UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION

ELIZABETH JANE HILL,

Plaintiff,

v. CASE NO:

COOK MEDICAL INCORPORATED
a/k/a COOK MEDICAL, INC.,
COOK INCORPORATED, and
COOK GROUP, INC.

Defendants.
_____/

COMPLAINT

Plaintiff, ELIZABETH JANE HILL, brings this action against the Defendants, COOK MEDICAL INCORPORATED a/k/a COOK MEDICAL, INC., COOK INCORPORATED, and COOK GROUP, INC. (collectively, the "Defendants") and allege as follows:

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

GENERAL ALLEGATIONS
THE PARTIES

2. At all times relevant to this action, Plaintiff, ELIZABETH JANE HILL, reside in Dunnellon, Florida, and is a citizen of Florida.

3. Defendant, COOK MEDICAL INCORPORATED d/b/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 a state of Indiana, is authorized to do so and is a citizen of Indiana.

4. 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 Indiana, is authorized to do so and is a citizen of Indiana.

5. 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 Indiana, is authorized to do so and is a citizen of Indiana.

6. Hereinafter, each of the above Defendants shall be collectively referred to as "COOK."

7. At all times alleged herein, Defendants, COOK, include and included any and all parent companies, subsidiaries, affiliates, divisions, franchises, partners, joint ventures, 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.

8. 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 Gunther Tulip Vena Cave Filter and the COOK Collect Vena Cava Filter, which are used for the prevention of recurrent pulmonary embolism via placement in the vena cava.

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

STATEMENT OF VENUE AND JURISDICTION

10. 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.

11. 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.

FACTUAL BACKGROUND

12. Defendants designed, researched, developed, manufactured, tested, marketed, advertised, promoted, distributed, and sell products such as IVC filters that are sold to and marketed as a temporary/retrievable device to prevent, among other things, recurrent pulmonary embolism via placement in the vena cava. One such Defendants' product, the Celect Vena Cava Filter, is introduced into the vena cava via a 7 or 8.5 French coaxial introducer sheath system, depending on the insertion location: femoral or jugular.

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

14. 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.

15. On or about November 10, 2003, 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.

16. 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.

17. 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.

18. 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.

19. 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.

20. The Celect Vena Cava Filter was sold and marketed as a temporary/retrievable filter, and is predicated on the Cook Tulip Filter (hereinafter referred to as the "predicate device").

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

22. On or about November 17, 2010, it was determined that ELIZABETH JANE HILL would be implanted with a temporary/retrievable IVC Filter known as the Celect Vena Cava Filter which was designed, manufactured, marketed, distributed and sold by COOK. The Celect Vena Cava Filter was implanted into ELIZABETH JANE HILL and there were no complications at the time of implantation.

23.On or about March 23, 2011 the decision was made to remove the COOK filter.

23. All attempts to remove the COOK filter on March 23, 2011 were unsuccessful and it was determined that the COOK filter could not be removed. Thus, further attempts at removal of the COOK Filter were abandoned.

24. Subsequently ELIZABETH JANE HILL developed severe gastrointestinal symptoms, fatigue, diarrhea, vomiting and abdominal pain. It was determined that she had developed inflammatory changes affecting the bowel, the cause of which was unknown.

25. Due to persistent severe gastrointestinal symptoms, fatigue, diarrhea, vomiting

and abdominal pain ELIZABETH JANE HILL underwent an endoscopy procedure where it was determined that Cook filter that had been implanted almost three (3) years earlier had perforated through her inferior vena cava and into her duodenum.

26. ELIZABETH JANE HILL was thereafter to a tertiary hospital, Penn State Hershey Medical Center, where her filter was removed; however, there was narrowing at the explant site of the inferior vena cava and the bowel.

27. At all times relevant hereto, the COOK filter was widely advertised and promoted by the Defendants as a safe and effective treatment for prevent of recurrent pulmonary embolism via placement in the vena cava as temporary/retrievable device.

28. 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.

29. The Defendants failed to disclose to physicians, patients, or Plaintiff that its COOK filter is subject to not being removed/retrieved ("retained filter") once the risk for pulmonary emboli has passed placing patients at risk for injury due to breakage, migration, perforation and damage to the vena cava and adjacent organs and structures. Patients who have a retained filter require lifetime anticoagulation medication(s) which places these patients at high risk for hemorrhage and which complicates other medical care and treatment of these patients.

30. At all times relevant hereto, the COOK filter had a safety profile that was not as good as or better than its predicate device, Defendant's misbranded the filter in that Defendant's statement's regarding the safety of the filter were false and misleading yet Defendants continued to promote the

COOK Filter as safe and effective even though the data available, studies, literature and/or clinical trials did not support long or short term safety and efficacy.

31. 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.

32. The COOK Filter is construed of conichrome.

33. The Defendants specifically advertise the safety of conichrome construction f of the filter.

34. 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 causing the filter to tilt, migrate, perforate, fracture and/or rendering this removable filter not removable.

35. At all times relevant hereto, the Defendants failed to provide sufficient warnings and instructions that would have put the Plaintiff, the general public and the medical community 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.

36. 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.

37. 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 tortious conduct that resulted in the injuries suffered by the Plaintiff.

COUNT I
STRICT PRODUCT LIABILITY

38. Plaintiffs repeats and re-alleges each and every allegation contained in paragraphs 1 through 37 of this Complaint as though specifically pled herein.

39. 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 ELIZABETH JANE HILL in November 17, 2010. Ordinary consumers would not have recognized the potential risks and dangers the COOK filter posed to patients, because its use was specifically promoted to protect patients and to improve health of such patients. The COOK Filter was used by the Plaintiff and her treating physicians in a reasonably foreseeable manner.

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

41. As a direct and proximate result of the COOK Filter's defects, as described herein, Plaintiff, ELIZABETH JANE HILL, 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, ELIZABETH JANE HILL, demands judgment

against the Defendants, COOK MEDICAL INCORPORATED a/k/a COOK MEDICAL, INC., COOK INCORPORATED, and COOK GROUP, INC., for whatever amount she may be entitled, together with costs of this action. This jurisdictional amount exceeds Seventy-Five Thousand Dollars ($75,000.00).

COUNT II
NEGLIGENCE

42. Plaintiff repeats and re-alleges each and every allegation contained in Paragraphs 1 through 37 of this Complaint as though specifically plead herein.

43. At all times relevant to this cause of action, the Defendants, COOK MEDICAL INCORPORATED a/k/a COOK MEDICAL, INC., COOK INCORPORATED, and COOK GROUP, INC., were in the business of designing, developing, manufacturing, marketing and selling sophisticated medical devices, including the COOK Filter.

44. At all times relevant hereto, the Defendants, COOK MEDICAL INCORPORATED a/k/a COOK MEDICAL, INC., COOK INCORPORATED, and COOK GROUP, INC., 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.

45. At the time of manufacture and sale of the COOK Filter, the Defendants, COOK MEDICAL INCORPORATED a/k/a COOK MEDICAL, INC., COOK INCORPORATED, and COOK GROUP, INC., 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;

d. Was designed and manufactured so as to present an unreasonable risk of tilt of the device within the vena cava;

e. Was designed and manufactured so as to present an unreasonable risk that the "removable" filter is not removable and/or extraordinary efforts are required to remove the filter; and/or,

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

46. Despite the aforementioned duty on the part of the Defendants, COOK MEDICAL INCORPORATED a/k/a COOK MEDICAL, INC., COOK INCORPORATED, and COOK GROUP, INC., they committed one or more breaches of their duty of reasonable care and were negligence 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, tilt, inability to remove/difficulty removing the filter 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.

47. As a direct and proximate result of the COOK Filter's defects, as

described herein, Plaintiff, ELIZABETH JANE HILL, 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, ELIZABETH JANE HILL, demands judgment against the Defendants, COOK MEDICAL INCORPORATED a/k/a COOK MEDICAL, INC., COOK INCORPORATED, and COOK GROUP, INC., for whatever amount he may be entitled, together with costs of this action. This jurisdictional amount exceeds Seventy-Five Thousand Dollars ($75,000.00).

COUNT III
BREACH OF EXPRESS & IMPLIED WARRANTY

48. Plaintiff repeats and re-alleges each and every allegation contained in Paragraphs 1 through 37 of this Complaint as though specifically placed herein.

49. Plaintiff, through her medical providers, purchased the COOK Filter from Defendants, COOK MEDICAL INCORPROATED a/k/a COOK MEDICAL, INC., COOK INCORPORATED, and COOK GROUP, INC.

50. At all times to this cause of action, the Defendants, COOK MEDICAL INCORPORATED a/k/a COOK MEDICAL, INC., COOK INCORPORATED, and COOK GROUP, INC., were merchants of goods of the kind including medical devices and vena cava filters (like the COOK Filter).

51. 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 of marketable quality.

52. 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, tilt, inability to remove or difficulty removing the filter and/or migration;

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

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

53. Additionally, warranties were breached 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.

54. Further, Defendants' marketing of the COOK Filter was false and/or misleading.

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

56. 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.

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

58. As a direct and proximate result of the COOK Filter's defects, as described herein, Plaintiff, ELIZABETH JANE HILL, 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, ELIZABETH JANE HILL, demands judgment against the Defendants, COOK MEDICAL INCORPROATED a/k/a COOK MEDICAL, INC., COOK INCORPORATED, and COOK GROUP, INC., for whatever amount she may be entitled, together with costs of this action. This jurisdictional amount exceeds Seventh-Five Thousand Dollars ($75,000.00).

COUNT V
PUNITIVE DAMAGES

59. Plaintiff re-alleges each and every allegation, paragraphs 1-58, in this Complaint and incorporates each allegation into this Count, as if set forth at length, in its entirety.

60. 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, ELIZABETH JANE HILL,

61. 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, ELIZABETH JANE HILL, 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, ELIZABETH JANE HILL.

REQUESTED RELIEF

WHEREFORE, the Plaintiff, ELIZABETH JANE HILL, demands judgment against the Defendants, COOK MEDICAL INCORPORATED a/k/a COOK MEDICAL, INC., COOK INCORPORATED, and COOK GROUP, INC., 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 ($75,000.00).

JURY TRIAL

The Plaintiff respectfully requests a trial by jury in the above case as to all issues.

DATED: This 23rd day of October, 2014.

Respectfully submitted,

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