UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF TENNESSEE

TIMOTHY SCHROEDER, individually and as husband of CYNTHIA SCHROEDER, Deceased	:	**Case No.**
PLAINTIFFS,	:	
v.	:	
	:	**COMPLAINT AND JURY DEMAND**
ETHICON ENDO SURGERY, INC., d/b/a ETHICON WOMEN'S HEALTH AND UROLOGY, d/b/a ETHICON JOHNSON & JOHNSON	:	
DEFENDANTS	:	

Plaintiff Timothy Schroeder, by his attorneys Burg Simpson Eldredge Hersh & Jardine, P.C., for his Complaint and Jury Demand alleges as follows:

PARTIES, JURISDICTION AND VENUE

1. Plaintiff Timothy Schroeder is a resident and citizen of Rutherford County, Tennessee.

2. Plaintiff was married to Cynthia Schroeder until her death on December 31, 2013. His late wife, Cynthia, was also a resident of Rutherford County, Tennessee.

3. Defendant Ethicon Endo Surgery, Inc., d/b/a Ethicon Women's Health and Urology, d/b/a Ethicon Johnson & Johnson (hereafter "Ethicon") is a New Jersey corporation with its principal place of business in New Jersey. Ethicon, Inc., d/b/a Ethicon Women's Health and Urology, d/b/a Ethicon Johnson & Johnson, is a fictitious name, 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 the GYNECARE MORCELLEX device used on Plaintiff's Decedent, with a principal place of business at Route 22 West, Somerville, New Jersey.

4. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §1332, as complete diversity exists between Plaintiffs and Defendants, and the amount in controversy exceeds $75,000.00.

5. This Court has personal jurisdiction over Defendants because said Defendants have regularly and purposefully transacted business and engaged in commercial activities within the State of Tennessee and this District.

6. Venue is proper within this the Middle District of Tennessee pursuant to 28 U.S.C. §1391(b)(2), because a substantial part of the events and omissions giving rise to the claim occurred in this district.

FACTUAL BACKGROUND

7. Plaintiff adopts and realleges each of the foregoing paragraphs as if fully restated herein and further states as follows:

8. Laparoscopic power morcellation is a technique for the removal of the uterus (hysterectomy) or uterine fibroids (myomectomy) in women.

9. Conventional hysterectomies and myomectomies are performed through surgical approaches in which the uterus or fibroids are removed either vaginally or through larger incisions in the abdomen.

10. Morcellation is a procedure that uses a medical device (known as a morcellator) to cut or core tissue into smaller pieces or fragments.

11. Intracorporeal morcellation of the uterus or fibroids allows the tissue to be removed through smaller incisions in the abdomen, such as are used in a laparoscopic surgical approach.

12. The only significant advantage to using a morcellator is that the surgery is "minimally invasive," i.e., it can be performed using smaller incisions.

13. It is estimated that 650,000 women in the United States each year will undergo a myomectomy or hysterectomy for the management of symptomatic uterine fibroids.

14. Approximately 1-in-350 women with fibroids also have undetected uterine sarcoma, a form of cancer. It is not possible to reliably detect the presence of uterine sarcoma before surgery.

15. If the woman has uterine sarcoma that has not spread beyond the uterus (known as stage I uterine sarcoma), a hysterectomy performed through conventional surgical removal of the entire uterus typically removes all cancerous tissue with the uterus.

16. By contrast, intracorporeal morcellation of the uterus or fibroids can result in spreading cancerous tissue within the abdominal cavity beyond the uterus.

17. This cancerous tissue can quickly spread, "upstaging" the localized (stage I) uterine cancer that could be easily removed through a hysterectomy to regional (stage II or III) or metastatic (stage IV) cancer.

18. The prognosis for a woman following morcellation of a sarcoma that has spread cancerous tissue is poor. For example, the 5-year survival rate of a patient diagnosed with Stage I uterine sarcoma is greater than 60%, whereas it is reduced to approximately 15% with a Stage IV diagnosis.

19. Defendant Ethicon's GYNECARE MORCELLEX device was granted 510(k) Pre-Market Approval by the Food and Drug Administration (FDA) on July 14, 2006, under 510(k) No.: K061050.

20. The 510(k) Approval Letter provides that "the GYNECARE MORCELLEX Tissue Morcellator is indicated for cutting, coring, and extracting tissue during operative laparoscopy, including laparoscopic general surgical procedures, laparoscopic urologic procedures, and laparoscopic gynecologic procedures."

21. There is no express provision in the 510(k) Approval Letter indicating the device is specifically indicated for myomectomy or hysterectomy.

22. The 510(k) Approval Letter also requires that Defendant Ethicon adhere to the controls provided by the Federal Food, Drug, and Cosmetic Act as they relate to labeling, misbranding, and adulteration, among other provisions.

23. Defendant Ethicon's product labeling has not been expressly reviewed and/or approved by the FDA.

24. Defendant Ethicon's product labeling includes a precaution indicating that when used on malignant tissue, use of the GYNECARE MORCELLEX Tissue Morcellator may lead to dissemination of malignant tissue.

25. On January 4, 2008 Plaintiff's Decedent, Cynthia Schroeder, underwent a surgical procedure known as Laparoscopic Supracervical Hysterectomy with removal of ovaries, due to Decedent's fibroids and bleeding.

26. Defendant Ethicon's GYNECARE MORCELLEX device was utilized to shred or morcellate and remove decedent's uterus above the cervix, fibroids, and ovaries during this surgery.

27. Prior to the Decedent's surgery of January 4, 2008, there was no evidence of disseminated and/or metastatic cancer/disease.

28. Decedent underwent two endometrial biopsies and multiple PAP smears prior to surgery, all of which were benign. Accordingly, neither Decedent nor her physician was aware or suspicious of uterine sarcoma prior to the surgery.

29. During the surgery of January 4, 2008, a sample of the uterine tissue that was removed was sent for pathological analysis. The pathology results indicated that Decedent had uterine leimyosarcoma cancer.

30. A CT scan of Decedent's abdomen was performed on January 24, 2008 which revealed no metastatsis.

31. An exploratory laparotomy was performed on February 4, 2008 in an effort to detect and remove any cancerous tissue. Pathology reports on the tissue that was removed revealed no metastatic disease at that time.

32. In 2009, Decedent began experiencing abdominal pain. A CT scan was performed, but recurrent cancer was not detected at that time.

33. In December 2010, Decedent's pain worsened and she also experienced frequent urination and incontinence. A repeat CT scan was performed on December 10, 2010 which revealed two large abdominal masses, a 15 x 9 x 13 cm mass in the right lower abdomen and a left-sided mass measuring 9 x 6 x 6 cm.

34. Surgery was performed on December 22, 2010 to remove these and any other tumors and to explore for and remove other possibly cancerous tissues.

35. Pathology results on the tissue specimens indicated that the tumors removed were Grade II leiomyosarcoma.

36. Over the next three years, Decedent and her physicians aggressively treated Decedent's recurrent leiomyosarcoma with multiple chemotherapy regimens and surgery.

37. Despite all of the efforts of Decedent and her physicians, Decedent died on December 31, 2013 as a result of metastatic leiomyosarcoma.

38. Defendant Ethicon was aware of the risks, complications, and/or adverse events associated with its products used for uterine morcellation, including the GYNECARE MORCELLEX device. In particular, Defendant Ethicon was aware of the risk that it device would cause dissemination of undiagnosed sarcoma tissue throughout the peritoneal cavity, thereby upstaging the cancer from a highly survivable or curable stage I disease to a poor prognosis stage II – IV disease.

39. Defendant Ethicon also was aware that it is not possible to reliably detect uterine sarcoma before surgery in women with fibroids. Accordingly, Ethicon was aware that even if its device was limited to use on women who had not been diagnosed with sarcoma, morcellation would nonetheless be performed each year on hundreds, if not thousands, of women with undiagnosed sarcoma.

40. Defendant Ethicon failed to warn about the risks of morcellation and undiagnosed sarcoma given the inability to reliably detect uterine sarcoma before surgery. In particular, Defendant Ethicon failed to warn about the risks of seeding undiagnosed sarcoma throughout the peritoneal cavity and upstaging the cancer.

41. The FDA issued a news release on April 17, 2014, discouraging use of laparoscopic power morcellation for removal of the uterus or uterine fibroids.

42. Defendant Ethicon suspended sales of its GYNECARE MORCELLEX morcellators on April 30, 2014 pending evaluation of the risks.

FIRST CAUSE OF ACTION

Strict Products Liability: Design Defect

43. Plaintiff adopts and realleges each of the foregoing paragraphs as if fully restated herein and further states as follows:

44. Defendant Ethicon manufactured, designed, marketed, distributed and sold the GYNECARE MORCELLEX morcellator.

45. The GYNECARE MORCELLEX manufactured by Defendants was expected to and did reach consumers, including Plaintiff's Decedent Cynthia Schroeder, without any alterations or changes.

46. The GYNECARE MORCELLEX manufactured, designed, marketed, distributed and sold by Defendant Ethicon was defective in design, because when it left the hands of the Defendant, the foreseeable risks of the product exceeded the benefits associated with its design or formulation.

47. The GYNECARE MORCELLEX manufactured, designed, marketed, distributed and sold by Defendant was defective in design, because when it left the hands of the Defendant, it was more dangerous than an ordinary consumer would expect.

48. The foreseeable risks associated with the GYNECARE MORCELLEX device include the risk of seeding an undiagnosed sarcoma, that was undiagnosable before surgery, throughout the abdomen, thereby both spreading and rapidly upstaging a previously occult sarcoma, which, if removed intact as part of the whole uterus or fibroid, would have been cured by virtue of a traditional surgical approach.

49. The fact that such harm as that suffered by Plaintiff's Decedent Cynthia Schroeder will occur in a percentage of women upon whom the GYNECARE MORCELLEX device is used is completely foreseeable because (1) there are no pathognomonic

symptoms or accurate preoperative diagnostic tests available for uterine sarcomas, which are therefore usually discovered postoperatively; (2) as a result, there is no reliable way for physicians to know, pre-operatively, that they are using the device on malignant tissue; (3) physicians are encouraged to use the device even when they do suspect malignancy, through language in the product labeling suggesting that a tissue extraction bag can make the device safe in the setting of malignancy; (4) there is evidence that malignant tissue can still be disseminated even with the proper use of a tissue extraction bag; and (5) once it has been disseminated by tissue morcellation, uterine sarcoma spreads and upstages rapidly, carries a poor prognosis, and is typically inoperable.

50. At the time Defendant Ethicon manufactured, designed, marketed, distributed, and sold its GYNECARE MORCELLEX device, safer, more practical, alternative treatment options were available to remove her uterus, including but not limited to vaginal or traditional laparotomy approaches to surgery, both of which pose much less risk of dissemination of malignant tissue with comparable efficacy.

51. As a direct and proximate result of the unreasonably dangerous and defective condition of the GYNECARE MORCELLEX device, which Defendant manufactured, designed, labeled, marketed, distributed, supplied and/or sold, and/or otherwise placed into the stream of commerce, it is strictly liable to the Plaintiff and to Plaintiff's Decedent pursuant to §402A of the Restatement (Second) of Torts for their injuries and/or losses, specifically including Decedent's death, which Defendant directly and proximately caused, based on the failure to properly and adequately design the GYNECARE MORCELLEX device.

52. In addition, the aforesaid incident and Plaintiff's and Decedent's injuries and losses were the direct and proximate result of Defendant's manufacturing, designing,

labeling, marketing, distributing, supplying and/or selling and/or otherwise placing into the stream of commerce the GYNECARE MORCELLEX device used for uterine morcellation, without proper and adequate warnings regarding the potential for said product's harm to humans and as otherwise set forth herein, when Defendant knew or should have known of the need for such warnings and/or recommendations.

WHEREFORE, Plaintiff, Timothy Schroeder, individually and as husband of Decedent Cynthia Schroeder, respectfully requests that this Honorable Court enter judgment in his favor and against Ethicon, Inc., d/b/a Ethicon Women's Health and Urology, d/b/a Ethicon Johnson & Johnson, in an amount in excess of $75,000.00 plus interest, costs, punitive damages, and attorney's fees.

SECOND CAUSE OF ACTION

Strict Products Liability: Defect Due To Inadequate Warning

53. Plaintiff adopts and realleges each of the foregoing paragraphs as if fully restated herein and further states as follows:

54. Defendant Ethicon is the manufacturer, designer, marketer, and seller of the GYNECARE MORCELLEX device.

55. It was reasonably foreseeable that women such as Plaintiff's Decedent Cynthia Schroeder would be unaware pre-operatively that their uterus or fibroids contained an undiagnosed, undiagnosable uterine sarcoma that, when disseminated through the use of tissue morcellation, would result in devastating, inoperable, advanced-stage cancer with poor prognosis.

56. The GYNECARE MORCELLEX device manufactured, designed, marketed, distributed and sold by Defendant Ethicon was defective due to inadequate warning or

instruction because at the time it left the control of Defendant and was placed into the stream of commerce, Defendant knew or should have known that its product was unreasonably dangerous, because it substantially and significantly increases the risk of spreading and rapidly upstaging undiagnosed cancer as compared to other treatment options for hysterectomy or myomectomy.

57. Despite the fact that Defendant knew or should have known about the increased risk of dissemination of malignant tissue associated with its GYNECARE MORCELLEX device as compared to other treatment options for hysterectomy and myomectomy, Defendant failed to exercise reasonable care to adequately warn of the increased risk. In fact, despite its knowledge that there was no reliable way to identify women with uterine sarcoma pre-operatively, Defendant even suggested in its product labeling that its GYNECARE MORCELLEX device was safe to use on suspected malignant tissue, if a tissue extractor bag was also utilized—a claim it knew or should have known was false or unverifiable.

58. As a direct and proximate result of the unreasonably dangerous and defective condition of the GYNECARE MORCELLEX device used for uterine morcellation, which Defendant manufactured, designed, labeled, marketed, distributed, supplied and/or sold, and/or otherwise placed into the stream of commerce, Defendant is strictly liable to the Plaintiff and to Plaintiff's Decedent pursuant to §402A of the Restatement (Second) of Torts for their injuries and/or losses, specifically including Decedent's death, which Defendant directly and proximately caused, based on its failure to properly and adequately manufacture its GYNECARE MORCELLEX device used for uterine morcellation.

59. In addition, the aforesaid incident and Plaintiff's and Decedent's injuries and

losses were the direct and proximate result of Defendant's manufacturing, designing, labeling, marketing, distributing, supplying and/or selling and/or otherwise placing into the stream of commerce the GYNECARE MORCELLEX device used for uterine morcellation, without proper and adequate warnings regarding the potential for said product's harm to humans and as otherwise set forth herein, when said Defendants knew or should have known of the need for such warnings and/or recommendations.

WHEREFORE, Plaintiff, Timothy Schroeder, individually and as husband of Cynthia Schroeder, respectfully requests that this Honorable Court enter judgment in his favor and against Ethicon, Inc., d/b/a Ethicon Women's Health and Urology, d/b/a Ethicon Johnson & Johnson, in an amount in excess of $75,000.00 plus interest, costs, punitive damages, and attorney's fees.

THIRD CAUSE OF ACTION

Negligence

60. Plaintiff adopts and realleges all foregoing paragraphs as if fully restated herein and further states as follows:

61. Defendant Ethicon owed a duty of reasonable care to design, manufacture, label, market, distribute, and supply and/or sell products, including its GYNECARE MORCELLEX device used for uterine morcellation in such a way as to avoid harm to persons upon whom they are used, such as Decedent herein, and to refrain from such activities following knowledge and/or constructive knowledge that such product is harmful to persons upon whom it is used.

62. Defendant knew or should have known that in a certain percentage of women, uterine and/or fibroid cancer exists in a state that is not only undiagnosed before

hysterectomy is contemplated, but also undiagnosable.

63. As such, in this segment of women, even the most thorough preoperative work-up that includes biopsies and other tissue sampling tests is unable to detect the presence of such cancers.

64. Defendant therefore knew or should have known that, in this segment of women especially, use of its product is associated with an unreasonably high risk that such undiagnosed, undiagnosable cancer will be spread throughout the abdomen through ordinary use of its device for tissue morcellation.

65. Defendant therefore owed a duty to warn of the hazards and dangers associated with the use of its GYNECARE MORCELLEX device for patients such as Decedent herein, so as to avoid exactly this type of harm.

66. Defendant failed to exercise ordinary care in the design, formulation, manufacture, design, distribution, marketing, labeling and sale of its GYNECARE MORCELLEX device in that Defendant knew, or should have known, that its product caused such significant bodily harm or death and was not safe for use by consumers.

67. Defendant also failed to exercise ordinary care in the labeling of the GYNECARE MORCELLEX device, and failed to issue, to consumers and/or their health care providers, adequate warnings of the increased risk of serious bodily injury or death due to the use of the GYNECARE MORCELLEX device, as compared to other alternative treatments.

68. Despite the fact that Defendant Ethicon knew or should have known that the GYNECARE MORCELLEX device posed a serious and increased risk of bodily harm to consumers, Defendant continued to manufacture and market the device for use by consumers, including women such as Plaintiff's Decedent Cynthia Schroeder, and continued

to knowingly withhold critical safety information, such as the increased risk of dissemination of malignant tissue as compared to other surgical approaches.

69. Defendant Ethicon knew or should have known that women with undiagnosed uterine sarcoma would undergo surgery in which its GYNECARE MORCELLEX device was used, and in so doing, would suffer the immediate spread and rapid upstaging of cancer with poor prognosis for survival.

70. Defendant, acting by and through its authorized divisions, subsidiaries, agents, servants, and employees, was 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 and/or selling and/or otherwise placing into the stream of commerce, minimally invasive gynecologic products, including its GYNECARE MORCELLEX device used for uterine morcellation, both generally, and in the following particular respects:

a. failing to conduct adequate and appropriate testing of its GYNECARE MORCELLEX device;

b. putting its GYNECARE MORCELLEX device on the market without first conducting adequate testing to determine possible side effects;

c. putting its GYNECARE MORCELLEX device on the market without adequate testing of its dangers to humans;

d. failing to recognize the significance of its own and other testing of, and information regarding, products used for uterine morcellation, including its GYNECARE MORCELLEX device, which testing evidenced its own and similar devices' potential harm to humans;

e. failing to respond promptly and appropriately to its own and other testing of, and information regarding products used for uterine morcellation, including its GYNECARE MORCELLEX device, which indicated its own and similar devices' potential harm to humans;

f. failing to promptly and adequately warn of the potential for its GYNECARE MORCELLEX device to be harmful to humans in violation of Restatement (Second) of Torts, §388;

g. failing to promptly and adequately warn of the potential for the metastases of cancer when using its GYNECARE MORCELLEX device in violation of Restatement (Second) of Torts, §388.

h. failing to promptly, adequately, and appropriately recommend testing and monitoring of patients upon whom its GYNECARE MORCELLEX device was used, in light of such products' potential harm to humans;

i. failing to properly, appropriately, and adequately monitor the post-market performance of its GYNECARE MORCELLEX device and the device's effects on patients;

j. concealing from the FDA, National Institutes of Health, the general medical community and/or physicians, its full knowledge and experience regarding the potential that its GYNECARE MORCELLEX is harmful to humans;

k. promoting, marketing, advertising and/or selling its GYNECARE MORCELLEX device for use on patients given its knowledge and experience of the device's potential harmful effects;

l. failing to timely withdraw the GYNECARE MORCELLEX device from the

market and/or warn of its potential dangers, given Defendant's 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 said products, specifically its GYNECARE MORCELLEX device used for uterine morcellation;

n. placing and/or permitting the placement of the GYNECARE MORCELLEX device into the stream of commerce without warnings of the potential for the product to be harmful to humans and/or without properly warning of said product's dangerousness;

o. failing to disclose to the medical community in an appropriate and timely manner facts within its knowledge relevant to the potential of its GYNECARE MORCELLEX device to be harmful to humans;

p. failing to respond or react promptly and appropriately to reports that its GYNECARE MORCELLEX device, and other similar devices, were causing harm to patients;

q. disregarding the safety of users and consumers such as Plaintiff's Decedent by failing adequately to warn of its GYNECARE MORCELLEX device's potential to harm humans;

r. disregarding the safety of users and consumers, such as Plaintiff's Decedent herein, by failing to timely withdraw its GYNECARE MORCELLEX device from the market;

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 products used for uterine morcellation, including its own GYNECARE MORCELLEX device, and their potential to harm humans;

t. failing to exercise reasonable care in informing physicians and/or hospitals using its GYNECARE MORCELLEX device for uterine morcellation about its own knowledge regarding said product's potential to harm humans;

u. promoting its device as safe and/or safer than other comparative methods of tissue removal;

v. promoting its device on websites aimed at creating user and consumer demand;

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

71. As a direct and proximate result of the negligent and/or reckless and/or wanton acts and/or omissions of Defendant, Plaintiff and/or Plaintiff's Decedent suffered serious injuries, death, and/or financial losses and harm.

WHEREFORE, Plaintiff, Timothy Schroeder, individually and as husband of Cynthia Schroeder, respectfully requests that this Honorable Court enter judgment in his favor and against Ethicon, Inc., d/b/a Ethicon Women's Health and Urology, d/b/a Ethicon Johnson & Johnson, in an amount in excess of $75,000.00 plus interest, costs, punitive damages, and attorney's fees.

FOURTH CAUSE OF ACTION

Breach of Express Warranty

72. Plaintiff adopts and realleges all foregoing paragraphs as if fully restated herein and further states as follows:

73. In the advertising and marketing of the products used for uterine morcellation, which was directed to both physicians and hospitals and consumers, Defendants warranted that said product or 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.

74. The aforesaid warranties were breached by Defendants in that the products used for uterine morcellation, constituted a serious danger to the user.

75. Defendant's acts were motivated by financial gain while the adverse consequences of Defendant's conduct was actually known by Defendant. Defendant's conduct was outrageous, fraudulent, oppressive, done with malice or gross negligence, and evidenced reckless indifference to Plaintiffs' rights, so as to warrant the imposition of punitive damages.

76. As a direct and proximate result of Defendants' breach of express warranty, Plaintiff and/or Plaintiffs Decedent suffered serious injuries, including death, and financial losses and harm.

WHEREFORE, Plaintiff, Timothy Schroeder, individually and as husband of Cynthia Schroeder, respectfully requests that this Honorable Court enter judgment in his favor and against Ethicon, Inc., d/b/a Ethicon Women's Health and Urology, d/b/a Ethicon Johnson & Johnson, in an amount in excess of $75,000.00 plus interest, costs, punitive damages, and attorney's fees.

FIFTH CAUSE OF ACTION

Breach of Implied Warranty of Merchantability

77. Plaintiff adopts and realleges all foregoing paragraphs as if fully restated herein and further states as follows:

78. At all relevant times, Defendant Ethicon manufactured, distributed, advertised, promoted, and sold the GYNECARE MORCELLEX device.

79. At all relevant times, Defendant intended that the GYNECARE MORCELLEX device would be used in the manner that the Decedent's surgeon in fact used it and Defendant impliedly warranted the product to be of merchantable quality, safe and fit for such use, and was adequately tested.

80. Defendant breached various implied warranties with respect to the GYNECARE MORCELLEX device, including:

a. Defendant represented through its labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that the GYNECARE MORCELLEX device was safe, and withheld and concealed information about the substantial risks of serious injury and/or death associated with using the GYNECARE MORCELLEX device;

b. Defendant represented that the GYNECARE MORCELLEX device was as safe and/or safer than other alternative surgical approaches that did not include the use of the device, and concealed information, which demonstrated that the GYNECARE MORCELLEX device was not safer than alternatives available on the market; and,

c. Defendant represented that the GYNECARE MORCELLEX device was more

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

81. In reliance upon Defendant's implied warranty, Decedent's surgeon used said products as prescribed and in the foreseeable manner normally intended, recommended, promoted, instructed, and marketed by Defendant.

82. Defendant breached its implied warranty to Decedent in that the GYNECARE MORCELLEX device was not of merchantable quality, safe and fit for its intended use, nor was it adequately tested.

83. As a direct and proximate consequence of Defendant's breach of implied warranty and/or intentional acts, omissions, misrepresentations and/or otherwise culpable acts described herein, the Plaintiff and his Decedent sustained injuries and damages alleged herein including pain and suffering and death.

WHEREFORE, Plaintiff, Timothy Schroeder, individually and as husband of Cynthia Schroeder, respectfully requests that this Honorable Court enter judgment in his favor and against Ethicon, Inc., d/b/a Ethicon Women's Health and Urology, d/b/a Ethicon Johnson & Johnson, in an amount in excess of $75,000.00 plus interest, costs, punitive damages, and attorney's fees.

SIXTH CAUSE OF ACTION

Breach of Implied Warranty of Fitness

84. Plaintiff adopts and realleges all foregoing paragraphs as if fully restated herein and further states as follows:

85. At the time Defendant manufactured, designed, marketed, sold, and/or distributed the GYNECARE MORCELLEX device, Defendant had actual or constructive

knowledge that consumers would choose Defendant's product for its ordinary purpose (the minimally invasive removal of uterus and/or fibroids).

86. Defendants impliedly warranted the GYNECARE MORCELLEX device to be just as fit and safe for this particular purpose as any other device or surgical approach to the performance of hysterectomy or myomectomy.

87. Contrary to this implied warranty of fitness, the GYNECARE MORCELLEX device was not fit or safe for Plaintiff Decedent's use, because the GYNECARE MORCELLEX device was unreasonably dangerous compared to other available surgical approaches to hysterectomy as previously described.

88. As a direct and proximate result Defendant's breach of implied warranty of fitness and/or failure to comply with applicable federal requirements, Plaintiff and Plaintiff's Decedent suffered damages, including but not limited to personal injury, bodily harm, emotional distress, pain and suffering, death, loss of enjoyment of life, as well as economic and non-economic damages.

89. Defendant's acts were motivated by financial gain while the adverse consequences of the conduct was actually known by Defendant. Defendants' conduct was outrageous, fraudulent, oppressive, done with malice or gross negligence, and evidenced reckless indifference to Plaintiffs' rights, so as to warrant the imposition of punitive damages.

WHEREFORE, Plaintiff, Timothy Schroeder, individually and as husband of Cynthia Schroeder, respectfully requests that this Honorable Court enter judgment in his favor and against Ethicon, Inc., d/b/a Ethicon Women's Health and Urology, d/b/a Ethicon Johnson & Johnson, in an amount in excess of $75,000.00 plus interest, costs, punitive damages, and

attorney's fees.

SEVENTH CAUSE OF ACTION

Wrongful Death

90. Plaintiff brings this Wrongful Death action pursuant to Tenn. Code Ann. §§ 20-5-106, 20-5-107, and 20-5-113.

91. As a result of the negligence, wrongful conduct, and misconduct of Defendant, as set forth herein, Decedent was caused grave injuries, conscious pain and suffering, and ultimately, death, resulting in the entitlement to damages by Plaintiff under the Tennessee Wrongful Death Act.

92. Plaintiff claims damages for Decedent's mental and physical suffering, loss of time and necessary expenses resulting to the deceased from the personal injuries, as well as the damages resulting to the Plaintiff, for whose use and benefit the right of action survives from the death, and other expenses recoverable under Tenn. Code Ann. §§ 20-5-106, 20-5-107, and 20-5-113.

93. Plaintiff claims damages for loss of the monetary support that Decedent Cynthia Schroeder would have provided during her lifetime, including, but not limited to earnings, maintenance, support, and other similar losses recognized under Tenn. Code Ann. §§ 20-5-106, 20-5-107, and 20-5-113.

94. Plaintiff Timothy Schroeder, as the husband of Decedent, claims damages for his past and future loss of spousal consortium, services, society, support, guidance, tutelage, comfort and other similar losses recognized under applicable Tennessee statutes.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against the Defendant on each of the above-referenced claims and Causes of Action and further demand as follows:

i. Compensatory damages in excess of the minimum jurisdictional amount, including but not limited to compensation for injury, pain, suffering, mental anguish, emotional distress, loss of enjoyment of life, and other non-economic damages in an amount to be determined by the trier of fact in this action;

ii. Economic damages in the form of medical expenses, out-of-pocket expenses, child care expenses, life care expenses, lost earnings, and other economic damages in an amount to be determined by the trier of fact in this action;

iii. Attorneys' fees, expenses, and costs of this action;

iv. Punitive damages; and

v. Such further relief as this Honorable Court deems necessary, just, and proper.

RESPECTFULLY SUBMITTED,

MEDLEY & SPIVY

/s/Barbara G. Medley
111 West Commerce, Suite 201
Lewisburg, TN 37091
931-359-7555
Fax: 931-359-7556

COUNSEL FOR PLAINTIFFS

DEMAND FOR JURY TRIAL

Plaintiffs hereby demand trial by jury as to all issues so triable.

/s/ Barbara G. Medley

JS 44 (Rev. 12/12)

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. *(SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)*

I. (a) PLAINTIFFS
Timothy Schroeder, individually and as husband of Cynthia Schroeder, deceased.

(b) County of Residence of First Listed Plaintiff Rutherford County
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
Barbara G. Medley, Medley & Spivy, 111 West Commerce, Suite 201
Lewisburg, TN 37091, phone: 931-359-7555

DEFENDANTS
Ethicon Endo Surgery, Inc., d/b/a Ethicon Women's Health And Urology, d/b/a Ethicon Johnson & Johnson.

County of Residence of First Listed Defendant Somerset County
(IN U.S. PLAINTIFF CASES ONLY)
NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys *(If Known)*

II. BASIS OF JURISDICTION *(Place an "X" in One Box Only)*

- ☐ 1 U.S. Government Plaintiff
- ☐ 3 Federal Question *(U.S. Government Not a Party)*
- ☐ 2 U.S. Government Defendant
- ☒ 4 Diversity *(Indicate Citizenship of Parties in Item III)*

III. CITIZENSHIP OF PRINCIPAL PARTIES *(Place an "X" in One Box for Plaintiff and One Box for Defendant)*
(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☒ 1	☐ 1	Incorporated *or* Principal Place of Business In This State	☐ 4	☐ 4
Citizen of Another State	☐ 2	☐ 2	Incorporated *and* Principal Place of Business In Another State	☐ 5	☒ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

IV. NATURE OF SUIT *(Place an "X" in One Box Only)*

CONTRACT
- ☐ 110 Insurance
- ☐ 120 Marine
- ☐ 130 Miller Act
- ☐ 140 Negotiable Instrument
- ☐ 150 Recovery of Overpayment & Enforcement of Judgment
- ☐ 151 Medicare Act
- ☐ 152 Recovery of Defaulted Student Loans (Excludes Veterans)
- ☐ 153 Recovery of Overpayment of Veteran's Benefits
- ☐ 160 Stockholders' Suits
- ☐ 190 Other Contract
- ☐ 195 Contract Product Liability
- ☐ 196 Franchise

REAL PROPERTY
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

TORTS

PERSONAL INJURY
- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers' Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury
- ☐ 362 Personal Injury - Medical Malpractice

PERSONAL INJURY
- ☐ 365 Personal Injury - Product Liability
- ☒ 367 Health Care/ Pharmaceutical Personal Injury Product Liability
- ☐ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

CIVIL RIGHTS
- ☐ 440 Other Civil Rights
- ☐ 441 Voting
- ☐ 442 Employment
- ☐ 443 Housing/ Accommodations
- ☐ 445 Amer. w/Disabilities - Employment
- ☐ 446 Amer. w/Disabilities - Other
- ☐ 448 Education

PRISONER PETITIONS

Habeas Corpus:
- ☐ 463 Alien Detainee
- ☐ 510 Motions to Vacate Sentence
- ☐ 530 General
- ☐ 535 Death Penalty

Other:
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Condition
- ☐ 560 Civil Detainee - Conditions of Confinement

FORFEITURE/PENALTY
- ☐ 625 Drug Related Seizure of Property 21 USC 881
- ☐ 690 Other

LABOR
- ☐ 710 Fair Labor Standards Act
- ☐ 720 Labor/Management Relations
- ☐ 740 Railway Labor Act
- ☐ 751 Family and Medical Leave Act
- ☐ 790 Other Labor Litigation
- ☐ 791 Employee Retirement Income Security Act

IMMIGRATION
- ☐ 462 Naturalization Application
- ☐ 465 Other Immigration Actions

BANKRUPTCY
- ☐ 422 Appeal 28 USC 158
- ☐ 423 Withdrawal 28 USC 157

PROPERTY RIGHTS
- ☐ 820 Copyrights
- ☐ 830 Patent
- ☐ 840 Trademark

SOCIAL SECURITY
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

FEDERAL TAX SUITS
- ☐ 870 Taxes (U.S. Plaintiff or Defendant)
- ☐ 871 IRS—Third Party 26 USC 7609

OTHER STATUTES
- ☐ 375 False Claims Act
- ☐ 400 State Reapportionment
- ☐ 410 Antitrust
- ☐ 430 Banks and Banking
- ☐ 450 Commerce
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced and Corrupt Organizations
- ☐ 480 Consumer Credit
- ☐ 490 Cable/Sat TV
- ☐ 850 Securities/Commodities/ Exchange
- ☐ 890 Other Statutory Actions
- ☐ 891 Agricultural Acts
- ☐ 893 Environmental Matters
- ☐ 895 Freedom of Information Act
- ☐ 896 Arbitration
- ☐ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ☐ 950 Constitutionality of State Statutes

V. ORIGIN *(Place an "X" in One Box Only)*

☒ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from Another District *(specify)* ☐ 6 Multidistrict Litigation

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing *(Do not cite jurisdictional statutes unless diversity)*:
28 USC Sec. 1332 Diversity

Brief description of cause:
Product Liability/Personal injury

VII. REQUESTED IN COMPLAINT:

☐ CHECK IF THIS IS A CLASS ACTION UNDER RULE 23, F.R.Cv.P.

DEMAND $ 75,000.00

CHECK YES only if demanded in complaint:
JURY DEMAND: ☒ Yes ☐ No

VIII. RELATED CASE(S) IF ANY

(See instructions): JUDGE _____ DOCKET NUMBER _____

DATE

SIGNATURE OF ATTORNEY OF RECORD
/s/Barbara G. Medley

FOR OFFICE USE ONLY

RECEIPT # AMOUNT APPLYING IFP JUDGE MAG. JUDGE