UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

LARRY JOHNSON and
BRENDA JOHNSON,

Plaintiffs,

Case No.
HON.

-v-

COOK MEDICAL INCORPORATED,
a/k/a COOK MEDICAL, INC.;
COOK INCORPORATED;
WILLIAM COOK EUROPE ApS;

Defendants.

WOLFGANG MUELLER (P43728)
MUELLER LAW FIRM
Attorney for Plaintiff
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COMPLAINT AND DEMAND FOR JURY TRIAL

Plaintiffs, LARRY JOHNSON and BRENDA JOHNSON, by and through their attorneys, MUELLER LAW FIRM, by WOLFGANG MUELLER, hereby complain against the Defendants, COOK MEDICAL INCORPORATED, a/k/a COOK MEDICAL, INC.; COOK INCORPORATED; and WILLIAM COOK EUROPE ApS (collectively referred to as “COOK”),and states the following:

1. Plaintiffs, LARRY JOHNSON, and BRENDA JOHNSON, his wife, are

citizens of the State of Michigan, residing in Fenton, Michigan.

2. Defendant, COOK MEDICAL INCORPORATED, a/k/a COOK MEDICAL, INC., is a citizen of the State of Indiana, having its principal place of business at 750 Daniels Way, P.O. Box 1068, Bloomington, Indiana, 47402, and conducts business in the State of Michigan.

3. Defendant, COOK INCORPORATED, is a citizen of the State of Indiana, having its principal place of business at 750 Daniels Way, P.O. Box 1068, Bloomington, Indiana, 47402, and conducts business in the State of Michigan.

4. Defendant, WILLIAM COOK EUROPE ApS, is a foreign citizen, whose corporate headquarters and principal place of business is in Bjqaeverskov, Denmark, and conducts business in the State of Michigan.

5. Jurisdiction is founded upon the diversity of citizenship of the parties pursuant to 28 USC § 1332 and damages which exceed $75,000, exclusive of interest and costs.

6. Venue is proper, based on the situs of the incident, which first occurred in Genesee County, Michigan, in the Eastern District of Michigan.

7. Cook is a manufacturer, distributor and marketer of medical devices, including the Cook Celect Vena Cava Filter (“Cook Filter”), a device designed and manufactured to prevent, among other things, pulmonary embolism formation via placement in the vena cava.

8. Cook sought and obtained Food and Drug Administration (“FDA”) approval for the Cook Filter via Section 510(k) of the Medical Device Amendment.

9. The Cook Filter is designed to filter blood clots, known as “thrombi,” that

travel from the lower portions of the body to the heart and lungs. The Cook Filter is designed to prevent deep vein thrombosis, or DVT, from reaching the lungs, where the pulmonary emboli can be fatal.

10. The Cook Filter, a retrievable filter, is based on the Gunther Tulip filter.

11. The Cook Filter has four anchoring struts for fixation and eight independent secondary struts to improve self-centering and clot trapping.

12. On or about October 22, 2010, Plaintiff, Larry Johnson, underwent knee surgery at Genesys Health Park in Grand Blanc, Michigan. In order to prevent blood clots from reaching his lungs, a Cook Filter was inserted in his vena cava.

13. On August 9, 2010, ten weeks before the Cook Filter was implanted in Plaintiff, the FDA had issued a Safety Communication regarding temporary, retrievable IVC filters. At the time of the communication, the FDA had received 921 adverse event reports. Of those reports, 328 involved device migration, 146 involved broken pieces of the IVC traveling in the bloodstream, becoming dangerous embolisms, 70 involved the device perforating the inferior vena cava, and 56 involved filter fractures.

14. On March 30, 2011, Cardiovascular Interventional Radiology electronically published a report regarding a study of Gunther Tulip and Cook Celect IVC filters undertaken between July, 2007, and May, 2009. The study, later published by a medical journal in April, 2012, discovered that 100% of Gunther Tulip and Cook Celect IVC filter had experienced some degree of filter perforation of the venal caval wall after 71 days. Durack, JC, et al, Cardiovasc Intervent Radiol, “Perforation of the IVC: rule rather than exception after longer indwelling times for the Gunther Tulip and Celect Retrievable Filters,” 2012 Apr.: 35(2):299-308. Epub2011 Mar. 30.

15. On or about November 11, 2014, Plaintiff began experiencing sharp pains in his chest and back.

16. On or about November 13, 2014, Plaintiff was seen by his primary care physician, who immediately had Plaintiff transported, via ambulance, to Hurley Hospital in Flint, Michigan. A CT scan was run at Hurley. Plaintiff was subsequently discharged home on November 14, 2014.

17. On or about November 16, 2014, while traveling home from the Soaring Eagle Casino in Mt. Pleasant, Michigan, Plaintiff again began experiencing sharp pains in his chest. He lost consciousness while in his car and ran off the road. He was discovered by a passerby and was rushed to Mid-Michigan Hospital in Midland, Michigan. On the way, Plaintiff experienced ventilator dependent respiratory failure.

18. While at Mid-Michigan Hospital, Plaintiff underwent three emergency heart surgeries. Plaintiff underwent an emergency pericardiocentesis. The pericardium was opened and 350 mL of blood was evacuated.

19. Following the first procedure, however, Plaintiff continued to bleed at up to 200 mL per hour, and his blood pressure got severely low, requiring CPR. Plaintiff was again rushed to the emergency room, where the pericardium was again incised, resulting in a large amount of blood and a blood clot being expressed. *"During exploration of the pericardium, a sharp object was palpated in the diaphragmatic surface of the pericardium. Upon further inspection, a filamentous wire was seen to project from the diaphragm and with each heartbeat lacerated the heart at the confluence of the left ventricle and right ventricular apices. There an epicardial coronary vessel was bleeding which was sutured with a pledgeted Prolene."*

20. The following day, a third surgery was performed to open the median sternotomy incision so as to prevent tissue infection.

21. As a direct and proximate result of Defendant's negligence and gross negligence set forth below, Plaintiff, LARRY JOHNSON, has suffered the following injuries and damages:

A. A lacerated pericardium, requiring three emergency heart surgeries;

B. Extreme physical pain and emotional suffering;

C. Inability to enjoy activities of daily living;

D. Significant scarring of his sternum;

E. Economic losses, including missing over ten weeks of work, and incurring significant medical expenses;

F. Other damages which may arise in the future.

22. As a direct and proximate result of Defendant's negligence and gross negligence set forth below, Plaintiff, BRENDA JOHNSON, has suffered the loss of society, companionship, and consortium of her husband.

COUNT I - NEGLIGENCE

23. Plaintiff incorporates by reference all prior paragraphs as if fully stated herein.

24. At the time of the design and manufacture of the Cook Filter, Defendant was under a duty to design and manufacture the product to prevent an unreasonable risk of injury while the product was being used in a foreseeable manner.

25. Defendant breached the duty set forth above in at least the following

respects:

A. Negligently and recklessly designing, testing and manufacturing the Cook Celect IVC device such that portions of the device could fracture and migrate to the heart, causing a perforation of the heart;

B. Negligently and recklessly failing to use appropriate and standard design principles, means and methods to identify the hazard of fracture of the device that could cause severe or fatal injury;

C. Negligently and recklessly failing to adequately test the subject Cook Celect IVC device to prevent an unreasonable risk of foreseeable injury as a result of fracture of portions of the device;

D. Negligently and recklessly failing to adequately warn physicians and patients of the hazards associated with the failure of the internal struts in the Cook Celect IVC device;

E. Negligently failing to design and develop the Cook Celect IVC device, such that it was unfit for its intended purpose when used in a reasonably foreseeable manner;

F. Other acts of negligence that may be discovered during the course of the litigation.

Accordingly, Plaintiffs respectfully request that the trier of fact award all damages allowed under Michigan law. Plaintiffs also request that this court award pre-judgment interest, costs and attorney fees so wrongfully incurred.

COUNT II - GROSS NEGLIGENCE

26. Plaintiff incorporates by reference all prior paragraphs as if fully stated herein.

27. Based upon information and belief, Defendant had actual knowledge of other instances of filter fracture, causing migration and perforation, prior to the date of manufacture of the subject Cook Filter.

28. Despite such knowledge, Defendant failed to make any design changes to

eliminate the unreasonable risk of injury. Furthermore, Defendant knew that the defect in the Cook Celect IVC device would cause the same injuries as those suffered by Plaintiff. Defendant willfully disregarded such danger in the manufacture and distribution of the subject Cook Celect IVC device.

29. Defendant's conduct constitutes a reckless disregard for the safety of foreseeable users, including Plaintiff. Such conduct constitutes gross negligence.

30. As a direct and proximate result of the gross negligence described herein, Plaintiffs have suffered the damages set forth above.

Accordingly, Plaintiffs respectfully request that the trier of fact award all damages allowed under Michigan law. Plaintiffs also request that this court award pre-judgment interest, costs and attorney fees so wrongfully incurred.

Respectfully submitted,

MUELLER LAW FIRM

s/Wolfgang Mueller

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Dated: February 20, 2015

DEMAND FOR JURY TRIAL

Plaintiffs, by and through their attorneys, MUELLER LAW FIRM, hereby demand a jury trial in this matter.

Respectfully submitted,

MUELLER LAW FIRM

s/Wolfgang Mueller
WOLFGANG MUELLER (P43728)
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Dated: February 20, 2015