UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF WISCONSIN

BABETTE DAVIS, Plaintiff, vs. ETHICON, INC.; ETHICON ENDO-SURGERY, INC.; JOHNSON & JOHNSON SERVICES; JOHNSON & JOHNSON; VENTION MEDICAL, INC. (f/k/a THE MEDTECH GROUP, INC.); VENTION MEDICAL ACQUISITION CO.; VENTION MEDICAL HOLDINGS, INC.; DOES ONE through FIFTY Defendants	Civil Action No.: **COMPLAINT AND DEMAND FOR JURY TRIAL**

Plaintiff BABETTE DAVIS (hereafter "Plaintiff"), alleges the following:

PROCEDURAL AND FACTUAL BACKGROUND

I. INTRODUCTION

1. Plaintiff brings a personal injury action against Defendants who were responsible for designing, researching, developing, testing, manufacturing, packaging, labeling, marketing, promoting, distributing and/or selling Gynecare Laparoscopic Power Morcellators, which are medical devices used during laparoscopic uterine surgery.

2. Plaintiff underwent a surgical procedure with a Gynecare Laparoscopic Power Morcellator, which caused the spread and upstaging[1] of occult (i.e., hidden) cancerous tissue.

II. PARTIES

3. Plaintiff BABETTE DAVIS ("Plaintiff") is over the age of majority, and a resident of the State of Wisconsin, County of Milwaukee.

4. Upon information and belief, Defendant ETHICON, INC. is a corporation organized under the laws of the State of New Jersey, with its principal place of business in West Somerville, New Jersey.

[1] "Upstaging" refers to an increase in the extent or severity of cancer in a given patient, in this case due to the spread, growth and dissemination of cancerous tissue caused by the Laparoscopic Power Morcellator.

5. Upon information and belief, Defendant ETHICON ENDO SURGERY, INC. is an Ohio corporation with its principal place of business in Blue Ash, Ohio.

6. Upon information and belief, Defendant JOHNSON & JOHNSON SERVICES, INC. is a New Jersey corporation with its principal place of business in New Brunswick, New Jersey.

7. Upon information and belief, Defendant JOHNSON & JOHNSON is a New Jersey corporation with its principal place of business in New Brunswick, New Jersey.

8. Upon 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., (hereinafter JOHNSON & JOHNSON, ETHICON, INC., ETHICON ENDO-SURGERY, INC., and JOHNSON & JOHNSON SERVICES are collectively referred to as "JOHNSON & JOHNSON").

9. Upon information and belief, 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 in South Plainfield, New Jersey.

10. Upon information and belief, 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 in Denver, Colorado.

11. Upon 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.).

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

13. Upon information and belief, VENTION MEDICAL HOLDINGS, INC., VENTION MEDICAL ACQUISITION CO., and VENTION MEDICAL, INC. (F/K/A THE

MEDTECH GROUP, INC.) were the agents, representatives, joint venturers, alter egos, co-conspirators, consultants, predecessors, successors, servants or employees of each other.

14. In doing the acts alleged herein, 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 VENTION MEDICAL HOLDINGS, INC., VENTION MEDICAL ACQUISITION CO., and VENTION MEDICAL, INC. (F/K/A THE MEDTECH GROUP INC.) are collectively referred to as "VENTION MEDICAL").

15. Upon 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.

16. 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.

17. The true names or capacities, whether individual, corporate, associate or otherwise, of Defendant DOES ONE through FIFTY inclusive are unknown to Plaintiff at this time. Plaintiff alleges that each said Defendants designated as a DOE is, in some manner, legally responsible for the causes of action herein. Plaintiff will amend this Complaint to show the identity of each fictitiously named Defendant when they have been ascertained. Hereinafter, "Defendants" or "All Defendants" includes all herein named Defendants as well as Defendant DOES ONE through FIFTY, inclusive.

18. Upon 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, the State of Wisconsin, and derived substantial revenue from interstate commerce.

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

20. Upon information and belief, at all relevant times, Defendants committed tortious acts within the State of Wisconsin causing injury within the State of Wisconsin out of which these causes of action arise.

III. VENUE AND JURISDICTION

21. The Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1332(a) because complete diversity exists between Plaintiff and Defendants. Plaintiff is a citizen of the State of Wisconsin, which is different from the states where the Defendants are incorporated and have their principal places of business. In addition, the amount in controversy for the Plaintiff exceeds $75,000, exclusive of interest and costs.

22. 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. Plaintiff's Surgery and the Resultant Spread the Resultant Spread of Life Threatening Cancerous Tissue

23. On November 25, 2008, Plaintiff BABETTE DAVIS underwent a laparoscopic hysterectomy at Aurora Sinai Medical Center in Milwaukee, Wisconsin for the removal of Plaintiff's uterus, at which time her surgeon, Dr. Danish Siddiqui, used Defendants' Gynecare Laparoscopic Power Morcellator for uterine tissue morcellation.

24. Prior to undergoing surgery, Plaintiff was not warned of the high-risk that use of a Laparoscopic Power Morcellator could cause the spread and recurrence of life threatening cancerous tissue.

25. During the surgery, a biopsy of the tissue was taken and the results of the biopsy revealed leiomyosarcoma.

26. In December 2008, Plaintiff was seen by Dr. Scott Kamelle, a Gynecologic Oncologist, who confirmed Plaintiff's leiomyosarcoma diagnosis and recommended chemotherapy. Plaintiff underwent multiple cycles of chemotherapy treatment for over two years.

27. In April 2011, Plaintiff had a CT scan which showed three large masses within her abdomen and pelvis, and her doctor noted this was consistent with metastatic disease. Plaintiff had to undergo additional cycles of chemotherapy.

28. Plaintiff continues to suffer from abdominal pain, weakness, fatigue and takes oral chemotherapy to treat the life-threatening cancer that use of Defendant's Gynecare Laparoscopic Power Morcellator caused to disseminate in her body.

29. Had the Laparoscopic Power Morcellator used on Plaintiff not disseminated her leiomyosarcoma, Plaintiff would not have suffered and continued to suffer these symptoms.

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

B. Background on Laparoscopic Power Morcellators

31. In the United States, it is estimated that 650,000 women a year will undergo a surgical myomectomy or hysterectomy for the management of symptomatic uterine fibroids.

32. In conventional non-Power Morcellator hysterectomies, the women's entire uterus is removed essentially intact.

33. In the last few decades, laparoscopic procedures with electric Laparoscopic Power Morcellator devices to remove uterine fibroids and other tissue, have increasingly replaced traditional open abdominal surgical hysterectomies, myomectomies, and laparotomies.

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

35. 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.

36. 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.

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

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

39. 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.

40. As a result, Laparoscopic Power Morcellator can spread occult cancerous tissue and require additional surgical procedures, significantly worsening a women's prognosis.

41. Defendants were responsible for designing, researching, developing, testing, manufacturing, packaging, labeling, marketing, promoting, distributing and/or selling Laparoscopic Power Morcellators.

C. <u>The Laparoscopic Power Morcellator Used in Plaintiff's Surgery Was Defective in Design and Created an Avoidable Risk of Harm to Plaintiff.</u>

42. Before Plaintiff underwent surgery in 2008, Defendants knew or should have known that their Laparoscopic Power Morcellators could cause occult malignant tissue fragments to be disseminated and implanted in the body, which, in turn, requires additional surgical procedures.

43. Although evidence was available to Defendants for years before Plaintiff's surgery, Defendants failed to respond to multiple published studies and reports describing the risk of disseminating and spreading life-threatening cancerous tissue with morcellator use, and

failed to design their Laparoscopic Power Morcellators, including the Gynecare Tissue Morcellator, in a manner to reduce this risk.

44. Upon information and belief, Defendants, as is industry practice, monitor daily the medical and lay media for articles on issues concerning their products, Laparoscopic Power Morcellators.

45. Upon information and belief, many, if not all, of the literature cited below was collected by and known to the Defendants (or should have been known to the Defendants) at or before the time the literature was published.

46. ***First***, Defendants knew or should have known that their Laparoscopic Power Morcellators could cause occult malignant tissue fragments to be disseminated and implanted in the body.

a. Indeed, on August 6, 1991, a patent for a Surgical Tissue Bag and Method for Percutaneously Debulking Tissue was issued that describes the potential for Laparoscopic Power Morcellators to disseminate and implant malignant tissue fragments in the body.

b. The patent for the surgical tissue bag stated:

> Another problem associated with the debulking, removal or morcellation of large tissue volume is the concern for containing malignant or pathogenic tissue. ***The morbidity of patients significantly increases when malignant cells of such large volume tissue are permitted to come in contact with surrounding healthy tissue***. A malignancy would typically indicate a more invasive procedure in which the cavity is opened and the affected tissue is removed. These invasive open cavity procedures increase the recovery period of the patient and subject the patient to additional discomfort and complications.
> As a result, ***the debulking of large malignant tissue volumes percutaneously through an access sheath presents significant morbidity risks to the patient***. (emphasis added).

c. The patent Summary of the invention further stated that "containment of the tissue within the bag also prevents the spread of malignant cells to healthy tissue in the body cavity."

d. The Surgical Tissue Bag patent was publically available and was available to the Defendants, and/or known to Defendants, before they first sought approval of their Laparoscopic Power Morcellators.

e. Also, prominent medical journals reporting on Laparoscopic Power Morcellators and the risk of spreading undetected cancer also began to accumulate in the 1990s, and continued thereafter.

f. In 1997, Schneider published a case report in a medical journal, known to the Defendants as THE AMERICAN JOURNAL OF OBSTETRICS AND GYNECOLOGY, titled "Recurrence of unclassifiable uterine cancer after modified laparoscopic hysterectomy with morcellation," which reported a patient who underwent a laparoscopic supracervical hysterectomy by manual morcellation. Schneider, Recurrence of unclassifiable uterine cancer after modified laparoscopic hysterectomy with morcellation, J. AM. OBSTET. GYNECOL., 177(1):478-9 (1997).

g. The following year the patient died due to the rapid progression of uterine adenocarcinoma that had been undetected prior to surgery. *Id*. at 478.

h. Schneider cautioned that evaluation for malignancy prior to surgery "grows even more important and should be mandatory when uteri are increasingly morcellated by introduction of laparoscopic techniques." *Id.* at 479.

i. In 1998, Hutchins and Reinoehl published a case report in THE JOURNAL OF THE AMERICAN ASSOCIATION OF GYNECOLOGIC LAPAROSCOPISTS, which was known to the Defendants, in which the authors explained that "[b]ecause of the large quantity of tissue of such a uterus, it would be anticipated that numerous fragments would be generated during morcellation." Hutchins and Reinoehl, Retained Myoma

after Laparoscopic Supracervical Hysterectomy with Morcellation, J. AM. ASSOC. GYNECOL. LAPAROSC., 5(3):293-295 (1998).

j. The authors cautioned that the morcellated fragments could become concealed in surrounding organs making it difficult for the surgeon to identify and remove all tissue fragments. *Id*. at 294.

k. In 2005, LaCoursiere et al. published a case report in THE JOURNAL OF MINIMALLY INVASIVE GYNECOLOGY which reported that "[t]he use of a power morcellator may produce smaller fragments than other techniques." LaCoursiere et al., Retained fragments after total laparoscopic hysterectomy, J. MINIM. INVAS. GYNCOL., 12:67-69, 68 (2005).

l. According to the authors, "implantation, rather than resorption of residual fragments of cervix and myometrium can occur," a problem which they reported "ha[d] implications for possible benign and malignant sequelae." *Id*.

m. Based on this evidence, Defendants were on notice that their Laparoscopic Power Morcellators exposed patients to a significant risk of disseminating and spreading parasitic uterine myomas.

47. ***Second***, Defendants knew or should have known that, for women undergoing laparoscopic hysterectomies or myomectomies for presumed fibroids, the risk of having a hidden deadly sarcoma was much higher than 1 in 10,000.

a. In 1990, Leibsohn et al. published a study titled "Leiomyosarcoma in a series of hysterectomies performed for presumed uterine leiomyomas" in the AMERICAN JOURNAL OF OBSTETRICS & GYNECOLOGY in which the authors found that "...women with signs and symptoms of [benign] uterine leiomyomas [fibroids] that warrant hysterectomy have about a 1 in 140 chance of having a uterine leiomyosarcoma." Leibsohn et

al., Leiomyosarcoma in a series of hysterectomies performed for presumed uterine leiomyomas, Am. J. Obstet. Gynecol. 162:968-76, 972 (1990) ("Leibsohn et al. paper") (emphasis added).

b. In 1999, Takamizawa et al. published another study titled "Risk of Complications and Uterine Malignancies in Women Undergoing Hysterectomy for Presumed Benign Leiomyomas" in GYNECOLOGIC AND OBSTETRIC INVESTIGATION, which found that 2/923 women who underwent hysterectomies for presumed benign fibroids had undiagnosable hidden sarcomas before their hysterectomies. Takamizawa et al., Risk of Complications and Uterine Malignancies in Women Undergoing Hysterectomy for Presumed Benign Leiomyomas, GYNECOL. OBSTET. INVEST., 48:193-196, 196 (1999).

c. Takamizawa et al. reported that their study results were consistent with the findings of other studies which suggested that 2–5 patients per 1,000 who undergo surgery for presumed fibroids have uterine sarcomas. *Id*.

d. This evidence was available to Defendants.

e. However, upon information and belief, in seeking for approval for their Laparoscopic Power Morcellators decades before Plaintiff underwent surgery, and, later, in promoting their devices to the medical community, Plaintiff and Plaintiff's surgeon, Defendants ignored this data and touted a much lower 1 in 10,000 risk.

48. ***Third***, Defendants knew or should have known that women could not be adequately screened for malignancy prior to undergoing Laparoscopic Power Morcellation surgery because certain types of cancers, including sarcomas, can mimic the radiographic appearance of benign uterine fibroids.

a. In the 1990 Leibsohn et al. study, discussed *supra*, the authors described the difficulties in diagnosing leiomyosarcoma (a particularly aggressive

form of cancer) preoperatively, noting that "abdominal ultrasonography of the pelvis and cervical cytology are not helpful preoperative tests for the diagnosis [of] leiomyosarcoma of the uterus." See Leibsohn et al. paper, at 192.

b. Additional evidence became available to Defendants in 2001, when Stewart published an article in THE LANCET, which explained that malignant leiomyosarcoma and benign fibroids may share histological features; thereby, making it more difficult for clinicians to identify the malignant potential of smooth muscle uterine tumors. Stewart, Uterine Fibroids, THE LANCET, 357:293-98 (2001).

c. The difficult in diagnosing uterine sarcoma preoperatively was not limited to leiomyosarcoma.

d. Upon information and belief, in 2006, Robert Lamparter, M.D., a pathologist at Evangelical Community Hospital in Lewisburg, Georgia, wrote to the former medical director of Ethicon Women's Health and Urology, a JOHNSON AND JOHNSON subsidiary, imploring the company to "reconsider the risk [of power morcellators] to the patient."

See http://www.bizjournals.com/pittsburgh/news/2014/05/30/j-j-alerted-in-2006-to-devices-surgical-risks.html (last checked 1/20/2016).

e. Dr. Lamparter advised Ethicon that, "[v]irtually all uteruses have some sort of pre-op screening, whether it be an endometrial biopsy or an ultrasound, so whatever screening is being done misses a certain number of malignancies." *Id.*

f. **However, "[w]hen the operative procedure is a standard hysterectomy, no damage is done. If a morcellation is done, the patient's survival is jeopardized."** *Id.*

g. In 2008, Bansal et al. published a study in GYNECOLOGIC ONCOLOGY, in which the authors found that the predictive value of endometrial biopsy or curettage for diagnosing uterine sarcoma was very poor and, thus, "novel diagnostic techniques are needed to accurately identify uterine sarcomas preoperatively." Bansal et al., The utility of preoperative endometrial sampling for the detection of uterine sarcoma, GNECOL. ONCOL., 110:43-48, 47 (2008).

49. ***Fourth***, Defendants knew or should have known that women undergoing surgery with Laparoscopic Power Morcellators suffer worse long-term medical outcomes than women undergoing other available treatment options because of the cancer risks associated with the use of their devices.

a. For example, in 2002, Goto et al. published a study in the INTERNATIONAL JOURNAL OF GYNECOLOGIC CANCER, which reported:

> Leiomyosarcoma of the uterus is one of the most difficult neoplasms to cure in gynecologic oncology. Its malignant behaviors such as rapid growth and high rate of metastasis are notorious.
>
> ***The 5-year survival in patients with advanced stages (stage III or higher) is less than 10%***, although leiomyosarcoma resembles leiomyoma in clinical features. Until now LMS was diagnosed only in advanced stages or accidentally at total abdominal hysterectomy.
>
> [...]
>
> Therefore it seems that the effective treatment of LMS is surgical removal of the tumor in the earlier stages. The problem regarding treatment of LMS is the difficult preoperative differential diagnosis of LMS in the early stages from leiomyoma, which is the most common tumor of the uterus.

Goto, et al., Usefulness of Gd-DTPA contrast-enhanced dynamic MRI and serum determination of LDH and its isozymes in the differential diagnosis of leiomyosarcoma from degenerated leiomyoma of the uterus, INT. J. GYNECOL. CANCER, 12:354-361, 358 (2002) (emphasis added).

b. Likewise, in 2003, Morice et al. published an article in the EUROPEAN JOURNAL OF GYNECOLOGIC ONCOLOGY, in which they found a substantial increase in pelvic recurrence of uterine sarcoma at three (3) months in 34 patients with uterine sarcoma who had morcellation during their initial surgery compared with 89 patients without morcellation. Morice et al., Prognostic value of initial surgical procedure for patients with uterine sarcoma: analysis of 123 patients, EUR. J. GYNAECOL. ONCOL., 24(3-4);237-40, 238-39 (2003).

c. The authors concluded that, when the diagnosis of uterine sarcoma is known preoperatively, the optimal treatment for uterine sarcoma is a "monobloc" total abdominal hysterectomy and bilateral salpingo-oophorectomy without morcellation. *Id*. at 239.

d. In 2008, Einstein et al. presented a prospective study in the INTERNATIONAL JOURNAL OF GYNECOLOGIC CANCER involving all patients who had undergone any type of hysterectomy for presumed benign disease and were, subsequently, referred to Memorial Sloan-Kettering between January, 2000 and March, 2006 with diagnosed malignancy based on the final surgical pathology. Einstein et al., Management of uterine malignancy found incidentally after supracervical hysterectomy or uterine morcellation for presumed benign disease, INT. J. GYNECOL. CANCER, 18: 1065-70, 1066 (2008).

e. According to their review, an astounding 40% percent of patients who underwent morcellation were found to have upstaged cancer compared with only 8% who had a supracervical hysterectomy. *Id*. at 1069.

f. According to the authors, *"**[this] data support this trend toward worse outcomes in patients who had morcellation procedures**." Id.*

50. ***Fifth***, Defendants knew or should have known that when malignant tissue undergoes Laparoscopic Power Morcellation, the resultant tissue specimens can delay diagnosis because their condition can prevent the pathologist from properly identifying and staging cancer, which can further worsen a patient's prognosis and treatment outcomes.

a. For example, in 2005, Rekha et al. discuss in their paper published in the AUSTRALIAN AND NEW ZEALAND JOURNAL OF OBSTETRICS AND GYNAECOLOGY, "[o]ne of the disadvantages of tissue morcellation is loss of the gross appearance of the specimen and the possibility of missing the most suspicious area for the microscopic evaluation." Rekha et al., Unexpected complications of uterine myoma morcellation, Aust. N.Z. J. Obstet. Gynecol., 45: 248-49, 248 (2005).

b. Rekha et al.'s case report involved a 40-year-old woman who underwent total laparoscopic hysterectomy for presumed benign uterine fibroids died several months after her initial surgery from dissemination of occult leiomyosarcoma. *Id.*

c. According to the authors, the patient's "malignant component was missed at the time of initial histological evaluation due to evaluation of limited tissue." *Id.*

51. As set forth herein, over the years numerous journal articles and published studies have examined Laparoscopic Power Morcellators' potential to spread cancerous tissue.

52. This evidence should have placed Defendants on notice that their Laparoscopic Power Morcellators were associated with and/or could cause the dissemination and spreading of cancerous tissue.

53. Yet, as designed and marketed, the Laparoscopic Power Morcellator used on Plaintiff during her 2008 surgery was unsafe for its intended purpose and defective in design in that it subjected the Plaintiff to the avoidable risks of harm, including, *inter alia*: (a) dissemination and implantation of cancerous tissue; (b) increasing Plaintiff's probability to

develop a recurrence and/or spread of cancerous tissue; and (c) decreasing the likelihood of Plaintiff's survival.

54. Knowing their Laparoscopic Power Morcellators had the potential to spread cancerous tissue, Defendants should have designed, marketed and sold their Laparoscopic Power Morcellators, including the Gynecare Tissue Morcellator, with a containment bag or system specifically designed to minimize or prevent the risk of disseminating tissue.

55. Upon information and belief, said containment bag or system should have been designed to accommodate and withstand the morcellator blade and the large tissues that are often encountered in gynecologic surgery.

56. Defendants' failure to design, develop, manufacture, market and sell the Laparoscopic Power Morcellator used in Plaintiff's surgery with a containment bag or system to minimize or prevent the risk of disseminating tissue was negligent and fell below the standard of care expected of a reasonable medical device manufacturer.

57. Additionally, at the time of Plaintiff's surgery, numerous other surgery options were available, which had more established safety profiles and considerably lower risk profiles than Laparoscopic Power Morcellators including, but not limited to, total abdominal hysterectomies ("TAH"), and minimally-invasive hysterectomies, including those using manual morcellation, and embolization and ablation treatments.

58. Accordingly, for this and the other reasons set forth here and below, the Laparoscopic Power Morcellator used in Plaintiff's surgery was defective in design.

59. As set forth here and below, the defective design of the Laparoscopic Power Morcellator used on Plaintiff during surgery, was the proximate cause of Plaintiff's injuries.

D. <u>The Laparoscopic Power Morcellator Used in Plaintiff's Surgery Contained an Inadequate Warning.</u>

60. The Defendants failed to provide a reasonable sufficient or adequate warning about the true risks of disseminating and spreading parasitic uterine myomas from the use of their Laparoscopic Power Morcellators, including the Gynecare Tissue Morcellator.

61. In 1995, the first Power Morcellator reached the market with an indication for gynecologic laparoscopic procedures based on literature involving the device's use in merely 11 patients.

62. Power Morcellators are Class II medical devices.

63. Class II devices are regulated by the Food and Drug Administration Center for Medical Devices and Radiological Health.

64. Such devices are required to undergo a "510(k)" process prior to being distributed, which simply requires the manufacturer to notify the Food and Drug Administration ("FDA") under section 510(k) of the Medical Device Amendments to the Food, Drug, and Cosmetics Act of 1938 ("MDA"), of its intent to market a device at least ninety (90) days prior to the device's introduction on the market, and to explain the device's "substantial equivalence" to a pre-MDA predicate device.

65. Each time the Defendants sought to market a new Laparoscopic Power Morcellator device they did so without submitting premarket approval-testing (required under FDA regulations for Class III devices) and merely based on the Defendants' assertions that the subject device was "substantially similar" to another legally marketed device.

66. Based on the Defendants' assertions that their device was "substantially similar" to a marketed device, the FDA cleared the device for sale in the United States.

67. FDA approval or clearance actions do not guarantee that a product will be found to be compliant or safe and effective for its intended uses for all times and for all purposes.

68. After the FDA cleared the Laparoscopic Power Morcellator used in Plaintiff's surgery for sale in the U.S., the Defendants were under an obligation to ensure the quality and safety of their marketed product.

69. Defendants have an ongoing duty of medical device surveillance and vigilance and were under a continuing duty to inform surgeons, regulatory agencies, and the public of new safety and efficacy information they learn, or should have learned, about their marketed devices once that information becomes available to Defendants.

70. According to the FDA guidance to medical device manufactures, an appropriate Warning should be included if there is reasonable evidence of an association of a serious hazard with the use of the device. A causal relationship need not have been proved. See Device Labeling Guidance #G91-1 - blue book memo, March 8, 1991.

71. However, Defendants ignored mounting evidence about the risks, and exposed Plaintiff to an avoidable risk of harm by failing to disclose:

a. The difficulty of effectively diagnosing cancer prior to (or during) surgery with available diagnostic tools;

b. The actual prevalence of undiagnosed uterine sarcomas in women undergoing morcellation;

c. The actual rates at which Laparoscopic Power Morcellators disseminate and spread cancerous tissue;

d. Laparoscopic Power Morcellators are associated with worse long-term medical outcomes than other treatments because of the risk because of the risk of cancerous tissue being spread and implanted by the use of the device; and

e. If cancer is discovered after morcellation, staging and pathological diagnosis could be impeded, thus yielding worse prognosis and outcomes for the patient, including Plaintiff.

72. Defendants' also failed to adequately warn of the risks associated with their Laparoscopic Power Morcellators including, but not limited to:

a. The failure to adequately warn because any Warnings given were not commensurate with the risks involved;

b. The failure to adequately warn because the Warnings contained no information about the risk of disseminating and spreading cancerous tissue;

c. The failure to timely include a Black Box Warning regarding the risks of disseminating and spreading cancerous tissue; and

d. The failure to timely include a Contraindication regarding the risks of disseminating and spreading cancerous tissue.

73. Defendants' failure to timely or appropriately warn of the foregoing risks prevented Plaintiff and Plaintiff's surgeon from fully or correctly evaluating the risks and benefits of undergoing surgery with the Defendants' Laparoscopic Power Morcellators.

74. Because of Defendants failure to adequately warn Plaintiff and Plaintiff's surgeons of the risks associated with morcellator use and the device's propensity to disseminate and spread cancerous tissue, Plaintiff was caused severe and permanent injuries.

F. FDA Action and the "World Wide Withdrawal" of Johnson & Johnson Laparoscopic Power Morcellators in 2014

75. 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 (emphasis added).

76. The FDA further warned the medical community that:

> Importantly, based on an FDA analysis of currently available data, it is estimated that ***1 in 350 women undergoing hysterectomy or myomectomy for the treatment of fibroids is found to have an unsuspected uterine sarcoma***, a type of uterine cancer that includes leiomyosarcoma. If laparoscopic power morcellation is performed in women with unsuspected uterine sarcoma, there is a risk that the procedure will spread the cancerous tissue within the abdomen and pelvis, significantly worsening the patient's likelihood of long-term survival.

Id. (emphasis added).

77. Significantly, in the FDA's "Quantitative Assessment of the Prevalence of Unsuspected Uterine Sarcoma in Women Undergoing Treatment of Uterine Fibroids," the FDA

listed the studies it relied on in reaching its conclusions on the prevalence of unsuspected uterine sarcoma and uterine leiomyosarcoma.

78. The studies cited by the FDA were published in prominent medical journals, ranging in publication dates from 1980 to 2014. Significantly, sixteen (16) of the eighteen (18) studies cited by the FDA in Table 1, were available to Defendants prior to the date on which Plaintiff underwent her surgery.

79. Shortly after the FDA released its prevalence data, the JOURNAL OF THE AMERICAN MEDICAL ASSOCIATION published the results of Wright et al.'s findings on how many women might have undetected cancer that a Laparoscopic Power Morcellator could unintentionally spread.

80. Wright et al. examined the Perspective Insurance Database, which collects data from over 500 hospitals, to identify women who had a minimally invasive hysterectomy from 2006-2012 with the use of a power morcellator being captured by charge codes.

81. Of the 232,882 women who had minimally invasive surgery during the study period, power morcellation was used in 36,470 surgeries (15.7%).

82. Of these, 99 women were identified as having uterine cancer, for a prevalence of 27/10,000 (95% CI, 22-32/10,000), a prevalence that was positively correlated with patient age, and translates into a 1 in 368 risk of occult malignancy, in keeping with the FDA's Quantitative Assessment, which found a 1 in 352 risk of unsuspected uterine sarcoma.

83. In July 2014, FDA convened an Advisory Committee ("AdCom") meeting of the Obstetrics and Gynecological Medical Device Advisory Committee on Laparoscopic Power Morcellators to discuss, among other topics, "whether a 'boxed warning' related to the risk of cancer spread should be required for laparoscopic power morcellators." *Id*.

84. In preparation for the AdCom meeting, the FDA prepared an Executive Summary, which detailed the results of the FDA's safety review and stated:

a. The risk of having an unsuspected sarcoma in the population of women undergoing hysterectomy or myomectomy for presumed fibroids may be

as high as approximately 1 in 350 for all types of uterine sarcomas, and 1 in 500 for LMS [leiomyosarcoma] specifically.

b. Peritoneal dissemination and/or cancer upstaging (to FIGO Stage III or IV) following morcellation of an unsuspected sarcoma may occur in approximately 25-65% of cases.

c. Patients with unsuspected uterine sarcoma who undergo morcellation may be at significantly higher risk for local (pelvic/abdominal) and overall cancer recurrence compared to those who do not undergo morcellation.

d. Patients with unsuspected sarcoma who undergo morcellation may have poorer disease-free survival and overall survival compared to patients who do not receive morcellation.

See Food and Drug Administration Executive Summary, prepared for the July 10-11, 2014 meeting of the Obstetrics and Gynecology Devices Advisory Committee, *Laparoscopic Power Morcellation during Uterine Surgery for Fibroids* ("FDA Executive Summary"), p. 23.

85. On July 10 and 11, 2014, FDA's Obstetrics and Gynecology Devices Panel of the Medical Devices Advisory Committee convened the AdCom meeting on Laparoscopic Power Morcellators. The two-day meeting consisted of presentations from FDA scientists, FDA invited speakers, Laparoscopic Power Morcellator manufacturers, and members of the public.

86. Based on the data and literature reviewed, the panel made a number of recommendations on Laparoscopic Power Morcellation labeling, including:

a. Laparoscopic Power Morcellators should not be used in patients with known or suspected malignancy. See FDA Brief Summary of the Obstetrics and Gynecology Devices Panel of the Medical Devices Advisory Committee Meeting – July 10-11, 2014 ("FDA AdCom Summary Panel Findings") p. 3.

b. A black boxed warning related to the risk of disseminating unsuspected malignancy during surgeries for presumed benign fibroids would be useful *but not enough* to address the issue alone. *Id*. (emphasis added).

c. The panel also expressed interest in exploring other ways to ensure that patients have the appropriate information related to the risk, including a mandatory patient consent form to be signed by the patient and physician. *Id.*

87. The AdCom panel also found that the patient populations for which the risks of Laparoscopic Power Morcellation may outweigh the benefits were quite limited, noting that several panel members identified peri- or post-menopausal women with symptomatic uterine fibroids. *Id*. at 2-3.

88. Facing mounting negative publicity about its devices spreading cancer, on April 30, 2014, the JOHNSON & JOHNSON Defendants suspended worldwide sale of their Laparoscopic Power Morcellators.

89. In a "Dear Healthcare Provider" letter, JOHNSON & JOHNSON explained:

> Based on this Safety Communication, in order to align with the FDA's recommendation and Ethicon's internal investigations, Ethicon has decided to suspend global commercialization (sales, distribution, and promotion) of its Morcellation Devices until the role of morcellation for patients with symptomatic fibroid disease is further redefined by FDA and the medical community.

90. In that same letter, the JOHNSON & JOHNSON Defendants emphasized that the decision to suspend global commercialization was "not a product removal." *Id*.

91. On July 30, 2014, the JOHNSON & JOHNSON Defendants issued an urgent worldwide withdrawal of the Ethicon Morcellators.

92. The JOHNSON & JOHNSON Defendants continued to defend their Laparoscopic Power Morcellator devices, stating that "Ethicon Morcellation Devices perform as intended and there are patients who can benefit from procedures using laparoscopic power morcellators, but

the risk-benefit assessment associated with the use of these devices in hysterectomy and myomectomy procedures for removing fibroids remains uncertain."

93. On November 24, 2014, the FDA issued and updated FDA Safety Communication regarding Laparoscopic Uterine Power Morcellation in Hysterectomy and Myomectomy.

94. According to the Safety Communication, the FDA was issuing an Immediately In Effect (IIE) guidance that asked manufacturers of Laparoscopic Power Morcellators 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, and recommends doctors share this information with their patients.

95. The boxed warning informs health care providers and patients that:

> 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.

96. The two contraindications advise of the following:

> Laparoscopic power morcellators are contraindicated (should not be used) for removal of uterine tissue containing suspected fibroids in patients who are: peri- or post-menopausal, or candidates for *en bloc* tissue removal (removing tissue intact) through the vagina or minilaparotomy incision. (These groups of women represent the majority of women with fibroids who undergo hysterectomy and myomectomy.)
>
> Laparoscopic power morcellators are contraindicated (should not be used) in gynecologic surgery in which the tissue to be morcellated is known or suspected to be cancerous.

97. In May of 2015, it was reported by the Wall Street Journal that the Federal Bureau of Investigation began to investigate whether the Defendants violated federal law by failing to report adverse events to the FDA relating to Laparoscopic Tissue Morcellators.

DISCOVERY RULE & FRAUDULENT CONCEALMENT

98. The discovery rule should be applied to toll the running of the statute of limitations until Plaintiff knew, or through the exercise of reasonable care and diligence should

have known of the existence of Plaintiff's claims against the Defendants. The nature of Plaintiff's injuries and damages and their relationship to Defendants' Laparoscopic Power Morcellators was not discovered, and through reasonable care and due diligence could not have been discovered, by Plaintiff, until a time less than three years before the filing of this Complaint. Therefore, under appropriate application of the discovery rule, Plaintiff's suit was filed well within the applicable statutory limitations period.

99. Defendants are estopped from asserting a statute of limitations defense because Defendants fraudulently concealed from Plaintiff, the nature of Plaintiff's injury, and the connection between Plaintiff's injury and all Defendants' tortious conduct.

100. Defendants, through their affirmative misrepresentations and omissions, actively concealed from Plaintiff and Plaintiff's physicians the true risks associated with Defendants' Laparoscopic Power Morcellators.

101. Defendants were under a duty to disclose the true character, quality and nature of the risks associated with use of a their Morcellators in laparoscopic uterine surgeries because this was a non-public information over which Defendants had (and continue to have exclusive control) and because Defendants knew that this information was not available to Plaintiff, Plaintiff's medical providers and/or to Plaintiff's health facilities. In addition, Defendants are estopped from relying on any statute of limitation because of their intentional concealment of these facts.

102. Plaintiff had no knowledge that Defendants were engaged in the wrongdoing alleged herein. Because of the fraudulent acts of concealment of wrongdoing by Defendants, Plaintiff could not have reasonably discovered the wrongdoing at any time prior.

FIRST CAUSE OF ACTION

Negligence (Against All Defendants)

103. Plaintiff incorporates by reference and realleges each paragraph set forth above.

104. Defendants were regularly engaged in the business of designing, researching, developing, testing, manufacturing, packaging, labeling, marketing, promoting, distributing

and/or selling medical devices known as Laparoscopic Power Morcellators, including the Gynecare Tissue Morcellator, for use in gynecological surgery to remove the uterus (hysterectomy) and/or to remove uterine fibroids (myomectomy) in women.

105. Defendants owed a duty to design, research, develop, test, manufacture, package, label, market, promote, distribute, sell and/or supply products, including gynecologic products used for uterine morcellation, in such a way as to avoid harm to persons upon whom they were used by adequately warning of the hazards and dangers associated with the use of said products.

106. Defendants, acting by and through their authorized divisions, subsidiaries, agents, servants, and employees, were careless, reckless, negligent, grossly negligent and exhibited 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, gynecologic products, including Laparoscopic Power Morcellators used for uterine morcellation, by:

a. failing to design their Laparoscopic Power Morcellators for safe use in fibroid removal surgery;

b. failing to conduct adequate and appropriate testing of their gynecologic products;

c. marketing their Laparoscopic Power Morcellators without first conducting adequate research to determine possible side effects on humans or selectively and misleadingly revealing or analyzing testing and research data;

d. failing to monitor registry data regarding their marketed devices and promptly report any safety concerns that arise through registry study or data;

e. failing to keeping abreast of scientific literature and studies which provided Defendants notice of the risks associated with the use of Laparoscopic Power Morcellators;

f. failing to appropriately respond to their own and others testing of, and information available regarding Laparoscopic Power Morcellators, which indicated such products' potential harm to humans;

g. failing to appropriately monitor the post-market performance, adverse events, and complications reported about their Laparoscopic Power Morcellators and their products' effects on patients;

h. failing to promptly disseminate new safety information and data regarding their products after their Laparoscopic Power Morcellators reached the market;

i. failing to adequately warn of the actual potential of their Laparoscopic Power Morcellators to be harmful to humans;

j. failing to adequately warn of the actual potential for the dissemination and/or spreading of parasitic uterine myomas when using Laparoscopic Power Morcellators for uterine morcellation;

k. concealing their full knowledge and experience regarding the potential that Laparoscopic Power Morcellators were harmful to humans because there was a substantial risk their products would spread parasitic uterine myomas;

l. failing to adequately define the patients populations, if any, for which Laparoscopic Power Morcellator could be safely used;

m. promoting, marketing, advertising and/or selling their Laparoscopic Power Morcellators for use for uterine morcellation given their knowledge and experience of such products' potential harmful effects;

n. failing to timely withdraw products used for uterine morcellation from the market, restrict their uses and adequately warn of such products' potential dangers, given their knowledge of the potential for its harm to humans;

o. failing to fulfill the standard of care required of a reasonably prudent medical device manufacturer;

p. disregarding publicity, government and/or industry studies, information, documentation and recommendations, consumer complaints and reports and/or other information regarding the hazards of uterine morcellation and its potential harm to humans;

q. failing to provide updated information in the form of reports, statistics and outcomes of studies to physicians, hospitals and other healthcare entities concerning the increased likelihood of cancerous tissue dissemination dissemination when such data became available;

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

s. advertising and promoting their products used for uterine morcellation as safe and/or safer than other methods; and

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

107. Despite the fact that Defendants knew or should have known that their Laparoscopic Power Morcellators were associated with and/or caused the dissemination and/or upstaging of unsuspected malignant tissue, Defendants continued to market, manufacture, distribute, and/or make available their Laparoscopic Power Morcellators to patients through their surgeons and/or health care facilities, including the Plaintiff and her surgeon.

108. Defendants, directly or through their sales staff and/or agents, paid consultants, and/or licensed distributors, among others, made false material representations and/or material omissions through the course of aggressive sales and marketing operations that implemented false and misleading statements by sales representatives, Defendant-sponsored literature, Defendant-sponsored events and conferences, online and/or video marketing, or other

promotional material in order to promote and sell their Laparoscopic Power Morcellators while omitting material facts regarding said devices' dangerous side effects and adverse events.

109. Defendants' negligence (and/or recklessness) was the cause of and substantial factor in bringing about Plaintiff's injuries, harm and economic loss which she suffered and will continue to suffer.

110. Defendants' acted in conscious disregard of the high degree of risk of physical harm to women undergoing surgery with their Laparoscopic Power Morcellators, including Plaintiff herein, of which Defendants knew or has reason to know, giving rise to punitive damages.

111. Defendants knew or should have known that consumers, such as the Plaintiff, would foreseeably suffer injury as a result of Defendants' failure to exercise ordinary care, as set forth above.

112. Defendants knew or should have known of the danger associated with the use of their Laparoscopic Power Morcellator as well as the defective nature of said products, but continued to design, manufacture, sell, distribute, market, promote and/or supply their Laparoscopic Power Morcellators so as to maximize sales and profits at the expense of the public health and safety.

113. Defendants are doing business in the State of Wisconsin.

114. Defendants carried on solicitation or service actives in State of Wisconsin.

115. The Defendants' Laparoscopic Power Morcellators were used within Wisconsin in the ordinary course of trade.

116. Defendants derived and derive substantial revenue from interstate commerce.

117. As a result of Defendants' negligence and/or recklessness, Plaintiff suffered serious and dangerous side effects including the dissemination and upstaging of unsuspected malignant cancerous tissue, physical pain and mental anguish, diminished enjoyment of life, and other severe personal injuries, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above.

118. By reason of the foregoing, Plaintiffs demands judgment against each Defendant, individually, jointly and severally for compensatory damages and punitive damages, together with interest, costs of suit, attorneys' fees and all such other and further relief as the Court deems proper.

SECOND CAUSE OF ACTION

Strict Product Liability—Defective Design (Against All Defendants)

119. Plaintiff incorporates by reference and realleges each paragraph set forth above.

120. 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 designed, produced, manufactured, labeled, sold, distributed, and/or marketed by Defendants.

121. Defendants' Laparoscopic Power Morcellators 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.

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

123. Defendants' Power Morcellators were defective in design or formulation when they left the manufacturers and suppliers' control and reached Plaintiff without substantial—if any—change, and 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.

124. 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.

125. Defendants' Laparoscopic Power Morcellators were defective in design or formulation and the dangers associated with their use were unknowable and unacceptable to the average or ordinary consumer.

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

127. 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.

128. As a foreseeable, direct, and proximate result of the aforementioned wrongful acts and omissions of Defendants, Plaintiff suffered from the aforementioned injuries and damages.

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

130. By reason of the foregoing, Plaintiff demands 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

Strict Products Liability – Failure to Warn (Against All Defendants)

131. Plaintiff incorporates by reference and realleges each paragraph set forth above.

132. 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.

133. 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, including, but not limited to:

a. the risk of aggressively disseminating unsuspected malignant tissue beyond the uterus;

b. the device's risk of spreading a patient's cancerous uterine tissue;

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 cancerous uterine tissue at an earlier date and to allow for appropriate treatment in the event of such a finding.

134. 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.

135. 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 uterine tissue and tumor spillage and site seeding. See e.g. Cai, et al., Electrical Prostate Morcellator: An Alternative to Manual Morcellation for Laparoscopic Nephrectomy Specimens? An In Vitro Study, ADULT UROLOGY, 61(6):1113-17, 1113 (2003) (finding a 90% perforation rate with mechanical morcellation without direct visualization).

136. Defendants failed to timely include a Black Box Warning regarding the risks of dissemination of cancerous uterine tissue.

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

138. 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 Plaintiff.

139. 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 cancerous uterine tissue, and therefore, would have avoided the injuries described herein.

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

141. As a foreseeable, direct, and proximate result of the aforementioned wrongful acts and omissions of Defendants, Plaintiff was caused to suffer from the aforementioned injuries and damages.

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

FOURTH CAUSE OF ACTION

Breach of Express Warranties (Against All Defendants)

143. Plaintiff incorporates by reference and realleges each paragraph set forth above.

144. Defendants expressly warranted through their labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that their Laparoscopic Power Morcellators were safe, and withheld and concealed information from Plaintiff and her surgeon about the substantial risks of serious injury associated with using the products used for uterine morcellation.

145. Defendants expressly warranted that their Laparoscopic Power Morcellators were safe for their intended use and as otherwise described in this complaint.

146. The Laparoscopic Power Morcellator used on Plaintiff during her surgery did not conform to these express representations, including, but not limited to, the representation that it was well accepted in patient studies, the representation that it was safe for use, the representation that it did not have high and/or unacceptable levels of life-threatening side effects, and that it would improve or maintain health, and potentially prolong life.

147. Defendants represented that the products used for uterine morcellation were safer and more efficacious than other alternative surgical approaches and techniques.

148. Defendants further concealed information, regarding the true efficacy of said products.

149. Defendants' Laparoscopic Power Morcellators failed to conform to the foregoing express representations because their devices were not safe or effective, could produce serious side effects, including among other things disseminating and spreading cancerous uterine tissue beyond the uterus, degrading Plaintiff's health, and decreasing her life expectancy.

150. Defendants made these material representations, which also included omissions of material fact, to the medical and healthcare community at large, the general public, to Plaintiff's medical or healthcare provider(s), and/or to Plaintiff with intent to induce medical and healthcare providers and patients to dispense, provide, prescribe, accept, and/or purchase their Laparoscopic Power Morcellators.

151. Defendants made false material representations and/or material omissions through the course of an aggressive sales and marketing operation that implemented false and misleading statements by sales representatives, Defendant-sponsored literature, and/or Defendant-sponsored promotional functions in order to promote and sell their Laparoscopic Power Morcellators while omitting material facts regarding said devices' dangerous side effects and adverse events.

152. The express warranties represented by the Defendants were a part of the basis for Plaintiff and her surgeon's consent to permit the use of the Laparoscopic Power Morcellator on Plaintiff during her uterine surgery.

153. Plaintiff and her surgeon relied on said express warranties in deciding to use the Laparoscopic Power Morcellator as a treatment option.

154. At the time of the making of the express warranties, the Defendants had knowledge of the purpose for which their Laparoscopic Power Morcellators were to be used, and expressly warranted the same to be in all respects safe, effective and proper for such purpose.

155. As a result of the foregoing breach of express warranty, Plaintiff was caused to suffer serious and dangerous side effects including dissemination and spreading of cancerous uterine tissue, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, any and all life complications caused by Plaintiff's injuries.

156. By reason of the foregoing, Plaintiff has been severely and permanently injured.

157. By reason of the foregoing, Plaintiffs demand judgment against each Defendant, individually, jointly and severally for compensatory damages in a sum that exceeds the jurisdictional limits of all lower courts that might otherwise have jurisdiction, and punitive damages, together with interest, costs of suit, attorneys' fees and all such other and further relief as the Court deem proper.

FIFTH CAUSE OF ACTION

Breach of Implied Warranty for a Particular Purpose (Against All Defendants)

158. Plaintiff incorporates by reference and realleges each paragraph set forth above.

159. The Defendants impliedly represented and warranted to the users of their Laparoscopic Power Morcellators and patients undergoing surgery with their Laparoscopic Power Morcellators that said devices was safe and fit for the particular purpose for which said products were to be used, namely for the safe removal of uterine tissue and/or uterine fibroids.

160. These aforementioned representations and warranties were false, misleading, and inaccurate in that Defendants' Laparoscopic Power Morcellators were unsafe, degraded Plaintiff's health and shortened her life expectancy.

161. Plaintiff relied on the implied warranty of fitness for a particular use and purpose.

162. Plaintiff and her surgeon reasonably relied upon the skill and judgment of Defendants as to whether the Defendants' Power Morcellator was safe and fit for its intended use (hysterectomies and myomectomies, among other indications).

163. Defendants' Laparoscopic Power Morcellators were placed into the stream of commerce by the Defendants in a defective, unsafe, and inherently dangerous condition and the products and materials were expected to and did reach users, handlers, and persons coming into contact with said products without substantial change in the condition in which they were sold.

164. Defendants breached the aforesaid implied warranty, as their Laparoscopic Power Morcellators, including the Laparoscopic Power Morcellator used on Plaintff, were not reasonably fit for their intended purposes and uses.

165. As a result of the foregoing breach of implied warranty, Plaintiff was caused to suffer serious and dangerous side effects including dissemination and spreading of cancerous tissue, physical pain and mental anguish, including diminished enjoyment of life, and other severe and personal injuries which were permanent and lasting in nature.

166. By reason of the foregoing, Plaintiff demands judgment against each Defendant, individually, jointly and severally for compensatory damages in a sum that exceeds the jurisdictional limits of all lower courts that might otherwise have jurisdiction and punitive damages, together with interest, costs of suit, attorneys' fees and all such other and further relief as the Court deem proper.

SIXTH CAUSE OF ACTION

Breach of Implied Warranty of Merchantability (Against All Defendants)

167. Plaintiff incorporates by reference and realleges each paragraph set forth above.

168. Defendants manufactured, compounded, portrayed, distributed, recommended, merchandized, advertised, promoted and sold their Laparoscopic Power Morcellators for the purpose of removing uterine tissue and/or uterine fibroids.

169. Defendants knew and promoted the use of their Laparoscopic Power Morcellators for the use for which said device was to be used on the Plaintiff, namely for the safe removal of

uterine tissue and/or uterine fibroids, improving health, maintaining health, and potentially prolonging life.

170. Defendants impliedly warranted to Plaintiff and her surgeon that their Laparoscopic Power Morcellators were of merchantable quality for the purposes for which they were to be used.

171. These aforementioned representations and warranties were false, misleading, and inaccurate in that the Power Morcellator used on Plaintiff was unsafe, degraded Plaintiff's health and shortened her life expectancy.

172. Plaintiff and her surgeon reasonably relied on the skill, expertise and judgment of the Defendants and their representations as to the fact that the Laparoscopic Power Morcellator selected for and used on Plaintiff was of merchantable quality.

173. Said Laparoscopic Power Morcellators were not of merchantable quality, in that said devices had dangerous and life threatening side effects and; thus, were not fit for the ordinary purpose for which they was intended.

174. As a direct and proximate result of the foregoing, Plaintiff was caused bodily injury, pain and suffering and economic loss.

175. By reason of the foregoing, Plaintiffs demand judgment against each Defendant, individually, jointly and severally for compensatory damages in a sum that exceeds the jurisdictional limits of all lower courts that might otherwise have jurisdiction, and punitive damages, together with interest, costs of suit, attorneys' fees and all such other and further relief as the Court deem proper.

SEVENTH CAUSE OF ACTION

Violation of Wisconsin's Deceptive Trade Practices Act (Against All Defendants) Wis. Stat. § 100.18

176. Plaintiff incorporates by reference and realleges each paragraph set forth above.

177. Upon information and belief, Plaintiff alleges that that Defendants, by the acts and misconduct alleged, violated the Wisconsin Deceptive Trade Practices Act (Wis. Stat. § 100.18).

178. The Wisconsin Deceptive Trade Practices Act applies to Defendants' actions and conduct described herein because it extends to transactions which are intended to result, of which have resulted, in the sale of goods to consumers.

179. Plaintiff purchased (through her surgeon, and/or the heath care facility at which her surgery was performed) the Laparoscopic Power Morcellator to be used on her during surgery.

180. Upon information and belief, said purchase occurred in the State of Wisconsin.

181. Defendants have violated the Wisconsin Deceptive Trade Practices Act in representing that goods have characteristics and benefits which they do not have. Defendants represented their Laparoscopic Power Morcellator as safe and fit to be used for the purpose for which they were intended, which was untrue, deceptive and misleading.

182. 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 (through her surgeon, and/or the heath care facility at which her surgery was performed), and would not have incurred related medical costs and injury.

183. Unfair methods of competition or deceptive acts or practices that were proscribed by law, including the following:

a. making untrue, misleading, and/or deceptive assertions, representations or statements of fact that goods or services have characteristics, components, uses benefits or quantities that they do not have;

b. advertising goods or services with the intent not to sell them as advertised; and engaging in fraudulent or deceptive conduct that creates a likelihood of confusion or misunderstanding.

184. The untrue, misleading, and/or deceptive assertions, representations or statement of fact regarding Laparoscopic Power Morcellators were made by Defendants to the public in promotional materials, Defendant-sponsored medical literature, videos, Defendant-sponsored

presentations, and/or face-to-face sales calls with Defendants sales representatives and/or agents, with the intent to induce an obligation.

185. Plaintiff and her surgeon justifiably relied on the untrue, misleading, and/or deceptive assertions, representations or statement of fact made by Defendants to the public in promotional materials, Defendant-sponsored medical literature, videos, Defendant-sponsored presentations, and/or face-to-face sales calls regarding Laparoscopic Power Morcellators, in selecting the Gynecare Tissue Morcellator for use in Plaintiff's surgery.

186. Defendants violated the statutes that were enacted to protect consumers against unfair, deceptive, and misleading business practices and false advertising, 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, and by other acts alleged herein.

187. Plaintiff was injured by the cumulative and indivisible nature of Defendants' conduct. The cumulative effect of Defendants' conduct directed at patients, physicians and consumers was to create demand for and sell their Laparoscopic Power Morcellator devices. Each aspect of Defendants' conduct combined to artificially create sales of said products.

188. The actions and omissions of Defendants alleged herein are uncured or incurable deceptive acts under the statutes enacted in the states to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising.

189. Defendants had actual knowledge of the defective and dangerous condition of the products and failed to take any action to cure such defective and dangerous conditions.

190. Plaintiff and the medical community relied upon Defendants' misrepresentations and omissions in determining which treatment to prescribe.

191. Reasonable consumers, including Plaintiff, were injured by Defendants' unfair and deceptive acts.

192. As a direct and proximate result of the false representations described herein, Plaintiff was injured as described above.

193. As a direct and proximate result of Defendants' violations of the Wisconsin Deceptive Trade Practices Act, Plaintiff has sustained economic losses, mental anguish, and other damages, and are entitled to statutory and compensatory damages in an amount to be proven at trial.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against the Defendants on each of the above-referenced claims as follows:

195. 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, and medical monitoring, with interest and costs as provided by law;

196. Punitive and/or exemplary damages for the malicious, wanton, willful, oppressive, and reckless acts of the Defendants who demonstrated an intentional disregard to the rights and safety of the general public and to the Plaintiff in an amount sufficient to punish Defendants and deter future similar conduct;

197. Plaintiff's attorney's fees, expenses, and costs; and

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

DEMAND FOR JURY TRIAL

Plaintiff hereby demands a trial by jury as to all issues.

Respectfully submitted this 27th day of January, 2016.

By: s/Kara Elgersma

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Attorneys for Plaintiff BABETTE DAVIS

JS 44 (Rev. 11/15)

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.)*

Place an "X" in the appropriate box (required): ☐ Green Bay Division ☒ Milwaukee Division

I. (a) PLAINTIFFS
BABETTE DAVIS

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

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
Kara Elgersma (SBN 1082121); WEXLER WALLACE LLP
55 W. Monroe Street, Suite 3300
Chicago, Illinois 60603
(312)-346-2222

DEFENDANTS
ETHICON, INC., et al.

County of Residence of First Listed Defendant
(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
☐ 376 Qui Tam (31 USC 3729 (a))
☐ 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 U.S.C. 1332(a)

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
01/27/2016

SIGNATURE OF ATTORNEY OF RECORD

INSTRUCTIONS FOR ATTORNEYS COMPLETING CIVIL COVER SHEET FORM JS 44

Authority For Civil Cover Sheet

The JS 44 civil cover sheet and the information contained herein neither replaces nor supplements the filings and service of pleading 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. Consequently, a civil cover sheet is submitted to the Clerk of Court for each civil complaint filed. The attorney filing a case should complete the form as follows:

I.(a) **Plaintiffs-Defendants.** Enter names (last, first, middle initial) of plaintiff and defendant. If the plaintiff or defendant is a government agency, use only the full name or standard abbreviations. If the plaintiff or defendant is an official within a government agency, identify first the agency and then the official, giving both name and title.

(b) **County of Residence.** For each civil case filed, except U.S. plaintiff cases, enter the name of the county where the first listed plaintiff resides at the time of filing. In U.S. plaintiff cases, enter the name of the county in which the first listed defendant resides at the time of filing. (NOTE: In land condemnation cases, the county of residence of the "defendant" is the location of the tract of land involved.)

(c) **Attorneys.** Enter the firm name, address, telephone number, and attorney of record. If there are several attorneys, list them on an attachment, noting in this section "(see attachment)".

II. **Jurisdiction.** The basis of jurisdiction is set forth under Rule 8(a), F.R.Cv.P., which requires that jurisdictions be shown in pleadings. Place an "X" in one of the boxes. If there is more than one basis of jurisdiction, precedence is given in the order shown below.
United States plaintiff. (1) Jurisdiction based on 28 U.S.C. 1345 and 1348. Suits by agencies and officers of the United States are included here.
United States defendant. (2) When the plaintiff is suing the United States, its officers or agencies, place an "X" in this box.
Federal question. (3) This refers to suits under 28 U.S.C. 1331, where jurisdiction arises under the Constitution of the United States, an amendment to the Constitution, an act of Congress or a treaty of the United States. In cases where the U.S. is a party, the U.S. plaintiff or defendant code takes precedence, and box 1 or 2 should be marked.
Diversity of citizenship. (4) This refers to suits under 28 U.S.C. 1332, where parties are citizens of different states. When Box 4 is checked, the citizenship of the different parties must be checked. (See Section III below**; NOTE: federal question actions take precedence over diversity cases.**)

III. **Residence (citizenship) of Principal Parties.** This section of the JS 44 is to be completed if diversity of citizenship was indicated above. Mark this section for each principal party.

IV. **Nature of Suit.** Place an "X" in the appropriate box. If the nature of suit cannot be determined, be sure the cause of action, in Section VI below, is sufficient to enable the deputy clerk or the statistical clerk(s) in the Administrative Office to determine the nature of suit. If the cause fits more than one nature of suit, select the most definitive.

V. **Origin.** Place an "X" in one of the six boxes.
Original Proceedings. (1) Cases which originate in the United States district courts.
Removed from State Court. (2) Proceedings initiated in state courts may be removed to the district courts under Title 28 U.S.C., Section 1441. When the petition for removal is granted, check this box.
Remanded from Appellate Court. (3) Check this box for cases remanded to the district court for further action. Use the date of remand as the filing date.
Reinstated or Reopened. (4) Check this box for cases reinstated or reopened in the district court. Use the reopening date as the filing date.
Transferred from Another District. (5) For cases transferred under Title 28 U.S.C. Section 1404(a). Do not use this for within district transfers or multidistrict litigation transfers.
Multidistrict Litigation. (6) Check this box when a multidistrict case is transferred into the district under authority of Title 28 U.S.C. Section 1407. When this box is checked, do not check (5) above.

VI. **Cause of Action.** Report the civil statute directly related to the cause of action and give a brief description of the cause. **Do not cite jurisdictional statutes unless diversity.** Example: U.S. Civil Statute: 47 USC 553 Brief Description: Unauthorized reception of cable service

VII. **Requested in Complaint.** Class Action. Place an "X" in this box if you are filing a class action under Rule 23, F.R.Cv.P.
Demand. In this space enter the actual dollar amount being demanded or indicate other demand, such as a preliminary injunction.
Jury Demand. Check the appropriate box to indicate whether or not a jury is being demanded.

VIII. **Related Cases.** This section of the JS 44 is used to reference related pending cases, if any. If there are related pending cases, insert the docket numbers and the corresponding judge names for such cases.

Date and Attorney Signature. Date and sign the civil cover sheet.