

UNITED STATES DISTRICT COURT
DISTRICT OF SOUTH CAROLINA
SPARTANBURG DIVISION

ANDREA PHILLIPS and KEVIN PHILLIPS,)	CIVIL ACTION NO. _____
)	
Plaintiffs,)	
)	
v.)	
)	COMPLAINT
ETHICON, INC., ETHICON)	AND DEMAND FOR
ENDO-SURGERY, INC.,)	JURY TRIAL
JOHNSON & JOHNSON SERVICES, and)	
JOHNSON & JOHNSON,)	
)	
Defendants.)	
_____)	

Plaintiffs, ANDREA PHILLIPS and KEVIN PHILLIPS, by and through the undersigned counsel, upon information and belief, at all times hereinafter mentioned, allege as follows:

I. INTRODUCTION

1. This lawsuit is a personal injury action against Defendants who were responsible for researching, designing, developing, testing, manufacturing, packaging, labeling, marketing, advertising, promoting, distributing, selling and/or making available certain Laparoscopic Power Morcellators, including the Gynecare Morcellex Tissue Morcellator, Morcellex Sigma Tissue Morcellator System and the Gynecare X-tract Tissue Morcellator (referred to herein interchangeably as the "Laparoscopic Power Morecellator" or "Gynecare Tissue Morcellator"), which are medical devices used during laparoscopic and other types of minimally invasive uterine surgeries.

2. Plaintiff, ANDREA PHILLIPS, underwent two separate surgical procedures in May 2012 and September 2013, in which Gynecare Tissue Morcellators were used, causing the spread and/or dissemination of cancerous and/or pre-cancerous and/or "atypical" tissue from

her uterus to other parts of her pelvis and abdomen. The direct result of this was an "upstaging" of an occult or hidden tumor, a "low grade leiomyosarcoma" or "smooth muscle tumor of unknown malignant potential" ("STUMP") with metastasis to other parts of her body.

II. PARTIES

3. Plaintiff, ANDREA PHILLIPS, is a citizen of the State of South Carolina, County of Cherokee, and resides at 2006 Overbrook Drive, Gaffney, South Carolina 29341.

4. Plaintiff, KEVIN PHILLIPS, is a citizen of the State of South Carolina, County of Cherokee, and resides at 2006 Overbrook Drive, Gaffney, South Carolina 29341.

5. Defendant ETHICON, INC. is a corporation organized under the laws of the State of New Jersey, with its principal place of business at Route 22 West, Sommerville, New Jersey 08876.

6. Defendant ETHICON ENDO SURGERY, INC. is an Ohio corporation with its principal place of business at 4545 Creek Road, Blue Ash, Ohio 45242.

7. Defendant JOHNSON & JOHNSON SERVICES, INC. is a New Jersey corporation with its principal place of business at 1 Johnson & Johnson Plaza, New Brunswick, New Jersey 08933.

8. Defendant JOHNSON & JOHNSON is a New Jersey corporation with its principal place of business at 1 Johnson & Johnson Plaza, New Brunswick, New Jersey 08933.

9. On information and belief, Defendant JOHNSON & JOHNSON owns all of the common stock and other ownership interests of Defendants ETHICON, INC., ETHICON ENDO-SURGERY, INC., and JOHNSON & JOHNSON SERVICES, INC.

10. On information and belief, JOHNSON & JOHNSON is either the direct or indirect owner of substantially all the stock or other ownership interests of ETHICON, INC., ETHICON ENDO-SURGERY, INC., and JOHNSON & JOHNSON SERVICES.

11. In doing the acts alleged herein, said Defendants were acting in the course and scope of such agency, representation, joint venture, conspiracy, consultancy, predecessor agreement, successor agreement, service and employment, with knowledge, acquiescence and ratification of each other (hereinafter JOHNSON & JOHNSON, ETHICON, INC., ETHICON ENDO- SURGERY, INC., and JOHNSON & JOHNSON SERVICES are collectively referred to as “JOHNSON & JOHNSON”).

12. On information and belief, at all relevant times, Defendants expected or should have expected that their acts would have consequences within the United States of America and the State of South Carolina, and derived and derive substantial revenue from interstate commerce.

13. On information and belief, at all relevant times, Defendants have transacted and conducted business in the State of South Carolina, and/or contracted to supply goods and services within the State of South Carolina, and these causes of action have arisen from same.

14. On information and belief, at all relevant times, Defendants committed tortious acts without the State of South Carolina causing injury within the State of South Carolina out of which act(s) these causes of action arise.

III. VENUE AND JURISDICTION

15. The Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1332 because complete diversity exists between Plaintiffs, who are citizens of the State of

South Carolina, and different from the states where the Defendants are incorporated and have their principal places of business.

16. The amount in controversy for the Plaintiffs exceeds \$75,000, exclusive of interest and costs.

17. Venue is proper within this District pursuant to 28 U.S.C. § 1391, and it is a judicial district where Defendants are subject to personal jurisdiction in accordance with 28 U.S.C. §§ 1391(a) and (c).

IV. BACKGROUND AND FACTS

A. The device at issue

18. Laparoscopic Power Morcellators are electrically powered medical tools with spinning blades that shred, grind, and core tissue into smaller pieces or fragments so that the tissue can be removed through small incisions or extraction “ports” in the abdomen.

19. Conventional myomectomies typically are performed in such a way that the uterine fibroids are removed essentially intact and the women’s uterus is left intact. In the case of hysterectomies that are not performed using power morcellators, the women’s entire uterus is removed essentially intact.

20. Over the last few decades, many conventional hysterectomy and myomectomy procedures have been supplanted with electric Laparoscopic Power Morcellator devices to remove uterine fibroids or other tissue, and have increasingly replaced traditional open abdominal surgical hysterectomies, myomectomies, and laparotomies.

21. Laparoscopic Power Morcellators are designed with a grasper that pulls the tissue up against the sharp, rotating blades, severing the shredded tissue from the rest of the large mass and continuously pulling cut portions of tissue up through the tube.

22. The morcellator's spinning blade shreds the tissue masses at a high velocity and can disperse cellular particles from the shredded tissue throughout the abdomen during surgery.

23. During tissue morcellation, the morcellated fragments can be left in the abdomino-pelvic cavity, or attach to surrounding organs (such as the loops of the bowel), and cancerous cells can travel to remote areas of the body through the vasculature or lymphatic system.

24. Once disseminated in the body, morcellated fragments can become implanted in surrounding tissue or organs, and begin to grow.

25. When tissue fragments escape into the abdomino-pelvic cavity and seed in other tissue or organs, complications can arise months or years after the surgery.

26. As a result, Laparoscopic Power Morcellator can spread and upstage or worsen a women's occult cancer, changing the stage of the cancer from an early stage cancer into a much higher stage cancer and, as discussed below, significantly worsening a women's prognosis. In addition, certain types of cells with malignant potential may be converted to frankly malignant cells capable of seeding and metastasizing to other parts of the female body.

B. The Surgery at Issue

27. On May 25, 2012, Plaintiff ANDREA PHILLIPS underwent a robotic myomectomy at Spartanburg Regional Medical Center, Spartanburg, South Carolina, for dysfunctional uterine bleeding at which time her surgeon, Dr. Robert Goodlet, used Defendants' Gynecare Tissue Morcellator to remove fibroids and other uterine tissue.

28. Prior to undergoing surgery, Plaintiff underwent testing and evaluation which showed no evidence of disseminated or metastatic cancer.

29. Prior to undergoing surgery, Plaintiff was not warned of the high-risk that use of a Power Morcellator during her surgery to remove fibroids could or would disseminate and/or "seed" and/or "upstage" an occult cancer and/or otherwise well-encapsulated tumor.

30. On July 9, 2013, due to complaints of pelvic pain and dysfunctional uterine bleeding, the plaintiff underwent a transvaginal sonogram that revealed the presence of additional fibroids, the largest of which measured 3cm.

31. Thereafter on September 4, 2013, Plaintiff underwent a supracervical laparoscopic hysterectomy at Spartanburg Regional Medical Center, at which time her surgeons, Dr. Robert Goodlet and Dr. Brandi D. Hardin, used Defendants' Gynecare Tissue Morcellator for removal of the plaintiff's uterus and parts of her cervix.

32. The pathology report describing the uterine tissue revealed a spindle-cell tumor of uncertain malignant potential (STUMP) and was noted to have infiltrated into the parametrial fiber dense tissue with high mitotic activity noted in the specimens.

33. Prior to undergoing surgery, Plaintiff underwent testing and evaluation which showed no evidence of disseminated or metastatic cancer.

34. Prior to undergoing surgery, Plaintiff was not warned of the high-risk that use of a Power Morcellator during her hysterectomy surgery could or would disseminate and/or "seed" and/or "upstage" an occult cancer and/or otherwise well-encapsulated tumor.

35. Thereafter, on or about February 24, 2014, an ultrasound was performed due to plaintiff's complaints of continued pelvic pain and revealed Two (2) heterogeneous masses near the vaginal cuff, the largest of which measured 4x4x4 cm.

36. On March 3, 2014, a follow-up CT scan of the abdomen and pelvis revealed multiple, heterogeneously enhancing masses throughout the pelvis, the largest of which measured 5.2 x 4cm.

37. As a result of the forgoing, the plaintiff was referred to Dr. James Hunter, gynecologic oncologist, at the Gibbs Cancer Center in South Carolina. On March 18, 2014, an exploratory laparotomy with resection/excision of multiple masses in the abdomen, pelvis and omentum was performed by Dr. Hunter. In addition to the aforesaid surgical procedures, the plaintiff's ovaries and fallopian tubes were removed and an omentectomy was performed.

38. The pathology, as initially interpreted by physicians at the MD Anderson Cancer Center Hospital, is that of a low grade spindle cell neoplasm (STUMP) present in the anterior abdominal wall, the cul-de-sac, sigmoid colon, omentum, left fallopian tube, sigmoid mesentery and the vaginal apex. The MD Anderson Cancer Center supplemental pathology report dated May 9, 2014, states that while some investigators would classify the plaintiff's tumor as a "low grade leiomyosarcoma," the pathology report was revised to read as follows: "LOW GRADE SMOOTH MUSCLE TUMORS OF MULLERIAN ORIGIN AND OF UNCERTAIN MALIGNANT POTENTIAL".

39. Upon information and belief, the Plaintiff continues to treat at the MD Anderson Cancer Center with antagonistic hormonal therapy, including the administration of Letrazole. Because of the potential for distant metastasis, the plaintiff is required to undergo frequent radiological imaging, including periodic CT scans of the abdomen and pelvis to assess tumor recurrence and imaging of other parts of her body to screen for distant metastasis as well as

PET scans. The plaintiff reasonably fears a recurrence of pelvic and abdominal tumors and metastatic progression to the present day.

40. Had the Gynecare Power Morcellator used on Plaintiff not disseminate the aforesaid atypical, pre-cancerous and/or cancerous cells and tissue at the time of the aforesaid surgeries, Plaintiff would not have suffered and been diagnosed with a recurrence of her pelvic and abdominal tumors, an "upstaging" of her tumors and the potential for distant metastatic disease for which she is now at high risk.

41. Had the Gynecare Power Morcellator not been used in the surgeries performed upon the plaintiff, she would not have sustained the aforesaid conditions, nor would she have been placed at considerable risk for recurrence of tumors or metastasis of tumors to other parts of her abdomen and pelvis, and with potential for distant metastasis to other organs.

42. As a result of the conduct alleged herein by Defendants, Plaintiff, ANDREA PHILLIPS, has suffered, and continues to suffer, serious bodily injury and has incurred, and continues to incur, medical expenses to treat her injuries and condition, and has lost wages.

FIRST CAUSE OF ACTION ON BEHALF OF PLAINTIFFS
(NEGLIGENCE)

43. Plaintiffs repeat, reiterate and reallege each and every allegation of this Complaint with the same force and effect as if more fully set forth herein.

44. Defendants, ETHICON, INC., ETHICON ENDO- SURGERY, INC., JOHNSON & JOHNSON SERVICES, JOHNSON & JOHNSON, (hereafter collectively referred to as "Defendants"), owed a duty to design, manufacture, label, market, distribute, and supply and/or sell a product like the Power Morcellator in such a way as to avoid harm to persons upon whom it was used, including plaintiff, ANDREA PHILLIPS, or to refrain from

such activities following knowledge and/or constructive knowledge that such product is harmful to persons upon whom it is used.

45. Defendants owed a duty to warn of the hazards and dangers associated with the use of its product the Gynecare Power Morcellator and its associated minimally invasive gynecologic products, for patients such as plaintiff herein, so as to avoid harm.

46. 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 and/or selling and/or placing into the stream of commerce, minimally invasive gynecologic products, including the Power Morcellator, both generally, and in the following particular respects:

- a. failing to conduct adequate and appropriate testing of minimally invasive Gynecologic products, specifically including, but not limited to, products used for uterine morcellation;
- b. putting products used for uterine morcellation on the market without first conducting adequate testing to determine possible side effects;
- c. putting products used for uterine morcellation on the market without adequate testing of its dangers to humans;
- d. failing to recognize the significance of their own and other testing of, and information regarding, products used for uterine morcellation, which testing evidenced such products potential harm to humans;
- e. failing to respond promptly and appropriately to their own and other testing of, and information regarding products used for uterine morcellation, which indicated such products potential harm to human;
- f. failing to promptly and adequately warn of the potential of the products used for uterine morcellation to be harmful to humans;
- g. failing to promptly and adequately warn of the potential for the metastases of cancer when using products used for uterine morcellation;

- h. failing to promptly, adequately, and appropriately recommend testing and monitoring of patients upon whom products used for uterine morcellation 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 products used for uterine morcellation are harmful to humans;
- k. promoting, marketing, advertising and/or selling products used for uterine morcellation for use on patients given their knowledge and experience of such products' potential harmful effects;
- l. failing to withdraw products used for uterine morcellation from the market, restrict its 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 engaged in the manufacture of said products, specifically including products used for uterine morcellation;
- n. placing and/or permitting the placement of the products used for uterine morcellation, 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 the products used for uterine morcellation 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 plaintiff herein, 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 plaintiff herein, 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 products used for uterine morcellation and their potential harm to humans;

- t. failing to exercise reasonable care in informing physicians and/or hospitals regarding the products used for uterine morcellation about their own knowledge regarding said products' potential harm to humans;
- u. failing to remove products used for uterine morcellation from the stream of commerce;
- v. failing to test products used for uterine morcellation properly and/or adequately so as to determine its safety for use;
- w. promoting the products used for uterine morcellation as safe and/or safer than other comparative methods of lesion removal;
- x. promoting the products used for uterine morcellation on websites aimed at creating user and consumer demand;
- y. failing to conduct and/or respond to post-marketing surveillance of complications and injuries; and
- z. failing to use due care under the circumstances; and,

47. Due to the aforesaid condition of the Laparoscopic Power Morcellator used on Plaintiff during her surgery, Defendants are liable to Plaintiffs.

48. As a direct and proximate result of the negligent and/or reckless and/or wanton acts and/or omissions of Defendants, plaintiff suffered serious physical injury, pain and suffering and severe mental and emotional distress and economic loss and harm.

49. By reason of the foregoing, Plaintiffs demand judgment against each Defendant, individually, jointly and severally for compensatory damages as well as for punitive damages, attorneys' fees and all such other and further relief as the Court deem proper.

SECOND CAUSE OF ACTION ON BEHALF OF PLAINTIFFS
(STRICT PRODUCTS LIABILITY - DEFECTIVE DESIGN)

50. Plaintiffs repeat, reiterate and reallege each and every allegation of this Complaint with the same force and effect as if more fully set forth herein.

51. Defendants' Laparoscopic Power Morcellators were expected to, and did, reach the intended consumers, handlers, and persons coming into contact with the product without substantial change in the condition in which they were researched, designed developed, tested, manufactured, packaged, labeled, marketed, advertised, promoted, distributed, sold and/or made available by Defendants.

52. Defendants' Laparoscopic Power Morcellators, including the Gynecare Tissue Morcellator, were defective in design or formulation in that they were not reasonably fit, suitable or safe for their intended purpose and/or their foreseeable risks exceed the benefits associated with their design.

53. Defendants' Laparoscopic Power Morcellators were defective in design or formulation in that they lacked efficacy, posed a greater likelihood of injury and were more dangerous than other available surgical treatment options indicated for the same conditions and uses, including those discussed above.

54. Defendants' Power Morcellators were defective in design or formulation in that when they left the hands of the manufacturers and/or suppliers, the foreseeable risks of harm posed by the product could have been reduced or avoided by the adoption of a reasonable alternative design, including those discussed above, which had more established safety profiles and a considerably lower risks, or by the provision of reasonable instructions or warnings.

55. Defendants' Laparoscopic Power Morcellators, as designed, posed a substantial and avoidable likelihood of harm and it was feasible to design said products in a safer manner.

56. Defendants' Laparoscopic Power Morcellators, including the Gynecare Tissue Morcellator, were defective in design or formulation in that the dangers associated with their use were unknowable and unacceptable to the average or ordinary consumer.

57. Defendants' Laparoscopic Power Morcellators failed to comply with state and federal standards when sold.

58. At the time of Plaintiff's surgery, the Laparoscopic Power Morcellator was being used for its advertised and intended purpose, and in the manner Defendants intended.

59. As a foreseeable, direct, and proximate result of the aforementioned wrongful acts and omissions of Defendants, Plaintiffs were caused to suffer from the aforementioned injuries and damages.

60. Due to the aforesaid condition of the Laparoscopic Power Morcellator used on Plaintiff during her surgery, Defendants are strictly liable to Plaintiffs.

61. As a direct and proximate result of the negligent and/or reckless and/or wanton acts and/or omissions of Defendants, plaintiff suffered serious physical injury, pain and suffering and severe mental and emotional distress and economic loss and harm.

62. By reason of the foregoing, Plaintiffs demand judgment against each Defendant, individually, jointly and severally for compensatory damages as well as for punitive damages, attorneys' fees and all such other and further relief as the Court deem proper.

**THIRD CAUSE OF ACTION ON BEHALF OF PLAINTIFFS
(STRICT PRODUCTS LIABILITY – FAILURE TO WARN)**

63. Plaintiffs repeat, reiterate and reallege each and every allegation of this Complaint with the same force and effect as if more fully set forth herein.

64. Defendants were under an ongoing duty to keep abreast of medically known or knowable information related to their products and to advise clinicians of these risks in a timely manner to ensure the safe use of their product.

65. Defendants failed to adequately warn health care professionals and the public, including Plaintiff and her surgeon, of the following risks associated with the use of their Laparoscopic Power Morcellators, all of which were known or scientifically knowable to Defendants prior to the date on which the Plaintiff underwent surgery in 2011, including, but not limited to:

- a. the risk of aggressively disseminating unsuspected malignant tissue beyond the uterus;
- b. the device's risk of upstaging a patient's undetected or occult cancer;
- c. failing to provide accurate warnings regarding the inadequacy of pre-operative screening for the presence of unsuspected malignant uterine tissue in women;
- d. failing to provide accurate rates of the prevalence of unsuspected malignant tissue in women undergoing uterine morcellation; and
- e. failing to advise doctors to carefully monitor patients following Laparoscopic Power Morcellator surgery to evaluate for the presence of uterine cancer at an earlier date and to allow for appropriate treatment in the event of such a finding.

66. Defendants' failure to adequately warn Plaintiff and Plaintiff's surgeon of the risks associated with Laparoscopic Power Morcellators prevented Plaintiff and Plaintiff's surgeon from correctly and fully evaluating the risks and benefits of undergoing surgery with the Defendants' devices.

67. Defendants also have known or should have known of the risks associated with the use of specimen containment bags that were not designed for use with a Laparoscopic Power Morcellator, including their potential to perforate or tear during laparoscopic surgery, thereby, creating a risk of tumor spillage and site seeding.

68. Defendants failed to timely include a Black Box Warning regarding the risks of dissemination of occult malignancy and the upstaging of a patient's occult cancer.

69. Defendants failed to timely include a Contraindication that Power Morcellators should not be used in women with tissue of unsuspected, occult, or unknown malignancy.

70. Had Defendants timely and adequately warned of the risks of the Laparoscopic Power Morcellator used during Plaintiff's surgery, such warnings would have been heeded by Plaintiff's surgeon, in that Plaintiff's surgeon would have changed the manner in which he prescribed or selected the Power Morcellator for Plaintiff's surgery, including but not limited to, communicating the risks to the Plaintiff prior to surgery, not using the Power Morcellator, and/or selecting an alternative and safer treatment option for the Plaintiff.

71. If Plaintiff had been adequately warned of the life-threatening risks of the use of the Laparoscopic Power Morcellator, as stated herein, she would have chosen an alternative treatment, one that did not carry the avoidable risks of disseminating and/or upstaging occult cancer and, therefore, would have avoided the injuries described herein.

72. Defendants' failure to adequately warn about the risk of their Power Morcellators was a substantial and contributing factor in causing Plaintiff's injuries.

73. As a direct and proximate result of the negligent and/or reckless and/or wanton acts and/or omissions of Defendants, plaintiff suffered serious physical injury, pain and suffering and severe mental and emotional distress and economic loss and harm.

74. By reason of the foregoing, Plaintiffs demand judgment against each Defendant, individually, jointly and severally for compensatory damages as well as for punitive damages, attorneys' fees and all such other and further relief as the Court deem proper.

FOURTH CAUSE OF ACTION ON BEHALF OF PLAINTIFFS
(BREACH OF EXPRESS WARRANTY)

75. Plaintiffs repeat, reiterate and reallege each and every allegation of this Complaint with the same force and effect as if more fully set forth herein.

76. 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.

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

78. As a direct and proximate result of the negligent and/or reckless and/or wanton acts and/or omissions of Defendants, plaintiff suffered serious physical injury, pain and suffering and severe mental and emotional distress and economic loss and harm.

79. By reason of the foregoing, Plaintiffs demand judgment against each Defendant, individually, jointly and severally for compensatory damages as well as for punitive damages, attorneys' fees and all such other and further relief as the Court deem proper

FIFTH CAUSE OF ACTION ON BEHALF OF PLAINTIFFS
(BREACH OF IMPLIED WARRANTY)

80. Plaintiffs repeat, reiterate and reallege each and every allegation of this Complaint with the same force and effect as if more fully set forth herein.

81. At all relevant and material times, Defendants manufactured, distributed, advertised, promoted, and sold the foregoing products used for uterine morcellation.

82. At all relevant times, Defendants intended that the products used for uterine morcellation be used in the manner that the Plaintiff's surgeons 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.

83. 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 used for uterine morcellation 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 used for uterine morcellation 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 available on the market; and,
- c. Defendants represented that the products used for uterine morcellation were more efficacious than other alternative surgical approaches and techniques and concealed information, regarding the true efficacy of said products.

84. In reliance upon Defendants' implied warranty, Plaintiff's surgeons used said products as prescribed and in the foreseeable manner normally intended, recommended, promoted, instructed, and marketed by Defendant.

85. Defendants breached their implied warranty to Plaintiff in that said products used for uterine morcellation were not of merchantable quality, safe and fit for their intended use, or adequately tested.

86. As a direct and proximate result of the negligent and/or reckless and/or wanton acts and/or omissions of Defendants, Plaintiff suffered serious physical injury, pain and suffering and severe mental and emotional distress and economic loss and harm.

87. By reason of the foregoing, Plaintiffs demand judgment against each Defendant, individually, jointly and severally for compensatory damages as well as for punitive damages, attorneys' fees and all such other and further relief as the Court deem proper.

**SIXTH CAUSE OF ACTION ON BEHALF OF PLAINTIFFS
(FRAUDULENT MISREPRESENTATION)**

88. Plaintiffs repeat, reiterate and reallege each and every allegation of this Complaint with the same force and effect as if more fully set forth herein

89. Defendants, having undertaken the design, formulation, testing, manufacture, marketing, sale, and distribution of devices used for uterine morcellation owed a duty to provide accurate and complete information regarding said devices.

90. Prior to Plaintiff ANDREA PHILLIPS undergoing her surgery Defendants fraudulently misrepresented, that the use of their device for uterine morcellation was safe and effective.

91. Defendants had a duty to provide plaintiff ANDREA PHILLIPS, physicians, and other consumers with true and accurate information regarding the devices for uterine morcellation it manufactured, marketed, distributed and sold.

92. Defendants made representations and failed to disclose material facts with the intent to induce consumers, including plaintiff, ANDREA PHILLIPS, and the medical community to act in reliance by purchasing and using the uterine morcellator sold by defendant.

93. Plaintiff ANDREA PHILLIPS and the medical community justifiably relied on Defendants' representations and omissions by purchasing and using the Power Morcellator

during Plaintiff's hysterectomy and or fibroidectomy.

94. Defendants' representations and omissions regarding use of its uterine morcellation devices were a direct and proximate cause of Plaintiff's injuries.

95. As a direct and proximate result of the fraud of Defendants, Plaintiff suffered serious physical injury, pain and suffering and severe mental and emotional distress and economic loss and harm.

96. By reason of the foregoing, Plaintiffs demand judgment against each Defendant, individually, jointly and severally for compensatory damages as well as for punitive damages, attorneys' fees and all such other and further relief as the Court deem proper.

SEVENTH CAUSE OF ACTION ON BEHALF OF PLAINTIFFS

(Violation of the South Carolina Unfair Trade Practices Act, S.C. Code Ann. §39-5-10 et seq.)

97. Plaintiffs repeat, reiterate, and reallege each and every allegation of this Complaint with the same force and effect as if more fully set forth herein.

98. By reason of their conduct as alleged herein, the Defendants willfully and/or knowingly violated the provision of S.C. Code Ann. §39-5-10 et seq. ("SCUTPA") as it refers to consumer protection by inducing Plaintiff to purchase (directly, or through her surgeon, and/or the health care facility at which her surgery was performed) primarily for personal use the Laparoscopic Power Morcellator used on her during surgery through the use of false and/or misleading promotions, advertising, representations, and statements. Defendants' actions had an adverse impact on the public interest as Defendants' practices are capable of repetition.

99. By engaging in the conduct described above, the Defendants have violated this state's Unfair Trade Practices Act by, among other things:

a. Engaging in unfair or deceptive trade practices as defined in the statute by making false and misleading oral and written statements that had, and have the capacity, tendency, or effect of deceiving or misleading consumers;

b. Engaging in unfair or deceptive trade practices as defined in the statute by failing to state material facts, the omission of which deceived or tended to deceive – both the public, generally, and Plaintiff, specifically – including, but not limited to, facts relating to the health consequences of the use of the Laparoscopic Power Morcellator; and

c. Engaging in unfair and deceptive trade as defined in the statute by promoting the Laparoscopic Power Morcellator as safe and effective by knowingly and falsely representing that their Laparoscopic Power Morcellators were fit to be used for the purpose for which they were intended, when in fact said devices were defective and dangerous.

100. As a direct and proximate result of the Defendants' conduct in violation of the South Carolina Unfair Trade Practices Act, Plaintiff suffered injuries and economic loss. Had Defendants not engaged in the deceptive conduct described herein, Plaintiff would not have purchased and/or paid for the Laparoscopic Power Morcellator that was used on her during her surgery (directly, or through her surgeon, and/or the health care facility at which her surgery was performed), and would not have incurred related medical costs and injury.

101. At all material times, the Defendants actually knew of the defective nature of Laparoscopic Power Morcellator as set forth herein, and blatantly continued to make false and/or misleading promotions, advertising, representations, and statements regarding the Laparoscopic Power Morcellator so as to maximize sales and profits at the expense of public health and safety, and they exhibited such an entire want of care as to establish that their actions were a result of fraud, actual malice and the conscious and deliberate disregard of

foreseeable harm to Plaintiff, thereby entitling Plaintiff to punitive damages. At all material time, Defendants used and employed the above stated unfair and deceptive methods, acts, and practices willfully and knowingly in violation of S.C. Ann. §39-5-20 and that Plaintiff is therefore entitled to treble damages pursuant to S.C. Ann. §39-5-140.

102. As a direct and proximate result of the defective and unreasonably dangerous condition of the Laparoscopic Power Morcellator, Plaintiff was injured in and about her body, or suffered aggravation of pre-existing conditions or injury, suffered pain therefrom, incurred medical and related expenses in the treatment of her injuries, suffered physical handicap, suffered psychological and emotional injuries, sustained permanent injuries with a reasonable degree of medical probability, and/or suffered permanent loss of an important bodily function, suffered increased risk and susceptibility to like or related injury in the future, suffered permanent impairment of the capacity for the enjoyment of life as a result of the wrongful acts of Defendants.

103. Plaintiff demands judgment against the Defendants for compensatory, treble, and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

EIGHTH CAUSE OF ACTION ON BEHALF OF PLAINTIFFS
(LOSS OF CONSORTIUM)

104. Plaintiffs repeat, reiterate and reallege each and every allegation of this Complaint with the same force and effect as if more fully set forth herein

105. Plaintiffs are legally married, and as such, are entitled to the comfort, enjoyment, society and services of one another.

106. As a direct and proximate result of the foregoing, Plaintiff, KEVIN PHILLIPS, was deprived of the comfort and enjoyment of the services and society of his spouse, the

Plaintiff ANDREA PHILLIPS, and have suffered and will continue to suffer economic loss, and have otherwise been emotionally and economically injured.

107. The Plaintiff's injuries and damages are permanent and will continue into the future, and as such, the injuries of the Plaintiff's spouse, KEVIN PHILLIPS, continue into the future.

108. By reason of the foregoing, Plaintiffs demand judgment against each Defendant, individually, jointly and severally for compensatory damages as well as for punitive damages, attorneys' fees and all such other and further relief as the Court deem proper

NINTH CAUSE OF ACTION ON BEHALF OF PLAINTIFFS
(PUNITIVE DAMAGES)

109. Plaintiffs repeat, reiterate and reallege each and every allegation of this Complaint with the same force and effect as if more fully set forth herein.

110. At all material times, the Defendants actually knew of the defective nature of Laparoscopic Power Morcellator as set forth herein, and blatantly continued to make false and/or misleading promotions, advertising, representations, and statements regarding the Laparoscopic Power Morcellator so as to maximize sales and profits at the expense of public health and safety, and they exhibited such an entire want of care as to establish that their actions were a result of fraud, actual malice and the conscious and deliberate disregard of foreseeable harm to Plaintiff, thereby entitling Plaintiff to punitive damages.

111. The conduct of Defendants, as set forth herein, above was intentional, willful, wanton, oppressive, malicious, and reckless, evidencing such an entire want of care as to raise the presumption of a conscious indifference to the consequences in that Defendants acted only out of self-interest and personal gain. Such conduct evidences a specific intent to cause harm to Plaintiff as provided. Accordingly, punitive damages should be imposed against

Defendants, to punish and deter each Defendant from repeating or continuing such unlawful conduct.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs demand judgment against the Defendants on each of the above-referenced claims and Causes of Action and as follows:

- (1) Awarding compensatory damages to Plaintiff for past and future damages including, but not limited to, pain and suffering for severe and permanent personal injuries sustained by the Plaintiff, past and future health care costs, medical monitoring, past and future loss of earnings and/or earning capacity, according to proof, together with interest and costs as provided by law;
- (2) Awarding compensatory damages to Plaintiff Spouse for past and future damages for loss of consortium, according to proof;
- (3) Punitive and/or exemplary damages for the malicious, wanton, willful, oppressive, and reckless acts of the Defendants who demonstrated a reckless indifference to the rights and safety of the general public and to the Plaintiffs in an amount sufficient to punish Defendants and deter future similar conduct;
- (4) Awarding Plaintiffs' attorney's fees;
- (5) Awarding Plaintiffs the costs of these proceedings; and
- (6) Such other and further relief as this Court deems just and proper.

DEMAND FOR JURY TRIAL

Plaintiffs hereby demand a trial by jury as to all issues

Respectfully submitted,

By: /s/Elizabeth Middleton Burke
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