IN THE UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

IN RE: COOK MEDICAL, INC., IVC FILTERS MARKETING, SALES PRACTICES AND PRODUCTS LIABILITY LITIGATION	)	1:14-ml-02570 MDL No. 2570

ARTHUR GAGE

PLAINTIFF,

V. CIVIL ACTION NO. _____

COOK MEDICAL INCORPORATED A/K/A COOK MEDICAL, INC.; COOK INCORPORATED; COOK GROUP, INC.; AND WILLIAM COOK EUROPE APS,

DEFENDANTS.

PLAINTIFF'S ORIGINAL COMPLAINT

Comes Now, Plaintiff Arthur Gage by and through his undersigned attorney, and files this, his 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").

I. THE PARTIES

2. Plaintiff Arthur Gage ("Plaintiff"), at all times relevant to this action is a citizen of and resides in and continues to reside in Woodridge, Illinois which is located in DuPage County, Illinois.

3. Plaintiff Arthur Gage was injured as a result of being implanted with a Cook Günther-Tulip Filter, and therefore seeks damages for pain and suffering, ascertainable economic losses, attorneys' fees, reimbursement of the cost of implanting the Cook IVC Filter, and reimbursement for all past, present, and future health and medical care costs related to the IVC Filter.

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 Indiana and is authorized to do so. Defendant also carried on solicitations or service activities in the state of Indiana.

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 Indiana and is authorized to do so. Defendant also carried on solicitations or service activities in the state of Indiana.

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 Indiana and is authorized to do so. Defendant also carried on solicitations or service activities in the state of Indiana.

7. Defendant William Cook Europe APS (hereinafter "Cook Europe") is a foreign corporation with its principal place of business located at Sandet 6, Bjaverskov 4632, Denmark. Cook Europe's business form most closely resembles that of an American Corporation. Cook Europe's headquarters is based at Sandet 6, Bjaverskov 4632, Denmark. Cook Europe is incorporated in and under the laws of Denmark. Cook Europe was not incorporated in the state of Illinois, nor does it have its principal place of business in the state of Illinois. Because Cook Europe is incorporated under the laws of Denmark and has its principal place of business in Denmark, diversity of citizenship exits between Plaintiff Arthur Gage and Cook Europe. Cook Europe conducted research and contributed to the development, the design, testing and manufacture, as well as marketing and distribution of the inferior vena cava filter implanted in Arthur Gage. Cook Europe conducted regular and

sustained business by selling and distributing its products in Indiana. Defendant also carried on solicitations or service activities in the state of Indiana.

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 Günther-Tulip 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 and are headquartered 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 as a temporary/retrievable device to prevent, among other things, recurrent pulmonary embolism via placement in the vena cava. One such Defendants' product, the Cook Günther-Tulip Filter, is introduced into the vena cava via an 8.5 French coaxial introducer sheath system.

15. The Cook Günther-Tulip 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 May 5, 2005, 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 Günther-Tulip Filter is a retrievable filter.

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

24. Plaintiff Arthur Gage had a history of Pulmonary Emboli which caused him to be admitted to Edward Hospital in Naperville, Illinois on April 25, 2011. There it was determined that an IVC Filter would be implanted. That same day, the Cook Günther-Tulip Filter was inserted into Plaintiff Arthur Gage. There were no complications at that time.

25. Plaintiff Arthur Gage began experiencing extreme chest pain and shortness of breath immediately after the implant of the Filter. Plaintiff was later told that the filter

perforated his vena cava and could not be removed due to such a high risk of death during the procedure.

26. 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.

27. 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.

28. The Defendants failed to disclose to physicians, patients, or Plaintiff 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.

29. 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.

30. 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.

31. The Cook Filter is constructed of Conichrome, a metal alloy.

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

33. 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.

34. 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.

35. 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.

36. 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. CAUSES OF ACTION

COUNT ONE: STRICT PRODUCT LIABILITY

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

38. 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 Arthur Gage in 2012. 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 his treating physicians in a reasonably foreseeable manner.

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

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

41. The Plaintiff Arthur Gage 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 he may be entitled, together with costs of this action. This jurisdictional amount exceeds seventy-five thousand dollars ($75,000.01+).

COUNT TWO: NEGLIGENCE

42. Plaintiff repeats and re-alleges each and every allegation contained in paragraphs one through thirty-six of Sections I, II and III 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, 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.

44. 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.

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, 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.

46. 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.

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

48. The Plaintiff Arthur Gage 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 he may be entitled, together with costs of this action. This jurisdictional amount exceeds seventy-five thousand dollars ($75,000.01+).

COUNT THREE: BREACH OF EXPRESS & IMPLIED WARRANTY

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

50. Plaintiff, through his 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.

51. 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).

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 marketable quality.

52. At the time of Plaintiffs 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 an 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.

53. 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.

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

55. Plaintiff, through his 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 Plaintiffs injuries and damages as alleged.

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

59. The Plaintiff Arthur Gage 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 he may be entitled, together with costs of this action. This jurisdictional amount exceeds seventy-five thousand dollars ($75,000.01+).

V. PUNITIVE DAMAGES

60. 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.

61. 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 Arthur Gage.

62. 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 Arthur Gage by failing to act to disclose these risks to him or his healthcare professionals.

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

VI. REQUEST RELIEF

WHEREFORE, the Plaintiff Arthur Gage 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 they 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+).

VI. JURY TRIAL

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

Respectfully Submitted,

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