UNITED STATES DISTRICT COURT OF MISSOURI
WESTERN DISTRICT

TERRY L. SHAFER, INDIVIDUALLY, AND AS PERSONAL REPRESENTATIVE OF THE ESTATE OF CAROL CECILLA MERRILL, DECEASED, and DORIS SIMPSON, INDIVIDUALLY,	)	Case No.
Plaintiffs,	)	
Vs.	)	
ETHICON INC., ETHICON ENDO SURGERY, INC., ETHICON WOMEN'S HEALTH AND UROLOGY, a division of ETHICON, INC., and JOHN DOES 1-10,	)	
Defendants.	)	

COMPLAINT

COME NOW Plaintiffs Terry Shafer, individually and as Representative of the Estate of Carol Merrill, and Doris Simpson, individually, by and through counsel, and for their Complaint against Defendants allege as follows:

INTRODUCTION

1. This action is a products liability action against Ethicon Inc., Ethicon Endo Surgery, Inc., Ethicon Women's Health and Urology, a division of Ethicon, Inc., as well as John Does 1-10 (hereafter collectively referred to as "Defendants"), resulting from the use of said Defendants' uterine power morcellator surgical product.

2. Decedent Carol Cecilia Merrill had a surgical procedure performed on her known as a robotically assisted hysterectomy with uterine morcellation for the removal of uterine fibroids on December 4, 2012 at Menorah Medical Center. As a result of Defendants' uterine power morcellator product, Decedent developed a rare, malignant cancer called leiomyosarcoma

that took her life on August 22, 2014.

JURISDICTION AND VENUE

3. This Court has original jurisdiction pursuant to 28 U.S.C. §1332, as the matter in controversy exceeds the sum or value of $75,000, exclusive of interest and costs, and is between citizens of different states as Plaintiff Terry L. Shafer resides in Missouri, Plaintiff Doris Simpson resides in Illinois and Defendants are residents of New Jersey.

4. The events which form the basis for this lawsuit, including Decedent's cancer diagnosis while she was residing in Kansas City, Missouri, arose in the Western District of Missouri. Accordingly, venue properly lies in this District.

PARTIES

5. Plaintiff Terry Shafer is the life partner of Carol Cecilia Merrill, deceased ("Decedent") and Plaintiff Doris Simpson is the sister of Decedent. They bring this action individually under the Missouri Wrongful Death Act, R.S.Mo. § 537.080. Plaintiff Terry Shafer also brings this action as the Representative of the Estate of Decedent under R.S.Mo. § 537.021.

6. Decedent was a resident of Kansas City, Missouri, prior to her death.

7. Defendant Ethicon, Inc. is a corporation, or other entity, organized and/or existing under the laws of the New Jersey, and who at all times material and relevant hereto was engaged in the business of manufacturing and/or selling and/or supplying and/or marketing and/or designing and/or distributing minimally invasive gynecological surgical products, including power morcellator products, with a principal place of business at Route 22 West, Somerville, New Jersey.

8. Defendant Ethicon Endo Surgery, Inc. is a corporation, or other entity, organized and/or existing under the laws of the New Jersey, and who at all times material and

relevant hereto was engaged in the business of manufacturing and/or selling and/or supplying and/or marketing and/or and/or designing and/or distributing minimally invasive gynecological surgical products, including power morcellator products, with a principal place of business at Route 22 West, Somerville, New Jersey.

9. Defendant Ethicon Women's Health and Urology, a division of Ethicon, Inc., is a corporation, or other entity, organized and/or existing under the laws of the New Jersey, and who at all times material and relevant hereto was engaged in the business of manufacturing and/or selling and/or supplying and/or marketing and/or designing and/or distributing minimally invasive gynecological surgical products, including power morcellator products, with a principal place of business at Route 22 West, Somerville, New Jersey.

10. Defendants John Does, 1-10, who were engaged in the business of manufacturing and/or selling and/or supplying and/or marketing and/or distributing minimally invasive gynecological surgical products, specifically, the product/s used upon Plaintiff Carol Cecilia Merrill, deceased.

BACKGROUND AND FACTS

11. Power morcellators are medical devices used during laparoscopic surgeries to treat uterine fibroids by removal of the uterus (hysterectomy) or removal of the fibroids (myomectomy) by grinding the tissue into small pieces and removing it through small incision sites.

12. When used for hysterectomy or myomectomy in women with uterine fibroids, laparoscopic power morcellators can seed and disseminate cancerous tissue, notably uterine sarcomas, within the abdomen and pelvis.

13. On December 4, 2012, Decedent underwent a robotically assisted laproscopic hysterectomy using a Gynecare morcellator at Menorah Medical Center performed by Dr. Laura Kenny.

14. Prior to the Decedent's surgery, there was no evidence that she had disseminated and/or metastatic cancer.

15. Following this procedure, Decedent was informed that she had cancer.

16. Decedent underwent aggressive treatment and therapy following her cancer diagnosis until she succumbed to the disease and died as a result of malignant leimyosarcoma on August 22, 2014.

17. Defendants knew or should have known of the significant cancer risks associated with their uterine power morcellator product at the time of Decedent's procedure in December 2012, but it was not accompanied with adequate warnings regarding these risks.

18. Defendants failed to warn about the risks of seeding and disseminating an occult uterine leiomyosarcoma throughout the peritoneal cavity associated with its uterine power morcellator.

19. Defendants have repeatedly and consistently failed to advise consumers and/or their healthcare providers of the causal relationship between their product and these cancer risks.

20. Defendants affirmatively and actively concealed information that demonstrated the dangers of their product and misled the public and healthcare providers with regard to the material and clear risks associated with their power morcellators. They did so with the intent that physicians would continue to use their product even though the Defendants knew that physicians would not be in a position to know the true risks of the product and the Defendants

knew that physicians would rely upon the misleading information the Defendants promulgated.

21. Had Decedent and/or her healthcare providers been warned about the risks associated with Defendants' power morcellator, she would not have consented to use of the product.

22. As a direct and proximate result of Defendants' power morcellator, Decedent developed leiomyosarcoma, suffered severe physical injury, pain and suffering, and death.

23. As a direct and proximate result of Defendants' power morcellator, Decedent was deprived of a substantial chance for a full and complete recovery, was deprived of a substantial chance for a more effective treatment for her cancer, and was denied a substantial chance of surviving her cancer.

24. As a direct and proximate result of Defendants' power morcellator, Decedent incurred pecuniary losses, including medical expenses, lost wages and other economic damages.

25. As a direct and proximate result of Defendants' power morcellator, Plaintiffs have also incurred pecuniary losses, including medical and funeral expenses and other economic damages due to Decedent's death. Plaintiffs also suffered damages by losing the consortium, services, companionship, instruction, guidance, counsel, training and support of Decedent.

26. Defendants' acts, conduct and omissions were vile, base, willful, malicious, wanton, oppressive and fraudulent, and were done with a conscious disregard for the health, safety and rights of Decedent and other users of Defendants' products, and for the primary purpose of increasing Defendants' profits. As such, Plaintiffs are entitled to exemplary damages and aggravating circumstances attending Decedent's death should be considered by the trier of fact pursuant to R.S.Mo. § 537.090.

COUNT I – NEGLIGENCE

27. The paragraphs above are incorporated by reference hereto as if set forth at length.

28. Defendants owed a duty to manufacture, compound, label, market, distribute, and supply and/or sell their power morcellator products in such a way as to avoid harm to persons upon whom they are used, such as Decedent, or to refrain from such activities following knowledge and/or constructive knowledge that such product is harmful to persons upon whom it is used.

29. Defendants owed a duty to warn of the hazards and dangers associated with the use of its products for patients such as Decedent herein, so as to avoid harm.

30. Defendants, acting by and through their authorized divisions, subsidiaries, agents, servants, and employees, were guilty of carelessness, recklessness, negligence, gross negligence and willful, wanton, outrageous and reckless disregard for human life and safety in manufacturing, designing, labeling, marketing, distributing, supplying, selling and/or placing into the stream of commerce their power morcellator products, including in the following particular respects:

a. failing to conduct adequate and appropriate testing of its power morcellator products;

b. putting power morcellator products on the market without first conducting adequate testing to determine possible side effects;

c. putting power morcellator products on the market without adequate testing their dangers to humans;

d. failing to recognize the significance of their own and other testing of, and

information regarding power morcellator products, which testing evidenced such products are potentially harmful to humans;

e. failing to respond promptly and appropriately to their own and other testing of, and information regarding power morcellator products, which indicated such products are potentially harmful to human;

f. failing to promptly and adequately warn of the potential of power morcellator products to be harmful to humans;

g. failing to promptly and adequately warn of the potential for the metastases of cancer when using power morcellator products;

h. failing to promptly, adequately, and appropriately recommend testing and monitoring of patients upon whom these products were used in light of such products potential harm to humans;

i. failing to properly, appropriately, and adequately monitor the post-market performance of products used for uterine morcellation and such products effects on patients;

j. concealing from the FDA, National Institutes of Health, the general medical community and/or physicians, their full knowledge and experience regarding the potential that power morcellator products are harmful to humans;

k. promoting, marketing, advertising and/or selling power morcellator products for use on patients given their knowledge and experience of such products' potential harmful effects;

l. failing to withdraw power morcellator products from the market, restrict their use and/or warn of such products' potential dangers, given their knowledge of the

potential for its harm to humans;

m. failing to fulfill the standard of care required of a reasonable, prudent, minimally invasive gynecological surgical products manufacturer engaged in the manufacture of power morcellator products in among other things, failing to deploy an intraperitoneal bag with said morcellator to prevent the spread of malignancy.

n. placing and/or permitting the placement of power morcellator products into the stream of commerce without warnings of the potential for said products to be harmful to humans and/or without properly warning of said products' dangerousness;

o. failing to disclose to the medical community in an appropriate and timely manner, facts relative to the potential of power morcellator products to be harmful to humans;

p. failing to respond or react promptly and appropriately to reports of products used for uterine morcellation causing harm to patients;

q. disregarding the safety of users and consumers of products used for uterine morcellation, including Decedent, under the circumstances by failing adequately to warn of said products' potential harm to humans;

r. disregarding the safety of users and consumers of the products used for uterine morcellation, including Decedent, and/or her physicians' and/or hospital, under the circumstances by failing to withdraw said products from the market and/or restrict their usage;

s. disregarding publicity, government and/or industry studies, information, documentation and recommendations, consumer complaints and reports and/or other information regarding the hazards of the power morcellator and their potential harm to

humans;

t. failing to exercise reasonable care in informing physicians and/or hospitals using power morcellator products about their own knowledge regarding said products' potential harm to humans;

u. failing to remove power morcellator products from the stream of commerce;

v. failing to test power morcellator products properly and/or adequately so as to determine its safety for use;

w. promoting power morcellator products as safe and/or safer than other comparative methods of lesion removal;

x. promoting power morcellator products on websites aimed at creating user and consumer demand;

y. failing to conduct and/or respond to post-marketing surveillance of complications and injuries;

z. failing to use due care under the circumstances; and,

aa. such other acts or omissions constituting negligence and carelessness as may appear during the course of discovery or at the trial of this matter.

31. As a direct and proximate result of Defendants' power morcellator, Decedent and Plaintiffs suffered the injuries and damages as set forth above.

COUNT II - STRICT PRODUCTS LIABILITY

32. The paragraphs above are incorporated by reference hereto as if set forth at length.

33. As a result of the unreasonably dangerous and defective condition of the power morcellator product, which Defendants manufactured, designed, labeled, marketed, distributed, supplied, sold and/or placed into the stream of commerce, they are strictly liable to the Plaintiffs for their injuries that they directly and proximately caused, based on the following:

a. failing to provide adequate warnings with their power morcellator product; and

b. failing to properly and adequately design their product by among other things failing to deploy an intraperitoneal bag with said morcellator.

34. Because of Defendants' failures, Decedent used the power morcellator product, which the Defendants manufactured, designed, sold, supplied, marketed or otherwise introduced into the stream of commerce.

35. As a direct and proximate result of Defendants' power morcellator, Decedent and Plaintiffs suffered the injuries and damages as set forth above.

COUNT III - BREACH OF EXPRESS WARRANTY

36. The paragraphs above are incorporated by reference hereto as if set forth at length.

37. In the advertising and marketing of their power morcellator products, Defendants warranted that their products were safe for the use, which had the natural tendency to induce physicians and hospitals to use the same for patients and for patients to want to be treated with the same.

38. The aforesaid warranties were breached by Defendants and constituted a serious danger to the user.

39. As a direct and proximate result of Defendants' breach of warranty as described

herein, Decedent and Plaintiffs suffered the injuries and damages as set forth above.

COUNT IV – BREACH OF IMPLIED WARRANTY

40. The paragraphs above are incorporated by reference hereto as if set forth at length.

41. At all relevant and material times, Defendants manufactured, distributed, advertised, promoted, and sold their power morcellator products for use in uterine morcellation.

42. At all relevant times, Defendants intended that their power morcellator products be used in the manner that the Decedent's physician in fact used it and Defendants impliedly warranted the product to be of merchantable quality, safe and fit for such use, and was adequately tested.

43. Defendants breached various implied warranties with respect to the products used for uterine morcellation, including:

a. Defendants represented through their labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that the products were safe, and withheld and concealed information about the substantial risks of serious injury and/or death associated with using the products used for uterine morcellation;

b. Defendant represented that the products were as safe and/or safer than other alternative surgical approaches that did not include the use of the said products, and concealed information, which demonstrated that said products were not safer than alternatives; and

c. Defendants represented that the products were more efficacious than

other alternative surgical approaches and techniques and concealed information, regarding the true efficacy of said products.

44. In reliance upon Defendants' implied warrant, Decedent's surgeons used said power morcellator as prescribed and in the foreseeable manner normally intended, recommended, promoted, instructed, and marketed by Defendants.

45. Defendants breached their implied warranty to Decedent's in that said power morcellator was not of merchantable quality, safe and fit for their intended use, or adequately tested.

46. As a direct and proximate result of Defendants' breach of warranty as described herein, Decedent and Plaintiffs suffered the injuries and damages as set forth above.

COUNT V - FRAUDULENT MISREPRESENTATION AND OMISSION

47. Plaintiffs incorporate by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows.

48. Defendant, having undertaken design, formulation, testing, manufacture, marketing, sale, and distribution of power morcellator devices owed a duty to provide accurate and complete information regarding said devices.

49. Prior to Decedent undergoing her surgery, Defendants fraudulently misrepresented that the use of their power morcellator was safe and effective.

50. Defendant had a duty to provide Decedent, physicians, and other consumers with true and accurate information regarding the power morcellator products it manufactured, marketed, distributed and sold.

51. Defendants made representations and failed to disclose material facts with the

intent to induce consumers, including Decedent and the medical community to act in reliance by purchasing and using the power morcellator sold by Defendants.

52. Decedent and the medical community justifiably relied on Defendants' representations and omissions by purchasing and using the uterine morcellator during Decedent's surgery.

53. As a direct and proximate result of Defendants' representations and omissions as described herein, Decedent and Plaintiffs suffered the injuries and damages as set forth above.

COUNT VI - NEGLIGENT MISREPRESENTATION

54. Plaintiffs incorporate by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows.

55. Defendants supplied the public and Decedent's healthcare providers with materially false and incomplete information with respect to the safety of their power morcellator products.

56. The false information supplied by Defendants was that their product was safe.

57. In supplying this false information, Defendants failed to exercise reasonable care.

58. The false information communicated by Defendants to Decedent and her healthcare providers was material and Decedent justifiably relied in good faith on the information to their detriment.

59. As a direct and proximate result of Defendants' representations and omissions as described herein, Decedent and Plaintiffs suffered the injuries and damages as set forth above.

COUNT VII - VIOLATION OF MISSOURI MERCHANDISING PRACTICES ACT

60. Plaintiffs incorporate by reference, as if fully set forth herein, each and every

allegation set forth in the preceding paragraphs and further allege as follows.

61. The actions of Defendants, as set forth herein, in withholding from doctors and healthcare providers information regarding defects and risks of the power morcellator product at issue constituted a deceptive and fraudulent practice under the Missouri Merchandising Practices Act.

62. By denying relevant material and important information from the consumer and the consumer's health care providers, Defendants marketed their power morcellator product at issue under false pretense. Such actions constituting an unfair and deceptive practice in violation of the Missouri Merchandising Practices Act

63. By failing to provide information regarding risks and known defects in design, Defendants acted in a manner to conceal and suppress material information about the product at issue so as to consummate a sale of the same. Such actions constituting an unfair and deceptive practice in violation of the Missouri Merchandising Practices Act.

64. As a direct and proximate result of the violations of the Missouri Merchandising Practices Act, Decedent and Plaintiffs suffered the injuries and damages as set forth above.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs Terry Shafer, individually and as Representative of the Estate of Carol Cecilia Merrill, and Doris Simpson, individually, pray for damages pursuant to the Missouri Wrongful Death Statute against Defendants in an amount the Court and jury determine to be fair and reasonable, for their costs and actual damages with the consideration of aggravating circumstances and for such other damages, expenses and interest allowed by Missouri law and that the Court deems just and proper. Further, Terry Shafer as Personal Representative of the Estate of Carol Cecilia Merrill prays for damages pursuant to R.S.Mo.

§537.021 against Defendants in an amount deemed fair and reasonable by the jury, for his costs, actual damages, punitive damages, and for any and all other relief that the Court deems just and proper.

DEMAND FOR JURY TRIAL

Plaintiff hereby demands a trial by jury to take place in Kansas City, Missouri.

Dated: December 3, 2014

Respectfully submitted,

/s/ Thomas J. Preuss
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JS 44 (Rev 09/10)

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF MISSOURI

CIVIL COVER SHEET

This automated JS-44 conforms generally to the manual JS-44 approved by the Judicial Conference of the United States in September 1974. The data is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. The information contained herein neither replaces nor supplements the filing and service of pleadings or other papers as required by law. This form is authorized for use only in the Western District of Missouri.

The completed cover sheet must be saved as a pdf document and filed as an attachment to the Complaint or Notice of Removal.

Plaintiff(s):	**Defendant(s):**
First Listed Plaintiff: Terry L. Shafer ; 1 Citizen of This State; **County of Residence:** Clay County	First Listed Defendant: ETHICON, INC. ; 5 Incorporated and Principal Place of Business in Another State; New Jersey **County of Residence:** Outside This District
Additional Plaintiff(s): Carol Cecilia Merrill, Deceased ; NA;	Additional Defendants(s): ETHICON ENDO SURGERY, INC. ; 5 Incorporated and Principal Place of Business in Another State; New Jersey
Doris Simpson ; 2 Citizen of Another State; Illinois	ETHICON WOMEN'S HEALTH AND UROLOGY, a division of ETHICON, INC. ; 5 Incorporated and Principal Place of Business in Another State; New Jersey
	JOHN DOES 1-10 ; NA;

County Where Claim For Relief Arose: Clay County

Plaintiff's Attorney(s):

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Defendant's Attorney(s):

Basis of Jurisdiction: 4. Diversity of Citizenship

Citizenship of Principal Parties (Diversity Cases Only)

Plaintiff: 1 Citizen of This State

Defendant: 5 Incorporated and Principal Place of Business in Another State

Origin: 1. Original Proceeding

Nature of Suit: 365 Other Personal Injury Product Liability

Cause of Action: 28 U.S.C. 1332

Requested in Complaint

Class Action: Not filed as a Class Action

Monetary Demand (in Thousands): 75

Jury Demand: Yes

Related Cases: Is NOT a refiling of a previously dismissed action

Signature: /s/ Thomas J. Preuss

Date: 12/3/2014

If any of this information is incorrect, please close this window and go back to the Civil Cover Sheet Input form to make the correction and generate the updated JS44. Once corrected, print this form, sign and date it, and submit it with your new civil action.