	1:13-cv-01219-MMM-JAG #1 Page 1 of 41 Saturday, 11 May, 2013 07:16:38 PM Clerk, U.S. District Court, ILCE
1 2 3 4 5 6 7 8 9 10	Tor A. Hoerman, IL Bar No. 6229439 Jacob W. Plattenberger, IL Bar No.6297431 TORHOERMAN LAW LLC 101 West Vandalia Street, Ste. 350 Edwardsville, IL 62025 Telephone: (618) 656-4400 Facsimile: (618) 656-4401 Ramon Rossi Lopez (CSB No. 86361) ( <i>Pro Hac Vice Application Anticipated</i> ) LOPEZ McHUGH LLP 100 Bayview Circle, Suite 5600 Newport Beach, CA 92660 Telephone: (949) 737-1501 Facsimile: (949) 737-1504 Attorneys for Plaintiff
11	UNITED STATES DISTRICT COURT
12 13	
13	CENTRAL DISTRICT OF ILLINOIS
14 15 16 17 18 19 20 21 22 23 24 25	HENRY KILVER and JUDY KILVER, individually and as husband and wife, Plaintiffs, VS. VS. COMPLAINT FOR DAMAGES VS. 1. NEGLIGENCE C.R. BARD, INC., a foreign corporation, BARD PERIPHERAL VASCULAR, INC., an Arizona corporation, and DOES 1 through 100 inclusive, Defendants. Defendants. (COMPLAINT FOR DAMAGES CASE No. (COMPLAINT FOR DAMAGES CASE No. (COMPLAINT FOR DAMAGES (COMPLAINT FOR DAMAGES (C
26 27 28	Plaintiffs HENRY and JUDY KILVER, individually and as husband and wife, by and through their undersigned attorneys, hereby sue defendants C.R. BARD, INC.; BARD

PERIPHERAL VASCULAR, INC.; and DOES 1 through 10 (collectively, the "Defendants") and allege as follows:

# **PARTIES**

# **Plaintiffs**

1. Plaintiff Henry Kilver at all times relevant to this action resided in and continues to reside in East Peoria, Illinois. On or about January 25, 2005, he underwent placement of a Recovery® Filter for the prevention of pulmonary embolism. On or before February 14, 2011 the device failed and migrated to Plaintiff's The Recovery® Filter subsequently failed and migrated to Plaintiff's heart causing life threatening injuries. Plaintiff was caused to undergo extensive medical care and treatment, including emergency open heart surgery on February 15, 2011, as a result of the failure of the Recovery® Filter. Plaintiff has suffered and will continue to suffer significant medical expenses, pain and suffering, loss of enjoyment of life, disability, and other losses.

2. Plaintiff Judy Kilver at all times relevant to this action resided in and continues to reside in East Peoria, Illinois. Plaintiffs Henry Kilver and Judy Kilver were and are, at all time relevant to this action, legally married as husband and wife. Plaintiff Judy Kilver brings this action for, *inter alia*, the loss of consortium, comfort, and society she suffered due to the personal injuries suffered by her husband, Henry Kilver.

# **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 Illinois.

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 Illinois.

5. All references to "Defendants" hereafter shall refer to defendants Bard, BPV, and DOES 1 through 10.

6. The true names, identities, or capacities, whether individual, associate, corporate or otherwise of defendants, DOES 1 through 10, inclusive, are unknown to Plaintiff who, therefore, sues said defendants by such fictitious names. When the true names, identities or capacities of said fictitiously designated defendants are ascertained, plaintiff 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.

Jurisdiction is proper in this Court under 28 U.S.C. § 1332(a) (1) because the

Plaintiffs and the Defendants are citizens of different states, and the amount in controversy exceeds seventy-five thousand dollars (\$75,000.00), excluding interest and costs

9. Venue is proper in this Court pursuant to 28 U.S.C. §1391 since the Plaintiffs resided in the Central District of Illinois at the time of implantation of the Recovery® filter and the resulting injury, and the Defendants regularly conduct business in this District.

# **GENERAL FACTUAL ALLEGATIONS**

10. Plaintiffs bring this case for serious personal injuries Henry Kilver suffered as result of a surgically implanted medical device, known as a Recovery® Filter System (hereafter "Recovery Filter"), failing and migrating within his body and causing serious and ongoing physical, emotional, and economic damages.

11. The Recovery® Filter was designed, manufactured, prepared, compounded, assembled, processed, labeled, marketed, distributed, and sold by Defendants from approximately 2003 through August 2005 for the prevention of blood clots (thrombi) from travelling from the lower portions of the body to the heart and lungs.

12. Prior to Plaintiff Henry Kilver being implanted with a Recovery® Filter in early 2005, 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 adequate clinical testing to determine how the device would function once permanently implanted in the human body and subjected to *in vivo* stresses.

b. Defendants knew and/or should have known that the Recovery® Filter had an
unreasonably 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 conditions or post-implant procedures, such as morbid obesity or open abdominal procedures, could affect the safety and integrity of the device. Further, Defendants knew or should have known that these risks for Recovery® Filter were and are substantially higher than other similar devices.

c. Further, Defendants knew and/or should have known that the Recovery® Filter
contained conditions, that Defendants did not intend, which resulted in the device not performing
as safely as the ordinary consumer would expect when used in an intended or reasonably
foreseeable manner.

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 notify consumers that a safer device was available.

A. INFERIOR VENA CAVA FILTERS GENERALLY

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.

14. 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.

15. 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.

16. 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.

17. 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.

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

from a patient after the risk of PE has subsided. These IVC filter designs, however, were not intended to remain within the human body for indeterminate periods of time. In other words, the initial designs of retrievable IVC filters were intended to remain implanted for a finite period of time. The Recovery® Filter System and the subsequent G2® Filter manufactured by Bard and BPV are examples of retrievable filters.

B.

# THE RECOVERY FILTER®

# i. FDA Clearance and Intended Use

19. 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.<sup>1</sup> 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;

<sup>&</sup>lt;sup>1</sup> 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.

d. Chronic, recurrent pulmonary embolism where anticoagulant therapy has failed or is contraindicated.

20. 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.

21. 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 Is It and How Is It Used

22. 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 primarily to prevent the device from migrating in response to "normal respiratory movement" or "pulmonary embolism."

23. 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." Meaning, 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.

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

25. 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%.<sup>2</sup> 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.

26. 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

 <sup>&</sup>lt;sup>2</sup> 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.

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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.

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

28. Soon after the Recovery Filter's introduction to the market, Bard and BPV began receiving large numbers of adverse event reports from health care providers.

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 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 or simulated use tests, 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 postimplantation. 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; and
- f. 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. From 2003 through September 2005, Bard and BPV received ever growing numbers of AERs reporting the above described failures and patient injuries.

35. In late 2003 Defendants opened a special review of the adequacy of the design of the Recovery® Filter as it related to migration failures. As part of this review, Bard conducted bench testing to compare the migration resistance of the Recovery® Filter to other available IVC Filters. The testing concluded in March of April 2004 that the Recovery Filter had the lowest ability to resist migration of any IVC Filter device on the market. Further, the testing demonstrated that the device failed to meet its own minimum safety specifications as they relate to migration resistance. Bard failed to ever warn consumers of these facts.

36. Further, 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, yet Bard and BPV failed to warn consumers of this fact. For example, in December 2004 Bard conducted a comparison of the reported failures rates between the Recovery Filter and other available IVC Filter devices and found that the Recovery Filter was reported to have migrated, fractured, or caused perforations at rates substantially higher than any other reported device.

37. Defendants began quietly redesigning the Recovery Filter in 2004 in an attempt to correct its design flaws. However, Defendants continued to sell the Recovery® Filter until the redesigned device was cleared for marketing in August 2005 despite knowing that that Recovery Filter was unreasonably dangerous. Further, Defendants failed to adequately warn consumers

about the known risks with the device or that they were in the process of instituting necessary design changes to make it safer. The redesigned filter is known as the G2® Filter, which stands for second generation Recovery® Filter.

C.

# THE G2® FILTER SYSTEM

38. 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.<sup>3</sup>

39. 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 in vivo stresses. In other words, despite these claims of a safer device, Bard and BPV failed to confirm that the changes made to the G2® Filter were sufficient to cure the defective and unreasonably dangerous nature of the device.

40. The G2® Filter's design causes it to be of insufficient integrity and strength to withstand normal *in vivo* body stresses within the human body so as to resist fracturing, migrating, tilting, and/or perforating the inferior vena cava.

28

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

41. 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.

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

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

44. 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.

45. 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.

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

46. 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.

47. 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 the 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.

48. 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.

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1	49. The conduct of Bard and BPV as alleged in this Complaint constitutes willful,
2	wanton, gross, and outrageous corporate conduct that demonstrates a conscious disregard for the
3	safety of Plaintiff. Bard and BPV had actual knowledge of the dangers presented by the
4 5	Recovery Filter® and G2® Filter, yet consciously failed to act reasonably to:
6	a. Inform or warn Plaintiff, his physicians, or the public at large of these
7	dangers; and
8	b. Establish and maintain an adequate quality and post-market surveillance
9	system;
0	50. Despite having knowledge as early as 2003 of the unreasonably dangerous and
2	defective nature of the Recovery® Filter, Bard and BPV consciously disregarded the known
3	risks and continued to actively market and offer for sale the Recovery® and G2® Filter Systems.
4	51. Plaintiff further alleges that the Manufacturing Defendants acted in willful,
5	wanton, gross and total disregard for the health and safety of the users or consumers of their
7	Recovery® Filter and G2® Filter Systems, acted to serve their own interests, and having reason
8	to know and consciously disregarding the substantial risk that their product might kill or
9	significantly harm patients, or significantly injure the rights of others, consciously pursued a
0	course of conduct knowing that such conduct created a substantial risk of significant harm to
1 2	other persons.
3	SPECIFIC FACTUAL ALLEGATIONS AS TO PLAINTIFF

52. On or about January 25, 2005, Plaintiff Henry Kilver underwent surgical placement of a Recovery® Filter to prevent pulmonary embolism (PE). The Recovery® Filter subsequently failed and migrated to the Plaintiff's heart. This Recovery® Filter device was

designed, manufactured, prepared, compounded, assembled, processed, marketed, distributed, and sold by Defendants Bard and BPV.

53. On or before February 14, 2011 the device failed and migrated to Plaintiff's The Recovery® Filter subsequently failed and migrated to Plaintiff's heart causing life threatening injuries. Plaintiff was caused to undergo extensive medical care and treatment, including emergency open heart surgery on February 15, 2011, as a result of the failure of the Recovery® Filter. Plaintiff has suffered and will continue to suffer significant medical expenses, pain and suffering, loss of enjoyment of life, disability, and other losses.

# CORPORATE/VICARIOUS LIABILITY

54. 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.

55. 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.

56. 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 his damages.

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

# FIRST CAUSE OF ACTION

# **NEGLIGENCE**

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

59. 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.

60. Defendants designed, manufactured, marketed, inspected, labeled, promoted, distributed and sold the Recovery® Filter that was implanted in Henry Kilver.

61. Defendants had a duty to exercise reasonable and prudent care in the development, testing, design, manufacture, inspection, marketing, labeling, promotion,

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distribution and sale of the Recovery® Filter so as to avoid exposing others to foreseeable and unreasonable risks of harm.

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

63. At the time of manufacture and sale of the Recovery® Filter (2002 until October 2005), Defendants knew or should have known that the Recovery® 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;

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

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

64. At the time of manufacture and sale of the Recovery® Filter (2002 until October 2005), Defendants knew or should have known that using the Recovery® 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.

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

66. 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 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;

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1	d.	Failing to use reasonable care to warn or instruct Plaintiff, Plaintiff's physicians,
2		or the general health care community about the Recovery® Filter's substantially
3		dangerous condition or about facts making the product likely to be dangerous;
4		
5	e.	Failing to perform reasonable pre and post-market testing of the Recovery® Filter
6		to determine whether or not the product was safe for its intended use;
7	f.	Failing to provide adequate instructions, guidelines, and safety precautions to
8		those persons to whom it was reasonably foreseeable would prescribe, use, and
9		
10		implant the Recovery® Filter;
11	g.	Advertising, marketing and recommending the use of the Recovery® Filter, while
12		concealing and failing to disclose or warn of the dangers known by Defendants to
13		be connected with and inherent in the use of the Recovery® Filter;
14	h.	Representing that the Recovery® Filter was safe for its intended use when in fact,
15		
16		Defendants knew and should have known the product was not safe for its intended
17		purpose;
18	i.	Continuing manufacture and sale of the Recovery® Filter with the knowledge that
19		said product was dangerous and not reasonably safe, and failing to comply with
20		FDA good manufacturing regulations and policy;
21		
22	j.	Failing to use reasonable and prudent care in the design, research, manufacture,
23		and development of the Recovery® Filter so as to avoid the risk of serious harm
24		associated with the use of the Recovery® Filter;
25	k.	Advertising, marketing, promoting and selling Recovery® Filter for uses other
26		than as approved and indicated in the product's label.
27		than as approved and indicated in the product's label;
28		

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

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

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

68. As a direct and proximate result of the foregoing negligent acts and omissions by Defendants, Plaintiff Henry Kilver 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**

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

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

71. 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 Recovery® Filter, which was implanted in Plaintiff, that the Recovery® 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.

72. 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.

73. Despite this duty, Defendants failed to adequately warn of material facts regarding the safety and efficacy of the Recovery® Filter, such as the device's unreasonably dangerous propensities, and further failed to adequately provide instructions on the safe and proper use of the device. The warnings, labels, and instructions provided by Defendants at all times relevant to this action, are and were inaccurate, intentionally misleading, and misrepresented the risks and benefits and lack of safety and efficacy associated with the device.

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

75. 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.

76. 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.

77. Therefore, the Recovery® 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.

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

79. As a direct and proximate result of Defendants' lack of sufficient warning and/or instructions, Plaintiff Henry Kilver 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**

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

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

82. The Recovery® 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 Recovery® Filter implanted in Plaintiff were reasonably foreseeable to Defendants.

83. The Recovery® 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. Defendants knew or reasonably should have known that consumers of the

Recovery® Filter would not realize the danger associated with using the device in its intended use and/or in a reasonably foreseeable manner.

84. Additionally, the Recovery® Filter implanted in Plaintiff was defective in design, in that its risks of harm exceeded its claimed benefits. The magnitude and probability of the foreseeable risks of harm are greater in the Recovery® than any other inferior vena cava filter; the instructions and warnings accompanying the device are misleading and inadequate; and the ordinary consumer would not expect the product to fail and cause injury, especially since the device was specifically promoted to improve the health of such patients and alternative filters on the market portraying the same benefits proved to be much more reliable when used in their intended manner.

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

86. 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.

87. As a direct and proximate result of the Recovery® Filter's defective design, Plaintiff Henry Kilver 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

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

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

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

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

92. Furthermore, due to the Defendants' inadequate warnings, Plaintiff was not subjectively aware of the unreasonably dangerous condition of the device, and thus did not voluntarily choose to act in disregard of such known dangers.

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.

94. As a direct and proximate result of the Recovery® Filter's manufacturing defect, Plaintiff Henry Kilver 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 WARRANTY

95. Plaintiff re-alleges and incorporates 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 Recovery® Filter.

97. Plaintiff alleges that the adverse event report and/or the filing of this lawsuit within a reasonable time after the breach was discovered qualifies as adequate notice of the Defendant's breach of warranty.

98. Defendants through their officers, directors, agents, representatives, and written literature and packaging, and written and media advertisement, expressly warranted that the Recovery® Filter was safe and fit for use by consumers, was of merchantable quality, did not produce dangerous side effects, and was adequately tested and fit for its intended use.

99. At the time of making these express warranties, Defendants knew and should have known that the Recovery® Filter did not conform to the express warranties and representations. In fact, the Recovery® Filter is unsafe and poses serious life-threatening health risks, which Defendants failed to accurately and adequately warn about.

100. As a foreseeable, direct, and proximate result of the breach of the express warranties, Plaintiff suffered severe personal injuries and direct economic loss.

101. Plaintiff, his health care providers, and other consumers reasonably relied on the express warranties made by Defendants regarding the safety and efficacy of the Recovery® Filter.

102. Defendants breached their express warranties because the Recovery® Filter was and continues to be defective and unreasonably dangerous for its intended purpose.

103. Defendants expressly represented and warranted to the medical community and American consumers, including Plaintiff and his healthcare providers, that the Recovery® Filter was safe and fit for the purposes intended, that it was of merchantable quality, that it did not pose dangerous health risks in excess of those associated with the use of other similar devices, that the side effects were accurately reflected in the warnings, and that it was adequately tested and fit for its intended use.

104. Defendants knew the Recovery® Filter was not safe and fit for its intended use, that the device caused its users serious injuries that were not sufficiently warned of, identified, or represented by these Defendants, and that adequate pre-market testing, such as animal studies or simulated use tests, was not conducted in the Defendant's rush to get the Recovery® Filter to the market. Defendants even failed to follow-up on red flags disclosed in the limited animal and clinical testing that was performed on the Recovery® Filter. Thus, the Defendants knew that the representations and express warranties were false, misleading, and untrue, and yet they continued to promote the Recovery® Filter under these false claims until market approval was obtained for the G2® Filter in August 2005.

105. Plaintiff, through his attending physicians, reasonably relied on Defendants' representations that the Recovery® Filter would not endanger the consumer's health when determining which IVC filter to use for implantation in the Plaintiff.

106. As a foreseeable, direct and proximate result of Defendants breaching their express warranties, as described above, Plaintiff Henry Kilver has suffered significant and severe injuries to his body resulting in significant expenses for medical treatment and a substantial loss of earnings, as well as loss of enjoyment of life, disability, and other losses.

# **SIXTH CAUSE OF ACTION**

# BREACH OF IMPLIED WARRANTY

107. Plaintiff re-alleges and incorporates by reference each and every allegation contained in the foregoing paragraphs as though fully set forth herein. 108. Plaintiff alleges that the adverse event report and/or the filing of this complaint within a reasonable time after the breach was discovered satisfies the statutory notice requirement.

109. At all times relevant to this action, Defendants designed, researched, developed, manufactured, tested, labeled, inspected, advertised, promoted, marketed, sold, and distributed into the stream of commerce the Recovery® 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.

110. At the time and place of the sale, distribution, and supply of the Defendants'
Recovery® 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 Recovery® Filter System was safe and effective for its intended and reasonably
foreseeable use.

111. Defendants knew of the intended and reasonably foreseeable use of the Recovery® 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.

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

113. The representations and implied warranties made by Defendants were false, misleading, and inaccurate because the Recovery® Filter was defective, unsafe, unreasonably

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1	dangerous, and not of merchantable quality, when used in its intended and/or reasonably					
2	foreseeable manner. Specifically, at the time of Plaintiff's purchase of the Recovery® Filter from					
3	the Defendants, through his attending physicians and medical facilities, it was not in a					
4 5	merchantable condition in that:					
6	a. It was designed in such a manner so as to be prone to a statistically and					
7	unreasonably high incidence of failure, including fracture, migration,					
8	excessive tilting, and perforation of the inferior vena cava;					
9	b. It was designed in such a manner so as to result in a statistically significant					
10						
11	incidence of injury to the organs and anatomy; and					
12	c. It was manufactured in such a manner so that the exterior surface of the					
13	Recovery® Filter System was inadequately, improperly and					
14 15	inappropriately prepared and/or finished causing the device to weaken and					
15 16	fail.					
17	114. Plaintiff and his health care providers reasonably relied on the superior skill and					
18	judgment of Defendants as the designers, researchers and manufacturers of the product, as to					
19	whether the Recovery® Filter was of merchantable quality and safe and fit for its intended use,					
20	and also relied on the implied warranty of merchantability and fitness for the particular use and					
21	purpose for which the Recovery® Filter was manufactured and sold.					
22 23	115. Defendants placed the Recovery® Filter into the stream of commerce in a					
23	defective, unsafe, and unreasonably dangerous condition, and the product was expected to and					
25	did reach Plaintiff without substantial change in the condition in which the Recovery® Filter was					
26						
27	manufactured and sold.					
28						

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

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

# **SEVENTH CAUSE OF ACTION**

# **NEGLIGENT MISREPRESENTATION**

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

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

a. The safety of the Recovery® Filter;

- b. The efficacy of the Recovery® Filter;
- c. The rate of failure of the Recovery® Filter; and
- d. The approved uses of the Recovery® Filter.

120. 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 Recovery® Filter.

121. The foregoing representations and omissions by Defendants were in fact false proving that Defendants were at the very least negligent and careless in determining the truth of those statements.

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

123. 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 negligently concealed and misrepresented by Defendants. As such, Defendants knew or should have known that Plaintiff, through his attending physicians, was relying on these representations in determining which IVC filter to use for implantation.

124. The public and general health care providers were forced to rely on Defendants representations; therefore, Defendants had a duty to provide accurate information relating to the efficacy, safety, and failure rates of the Recovery® Filter.

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

126. Plaintiff Henry Kilver and his health care provider's reliance on the foregoing misrepresentations and omissions by Defendants' was the direct and proximate cause of Plaintiff's significant physical and economic harm as described herein.

# FRAUDULENT MISREPRESENTATION

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

128. At all times relevant to this cause, and as detailed above, Defendants intentionally provided Plaintiff, his physicians and the medical community, as well as the public at large, with false or inaccurate information, and/or omitted material information concerning the Recovery®
Filter System, including, but not limited to, misrepresentations regarding the following topics:

- a. The safety of the Recovery® Filter;
- b. The efficacy of the Recovery® Filter;
- c. The rate of failure of the Recovery® Filter;
- d. The pre-market testing of the Recovery® Filter; and
- e. The approved uses of the Recovery® Filter.

129. The information distributed by Defendants to the public, the medical community, and the Plaintiff was in the form of reports, press releases, advertising campaigns, labeling materials, print advertisements, commercial media containing material representations, and instructions for use, as well as through their officers, directors, agents, and representatives. These materials contained false and misleading material representations stating that the Recovery® Filter was safe and fit when used for its intended purpose or in a reasonably foreseeable manner, that it did not pose dangerous health risks in excess of those associated with the use of other similar devices, that any and all side effects were accurately reflected in the warnings, and that it was adequately tested to withstand normal placement within the human body.

130. Defendants made the foregoing misrepresentations knowing that they were false or without reasonable basis. These materials included instructions for use and a warning document that was included in the package of the Recovery® Filter that was implanted in Plaintiff.

131. Defendants' intent and purpose in making these misrepresentations was to deceive and defraud the public and the medical community, including Plaintiff's health care providers; to gain the confidence of the public and the medical community, including Plaintiff's health care providers; to falsely assure them of the quality of the Recovery® 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 Recovery® Filter.

132. The foregoing representations and omissions by Defendants were in fact false. The Recovery® Filter is not safe, fit, and effective for human use in its intended and reasonably foreseeable manner. The use of the Recovery® 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 Plaintiff suffered. Further, the device has a statistically significant higher rate of failure and injury than do other comparable devices.

133. Defendants acted to serve their own interests and having reasons to know consciously disregarded the substantial risk that the Recovery® Filter could kill or significantly harm patients.

134. 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 Recovery® Filter, thereby causing Plaintiff to sustain severe and permanent personal injuries.

1

135. 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.

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

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

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

139. 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 implantation of the Recovery® Filter as well as the numerous substantial injuries that followed. As a proximate result of Defendants' fraudulent course of action, Plaintiff Henry Kilver suffered and will continue to suffer serious physical injuries, direct economic loss, loss of enjoyment of life, disability, and other losses, in the amount to be determined at trial.

# **NINTH CAUSE OF ACTION**

#### LOSS OF CONSORTIUM

140. Plaintiff Henry Kilver 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.

141. Judy Kilver is and was at all times relevant to this action, the legal wife of Henry Kilver, and they have at all times relevant to this action, lived together as husband and wife.

142. As a proximate result of the personal injuries suffered by Henry Kilver, as described in this complaint, Judy Kilver has been deprived of the benefits of their marriage including her love, affection, society, and consortium, and other wifely duties and actions. Henry Kilver provided Judy Kilver with all of the benefits of a marriage between husband and wife, prior to his implantation with the defective and unreasonably dangerous Recovery® Filter and the resulting injuries described herein.

143. Judy Kilver has also suffered the permanent 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.

144. Judy Kilver has also incurred the costs and expenses related to the medical care, treatment, medications, and hospitalization to which Henry Kilver was subjected for the physical injuries he suffered as a proximate result of his use of the Recovery® Filter. Judy Kilver will continue to incur the future costs and expenses related to the care, treatment, medications, and hospitalization of Henry Kilver due to his injuries from the Recovery® Filter.

145. Judy Kilver has suffered loss of consortium, as described herein, including the past, present, and future loss of her husband's companionship, services, society, and the ability of Henry Kilver to provide Judy Kilver with the benefits of marriage, including *inter alia*, loss of

1	contribution to household income and loss of household services, all of which has resulted in her							
2	pain, suffering, and mental and emotional distress and worry.							
3								
4	PRAYER FOR DAMAGES							
5 6	WHEREFOR	WHEREFORE, Plaintiffs Henry Kilver and Judy Kilver, individually and as husband						
7		of on the entire complaint, as follows:						
8		Judgment to be entered against all defendants on all causes of action of						
9								
10		this Complaint;						
11	b	Plaintiffs be awarded their full, fair, and complete recovery for all claims						
12		and causes of action relevant to this action;						
13	c. 1	Plaintiffs be awarded all appropriate costs, fees, expenses, and pre-						
14		judgment and post judgment interest, as authorized by law on the						
15 16		judgments entered in Plaintiff's behalf; and,						
10	d.	Such other relief the court deems just and proper.						
18	WHEREFORE, Plaintiffs Henry Kilver and Judy Kilver, individually and as husband							
19	and wife, pray for relie	of on the entire complaint, as follows:						
20	AS TO THE FI	<b>IRST CAUSE OF ACTION FOR NEGLIGENCE AGAINST</b>						
21	DEFENDANTS BARD, BPV AND DOES 1 THROUGH 100.							
22								
23		damages according to proof at the time of trial;						
24	2. Medical	and other special damages, past, present, and future, according to proof at						
25 26	the time	of trial;						
27	3. Pre-judg	gment and post-judgment interest pursuant to the laws of the State of						
28	Illinois;							
		27						
	11	37						

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1 2 3 4 5 6 7 8 9 10 11		Costs of suit incurred herein; and For such other and further relief as the court may deem just and proper. <b>TO THE SECOND CAUSE OF ACTION FOR STRICT LIABILITY –</b> <b>TO WARN AGAINST DEFENDANTS BARD, BPV AND DOES 1 THROUGH</b> General damages according to proof at the time of trial; Medical and other special damages, past, present, and future, according to proof at the time of trial; Pre-judgment and post-judgment interest pursuant to the laws of the State of			
12 13 14 15 16 17		Illinois; Costs of suit incurred herein; and For such other and further relief as the court may deem just and proper. <b>TO THE THIRD CAUSE OF ACTION FOR STRICT LIABILITY – DESIGN</b> AGAINST DEFENDANTS BARD BPV, AND DOES 1 THROUGH 100.			
<ol> <li>18</li> <li>19</li> <li>20</li> <li>21</li> <li>22</li> <li>23</li> <li>24</li> <li>25</li> <li>26</li> <li>27</li> <li>28</li> </ol>		<ul> <li>General damages according to proof at the time of trial;</li> <li>Medical and other special damages, past, present, and future, according to proof at the time of trial;</li> <li>Pre-judgment and post-judgment interest pursuant to the laws of the State of Illinois;</li> <li>Costs of suit incurred herein; and</li> <li>For such other and further relief as the court may deem just and proper.</li> </ul>			

#### 1:13-cv-01219-MMM-JAG #1 Page 39 of 41 THROUGH 100. 1 2 1. General damages according to proof at the time of trial; 3 2. Medical and other special damages, past, present, and future, according to proof at 4 the time of trial; 5 3. Pre-judgment and post-judgment interest pursuant to the laws of the State of 6 7 Illinois; 8 4. Costs of suit incurred herein: and 9 6. For such other and further relief as the court may deem just and proper. 10 AS TO THE FIFTH CAUSE OF ACTION FOR BREACH OF EXPRESS 11 WARRANTY AGAINST DEFENDANTS BARD, BPV AND DOES 1 THROUGH 100. 12 13 1. General damages according to proof at the time of trial; 14 2. Medical and other special damages, past, present, and future, according to proof at 15 the time of trial; 16 3. Pre-judgment and post-judgment interest pursuant to the laws of the State of 17 Illinois; 18 19 4. Costs of suit incurred herein; and 20 5. For such other and further relief as the court may deem just and proper. 21 AS TO THE SIXTH CAUSE OF ACTION FOR BREACH OF IMPLIED 22 WARRANTY AGAINST DEFENDANTS BARD, BPV AND DOES 1 THROUGH 100. 23 24 1. General damages according to proof at the time of trial; 25 2. Medical and other special damages, past, present, and future, according to proof at 26 the time of trial; 27 3. Pre-judgment and post-judgment interest pursuant to the laws of the State of 28

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1 2 3 4 5 6 7 8 9		Illinois; Costs of suit incurred herein; and For such other and further relief as the court may deem just and proper. <b>O THE SEVENTH CAUSE OF ACTION FOR NEGLIGENT</b> <b>SENTATION AGAINST DEFENDANTS BARD, BPV AND DOES 1</b> <b>100.</b> General damages according to proof at the time of trial; Medical and other special damages, past, present, and future, according to proof at				
10	2.					
<ol> <li>11</li> <li>12</li> <li>13</li> <li>14</li> </ol>	2 3. Pre-judgment and post-judgment interest pursuant to the laws of the State of					
14 15	4.	Costs of suit incurred herein; and				
16	5.	For such other and further relief as the court may deem just and proper.				
17		O THE EIGHTH CAUSE OF ACTION FOR FRAUDULENT				
18 19		SENTATION AGAINST DEFENDANTS BARD, BPV AND DOES 1				
20	THROUGH					
21	1.	General damages according to proof at the time of trial;				
22	2.	Medical and other special damages, past, present, and future, according to proof at				
23		the time of trial;				
24	3.	Pre-judgment and post-judgment interest pursuant to the laws of the State of				
25 26		Illinois;				
26 27	4.	Costs of suit incurred herein; and				
28	5.	For such other and further relief as the court may deem just and proper.				

# COMPLAINT FOR DAMAGES

1	AS TO THE NINTH CAUSE OF ACTION FOR LOSS OF CONSORTIUM							
2	AGAINST DEFENDANTS BARD BPV, AND DOES 1 THROUGH 100.							
3	1. General damages according to proof at the time of trial;							
4 5	2. Medical and other special damages, past, present, and future, according to proof at							
6		the time of trial;						
7	3.	Pre-judgment and post-judgment interest pursuant to the laws of the State of						
8		Illinois;						
9	4.	Costs of suit incurred herein; and						
10	6.	For such other and further relief as the court may deem just and proper.						
11	0.							
12 13		DEMAND FOR JURY TRIAL						
13		ntiff hereby demands trial by jury on all issues.						
15	Dated: May	y 11, 2013 Respectfully Submitted,						
16		<u>/s/ Jacob W. Plattenberger</u> Jacob W. Plattenberger, IL Bar # 6297431						
17		Tor A. Hoerman, IL Bar # 6229439 TorHoerman Law LLC						
18		101 W. Vandalia, Suite 350						
19	Edwardsville, IL 62025 Phone: (618) 656-4400							
20		Fax: (618) 656-4401 inlattenberger@torhoermanlaw.com						
21	jplattenberger@torhoermanlaw.com thoerman@torhoermanlaw.com							
22		Ramon Rossi Lopez (CSB No. 86361)						
23		LOPEZ McHUGH LLP 100 Bayview Circle, Suite 5600						
24		Newport Beach, CA 92660						
25		Telephone: (949) 737-1501 Facsimile: (949) 737-1504						
26	rlopez@lopezmchugh.com							
27		Attorneys for Plaintiffs						
28								
		A 1						
	41 COMPLAINT FOR DAMAGES							

# 1:13-cv-01219-MMM-JAGV#L1-COVER SHEET

JS 44 (Rev. 12/12)

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 purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)

**E-FILED** 

1 1 8	ч. Ч			,		
I. (a) PLAINTIFFS HENRY KILVER and JUI wife	DY KILVER, individual	ly and as husband a	and	<b>DEFENDANTS</b> C.R. BARD, INC., a foreign corporation, BARD PERIPHERAL VASCULAR, INC., an Arizona corporation, and DOES 1 through 100 inclusive,		
(b) County of Residence of First Listed Plaintiff <u>Tazewell</u> (EXCEPT IN U.S. PLAINTIFF CASES)				County of Residence of First Listed Defendant (IN U.S. PLAINTIFF CASES ONLY) NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.		
(c) Attorneys (Firm Name, J Jacob Plattenberger, Tor Chicago, Illinois, 60604, I	Hoerman Law LLC, 2		Floor,	Attorneys (If Known)		
II. BASIS OF JURISDI	CTION (Place an "X" in C	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)			<b>IF DEF</b> C 1 □ 1 Incorporated <i>or</i> Pr of Business In 1	
2 U.S. Government Defendant	A Diversity (Indicate Citizensh	ip of Parties in Item III)			2 2 Incorporated and I of Business In A	Another State
				en or Subject of a reign Country	3 🗖 3 Foreign Nation	
IV. NATURE OF SUIT						
CONTRACT ☐ 110 Insurance	PERSONAL INJURY	D <u>RTS</u> PERSONAL INJUR		S Drug Balatad Saimura	BANKRUPTCY	OTHER STATUTES         □ 375 False Claims Act
<ul> <li>120 Marine</li> <li>130 Miller Act</li> <li>140 Negotiable Instrument</li> <li>150 Recovery of Overpayment &amp; Enforcement of Judgment</li> <li>151 Medicare Act</li> <li>152 Recovery of Defaulted Student Loans</li> </ul>	<ul> <li>310 Airplane</li> <li>315 Airplane Product Liability</li> <li>320 Assault, Libel &amp; Slander</li> <li>330 Federal Employers' Liability</li> <li>340 Marine</li> </ul>	<ul> <li>365 Personal Injury - Product Liability</li> <li>367 Health Care/ Pharmaceutical Personal Injury Product Liability</li> <li>368 Asbestos Personal Injury Product</li> </ul>	□ 69	5 Drug Related Seizure of Property 21 USC 881 0 Other	<ul> <li>422 Appeal 28 USC 158</li> <li>423 Withdrawal 28 USC 157</li> <li>PROPERTY RIGHTS</li> <li>820 Copyrights</li> <li>830 Patent</li> <li>840 Trademark</li> </ul>	<ul> <li>400 State Reapportionment</li> <li>410 Antitrust</li> <li>430 Banks and Banking</li> <li>450 Commerce</li> <li>460 Deportation</li> <li>470 Racketeer Influenced and Corrupt Organizations</li> <li>480 Consumer Credit</li> </ul>
<ul> <li>(Excludes Veterans)</li> <li>153 Recovery of Overpayment of Veteran's Benefits</li> <li>160 Stockholders' Suits</li> <li>190 Other Contract</li> <li>195 Contract Product Liability</li> <li>196 Franchise</li> </ul>	<ul> <li>345 Marine Product Liability</li> <li>350 Motor Vehicle</li> <li>355 Motor Vehicle Product Liability</li> <li>360 Other Personal Injury</li> <li>362 Personal Injury - Medical Malpractice</li> </ul>	Liability <b>PERSONAL PROPER</b> <b>370</b> Other Fraud <b>371</b> Truth in Lending <b>380</b> Other Personal Property Damage <b>385</b> Property Damage Product Liability	□ 72 □ 74 □ 75	LABOR 0 Fair Labor Standards Act 0 Labor/Management Relations 0 Railway Labor Act 1 Family and Medical Leave Act 0 Other Labor Litigation	SOCIAL SECURITY           0         861 HIA (1395ff)           0         862 Black Lung (923)           0         863 DIWC/DIWW (405(g))           0         864 SSID Title XVI           0         865 RSI (405(g))	<ul> <li>490 Cable/Sat TV</li> <li>850 Securities/Commodities/ Exchange</li> <li>890 Other Statutory Actions</li> <li>891 Agricultural Acts</li> <li>893 Environmental Matters</li> <li>895 Freedom of Information Act</li> <li>896 Arbitration</li> </ul>
REAL PROPERTY         210 Land Condemnation         220 Foreclosure         230 Rent Lease & Ejectment         240 Torts to Land         245 Tort Product Liability	CIVIL RIGHTS 440 Other Civil Rights 441 Voting 442 Employment 443 Housing/ Accommodations	PRISONER PETITION         Habeas Corpus:         463 Alien Detainee         510 Motions to Vacate Sentence         530 General	<u>NS</u> ⊡ 79	1 Employee Retirement Income Security Act	FEDERAL TAX SUITS         □       870 Taxes (U.S. Plaintiff or Defendant)         □       871 IRS—Third Party 26 USC 7609	<ul> <li>S96 Arbitration</li> <li>S99 Administrative Procedure Act/Review or Appeal of Agency Decision</li> <li>950 Constitutionality of State Statutes</li> </ul>
290 All Other Real Property	<ul> <li>445 Amer. w/Disabilities - Employment</li> <li>446 Amer. w/Disabilities - Other</li> <li>448 Education</li> </ul>	<ul> <li>535 Death Penalty Other:</li> <li>540 Mandamus &amp; Oth</li> <li>550 Civil Rights</li> <li>555 Prison Condition</li> <li>560 Civil Detainee - Conditions of Confinement</li> </ul>		IMMIGRATION 2 Naturalization Application 5 Other Immigration Actions		
V. ORIGIN (Place an "X" in	n One Box Only)	•				-
	te Court	Appellate Court	1	ened Anothe (specify)	er District Litigation	
VI. CAUSE OF ACTIO	28 U.S.C. & 1332	(a) ause:	re filing (L	Do not cite jurisdictional stat	tutes unless diversity):	
VII. REQUESTED IN COMPLAINT:	CHECK IF THIS UNDER RULE 2	IS A <b>CLASS ACTION</b> 3, F.R.Cv.P.	N DI	EMAND \$	CHECK YES only JURY DEMAND	if demanded in complaint: <b>∴ XI</b> Yes □ No
VIII. RELATED CASI IF ANY	<b>E(S)</b> (See instructions):	JUDGE			DOCKET NUMBER	
DATE 05/11/2013		SIGNATURE OF ATT /s/ Jacob W. Pl				
FOR OFFICE USE ONLY       RECEIPT #   AN	MOUNT	APPLYING IFP		JUDGE	MAG. JU	DGE

1:13-cv-01219-MMM-JAG # 1-2 Page 1 of 2

AO 440 (Rev. 06/12) Summons in a Civil Action

E-FILED Saturday, 11 May, 2013 07:16:40 PM <u>Clerk, U.S. District Court, IL</u>CD

# UNITED STATES DISTRICT COURT

for the

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Central District of Illinois

HENRY KILVER and JUDY KILVER, individually and as husband and wife,

Plaintiff(s)

v.

Civil Action No.

C.R. BARD, INC., a foreign corporation, BARD PERIPHERAL VASCULAR, INC., an Arizona corporation, and DOES 1 through 100 inclusive,

Defendant(s)

# SUMMONS IN A CIVIL ACTION

To: (Defendant's name and address) C.R. Bard, Inc. c/o The Corporation Trust Company of Neveda 311 S. Division St. Carson City, NV 89703

A lawsuit has been filed against you.

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

Tor Hoerman Law, LLC. 234 S. Wabash Ave., 7th Floor, Chicago, Illinois 60604

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

CLERK OF COURT

Date:

Signature of Clerk or Deputy Clerk

AO 440 (Rev. 06/12) Summons in a Civil Action (Page 2)

# Civil Action No.

# **PROOF OF SERVICE**

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

	This summons for (nam	ne of individual and title, if any)		
was ree	ceived by me on (date)	·		
	□ I personally served	the summons on the individual	at (place)	
			on (date)	; or
	□ I left the summons	at the individual's residence or u	usual place of abode with (name)	
		, a perso	n of suitable age and discretion who res	sides there,
	on (date)	, and mailed a copy to	the individual's last known address; or	
	$\Box$ I served the summa	ns on (name of individual)		, who is
	designated by law to a	accept service of process on beh	alf of (name of organization)	
			on (date)	; or
	$\Box$ I returned the summ	nons unexecuted because		; or
	<b>Other</b> ( <i>specify</i> ):			
	My fees are \$	for travel and \$	for services, for a total of \$	0.00
	I declare under penalty	v of perjury that this information	is true.	
Date:				
			Server's signature	
			Printed name and title	

Server's address

Additional information regarding attempted service, etc:

1:13-cv-01219-MMM-JAG # 1-3 Page 1 of 2

AO 440 (Rev. 06/12) Summons in a Civil Action

E-FILED Saturday, 11 May, 2013 07:16:40 PM <u>Clerk, U.S. District Court, IL</u>CD

# UNITED STATES DISTRICT COURT

for the

Central District of Illinois

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HENRY KILVER and JUDY KILVER, individually and as husband and wife,

Plaintiff(s)

v.

Civil Action No.

C.R. BARD, INC., a foreign corporation, BARD PERIPHERAL VASCULAR, INC., an Arizona corporation, and DOES 1 through 100 inclusive,

Defendant(s)

# SUMMONS IN A CIVIL ACTION

)

To: (Defendant's name and address) Bard Peripheral Vascular, Inc. c/o The Corporation Trust Company of Neveda 311 S. Division St. Carson City, NV 89703

A lawsuit has been filed against you.

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

Tor Hoerman Law, LLC. 234 S. Wabash Ave., 7th Floor, Chicago, Illinois 60604

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

CLERK OF COURT

Date:

Signature of Clerk or Deputy Clerk

AO 440 (Rev. 06/12) Summons in a Civil Action (Page 2)

# Civil Action No.

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	This summons for (nam	e of individual and title, if any)							
was ree	ceived by me on (date)								
	□ I personally served	the summons on the individual	at (place)						
			on (date)	; or					
	$\Box$ I left the summons a	□ I left the summons at the individual's residence or usual place of abode with ( <i>name</i> )							
		, a pers	on of suitable age and discretion who res	sides there,					
	on (date)	, and mailed a copy to	the individual's last known address; or						
	□ I served the summor	ns on (name of individual)		, who is					
designated by law to accept service of process on behalf of (name of organi									
			on (date)	; or					
	$\Box$ I returned the summ	nons unexecuted because		; or					
	<b>O</b> Other ( <i>specify</i> ):								
	My fees are \$	for travel and \$	for services, for a total of \$	0.00					
	I declare under penalty	of perjury that this informatio	n is true.						
Date:									
			Server's signature						
			Printed name and title						

Server's address

Additional information regarding attempted service, etc: