a permanent filter with no option to retrieve it after implantation.

44. The SNF was initially manufactured by a company known as Nitinol Medical Technologies. In late 1999, Bard worked with Nitinol on the redesign of the SNF in order to make it retrievable. On October 19, 2001, Bard purchased the rights to manufacture, market, and sell this new, redesigned product in development at the time. This product ultimately became the Recovery® filter.

45. Bard’s purpose for making a retrievable IVC filter was to increase profits by expanding the overall IVC filter market and, in turn, Bard’s percentage share of that market.

46. Bard engaged in an aggressive marketing campaign for the filter, despite negative clinical data.

47. On November 27, 2002, Bard bypassed the more onerous Food and Drug Administration’s (“FDA’s”) approval process for new devices and obtained “clearance” under Section 510(k) of the Medical Device Amendments to the Food, Drug, and Cosmetic Act to market the Recovery® filter as a *permanent* filter by claiming it was substantially similar in respect to safety, efficacy, design, and materials as the SNF.

48. Section 510(k) permits the marketing of medical devices if the device is substantially equivalent to other legally marketed predicate devices without formal review for the safety or efficacy of the said device. The FDA explained the difference between the 510(k)

process and the more rigorous “premarket approval” (PMA) process in its amicus brief filed with the Third Circuit in *Horn v. Thoratec Corp.*, which the court quoted from:

A manufacturer can obtain an FDA finding of ‘substantial equivalence’ by submitting a premarket notification to the agency in accordance with section 510(k) of the [Food Drug and Cosmetic Act]. 21 U.S.C. § 360(k). A device found to be ‘substantially equivalent’ to a predicate device is said to be ‘cleared’ by FDA (as opposed to ‘approved’ by the agency under a PMA. *A pre-market notification submitted under 510(k) is thus entirely different from a PMA which must include data sufficient to demonstrate that the IVC Filters is safe and effective.*

376 F.3d 163, 167 (3d Cir. 2004) (emphasis in original).

49. In *Medtronic, Inc. v. Lohr*, the U.S. Supreme Court similarly described the 510(k) process, observing:

If the FDA concludes on the basis of the [manufacturer’s] § 510(k) notification that the device is “substantially equivalent” to a pre-existing device, it can be marketed without further regulatory analysis. . . . The § 510(k) notification process is by no means comparable to the PMA process; in contrast to the 1,200 hours necessary to complete a PMA review, the § 510(k) review is completed in average of 20 hours. . . . As one commentator noted: “The attraction of substantial equivalence to manufacturers is clear. Section 510(k) notification requires little information, rarely elicits a negative response from the FDA, and gets processed quickly.”

518 U.S. 470, 478-79 (1996) (quoting Adler, *The 1976 Medical Device Amendments: A Step in the Right Direction Needs Another Step in the Right Direction*, 43 Food Drug Cosm. L.J. 511, 516 (1988)).

50. Pursuant to *Wyeth v. Levine*, 555 U.S. 555 (2009), once a product is cleared “the manufacturer remains under an obligation to investigate and report any adverse events associated with the drug . . . and must periodically submit any new information that may affect the FDA’s previous conclusions about the safety, effectiveness, or labeling” This obligation extends to post-market monitoring of adverse events/complaints.

51. In July 2003, through this 510(k) process, Bard obtained clearance from the FDA to market the Recovery[®] filter for optional retrieval.

52. Although Bard began aggressively marketing the Recovery[®] filter in 2003, full market release did not occur until January 2004.

53. Bard was 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 (weight loss) and orthopedic procedures.

54. The Recovery[®] filter consists of two (2) levels of six (6) radially distributed NITINOL (a nickel titanium alloy whose full name is Nickel Titanium Naval Ordinance Laboratory) struts that are designed to anchor the filter into the inferior vena cava and to catch any embolizing clots.

55. This filter has six short struts, which are commonly referred to as the “arms,” and six long struts, which are commonly referred to as the “legs.”

56. Each strut is held together by a single connection to a cap located at the top of the filter. According to the patent application 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 primarily to prevent the device from migrating in response to “normal respiratory movement” or “pulmonary embolism.”

57. The alloy NITINOL possesses “shape memory,” meaning NITINOL will change shape according to changes in temperature, then retake its prior shape after returning to its initial temperature.

58. When placed in saline, the Recovery[®] filter’s NITINOL struts become soft and can be straightened to allow delivery through a small-diameter catheter. The NITINOL struts then resume their original shape when warmed to body temperature in the vena cava.

59. The Recovery[®] filter is inserted via catheter guided by a physician (normally an interventional radiologist) through a blood vessel into the inferior vena cava. The Recovery[®] Filter is designed to be retrieved in a similar fashion.

60. According to the Instructions for Use of this medical device, only the Recovery[®] Cone System could be used to retrieve the Recovery[®] filter (as well as subsequent generations of Bard's IVC filters).

61. The Recovery[®] Cone System is an independent medical device requiring approval by the FDA under the pre-market approval process or, if a substantially equivalent medical device was already on the market, clearance by the FDA pursuant to the 510(k) application process.

62. Although Bard marketed and sold the Recovery[®] Cone System separately, it never sought or obtained approval or clearance from the FDA for this device.

63. Bard's sale of the Recovery[®] Cone System was, therefore, illegal.

64. Bard illegally sold the Recovery[®] Cone System in order to promote the Recovery[®] filter as having a retrieval option.

B. Post-Market Performance Revealed The IVC Filters Failed to Perform as Expected

65. Once placed on the market, Bard immediately became aware of numerous confirmed events where its Recovery[®] filter fractured, migrated, or perforated the vena cava, caused thrombus and clotting, and caused serious injury, including death.

66. Premarket and post-market clinical trials revealed that the Recovery[®] failed and caused serious risk of harm. In addition, peer-reviewed literature reflected that such filters actually increased the risk of patients developing thromboembolic events.

67. Approximately a month after the full-scale launch of the Recovery[®] filter, on February 9, 2004, Bard received notice of the first death associated with this filter. The next day,

a MAUDE analysis was performed which revealed that there had been at least two other migration-related adverse events reported to Bard in 2003.

68. MAUDE is a database maintained by the FDA to house medical device reports submitted by mandatory reporters (such as manufacturers and device user facilities) and voluntary reporters (such as health care providers and patients).

69. Instead of pulling the Recovery[®] filter off the market, Bard focused on public relations and protecting its brand and image. By February 12, 2004, Bard had formed a crisis communication team and drafted at least four communiques to pass onto its sales force containing false information designed to be relayed to concerned doctors.

70. By April of 2004, at least three deaths had been reported to Bard. Yet again, instead of recalling its deadly device, Bard concealed this information from doctors and patients and hired the public relations firm Hill & Knowlton to address anticipated publicity that could affect stock prices and sales.

71. Bard made the decision to continue to market and sell the Recovery[®] filter until its next generation product, the G2[®] IVC filter, was cleared by the FDA.

72. The G2[®] filter, however, was not cleared for market until August 29, 2005.

73. Meanwhile, the death count escalated.

74. On July 12, 2004, C.R. Bard CEO Timothy Ring received an executive summary reporting that there were at least 12 filter migrations resulting in four deaths and at least 17 reports of filter fracture, six cases of which involved strut embolization to the heart.

75. This same report advised that fracture rates for the Recovery[®] filter exceed reported rates of other filters.

76. These events revealed, or should have revealed, to Bard that the Recovery[®] filter is prone to an unreasonably high risk of failure and patient injury following placement in the human body.

77. Bard also learned that the Recovery[®] filter failed to meet migration resistance testing specifications.

78. In addition, multiple early studies reported that the Recovery[®] filter has a fracture and migration rate ranging from 21% to 31.7%, rates that are substantially higher compared to other IVC filters. More recently, fractures were reported to be as high as 40% after five and a half years from the date of implant.

79. Bard had clear evidence that the Recovery[®] filter was not substantially equivalent to the predecessor SNF, making the Recovery[®] filter adulterated and misbranded, requiring its immediate withdrawal from the market.

80. At least one Bard executive concluded the Recovery[®] filter posed an unreasonable risk of harm and required corrective action, including a recall.

81. Likewise, Bard's G2[®] filter was predicted to have fracture rates as high as 37.5% after five years from date of implant.

82. Subsequent Bard IVC Filter models, including the electropolished version of the G2[®] filter known as the Eclipse, only marginally increased fracture resistance.

83. When IVC filter fractures occur, shards of the filter or even the entire filter can travel to the heart, where they can cause cardiac tamponade, perforation of the atrial wall, myocardial infarction, and/or death.

84. Bard IVC Filters similarly pose a high risk of tilting and perforating the vena cava walls. When such tilting occurs, the filters can also perforate the adjacent aorta, duodenum, small

bowel, spine, or ureter, which may lead to and, upon information and belief, already have led to retroperitoneal hematomas, small-bowel obstructions, extended periods of severe pain, and/or death.

85. The Adverse Event Reports (“AERs”) associated with all IVC filters demonstrate that Bard IVC Filters are far more prone to failure than are other similar IVC filters. A review of the FDA MAUDE database from the years 2004 through 2008 shows that Bard IVC Filters are responsible for the following percentages of all IVC filter AERs:

- a. 50% of all adverse events;
- b. 64% of all occurrences of migration of the IVC Filters;
- c. 69% of all occurrences of vena cava wall perforation; and
- d. 70% of all occurrences of filter fracture.

86. These failures were often associated with 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; and
- f. Perforations of tissue, vessels and organs.

87. These failures and resulting injuries are attributable, in part, to the fact that the Bard IVC Filter design was unable to withstand the normal anatomical and physiological loading cycles exerted *in vivo*.

88. In addition to design defects, Bard IVC 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 filters.

89. The presence of these draw markings and/or circumferential grinding markings further compromises the structural integrity of the Bard IVC Filters while in the body. 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 filters. These exterior manufacturing defects render Bard IVC Filters too weak to withstand normal placement within the human body.

90. Bard was aware that Bard IVC Filters had substantially higher reported failure rates than all other IVC filters for fracture, perforation, migration, and death. For example:

- a. On April 23, 2004, Bard’s Corporate VP of Quality Assurance sent an email noting that the Recovery[®] filter’s reported failure rates “did not look good compared to permanent filters” and promised to remove the filter from the market if its reported death rate became “significantly greater than the rest of the pack.”
- b. On July 9, 2004, a BPV safety analysis of reported failure rates determined that the Recovery[®] filter had a reported failure rate that was 28 times higher than all other IVC filters.
- c. On December 17, 2004, analysis determined that the “[r]eports of death, filter migration (movement), IVC perforation, and filter fracture associated with the Recovery[®] filter were seen in the MAUDE database at reporting rates that were 4.6, 4.4, 4.1, and 5.3 times higher, respectively, than

reporting rates for all other filters. . . . These deficiencies were all statistically significant . . . [and were] significantly higher than those for other removable filters.”

- d. By December 2004, according to BPV’s own findings pursuant to its safety procedure, the Recovery[®] filter had so many reported failures that it was deemed not reasonably safe for human use and required “correction.”
- e. A BPV safety analysis from June 28, 2011, revealed that the Recovery[®] filter had a reported fracture rate 55 times higher than the SNF.
- f. Whereas the Recovery[®] filter was reported to have caused over a dozen deaths by early 2005, the SNF has never — to Plaintiffs’ knowledge — been reported as associated with a patient death.

C. Defendants Knew Why the Recovery[®] Filter Was Failing and Were Aware of Available Design Changes that Could Substantially Reduce Failures

91. Bard knew why the design changes made to the Recovery[®] filter were causing failures.

92. Bard was aware that the diameter of the leg hooks was a substantial factor in a filter’s ability to resist migration and fatigue.

93. By reducing the diameter of the hooks on the Recovery[®] filter, Bard had reduced the device’s ability to remain stable and not fracture.

94. Bard also reduced the leg span of the Recovery[®] filter from that of the SNF filter by 25%. As a result, Bard knew its retrievable IVC filters lacked a sufficient margin of safety to accommodate expansion of the vena cava (distension) after placement.

95. Bard was also aware that its failure to electropolish the wire material prior to distribution meant that Bard IVC Filters had surface damage that reduced their fatigue resistance.

96. Bard was also aware that the Recovery[®] filter had a high propensity to tilt and perforate the vena cava, which substantially increased the risk of fracture.

97. Bard was also aware that fatigue resistance could be increased by decreasing the sharpness of the angle of the wire struts where they exited the cap at the top of the IVC filters, and by chamfering (rounding or reducing the sharpness) of the cap edge against which the struts rubbed.

98. A few examples of Bard's awareness of the unreasonably dangerous problems with Bard IVC Filters include:

- a. On June 18, 2003, BPV engineer Robert Carr sent an email noting that chamfering the edge of the cap would reduce the likelihood of fracture.
- b. On March 16, 2004, a BPV engineer sent an email admitting that the surface damage seen on the Recovery[®] filter from the manufacturing process decreases fatigue resistance and that electropolishing increases fatigue resistance.
- c. In an April 2004 meeting, BPV was warned by its physician consultants, Drs. Venbrux and Kaufman, that the migration resistance of the Recovery[®] filter needed to be raised from 50 mmHg to 140 mmHg. They further warned BPV that Bard's Recovery[®] filter was a "wimpy" filter and its radial force was inadequate to assure stability.
- d. On May 5, 2004, a BPV engineer sent an email stating that adding a "chamfer" to the filter would "address the arm fracture issue."
- e. 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 ten bending cycles.

99. Prior to Plaintiff being implanted with a Bard IVC Filter, Bard was aware of other design changes that could make the Recovery® filter substantially safer. In a report dated February 16, 2005, BPV describes the design changes to the Recovery® filter, which became known as the G2® Filter. The report states that the Recovery® filter has been modified to “to increase migration and fracture resistance, and to minimize the likelihood of leg twisting, appendage snagging, filter tilting, and caval perforation.” The document goes on to describe the design modifications, which include:

- a. Increased ground wire diameter of the hook from .0085” to .0105” in order to improve the fracture resistance of the hook and to improve the migration resistance of the filter.
- b. The leg span has been increased from 32mm to 40mm in order to improve the ability of the filter to expand with a distending vena cava reducing risk of migration.
- c. The total filter arm length has increased from 20mm to 25mm, enlarging the arm span from 30mm to 33mm to aid in filter centering.
- d. An additional inward bend has been applied to the end of the filter arm in order to improve arm interaction with the vessel wall and to address caval perforations and appendage snagging.
- e. The arc of filter arm, as it attaches to the sleeve, has been modified to have a smooth radial transition instead of sharp angle. This change was made

in order to reduce the stress concentration generated by the sharp angle and thus improve fracture resistance in the area of the filter.

- f. The report concludes that the design modifications have substantially reduced the risk of fracture.

100. Subsequent design changes only marginally improved product safety, but did not fully or adequately address the Bard IVC Filters' deadly defects.

101. Electropolishing was added to the Bard IVC Filters in 2010 to reduce the risk of fracture. Electropolishing implanted Nitinol IVC filters was the industry standard, and increased fatigue resistance by at least 25%, according to Bard's internal testing.

102. Additional anchors were added to the anchoring system on the filter in 2011, in what became known as the Meridian filter. The purpose of this improvement was to decrease the risk of tilting, which increases the risk of fracture and perforation, and reduce caudal migration.

103. Bard added penetration limiters with the introduction of Denali Filter in May 2013.

104. Penetration limiters are designed to reduce perforation and penetration of the vena cava.

D. Bard Misrepresented and Concealed the IVC Filters' Risks and Benefits

105. Despite knowing that the Recovery® filter was substantially more likely to fracture, migrate, tilt, and cause death than any other filter, Bard marketed its IVC filters as being safer and more effective than all other filters throughout the lifecycle of the product.

106. Bard further provided mandatory scripts to its Bard IVC filter sales force, which required the sales force to falsely tell physicians that the Recovery® filter was safe because it had the same reported failure rates as all other filters.

107. Even Bard's updated labeling in December 2004 downplayed and concealed the Recovery[®] filter's dangerous effects because it suggested fractures almost always cause no harm and that all filters had the same risk of failure.

108. Bard's updated labeling also downplayed the risk of harm by stating that serious injuries had only been "reported" when Bard knew such injuries had in fact occurred.

E. Bard Chose to Keep Selling an Unsafe IVC Filter and Lied to Its Own Sales Force to Ensure Market Share and Stock Prices

109. Instead of warning the public or withdrawing the IVC Filters from the market to fix the problems with its IVC filters, Defendants retained a public relations firm, opened a task force to prevent information from getting out to the public, and devised a plan to address the public if it did.

110. In 2004, Bard created a Crisis Communication Team that included members of Bard's upper level management, Bard's legal department, and independent consultants.

111. The Crisis Communication Team created a Crisis Communication Plan, which summarized Bard's motivation for withholding risk information from the public as follows:

The proliferation of unfavorable press in top-tier media outlets can cause an onslaught of negative activity: a company's employee morale may suffer, stock prices may plummet, analysts may downgrade the affected company's rating, reputations may be ruined temporarily or even permanently. Extensive preparation is critical to help prevent the spread of damaging coverage.

112. In an April 2004 email, BPV consultant Dr. John Lehmann, a member of the Crisis Communication Team, advised Bard to conceal from the public Bard's information about the material risk of its IVC filters. Bard adopted his advice. His email states, among other things:

Comparison with other filters is problematic in many ways, and we should avoid/downplay this as much as possible. When pressed, we simply paraphrase what was said in the Health Hazard. That "Estimates based on available data suggest that there is no significant difference in the rates of these complications between any of the IVC Filters currently marketed in the U.S., including the Recovery IVC Filters.

I wouldn't raise this subject if at possible. It would be a most unusual reporter that will get this far. The testing data I saw in Arizona showed that although RF was certainly within the boundaries of IVC Filters tested, in larger veins it was near the bottom. I would avoid as much as possible getting into this subject, because I'm not sure others would agree with the conclusion that "Recovery Vena Cava Filter was just as or more resistant to migration than all retrievable and non-retrievable competitors.

113. Bard also made false representations and/omissions to the BPV sales force to keep them selling the IVC filters. Bard reassured the sales force that despite the failures with the Recovery[®] filter, the Bard IVC Filters were safe because they had the same failure rates as all other IVC filters.

114. By December 2004, BPV's own safety procedure deemed the Recovery[®] filter not reasonably safe for human use. Yet Bard continued to market and sell the Recovery[®] filter into September 2005 and continued to allow its defective product to sit on shelves available to be implanted for an unknown period of time after September 2005.

115. Even after the G2[®] filter was launched in September 2005, Bard still failed to warn consumers of the increased risk posed by the Recovery[®] filter. Instead, Bard again chose to conceal information about the serious risks of substantial harm from the use of its defective product.

THE G2[®], RECOVERY[®] G2 AND G2[®] EXPRESS FILTERS

116. On or about March 2, 2005, Bard submitted a Section 510(k) premarket notification of intent to market the G2[®] filter for the prevention of recurrent pulmonary embolism via placement in the inferior vena cava. In doing so, Bard cited the Recovery[®] filter as the substantially equivalent predicate IVC filter, which was an inappropriate and illegal predicate device since it was being marketed while adulterated and misbranded for failing, among other things, to be as safe and effective as its predicate device, SNF. Bard stated that the only

differences between the Recovery[®] filter and the G2[®] filter were primarily dimensional, and no material changes or additional components were added. It was considered by Bard the next generation of the Recovery[®] filter

117. On March 30, 2005, however, the FDA rejected this application unless Bard and BPV included “black box” warnings that read:

Warning: The safety and effectiveness of the Recovery[®] Filter System in morbidly obese patients has not been established. There have been fatal device-related adverse events reported in this population.

[and]

[C]entral venous lines may cause the filters to move or fracture.

118. On April 19, 2005, prior to formally responding to the FDA’s request to add a black box warning, BPV CEO Timothy Ring and C.R. Bard CEO John Weiland received an executive summary reporting that there were at least 34 migrations and 51 fractures associated with Bard IVC Filters.

119. This same report advised Bard executives that there were then nine deaths, six of which related to morbidly obese patients. Further, 18 of the 51 fractures resulted in fragments migrating to the heart.

120. On April 20, 2005, without alerting the FDA to the alarming information Bard executives had the day before, Bard submitted a letter in response to the FDA’s request to add this black box warning stating that, “There is currently a statement in the IFU linking all of our complications to death.”

121. On August 29, 2005, the FDA cleared the G2[®] filter for the same intended uses as the Recovery[®] filter, except that it was not cleared for retrievable use.¹ Contrary to the FDA’s

¹ The FDA did not clear the G2[®] filter to be used as a retrievable filter until January 15, 2008.

suggestion, no black box warning was added to warn the bariatric patient population of fatalities associated with the use of the filter.²

122. In September of 2005, Bard quietly and belatedly replaced the Recovery[®] filter on hospital shelves with the G2[®] filter. Bard either told doctors or led them to believe that the G2[®] was a new and improved version of the Recovery[®] filter with the same option to retrieve the filter after implant.

123. At the same time Bard was selling the G2[®] (then a permanent use filter without any retrievability option), Bard was also selling the SNF, which had the same indication for use with nearly zero adverse events.

124. Bard marketed the G2[®] filter as having “enhanced fracture resistance,” “improved centering,” and “increased migration resistance” without any data to back up these representations. Even if such data existed, Bard witnesses have testified that Bard would not share any such information with doctors if requested.

125. Moreover, as with its predecessor Recovery[®] filter, Bard failed to conduct adequate clinical and bench testing to ensure that the G2[®] filter would perform safely and effectively once implanted in the human body.

126. The G2[®] filter’s design causes it to be of insufficient integrity and strength to withstand normal stresses within the human body so as to resist fracturing, migrating, and/or tilting, and/or perforating the inferior vena cava.

127. In addition to the same design defects as its predecessor device, the G2[®] filter suffers from the same manufacturing defects. These manufacturing defects include, but are not limited to, the existence of “draw markings” and circumferential grinding markings on the

² A warning was eventually added to the IFU in October of 2009.

exterior of the surface of Bard IVC Filters. The presence of these draw markings and/or circumferential grinding markings further compromises the structural integrity of the G2[®] filter while *in vivo*.

128. 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 IVC Filters.

129. 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 Bard IVC Filters more susceptible to fatigue, failure, and migration.

130. Similarly, although Bard rounded the chamfer at the edge of the cap of the G2[®] filter, it continued to fracture at that same location.

131. Thus, the G2[®] filter shares similar defects and health risks as the Recovery[®] filter.

132. Almost immediately upon the release of the G2[®] filter, Bard received notice of the same series of adverse events of migration, fracture, tilt, and perforation causing the same type of harm as the Recovery[®] filter. This time, however, a new and different adverse event emerged: the G2[®] filter would caudally (moving against blood flow) migrate in the direction toward the groin.

133. The G2[®] filter failures were again 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; and

f. Perforations of tissue, vessels and organs.

134. Bard represents the fracture rate of the G2[®] filter 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 frequency of fractures for the G2[®] filter.

135. As with the Recovery[®] filter, Bard was aware of clinical data showing that the G2[®] filter was not the substantial equivalent of its predecessor SNF device, requiring immediate recall of the adulterated and misbranded product.

136. A review of the MAUDE database from the years 2004 through 2008 demonstrates that the Bard IVC Filters (including the G2[®] Filter) are responsible for the majority of all reported adverse events related to IVC filters.

137. On December 27, 2005, Bard's Medical Affairs Director sent an email questioning why Bard was even selling the modified version of the Recovery[®] filter, when Bard's SNF had virtually no complaints associated with it.

138. This further confirms the misbranded and adulterated nature of the device, requiring corrective action, including recall.

139. On January 15, 2008, the FDA allowed a retrievable option for the G2[®] filter, the G2 Express[®] filter. The G2 Express[®] filter (also known as the "G2[®]X") is identical in design to the G2[®] filter except that it has a hook at the top of the filters that allows it to be retrieved by snares, as well as Bard's Recovery Cone.

140. The G2[®]X filter contained no design modifications or improvements to alleviate the instability, structural integrity, and perforation problems that Bard knew to exist with the G2[®]X Filter via the 510(k) process.

THE ECLIPSE® FILTER

141. In a failed effort to resolve the complications associated with its previous filters, Bard designed the Eclipse® Vena Cava Filter as the next generation in its retrievable IVC filter family.

142. The Eclipse® filter was cleared by the FDA on January 14, 2010. The only design changes from the G2® family of filters to the Eclipse® filter was that the Eclipse® filter was electropolished.

143. According to Bard's internal testing, electropolishing supposedly increased fracture resistance by 25%. However, longitudinal studies published in peer-reviewed medical literature found that among 363 patients implanted with the Recovery® filter and 658 patients implanted with the G2® filter, the devices experienced fracture rates of 40% and 37.5%, respectively, after five and a half years. Thus, approximately 28.125% to 30% of Eclipse® filters would still be projected to fracture within five and a half years.

144. Without meaningful design changes, the Eclipse® filter continued to share the majority of the same design defects and complications associated with the Recovery® filter and G2® family of filters.

145. Soon after Bard launched the Eclipse® filter, it began receiving complaints and reports of injuries associated with the Eclipse® filter similar to those received with its predecessor filters.

146. Bard knew and/or soon learned that the Eclipse® filter was not the substantial equivalent of the SNF, making this device also misbranded and adulterated, and subject to recall.

THE MERIDIAN® FILTER

147. The Meridian® filter was cleared by the FDA in August of 2011.

148. Bard represented to the FDA that the Meridian was substantially similar to the Eclipse[®] filter and could therefore be cleared via the less onerous 510(k) process.

149. Bard, however, knew and/or soon learned that the Meridian[®] filter was not the substantial equivalent of the SNF, making this device also misbranded and adulterated, and subject to recall.

150. The Meridian[®] filter system was the next-generation of Bard's retrievable or optional filters. The Meridian[®] filter is made of the same nickel-titanium alloy, NITINOL, as the Bard Recovery[®], G2[®], and Eclipse[®] filters.

151. The design of the Meridian is based on the Eclipse[®] filter, which, in turn, is based entirely on the G2[®] filter, which, in turn is based on the Recovery[®] Filter. Like the Eclipse[®], the wires used in the Meridian[®] filter are electropolished prior to the forming of the filter. The only added feature to the Meridian[®] filter was a caudal anchoring system added in an attempt to reduce the prevalence of the filter caudal migrating toward the groin.

152. However, as seen with the Recovery[®], G2[®], and Eclipse[®] filters, soon after its introduction to the market reports surfaced that the Meridian[®] filters were fracturing, perforating, migrating, and/or tilting in the patients in which they were implanted.

153. The Meridian[®] filter was also plagued with the same manufacturing and design defects that were causing damage to the general public as Bard's predecessor retrievable filters.

THE DENALI[®] FILTER

154. The Denali[®] filter was cleared by the FDA on May 15, 2013. It is Bard's latest generation device in the IVC filter product line.

155. Bard represented to the FDA that the Denali[®] was substantially similar to the Eclipse[®] filter, again bypassing formal pre-market FDA approval and instead utilizing the 510(k) process.

156. The Denali[®] Filter is also made of NITINOL. Its design is based on the Eclipse[®] filter, which in turn, was based on Bard's predecessor filter line. Like the Eclipse[®], the NITINOL wires used in the Denali[®] filter are electropolished prior to the forming of the filter. The added features to the Denali[®] Filter were cranial and caudal anchoring systems (to reduce the prevalence of the filter migration) and penetration limiters.

157. However, as seen with the Recovery[®], G2[®], G2X[®] (G2 Express[®]), and Eclipse[®] Filters, soon after its introduction to the market, reports were made that the Denali[®] filters were fracturing, perforating, migrating, and/or tilting in the patients in which they were implanted.

158. The Denali[®] filter was likewise plagued with the same manufacturing and design defects that were causing damage to the general public in Bard's predecessor retrievable filter family.

159. At all times material hereto from the design phase, testing, and manufacture of the Recovery[®] filter through the Denali[®] filter (which includes the Eclipse filter at issue in this case), Bard lacked a thorough understanding dynamics of caval anatomy that impacted testing methods.

160. At this time, all Bard IVC Filters, including the Eclipse filter at issue in this case, contain the same or substantially similar defects resulting in the same or substantially similar mechanism of injury to Plaintiff's.

161. At this time, all Bard IVC Filters, including the Eclipse filter at issue in this case, are misbranded and adulterated by virtue of them failing to be the substantial equivalent of their predecessor devices, all of which were required to be as safe and effective as the original

predicate device, the Simon Nitinol Filter, and none were/are, making them subject to corrective action, including recall, in the interest of patient safety. The use of each of these subject devices was inappropriate and illegal since each was being marketed while adulterated and misbranded for failing, among other things, to be as safe and effective as the originating predicate device, SNF.

162. At all relevant times, safer and more efficacious designs existed for this product, as well as reasonable treatment alternatives.

SPECIFIC FACTUAL ALLEGATIONS CONCERNING PLAINTIFF

163. Plaintiff incorporates by reference all prior allegations.

164. On or about September 29, 2010, plaintiff underwent placement of an Eclipse filter in Lee County, Mississippi.

165. The Eclipse Filter implanted in plaintiff subsequently “grossly tilted” to the point where it was “almost horizontal”; perforated the inferior vena cava to the extent that “at least 5 of the prominence of the filter [were] seen outside of the IVC with 2 of the legs abutting the anterior and posterior wall of the abdominal aorta”; migrated such that the legs of the Eclipse filter now overlap the central end of plaintiff’s venous stent; and the filter, which was intended to be retrievable, can no longer be removed, which will ultimately result in the arms and/or legs of the Eclipse filter fracturing and embolizing (if this has not already occurred).

166. At the time Plaintiff was implanted with the Eclipse Filter on September 29, 2010, Bard knew the Eclipse Filter had serious design and manufacturing flaws causing it to have inadequate stability and structural integrity, as well as a high propensity to perforate the vena cava.

167. At all relevant times, the Eclipse filter at issue was misbranded and adulterated by virtue of failing to be the substantial equivalent of its predecessor devices, as it was required to be as safe and effective as the original predicate device, the Simon Nitinol Filter, and it was not, making it subject to corrective action, including recall, in the interest of patient safety. The use of the Eclipse filter was inappropriate and illegal since it was being marketed while adulterated and misbranded for failing, among other things, to be as safe and effective as the originating predicate device, SNF.

168. At the time Plaintiff was implanted with the Eclipse filter, Bard knew that it marketed a safer alternative design that could have been used to treat Plaintiff - the SNF filter.

169. At that time, Bard was also aware of other available, safer, non-Bard manufactured filters and non-IVC Filter treatment options.

170. As a direct and proximate result of the failure of the Eclipse filter, plaintiff has suffered and will continue to suffer significant past and future medical expenses, pain, suffering, emotional distress, loss of enjoyment of life, psychological trauma, anxiety, hedonic damages, lost wages, loss of earning capacity, the need for medical monitoring of the Eclipse filter, and any other form of damages available and applicable under the law of the subject forum.

ESTOPPEL FROM PLEADING STATUTES OF LIMITATIONS OR REPOSE

171. Plaintiff incorporates by reference all prior allegations.

172. Plaintiff is within the applicable statute of limitations for his claims because Plaintiff (and his healthcare professionals) did not discover, and could not reasonably discover, the defects and unreasonably dangerous condition of the subject Eclipse filter.

173. Plaintiff's ignorance of the defective and unreasonably dangerous nature of the Eclipse filter, and the causal connection between these defects and Plaintiff's injuries and

damages, is due in large part to Bard's acts and omissions in fraudulently concealing information from the public and misrepresenting and/or downplaying the serious threat to public safety its products present.

174. In addition, Bard is estopped from relying on any statutes of limitation or repose by virtue of its unclean hands, acts of fraudulent concealment, affirmative misrepresentations and omissions.

175. Such conduct includes intentional concealment from Plaintiff, Plaintiff's prescribing health care professionals, and the general consuming public of material information that Bard IVC Filters, including the subject Eclipse filter, had not been demonstrated to be safe or effective, and carried with them the risks and dangerous defects described above.

176. Bard had a duty to disclose the fact that Bard IVC Filters, including the subject Eclipse filter, are not safe or effective, not as safe as other filters on the market, defective, and unreasonably dangerous, and that their implantation and use carried with it the serious risk of developing perforation, migration, tilting, and/or fracture.

COUNT I: STRICT PRODUCTS LIABILITY – MANUFACTURING DEFECT

177. Plaintiff incorporates by reference all prior allegations.

178. Prior to, on, and after the date the Eclipse filter was implanted in Plaintiff, Bard designed, distributed, manufactured, sold, and marketed the Eclipse filter for use in the United States.

179. Bard designed, manufactured, marketed, inspected, labeled, promoted, distributed and sold the Eclipse Filter that was implanted in Plaintiff on September 29, 2010.

180. At all relevant times, Bard designed, distributed, manufactured, marketed, and sold Bard IVC Filters (including the Eclipse) that were unreasonably dangerous, unsafe, and defective in manufacture when they left Bard's possession.

181. Upon information and belief, Bard IVC Filters (including the Eclipse) contain a manufacturing defect, in that they differed from the manufacturer's design or specifications, or from other typical units of the same product line.

182. As a direct and proximate cause of Bard's design, manufacture, marketing, and sale of Bard IVC Filters prior to, on, and after the date Plaintiff used the Eclipse filter, Plaintiff suffered injuries and damages as detailed in this Complaint.

COUNT II: STRICT PRODUCTS LIABILITY – INFORMATION DEFECT

183. Plaintiff incorporates by reference all prior allegations.

184. At all relevant times, Bard engaged in the business of testing, developing, designing, manufacturing, packaging, labeling, marketing and/or promoting, selling and/or distributing the Eclipse filter and through that conduct has knowingly and intentionally placed Eclipse filters into the stream of commerce with full knowledge that they reach consumers such as Plaintiff who become implanted with them.

185. Bard did in fact test, develop, design, manufacture, package, label, market and/or promote, sell and/or distribute the Eclipse filter to Plaintiff, Plaintiff's prescribing health care professionals, and the consuming public. Additionally, Bard expected that the Eclipse filters they were selling, distributing, supplying, manufacturing, and/or promoting to reach, and did in fact reach, prescribing health care professionals and consumers, including Plaintiff and Plaintiff's prescribing health care professionals, without any substantial change in the condition of the product from when it was initially distributed by Bard.

186. Bard designed, manufactured, marketed, inspected, labeled, promoted, distributed and sold the Eclipse Filter that was implanted in Plaintiff on September 29, 2010.

187. The Eclipse filter had potential risks and side effects that were known or knowable to Bard by the use of scientific inquiry and information available before, at, and after the manufacture, distribution, and sale of that filter.

188. Bard knew or should have known of the defective condition, characteristics, and risks associated with the Eclipse filter. These defective conditions included, but were not limited to: (1) posing a significant and higher risk of failure than other similar IVC filters (fracture, migration, tilting, and perforation of the vena cava wall); (2) failures that result in serious injuries and death; and (3) certain conditions or post-implant procedures, such as morbid obesity or open abdominal procedures, could affect the safety and integrity of all Bard IVC Filters.

189. Eclipse Filters were in a defective and unsafe condition that was unreasonably and substantially dangerous to any user or consumer implanted with Eclipse Filters, such as Plaintiff, when used in an intended or reasonably foreseeable way.

190. The warnings and directions Bard provided with the Eclipse Filter failed to adequately warn of the potential risks and side effects of that filter.

191. These risks were known or were reasonably scientifically knowable to Bard, but not known or recognizable to ordinary consumers, such as Plaintiff, or to Plaintiff's treating doctors.

192. The Eclipse filter was expected to and did reach Plaintiff without substantial change in its condition, labeling, or warnings as manufactured, distributed, and sold by Bard.

193. Additionally, Plaintiff and Plaintiff's physicians used the Eclipse filter in the manner in which it was intended to be used, making such use reasonably foreseeable to Bard.

194. As a direct and proximate result of Bard's information defects, lack of sufficient instructions or warnings prior to, on, and after the date Plaintiff was implanted with the Eclipse filter, Plaintiff suffered injuries and damages as detailed in this Complaint.

COUNT III: STRICT PRODUCTS LIABILITY – DESIGN DEFECT

195. Plaintiff incorporates by reference all prior allegations.

196. At all relevant times, Bard designed, tested, distributed, manufactured, advertised, sold, marketed and otherwise placed into the stream of commerce Eclipse filters for use by consumers, such as Plaintiff, in the United States.

197. Bard designed, manufactured, marketed, inspected, labeled, promoted, distributed and sold the Eclipse Filter that was implanted in Plaintiff on September 29, 2010.

198. The Eclipse filter was expected to, and did, reach Bard's intended consumers, handlers, and persons coming into contact with the product without substantial change in the condition in which it was researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Bard.

199. At all times relevant, the Eclipse filter was manufactured, designed and labeled in an unsafe, defective, and inherently dangerous condition which was dangerous for use by the public in general and Plaintiff in particular.

200. The Eclipse filter, as researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Bard was defective in design and formulation and unreasonably dangerous in that when they left the hands of Bard's manufacturers and/or suppliers, the foreseeable risks exceeded the alleged benefits associated with the use of that filter, and the device was more dangerous than the ordinary customer would expect.

201. Plaintiff's physicians implanted the Eclipse filter as instructed via the Instructions for Use and in a foreseeable manner as normally intended, recommend, promoted, and marketed by Bard.

202. Plaintiff received and utilized the Eclipse filter in a foreseeable manner as normally intended, recommended, promoted, and marketed by Bard.

203. At the time Bard placed its defective and unreasonably dangerous Eclipse filter into the stream of commerce commercially, technologically, and scientifically feasible alternative designs were attainable and available.

204. These alternative designs would have prevented the harm resulting in Plaintiff's injuries and damages, as detailed in this Complaint, without substantially impairing the reasonably anticipated or intended function of the Eclipse filter.

205. As a direct and proximate result of the defective and unreasonably dangerous condition of the Eclipse filter, Plaintiff suffered injuries and damages as detailed in this Complaint.

COUNT IV: NEGLIGENCE – DESIGN

206. Plaintiff incorporates by reference all prior allegations.

207. Bard designed, manufactured, marketed, inspected, labeled, promoted, distributed and sold the Eclipse Filter that was implanted in Plaintiff on September 29, 2010.

208. At the time of the design, distribution, manufacture, advertising, sale, and marketing of the Eclipse filter, and its implantation in Plaintiff, Bard was aware that filter was designed and manufactured in a manner presenting:

- a. An unreasonable risk of fracture of portions of the filters;

- b. An unreasonable risk of migration of the filters and/or portions of the filters;
- c. An unreasonable risk of filters tilting and/or perforating the vena cava wall and other surrounding organs and blood vessels; and
- d. Insufficient strength or structural integrity to withstand normal placement within the human body.

209. At the time of the design, distribution, manufacture, advertising, sale, and marketing of the Eclipse filter, and its implantation in Plaintiff, Bard also was aware that filter:

- a. Would be used without inspection for defects;
- b. Would be used by patients with special medical conditions such as those of the Plaintiff;
- c. Had previously caused serious bodily injury to its users with special medical conditions such as those of the Plaintiff;
- d. Had no established efficacy;
- e. Were less effective, efficient and safe than the predicate SNF;
- f. Would be implanted in patients where the risk outweighed any benefit or utility of the filters;
- g. Contained instructions for use and warnings that were inadequate; and
- h. Required retrieval by a device that was not approved or cleared by the FDA.

210. Bard had a duty to exercise due care and avoid unreasonable risk of harm to others in the design of all Bard IVC Filters, including the Eclipse filter.

211. Bard breached these duties by, among other things:

- 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;
- b. Designing and distributing a product 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 IVC filters available for the same purpose;
- c. Failing to perform reasonable pre- and post-market testing of its IVC Filters, including the Eclipse filter, to determine whether or not the products were safe for their intended use;
- d. Failing to use reasonable and prudent care in the design, research, manufacture, and development of its Filters, including the Eclipse filter, so as to avoid the risk of serious harm associated with the use of Bard IVC Filters;
- e. Advertising, marketing, promoting, and selling its IVC Filters, including the Eclipse filter, for uses other than as approved and indicated in the products' labels;
- f. Failing to establish an adequate quality assurance program used in the manufacturing of Bard IVC Filters, including the Eclipse filter; and
- g. Failing to perform adequate evaluation and testing of its IVC Filters, including the Eclipse filter, when such evaluation and testing would have revealed the propensity of those filters to cause injuries similar to those that Plaintiff suffered.

212. As a direct and proximate result of the above-described negligence in design of the Eclipse filter, Plaintiff suffered injuries and damages as detailed in this Complaint.

COUNT V: NEGLIGENCE – MANUFACTURE

213. Plaintiff incorporates by reference all prior allegations.

214. Bard designed, manufactured, marketed, inspected, labeled, promoted, distributed and sold the Eclipse Filter that was implanted in Plaintiff on September 29, 2010.

215. At all relevant times, Bard had a duty to exercise due care in the manufacturing of Bard IVC Filters, including the Eclipse filter.

216. Bard breached this duty by, among other things:

- a. Failing to adopt manufacturing processes that would reduce the foreseeable risk of product failure;
- b. Failing to use reasonable care in manufacturing the product and by producing a product that differed from their design or specifications or from other typical units from the same production line;
- c. Failing to use reasonable and prudent care in the design, research, manufacture, and development of the Eclipse filter and its manufacturing process so as to avoid the risk of serious harm associated with the use of that filter; and
- d. Failing to establish an adequate quality assurance program used in the manufacturing of the Eclipse filter.

217. As a direct and proximate result of the above-described negligence in manufacture of the Eclipse filter, Plaintiff suffered injuries and damages as detailed in this Complaint.

COUNT VI: NEGLIGENCE – FAILURE TO RECALL/RETROFIT

218. Plaintiff incorporates by reference all prior allegations.

219. At this time, all Bard IVC Filters, including the Eclipse filter, are misbranded and adulterated by virtue of failing to be the substantial equivalent of their predecessor device, making them subject to corrective action, including recall, in the interest of patient safety.

220. Prior to, on, and after the date of Plaintiff's implantation with the Eclipse filter on September 29, 2010, and at all relevant times, Bard knew or reasonably should have known that filter and its warnings were defective and dangerous or were likely to be dangerous when used in a reasonably foreseeable manner.

221. Prior to, on, and after the date of Plaintiff's implantation with the Eclipse filter and at all relevant times thereafter, Bard became aware that the defects of Bard IVC Filters, including the Eclipse filter, resulted in those filters causing injuries similar to those Plaintiff suffered.

222. Reasonable manufacturers and distributors under the same or similar circumstances would have recalled or retrofitted the Eclipse filter, and would thereby have avoided and prevented harm to many patients, including Plaintiff.

223. In light of this information and Bard's knowledge described above, Bard had a duty to recall and/or retrofit the Eclipse filter.

224. Bard breached its duty to recall and/or retrofit the Eclipse filter.

225. As a direct and proximate result of Bard's negligent failure to recall or retrofit, Plaintiff suffered injuries and damages as detailed in this Complaint.

COUNT VII: NEGLIGENCE – FAILURE TO WARN

226. Plaintiff incorporates by reference all prior allegations.

227. At all relevant times, Bard knew or should have known that Bard IVC Filters, including the Eclipse filter, were defective and dangerous or were likely to be dangerous when used in a reasonably foreseeable manner.

228. Such danger included the propensity of the Eclipse filter to cause injuries and death similar to those suffered by Plaintiff.

229. At all relevant times, Bard also knew or reasonably should have known that the users of Eclipse filters, including Plaintiff, would not realize or discover on their own the dangers presented by those filters.

230. Reasonable manufacturers and reasonable distributors, under the same or similar circumstances as those of Bard prior to, on, and after the date of Plaintiff's use of the Eclipse filter, would have warned of the dangers presented by that filter, or instructed on the safe use of that filter.

231. Prior to, on, and after the date of Plaintiff's use of the Eclipse filter, Bard had a duty to adequately warn of the dangers presented by that filter and/or instruct on the safe use of that filter.

232. Bard breached these duties by failing to provide adequate warnings to Plaintiff communicating the information and dangers described above and/or providing instruction for safe use of the Eclipse filter.

233. As a direct and proximate result of Bard's negligent failure to warn, Plaintiff suffered injuries and damages as detailed in this Complaint.

COUNT VIII: NEGLIGENT MISREPRESENTATION

234. Plaintiff incorporates by reference all prior allegations.

235. Bard designed, manufactured, marketed, inspected, labeled, promoted, distributed and sold the Eclipse Filter that was implanted in Plaintiff on September 29, 2010.

236. Prior to, on, and after the dates during which Plaintiff was implanted with the Eclipse filter, Bard negligently and carelessly represented to Plaintiff, Plaintiff's treating physicians, and the general public that Eclipse filters were safe, fit, and effective for use.

237. These representations were untrue.

238. Bard owed a duty in all of its undertakings, including the dissemination of information concerning its IVC filters, such as the Eclipse filter, to exercise reasonable care to ensure that it did not in those undertakings create unreasonable risks of personal injury to others, such as Plaintiff.

239. Bard disseminated to health care professionals and consumers through published labels, labeling, marketing materials, and otherwise information concerning the properties and effects of Bard IVC filters, including the Eclipse filter, with the intention that health care professionals and consumers would rely upon that information in their decisions concerning whether to prescribe and use those filters.

240. Bard, as medical device designers, manufacturers, sellers, promoters and/or distributors, knew or should reasonably have known that health care professionals and consumers, in weighing the potential benefits and potential risks of prescribing or using the Eclipse filter, would rely upon information disseminated and marketed by Bard to them regarding those filters.

241. Bard failed to exercise reasonable care to ensure that the information they disseminated to health care professionals and consumers concerning the properties and effects of Bard IVC Filters, including the Eclipse filter, was accurate, complete, and not misleading and, as a result, disseminated information to health care professionals and consumers that was negligently

and materially inaccurate, misleading, false, and unreasonably dangerous to consumers such as Plaintiff and Plaintiff's physicians.

242. Bard, as designers, manufacturers, sellers, promoters, and/or distributors, also knew or reasonably should have known that patients, such as Plaintiff, receiving Bard IVC Filters, such as the Eclipse filter, as recommended by health care professionals in reliance upon information disseminated by Bard as the manufacturer/distributor of those Filters would be placed in peril of developing the serious, life-threatening, and life-long injuries including, but not limited to, tilting, migration, perforation, fracture, lack of efficacy, and increased risk of the development of blood clots, if the information disseminated and relied upon was materially inaccurate, misleading, or otherwise false.

243. Bard had a duty to promptly correct material misstatements it knew others were relying upon in making healthcare decisions.

244. Bard failed in each of these duties by misrepresenting to Plaintiff, Plaintiff's physicians, and the entire medical community the safety and efficacy of Bard IVC Filters, including the Eclipse filter, and failing to correct known misstatements and misrepresentations.

245. As a direct and proximate result of Bard's negligent misrepresentations, Plaintiff suffered injuries and damages as detailed in this Complaint.

COUNT IX: NEGLIGENCE *PER SE*

(Violations of 21 U.S.C. §§321, 331, 352 and 21 C.F.R. §§1.21, 801, 803, 807, 820)

246. Plaintiff incorporates by reference all prior allegations.

247. At all times herein mentioned, Bard was subject to a variety of federal, state, and local laws, rules, regulations and ordinances, including the Federal Food, Drug and Cosmetic Act ("FFDCA") and its applicable regulations, concerning the manufacture, design, testing,

production, processing, assembling, inspection, research, promotion, advertising, distribution, marketing, promotion, labeling, packaging, preparation for use, consulting, sale, warning, and post-sale warning and other communications of the risks and dangers of Bard IVC Filters, including the subject Eclipse filter.

248. By reason of its conduct as alleged herein, Bard violated provisions of statutes and regulations, including but not limited to:

- a. FFDCA, 21 U.S.C. §§331 and 352, by misbranding the Eclipse filter;
- b. FFDCA, 21 U.S.C. § 321, by making statements and/or representations via word, design, device, or any combination thereof failing to reveal material facts with respect to the consequences that may result from the use of Bard IVC Filters, such as the Eclipse filter, to which the labeling and advertising relates;
- c. 21 C.F.R. § 1.21, by misleading its consumers and patients by concealing material facts in light of representations made regarding safety and efficacy of its Bard IVC Filters, such as the Eclipse filter;
- d. 21 C.F.R. § 801, by mislabeling Bard IVC Filters, such as the Eclipse filter, as to safety and effectiveness of its products and by failing to update its label to reflect post-marketing evidence that those filters were associated with an increased risk of injuries due to tilting, fracture, migration and perforation;
- e. 21 C.F.R. §§801.109 and 801.4 by learning that Bard IVC Filters, such as the Eclipse filter, were adulterated and misbranded and failing to correct and recall the devices;

- f. 21 C.F.R. § 803, by not maintaining accurate medical device reports regarding adverse events of tilting, fracture, migration and perforation and/or misreporting these adverse events maintained via the medical device reporting system;
- g. 21 C.F.R. § 807, by failing to notify the FDA and/or the consuming public when its Bard IVC Filters, such as the Eclipse filter, were no longer substantially equivalent with regard to safety and efficacy with regard to post-marketing adverse events and safety signals;
- h. 21 C.F.R. § 820, by failing to maintain adequate quality systems regulation including, but not limited to, instituting effective corrective and preventative actions;
- i. 21 CFR 201.128, by promoting each of their subject devices, including the Eclipse filter, off-label and for conditions, purposes and uses beyond their labeled and intended uses; and
- j. 210 CFR 801.4, by their knowledge of off-label uses of their devices, including the Eclipse filter, for unintended and unlabeled conditions, purposes and uses, and failing as required to provide adequate labeling which accords with such unlabeled and unintended uses.

249. These statutes, rules and regulations, along with those listed in Count XIV, are designed to protect the health, safety, and well-being of consumers like Plaintiff.

250. Bard's violation of these statutes, rules and regulations, as well as those detailed in Count XIV, constitutes negligence *per se*.

251. As a direct and proximate result of Bard's negligence *per se*, Plaintiff suffered injuries and damages as detailed in this Complaint.

COUNT X: BREACH OF EXPRESS WARRANTY

252. Plaintiff incorporates by reference all prior allegations.

253. Plaintiff, through his medical providers, purchased the Eclipse Filter from Bard.

254. At all relevant times, Bard was a merchant of goods of the kind including medical devices and vena cava filters (i.e., Bard IVC Filters, such as the Eclipse filter,).

255. At the time and place of sale, distribution, and supply of the Eclipse Filter to Plaintiff (and to other consumers and the medical community), Bard expressly represented and warranted that Bard IVC Filters, such as the Eclipse filter, were safe; that they were well-tolerated, efficacious, fit for their intended purpose, and of marketable quality; that they did not produce any unwarned-of dangerous side effects; and that they were adequately tested.

256. At the time of Plaintiff's purchase from Defendants, the Eclipse filter was not in a merchantable condition, and Bard breached its expressed warranties, in that filter:

- a. Was designed in such a manner so as to be prone to an unreasonably high incidence of fracture, perforation of vessels and organs, and/or migration;
- b. Was designed in such a manner so as to result in an unreasonably high incidence of injury to the vessels and organs of its purchaser;
- c. Was manufactured in such a manner that the exterior surface of the filter was inadequately, improperly, and inappropriately constituted, causing the device to weaken and fail;
- d. Was unable to be removed at any time during a person's life;
- e. Was not efficacious in the prevention of pulmonary emboli;

- f. Carried a risk of use outweighed any benefit; and
- g. Was not self-centering.

257. As a direct and proximate result of Bard's breach of express warranty, Plaintiff suffered injuries and damages as detailed in this Complaint.

COUNT XI: BREACH OF IMPLIED WARRANTY

258. Plaintiff incorporates by reference all prior allegations.

259. Bard impliedly warranted that the Eclipse filter was of merchantable quality and safe and fit for the use for which Bard intended, and Plaintiff in fact used that filter.

260. Bard breached its implied warranties by:

- a. Failing to provide adequate instruction that a manufacturer exercising reasonable care would have provided concerning the likelihood that Bard IVC Filters, such as the Eclipse filter, would cause harm;
- b. Manufacturing and/or selling Bard IVC Filters, such as the Eclipse filter, when those filters did not conform to representations made by Bard when they left Bard's control;
- c. Manufacturing and/or selling Bard IVC Filters, such as the Eclipse filter, that were more dangerous than an ordinary consumer would expect when used in an intended or reasonably foreseeable manner;
- d. Manufacturing and/or selling Bard IVC Filters, such as the Eclipse filter, that carried foreseeable risks associated with that filter's design or formulation which exceeded the benefits associated with that design;
- e. Manufacturing and/or selling Bard IVC Filters, such as the Eclipse filter, when they deviated in a material way from the design specifications,

formulas, or performance standards or from otherwise identical units manufactured to the same design specifications, formulas, or performance standards; and

- f. Impliedly representing that its filters, such as the Eclipse filter, would be effective in the prevention of pulmonary emboli.

261. As a direct and proximate result of Bard's breach of its implied warranty, Plaintiff suffered injuries and damages as detailed in this Complaint.

COUNT XII: FRAUDULENT MISREPRESENTATION

262. Plaintiff incorporates by reference all prior allegations.

263. At all times relevant to this cause, and as detailed above, Bard intentionally provided Plaintiff, Plaintiff's physicians, the medical community, and the public at large with false or inaccurate information. Bard also omitted and misrepresented material information concerning Bard IVC Filters, such as the Eclipse filter, including but not limited to the following topics:

- a. The safety of the Bard IVC Filters including the Eclipse filter;
- b. The efficacy of the Bard IVC Filters including the Eclipse filter;
- c. The rate of failure of the Bard IVC Filters including the Eclipse filter;
- d. The pre-market testing of the Bard IVC Filters including the Eclipse filter;
- e. The approved uses of the Bard IVC Filters including the Eclipse filter; and
- f. The ability to retrieve the device at any time over a person's life.

264. The information Bard distributed to the public, the medical community, and Plaintiff was in the form of reports, press releases, advertising campaigns, labeling materials, print

advertisements, commercial media containing material representations, and instructions for use, as well as through their officers, directors, agents, and representatives.

265. These materials contained false and misleading material representations, which included: that Bard IVC Filters, such as the Eclipse filter, were safe and fit when used for their intended purpose or in a reasonably foreseeable manner; that they did not pose dangerous health risks in excess of those associated with the use of other similar IVC filters; that any and all side effects were accurately reflected in the warnings; and that they were adequately tested to withstand normal placement within the human body.

266. Bard made the foregoing misrepresentations knowing that they were false or without reasonable basis. These materials included instructions for use and a warning document that was included in the package of the Eclipse filter implanted in Plaintiff.

267. Bard's 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 the public and the medical community of the quality of Bard IVC Filters, including the Eclipse filter, and their 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 Bard IVC Filters, including the Eclipse filter, all in reliance on Bard's misrepresentations.

268. The foregoing representations and omissions by Bard were false.

269. Bard IVC Filters, including the Eclipse filter, are not safe, fit, and effective for human use in their intended and reasonably foreseeable manner.

270. Further, the use of Bard IVC Filters, including the Eclipse filter, is hazardous to the users' health, and those filters have a serious propensity to cause users to suffer serious injuries, including without limitation the injuries Plaintiff suffered.

271. Finally, Bard IVC Filters, including the Eclipse filter, have a statistically significant higher rate of failure and injury than do other comparable IVC filters.

272. In reliance upon the false and negligent misrepresentations and omissions made by Bard, Plaintiff and Plaintiff's health care providers were induced to, and did, use the Eclipse filter, thereby causing Plaintiff to sustain severe and permanent personal injuries.

273. Bard 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 Bard, and would not have prescribed and implanted the Eclipse filter if the true facts regarding that filter had not been concealed and misrepresented by Bard.

274. Bard had sole access to material facts concerning the defective nature of the products and their propensities to cause serious and dangerous side effects in the form of dangerous injuries and damages to persons who were implanted with Bard IVC Filters, including the Eclipse filter.

275. At the time Bard failed to disclose and intentionally misrepresented the foregoing facts, and at the time Plaintiff used the Eclipse filter, Plaintiff and Plaintiff's health care providers were unaware of Bard's misrepresentations and omissions.

276. As a direct and proximate result of Bard's fraudulent misrepresentations, Plaintiff suffered injuries and damages as detailed in this Complaint.

COUNT XIII: FRAUDULENT CONCEALMENT

277. Plaintiff incorporates by reference all prior allegations.

278. In marketing and selling Bard IVC Filters, including the Eclipse filter, Bard concealed material facts from Plaintiff and Plaintiff's healthcare providers.

279. These concealed material facts include, but are not limited to:

- a. Bard IVC Filters, including the Eclipse filter, were unsafe and not fit when used for their intended purpose or in a reasonably foreseeable manner;
- b. Bard IVC Filters, including the Eclipse filter, posed dangerous health risks in excess of those associated with the use of other similar IVC filters;
- c. That there were additional side effects related to implantation and use of Bard IVC Filters, including the Eclipse filter, that were not accurately and completely reflected in the warnings associated with those filters; and
- d. That Bard IVC Filters, including the Eclipse filter, were not adequately tested to withstand normal placement within the human body.

280. Plaintiff and Plaintiff's healthcare providers were not aware of these and other facts concealed by Bard.

281. In concealing these and other facts, Bard intended to deceive Plaintiff and Plaintiff's healthcare providers.

282. Plaintiff and Plaintiff's healthcare providers were ignorant of and could not reasonably discover the facts Bard fraudulently concealed, and reasonably and justifiably relied on Bard's representations concerning the supposed safety and efficacy of the Eclipse filter.

283. As a direct and proximate result of Defendants' fraudulent concealment of material facts, Plaintiff suffered injuries and damages as detailed in this Complaint.

COUNT XIV: VIOLATIONS OF MISSISSIPPI CONSUMER PROTECTION ACT
(Miss. Code Ann. §§ 75-24-1 through 75-24-27)

284. Plaintiff incorporates by reference all prior allegations.

285. Bard had a statutory duty to refrain from unfair or deceptive acts or practices in the sale and promotion of Bard IVC Filters, including the Eclipse filter.

286. Bard knowingly, deliberately, willfully and/or wantonly engaged in unfair, unconscionable, deceptive, fraudulent, and misleading acts or practices in violation of Mississippi's consumer protection laws.

287. Through its false, untrue, and misleading promotion of Bard IVC Filters, including the Eclipse filter, Bard induced Plaintiff to purchase and/or pay for the purchase of the Eclipse filter.

288. Bard misrepresented the alleged benefits and characteristics of Bard IVC Filters, including the Eclipse filter; suppressed, omitted, concealed, and failed to disclose material information concerning known adverse effects of Bard IVC Filters, including the Eclipse filter; misrepresented the quality and efficacy of Bard IVC Filters, including the Eclipse filter, as compared to much lower-cost alternatives; misrepresented and advertised that Bard IVC Filters, including the Eclipse filter, were of a particular standard, quality, or grade that they were not; misrepresented Bard IVC Filters, including the Eclipse filter, in such a manner that later, on disclosure of the true facts, there was a likelihood that Plaintiff and Plaintiff's physicians would have opted for an alternative IVC filter or method of preventing pulmonary emboli.

289. Bard's conduct created a likelihood of, and in fact caused, confusion and misunderstanding.

290. Bard's conduct misled, deceived, and damaged Plaintiff, and Bard's fraudulent, misleading, and deceptive conduct was perpetrated with an intent that Plaintiff rely on said conduct by purchasing and/or paying for the Eclipse filter.

291. Moreover, Bard knowingly took advantage of Plaintiff, who was unable to protect his own interests due to ignorance of the harmful adverse effects of Bard IVC Filters, including the Eclipse filter.

292. Bard's conduct was willful, outrageous, immoral, unethical, oppressive, unscrupulous, unconscionable, and substantially injurious to Plaintiff, and offends the public conscience.

293. Plaintiff purchased the Eclipse filter primarily for personal, family, or household purposes.

294. As a result of Bard's violative conduct, Plaintiff purchased and/or paid for the Eclipse filter, which purchase was not made for resale.

295. Bard engaged in unfair competition or deceptive acts or practices in violation of Miss. Code Ann. § 75-24-1, *et seq.*

296. As a direct and proximate result of Bard's violations of these statutes, Plaintiff suffered injuries and damages as detailed in this Complaint, and seeks all available damages under Miss. Code Ann. § 75-24-1, *et seq.*

PUNITIVE DAMAGES ALLEGATIONS

297. Plaintiff incorporates by reference all prior allegations.

298. At all times material hereto, Bard knew or should have known that Bard IVC Filters, such as the Eclipse filter, were unreasonably dangerous with respect to the risk of tilt, fracture, migration and/or perforation.

299. At all times material hereto, Bard attempted to misrepresent and did knowingly misrepresent facts concerning the safety of Bard IVC Filters, such as the Eclipse filter.

300. Bard's misrepresentations included knowingly withholding material information from the medical community and the public, including Plaintiff's physicians, concerning the safety of its Bard IVC Filters, such as the Eclipse filter.

301. Bard's conduct, alleged throughout this Complaint, was willful, wanton, and undertaken with a conscious indifference and disregard to the consequences that consumers of their products faced, including Plaintiff.

302. At all times material hereto, Bard knew and recklessly disregarded the fact that Bard IVC Filters, such as the Eclipse filter, have an unreasonably high rate of tilt, fracture, migration, and/or perforation.

303. Notwithstanding the foregoing, Bard continued to market Bard IVC Filters, such as the Eclipse filter, aggressively to consumers, including Plaintiff, without disclosing the aforesaid side effects.

304. Bard knew of its Bard IVC Filters, such as the Eclipse filter, lack of warnings regarding the risk of fracture, migration, and/or perforation, but intentionally concealed and/or recklessly failed to disclose that risk and continued to market, distribute, and sell its filters without said warnings so as to maximize sales and profits at the expense of the health and safety of the public, including Plaintiff, in conscious disregard of the foreseeable harm caused by those filters.

305. Bard's intentional and/or reckless failure to disclose information deprived Plaintiff's physicians of necessary information to enable them to weigh the true risks of using the Eclipse filter against its benefits.

306. Bard's conduct is reprehensible; evidencing an evil hand guided by an evil mind and was undertaken for pecuniary gain in reckless and conscious disregard for the substantial risk of death and physical injury to consumers, including Plaintiff.

307. Such conduct justifies an award of punitive or exemplary damages in an amount sufficient to punish Bard's conduct and deter like conduct by Bard and other similarly situated persons and entities in the future.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against Defendants for:

A. Compensatory damages, including without limitation past and future medical expenses; past and future pain and suffering; past and future emotional distress; past and future loss of enjoyment of life; past and future loss of consortium; past and future lost wages and loss of earning capacity; medical monitoring expenses; cost of life care; and other consequential damages as allowed by law;

B. Punitive damages in an amount sufficient to punish Defendants and deter similar conduct in the future;

C. Disgorgement of profits;

D. Restitution;

E. Statutory damages, where authorized;

F. Costs of suit;

G. Reasonable attorneys' fees, where authorized;

H. Prejudgment interest as allowed by law;

I. Post-judgment interest at the highest applicable statutory or common law rate from the date of judgment until satisfaction of judgment;

- J. Any other interest recoverable under Mississippi or any other applicable law; and
- K. Such other additional and further relief as Plaintiff may be entitled to in law or in equity.

DEMAND FOR JURY TRIAL

Plaintiff hereby demands trial by jury on all issues.

RESPECTFULLY SUBMITTED this 9th day of December, 2015.

By: /s/ Sheila M. Bossier
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Attorneys for Plaintiffs

CIVIL COVER SHEET

1:15cv208-SA-DAS

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

Alec Caldwell

(b) County of Residence of First Listed Plaintiff Lee County
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys (Firm Name, Address, and Telephone Number)

Freese and Goss, PLLC 1520 N. State St., Jackson, MS 39202 and
Wagstaff and Cartmell, LLP 4740 Grand Ave. Suite 300, Kansas City,
MO 64112

DEFENDANTS

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

County of Residence of First Listed Defendant
(IN U.S. PLAINTIFF CASES ONLY)

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

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
(U.S. Government Not a Party)
- ☒ 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)

- | | PTF | DEF | | PTF | DEF |
|---|---------------------------------------|----------------------------|---|----------------------------|---------------------------------------|
| Citizen of This State | <input checked="" type="checkbox"/> 1 | <input type="checkbox"/> 1 | Incorporated or Principal Place of Business In This State | <input type="checkbox"/> 4 | <input type="checkbox"/> 4 |
| Citizen of Another State | <input type="checkbox"/> 2 | <input type="checkbox"/> 2 | Incorporated and Principal Place of Business In Another State | <input type="checkbox"/> 5 | <input checked="" type="checkbox"/> 5 |
| Citizen or Subject of a Foreign Country | <input type="checkbox"/> 3 | <input type="checkbox"/> 3 | Foreign Nation | <input type="checkbox"/> 6 | <input type="checkbox"/> 6 |

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

CONTRACT	TORTS	FORFEITURE/PENALTY	BANKRUPTCY	OTHER STATUTES
<input type="checkbox"/> 110 Insurance <input type="checkbox"/> 120 Marine <input type="checkbox"/> 130 Miller Act <input type="checkbox"/> 140 Negotiable Instrument <input type="checkbox"/> 150 Recovery of Overpayment & Enforcement of Judgment <input type="checkbox"/> 151 Medicare Act <input type="checkbox"/> 152 Recovery of Defaulted Student Loans (Excludes Veterans) <input type="checkbox"/> 153 Recovery of Overpayment of Veteran's Benefits <input type="checkbox"/> 160 Stockholders' Suits <input type="checkbox"/> 190 Other Contract <input type="checkbox"/> 195 Contract Product Liability <input type="checkbox"/> 196 Franchise	PERSONAL INJURY <input type="checkbox"/> 310 Airplane <input type="checkbox"/> 315 Airplane Product Liability <input type="checkbox"/> 320 Assault, Libel & Slander <input type="checkbox"/> 330 Federal Employers' Liability <input type="checkbox"/> 340 Marine <input type="checkbox"/> 345 Marine Product Liability <input type="checkbox"/> 350 Motor Vehicle <input type="checkbox"/> 355 Motor Vehicle Product Liability <input type="checkbox"/> 360 Other Personal Injury <input type="checkbox"/> 362 Personal Injury - Medical Malpractice PERSONAL INJURY <input checked="" type="checkbox"/> 365 Personal Injury - Product Liability <input type="checkbox"/> 367 Health Care/Pharmaceutical Personal Injury Product Liability <input type="checkbox"/> 368 Asbestos Personal Injury Product Liability PERSONAL PROPERTY <input type="checkbox"/> 370 Other Fraud <input type="checkbox"/> 371 Truth in Lending <input type="checkbox"/> 380 Other Personal Property Damage <input type="checkbox"/> 385 Property Damage Product Liability	<input type="checkbox"/> 625 Drug Related Seizure of Property 21 USC 881 <input type="checkbox"/> 690 Other LABOR <input type="checkbox"/> 710 Fair Labor Standards Act <input type="checkbox"/> 720 Labor/Management Relations <input type="checkbox"/> 740 Railway Labor Act <input type="checkbox"/> 751 Family and Medical Leave Act <input type="checkbox"/> 790 Other Labor Litigation <input type="checkbox"/> 791 Employee Retirement Income Security Act IMMIGRATION <input type="checkbox"/> 462 Naturalization Application <input type="checkbox"/> 465 Other Immigration Actions	<input type="checkbox"/> 422 Appeal 28 USC 158 <input type="checkbox"/> 423 Withdrawal 28 USC 157 PROPERTY RIGHTS <input type="checkbox"/> 820 Copyrights <input type="checkbox"/> 830 Patent <input type="checkbox"/> 840 Trademark SOCIAL SECURITY <input type="checkbox"/> 861 HIA (1395ff) <input type="checkbox"/> 862 Black Lung (923) <input type="checkbox"/> 863 DIWC/DIWW (405(g)) <input type="checkbox"/> 864 SSID Title XVI <input type="checkbox"/> 865 RSI (405(g)) FEDERAL TAX SUITS <input type="checkbox"/> 870 Taxes (U.S. Plaintiff or Defendant) <input type="checkbox"/> 871 IRS—Third Party 26 USC 7609	<input type="checkbox"/> 375 False Claims Act <input type="checkbox"/> 400 State Reapportionment <input type="checkbox"/> 410 Antitrust <input type="checkbox"/> 430 Banks and Banking <input type="checkbox"/> 450 Commerce <input type="checkbox"/> 460 Deportation <input type="checkbox"/> 470 Racketeer Influenced and Corrupt Organizations <input type="checkbox"/> 480 Consumer Credit <input type="checkbox"/> 490 Cable/Sat TV <input type="checkbox"/> 850 Securities/Commodities/Exchange <input type="checkbox"/> 890 Other Statutory Actions <input type="checkbox"/> 891 Agricultural Acts <input type="checkbox"/> 893 Environmental Matters <input type="checkbox"/> 895 Freedom of Information Act <input type="checkbox"/> 896 Arbitration <input type="checkbox"/> 899 Administrative Procedure Act/Review or Appeal of Agency Decision <input type="checkbox"/> 950 Constitutionality of State Statutes
REAL PROPERTY <input type="checkbox"/> 210 Land Condemnation <input type="checkbox"/> 220 Foreclosure <input type="checkbox"/> 230 Rent Lease & Ejectment <input type="checkbox"/> 240 Torts to Land <input type="checkbox"/> 245 Tort Product Liability <input type="checkbox"/> 290 All Other Real Property	CIVIL RIGHTS <input type="checkbox"/> 440 Other Civil Rights <input type="checkbox"/> 441 Voting <input type="checkbox"/> 442 Employment <input type="checkbox"/> 443 Housing/Accommodations <input type="checkbox"/> 445 Amer. w/Disabilities - Employment <input type="checkbox"/> 446 Amer. w/Disabilities - Other <input type="checkbox"/> 448 Education PRISONER PETITIONS Habeas Corpus: <input type="checkbox"/> 463 Alien Detainee <input type="checkbox"/> 510 Motions to Vacate Sentence <input type="checkbox"/> 530 General <input type="checkbox"/> 535 Death Penalty Other: <input type="checkbox"/> 540 Mandamus & Other <input type="checkbox"/> 550 Civil Rights <input type="checkbox"/> 555 Prison Condition <input type="checkbox"/> 560 Civil Detainee - Conditions of Confinement			

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

Brief description of cause:

diversity (Personal injury arising to plaintiff from malfunction of IVC Filters manufactured by defendants)

VII. REQUESTED IN COMPLAINT:

☐ CHECK IF THIS IS A CLASS ACTION UNDER RULE 23, F.R.Cv.P.

DEMAND \$
In excess of \$75,000

CHECK YES only if demanded in complaint:
JURY DEMAND: ☒ Yes ☐ No

VIII. RELATED CASE(S) IF ANY

(See instructions):

JUDGE Judge David G. Campbell

DOCKET NUMBER MDL 2641

DATE

December 9, 2015

SIGNATURE OF ATTORNEY OF RECORD

/s/ Sheila M. Bossier

FOR OFFICE USE ONLY

RECEIPT #

AMOUNT

\$400

APPLYING IFP

JUDGE

SA

MAG. JUDGE

DAS

0537-1277108