UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF NORTH CAROLINA
STATESVILLE DIVISION

Lorraine Waters, individually, as personal representative, and on behalf of all statutory beneficiaries of Keith Allen Waters, deceased.	)	
Plaintiff,	)	Civil Action No. 5:17-CV-61
v.	)	**JURY TRIAL DEMANDED**
B. Braun Medical Inc., a Pennsylvania corporation, Aesculap Incorporated, a Pennsylvania corporation, Aesculap Implant Systems, LLC, a Pennsylvania Limited Liability Company, B. Braun Interventional Systems, John and Jane Does I-X, and Black and White Corporations I-X,	)	
Defendants.	)	

COMPLAINT FOR DAMAGES

COMES NOW, Plaintiff Lorraine Waters (hereinafter, "PLAINTIFF"), individually and as personal representative, and on behalf of all statutory beneficiaries of Keith Allen Waters (hereinafter, "DECEDENT"), by and through her undersigned attorneys, hereby sues Defendants, B. Braun Medical Inc., a Pennsylvania corporation, Aesculap Incorporated, a Pennsylvania corporation, Aesculap Implant Systems, a Pennsylvania Corporation, John and Jane Does I-X and Black and White Corporations I-X, and alleges the following causes of action against DEFENDANTS, and each of them, as follows:

PARTIES

1. PLAINTIFF is DECEDENT'S widow and has standing under N.C. Gen. Stat. § 28A et al., to be appointed as Personal Representative of the Estate of DECEDENT for purposes

of bringing claims for wrongful death and survival on behalf of DECEDENT'S Estate. DECEDENT died leaving one son, Levi Waters, who is, and at all relevant times was, a resident of Catawba, North Carolina, as well one daughter, Ashley Waters Marshall, who is, and at all relevant times was, a resident of Greensboro, North Carolina. Upon information and belief, the following individuals are the only survivors and beneficiaries of a recovery for the wrongful death of DECEDENT: PLAINTIFF, Levi Waters, and Ashley Waters Marshall. PLAINTIFF is, and at all times mentioned in this complaint was, a resident of Catawba County, North Carolina.

2. Defendant B. Braun Medical Inc. (hereafter, "Braun"), is a foreign corporation authorized to do business in North Carolina. Braun was doing business in North Carolina. Braun, at all times relevant to this action, designed, set specifications, manufactured, prepared, compounded, assembled, processed, marketed, distributed, and sold its VenaTech LP™ IVC Filter to be implanted in patients such as DECEDENT throughout the United States, including North Carolina. Braun can be served via its registered agent, Corporation Service Company, located at 327 Hillsborough Street, Raleigh, North Carolina 27603.

3. Defendant Aesculap Incorporated (hereafter, "Aesculap Inc."), is a foreign corporation authorized to do business in North Carolina. On information and belief, Aesculap Inc. was doing business in North Carolina. Aesculap Inc., at all times relevant to this action, designed, set specifications, manufactured, prepared, compounded, assembled, processed, marketed, distributed, and sold the VenaTech™ LP IVC Filter to be implanted in patients such as DECEDENT throughout the United States, including North Carolina. Aesculap Inc. can be served via its registered agent, Corporation Service Company, located at 327 Hillsborough Street, Raleigh, North Carolina 27603.

4. Defendant Aesculap Implant Systems, LLC (hereafter, "Aesculap IS"), is a foreign corporation authorized to do business in North Carolina. On information and belief, Aesculap IS was doing business in North Carolina. Aesculap IS., at all times relevant to this action, designed, set specifications, manufactured, prepared, compounded, assembled, processed, marketed, distributed, and sold its VenaTech™ LP IVC filter to be implanted in patients such as DECEDENT throughout the United States, including North Carolina. Aesculap Inc. can be served via its registered agent, Corporation Service Company, located at 327 Hillsborough Street, Raleigh, North Carolina 27603.

5. Defendant B. Braun Interventional Systems (hereafter, "Braun IS"), is a foreign corporation authorized to do business in North Carolina. Braun IS was doing business in North Carolina. Upon information and belief, Braun IS, at all times relevant to this action, designed, set specifications, manufactured, prepared, compounded, assembled, processed, marketed, distributed, and sold its VenaTech™ LP IVC filter to be implanted in patients such as DECEDENT, throughout the United States, including North Carolina. Braun IS can be served via its registered agent, Corporation Service Company, located at 327 Hillsborough Street, Raleigh, North Carolina 27603.

6. John and Jane Does I-X and Black and White Corporations I-X are persons, organizations, entities, sole proprietorships, partnerships, limited liability companies, and corporations whose conduct, true names and identities are unknown at this time but that were responsible for the design and/or manufacture of its filter. Plaintiffs request leave to amend this pleading when that information is discovered.

7. Defendants caused events, injuries, and damages to occur in the State of North Carolina.

JURISDICTION AND VENUE

8. Jurisdiction is proper in this Court pursuant to 28 U.S.C. § 1332 because complete diversity of citizenship exists amongst the parties and the amount in controversy exceeds seventy-five thousand dollars.

9. Venue is proper in this Court, as the facts and circumstances leading to injuries and death of DECEDENT occurred in this Judicial District.

10. Defendants' Vena Tech™ LP IVC Filter was sold, purchased and implanted in North Carolina. Furthermore, the Defendants herein were authorized to conduct business in the State of North Carolina and did conduct business in North Carolina.

FACTUAL ALLEGATIONS: IVC FILTERS, GENERALLY

11. The inferior vena cava ("IVC") is a vein that returns blood to the heart from the lower portions of the body. In certain people, for various reasons, blood clots travel from the vessels in the legs and pelvis, through the vena cava and into the lungs. Often, these blood clots develop in the deep leg veins, a condition called "deep-vein thrombosis" or "DVT." Once blood clots reach the lungs, they are considered "pulmonary emboli" or "PE." Pulmonary emboli present risks to human health.

12. An IVC filter is a device that is designed to filter or "catch" blood clots that travel from the lower portions of the body to the heart and lungs. IVC filters were originally designed to be permanently implanted in the IVC.

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

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

15. As stated above, IVC filters have been on the market for decades. All IVC filters are only cleared for use by the Food & Drug Administration ("FDA") for prevention of recurrent pulmonary embolism in patients at risk for pulmonary embolism and where anticoagulation therapy has failed or is contraindicated.

16. There is no evidence that DEFENDANTS' IVC filters were effective in preventing pulmonary embolism (the very condition the products were indicated to prevent).

17. Studies have also revealed these devices suffer common failure modes such as migration, perforation, thrombosis, and fracture, all of which can cause serious injury or death. For example, recent studies have revealed fracture rates over 50%.

FACTUAL ALLEGATIONS: THE VENA TECH ™ LP VENA CAVA FILTER SYSTEM

18. The IVC filter at issue in this case is a Vena Tech™ LP Permanent Vena Cava Filter ("IVC FILTER"), a medical device developed, designed, licensed, manufactured, prepared, packaged, maintained, labeled, compounded, assembled, processed, sold, distributed and/or marketed by DEFENDANTS.

19. On or about May 18, 2001, DEFENDANTS bypassed the more onerous approval process of the FDA for new devices and obtained "clearance" under Section 510(k) of the Medical Device Amendments to the Food, Drug, and Cosmetic Act to market the IVC FILTER

as a permanent filter by claiming it was substantially similar in respect to safety, efficacy, design, and materials as the IVC filters already available on the market.

20. Section 510(k) permits the marketing of medical devices if the device is substantially equivalent to other legally marketed predicate devices without formal review for the safety or efficacy of the said device. The FDA explained the difference between the 510(k) process and the more rigorous "premarket approval" (PMA) process in its amicus brief filed with the Third Circuit in *Horn v. Thoratec Corp*., which the court quoted from:

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

3763d 163, 167 (3d Cir. 2004).

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

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

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

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

24. In 2001, through this 510(k) process, DEFENDANTS obtained clearance from the FDA to market the IVC Filter as a permanent filter.

25. The IVC FILTER is made with a chromium cobalt alloy and has been described as a "low profile" version of DEFENDANTS' Vena Tech LGM permanent filter. Specifically, the Vena Tech™ LP has been described as having "thinner legs" and "softer hooks" when compared to the LGM design.

26. At relevant times, DEFENDANTS have claimed that the IVC FILTER embodies "[T]he scientific art of capture" with an "[E]xtraordinary design for exceptional performance."[1]

27. At relevant times, DEFENDANTS have claimed that the IVC FILTER is "the new standard in vena caval filtration" and that DEFENDANT is a "worldwide leader in the prevention of Pulmonary Embolism." *Id.*

[1]http://www.bisusa.org/sites/bbrauninterventionalsystems.com/files/documents/venacavalpsellsht_0.pdf

28. DEFENDANTS describe their IVC FILTER as having a self-expanding conical filter design with self-centering stabilization legs with eight anchoring hooks that are intended to securely position the filter in the center of the Vena Cava.

29. Despite changes made by DEFENDANTS with regard to the IVC FILTER's design, both the Vena Tech LP and LGM products have been associated with incomplete deployments, migration, and other serious adverse events.

29. The design for the IVC FILTER suffers flaws making them defective and unreasonably dangerous. The IVC FILTER is designed in such a way that, when exposed to expected and reasonably foreseeable in-vivo conditions, the device will fracture, migrate, tilt, perforate internal organs and vasculature, and lead to the formation of thromboembolism and pulmonary embolism.

30. DEFENDANTS represented that the self-centering design of the IVC FILTER allows accurate, predictable placement, and that its site struts help reduce the risk of tilting and migration while, in reality, the filters regularly tilt, migrate, and become embedded in the IVC wall.

31. The anchoring mechanism of the IVC FILTER is also insufficient to prevent tilting and migration post-placement.

32. Upon information and belief, the configuration of the IVC FILTER actually leads to the formation of blood clots and pulmonary embolism – the exact condition the devices are meant to protect against.

33. DEFENDANTS allowed this device to proceed to market indicates that they failed to establish and maintain an appropriate Quality System concerning design and risk analysis.

34. A medical device manufacturer must, at a minimum, undertake research and testing to understand the anatomy of where a medical device will be implanted and understand the forces the device may be exposed to once implanted in a human body. This design input must then be used to determine the minimum safety requirements or attributes the device must have to meet user needs. In the case of the IVC FILTER, user needs include a device that will capture blood clots of sufficient size to cause harmful consequences and that will not fracture, migrate, tilt, perforate the IVC, or malfunction in some other way, or be prothombotic. DEFENDANTS failed to undertake any such efforts in these regards.

35. Prior to bringing a medical device to market, a medical device manufacturer must also conduct sufficient testing under real world or simulated use conditions to ensure that the device will meet user needs even when exposed to reasonably foreseeable worst-case conditions. DEFENDANTS failed to adequately establish and maintain such policies, procedures, or protocols with respect to the IVC FILTER.

36. Once placed on the market, DEFENDANTS' post-market surveillance system should have revealed to DEFENDANTS that the IVC FILTER was unreasonably dangerous and substantially more prone to fail or malfunction and cause great bodily harm to patients compared to other available treatment options.

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

38. Shortly after going on market, DEFENDANTS began receiving large numbers of adverse event reports ("AERs") from health care providers reporting that the IVC FILTER was fracturing post-implantation and that fractured pieces and/or the entire device was migrating to other areas of the body, including the heart and lungs.

39. DEFENDANTS also received large numbers of AERs reporting that the IVC FILTER was found to have excessively tilted, perforated the IVC, or caused thrombosis or stenosis of the vena cava post-implantation.

40. These failures were often associated with severe patient injuries such as:

a. Death;

b. Hemorrhage;

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

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

e. Severe and persistent pain;

f. Perforations of tissue, vessels and organs;

g. Chronic deep vein thrombosis;

h. Pulmonary embolism; and

i. Compartment syndrome.

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

42. Recent medical studies have confirmed what DEFENDANTS have known or should have known since shortly after the release of each of these filters – not only does the IVC FILTER fail at alarming rates, but they also fail at rates substantially higher than other available IVC filters.

43. As a minimum safety requirement, medical device manufacturers must establish and maintain post-market procedures to timely identify the cause of device failures and other quality problems and to take adequate corrective action to prevent the recurrence of these problems. Yet, DEFENDANTS failed to identify or acknowledge these device failures or determine their causes.

44. DEFENDANTS failed to take timely and adequate remedial measures to correct known design and manufacturing defects with the IVC FILTER.

45. DEFENDANTS also misrepresented and concealed the risks and benefits of the IVC FILTER in the labeling and marketing distributed to the FDA, physicians, and the public. For instance, DEFENDANTS represented that the IVC FILTER was safe and effective – more safe and effective than other available IVC filters. However, there is no reliable evidence to support these claims and, to the contrary, the IVC FILTER has been associated with a high rate of failure.

46. DEFENDANTS also represented that the design of the IVC FILTER would eliminate the risk that pieces of the device could perforate the vena cava, that the device could

tilt, and that fractures could occur and migrate throughout the body. The medical literature and AERs have proven these claims to be false.

47. DEFENDANTS also failed to adequately disclose the risks of the IVC FILTER, such as migration, fracture, perforation, tilt, thrombosis, the prothrombotic nature of the device, and that these failures were causing severe injuries and death. DEFENDANTS further failed to disclose the rate at which these events were occurring.

48. On April 5, 2016, at the annual Society of Interventional Radiology in Vancouver, Canada, Dr. Steven Wang, an interventional radiologist from Palo Alto, California who is affiliated with Kaiser Permanente, presented the results of a retrospective study involving 96 patients in which he sought to understand the prevalence of long-term (greater than 46 months) complications of both permanent and retrievable IVC filters. The study looked at all IVC filters implanted in patients from January 2007 through December 2009 at multiple health care facilities across the United States. Dr. Wang then identified all patients who had imaging of the filter taken at four years or more after implantation. Of those patients (96), he then evaluated the imaging to determine whether the IVC filter had malfunctioned. After reviewing the data, the authors concluded that device complications at four or more years after implantation "are relatively common." They also found that the IVC FILTER suffered fracture rates of 23.1%.

49. For the foregoing reasons, the IVC FILTER manufactured and sold by DEFENDANTS was extremely dangerous, defective, and unsafe for use by the general public for its intended purposes.

50. Prior to the date on which the IVC FILTER was surgically placed in DECEDENT'S body, DEFENDANTS knew that the IVC FILTER was defective and was

extremely dangerous, defective, and unsafe for use by the general public for its intended purposes.

51. DEFENDANTS nonetheless failed to take appropriate action to cure the nature of the defect or to appropriately warn users of the IVC FILTER or their physicians of such dangerous characteristics. DEFENDANTS thereby acted with malice towards DECEDENT, and PLAINTIFF accordingly requests that the trier of fact, in the exercise of its sound discretion, should award PLAINTIFF additional damages for the sake of example and for the purpose of punishing DEFENDANTS for its conduct, in an amount sufficiently large to be an example to others and to deter DEFENDANTS from engaging in similar conduct in the future.

52. The wrongful conduct described above was done with the advance knowledge, authorization, and/or ratification of an officer, director, and/or managing agent of DEFENDANTS.

FACTUAL ALLEGATIONS: IMPLANTATION OF THE IVC FILTER IN THE DECEDENT AND RESULTING INJURIES AND DEATH

53. On or about March 12, 2015, DECEDENT was implanted with the IVC FILTER at Catawba Valley Medical Center, in Catawba County, North Carolina.

54. The IVC FILTER that is the subject of this action reached DECEDENT and his physicians without substantial change in the condition from the time it left DEFENDANTS' possession.

55. DECEDENT and his physicians used the IVC FILTER in the manner in which it was intended.

56. After implantation, the IVC FILTER malfunctioned and caused injury to surrounding tissues, vessels, and organs, and fractured pieces of the IVC Filter, and/or the entire device, migrated to other areas of DECEDENT'S body including, but not limited to his lungs and/or heart, and/or otherwise caused or contributed to cause the formation of blood clots above the location of the IVC FILTER

57. On or about April 2, 2015, DECEDENT died from complications related to the defective IVC FILTER, including but not limited to, filter thrombosis, multiple pulmonary emboli, and cardiac arrest.

58. DECEDENT'S spouse, PLAINTIFF, suffered mental pain and suffering as a direct and proximate result of DECEDENT'S injury and death. Moreover, because of DECEDENT'S severe injury from the IVC FILTER, PLAINTIFF suffered a loss of such intangibles as love, sex, companionship, society, comfort, solace, and household services.

COUNT I:

NEGLIGENCE OF DEFENDANTS;
WRONGFUL DEATH OR, ALTERNATIVELY, SURVIVAL ACTION

59. PLAINTIFF realleges and incorporates by reference each allegation contained in Paragraphs 1 through 58 above and further alleges as follows:

60. At all times herein mentioned, DEFENDANTS had a duty to properly develop, design, set specifications for, license, manufacture, prepare, package, maintain, label, compound, assemble, process, test, inspect, examine, sell, distribute and/or market the IVC FILTER.

61. At all times herein mentioned, DEFENDANTS knew, or in the exercise of reasonable care should have known, that the IVC FILTER was of such a nature that it would be

likely to injure someone using it if it was not properly developed, designed, licensed, manufactured, prepared, packaged, maintained, labeled, compounded, assembled, processed, tested, inspected, examined, sold, distributed and/or marketed.

62. DEFENDANTS so negligently and carelessly developed, designed, licensed, manufactured, prepared, packaged, maintained, labeled, compounded, assembled, processed, tested, inspected, examined, sold, distributed and/or marketed the IVC FILTER that it was dangerous and unsafe for the user and purpose for which it was intended.

63. As a proximate result of the aforesaid carelessness and negligence of DEFENDANTS, the IVC FILTER caused DECEDENT'S death. Thus, PLAINTIFF is entitled to recover, as allowed by North Carolina law, the following damages for the estate and the survivors:

a. loss of support and services and consortium pursuant to North Carolina;
b. loss of DECEDENT'S companionship and protection and for mental pain and suffering from the date of injury;
c. lost parental companionship, instruction, and guidance, and for mental pain and suffering from the date of injury;
d. loss of earnings and net accumulations of the Estate of DECEDENT, beyond the death of DECEDENT; and
e. hospital, medical, funeral, and burial expenses that may become a charge on the Estate of DECEDENT.

64. Alternatively, as a proximate result of the aforesaid carelessness and negligence of DEFENDANTS, the IVC FILTER caused severe injury to DECEDENT'S body, leading to damages in the form of pain, suffering, and medical expenses. Moreover, because of

DECEDENT'S severe injury from the IVC FILTER, PLAINTIFF suffered a loss of such intangibles as love, sex, companionship, society, comfort, solace, and household services. Thus, PLAINTIFF is entitled to recover, as allowed by North Carolina law, the following damages for the estate and herself:

a. DECEDENT'S pain and suffering sustained between the time of injury and his death;

b. The medical expenses incurred by DECEDENT between the time of injury and his death; and

c. Loss of consortium.

COUNT II:

STRICT LIABILITY OF DEFENDANTS RE DESIGN DEFECT;
WRONGFUL DEATH OR, ALTERNATIVELY, SURVIVAL ACTION

65. PLAINTIFF realleges and incorporates by reference each allegation contained in Paragraphs 1 through 58 above and further alleges as follows:

66. At the time DECEDENT was implanted with the IVC FILTER, DEFENDANTS were engaged in the business of developing, designing, setting specifications for, licensing, manufacturing, preparing, packaging, maintaining, labeling, compounding, assembling, processing, selling, distributing, and marketing this device.

67. The IVC FILTER was defectively designed when sold.

68. At all times herein mentioned, the IVC FILTER was defective and unsafe because it was dangerous for its intended purposes and caused grievous injuries to the body when used for such purposes.

69. The IVC FILTER reached DECEDENT and his physicians without substantial change in the condition in which it was sold.

70. DEFENDANTS knew that the IVC FILTER was to be used by the user without inspection for defects therein or in any of its components or ingredients.

71. DECEDENT and his physicians neither knew, nor had reason to know, at the time of the implant of the IVC FILTER, or at any time prior thereto, of the existence of the foregoing described defect.

72. As a proximate result of the foregoing described defect, the IVC FILTER caused DECEDENT'S death. Thus, PLAINTIFF is entitled to recover, as allowed by North Carolina law, the following damages for the estate and the survivors:

a. loss of support and services and consortium pursuant to North Carolina law;

b. loss of DECEDENT'S companionship and protection and for mental pain and suffering from the date of injury;

c. lost parental companionship, instruction, and guidance, and for mental pain and suffering from the date of injury;

d. loss of earnings and net accumulations of the Estate of DECEDENT, beyond the death of DECEDENT; and

e. hospital, medical, funeral, and burial expenses that may become a charge on the Estate of DECEDENT.

73. Alternatively, as a proximate result of the foregoing described defect, the IVC FILTER caused severe injury to DECEDENT'S body, leading to damages in the form of pain,

suffering, and medical expenses. Moreover, because of DECEDENT'S severe injury from the IVC FILTER, PLAINTIFF suffered a loss of such intangibles as love, sex, companionship, society, comfort, solace, and household services. Thus, PLAINTIFF is entitled to recover, as allowed by North Carolina law, the following damages for the estate and herself:

a. DECEDENT'S pain and suffering sustained between the time of injury and his death;

b. The medical expenses incurred by DECEDENT between the time of injury and his death; and

c. Loss of consortium.

COUNT III:

STRICT LIABILITY OF DEFENDANTS RE MANUFACTURING DEFECT; WRONGFUL DEATH OR, ALTERNATIVELY, SURVIVAL ACTION

74. PLAINTIFF realleges and incorporates by reference each allegation contained in Paragraphs 1 through 58 above and further alleges as follows:

75. At the time DECEDENT was implanted with the IVC FILTER, DEFENDANTS were engaged in the business of developing, designing, setting specifications for, licensing, manufacturing, preparing, packaging, maintaining, labeling, compounding, assembling, processing, selling, distributing, and marketing this device.

76. The IVC FILTER was defective in its manufacture when sold.

77. At all times herein mentioned, the IVC FILTER was defective and unsafe because it was dangerous for its intended purposes and caused grievous injuries to the body when used for such purposes.

78. The IVC FILTER reached DECEDENT and his physicians without substantial change in the condition in which it was sold.

79. DEFENDANTS knew that the IVC FILTER was to be used by the user without inspection for defects therein or in any of its components or ingredients.

80. DECEDENT and his physicians neither knew, nor had reason to know, at the time of the implant of the IVC FILTER, or at any time prior thereto, of the existence of the foregoing described defect.

81. As a proximate result of the foregoing described defect, the IVC FILTER caused DECEDENT'S death. Thus, PLAINTIFF is entitled to recover, as allowed by North Carolina law, the following damages for the estate and the survivors:

a. loss of support and services and consortium pursuant to North Carolina law;

b. loss of DECEDENT'S companionship and protection and for mental pain and suffering from the date of injury;

c. lost parental companionship, instruction, and guidance, and for mental pain and suffering from the date of injury;

d. loss of earnings and net accumulations of the Estate of DECEDENT, beyond the death of DECEDENT; and

e. hospital, medical, funeral, and burial expenses that may become a charge on the Estate of DECEDENT.

82. Alternatively, as a proximate result of the foregoing described defect, the IVC FILTER caused severe injury to DECEDENT'S body, leading to damages in the form of pain,

suffering, and medical expenses. Moreover, because of DECEDENT'S severe injury from the IVC FILTER, PLAINTIFF suffered a loss of such intangibles as love, sex, companionship, society, comfort, solace, and household services. Thus, PLAINTIFF is entitled to recover, as allowed by North Carolina law, the following damages for the estate and herself:

a. DECEDENT'S pain and suffering sustained between the time of injury and his death;

b. The medical expenses incurred by DECEDENT between the time of injury and his death; and

c. Loss of consortium.

COUNT IV:

STRICT LIABILITY OF DEFENDANTS RE FAILURE TO WARN;
WRONGFUL DEATH OR, ALTERNATIVELY, SURVIVAL ACTION

83. PLAINTIFF realleges and incorporates by reference each allegation set forth above and further alleges as follows:

84. At the time DECEDENT was implanted with the IVC FILTER, DEFENDANTS were engaged in the business of developing, designing, setting specifications for, licensing, manufacturing, preparing, packaging, maintaining, labeling, compounding, assembling, processing, selling, distributing, and marketing this device.

85. DEFENDANTS failed to adequately warn of risks of the IVC FILTER that were known or knowable in light of the generally recognized and prevailing best scientific and medical knowledge available at the time of the manufacture and distribution of the IVC FILTER.

86. At all times herein mentioned, the IVC FILTER was defective and unsafe because it was dangerous for its intended purposes and caused grievous injuries to the body when used for such purposes.

87. The IVC FILTER reached DECEDENT and his physicians without substantial change in the condition in which it was sold.

88. DEFENDANTS knew that the IVC FILTER was to be used by the user without inspection for defects therein or in any of its components or ingredients.

89. DECEDENT and his physicians neither knew, nor had reason to know, at the time of the implant of the IVC FILTER, or at any time prior thereto, of the existence of the foregoing described defect.

90. As a proximate result of the foregoing described defect, the IVC FILTER caused DECEDENT'S death. Thus, PLAINTIFF is entitled to recover, as allowed by North Carolina law, the following damages for the estate and the survivors:

a. loss of support and services and consortium pursuant to North Carolina law;

b. loss of DECEDENT'S companionship and protection and for mental pain and suffering from the date of injury;

c. lost parental companionship, instruction, and guidance, and for mental pain and suffering from the date of injury;

d. loss of earnings and net accumulations of the Estate of DECEDENT, beyond the death of DECEDENT; and

e. hospital, medical, funeral, and burial expenses that may become a charge on the Estate of DECEDENT.

91. Alternatively, as a proximate result of the foregoing described defect, the IVC FILTER caused severe injury to DECEDENT'S body, leading to damages in the form of pain, suffering, and medical expenses. Moreover, because of DECEDENT'S severe injury from the IVC FILTER, PLAINTIFF suffered a loss of such intangibles as love, sex, companionship, society, comfort, solace, and household services. Thus, PLAINTIFF is entitled to recover, as allowed by North Carolina law, the following damages for the estate and herself:

a. DECEDENT'S pain and suffering sustained between the time of injury and his death;

b. The medical expenses incurred by DECEDENT between the time of injury and his death; and

c. Loss of consortium.

COUNT V:

BREACH OF IMPLIED WARRANTY BY DEFENDANTS;
WRONGFUL DEATH OR, ALTERNATIVELY, SURVIVAL ACTION

92. PLAINTIFF realleges and incorporates by reference each allegation set forth above and further alleges as follows:

93. At the time DECEDENT was implanted with the IVC FILTER, DEFENDANTS were engaged in the business of developing, designing, setting specifications for, licensing, manufacturing, preparing, packaging, maintaining, labeling, compounding, assembling, processing, selling, distributing, and marketing this device.

94. Prior to the time that DECEDENT was implanted with the IVC FILTER, DEFENDANTS impliedly warranted to DECEDENT and to his physicians that the IVC FILTER was of merchantable quality and safe for the use for which it was intended.

95. DECEDENT and his physicians relied on the skill and judgment of DEFENDANTS in implanting the IVC FILTER.

96. The IVC FILTER was unsafe for its intended use and was not of merchantable quality because it had very dangerous propensities when put to its intended use and could cause severe injury to the user.

97. After PLAINTIFF was made aware of DECEDENT'S injuries as a result of the use of the implant, notice was duly given to DEFENDANTS of the breach of their implied warranty.

98. As a proximate result of the foregoing described breach of warranty, the IVC FILTER caused DECEDENT'S death. Thus, PLAINTIFF is entitled to recover, as allowed by North Carolina law, the following damages for the estate and the survivors:

a. loss of support and services and consortium pursuant to North Carolina law;

b. loss of DECEDENT'S companionship and protection and for mental pain and suffering from the date of injury;

c. lost parental companionship, instruction, and guidance, and for mental pain and suffering from the date of injury;

d. loss of earnings and net accumulations of the Estate of DECEDENT, beyond the death of DECEDENT; and

e. hospital, medical, funeral, and burial expenses that may become a charge on the Estate of DECEDENT.

99. Alternatively, as a proximate result of the foregoing described breach of warranty, the IVC FILTER caused severe injury to DECEDENT'S body, leading to damages in the form of pain, suffering, and medical expenses. Moreover, because of DECEDENT'S severe injury from the IVC FILTER, PLAINTIFF suffered a loss of such intangibles as love, sex, companionship, society, comfort, solace, and household services. Thus, PLAINTIFF is entitled to recover, as allowed by North Carolina law, the following damages for the estate and herself:

a. DECEDENT'S pain and suffering sustained between the time of injury and his death;

b. The medical expenses incurred by DECEDENT between the time of injury and his death; and

c. Loss of consortium.

COUNT VI:

BREACH OF EXPRESS WARRANTY BY DEFENDANTS;
WRONGFUL DEATH OR, ALTERNATIVELY, SURVIVAL ACTION

100. PLAINTIFF realleges and incorporates by reference each allegation set forth above and further alleges as follows:

101. At the time DECEDENT was implanted with the IVC FILTER, DEFENDANTS were engaged in the business of developing, designing, setting specifications for, licensing, manufacturing, preparing, packaging, maintaining, labeling, compounding, assembling, processing, selling, distributing, and marketing this device.

102. Prior to the time that DECEDENT was implanted with the IVC FILTER, DEFENDANTS expressly warranted to DECEDENT and to his physicians that the IVC FILTER was safe for the use for which it was intended.

103. At the time of making the express warranties, DEFENDANTS had knowledge of the purpose for which the IVC FILTER was to be used and warranted the same to be, in all respects, fit, safe, effective, and proper for such purpose.

104. DECEDENT and his physicians reasonably relied upon the skill and judgment of DEFENDANTS, and upon said express warranty, in using the IVC FILTER. The said warranty and representations were untrue because the IVC FILTER caused severe injury and death to DECEDENT and was unsafe and, therefore, unsuited for the use for which it was intended.

105. As soon as the true nature of the IVC FILTER and the fact that the warranty and representations were false were ascertained, DEFENDANTS were notified of the breach of its express warranty.

106. As a proximate result of the foregoing described breach of warranty, the IVC FILTER caused DECEDENT'S death. Thus, PLAINTIFF is entitled to recover, as allowed by North Carolina law, the following damages for the estate and the survivors:

a. loss of support and services and consortium pursuant to North Carolina law;

b. loss of DECEDENT'S companionship and protection and for mental pain and suffering from the date of injury;

c. lost parental companionship, instruction, and guidance, and for mental pain and suffering from the date of injury;

d. loss of earnings and net accumulations of the Estate of DECEDENT, beyond the death of DECEDENT; and

e. hospital, medical, funeral, and burial expenses that may become a charge on the Estate of DECEDENT.

107. Alternatively, as a proximate result of the foregoing described breach of warranty, the IVC FILTER caused severe injury to DECEDENT'S body, leading to damages in the form of pain, suffering, and medical expenses. Moreover, because of DECEDENT'S severe injury from the IVC FILTER, PLAINTIFF suffered a loss of such intangibles as love, sex, companionship, society, comfort, solace, and household services. Thus, PLAINTIFF is entitled to recover, as allowed by North Carolina law, the following damages for the estate and herself:

a. DECEDENT'S pain and suffering sustained between the time of injury and his death;

b. The medical expenses incurred by DECEDENT between the time of injury and his death; and

c. Loss of consortium.

COUNT VIII:

FRAUD BY DEFENDANTS;
WRONGFUL DEATH OR, ALTERNATIVELY, SURVIVAL ACTION

108. PLAINTIFF realleges and incorporates by reference each and allegation set forth above and further alleges as follows:

109. At the time DECEDENT was implanted with the IVC FILTER, DEFENDANTS were engaged in the business of developing, designing, setting specifications for, licensing,

manufacturing, preparing, packaging, maintaining, labeling, compounding, assembling, processing, selling, distributing, and marketing this device.

110. DEFENDANTS falsely and fraudulently represented to DECEDENT, his physicians, and other members of the general public, that the IVC FILTER was safe for use in surgery. The representations by DEFENDANTS were, in fact, false. The true facts were that the IVC FILTER was not safe for said purpose and was, in fact, dangerous to the health and body of DECEDENT.

111. When DEFENDANTS made the aforesaid representations, they knew them to be false, and those representations were made by DEFENDANTS with the intent to defraud and deceive DECEDENT and his physicians, and with the intent to induce DECEDENT and his physicians to act in the manner herein alleged, *i.e.*, to use the IVC FILTER in surgery.

112. In doing the acts herein alleged, DEFENDANTS acted with oppression, fraud, and malice, and PLAINTIFF is therefore entitled to damages to deter DEFENDANTS and others from engaging in similar conduct in the future. Said wrongful conduct was done with the advance knowledge, authorization, and/or ratification of an officer, director, and/or managing agent of DEFENDANTS.

113. As a proximate result of the foregoing described fraud and deceit, the IVC FILTER caused DECEDENT'S death. Thus, PLAINTIFF is entitled to recover, as allowed by North Carolina law, the following damages for the estate and the survivors:

a. loss of support and services and consortium pursuant to North Carolina law;

b. loss of DECEDENT'S companionship and protection and for mental pain and suffering from the date of injury;

c. lost parental companionship, instruction, and guidance, and for mental pain and suffering from the date of injury;

d. loss of earnings and net accumulations of the Estate of DECEDENT, beyond the death of DECEDENT; and

e. hospital, medical, funeral, and burial expenses that may become a charge on the Estate of DECEDENT.

114. Alternatively, as a proximate result of the foregoing described fraud and deceit, the IVC FILTER caused severe injury to DECEDENT'S body, leading to damages in the form of pain, suffering, and medical expenses. Moreover, because of DECEDENT'S severe injury from the IVC FILTER, PLAINTIFF suffered a loss of such intangibles as love, sex, companionship, society, comfort, solace, and household services. Thus, PLAINTIFF is entitled to recover, as allowed by North Carolina law, the following damages for the estate and herself:

a. DECEDENT'S pain and suffering sustained between the time of injury and his death;

b. The medical expenses incurred by DECEDENT between the time of injury and his death; and

c. Loss of consortium.

COUNT IX:

NEGLIGENT MISREPRESENTATION BY DEFENDANTS;
WRONGFUL DEATH OR, ALTERNATIVELY, SURVIVAL ACTION

115. PLAINTIFF realleges and incorporates by reference each allegation set forth above and further alleges as follows:

116. At the time DECEDENT was implanted with the IVC FILTER, DEFENDANTS were engaged in the business of developing, designing, setting specifications for, licensing, manufacturing, preparing, packaging, maintaining, labeling, compounding, assembling, processing, selling, distributing, and marketing this device.

117. DEFENDANTS falsely represented to DECEDENT, his physicians, and other members of the general public, that the IVC FILTER was safe for its intended use and implantation into the human body. The representations by DEFENDANTS were, in fact, false. The true facts were that the IVC FILTER was not safe for said purpose and was, in fact, dangerous to the health and body of DECEDENT.

118. DEFENDANTS made the aforesaid representations with no reasonable grounds for believing them to be true, DEFENDANTS did not have accurate or sufficient information concerning the aforesaid representations, and DEFENDANTS were aware that without such information, they could not accurately make the aforesaid representations.

119. At the time the aforesaid representations were made, DEFENDANTS concealed from DECEDENT, and his physicians, their lack of information and consequent inability to make the aforesaid representations accurately.

120. At the time the aforesaid representations were made by DEFENDANTS, and at the time DECEDENT and his physicians took the actions alleged herein, DECEDENT and his physicians were ignorant of the falsity of DEFENDANTS' representations and reasonably believed them to be true. In reliance upon said representations, DECEDENT and his physicians were induced to, and did, use the IVC FILTER. If DECEDENT and his physicians had known the actual facts, they would not have taken such action. The reliance of DECEDENT and his

physicians upon DEFENDANTS' representations was justified because the representations were made by individuals and entities who appeared to be in a position to know the true facts.

121. As a proximate result of the foregoing described false representations and concealment, the IVC FILTER caused DECEDENT'S death. Thus, PLAINTIFF is entitled to recover, as allowed by North Carolina law, the following damages for the estate and the survivors:

a. loss of support and services and consortium pursuant to North Carolina law;

b. loss of DECEDENT'S companionship and protection and for mental pain and suffering from the date of injury;

c. lost parental companionship, instruction, and guidance, and for mental pain and suffering from the date of injury;

d. loss of earnings and net accumulations of the Estate of DECEDENT, beyond the death of DECEDENT; and

e. hospital, medical, funeral, and burial expenses that may become a charge on the Estate of DECEDENT.

122. Alternatively, as a proximate result of the foregoing described false representations and concealment, the IVC FILTER caused severe injury to DECEDENT'S body, leading to damages in the form of pain, suffering, and medical expenses. Moreover, because of DECEDENT'S severe injury from the IVC FILTER, PLAINTIFF suffered a loss of such intangibles as love, sex, companionship, society, comfort, solace, and household services. Thus, PLAINTIFF is entitled to recover, as allowed by North Carolina law, the following damages for the estate and herself:

a. DECEDENT'S pain and suffering sustained between the time of injury and his death;

b. The medical expenses incurred by DECEDENT between the time of injury and his death; and

c. Loss of consortium.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff Lorraine Waters, Individually and as Personal Representative of the Estate of Keith Allen Waters, deceased, demands judgment for damages against DEFENDANTS, jointly and/or severally, as follows:

1. For general damages for personal injuries to Plaintiff, according to proof;
2. For all past, current and future medical and incidental expenses, according to proof;
3. For all loss of earnings, present and future and loss of earning capacity, according to proof;
4. For prejudgment interest, as provided by law;
5. For reasonable attorney's fees;
6. For costs of litigation; and
7. For such other and further relief as this Court may deem just and proper.

DEMAND FOR JURY TRIAL

Plaintiff hereby demands a trial by jury to the fullest extent permitted by law.

Respectfully submitted,

/s/ H. Clay Hodges
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and

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Date: March 31, 2017