

**IN THE UNITED STATE DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF INDIANA  
INDIANAPOLIS DIVISION**

	)	
<b>LARA L. ADAMS, and</b>	)	
<b>KEITH N. ADAMS</b>	)	
	)	
Plaintiffs,	)	
	)	Case No. 1:13-cv-13
	)	
vs.	)	<b>JURY TRIAL DEMANDED</b>
	)	
<b>COOK MEDICAL INCORPORATED</b>	)	
<b>a/k/a COOK MEDICAL, INC.;</b>	)	
<b>COOK INCORPORATED;</b>	)	
<b>COOK GROUP, INC.;</b>	)	
<b>WILLIAM COOK EUROPE APS;</b>	)	
<b>DOES I-XX and</b>	)	
<b>ROE Corporations XXI –XL</b>	)	
	)	
Defendants.	)	

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**COMPLAINT AT LAW AND DEMAND FOR JURY TRIAL**

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**NOW COME** the Plaintiffs, LARA L. ADAMS and KEITH N. ADAMS, by and through their counsel, and complaining of the Defendants, COOK MEDICAL INCORPORATED a/k/a COOK MEDICAL, INC., COOK INCORPORATED, COOK GROUP, INC., WILLIAM COOK EUROPE APS, DOES I-XX AND ROE CORPORATIONS XXI-XL for causes of action and state as follows:

**I. THE PARTIES**

1. The Plaintiff, Lara L. Adams is the wife of Keith N. Adams and currently resides in Montrose, Colorado. Plaintiff Lara L. Adams underwent prophylactic placement of a Cook Select Inferior Vena Cava ("IVC") Filter at the Billings Hospital located in Billings, Montana while a resident of that state. On or about March of 2011, this IVC Filter subsequently fractured in multiple pieces migrated to her vital organs causing injury and damage. She was caused to undergo surgery, and

extensive medical care as a result of the failure of the Cook Celect IVC filter device manufactured by Defendants. Plaintiff has incurred significant medical expenses and has endured extreme pain and suffering, loss of enjoyment of life, disability, and other losses. She will require ongoing medical care to monitor her condition.

2. The Plaintiff Keith N. Adams at all times relevant to this action resided in Montana and presently resides in Montrose, Colorado. Plaintiffs Keith N. Adams and Lara L. Adams were and are, at all time relevant to this action, legally married as husband and wife. Plaintiff Keith N. Adams brings this action for, *inter alia*, the loss of consortium, comfort, and society he suffered due to the personal injuries suffered by his wife Lara L. Adams.

3. 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 Montana and Indiana, and is authorized to do so.

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 Montana and Indiana, and is authorized to do so.

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 Montana and Indiana, and is authorized to do so.

6. Defendant William Cook Europe APS is based in Bjaeverskov, Denmark and regularly conducts business in the State of Montana and Indiana, and is authorized to do so.

7. Hereinafter, each of the above defendants shall be collectively referred to as "Cook."

8. 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.

9. 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.

10. The identity of defendants designated as DOES I through XX are unknown at the present time; however, it is alleged and believed these defendants were involved in the initiation, approval, support or execution of the wrongful acts upon which this litigation is premised, or of similar actions directed against Plaintiff about which she/it is presently unaware. These defendants are in some manner negligently, vicariously or statutorily responsible for the events and happenings referred to and caused damages proximately to Plaintiffs herein. As the specific identities of these parties are revealed through the course of discovery, the DOE appellation will be replaced to identify these parties by their true names and capacities.

11. The identify of defendants designed as ROE CORPORATIONS XI through XL are unknown at the present time; however, it is alleged and believed these defendants were involved in the initiation, approval, support or execution of the wrongful acts upon which this litigation is premised, or of similar actions directed against Plaintiff about which she/it is presently unaware. These defendants

are in some manner negligently, vicariously or statutorily responsible for the events and happenings referred to and caused damages proximately to Plaintiffs herein. As the specific identities of these parties are revealed through the course of discovery, the DOE appellation will be replaced to identify these parties by their true names and capacities.

## **II. STATEMENT OF VENUE AND JURISDICTION**

12. Jurisdiction is proper in this Court under 28 U.S.C. § 1332(a)(1) because the Plaintiffs and the Defendants are citizens of different states, and the amount in controversy exceeds seventy-five thousand dollars (\$75,000.00), excluding interest and costs.

13. Venue is proper in this Court under 28 U.S.C. §1391, as the Defendants reside in this District and all Defendants regularly conduct business in this State. The Defendants' headquarters are located within the Bloomington, Indiana, said facility being within this judicial district, and the Defendants are subject to personal jurisdiction of this judicial district.

## **III. FACTUAL BACKGROUND**

14. Defendants design, research, develop, manufacturer, test, market, advertise, promote, distribute, and sell products that are sold to and marketed to prevent, among other things, recurrent pulmonary embolism via placement in the vena cava. One such Defendant's product, the Cook Select Vena Cava Filter, is introduced via an 8.5 French coaxial introducer sheath system.

15. The Cook Select 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 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 grave risk to human life and often result in death.

21. An IVC filter, like the Cook Filter, is designed to prevent thromboembolic events.

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 or about September 22, 2009, the Plaintiff, Lara L. Adams was admitted to Billings Clinic Hospital located in Billings, Montana for an emergency colostomy.

25. On or about September 24, 2009, the Cook Celect IVC Filter was positioned and deployed in the infrarenal position. There were no complications.

26. On or about September 27, 2009, the Plaintiff, Lara L. Adams had a chest x-ray wherein the filter was noted. No tilt or breakage was reported at this time.

27. On or about January 7, 2010, the Plaintiff, Lara L. Adams was admitted to West Park Hospital in Cody, Wyoming for a small bowel obstruction unrelated to her Cook Filter.

During this hospitalization, she underwent a CT Scan which showed her Cook Filter to be tilted medially with deformity of the vena cava. At that time, however, the doctors believed that the IVC filter device was stable and kept it in place.

28. On or about March 11, 2011, the Plaintiff, Lara L. Adams went to the hospital complaining of crippling pain and discomfort. At the time, the pain was thought to be caused by a kidney stone rendering Lara Adams unable to even stand during examination. CT scan images were taken at this time, and it was discovered that the Cook Celect IVC filter broke apart and several fragments migrated throughout her body. One fragment has migrated to her lung, the second is in her liver and the third was embedded into her vena cava.

29. On or about March 14, 2011, Dr. Alex Westerband at the Oro Valley Hospital located in Oracle, Arizona attempted to remove this device and the fragments. Although he was successful in extracting the main components, he was unable to retrieve the fragments from her lung and liver, and a third fragment from her vena cava. Dr. Westerband is particularly concerned about this third fragment as it is susceptible to migration.

30. 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. 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*.

31. In a study of Gunther Tulip and Celect IVC filters implanted between July 2007 and May of 2009 reported by Cardiovascular Interventional Radiology electronically on March 30, 2011 and published by journal in April 2012, one hundred percent of the Cook Celect filters and Gunther Tulip filters imaged after 71 days of implant caused some degree of filter perforation of the venal caval wall.

Durack JC, et al, Cardiovasc Intervent Radiol "Perforation of the IVC: rule rather than the exception after longer indwelling times for the Gunther Tulip and Celect Retrievable Filters," 2012 Apr.; 35(2):299-308. Epub 2011 Mar 30. Defendants knew or should have known that their IVC filters were more likely than not perforate the vena cava wall.

32. This same study reported that tilt was seen in forty percent of the implanted Gunther Tulip and Celect IVC filters. Defendants knew or should have known that their IVC filters were more likely than not tilt.

33. The Defendants failed to disclose to physicians, patients or Plaintiffs that its Cook Filter was subject to breakage and migration.

34. At all times relevant hereto, the Defendants continued to promote the Cook Filter as safe and effective even when inadequate clinical trials had been performed to support long or short to 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 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 Defendant, and was marketed while defective due to the inadequate warnings, instructions, labeling, and/or inadequate testing in light of Defendant's 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, Lara L. Adams, repeats and re-alleges each and every allegation contained in paragraphs one through forty-one of Sections I, II and III of this Complaint as paragraphs one through forty-one of this First Count, as though specifically plead herein.

43. At all times relevant hereto, the Cook IVC Filter was defective and unreasonably dangerous and presented a substantial danger to patients who were implanted with the Cook IVC Filter, and these risks and dangers were known or knowable at the times of distribution and implantation in Plaintiff, Lara L. Adams 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.

44. The Cook Filter was used by the Plaintiff, Lara L. Adams, in a reasonably foreseeable way to the Defendants.



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

46. As a direct and proximate result of the Cook IVC Filter's defects, as described herein, the Plaintiff, Lara L. Adams, suffered permanent and continuous injuries, pain and suffering, disability and impairment. The Plaintiff has suffered emotional trauma, harm and injuries that will continue into the future. The Plaintiff has lost her ability to live a normal life, and will continue to be so diminished into the future. Furthermore, the Plaintiff has lost earnings and will continue to lose earnings into the future.

**WHEREFORE**, the Plaintiff, Lara L. Adams, demands judgment against the Cook Defendants for whatever amount she may be entitled, together with costs of this action. The jurisdictional amount exceeds seventy-five thousand dollars (\$75,000.01+); further,

**V. COUNT TWO: NEGLIGENCE**

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

48. At all times relevant to this cause of action, the Cook Defendants were in the business of designing, developing, manufacturing, marketing and selling sophisticated medical devices, including the Cook Filter.

49. At all times relevant hereto, the Cook Defendants 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, Lara L. Adams, and to those people receiving the Cook Filter.

50. At the time of manufacture and sale of the Cook Filter, the Cook Defendants 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, as aforesaid;
- b. was designed and manufactured so as to present an unreasonable risk of migration of the device and/or portions of the device, as aforesaid; and/or
- 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 perforation and damage to the vena caval wall.

51. Despite the aforementioned duty on the party of the Cook Defendants they committed one or more breaches of their duty of reasonable care and were negligent in:

- i. 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;
- ii. 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;
- iii. 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
- iv. 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.

52. As a direct and proximate result of the foregoing negligence by the Cook Defendants, the Plaintiff, Lara L. Adams, suffered permanent and continuous injuries, pain and suffering, disability and impairment. The Plaintiff has suffered emotion trauma, harm and injuries that will continue in the future. The Plaintiff has lost her ability to live a normal life, and will continue to be so diminished in the future. Furthermore, the Plaintiff has lost earnings and will continue to loose earnings into the future.

**WHEREFORE**, The Plaintiff, Lara L. Adams, demands judgment against the Cook Defendants for whatever amount she may be entitled, together with costs of this action. The jurisdictional amount exceeds seventy-five thousand dollars (\$75,000.01+); further,

**VI. COUNT THREE; BREACH OF EXPRESS & IMPLIED WARRANTY**

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

54. Plaintiff, though Lara L. Adams's medical providers, purchased the Cook IVC Filter from the Cook Defendants.

55. At all times to this cause of action, the Cook Defendants were merchants of goods of the kind including medical devices and vena cava filters (like the Cook IVC Filter).

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

57. At the time of Plaintiff's purchase from Defendants, the Cook IVC 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 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.

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

59. Further, Defendants marketing of the Cook IVC Filter was false and/or misleading.

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

61. 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.

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

63. As a direct and proximate result of the foregoing warranties by the Cook Defendants, the Plaintiff, Lara L. Adams, suffered permanent and continuous injuries, pain and suffering, disability and impairment. The Plaintiff has suffered emotional trauma, harm and injuries that will continue into the future. The Plaintiff has lost her ability to live a normal life, and will continue to be so diminished into

the future. Furthermore, the Plaintiff has lost earnings and will continue to lose earnings into the future.

**WHEREFORE**, the Plaintiff, Lara L. Adams, demands judgment against the Cook Defendants for whatever amount she may be entitled, together with costs of this action. The jurisdictional amount exceeds seventy-five thousand dollars (\$75,000.01+); further;

**VII. COUNT FIVE: LOSS OF CONSORTIUM**

64. Plaintiff, Keith N. Adams, 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.

65. Keith N. Adams is and was at all times relevant to this action, the legal husband of Lara L. Adams, and they have at all times relevant to this action, lived together as husband and wife.

66. As a direct and proximate result of the personal injuries suffered by Lara L. Adams, as described in this complaint, Keith N. Adams has been deprived of the benefits of their marriage including her love, affection, society, and consortium, and other wifely duties and actions. Lara L. Adams provided Keith N. Adams with all of the benefits of a marriage between husband and wife, prior to her implantation with the defective and unreasonably dangerous Cook IVC Filter and resulting injuries described herein.

67. As a direct and proximate result of the personal injuries suffered by Lara L. Adams, Keith N. Adams has also suffered the permanent loss of his wife's daily and regular contribution to the household duties and services, which each provides to the household as husband and wife.

68. As a direct and proximate result of the personal injuries suffered by Lara L. Adams, Keith N. Adams has also incurred the costs and expenses related to the medical care, treatment, medications, and hospitalization to which Lara L. Adams was subjected for the physical injuries she suffered as a proximate result of her use of the Cook Filter. Keith N. Adams will continue to incur

the future costs and expenses related to the care, treatment, medications, and hospitalization of Lara L. Adams due to her injuries from the Cook Filter.

69. As a direct and proximate result of the personal injuries suffered by Lara L. Adams, Keith N. Adams has suffered loss of consortium, as described herein, including the past, present, and future loss of his wife's companionship, services, society, and the ability of Lara L. Adams to provide Keith N. Adams with the benefits of marriage, including inter alia, loss of contribution to household income and loss of household services, all of which has resulted in his pain, suffering, and mental and emotional distress and worry.

**VIII. REQUEST RELIEF**

**WHEREFORE**, the Plaintiffs, Lara L. Adams and Keith N. Adams, demand judgment against the Cook Defendants for whatever amount they may be entitled, including punitive damages if deemed applicable, together with costs of this action, attorneys fees and interest. This jurisdictional amount exceeds seventy-five thousand dollars (\$75,000.01+). Plaintiffs further seek any other relief as this Court and the trier of fact deems just and appropriate.

**IX. DEMAND FOR JURY TRIAL**

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

Respectfully Submitted,  
Lara L. Adams and  
Keith N. Adams

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