UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA

DONALD E. YATES and JOY E. YATES, *Plaintiffs*, vs. C.R. BARD, INC., a foreign corporation, BARD PERIPHERAL VASCULAR, INC., an Arizona corporation, and DOES 1 through 100 inclusive, *Defendants*.	**C.A. No. 15-1466** **COMPLAINT FOR DAMAGES** **PLAINTIFFS DEMAND A TRIAL BY JURY**

Plaintiffs, DONALD E. YATES and JOY E. YATES, by and through their undersigned attorneys, hereby sue defendants C.R. BARD, INC.; BARD PERIPHERAL VASCULAR, INC.; and DOES 1 through 100 (collectively, the "Defendants") and allege as follows:

PARTIES

Plaintiffs

1. Plaintiff, Donald E. Yates, at all times relevant to this action resided in and continues to reside in Greensburg, Indiana and is the husband of Joy E. Yates. On or about December 30, 2008, Donald E. Yates underwent placement of a G2® Express filter or G2 Filter System® (hereafter G2®, G2 Filter® or G2 Filter System®) at the Saint Vincent Hospital located at 2001 W. 86th Street, Indianapolis, Indiana. On or about October of 2013, this G2® filter fractured and further failed permitting clots to migrate to the lung causing pulmonary emboli. Moreover, plaintiff has not been able to have the filter removed. Plaintiff has incurred significant medical expenses and has endured extreme pain and suffering, loss of enjoyment of life, disability, and other losses.

2. Plaintiff, Joy E. Yates, at all times relevant to this action resided in and continues to reside in Greensburg, Indiana and is the wife of Donald E. Yates.

Defendants

3. Defendant C.R. Bard, Inc. ("Bard") is a corporation duly organized and existing under the laws of the state of Delaware and has its principal place in New Jersey. Bard at all times relevant to this action, designed, set specifications, manufactured, prepared, compounded, assembled, processed, marketed, distributed, and sold the Recovery® Filter System and G2® Filter System to be implanted in patients throughout the United States, including Indiana.

4. Defendant Bard Peripheral Vascular, Inc. ("BPV") is a wholly owned subsidiary corporation of defendant Bard, with its principal place of business at 1625 West 3rd Street, Tempe, Arizona. BPV at all times relevant to this action, designed, set specifications, manufactured, prepared, compounded, assembled, processed, marketed, distributed, and sold the Recovery® Filter System and the G2® Filter System to be implanted in patients throughout the United States, including Indiana.

5. All references to "Defendants" hereafter shall refer to defendants Bard, BPV, and DOES 1 through 100.

6. The true names, identities, or capacities, whether individual, associate, corporate or otherwise of defendants, DOES 1 through 100, inclusive, are unknown to plaintiffs who, therefore, sues said defendants by such fictitious names. When the true names, identities or capacities of said fictitiously designated defendants are ascertained, plaintiffs will seek leave of Court to amend this complaint to insert the true names, identities, and/or capacities of DOE Defendants, together with the proper charging allegations against said DOE Defendants.

7. Plaintiff is informed and believes, and thereon alleges that each of the defendants sued herein as a DOE defendant is responsible in some manner for the acts, omissions, and conduct, which proximately resulted in and/or was a substantial contributing factor in Plaintiff's injuries.

JURISDICTION AND VENUE

8. Plaintiff has suffered damages in an amount that exceeds the jurisdictional minimum of this Court.

9. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332 because there is complete diversity of citizenship between the parties and the amount in controversy exceeds $75,000.00 exclusive of costs and interests.

10. Venue in this district is appropriate under 28 U.S.C. § 1391 because a substantial part of

the events giving rise to this cause of action occurred in the District as defendants sold these products in this District and have at all relevant times plaintiff has resided in this District.

GENERAL FACTUAL ALLEGATIONS

11. Plaintiff brings this case for serious personal injuries that Donald E. Yates suffered as result of **a** surgically implanted medical device, known as a G2 Express Filter System® (hereafter G2®, G2 Filter® or G2 Filter System®), that failed causing serious and ongoing physical, emotional, and economic damages.

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

13. Prior to Plaintiff Donald E. Yates being implanted with a G2® Filter on or about December 30, 2008, Defendants knew and should have known that the device was defective and unreasonably dangerous for, *inter alia*, the following reasons:

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

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

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

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

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

f. Defendants misrepresented to doctors and patients that its filters were actually efficacious and "saved lives" without any clinical evidence, that plaintiff and his doctor relied upon in deciding whether or not to select the particular device implanted in plaintiff.

A. INFERIOR VENA CAVA FILTERS GENERALLY

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

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

16. The inferior vena cava is a vein that returns blood to the heart from the lower portions of the body. In certain people, for various reasons, thrombi travel from the vessels in the legs and pelvis, through the vena cava and into the lungs. Often times, these thrombi develop in the deep leg veins. These thrombi are called "deep vein thrombosis" or "DVT". Once thrombi reach the lungs, they are considered "pulmonary emboli" or "PE". Pulmonary emboli present risks to human health. They can, and often do, result in death.

17. Certain people are at increased risk for the development of DVT or PE. For instance, someone who undergoes knee or hip joint replacement surgery is at risk for developing DVT/PE. Obese patients are also at increased risk for DVT/PE. So too are people who have vascular diseases or whom

have experienced previous strokes. A number of other conditions predispose people to develop DVT/PE, including "coagulopathies" and clotting disorders.

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

19. As stated above, IVC filters have been on the market for decades. The first IVC filters marketed were permanent filters. These devices were designed to be left in a patient's IVC permanently and have long-term follow-up data (of up to 20 years and longer) supporting their use and efficacy. Beginning in 2003, manufacturers also began marketing what are known as optional or retrievable filters. These filters are designed so that they can be surgically removed from a patient after the risk of PE has subsided. These IVC filter designs, however, were not intended to remain within the human body for indeterminate periods of time. In other words, the initial designs of retrievable IVC filters were intended to remain implanted for a finite period of time. Although the Recovery® Filter System and the subsequent G2® Filter manufactured by Bard and BPV are examples of retrievable filters, these filters were marketed as permanent filters with the option of retrieval.

B. THE RECOVERY FILTER®

i. FDA Clearance and Intended Use

20. In 2002, Bard and BPV submitted a notification of intent to the FDA to market the "Recovery® Filter System" (hereafter "Recovery®" or "Recovery® Filter") for the prevention of recurrent pulmonary embolism by placement in the inferior vena cava.[1] On November 27, 2002, the

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

FDA cleared the Recovery® Filter for marketing and use in the prevention of recurrent pulmonary embolism via *permanent* placement in the vena cava in the following situations: (a) pulmonary thromboembolism when anticoagulants are contraindicated; (b) failure of anticoagulant therapy for thromboembolic disease; (c) emergency treatment following massive pulmonary embolism where anticipated benefits of conventional therapy are reduced; and (d) chronic, recurrent pulmonary embolism where anticoagulant therapy has failed or is contraindicated.

21. In April 2003, Bard and BPV submitted a Section 510(k) premarket notification of intent to market the Recovery® Filter for the additional intended use of *optional retrieval*. The FDA cleared this additional intended use on July 25, 2003.

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

ii. What Is It and How Is It Used

23. The Recovery® Filter consists of two (2) levels of six (6) radially distributed NITINOL struts that are designed to anchor the filter into the inferior vena cava and to catch any embolizing clots. There are six short struts, which are commonly referred to as the arms, and six long struts, which are commonly referred to as the legs. Each strut is held together by a single connection to a cap located at the top of the device. According to the Patent filed for this device, the short struts are primarily for "centering" or "positioning" within the vena cava, and the long struts with attached hooks are designed primarily to prevent the device from migrating in response to "normal respiratory movement" or "pulmonary embolism."

24. As noted above, the Recovery® Filter is constructed with NITINOL, which is an acronym that stands for Nickel Titanium Naval Ordnance Laboratory. NITINOL possesses "shape memory." That is, NITINOL will change shape according to changes in temperature, and then, retake its prior shape after returning to its initial temperature. When placed in saline, therefore, the NITINOL struts become soft and can be straightened to allow delivery through a small diameter catheter. The metal struts then reassume their original shape when warmed to body temperature in the vena cava.

25. The Recovery® filter is inserted by a catheter that is guided by a physician through a blood vessel into the inferior vena cava. The Recovery® Filter is designed to be retrieved in a similar fashion. The implanting physician normally reviews an imaging study prior to placement to determine size of IVC, renal vein location, and to identify any venous anomalies or clots in the vena cava. Following placement, the physician will normally use an imaging study to confirm successful placement.

iii. Inherent Risks of the Recovery® Filter

26. The Recovery® Filter is prone to an unreasonably high risk of failure and patient injury following placement in the human body. Multiple studies have reported Bard's Recovery® Filter to have a fracture and migration rate ranging from 21% to 31.7%.[2] When such failures occur, shards of the device or the entire device can travel to the heart, where it can cause cardiac tamponade, perforation of the atrial wall, myocardial infarction and death. These fractured shards may also become too embedded in tissue or migrate to locations, such as the lungs, such that they are too dangerous to remove. These patients are exposed to a lifetime of future risk.

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

28. The Recovery Filter failures described above occur at a substantially higher rate than with other IVC filters.

29. The adverse event reports (AERs) associated with IVC filter devices demonstrates that Bard's IVC Filters are far more prone to device failure then are other similar devices. A review of the

[2] *See e.g.,* Hull JE, Donaldson SW. Bard Recovery Filter: evaluation and management of vena cava limb perforation, fracture, and migration. *J Vasc Interv Radiol.* 2009;20(1):52-60; Nicholson W, *et al.* Prevalence of Fracture and Fragment Embolization of the Bard Recovery and Bard G2 Cava Filters and Clinical Implications Including Cardiac Perforation and Tamponade. *Arch. Int. Med.* 2010 Nov.; 170:1827-31.

FDA MAUDE database from the years 2004-2008 reveals data to establish that Bard's IVC filters are responsible for the following percentages of all AERs:

a. 50% of all adverse events

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

c. 69% of all occurrences of vena cava wall perforation

d. 70% of all occurrences of filter fracture.

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

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

iv. What Bard and BPV Knew or Should Have Known

32. Bard and BPV knew that no clinical testing, such as animal studies, was conducted to determine whether the Recovery® Filter would perform safely once implanted in the human body and subjected normal *in vivo* stresses.

33. Soon after the Recovery® Filter's introduction to the market in 2003, Bard and BPV began receiving large numbers of adverse event reports ("AERs") from health care providers reporting that the Recovery® Filter was fracturing post-implantation and that fractured pieces and/or the entire device were migrating throughout the human body, including to the heart and lungs. Bard and BPV also received large numbers of AERs reporting that the Recovery® Filter was found to have excessively tilted and/or perforated the inferior vena cava post-implantation. These failures were often associated with reports of severe patient injuries such as:

a. death;

b. hemorrhage;

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

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

e. severe and persistent pain;

f. and perforations of tissue, vessels and organs.

34. Within the first year of full market release of the Recovery® Filter, Bard and BPV received at least 32 AERs reporting that the Recovery® Filter had fractured *in vivo* and at least 22 AERs reporting that the entire device had migrated *in vivo*. Of the 22 reported migration failures, at least nine (9) were reported to have been associated with patient death.

35. From 2003 through September 2005, Bard and BPV received ever growing numbers of AERs reporting the above described failures and patient injuries. Defendants knew or should have known that the failure rates associated with the Recovery® Filter were substantially higher than other similar products on the market and that there were safer alternative devices, including the Simon Nitinol Filter manufactured and distributed by Bard and BPV.

v. Market Withdrawal, but no Recall

36. In late 2004 or early 2005 Bard and BPV, without notifying consumers of the design and manufacturing flaws inherent in the Recovery® Filter, began redesigning the Recovery® Filter in an attempt to correct those flaws. The redesigned filter is known as the G2® Filter, which stands for second generation Recovery® Filter. Once Bard and BPV had obtained FDA approval to market the redesigned product in or around August 2005, Bard and BPV quietly stopped marketing the Recovery® Filter. Bard and BPV failed, however, to make any effort to notify consumers of the risk inherent in the use of the Recovery® Filter.

C. THE G2® FILTER SYSTEM

37. On August 10, 2005, Bard and BPV 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. Bard and BPV cited the Recovery® Filter as the substantially equivalent predicate device. Bard and BPV stated that the differences between the Recovery® Filter and the G2®

Filter were primarily dimensional and no material changes or additional components were added. On August 29, 2005, the FDA cleared the Recovery® Filter for the same intended uses as the Recovery® Filter, except that it was not cleared for retrievable use.[3]

38. Bard and BPV marketed the G2® Filter as having "enhanced fracture resistance," "improved centering," and "increased migration resistance." However, Bard and BPV again failed to conduct adequate clinical testing, such as animal studies, to ensure that the device would perform safely and effectively once implanted in the human body and subjected to *in vivo* stresses. Not surprisingly, the G2® Filter's design causes it to be of insufficient integrity and strength to withstand normal *in vivo* stresses within the human body so as to resist fracturing, migrating, tilting, and/or perforating the inferior vena cava.

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

40. Thus, the G2® Filter shares the same defects and health risks as its predicate device.

41. As with the Recovery® Filter, Bard and BPV immediately began receiving large numbers of AERs reporting that the G2® Filter was, *inter alia*, fracturing, migrating, excessively tilting, and perforating the vena cava once implanted. These failures were again often associated with reports of severe patient injuries such as:

a. death;

b. hemorrhage;

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

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

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

e. severe and persistent pain;

f. and perforations of tissue, vessels and organs.

42. Defendants represent the fracture rate of the G2® 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 incidence of device fracture for the G2® Filter.

43. A review of the MAUDE database from the years 2004-2008 reveals data to establish that the Bard and BPV's vena cava filters (including the G2® Filter) are responsible for the majority of all reported adverse events related to inferior vena cava filters and that there were safer alternative devices, including the Simon Nitinol Filter manufactured and distributed by Bard and BPV.

D. BARD AND BPV'S KNOWLEDGE OF THE RISK OF FAILURE AND RESULTING DANGERS

44. Upon information and belief, Plaintiff alleges that as early as 2003, Bard and BPV were aware and had knowledge of the fact that the Recovery® Filter was defective and unreasonably dangerous and was causing injury and death to patients who had received it. Similarly, Bard and BPV were aware as early as 2005 that the G2® Filter System was defective and unreasonably dangerous and was causing injury and death to patients who had received it.

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

46. Upon information and belief, from the time the G2® Filter System became available on the market, the Defendants Bard and BPV embarked on an aggressive campaign of "off label marketing" concerning the G2® Filter System. This included representations made to physicians,

healthcare professionals, and other members of the medical community that the G2® Filter System was safe and effective for retrievable use prior to the FDA approving the G2® Filter System for retrievable use.

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

a. Inform or warn Plaintiff, his physicians, or the public at large of these dangers;

b. Establish and maintain an adequate quality and post-market surveillance system; and

c. Recall the Recovery® Filter and G2® Filter from the market.

48. Despite having knowledge as early as 2003 of the unreasonably dangerous and defective nature of the Recovery® Filter, Bard and BPV consciously disregarded the known risks and continued to actively market and offer for sale the Recovery® and G2® Filter Systems.

49. Plaintiff further alleges that the Defendants acted in willful, wanton, gross and total disregard for the health and safety of the users or consumers of their Recovery® Filter and G2® Filter Systems, acted to serve their own interests, and having reason to know and consciously disregarding the substantial risk that their product might kill or significantly harm patients, or significantly injure the rights of others, consciously pursued a course of conduct knowing that such conduct created a substantial risk of significant harm to other persons.

SPECIFIC FACTUAL ALLEGATIONS AS TO DONALD E. YATES

50. On December 30, 2008, Bard G2® Filter was implanted in plaintiff.

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

52. The G2® filter implanted in the Plaintiff subsequently fractured, failed to perform as represented and cause plaintiff to suffer from pulmonary emboli. Moreover, the filter was unable to be removed from Plaintiff. Plaintiff has incurred significant medical expenses and has endured extreme pain and suffering, loss of enjoyment of life, disability, and other losses. He will require ongoing medical care to monitor his condition.

FRUADULENT CONCEALMENT

53. Any applicable statutes of limitation have been tolled by the knowing and active concealment and denial of material facts known by Defendants when they had a duty to disclose those facts. They have kept Plaintiff ignorant of vital information essential to the pursuit of her claim, without any fault or lack of diligence on Plaintiff's part, for the purpose of obtaining delay on Plaintiff's part in filing on their causes of action. Defendants' fraudulent concealment did result in such delay.

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

55. Donald E. Yates and his health care providers could not reasonably have discovered the claims made herein until the date of the filing of this complaint as defendants continue to mislead the public.

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

CORPORATE/VICARIOUS LIABILITY

57. At all times herein mentioned, each of the Defendants was the agent, servant, partner, aider and abettor, co-conspirator and/or joint venturer of each of the other Defendants herein and was at all times operating and acting within the purpose and scope of said agency, service, employment, partnership, conspiracy and/or joint venture and rendered substantial assistance and encouragement to the other Defendants, knowing that their collective conduct constituted a breach of duty owed to the Plaintiff.

58. There exists and, at all times herein mentioned, there existed a unity of interest in ownership between certain Defendants and other certain Defendants such that any individuality and separateness between the certain Defendants has ceased and these Defendants are the alter ego of the

other certain Defendants and exerted control over those Defendants. Adherence to the fiction of the separate existence of these certain Defendants as entities distinct from other certain Defendants will permit an abuse of the corporate privilege and would sanction a fraud and/or would promote injustice.

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

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

FIRST CAUSE OF ACTION

NEGLIGENCE

61. Plaintiff Donald E. Yates re-alleges and incorporates by reference each and every allegation contained in the foregoing paragraphs as though fully set forth herein.

62. At all times relevant to this cause of action, the Defendants Bard, BPV, and DOES 1 - 100 were in the business of designing, developing, setting specifications, manufacturing, marketing, selling, and distributing the Recovery® and G2® Filters.

63. Defendants designed, manufactured, marketed, inspected, labeled, promoted, distributed and sold the G2® Filter implanted in Donald E. Yates.

64. Defendants had a duty to exercise reasonable and prudent care in the development, testing, design, manufacture, inspection, marketing, labeling, promotion, distribution and sale of the Recovery® Filter and G2® Filter System so as to avoid exposing others to foreseeable and unreasonable risks of harm.

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

66. At the time of manufacture and sale of the Recovery® Filter and G2® Filter System, Defendants knew or should have known that its IVC Filter:

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

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

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

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

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

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

69. Defendants breached their to duty to exercise reasonable and prudent care in the development, testing, design, manufacture, inspection, marketing, labeling, promotion, distribution and

sale of the Recovery® Filter and G2® Filter System in, among other ways, the following acts and omissions:

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

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

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

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

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

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

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

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

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

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

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

l. Failing to establish an adequate quality assurance program used in the manufacturing of the Recovery® Filter and G2® Filter System.

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

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

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

SECOND CAUSE OF ACTION

STRICT PRODUCTS LIABILITY - FAILURE TO WARN

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

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

74. At the time Defendants designed, manufactured, prepared, compounded, assembled, processed, marketed, labeled, distributed, and sold the device into the stream of commerce, Defendants knew or should have known the device presented an unreasonable danger to users of the product when put to its intended and reasonably anticipated use. Specifically, Defendants knew or should have

known at the time they manufactured, labeled, distributed and sold the G2® Filter, which was implanted in Plaintiff, that the G2® Filter, *inter alia*, posed a significant and higher risk than other similar devices of device failure (fracture, migration, tilting, and perforation of the vena cava wall) and resulting serious injuries. Upon information and belief, Defendants also knew or should have known that certain conditions or post-implant procedures, such as morbid obesity or open abdominal procedures, could affect the safety and integrity of the device.

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

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

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

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

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

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

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

82. As a direct and proximate result of Defendants' lack of sufficient warning and/or instructions, Plaintiff Donald E. Yates has suffered and will continue to suffer serious physical injuries,

economic loss, loss of enjoyment of life, disability, and other losses, in an amount to be determined at trial.

THIRD CAUSE OF ACTION

STRICT PRODUCTS LIABILITY – DESIGN DEFECTS

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

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

85. The G2® Filter was expected to, and did, reach its intended consumers without substantial change in the condition in which it was in when it left Defendants' possession. In the alternative, any changes that were made to G2® Filter implanted in Plaintiff were reasonably foreseeable to Defendants.

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

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

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

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

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

FOURTH CAUSE OF ACTION

STRICT PRODUCTS LIABILITY – MANUFACTURING DEFECT

91. Plaintiff re-alleges and incorporates by reference each and every allegation contained in the foregoing paragraphs as though fully set forth herein.

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

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

94. Plaintiff and his health care providers used the device in a manner that was reasonably foreseeable to Defendants.

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

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

FIFTH CAUSE OF ACTION

BREACH OF EXPRESS/IMPLIED WARRANTY OF MERCHANTABILITY

97. Plaintiff re-alleges and incorporates by reference each and every allegation contained in the foregoing paragraphs as though fully set forth herein.

98. At all times relevant to this action, Defendants designed, researched, developed, manufactured, tested, labeled, inspected, advertised, promoted, marketed, sold, and distributed into the stream of commerce the G2® Filter for use as a surgically implanted device used to prevent pulmonary embolisms and for uses other than as approved and indicated in the product's instructions, warnings, and labels.

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

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

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

102. The representations and implied warranties made by Defendants were false, misleading, and inaccurate because the G2® Filter was defective, unsafe, unreasonably dangerous, and not of merchantable quality, when used in its intended and/or reasonably foreseeable manner. Specifically, at the time of Plaintiff purchase of the G2® Filter from the Defendants, through his attending physicians and medical facilities, it was not in a merchantable condition in that:

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

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

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

103. Plaintiff and his health care providers reasonably relied on the superior skill and judgment of Defendants as the designers, researchers and manufacturers of the product, as to whether G2® Filter was of merchantable quality and safe and fit for its intended use, and also relied on the implied warranty of merchantability and fitness for the particular use and purpose for which the G2® Filter was manufactured and sold.

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

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

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

SIXTH CAUSE OF ACTION

NEGLIGENT MISREPRESENTATION/ CONSUMER FRAUD

107. Plaintiff re-alleges and incorporates by reference each and every allegation contained in the foregoing paragraphs as though fully set forth herein.

108. At all times relevant to this cause, and as detailed *supra*, Defendants negligently provided Plaintiff, his health care providers, and the general medical community, with false or incorrect information, or omitted or failed to disclose material information concerning the G2® Filter, including, but not limited to, misrepresentations relating to the following subject areas:

a. The safety of the G2® Filter;

b. The efficacy of the G2® Filter;

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

d. The approved uses of the G2® Filter.

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

110. Defendants' intent and purpose in making these misrepresentations was to deceive and defraud the public and the medical community, including Plaintiff's health care providers; to gain the confidence of the public and the medical community, including Plaintiff's health care providers; to falsely assure them of the quality of the G2® Filter and its fitness for use; and to induce the public and

the medical community, including Plaintiff's healthcare providers to request, recommend, prescribe, implant, purchase, and continue to use the G2® Filter.

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

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

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

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

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

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

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

SEVENTH CAUSE OF ACTION

LOSS OF CONSORTIUM

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

119. Joy E. Yates is and was at all times relevant to this action, the legal wife of Donald E. Yates, and they have at all times relevant to this action, lived together as husband and wife.

120. As a proximate result of the personal injuries suffered by Donald E. Yates, as described in this complaint, Joy E. Yates has been deprived of the benefits of their marriage including his love, affection, society, and consortium, and other husbandly duties and actions. Donald E. Yates provided Joy E. Yates with all the benefits of a marriage between husband and wife, prior to his implantation with the defective and unreasonably dangerous Bard Filter and resulting injuries described herein.

121. Joy E. Yates has also suffered loss of her husband's daily and regular contribution to the household duties and services, which each provides to the household as husband and wife.

122. Joy E. Yates has also incurred the costs and expenses related to the medical care, treatment, medications, and hospitalization to which Donald E. Yates was subjected for the physical injuries he suffered as a proximate result of his use of the Bard Filter. Joy E. Yates will continue to incur the future expenses related to the care, treatment, medications, and hospitalization of Donald E. Yates due to his injuries from the Bard Filter.

123. Joy E. Yates has suffered a loss of consortium as described herein, including the past, present, and future loss of her husband's companionship, services, society, and the ability of Donald E. Yates to provide Joy E. Yates with the benefits of marriage, including inter alia, loss of contribution to household income and loss of household services, all of which has resulted in her pain, suffering, and mental and emotional distress and worry.

PUNITIVE DAMAGES ALLEGATIONS

124. Plaintiffs re-allege each and every allegation in this Complaint and incorporate each allegation into this Count, as if set forth at length, in its entirety.

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

126. Defendants had knowledge of, and were in possession of evidence demonstrating that, the G2® Filter was defective and unreasonably dangerous and had a substantially higher failure rate than did other similar devices on the market. Yet, Defendants failed to:

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

b. Establish and maintain an adequate quality and post-market surveillance system; and

c. Recall the G2® Filter from the market

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

128. As a direct, proximate, and legal result of Defendants' acts and omissions a described herein, and Plaintiff's implantation with Defendants' defective product, Plaintiffs have suffered and will continue to suffer serious physical injuries, economic loss, loss of enjoyment of life, disability, and other losses, in an amount to be determined at trial.

PRAYER FOR DAMAGES

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

a. Judgment to be entered against all defendants on all causes of action of this Complaint;

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

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

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

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

AS TO THE FIRST CAUSE OF ACTION FOR NEGLIGENCE AGAINST DEFENDANTS BARD, BPV AND DOES 1 THROUGH 100.

1. General damages according to proof at the time of trial;

2. Medical and other special damages, past, present, and future, according to proof at the

time of trial;

3. For pre-judgment and post-judgment interest pursuant to the laws of the State of Indiana;
4. Costs of suit incurred herein;
5. Punitive damages; and
6. For such other and further relief as the court may deem just and proper.

AS TO THE SECOND CAUSE OF ACTION FOR STRICT LIABILITY – FAILURE TO WARN AGAINST DEFENDANTS BARD, BPV AND DOES 1 THROUGH 100.

1. General damages according to proof at the time of trial;
2. Pain and Suffering,
3. Emotional distress
4. Medical and other special damages, past, present, and future, according to proof at the time of trial;
5. For pre-judgment and post-judgment interest pursuant to the laws of the State of Indiana;
6. Costs of suit incurred herein;
7. Punitive damages; and
8. For such other and further relief as the court may deem just and proper.

AS TO THE THIRD CAUSE OF ACTION FOR STRICT LIABILITY – DESIGN DEFECT AGAINST DEFENDANTS BARD BPV, AND DOES 1 THROUGH 100.

1. General damages according to proof at the time of trial;
2. Pain and Suffering,
3. Emotional distress
4. Medical and other special damages, past, present, and future, according to proof at the time of trial;
5. For pre-judgment and post-judgment interest pursuant to the laws of the State of Indiana;
6. Costs of suit incurred herein;

7. Punitive damages; and
8. For such other and further relief as the court may deem just and proper.

AS TO THE FOURTH CAUSE OF ACTION FOR STRICT LIABILITY – MANUFACTURING DEFECT AGAINST DEFENDANTS BARD, BPV AND DOES 1 THROUGH 100.

1. General damages according to proof at the time of trial;
2. Pain and Suffering,
3. Emotional distress
4. Medical and other special damages, past, present, and future, according to proof at the time of trial;
5. For pre-judgment and post-judgment interest pursuant to the laws of the State of Indiana;
6. Costs of suit incurred herein;
7. Punitive damages; and
8. For such other and further relief as the court may deem just and proper.

AS TO THE FIFTH CAUSE OF ACTION FOR BREACH OF IMPLIED WARRANTY AGAINST DEFENDANTS BARD, BPV AND DOES 1 THROUGH 100.

1. General damages according to proof at the time of trial;
2. Pain and Suffering,
3. Emotional distress
4. Medical and other special damages, past, present, and future, according to proof at the time of trial;
5. For pre-judgment and post-judgment interest pursuant to the laws of the State of Indiana;
6. Costs of suit incurred herein; and
7. For such other and further relief as the court may deem just and proper.

AS TO THE SIXTH CAUSE OF ACTION FOR NEGLIGENT MISREPRESENTATION AGAINST DEFENDANTS BARD, BPV AND DOES 1 THROUGH 100.

1. General damages according to proof at the time of trial;
2. Pain and Suffering,
3. Emotional distress
4. Medical and other special damages, past, present, and future, according to proof at the time of trial;
5. For pre-judgment and post-judgment interest pursuant to the laws of the State of Indiana;
6. Costs of suit incurred herein; and
7. For such other and further relief as the court may deem just and proper.

AS TO THE SEVENTH CAUSE OF ACTION FOR LOSS OF CONSORTIUM AGAINST DEFENDANTS BARD, BPV AND DOES 1 THROUGH 100.

1. General damages according to proof at the time of trial;
2. Pain and Suffering,
3. Emotional distress
4. Medical and other special damages, past, present, and future, according to proof at the time of trial;
5. For pre-judgment and post-judgment interest pursuant to the laws of the State of Indiana;
6. Costs of suit incurred herein; and

For such other and further relief as the court may deem just

DEMAND FOR JURY TRIAL

Plaintiff hereby demands trial by jury on all issues.

Dated: September 16, 2015.

Respectfully Submitted,

Attorney for Donald E. Yates

By: */s/Frederick R. Hovde*

Frederick R. Hovde, Esq.
Bar No: 10649-49
HOVDE, DASSOW & DEETS
201 West 103rd Street, Suite 500
Indianapolis, IN 46290
Tel: (317) 818-3100
Fax: (317) 818-3111
Email: rhovde@hovdelaw.com

To be admitted pro hac vice

John A. Dalimonte, Esq.
KARON & DALIMONTE LLP
85 Devonshire Street, Suite 1000
Boston, MA 02109
Tel: 617-367-3311
Fax: 617-742-9130
Email: johndalimonte@kdlaw.net

Counsel for Plaintiffs

JS 44 (Rev. 12/12)

CIVIL COVER SHEET

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

I. (a) PLAINTIFFS

Donald E. Yates and Joy. E Yates

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

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
Frederick R. Hovde, Hovde, Dassow & Deets, 201 West 103rd Street, Suite 500, Indianapolis, IN 46290 (317) 818-3100

DEFENDANTS

C.R. Bard, Inc., Bard Peripheral Vascular, Inc. and Does 1 through 100

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

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

Attorneys *(If Known)*

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

- ☐ 1 U.S. Government Plaintiff
- ☐ 3 Federal Question *(U.S. Government Not a Party)*
- ☐ 2 U.S. Government Defendant
- ☒ 4 Diversity *(Indicate Citizenship of Parties in Item III)*

III. CITIZENSHIP OF PRINCIPAL PARTIES *(Place an "X" in One Box for Plaintiff and One Box for Defendant)*
(For Diversity Cases Only)

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

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

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

REAL PROPERTY
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

TORTS

PERSONAL INJURY
- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers' Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury
- ☐ 362 Personal Injury - Medical Malpractice

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

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

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

PRISONER PETITIONS

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

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

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

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

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

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

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

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

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

OTHER STATUTES
- ☐ 375 False Claims Act
- ☐ 400 State Reapportionment
- ☐ 410 Antitrust
- ☐ 430 Banks and Banking
- ☐ 450 Commerce
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced and Corrupt Organizations
- ☐ 480 Consumer Credit
- ☐ 490 Cable/Sat TV
- ☐ 850 Securities/Commodities/ Exchange
- ☐ 890 Other Statutory Actions
- ☐ 891 Agricultural Acts
- ☐ 893 Environmental Matters
- ☐ 895 Freedom of Information Act
- ☐ 896 Arbitration
- ☐ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ☐ 950 Constitutionality of State Statutes

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

☒ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from Another District *(specify)* ☐ 6 Multidistrict Litigation

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing *(Do not cite jurisdictional statutes unless diversity)*:
28 USC 1332 - Diversity

Brief description of cause:
IVC Filter Medical Device failed causing personal injury

VII. REQUESTED IN COMPLAINT:

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

DEMAND $

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

VIII. RELATED CASE(S) IF ANY

(See instructions): JUDGE David G. Campbell USDC Ariz DOCKET NUMBER MDL 02641

DATE 09/16/2015

SIGNATURE OF ATTORNEY OF RECORD /s/ Frederick R. Hovde

FOR OFFICE USE ONLY

RECEIPT # AMOUNT APPLYING IFP JUDGE MAG. JUDGE