UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

TONYA BRAND and ALLEN BRAND	)	
Plaintiffs,	)	
	)	**Case No. 1:13-CV-1469**
vs.	)	
	)	**Jury Trial Demanded**
COOK MEDICAL INCORPORATED a/k/a COOK MEDICAL, INC. ; COOK INCORPORATED; COOK GROUP, INC.; and WILLIAM COOK EUROPE APS	)	
Defendants.	)	

PLAINTIFFS' COMPLAINT AT LAW FOR MONEY DAMAGES AND DEMAND FOR JURY TRIAL

COME NOW TONYA BRAND and ALLEN BRAND, Plaintiffs in the above-styled action, by and through their undersigned attorneys, and file this Complaint at Law for Money Damages and Demand for Jury Trial against the Defendants, COOK MEDICAL INCORPORATED a/k/a COOK MEDICAL, INC., COOK INCORPORATED, COOK GROUP, INC., and WILLIAM COOK EUROPE APS (collectively, the "Defendants") and allege as follows:

1. This is an action for damages relating to Defendants' development, testing, assembling, manufacture, packaging, labeling, preparing, distribution, marketing, supplying, and/or selling the defective product sold under the name "inferior vena cava filter" (hereinafter "IVC filter").

2. This is a renewal action pursuant to O.C.G.A § 9-2-61 of case number 1:13-CV-1469 that was pending in the Northern District of Georgia between these same parties dismissed without prejudice on May 22, 2014. All costs from the previous action have been paid.

I. THE PARTIES

3. Plaintiffs, Tonya Brand and Allen Brand ("Plaintiffs"), at all times relevant to this action resided in and continue to reside in Snellville, Georgia, which is located in Gwinnett County, Georgia.

4. Defendant Cook Medical Incorporated a/k/a Cook Medical, Inc. is an Indiana Corporation with a principal place of business located at 750 Daniels Way, Bloomington, Indiana 47404. Defendant Cook Medical Incorporated a/k/a Cook Medical, Inc. regularly conducts business in the state of Georgia and is authorized to do so.

5. Defendant Cook Incorporated is the parent company of Defendant Cook Medical Incorporated a/k/a Cook Medical, Inc. and is an Indiana Corporation with a principal place of business located at 750 Daniels Way, P.O. Box 489,

Bloomington, Indiana 47402. Defendant Cook Incorporated regularly conducts business in the state of Georgia and is authorized to do so.

6. Defendant Cook Group, Inc. is the parent company of Defendant Cook Medical Incorporated and Cook Incorporated and is an Indiana Corporation with a principal place of business located at 750 Daniels Way, P.O. Box 1608, Bloomington, Indiana 47402. Defendant Cook Group Inc. regularly conducts business in the state of Georgia and is authorized to do so.

7. Defendant William Cook Europe APS is based in Bjaeverskov, Denmark and regularly conducts business in the state of North Carolina and is authorized to do so. Defendant also carried on solicitations or service activities in the state of Georgia.

8. Hereinafter, each of the above Defendants shall be collectively referred to as "Cook."

9. At all times alleged herein, Defendants Cook include and included any and all parent companies, subsidiaries, affiliates, divisions, franchises, partners, joint venturers, and organizational units of any kind, their predecessors, successors and assigns and their officers, directors, employees, agents, representatives and any and all other persons acting on their behalf.

10. Cook develops, manufactures, sells and distributes medical devices for use in various medical applications including endovascular cardiology, and surgical

products throughout the United States and around the world. Cook's products include the Cook Celect Vena Cava Filter, which is used for the prevention of recurrent pulmonary embolism via placement in the vena cava.

11. This Court has jurisdiction over the subject matter of this action and the parties. This Court is also the proper venue for this action.

II. STATEMENT OF VENUE AND JURISDICTION

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

13. Venue is proper in this Court under 28 U.S.C. § 1391, as a substantial part of the events or omissions giving rise to the claim occurred within this judicial district and the Defendants regularly conduct business in this District.

III. FACTUAL BACKGROUND

14. Defendants designed, researched, developed, manufactured, tested, marketed, advertised, promoted, distributed, and sell products such as IVC filters that are sold to and marketed to prevent, among other things, recurrent pulmonary embolism via placement in the vena cava. One such Defendants' product, the Cook Celect Vena Cava Filter, is introduced into the vena cava via an 8.5 French coaxial introducer sheath system.

15. The Cook Celect Filter Set is collectively referred to herein as the Cook Filter.

16. Defendants sought Food and Drug Administration ("FDA") approval to market the Cook Filter device and/or its components under Section 510(k) of the Medical Device Amendment.

17. On or about March 19, 2008, Defendants obtained Food and Drug Administration ("FDA") approval to market the Cook Filter device and/or its components under section 510(k) of the Medical Device Amendment.

18. Section 510(k) allows marketing of medical devices if the device is deemed substantially equivalent to other legally marketed predicate devices without formal review for the safety or efficacy of the said device.

19. An IVC filter, like the Cook Filter, is a device designed to filter blood clots (called "thrombi") that would otherwise travel from the lower portions of the body to the heart and lungs. IVC filters may be designed to be implanted, either temporarily or permanently, within the vena cava.

20. The inferior vena cava is a vein that returns blood to the heart from the lower portion of the body. In certain people, and for various reasons, thrombi travel from vessels in the legs and pelvis, through the vena cava into the lungs. Often these thrombi develop in the deep leg veins. The thrombi are called "deep vein thrombosis" or DVT. Once the thrombi reach the lungs they are considered

"pulmonary emboli" or PE. PE presents a grave risk to human life and often results in death.

21. An IVC filter, like the Cook Filter, is designed to prevent thromboembolic events by filtering or preventing blood clots/thrombi from traveling to the heart and/or lungs.

22. The Cook Celect Filter is a retrievable filter, and is based on the Gunther Tulip filter.

23. The Cook Celect Filter has four (4) anchoring struts for fixation and eight (8) independent secondary struts to improve self-centering and clot trapping.

24. On March 19, 2009, Plaintiff Tonya Brand presented herself for a spinal fusion surgery. Because Plaintiff had developed DVT in 2008, it was determined that an IVC Filter would be implanted in her prior to the spinal fusion surgery. On March 19, 2009, the Cook Celect Filter was inserted into Plaintiff. There were no complications.

25. On or about May 7, 2011, Plaintiff discovered a painful region on the inside of her right thigh. This region worsened to span a four- or five-inch area. Plaintiff went to Eastside Medical Center, where she was informed it was likely a blood clot. On this date, the Cook Filter was considered to be correctly positioned, without complication, and performing as expected.

26. The next day, Plaintiff was given an ultrasound test which revealed no blood clot in the painful area. Instead, an object about the size of a toothpick was located in the painful area.

27. On or about June 17, 2011, Plaintiff pressed upon the protrusion that had developed on her right thigh. The protrusion popped and a piece of metal wire pierced through her skin. It was approximately one-and-a-half inches long and was later determined to be one of the struts of the Cook Celect Filter.

28. On or about June 28, 2011, Plaintiff had x-rays taken to examine the Cook Celect Filter. A second strut fracture of the Cook Filter was located. This second strut had broken from the Cook Filter and migrated to a spot near Plaintiff's spine. This strut remains in place as it is too risky to remove.

29. Then, Plaintiff underwent a surgery on July 14, 2011 to remove what remained of the fractured Cook Celect Filter, but after several unsuccessful attempts to remove the Filter during this surgery, the procedure was halted. The fractured Cook Celect Filter as well as the fractured strut near her spine remain implanted in Plaintiff's body.

30. Plaintiff is at risk for future Cook Celect Filter fractures and migrations. She faces numerous health risks, including the risk of death. For the rest of Plaintiff's life, she will require on-going medical monitoring.

31. At all times relevant hereto the Cook Filter was widely advertised and promoted by the Defendants as a safe and effective treatment for prevention of recurrent pulmonary embolism via placement in the vena cava.

32. At all times relevant hereto, Defendants knew its Cook Filter was defective and knew that defect was attributable to the design's failure to withstand the normal anatomical and physiological loading cycles exerted in vivo.

33. The Defendants failed to disclose to physicians, patients, or Plaintiffs that its Cook Filter was subject to breakage and migration or the appropriate degree of risk of perforation and damage to the vena cava wall.

34. At all times relevant hereto, the Defendants continued to promote the Cook Filter as safe and effective even though the clinical trials that had been performed were not adequate to support long or short term efficacy.

35. The Defendants concealed the known risks and failed to warn of known or scientifically knowable dangers and risks associated with the Cook Filter, as aforesaid.

36. The Cook Filter is constructed of conichrome.

37. The Defendants specifically advertise the conichrome construction of the filter as a frame which "reduces the risk of fracture."

38. The failure of the Cook Filter is attributable, in part, to the fact that the Cook Filter suffers from a design defect causing it to be unable to withstand the normal anatomical and physiological loading cycles exerted in vivo.

39. At all times relevant hereto the Defendants failed to provide sufficient warnings and instructions that would have put the Plaintiff and the general public on notice of the dangers and adverse effects caused by implantation of the Cook Filter, including, but not limited to the design's failure to withstand the normal anatomical and physiological loading cycles exerted in vivo.

40. The Cook Filter was designed, manufactured, distributed, sold and/or supplied by the Defendants, and was marketed while defective due to the inadequate warnings, instructions, labeling, and/or inadequate testing in light of Defendants' knowledge of the products failure and serious adverse events.

41. That at all times relevant hereto, 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 should have known of the hazardous and dangerous propensities of the said products, and thereby actively participated in the tortuous conduct that resulted in the injuries suffered by the Plaintiff.

IV. COUNT ONE: STRICT PRODUCT LIABILITY

42. Plaintiff repeats and re-alleges each and every allegation contained in paragraphs one through forty of Sections I, II and III of this Complaint as though specifically pled herein.

43. At all times relevant hereto, the Cook Filter was dangerous and presented a substantial danger to patients who were implanted with the Cook Filter and these risks and dangers were known or knowable at the times of distribution and implantation in Plaintiff Tonya Brand in 2009. Ordinary consumers would not have recognized the potential risks and dangers the Cook Filter posed to patients, because its use was specifically promoted to improve health of such patients. The Cook Filter was used by the Plaintiff and her treating physicians in a reasonably foreseeable manner.

44. The Defendants failed to provide warnings of such risks and dangers to the Plaintiff and her medical providers as described herein.

45. As a direct and proximate result of the Cook Filter's defects, as described herein, Plaintiff Tonya Brand suffered significant and severe injuries to her body resulting in significant expenses for medical treatment, as well as incurred a substantial loss of earnings, as well as non-economic damages.

WHEREFORE, the Plaintiff Tonya Brand demands judgment against the Defendants Cook Medical Incorporated a/k/a Cook Medical, Inc., Cook Incorporated, Cook Group, Inc., and William Cook Europe APS for whatever amount she may be entitled, together with costs of this action. This jurisdictional amount exceeds seventy-five thousand dollars ($75,000.01+).

V. COUNT TWO: NEGLIGENCE

46. Plaintiff repeats and re-alleges each and every allegation contained in paragraphs one through forty of Sections I, II and III of this Complaint as though specifically plead herein.

47. At all times relevant to this cause of action, the Defendants Cook Medical Incorporated a/k/a Cook Medical, Inc., Cook Incorporated, Cook Group, Inc., and William Cook Europe APS were in the business of designing, developing, manufacturing, marketing and selling sophisticated medical devices, including the Cook Filter.

48. At all times relevant hereto, the Defendants Cook Medical Incorporated a/k/a Cook Medical, Inc., Cook Incorporated, Cook Group, Inc., and William Cook Europe APS were under a duty to act reasonably to design, develop, manufacture, market and sell a product that did not present a risk of harm or injury to the Plaintiff and to those people receiving the Cook Filter.

49. At the time of manufacture and sale of the Cook Filter, the Defendants Cook Medical Incorporated a/k/a Cook Medical, Inc., Cook Incorporated, Cook Group, Inc., and William Cook Europe APS knew or reasonably should have known the Cook 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 an unreasonable risk of migration of the device and/or portions of the device;

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

d. Was designed and manufactured so as to present an unreasonable risk of perforation and damage to the vena cava wall.

50. Despite the aforementioned duty on the part of the Defendants Cook Medical Incorporated a/k/a Cook Medical, Inc., Cook Incorporated, Cook Group, Inc., and William Cook Europe APS, they committed one or more breaches of their duty of reasonable care and were negligent in:

a. Unreasonably and carelessly failing to properly warn of the dangers and risks of harm associated with the Cook Filter, specifically its incidents fracture, migration, perforation and other failure;

b. Unreasonably and carelessly manufactured a product that was insufficient in strength or structural integrity to withstand the foreseeable use of normal placement within the human body;

c. Unreasonably and carelessly designed a product that was insufficient in strength or structural integrity to withstand the foreseeable use of normal placement within the human body; and

d. Unreasonably and carelessly designed a product that presented a risk of harm to the Plaintiff and others similarly situated in that it was prone to fail.

51. As a direct and proximate result of the Cook Filter's defects, as described herein, Plaintiff Tonya Brand suffered significant and severe injuries to her body resulting in significant expenses for medical treatment, as well as incurred a substantial loss of earnings, as well as non-economic damages.

WHEREFORE, the Plaintiff Tonya Brand demands judgment against the Defendants Cook Medical Incorporated a/k/a Cook Medical, Inc., Cook Incorporated, Cook Group, Inc., and William Cook Europe APS for whatever amount she may be entitled, together with costs of this action. This jurisdictional amount exceeds seventy-five thousand dollars ($75,000.01+).

VI. COUNT THREE: BREACH OF EXPRESS & IMPLIED WARRANTY

52. Plaintiff repeats and re-alleges each and every allegation contained in paragraphs one through forty of Sections I, II and III of this Complaint as though specifically placed herein.

53. Plaintiff, through her medical providers, purchased the Cook Filter from Defendants Cook Medical Incorporated a/k/a Cook Medical, Inc., Cook Incorporated, Cook Group, Inc., and William Cook Europe APS.

54. At all times to this cause of action, the Defendants Cook Medical Incorporated a/k/a Cook Medical, Inc., Cook Incorporated, Cook Group, Inc., and William Cook Europe APS were merchants of goods of the kind including medical devices and vena cava filters (like the Cook Filter).

55. At the time and place of sale, distribution and supply of the Cook Filter to Plaintiff, the Defendants expressly represented and warranted that the Cook Filter was safe, and impliedly warranted that the product was reasonably fit for its intended purpose and was marketable quality.

56. At the time of Plaintiff's purchase from Defendants, the Cook Filter was not in a merchantable condition, in that:

a. It was designed in such a manner so as to be prone to a unreasonably high incident of fracture, perforation of vessels and organs, and/or migration;

b. It was designed in such a manner so as to result in a unreasonably high incident of injury to the organs including the vena cava of its purchaser; and

c. It was manufactured in such a manner so that the exterior surface of the Cook Filter was inadequately, improperly and inappropriately designed causing the device to weaken and fail.

57. Additionally, implied warranties were beached as follows:

a. The Defendants failed to provide the warning or instruction and/or an adequate warning or instruction which a manufacturer exercising reasonable care would

have provided concerning that risk, in light of the likelihood that the Cook Filter would cause harm;

b. The Defendants manufactured and/or sold the Cook Filter and that filter did not conform to representations made by the Defendant when it left the Defendant's control;

c. The Defendants manufactured and/or sold the Cook Filter that was more dangerous than an ordinary consumer would expect when used in an intended or reasonably foreseeable manner, and the foreseeable risks associated with the Cook Filter design or formulation exceeded the benefits associated with that design. These defects existed at the time the product left the Defendants' control; and

d. The Defendants manufactured and/or sold the Cook Filter when it deviated in a material way from the design specifications, formulas or performance standards or form otherwise identical units manufactured to the same design specifications, formulas, or performance standards, and these defects existed at the time the product left the Defendants' control.

58. Further, Defendants' marketing of the Cook Filter was false and/or misleading.

59. Plaintiff, through her attending physicians, relied on these representations in determining which IVC filter to use for implantation in the Plaintiff.

60. Defendants' filter was unfit and unsafe for use by users as it posed an unreasonable and extreme risk of injury to persons using said products, and accordingly Defendants breached their expressed warranties and the implied warranties associated with the product.

61. The foregoing warranty breaches were a substantial factor in causing Plaintiff's injuries and damages as alleged.

62. As a direct and proximate result of the Cook Filter's defects, as described herein, Plaintiff Tonya Brand suffered significant and severe injuries to her body resulting in significant expenses for medical treatment, as well as incurred a substantial loss of earnings, as well as non-economic damages.

WHEREFORE, the Plaintiff Tonya Brand demands judgment against the Defendants Cook Medical Incorporated a/k/a Cook Medical, Inc., Cook Incorporated, Cook Group, Inc., and William Cook Europe APS for whatever amount she may be entitled, together with costs of this action. This jurisdictional amount exceeds seventy-five thousand dollars ($75,000.01+).

VII. COUNT FIVE: LOSS OF CONSORTIUM ON BEHALF OF PLAINTIFF ALLEN BRAND

63. Plaintiffs hereby restate and allege each and every allegation set forth above, with the same force and effect as if herein repeated and set forth at length.

64. Plaintiff Allen Brand is and at all times relevant hereto has been the lawful spouse of Plaintiff Tonya Brand and as such Plaintiff Allen Brand is entitled to the comfort and enjoyment of her society and services.

65. As a direct and proximate result of the foregoing misconduct of the Defendants, Plaintiff Allen Brand has been deprived of his spouse's companionship, services, solace, consortium, affection and attention to which he is entitled.

66. As a result of all of the foregoing, Plaintiff Allen Brand has been and will continue to be injured and damaged.

VIII. COUNT SIX: PUNITIVE DAMAGES

67. Plaintiff 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.

68. The actions and inactions of all the Defendants, and or alternatively the employees or agents of Defendants, and their predecessors-in-interest, whether taken separately, or together, were of such a character as to constitute a pattern or practice of intentional wrongful conduct and/or malice resulting in the injury and damages of Plaintiff Tonya Brand.

69. More specifically, Defendants, or alternatively the employees or agents of Defendants, and their predecessors-in-interest, consciously and/or deliberately concealed risks associated with their product and nevertheless proceeded with conscious indifference to the rights, safety, and welfare of Plaintiff Tonya Brand by failing to act to disclose these risks to her or her healthcare professionals.

WHEREFORE, Defendants are guilty of oppression, fraud, and/or malice, express or implied for which they should be held liable in punitive damages to Plaintiff Tonya Brand.

IX. REQUEST RELIEF

WHEREFORE, the Plaintiff, Tonya Brand, demands judgment against the Defendants Cook Medical Incorporated a/k/a Cook Medical, Inc., Cook Incorporated, Cook Group, Inc., and William Cook Europe APS, for whatever amount she may be entitled, including punitive damages if deemed applicable, together with costs of this action. The jurisdictional amount exceeds seventy-five thousand dollars ($75,000.01+).

X. JURY TRIAL

The Plaintiffs respectfully request a trial by jury in the above case as to all issues.

This 13th Day of November, 2014.

Respectfully Submitted,

Jason T. Schneider, P.C.

By: */s/ Robert M. Hammers, Jr.*
Robert M. Hammers, Jr.
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