UNITED STATES DISTRICT COURT EASTERN DISTRICT OF MISSOURI

AVA E. LANGFORD, and) Case No			
DAVID R. BROWN, individually and as wife and husband)) COMPLAINT FOR DAMAGES			
Plaintiffs,) 1. NEGLIGENCE			
50 ×) 2. FAILURE TO WARN			
VS.	3. DESIGN DEFECT			
) 4. MANUFACTURING DEFECT			
) 5. BREACH OF IMPLIED			
) WARRANTY			
C.R. BARD, INC., a foreign corporation,) 6. NEGLIGENT			
and BARD PERIPHERAL VASCULAR,) MISREPRESENTATION			
INC., a foreign corporation,) 7. LOSS OF CONSORTIUM			
Defendants.) DEMAND FOR A JURY TRIAL			

COMPLAINT

Plaintiffs, AVA ELIZABETH LANGFORD (hereinafter referred to as "Ava Langford") and DAVID RICARDO BROWN (hereinafter referred to as "David Brown), individually and as wife and husband, by and through their undersigned attorneys, hereby sues defendants C. R. BARD, INC., and BARD PERIPHERAL VASCULAR, INC. (collectively, the "Defendants") and allege as follows:

PARTIES

Plaintiffs

1. Plaintiffs, Ava Langford and David Brown, at all times relevant and material herein to this action, were and are citizens of, resided in, and continues to reside in St. Louis, St. Louis County, Missouri. On or about September of 2008, Plaintiff, Ava Langford underwent placement of a Bard G2 filter or G2 Filter System (hereafter G2, G2 Filter or G2 Filter System) at St. Joseph's Medical Center in Peoria, Illinois. This G2 filter system subsequently failed.

Case: 4:15-cv-01749 Doc. #: 1 Filed: 11/24/15 Page: 2 of 32 PageID #: 2

Specifically, during her explant procedure it was discovered that at least one (1) of the struts of the IVC filter fractured and became lodged within her back. Plaintiffs have incurred significant medical expenses and have endured extreme pain and suffering, loss of enjoyment of life, disability, and other losses.

2. Plaintiffs, Ava Langford and David Brown, were and are, at all times relevant to this action, legally married as husband and wife. Plaintiff, David Brown, brings this action for *inter alia*, the loss of consortium, comfort, and society he suffered due to the personal injuries suffered by his wife, Ava Langford.

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 of business 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 Missouri. At all times relevant hereto, Defendant Bard was or has been engaged in business in Missouri and has conducted substantial business activity in Missouri. Defendant has also carried on solicitation or service activities in the State of Missouri.

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 is a corporation duly organized and existing under the laws of the State of 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,

[2]

Case: 4:15-cv-01749 Doc. #: 1 Filed: 11/24/15 Page: 3 of 32 PageID #: 3

including Missouri. At all times relevant hereto, Defendant Bard was or has been engaged in business in Missouri and has conducted substantial business activity in Missouri. Defendant has also carried on solicitation or service activities in the State of Missouri.

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

JURISDICTION AND VENUE

6. Plaintiffs have suffered damages in an amount that exceeds the jurisdictional minimum of this Court.

7. 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.

8. 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 this District as defendants sold these products in this District and have at all relevant times the plaintiffs have resided in this District.

GENERAL FACTUAL ALLEGATIONS

9. Plaintiffs bring this case for serious personal injuries that Ava Langford suffered as result of a surgically implanted medical device, known as a Bard G2 Filter System, which fractured within her body and causing serious and ongoing physical, emotional, and economic damages.

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

[3]

Case: 4:15-cv-01749 Doc. #: 1 Filed: 11/24/15 Page: 4 of 32 PageID #: 4

11. Prior to Plaintiff, Ava Langford, being implanted with a G2 Filter on or about September 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, 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 or should have known that these risks for the Recovery Filter and the 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 the G2 Filter System contained conditions, which Defendants did not intend, which resulted in the device not performing as safely as the ordinary consumer would expect.
- d. Despite being aware of these risks, Defendants misrepresented, omitted, and/or failed to provide adequate warnings of these risks or instructions for safe use.
- e. Even when Defendants designed and began marketing what they alleged to be a device that specifically reduced these risks, they still failed to issue a recall or notify consumers that a safer device was available.

A. INFERIOR VENA CAVA FILTERS GENERALLY

12. 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.

Case: 4:15-cv-01749 Doc. #: 1 Filed: 11/24/15 Page: 5 of 32 PageID #: 5

13. 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.

14. 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.

15. 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.

16. 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.

17. 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

[5]

Case: 4:15-cv-01749 Doc. #: 1 Filed: 11/24/15 Page: 6 of 32 PageID #: 6

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

18. 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 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.

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 manufacture to bypass the rigorous safety scrutiny required by the pre-market approval process.

Case: 4:15-cv-01749 Doc. #: 1 Filed: 11/24/15 Page: 7 of 32 PageID #: 7

19. 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.

20. 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.

ii. What It Is and How It Is Used

21. 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" with the vena cava, and the long struts with attached hooks are designed to primarily to prevent the device from migrating in response to "normal respiratory movement" or "pulmonary embolism."

22. 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

Case: 4:15-cv-01749 Doc. #: 1 Filed: 11/24/15 Page: 8 of 32 PageID #: 8

small diameter catheter. The metal struts then reassume their original shape when warmed to body temperature in the vena cava.

23. 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 the 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

24. 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.

25. 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, and 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

² See e.g., Hull JE, Robertson 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.

Case: 4:15-cv-01749 Doc. #: 1 Filed: 11/24/15 Page: 9 of 32 PageID #: 9

devices that have perforated the vena cava, the device may be irremovable. These patients are faced with a lifetime of future risk.

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

27. 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 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.

28. 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*.

29. 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

Case: 4:15-cv-01749 Doc. #: 1 Filed: 11/24/15 Page: 10 of 32 PageID #: 10

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

30. 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.

31. 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.

32. 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.

33. 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

Case: 4:15-cv-01749 Doc. #: 1 Filed: 11/24/15 Page: 11 of 32 PageID #: 11

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

34. In 2004, 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 clearance 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

35. 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 Bard G2 for the same intended uses as the Recovery Filter, except that it was not cleared for retrievable use.³

36. 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*

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

Case: 4:15-cv-01749 Doc. #: 1 Filed: 11/24/15 Page: 12 of 32 PageID #: 12

stresses. Not surprisingly, the G2 Filter's design causes it to be of insufficient integrity and strength to withstand normal *in vivo* body stresses so as to resist fracturing, migrating, tilting, and/or perforating the inferior vena cava.

37. 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.

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

39. 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; (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.

40. 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

[12]

Case: 4:15-cv-01749 Doc. #: 1 Filed: 11/24/15 Page: 13 of 32 PageID #: 13

and the published medical literature), this representation does not accurately reflect the true incidence of device fracture for the G2 Filter.

41. 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

42. Upon information and belief, Plaintiffs allege 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.

43. 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 and 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.

44. 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

Case: 4:15-cv-01749 Doc. #: 1 Filed: 11/24/15 Page: 14 of 32 PageID #: 14

was safe and effective for retrievable use prior to the FDA approving the G2 Filter System for retrievable use.

45. 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, her 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.

46. 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.

47. Plaintiffs further allege 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 AVA LANGFORD

48. On or about September 2008, a Bard G2 Filter was implanted in Plaintiff, Ava Langford.

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

[14]

Case: 4:15-cv-01749 Doc. #: 1 Filed: 11/24/15 Page: 15 of 32 PageID #: 15

50. This G2 filter system subsequently failed. Specifically, during her explant procedure it was discovered that at least one (1) of the struts of the IVC filter fractured and became lodged within her back. Plaintiff has incurred significant medical expenses and have endured extreme pain and suffering, loss of enjoyment of life, disability, and other losses.

FRAUDULENT CONCEALMENT

51. 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 Plaintiffs' part, for the purpose of obtaining delay on Plaintiffs' part in filing on their causes of action. Defendants' fraudulent concealment did result in such delay.

52. 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.

53. Ava Langford and her health care providers could not reasonably have discovered the claims made herein until at the earliest the date of May of 2012.

54. 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

55. 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.

56. 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.

57. 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 Plaintiffs for their damages.

58. 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

[16]

Case: 4:15-cv-01749 Doc. #: 1 Filed: 11/24/15 Page: 17 of 32 PageID #: 17

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

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

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

61. Defendants designed, manufactured, marketed, inspected, labeled, promoted, distributed and sold the G2 Filter implanted in Ava Langford.

62. 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.

63. 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.

64. 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;

Case: 4:15-cv-01749 Doc. #: 1 Filed: 11/24/15 Page: 18 of 32 PageID #: 18

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

65. 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.

66. 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.

67. Defendants breached their duty to exercise reasonable and prudent care in the development, testing, design, manufacture, inspection, marketing, labeling, promotion, distribution and sale of the Recovery Filter 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 devices available for the same purpose;
- c. Failing to use reasonable care in manufacturing the product and producing a product that differed from the Defendants' 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;
- 1. 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 adequate post-market surveillance program.

Case: 4:15-cv-01749 Doc. #: 1 Filed: 11/24/15 Page: 20 of 32 PageID #: 20

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

69. As a direct and proximate result of the foregoing negligent acts and omissions by Defendants, Plaintiffs 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

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

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

72. 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.

73. 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.

[20]

Case: 4:15-cv-01749 Doc. #: 1 Filed: 11/24/15 Page: 21 of 32 PageID #: 21

74. 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.

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

76. 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.

77. Plaintiff and her 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.

78. 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.

79. 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.

80. As a direct and proximate result of Defendants' lack of sufficient warning and/or instructions, Plaintiff Ava Langford 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

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

82. 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.

83. The G2 Filter was expected to, and did reach its intended consumers without substantial change in the condition it was in when it left Defendants' possession. In the

Case: 4:15-cv-01749 Doc. #: 1 Filed: 11/24/15 Page: 22 of 32 PageID #: 22

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

84. 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.

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

86. Plaintiff and her health care providers used the G2 Filter in a manner that was reasonably foreseeable to Defendants.

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

88. As a direct and proximate result of the G2 Filter's defective design, 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.

<u>FOURTH CAUSE OF ACTION</u> <u>STRICT PRODUCTS LIABILITY – MANUFACTURING DEFECT</u>

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

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

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

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

93. 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.

[22]

Case: 4:15-cv-01749 Doc. #: 1 Filed: 11/24/15 Page: 23 of 32 PageID #: 23

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

FIFTH CAUSE OF ACTION BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY

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

96. 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.

97. At the time and place of the sale, distribution, and supply of the Defendants' G2 Filter System to Plaintiff by way of her 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.

98. 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.

99. Defendants impliedly represented and warranted to the healthcare community, Plaintiff and her 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.

100. 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,

[23]

Case: 4:15-cv-01749 Doc. #: 1 Filed: 11/24/15 Page: 24 of 32 PageID #: 24

through her 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.

101. Plaintiff and her 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.

102. 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.

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

104. As a proximate result of Defendants breaching their implied warranties, Plaintiff Ava Langford 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

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

Case: 4:15-cv-01749 Doc. #: 1 Filed: 11/24/15 Page: 25 of 32 PageID #: 25

106. At all times relevant to this cause, and as detailed *supra*, Defendants negligently provided Plaintiff, her 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.

107. 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 documents that were included in the packaging of the G2 Filter that was implanted in Plaintiff.

108. 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.

Case: 4:15-cv-01749 Doc. #: 1 Filed: 11/24/15 Page: 26 of 32 PageID #: 26

109. 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.

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

111. Defendants knew and had reason to know that Plaintiff, her 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.

112. 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.

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

114. Plaintiff, her health care providers and general medical community reasonably relied upon misrepresentations and omissions made by Defendants where the concealed and

[26]

Case: 4:15-cv-01749 Doc. #: 1 Filed: 11/24/15 Page: 27 of 32 PageID #: 27

misrepresented facts were critical to understanding the true dangers inherent in the use of the G2 Filter.

115. Plaintiff and her 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

116. Plaintiff, David Brown 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.

117. David Brown is and was at all times relevant to this action, the legal husband of Ava Langford, and they have at all times relevant to this action, lived together as husband and wife.

118. As a proximate result of the personal injuries suffered by Ava Langford, as described in this complaint, David Brown has been deprived of the benefits of their marriage including her love, affection, society, and consortium, and other wifely duties and actions. Ava Langford provided David Brown with all of the benefits of a marriage between husband and wife, prior to her implantation with the defective and unreasonably dangerous G2 Filter and resulting injuries described herein.

119. David Brown has also suffered the permanent loss of his wife's daily and regular contribution to the household duties and services, which each provides to the household as husband and wife.

120. David Brown has also incurred the costs and expenses related to the medical care, treatment, medications, and hospitalization to which Ava Langford was subjected for the physical injuries she suffered as a proximate result of her use of the G2 Filter. David Brown will

[27]

Case: 4:15-cv-01749 Doc. #: 1 Filed: 11/24/15 Page: 28 of 32 PageID #: 28

continue to incur the future costs and expenses related to the care, treatment, medications, and hospitalization of Ava Langford due to her injuries from the G2 Filter.

121. David Brown has suffered loss of consortium, as described herein, including the past, present, and future loss of his wife's companionship, services, society, and the ability of Ava Langford to provide him 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 his pain, suffering, and mental and emotional distress and worry.

PUNITIVE DAMAGES ALLEGATIONS

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

123. 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.

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

- a. Inform or warn Plaintiff or her health care providers of the dangers;
- b. To establish and maintain an adequate quality and post-market surveillance system; and
- c. Recall the G2 Filter from the market

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

126. 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 pain and suffering, for all claims and causes of action relevant to this action;
- c. Plaintiffs be awarded all appropriate costs, fees, expenses, and prejudgment 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 AND BPV.

- 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;
- For pre-judgment and post-judgment interest pursuant to the laws of the State of Missouri;
- 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 AND BPV.

- 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 Missouri;
- 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 THIRD CAUSE OF ACTION FOR STRICT LIABILITY – DESIGN DEFECT AGAINST DEFENDANTS BARD AND BPV.

- 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;
- For pre-judgment and post-judgment interest pursuant to the laws of the State of Missouri;
- 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 FOURTH CAUSE OF ACTION FOR STRICT LIABILITY – MANUFACTURING DEFECT AGAINST DEFENDANTS BARD AND BPV.

- 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 Missouri;
- 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 FIFTH CAUSE OF ACTION FOR BREACH OF IMPLIED WARRANTY AGAINST DEFENDANTS BARD AND BPV.

- 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 Missouri;
- 4. Costs of suit incurred herein; and
- 5. For such other and further relief as the court may deem just and proper.

AS TO THE SIXTH CAUSE OF ACTION FOR NEGLIGENT MISREPRESENTATION/ CONSUMER FRAUD AGAINST DEFENDANTS BARD AND BPV.

- 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;
- For pre-judgment and post-judgment interest pursuant to the laws of the State of Missouri;
- 4. Costs of suit incurred herein; and
- 5. 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 AND BPV.

- 1. General damages including loss of consortium 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

Missouri;

- 4. Costs of suit incurred herein; and
- 5. For such other and further relief as the court may deem just and proper.

DEMAND FOR JURY TRIAL

Plaintiffs hereby demand a trial by jury on all issues.

Case: 4:15-cv-01749 Doc. #: 1 Filed: 11/24/15 Page: 32 of 32 PageID #: 32

Dated: November 24, 2015.

By: <u>/s/ Robert D. Rowland</u> Robert D. Rowland, Esq. #39079MO Goldenberg Heller Antognoli & Rowland, P.C. 2227 South State Route 157 P.O. Box 959 Edwardsville, IL 62025 Telephone: 618-656-5150 Facsimile: 618-656-6230 Email: rrowland@ghalaw.com

To be admitted Pro Hac Vice:

Teresa C. Toriseva, Esq. TORISEVA LAW 1446 National Road Wheeling, West Virginia 26003 Telephone: (304) 238-0066 Email: <u>ceo@torisevalaw.com</u>

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

JS 44 (Rev. 12/12) Case: 4:15-cv-01749 Doc #: 12-2 Filed: 11/24/15 Page: 1 of 1 PageID #: 33

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 Ava E. Langford and Dav husband, (b) County of Residence of (E)		t. Louis County		Inc., a foreign corp foreign corporation County of Residence	foreign corporation and E poration and Bard Periph n,	New Jersey DNLY)
(c) Attorneys (Firm Name, Robert D. Rowland, Esq. 2227 South State Route Telephone: 618-656-515	157, P.O. Box 959, Ed	-				, Atlantic Station, 201 17th 3, Phone: 404-322-6050
II. BASIS OF JURISDI	CTION (Place an "X" in G	ne Box Only)	III. CI	TIZENSHIP OF P	RINCIPAL PARTIES	(Place an "X" in One Box for Plaintiff
□ 1 U.S. Government Plaintiff	□ 3 Federal Question (U.S. Government)	Not a Party)			TF DEF ↓ □ ↓ Incorporated or P of Business In 7	
2 U.S. Government Defendant	A Diversity (Indicate Citizensh)	ip of Parties in Item III)			2 D 2 Incorporated and of Business In	Another State
				en or Subject of a 🛛 🗖 reign Country	3 🗇 3 Foreign Nation	
IV. NATURE OF SUIT		1				
	TO PERSONAL INJURY □ 310 Airplane □ 315 Airplane Product Liability □ 320 Assault, Libel &	PERSONAL INJUR' → 365 Personal Injury - Product Liability → 367 Health Care/ Pharmaceutical Personal Injury Product Liability → 368 Asbestos Personal Injury Product Liability → 200 Other Fraud → 371 Truth in Lending → 380 Other Personal → Property Damage → 700 Other Fraud → 371 Truth in Lending → 380 Other Personal → Property Damage → roduct Liability → PRISONER PETITION → Habeas Corpus: → 463 Alien Detainee → 510 Motions to Vacate Sentence → 530 General → 535 Death Penalty → Other: → 540 Mandamus & Othe → 550 Civil Rights → 555 Prison Condition → 560 Civil Detainee - Conditions of Confinement	Y □ 62 □ 69 XTY □ 71 □ 72 □ 74 □ 75 NS □ 79 × □ 46	DRFEITURE/PENALTY 5 Drug Related Seizure of Property 21 USC 881 0 Other 10 Other 10 Fair Labor Standards Act 10 Labor/Management Relations 10 Railway Labor Act 11 Family and Medical Leave Act 10 Other Labor Litigation 11 Employee Retirement Income Security Act 11 Income Security Act 11 MMIGRATION 21 Naturalization Application 5 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 440 Ocommerce 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
	moved from 3 te Court	Appellate Court		bened Anothe (specify)	er District Litigation	
VI. CAUSE OF ACTIO	Jurisdictional - 28	USC 1332(a)(1)	re filing (1	Do not cite jurisdictional sta	tutes unless diversity):	
VII. REQUESTED IN COMPLAINT:	UNDER RULE 2			EMAND \$	CHECK YES only JURY DEMAND	r if demanded in complaint: : X Yes □ No
VIII. RELATED CASI IF ANY	E(S) In Re: Barb IVC (See instructions):	C Filters Products Li _{JUDGE} David C. C	-	-	docket number M	DL No. 2641
DATE 11/24/2015		SIGNATURE OF ATT		DF RECORD		
FOR OFFICE USE ONLY RECEIPT #	MOUNT	APPLYING IFP		JUDGE	MAG. JU	DGE

UNITED STATES DISTRICT COURT EASTERN DISTRICT OF MISSOURI

Ava E. Langford, and David R. Brown, individually and as wife and husband,))
Plaintiff,)
V. C.R. Bard, Inc., a foreign corporation, and Bard Peripheral Vascular Inc., a foreign , corporation,)) Case No.))
Defendant,)

ORIGINAL FILING FORM

THIS FORM MUST BE COMPLETED AND VERIFIED BY THE FILING PARTY WHEN INITIATING A NEW CASE.

THIS SAME CAUSE, OR A SUBSTANTIALLY EQUIVALENT COMPLAINT, WAS

PREVIOUSLY FILED IN THIS COURT AS CASE NUMBER

AND ASSIGNED TO THE HONORABLE JUDGE

THIS CAUSE IS RELATED, BUT IS NOT SUBSTANTIALLY EQUIVALENT TO ANY

PREVIOUSLY FILED COMPLAINT. THE RELATED CASE NUMBER IS ______ AND

THAT CASE WAS ASSIGNED TO THE HONORABLE ______. THIS CASE MAY,

THEREFORE, BE OPENED AS AN ORIGINAL PROCEEDING.

NEITHER THIS SAME CAUSE, NOR A SUBSTANTIALLY EQUIVALENT

COMPLAINT, HAS BEEN PREVIOUSLY FILED IN THIS COURT, AND THEREFORE

MAY BE OPENED AS AN ORIGINAL PROCEEDING.

The undersigned affirms that the information provided above is true and correct.

Date: <u>11/24/2015</u>

| |

/s/ Robert D. Rowland Signature of Filing Party AO 399 (01/09) Waiver of the Service of Summons

UNITED STATES DISTRICT COURT

for the

Eastern District of Missouri

Ava E. Langford, and David R. Brown, individually and as wife and husband.

Plaintiff

v.

Civil Action No.

C.R. Bard, Inc., a foreign corporation

Defendant

WAIVER OF THE SERVICE OF SUMMONS

To: Robert D. Rowland

(*Name of the plaintiff's attorney or unrepresented plaintiff*)

I have received your request to waive service of a summons in this action along with a copy of the complaint, two copies of this waiver form, and a prepaid means of returning one signed copy of the form to you.

I, or the entity I represent, agree to save the expense of serving a summons and complaint in this case.

I understand that I, or the entity I represent, will keep all defenses or objections to the lawsuit, the court's jurisdiction, and the venue of the action, but that I waive any objections to the absence of a summons or of service.

I also understand that I, or the entity I represent, must file and serve an answer or a motion under Rule 12 within 60 days from _______, the date when this request was sent (or 90 days if it was sent outside the United States). If I fail to do so, a default judgment will be entered against me or the entity I represent.

Date:

Printed name of party waiving service of summons

Signature of the attorney or unrepresented party

Printed name

Address

E-mail address

Telephone number

Duty to Avoid Unnecessary Expenses of Serving a Summons

Rule 4 of the Federal Rules of Civil Procedure requires certain defendants to cooperate in saving unnecessary expenses of serving a summons and complaint. A defendant who is located in the United States and who fails to return a signed waiver of service requested by a plaintiff located in the United States will be required to pay the expenses of service, unless the defendant shows good cause for the failure.

"Good cause" does *not* include a belief that the lawsuit is groundless, or that it has been brought in an improper venue, or that the court has no jurisdiction over this matter or over the defendant or the defendant's property.

If the waiver is signed and returned, you can still make these and all other defenses and objections, but you cannot object to the absence of a summons or of service.

If you waive service, then you must, within the time specified on the waiver form, serve an answer or a motion under Rule 12 on the plaintiff and file a copy with the court. By signing and returning the waiver form, you are allowed more time to respond than if a summons had been served. AO 399 (01/09) Waiver of the Service of Summons

UNITED STATES DISTRICT COURT

for the

Eastern District of Missouri

Ava E. Langford, and David R. Brown, individually and as wife and husband,

, Plaintiff

v.

Bard Peripheral Vascular Inc., a foreign corporation

Defendant

Civil Action No.

WAIVER OF THE SERVICE OF SUMMONS

To: Robert D. Rowland

(*Name of the plaintiff's attorney or unrepresented plaintiff*)

I have received your request to waive service of a summons in this action along with a copy of the complaint, two copies of this waiver form, and a prepaid means of returning one signed copy of the form to you.

I, or the entity I represent, agree to save the expense of serving a summons and complaint in this case.

I understand that I, or the entity I represent, will keep all defenses or objections to the lawsuit, the court's jurisdiction, and the venue of the action, but that I waive any objections to the absence of a summons or of service.

I also understand that I, or the entity I represent, must file and serve an answer or a motion under Rule 12 within 60 days from _______, the date when this request was sent (or 90 days if it was sent outside the United States). If I fail to do so, a default judgment will be entered against me or the entity I represent.

Date:

Printed name of party waiving service of summons

Signature of the attorney or unrepresented party

Printed name

Address

E-mail address

Telephone number

Duty to Avoid Unnecessary Expenses of Serving a Summons

Rule 4 of the Federal Rules of Civil Procedure requires certain defendants to cooperate in saving unnecessary expenses of serving a summons and complaint. A defendant who is located in the United States and who fails to return a signed waiver of service requested by a plaintiff located in the United States will be required to pay the expenses of service, unless the defendant shows good cause for the failure.

"Good cause" does *not* include a belief that the lawsuit is groundless, or that it has been brought in an improper venue, or that the court has no jurisdiction over this matter or over the defendant or the defendant's property.

If the waiver is signed and returned, you can still make these and all other defenses and objections, but you cannot object to the absence of a summons or of service.

If you waive service, then you must, within the time specified on the waiver form, serve an answer or a motion under Rule 12 on the plaintiff and file a copy with the court. By signing and returning the waiver form, you are allowed more time to respond than if a summons had been served.