IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF SOUTH CAROLINA
CHARLESTON DIVISION

JOAN L. SCHWARTZ,

Plaintiffs,

v.

ETHICON, INC.; ETHICON ENDO-SURGERY, INC.; ETHICON WOMEN'S HEALTH AND UROLOGY, A DIVISION OF ETHICON, INC.; JOHNSON & JOHNSON; JOHNSON & JOHNSON SERVICES, INC., VENTION MEDICAL, INC. (f/k/a THE MEDTECH GROUP, INC.); VENTION MEDICAL ACQUISITION CO.; and VENTION MEDICAL HOLDINGS, INC.,

Defendants.

CIVIL ACTION NO.: 2:16-cv-00355-MDL

COMPLAINT AND JURY DEMAND

COMES NOW, Plaintiff Joan L. Schwartz, by and through the undersigned counsel, and hereby alleges against Ethicon, Inc.; Ethicon Endo-Surgery, Inc.; Ethicon Women's Health & Urology, a Division of Ethicon, Inc.; Johnson & Johnson; Johnson & Johnson Services, Inc.; Vention Medical, Inc. (f/k/a The Medtech Group, Inc.); Vention Medical Acquisition Co.; and Vention Medical Holdings, Inc., (collectively "Defendants"), as follows:

Jurisdiction and Venue

1. This Court has original jurisdiction pursuant to 28 U.S.C. § 1332, because the matter in controversy exceeds the sum or value of $75,000, exclusive of interest and costs, and is between citizens of different states.

Tag-Along Action

2. This is a potential tag-along action and in accordance with 28 U.S.C. §14-7, it should be transferred to the United States District Court for the District of Kansas for inclusion in *In re Ethicon, Inc., Power Morcellator Products Liability Litigation,* MDL 2652 (Hon. Kathryn H. Vratil).

PARTIES, JURISDICTION AND CITIZENSHIP

3. Plaintiff Joan L. Schwartz (hereinafter "Ms. Schwartz" or "Plaintiff") is, and at the times mentioned in this Complaint a resident of Johns Island, South Carolina, and is a citizen of the State of South Carolina.

4. Defendant ETHICON, INC. is a corporation, or other entity, organized and/or existing under the laws of the State of 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, with a principal place of business at 737 U.S. Highway 22, Bridgewater, New Jersey 08807.

5. Defendant ETHICON ENDO-SURGERY, INC. is a corporation, or other entity, organized and/or existing under the laws of the State of Ohio, 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, with a principal place of business at 4545 Creek Road, Blue Ash, Ohio 45242.

6. Defendant ETHICON WOMEN'S HEALTH AND UROLOGY, a DIVISION OF ETHICON, INC., a corporate division of ETHICON, INC., is a corporation, or other entity, organized and/or existing under the laws of the State of 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, with a principal place of business at Route 22 West, Somerville, New Jersey 08876.

7. Defendant JOHNSON & JOHNSON, is a corporation, or other entity, organized and/or existing under the laws of the State of 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, with a principal place of business at 1 Johnson & Johnson Plaza, New Brunswick, New Jersey 08933.

8. Defendant JOHNSON & JOHNSON SERVICES, INC., is a corporation, or other entity, organized and/or existing under the laws of the State of 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, with a principal place of business at 1 Johnson & Johnson Plaza, New Brunswick, New Jersey 08933.

9. Defendant VENTION MEDICAL, INC. (F/K/A THE MEDTECH GROUP INC.) is a corporation organized and/or existing under the laws of the State of New Jersey with its principal place of business at 6 Century Road, South Plainfield, NJ 07080.

10. Defendant VENTION MEDICAL ACQUISITION CO. is a corporation organized and/or existing under the laws of the State of Delaware with its principal place of business at 1800 Larimer Street, Suite 2200, Denver, Colorado 80202.

11. Defendant VENTION MEDICAL HOLDINGS, INC. is a corporation organized and/or existing under the laws of the State of Delaware with its principal place of business at 1800 Larimer Street, Suite 2200, Denver, Colorado 80202.

12. On information and belief, Defendant VENTION MEDICAL ACQUISITION CO. owns all of the common stock and other ownership interests of Defendant VENTION MEDICAL, INC. (F/K/A THE MEDTECH GROUP INC.).

13. On information and belief, Defendant VENTION MEDICAL HOLDINGS, INC. owns all of the common stock and other ownership interests of Defendant VENTION MEDICAL ACQUISITION CO.

14. On information and belief, JOHNSON & JOHNSON and VENTION MEDICAL, INC. were the agents, representatives, joint venturers, alter egos, co-conspirators, consultants, predecessors, successors, servants or employees of each other.

15. Defendants have been engaged in the business of researching, testing, developing, manufacturing, packaging, distributing, licensing, labeling, promoting, marketing and selling, either directly or indirectly through third parties or related entities, Gynecare laparoscopic power morcellators, both in South Carolina and throughout the United States.

16. All Defendants are diverse from the Plaintiff and are subject to service of process. This Court properly may exercise personal jurisdiction over them. Each Defendant has sufficient minimum contacts with the state of South Carolina to be sued and be required to defend here.

17. Venue is proper here because all or a substantial part of the events at issue occurred within this U.S. Judicial District, and in Charleston County, South Carolina, specifically.

ALLEGATIONS

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 are performed by removing uterine fibroids essentially intact and leaving a woman’s uterus intact. Conventional hysterectomies without the use of

power morcellators, remove the entire uterus 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 and non-cancerous fibrotic 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, the Laparoscopic Power Morcellator can disseminate benign tissue following morcellation with subsequent prolific and "parasitic" growth including fibroids, endometriosis, and adenomyosis as well as abscess formation and peritonitis.

27. An alternative method of performing this procedure is with the use of a surgical bag to contain tissue that might otherwise be disseminated throughout the abdomen. At the time of

Plaintiff's procedure in 2008, Defendants did not manufacture a bag that could be used during a morcellation procedure to prevent the dissemination of tissue.

28. Plaintiff JOAN L. SCHWARTZ underwent a laparoscopic surgical procedure on April 11, 2008, at MUSC in Charleston, South Carolina. Her surgeon, David E. Soper, M.D., noted in his operative report that he performed a "laparoscopic supracervical hysterectomy and left salpingo oophorectomy" and "…we systematically morcellated 980 g worth of uterus and fibroid and left tube and ovary." On information and belief, the morcellation of the uterus was performed using a Gynecare Morcellex Morcellator.

29. Plaintiff JOAN L. SCHWARTZ trusted that serious risks associated with the use of a Gynecare Morcellex Morcellator such as the upstaging, dissemination and seeding of endometriosis and fibroid tissue, fibroid tissue, and endometriosis would have been included and emphasized in the written product information provided to her surgeon. The Plaintiff relied upon the fact that the occurrence of upstaging, dissemination and seeding of endometriosis and fibroid tissue, fibroid tissue, and endometriosis were not listed or emphasized in the product's warnings as a basis to believe that the Gynecare Morcellex Morcellator was safe for use during her surgery and would not cause the upstaging, dissemination and seeding of endometriosis and fibroid tissue.

30. Had the Plaintiff been adequately warned that Gynecare Morcellex Morcellator could cause the upstaging, dissemination and seeding of endometriosis and fibroid tissue, fibroid tissue, and endometriosis she would not have agreed to the procedure.

31. In 2012, Plaintiff was found to have endometriosis, a spreading of uterine cells into the abdomen, and leiomyomatosis, an overgrowth of fibroid masses, both of which are painful conditions and were later determined to be directly attributable to the surgery performed on her using the Gynecare Morcellex Morcellator.

32. Plaintiff has had to undergo major exploratory surgery, right salpingo-oophorectomy, radical resection of peritoneal masses and a partial sigmoid resection and reanastomosis. She will likely have to undergo additional surgeries and treatments in the future.

33. Plaintiff was forced to miss between eight and nine weeks of work and was required to hire a caregiver for several weeks as she was unable to drive or care for herself due to the her exploratory surgery.

34. Defendants were responsible for designing, researching, developing, testing, manufacturing, packaging, labeling, marketing, promoting, distributing and/or selling Laparoscopic Power Morcellators under the following trade names: the Gynecare Morcellex Tissue Morcellator, the Morcellex Sigma Tissue Morcellator System, and the Gynecare X-tract Tissue Morcellator.

A. FDA Action and the "World Wide Withdrawal" of Johnson & Johnson Laparoscopic Power Morcellators

35. On April 17, 2014, the FDA released a Safety Communication Notice and Quantitative Assessment to inform health care providers and the public that "based on currently available information, the FDA discourages the use of laparoscopic power morcellation during hysterectomy or myomectomy for the treatment of women with uterine fibroids." 4/17/2014 FDA Safety Communication.

36. On April 30, 2014, Defendants suspended worldwide sale of their Laparoscopic Power Morcellators, which according to Defendants, was "not a product removal."

37. On July 30, 2014, Defendants issued an urgent worldwide withdrawal of the Gynecare Morcellators. Even so, Defendants continued to defend their Laparoscopic Power Morcellators urging that patients could benefit from their use.

38. On November 24, 2014, the FDA issued an updated FDA Safety Communication regarding Laparoscopic Power Morcellators asking product manufacturers to include two contraindications and a boxed warning in their product labeling, which warned the medical community against using laparoscopic power morcellators in the majority of women undergoing myomectomy or hysterectomy. The warnings included:

CONTRAINDICATION: Laparoscopic power morcellators are contraindicated for removal of uterine tissue containing suspected fibroids in patients who are:

a. peri- or post-menopausal, or
b. candidates for* en bloc *tissue removal, for example, through the vagina or via a mini-laparotomy incision.

> ***WARNING*: Uterine tissue may contain unsuspected cancer. The use of laparoscopic power morcellators during fibroid surgery may spread cancer, and decrease the long-term survival of patients. This information should be shared with patients when considering surgery with the use of these devices.**

Immediately In Effect Guidance Document: Product Labeling for Laparoscopic Power Morcellators, November 25, 2014) available at the FDA website[1].

AS A FIRST CAUSE OF ACTION: NEGLIGENCE

39. The allegations above are incorporated by reference to support this Count.

40. The Defendants owed a duty to manufacture, compound, label, market, distribute, and supply and/or sell products, including instruments for uterine morcellation, specifically the Gynecare Morcellator, in such a way as to avoid harm to persons upon whom they are used, such as Plaintiff herein, and to refrain from such activities following knowledge and/or constructive

[1] http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm424123.pdf

knowledge that such product is harmful to persons upon whom it is used.

41. 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.

42. 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, the Gynecare Morcellator, both generally and in the following particular respects:

a. failing to conduct adequate and appropriate testing of instruments such as the Gynecare Morcellator, specifically including, but not limited to, products used for uterine morcellation;

b. putting products used for uterine morcellation such as the Gynecare Morcellator on the market without first conducting adequate testing to determine possible side effects;

c. putting products used for uterine morcellation such as the Gynecare Morcellator 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, such as the Gynecare Morcellator, 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, such as the Gynecare Morcellator which indicated such products potential harm to humans;

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, 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;

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

i. 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, specifically the Gynecare Morcellator, are harmful to humans;

j. promoting, marketing, advertising and/or selling products used for uterine morcellation such as the Gynecare Morcellator, for use on patients Given their knowledge and experience of such products' potential harmful effects;

k. 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;

l. 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 including products used for uterine morcellation such as the Gynecare Morcellator;

m. placing and/or permitting the placement of the products used for uterine morcellation, specifically the Gynecare Morcellator, 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;

n. 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, including the Gynecare

Morcellator, to be harmful to humans;

o. failing to respond or react promptly and appropriately to reports of products used for uterine morcellation causing harm to patients, including the Gynecare Morcellator;

p. 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;

q. 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;

r. 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;

s. failing to exercise reasonable care in informing physicians and/or hospitals using the products used for uterine morcellation about their own knowledge regarding said products' potential harm to humans;

t. failing to remove products used for uterine morcellation from the stream of commerce;

u. failing to test products used for uterine morcellation properly and/or adequately so as to determine its safety for use;

v. promoting the products used for uterine morcellation as safe and/or safer than other comparative methods;

w. promoting the products used for uterine morcellation on websites aimed at creating user and consumer demand;

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

y. failing to use due care under the circumstances;

z. failing to monitor, analyze and report adverse post-surgical outcomes stemming from the use of the Gynecare Morcellator.

aa. failing to monitor, analyze and report adverse post-surgical outcomes stemming from the use of the Gynecare Morcellator to the FDA;

bb. failing to utilize, include, require or adequately recommend the use of a closed system such as a tissue bag to contain morcellated tissue fragments and thereby prevent the relevant risk known to Defendants from use of their product, namely dissemination of parasitic fibroids, the adverse event which specifically occurred in Ms. Schwartz's case;

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

43. As a direct and proximate result of the negligent and/or reckless and/or wanton acts and/or omissions of Defendants, Plaintiff suffered serious injuries, and/or financial losses and harm.

WHEREFORE, Plaintiffs demand judgment against each Defendant for compensatory, statutory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems appropriate pursuant to the common law and statutory law.

AS A SECOND CAUSE OF ACTION: DEFECTIVE MANUFACTURING

44. Plaintiffs incorporate by reference all other paragraphs of this complaint as if fully set forth, and further allege as follows:

45. Defendants were and are engaged in the business of selling the Gynecare Morcellator in the State of South Carolina.

46. The Gynecare Morcellator manufactured, marketed, promoted and sold by Defendants was expected to, and did, reach Plaintiff Joan L. Schwartz without substantial change in the condition in which it was sold.

47. Defendants have introduced a product into the stream of commerce which is dangerous and unsafe in that the harm of the Gynecare Morcellator outweighs any benefit derived therefrom. The unreasonably dangerous nature of Gynecare Morcellator caused serious harm to Plaintiff.

48. Defendants manufactured, marketed, promoted and sold a product that was not merchantable and/or reasonably suited to the use intended, and its condition when sold was the proximate cause of the injuries sustained by the Plaintiff.

49. As a direct and proximate result of the subject product's defective design, Plaintiff suffered severe and permanent physical injuries. Plaintiff has endured substantial pain and suffering. She has incurred significant expenses for medical care and treatment, and will continue to incur such expenses in the future. Plaintiff has suffered and will continue to suffer economic loss, and has otherwise been physically, emotionally and economically injured. Plaintiff's injuries and damages are permanent and will continue into the future. The Plaintiff seeks actual and punitive damages from the Defendants as alleged herein

50. Defendants placed Gynecare Morcellator into the stream of commerce with wanton and reckless disregard for the public safety.

51. Defendants knew and, in fact, advertised and promoted the use of Gynecare Morcellator despite their failure to test or otherwise determine the safety and efficacy of such use. As a direct and proximate result of the Defendants' widespread promotional activity, physicians began commonly utilizing this product as safe and effective.

52. Despite the fact that evidence existed that the use of Gynecare Morcellator was dangerous and likely to place users at serious risk to their health, Defendants failed to disclose and warn of the health hazards and risks associated with the Gynecare Morcellator and in fact acted to deceive the medical community and public at large, including all potential users of Gynecare Morcellator by promoting it as safe and effective.

53. Defendants knew or should have known that physicians and other healthcare providers began commonly using this device as a safe and effective tool for uterine surgery despite its lack of efficacy and potential for serious permanent side effects.

54. There are comparative products on the market with safer alternative designs in that they provide equal or greater efficacy and far less risk. There are also safer medical procedures that exist where the physicians do not need to use a morcellator.

55. As a direct and proximate result of one or more of these wrongful acts or omissions of the Defendants, Plaintiff suffered profound injuries, required and continues to require medical treatment, and incurred and continues to incur medical and hospital expenses.

AS A THIRD CAUSE OF ACTION: DESIGN DEFECT

56. Plaintiffs incorporate by reference all other paragraphs of this complaint as if fully set forth, and further allege as follows:

57. Defendants were and are engaged in the business of selling Gynecare Morcellator in the State of South Carolina.

58. The Gynecare Morcellator manufactured, marketed, promoted and sold by Defendants was expected to, and did, reach Plaintiff without substantial change in the condition in which it was sold.

59. The foreseeable risks associated with the design or formulation of the Gynecare Morcellator include, but are not limited to, the fact that the design or formulation of Gynecare Morcellator is more dangerous than a reasonably prudent consumer would expect when used in an intended or reasonably foreseeable manner.

60. Defendants manufactured, marketed, promoted and sold a product that was not merchantable and/or reasonably suited to the use intended, and its condition when sold was the proximate cause of the injuries sustained by the Plaintiff.

61. Defendants placed Gynecare Morcellator into the stream of commerce with wanton and reckless disregard for the public safety.

62. Defendants knew or should have known that physicians and other healthcare providers began commonly utilizing this product as a safe and effective device for uterine surgery despite its lack of efficacy and potential for serious side effects.

63. There are products on the market with safer alternative designs in that they provide equal or greater efficacy and far less risk. Physicians can also remove the uterus and fibroids intact without using the morcellator avoiding the risk posed by morcellation.

64. As a direct and proximate result of one or more of these wrongful acts or omissions of the Defendants, Plaintiff suffered profound injuries, required and continues to require medical treatment, and incurred and continues to incur medical and hospital expenses.

AS A FOURTH CAUSE OF ACTION:
FAILURE TO WARN

65. Plaintiffs incorporate by reference all other paragraphs of this complaint as if fully set forth, and further allege as follows:

66. The Gynecare Morcellator is a defective and therefore unreasonably dangerous product, because its labeling fails to adequately warn consumers and prescribers of, among other things:

a. the risk of aggressively disseminating parasitic tissue beyond the uterus;

b. failing to advise doctors to carefully monitor patients following Laparoscopic Power Morcellator surgery to evaluate for the presence of iatrogenic endometriosis and/or leiomyomatosis at an earlier date and to allow for appropriate treatment in the event of such a finding;

c. The actual rates at which laparoscopic power morcellators disseminate and/or upstage cancerous and non-cancerous fibroid tumors;

d. That laparoscopic power morcellators are associated with worse long-term medical outcomes than other fibroid treatments because of the risk of tumors being spread and implanted by the use of the device; and

e. The risks of spreading and upstaging cancer and non-cancerous tumors, the need for additional treatment and procedures and/or the need for additional surgery as well as other severe and permanent health consequences, notwithstanding Defendants' knowledge of an increased risk of these injuries and side effects over other forms of treatment for uterine fibroid removal.

67. Defendants researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and otherwise released into the stream of commerce the pharmaceutical, Gynecare Morcellator, and in the course of same, directly advertised or marketed the product to consumers or persons responsible for consumers, and therefore had a duty to warn of the risks associated with the use of Gynecare Morcellator.

68. The Gynecare Morcellator was under the exclusive control of Defendants and was unaccompanied by appropriate warnings regarding all of the risks associated with its use. The warnings given did not accurately reflect the risk, incidence, symptoms, scope or severity of such

injuries to the consumer or physicians. The promotional activities of Defendants further diluted or minimized the warnings given with the product.

69. Defendants downplayed the serious and dangerous side effects of Gynecare Morcellator to encourage sales of the product; consequently, Defendants placed its profits above its customers' safety.

70. The Gynecare Morcellator was defective and unreasonably dangerous when it left the possession of Defendants in that it contained warnings insufficient to alert Plaintiffs to the dangerous risks and reactions associated with it. Even though Defendants knew or should have known of the risks and reactions associated with Gynecare Morcellator, they still failed to provide warnings that accurately reflected the signs, symptoms, incident, scope, or severity of the risks associated with the product.

71. Plaintiff used Gynecare Morcellator as intended and as indicated by the package labeling and instructions or in a reasonably foreseeable manner.

72. Plaintiff could not have discovered any defect in Gynecare Morcellator through the exercise of reasonable care.

73. Defendants, as manufacturers of pharmaceutical drugs, are held to the level of knowledge of an expert in the field and, further, Defendants had knowledge of the dangerous risks and side effects of the Gynecare Morcellator.

74. Plaintiff did not have the same knowledge as Defendants and no adequate warning was communicated to her physician(s).

75. Defendants had a continuing duty to warn consumers, including Plaintiff, her physicians, and the medical community of the dangers associated with the Gynecare Morcellator, and by

negligently and/or wantonly failing to adequately warn of the dangers associated with its use, Defendants breached their duty.

76. Although Defendants knew, or were reckless in not knowing, of the defective nature of the Gynecare Morcellator, they continued to design, manufacture, market, and sell the product without providing adequate warnings and instructions concerning the use of the morcellator so as to maximize sales and profits at the expense of the public health and safety, in knowing, conscious, and deliberate disregard of the foreseeable harm caused by the Gynecare Morcellator.

77. As a direct and proximate result of one or more of these wrongful acts or omissions of the Defendants, Plaintiff suffered profound injuries, required and continues to require medical treatment, and incurred and continues to incur medical and hospital expenses.

WHEREFORE, Plaintiffs demand judgment against each Defendants for compensatory, statutory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems appropriate pursuant to the common law and statutory law.

AS A FIFTH CAUSE OF ACTION:
STRICT LIABILITY

78. Plaintiffs incorporate by reference all other paragraphs of this complaint as if fully set forth herein, and further allege as follows:

79. Defendants are manufacturers and/or suppliers of Gynecare Morcellator and are strictly liable to Plaintiffs for designing, creating, manufacturing, distributing, selling and placing Gynecare Morcellator into the stream of commerce.

80. The Gynecare Morcellator manufactured and/or supplied by Defendants was defective in design or formulation in that, when it left the hands of the manufacturer and/or suppliers, it was unreasonably dangerous, it was more dangerous than an ordinary consumer would expect and more dangerous than other surgical alternatives.

81. The Gynecare Morcellator was defective in design or formulation in that, when it left the hands of the manufacturer and/or suppliers, the foreseeable risks exceeded the benefits associated with the product design.

82. The Gynecare Morcellator was also defective due to inadequate warnings or instructions because the manufacturer knew or should have known that Gynecare Morcellator created, among other things, a risk of dissemination of parasitic tissue beyond the uterus and/or leiomyomatosis and requirement of subsequent preventative treatment, and the Defendants failed to adequately warn of these risks.

83. The Gynecare Morcellator was defective due to inadequate pre-marketing testing.

84. Defendants failed to provide adequate initial warnings and post-marketing warnings or instructions after the manufacturer and/or supplier knew or should have known of the extreme risks associated with the Gynecare Morcellator and continues to promote and sell the Gynecare Morcellator in the absence of those adequate warnings.

85. As a direct and proximate result of one or more of these wrongful acts or omissions of the Defendants, Plaintiff suffered profound injuries, required and continues to require medical treatment, and incurred and continues to incur medical and hospital expenses.

WHEREFORE, Plaintiffs demand judgment against each Defendant for compensatory, statutory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems appropriate pursuant to the common law and statutory law.

AS A SIXTH CAUSE OF ACTION:
BREACH OF IMPLIED WARRANTY

86. Plaintiffs incorporate by reference all other paragraphs of this complaint as if fully set forth herein, and further allege as follows:

87. Defendants marketed, manufactured, promoted, distributed and/or sold Gynecare Morcellator as safe for use by the public at large, including Plaintiff, who underwent a procedure involving the Gynecare Morcellator. Defendants knew the use for which their product was intended and impliedly warranted the product to be of merchantable quality, safe and fit for use.

88. Plaintiff reasonably relied on the skill and judgment of the Defendants, and as such their implied warranty, in undergoing a procedure involving the Gynecare Morcellator.

89. Contrary to same, Gynecare Morcellator was not of merchantable quality or safe or fit for its intended use, because it is unreasonably dangerous and unfit for the ordinary purpose for which it was used.

90. As a direct and proximate result of one or more of these wrongful acts or omissions of the Defendants, Plaintiff suffered profound injuries, required and continues to require medical treatment, and incurred and continues to incur medical and hospital expenses.

WHEREFORE, Plaintiffs demand judgment against each Defendants for compensatory, statutory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems appropriate pursuant to the common law and statutory law.

AS A SEVENTH CAUSE OF ACTION:
PERSONAL INJURY – JOAN L. SCHWARTZ

91. Plaintiffs incorporate by reference all other paragraphs of this complaint as if fully set forth, and further allege as follows:

92. Plaintiff underwent a hysterectomy wherein a Gynecare Morcellex Morcellator manufactured by the Defendants was utilized on April 11, 2008.

93. The Gynecare Morcellator inserted into Plaintiff was in substantially the same form when inserted as it was when placed into the stream of commerce by the Defendants.

94. In 2012, Plaintiff was found to have endometriosis, a spreading of uterine cells into the abdomen, and leiomyomatosis, an overgrowth of fibroid masses, both of which are painful conditions and are directly attributed to the surgery performed on her using the Gynecare Morcellex Morcellator.

95. Plaintiff has had to undergo major exploratory surgery, right salpingo-oophorectomy, radical resection of peritoneal masses and a partial sigmoid resection and reanastomosis as a result of her conditions caused by the use of Defendants' morcellator, and will likely have to undergo additional surgeries and treatments in the future.

96. Defendants' conduct, and/or their Gynecare Morcellator product, as set forth in any one, all, or a combination of the bases of liability identified above, substantially contributed to causing Plaintiff's medical problems.

97. Plaintiff was unaware, and did not have the capacity to be aware, of the connection between the Gynecare Morcellator and the potential dissemination of and seeding of endometriosis and fibroid tissue, fibroid tissue, and endometriosis at the time the Gynecare Morcellator was used in her procedure.

98. As a result of her medical problems, Plaintiff Schwartz:

a. Suffered severe pain;

b. Underwent surgical procedures;

c. Received medical treatment, and will require additional medical treatment in the future; and

d. incurred medical expenses and will incur additional medical expenses in the future.

92. As a direct and proximate result of one or more of these wrongful acts or omissions of the Defendants, Plaintiff suffered profound injuries, required and continues to require medical treatment, and incurred and continues to incur medical and hospital expenses.

WHEREFORE, Plaintiffs demand judgment against each Defendants for compensatory, statutory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems appropriate pursuant to the common law and statutory law.

AS A EIGHTH CAUSE OF ACTION:
BREACH OF EXPRESS WARRANTY

93. Plaintiffs incorporate by reference all other paragraphs of this complaint as if fully set forth and further alleges as follows:

94. The aforementioned manufacturing, designing, distributing, marketing, and promoting of Gynecare Morcellator were expressly warranted to be safe by Defendants for Plaintiff and members of the public generally. At the time of the making of these express warranties, Defendants had knowledge of the foreseeable purposes for which Gynecare Morcellator was to be used and Defendants warranted the Gynecare Morcellator to be in all respects safe, effective and proper for such purposes.

95. The Gynecare Morcellator does not conform to these express warranties and representations because Gynecare Morcellator is not safe or effective and may produce serious side effects.

96. As a direct and proximate result of one or more of these wrongful acts or omissions of the Defendants, Plaintiff suffered profound injuries that required medical treatment and incurred medical and hospital expenses.

WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory, statutory and punitive damages, together with interest, costs of suit, attorneys' fees and all such

other relief as the Court deems appropriate pursuant to the common law and statutory law.

AS A NINTH CAUSE OF ACTION:
NEGLIGENT MISREPRESENTATION

97. Plaintiffs incorporate by reference all other paragraphs of this complaint as if fully set forth and further alleges as follows:

98. Defendants, having undertaken the designing, manufacturing, marketing, distribution and/or promotion of Gynecare Morcellator, owed a duty to provide accurate and complete information regarding Gynecare Morcellator.

99. Defendants falsely represented to Plaintiff that Gynecare Morcellator was a safe and effective surgical tool. The representations by Defendants were in fact false, as Gynecare Morcellator is not safe and is dangerous to the health of its users.

100. At the time the aforesaid representations were made, Defendants concealed from Plaintiff and health care providers information about the propensity of Gynecare Morcellator to cause great harm. Defendants negligently misrepresented claims regarding the safety and efficacy of Gynecare Morcellator despite the lack of information regarding same.

101. These misrepresentations were made by Defendants with the intent to induce Plaintiff to undergo a procedure using the Gynecare Morcellator, which caused her injury.

102. At the time of Defendants' misrepresentations and omissions, Plaintiff was ignorant of the falsity of these statements and reasonably believed them to be true.

103. Defendants breached their duties to Plaintiff by providing false, incomplete and/or misleading information regarding their product. Plaintiff reasonably believed Defendants' representations and reasonably relied on the accuracy of those representations when agreeing to treatment with Gynecare Morcellator.

104. As a direct and proximate result of one or more of these wrongful acts or omissions of the Defendants, Plaintiff suffered a profound injury that required medical treatment and incurred medical and hospital expenses.

WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory, statutory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems appropriate pursuant to the common law and statutory law.

AS A TENTH CAUSE OF ACTION:
FRAUDULENT MISREPRESENTATION AND OMISSION

105. Plaintiffs incorporate by reference all other paragraphs of this complaint as if fully set forth, and further allege as follows:

106. Upon information and belief, the Defendants' statements about the Gynecare Morcellator, as they appear in the manual which accompanied the device used for Ms. Schwartz's surgery in 2008, wrongly and falsely convey that the device may be used safely in surgeries of the type performed on Ms. Schwartz without a tissue bag to contain fragmented tissue. The Defendants knew or should have known that (a) the device is unsafe for use without containment of tissue fragments even when cancer is not suspected and detected by standard procedures prior to the morcellation surgery, and (b) in at least 1 in 350 cases, the device will disseminate cancer which is not suspected and detected prior to the surgery.

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

108. Defendants, having undertaken design, formulation, testing, manufacture, marketing, sale, and distribution of devices used for uterine morcellation, including the Gynecare Morcellator, owed a duty to monitor, analyze and report adverse outcomes stemming from the use

of the Gynecare Morcellator.

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

110. Defendants had a duty to provide Plaintiff, her physicians, and other patients and doctors concerned with true and accurate information regarding the devices for uterine morcellation it manufactured, marketed, distributed and sold, including the Gynecare Morcellator. They failed to perform that duty, omitting material information about the instrument's risks.

111. Defendants made representations and failed to disclose material facts with the intent to induce consumers, including Plaintiff, and the medical community to act in reliance by using and having used on her the Gynecare Morcellator. The Plaintiff's doctor, the Plaintiff, and the medical community justifiably relied on Defendants' representations and omissions by using and having used on her the Gynecare Morcellator.

112. Defendants' representations and omissions regarding use of its uterine morcellation device were a direct and proximate cause of the Plaintiffs injuries, specifically the dissemination of parasitic tissue, requiring her to undergo invasive and dangerous subsequent treatment. Wherefore, on this Count, Plaintiff respectfully requests that the Court enter judgment in her favor against Defendants for all damages allowed by law, compensatory and punitive, in the utmost amounts allowed by law, to be decided by a jury, plus interest, costs, and attorneys' fees.

AS AN ELEVENTH CAUSE OF ACTION:
FRAUD BY CONCEALMENT

113. Plaintiffs incorporate by reference all other paragraphs of this complaint as if fully set forth and further alleges as follows:

114. Defendants had a duty and obligation to disclose to Plaintiff that the aforesaid product was dangerous and likely to cause serious health consequences to users when used as manufactured.

115. Defendants intentionally, willfully, and maliciously concealed and/or suppressed the facts set forth above from Plaintiff with the intent to defraud her as herein alleged.

116. Neither Plaintiff nor her physicians were aware of the facts set forth above, and had they been aware of said facts would not have used this device.

117. As a proximate result of the concealment and/or suppression of the facts set forth above, Plaintiff has proximately sustained damage, as set forth herein.

118. As a direct and proximate result of one or more of these wrongful acts or omissions of the Defendants, Plaintiff suffered injuries that required medical treatment and incurred medical and hospital expenses.

WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory, statutory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems appropriate pursuant to the common law and statutory law.

REQUEST FOR PUNITIVE DAMAGES

119. Plaintiffs incorporate by reference all other paragraphs of this complaint as if fully set forth, and further alleges as follows:

120. At all times relevant herein, Defendants:

a. knew that Gynecare Morcellator was dangerous and ineffective;

b. concealed the dangers and health risks from Plaintiff, physicians, pharmacists, other medical providers, the FDA, and the public at large;

c. made misrepresentations to Plaintiff, her physicians, pharmacists, hospitals and medical providers and the public in general as previously stated herein as to the safety and efficacy of the Gynecare Morcellator;

d. with full knowledge of the health risks associated with the Gynecare Morcellator and without adequate warnings of the same, manufactured, marketed, promoted, developed, sold and/or distributed Gynecare Morcellator for routine use.

121. Defendants, by and through officers, directors, managing agents, authorized sales representatives, employees and/or other agents who engaged in malicious, fraudulent and oppressive conduct towards Plaintiff and the public, acted with willful and wanton and/or conscious and reckless disregard for the safety of Plaintiff and the general public.

122. As a direct and proximate result of one or more of these wrongful acts or omissions of the Defendants, Plaintiff suffered profound injuries that required medical treatment and incurred medical and hospital expenses, for which Plaintiff has become liable.

WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory, statutory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems appropriate pursuant to the common law and statutory law.

PRAYER FOR RELIEF

Plaintiffs demand judgment against Defendants for compensatory, statutory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems appropriate pursuant to the common law and statutory law.

JURY DEMAND

Demand is hereby made for trial by jury on all issues raised by these pleadings.

Respectfully submitted this the 4th day of February, 2016.

MOTLEY RICE LLC

/s/ Carmen S. Scott
Carmen S. Scott, Esq., SC Bar # 15354
cscott@motleyrice.com
28 Bridgeside Boulevard
Mt. Pleasant, SC 29464
Phone: 843-216-9000; Fax: 843-216-9440

Attorneys for Plaintiff