

**UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION**

**JEFFREY WILSON, personally and on
behalf of the ESTATE OF MARGUERITE
WILSON, deceased, and her survivors,**

PLAINTIFF,

Case No. 1:15-cv-11700

v.

**COMPLAINT AND
JURY DEMAND**

**NOUVAG USA, INC., a California
corporation; NOUVAG GmbH, a business
organized in Germany; NOUVAG AG; a
business organized in Switzerland;
RICHARD WOLF MEDICAL
INSTRUMENTS CORP. a Delaware
Corporation; RICHARD WOLF GmbH, a
business organized in Germany,**

DEFENDANTS.

Plaintiff Jeffrey Wilson, personally and on behalf of the survivors and estate of Marguerite Wilson, by her attorneys Burg Simpson Eldredge Hersh & Jardine, P.C., for her Complaint and Jury Demand alleges, as follows:

1. This is a lawsuit by Jeffrey Wilson as personal representative of the estate of his wife, Marguerite Wilson, and on behalf of its survivors, for wrongful death, negligence, negligent failure to warn, product liability, and breach of express and implied warranties against the individual and concerted actions of defendants Nouvag USA, Inc.; Nouvag GmbH; Nouvag AG; Richard Wolf Medical Instruments Corp.; Richard Wolf GmbH (together "Defendants"). The claims arise from the design, manufacture, importation, distribution, marketing, promotion, and sale of the Defendants' Morce Power Plus Morcellator, which injured Marguerite Wilson when used in her laparoscopic supracervical

hysterectomy, left salpingo-oophorectomy on December 17, 2012. Use of Defendants' morcellator device caused unknown cancer to spread and upstaged that cancer within Marguerite Wilson's body. As a result, Marguerite suffered severely and painfully, and endured cancer treatment. Then, on December 31, 2013, Marguerite Wilson died as a result of the use of Defendant's Morce Power Plus device.

I. PARTIES, JURISDICTION, AND VENUE

2. Plaintiff Jeffrey Wilson is a resident and citizen of York County, Virginia.

3. The York County - Poquoson Circuit Court of York County, Virginia, has appointed Jeffrey Wilson to serve as the personal representative of the Estate of Marguerite Wilson.

4. Defendant Nouvag USA, Inc. is a California corporation with its principal place business at 18058 Albyn Court, Lake Hughes, CA 93532.

5. Defendant Nouvag GmbH is a corporation or other business entity organized or existing under the laws of Germany with its principal place of business at Schulthaißstraße 15, D-Konstanz 78462, Germany.

6. Defendant Nouvag AG is a corporation or other business entity organized or existing under the laws of Switzerland with its principal place of business at St. Gallerstraße 23-25, CH – 9403, Goldach Switzerland.

7. At the time of this filing and at all relevant times, Nouvag AG lists its U.S. Agent for FDA purposes as Paul Crandall of Electronic Services Company, at Nouvag USA's Lake Hughes, California address, with the phone number (661) 724-0217, and an email address at nouvagusa.com.

8. Paul Crandall also serves as the Official Correspondent for Nouvag USA, at the same Lake Hughes, California address and phone number.

9. On information and belief, Nouvag AG is the parent company of and is the direct or indirect owner of substantially all of the stock or other ownership interests of Nouvag USA, INC. and Nouvag GmbH.

10. On information and belief, at all relevant times, Nouvag AG, Nouvag USA, INC. and Nouvag GmbH (collectively “Nouvag”) were agents, representatives, joint venturers, alter egos, coconspirators, consultants, predecessors, successors, servants, or employees of each other.

11. On information and belief, in doing the acts alleged herein, Nouvag AG, Nouvag USA, INC. and Nouvag GmbH acted in the course and scope of such agency, representation, joint venture, conspiracy, consultancy, predecessor agreement, successor agreement, service, or employment, with knowledge, acquiescence and ratification of each other.

12. On information and belief, Nouvag AG and Nouvag USA share the same logo, website (www.nouvag.com), interests, sales executives, attorneys, and computer information, databases, and software. Nouvag AG’s website indicates it operates a sales office in California—and on information and belief, Nouvag USA is that sales office.

13. Defendant Richard Wolf Medical Instruments Corp. (Wolf Medical Instruments) is a Delaware corporation with its principal place of business at 353 Corporate Woods Parkway, Vernon Hills, Illinois 60061.

14. Defendant Richard Wolf GmbH (Wolf GmbH) is a corporation or other business entity organized or existing under the laws of Germany with its principal place of business at Pforzheimer Straße 3275438 Knittlingen, Germany and an additional German address in Baden-Wurttemberg, Germany.

15. At the time of this filing and at all relevant times, Wolf GmbH has listed its Official Correspondent with the FDA as Michele McDonald of Wolf Medical Instruments at its Vernon Hills Illinois address, with the phone number (847) 913-1113, ext. 380.

16. Michelle McDonald also serves as the Official Correspondent for Wolf Medical Instruments at the same Vernon Hills, Illinois address and phone number.

17. At the time of this filing and at all relevant times, Wolf GmbH lists its U.S. Agent for FDA purposes as Ron Haselhorst of Wolf Medical Instruments at its Vernon Hills Illinois address, with the phone number (847) 913-1113, ext. 380, and an email address at richardwolfusa.com.

18. On information and belief, Wolf GmbH is the parent company of and is the direct or indirect owner of substantially all of the stock or other ownership interests of Wolf Medical Instruments. Wolf GmbH's website (www.richard-wolf.com) lists Wolf Medical Instruments as a subsidiary. Wolf GmbH's website provides links to Wolf Medical Instruments' salesforce, including links to email addresses for its subsidiary's salespeople in the United States, and links to its subsidiary's website.

19. Wolf GmbH's website lists the contact information at Wolf Medical Instruments at the same phone number and Vernon Hills, Illinois address as it used with the FDA when it registered its United States correspondent and agent.

20. On information and belief, Wolf GmbH and Wolf Medical Instruments share the same logo, interests, sales executives, attorneys, and computer information, databases, and software.

21. On information and belief, at all relevant times, Wolf GmbH and Wolf Medical Instruments were agents, representatives, joint venturers, alter egos, coconspirators, consultants, predecessors, successors, servants, or employees of each other.

22. On information and belief, in doing the acts alleged herein, Wolf GmbH and Wolf Medical Instruments acted in the course and scope of such agency, representation, joint venture, conspiracy, consultancy, predecessor agreement, successor agreement, service, or employment, with knowledge, acquiescence and ratification of each other.

23. Defendant Nouvag USA is the alter ego of Defendants Nouvag AG. So all of the activities of one in the United States, including the states of California and Virginia are imputed on the other.

24. Defendant Wolf Medical Instruments is the alter ego of Wolf GmbH. So all of the activities of one in the United States, including the states of Illinois and Virginia are imputed on the other.

25. According to the intraoperative record from Marguerite Wilson's December 17, 2012, Laparoscopic Supracervical Hysterectomy and Left Salpingo-Oophrectomy, "Needham, Wolf Rep." attended the surgery.

26. On information and belief, "Needham, Wolf Rep." is an employee or agent of one or both of the Wolf defendants.

27. On information and belief, at all relevant times, Nouvag USA, Inc.; Nouvag GmbH; Nouvag AG; Richard Wolf Medical Instruments Corp.; Richard Wolf GmbH each were registered as an "Establishment" with the Food and Drug Administration (FDA).

28. On information and belief, at all relevant times, as an Establishment with FDA, each of the Defendants was registered as one or more of the following: manufacturer,

contract manufacturer, exporter, importer, initial distributor, repackager, relabeler, or specification developer, with respect to the Nouvag or Wolf Morce Power Morcellator.

29. On information and belief, at all relevant times, Defendants were agents, representatives, joint venturers, alter egos, coconspirators, consultants, predecessors, successors, servants, or employees of each other.

30. On information and belief, in doing the acts alleged herein, Defendants acted in the course and scope of such agency, representation, joint venture, conspiracy, consultancy, predecessor agreement, successor agreement, service, or employment, with knowledge, acquiescence, and ratification of each other.

31. On information and belief, one or more of the Defendants, acting alone or in the course and scope of an agency, representation, joint venture, conspiracy, consultancy, predecessor agreement, successor agreement, service, or employment, and with knowledge, acquiescence, and ratification of each other at all times material and relevant hereto, were engaged in the business of manufacturing, selling, supplying, marketing, designing, and distributing minimally invasive gynecological surgical products, including the morcellator device used on Marguerite Wilson.

32. On information and belief, Defendants have purposefully availed themselves of the benefits of doing business in the United States, including the states of California, Illinois, and Virginia, through manufacturing, designing, labeling, marketing, distributing, supplying and/or selling the Morce Power Plus Morcellator, and by placing it into the stream of commerce for those purposes, and by promoting and selling it for use in connection with surgeries performed on residents of Virginia, including Decedent Marguerite Wilson.

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

34. On information and belief, at all relevant times, Defendants Wolf GmbH and Wolf Medical Instruments expected or should have expected that their acts would have consequences within the States of Illinois and Virginia, and they derived and derive substantial revenue from interstate commerce. On information and belief, at all relevant times, Defendants have transacted and conducted business in the State of Illinois or contracted to supply goods or services within the State of Illinois, and these causes of action alleged in this Complaint and Jury Demand arise from those acts or omissions.

35. On information and belief, at all relevant times, Defendants have committed tortious acts or omissions without the State of Virginia, including acts or omissions committed in and from the State of Illinois, which acts or omissions have caused injury within the State of Virginia and out of which acts or omissions the foregoing causes of action arise.

36. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §1332, as complete diversity exists between Plaintiff and Defendants, and the amount in controversy exceeds \$75,000.

37. This Court has personal jurisdiction over Defendants because said Defendants have regularly and purposefully transacted business and engaged in commercial activities within the United States, the State of Illinois, and this District.

38. Venue is proper within this District pursuant to 28 U.S.C. §1391(b)(3), because there is no district in which an action may otherwise be brought as provided in

§1391(b) and Wolf Medical Instruments operates out of this Court's jurisdiction and is subject to the Court's personal jurisdiction. Additionally, as defendants not resident in the United States, venue for suit against Wolf GmbH and Nouvag AG is proper in any jurisdiction in the United States and joinder of those defendants is disregarded in determining the appropriate venue. 28 U.S.C. §1391(c)(3).

II. FACTUAL BACKGROUND

39. Plaintiff adopts and re-alleges each of the foregoing paragraphs as if fully restated in this sentence and further state as follows:

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

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

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

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

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

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

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

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

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

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

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

51. Defendants’ Morce Power Plus Morcellator device was granted 510(k) market clearance by the Food and Drug Administration (FDA) on June 29, 2009 under 510(k) No. K080365.

52. The 510(k) Approval Letter for K080365 provides that the “The Morce Power Plus morcellator is intended for use in operative laparoscopy, including laparoscopic general surgical procedures and laparoscopic gynecological procedures to morcellate and remove tissue.”

53. There is no express provision in the 510(k) Approval Letter for K080365 indicating the Morce Power Plus Morcellator is specifically indicated for myomectomy or hysterectomy.

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

55. Defendants had other morcellators on the market over the years and continue to manufacture, market, distribute, and sell similar morcellators with 510(k) approval in the United States.

56. Defendants' product labeling has not been expressly reviewed or approved by the FDA.

57. Defendants' product labeling includes a precaution indicating that when used on malignant tissue, use of the Morce Power Plus Morcellator may lead to dissemination of malignant tissue.

58. On December 17, 2012, Marguerite Wilson underwent a surgical procedure known as a Laparoscopic Supracervical Hysterectomy and Left Salpingo-Oophrectomy in Newport News, Virginia.

59. During that procedure, Ms. Wilson's surgeon utilized Defendants' power morcellator device to shred or morcellate and remove Plaintiff's uterus during this surgery.

60. Before the Plaintiff's surgery of December 17, 2012, there was no evidence that Marguerite Wilson had disseminated or metastatic cancer or disease.

61. Plaintiff underwent a mammogram and regular pap smears before the surgery, all of which were benign. Neither Plaintiff nor her physician was aware or suspicious of uterine sarcoma prior to the surgery.

62. After the surgery, a pathology report showed leiomyosarcoma in the morcellated tissue.

63. Ms. Wilson began chemotherapy treatment within a very short time after the December 17, 2012 surgery.

64. That December 17, 2012 morcellation surgery with Defendants' device seeded or upstaged Ms. Wilson's leiomyosarcoma.

65. As a result of the morcellation and upstaging of the leiomyosarcoma, Ms. Wilson then endured the horrible pain of radiation treatment, additional painful surgery and treatment, and the fear of dying until she died on December 31, 2013.

66. She left her husband without a wife because Defendants' device spread cancer cells and upstaged her cancer.

67. Defendants were aware of the risks, complications, and adverse events associated with its products used for uterine morcellation, including Defendants' power morcellator devices. In particular, Defendants was aware of the risk that its device would cause dissemination of undiagnosed sarcoma tissue throughout the peritoneal cavity, thereby upstaging the cancer from a highly survivable or curable stage I disease to a poor prognosis stage II - IV disease.

68. Defendants also were aware that it is not possible to reliably detect uterine sarcoma before surgery in women with fibroids. Accordingly, Defendants were aware that even if their device was limited to use on women who had not been diagnosed with

sarcoma, morcellation would nonetheless be performed each year on hundreds, if not thousands, of women with undiagnosed sarcoma.

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

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

71. Johnson & Johnson and Ethicon suspended sales of their power morcellator devices on April 30, 2014 pending evaluation of the risks.

72. On July 30, 2014, some manufacturers withdrew their morcellation devices from the global market, admitting that the “risk-benefit assessment associated with the use of these devices in hysterectomy and myomectomy procedures for removing fibroids remains uncertain.”

73. In late 2014 or early 2015, the Federal Bureau of Investigation opened an investigation into what morcellator manufacturers knew about the risks and dangers associated with the propensity of power morcellation devices to disseminate cancer cells and upstage a woman’s cancer when used during hysterectomy and myomectomy procedures.

74. Ethicon’s market withdrawal of their power morcellator devices came as a result of the difficulty for medical professionals to preoperatively diagnose some malignancies, such as leiomyosarcoma and the risk of disseminating unsuspected malignant tissue while using power morcellation devices.

75. This difficulty was well known to Defendants at the time that they manufactured and distributed their morcellator products. But the Defendants have not withdrawn their morcellator devices from the market.

76. As a direct and proximate consequence of Defendants' design defects, failure to warn of harms, acts, omissions, misrepresentations, or other culpable acts described in this Complaint, the plaintiffs, as the survivors and the estate of Decedent Marguerite Wilson, sustained injuries and damages, including economic and non-economic losses, pain, suffering, disfigurement, impairment, sorrow, mental anguish, solace, society, companionship, comfort, guidance, kindly offices, advice of the decedent, medical and funeral expenses, loss of prospective net accumulations, including income, lost support and services, lost care, protection, and assistance, and all other injuries, damages, and losses available in law or equity, including punitive damages, in an amount to be determined by the jury.

III. FIRST CAUSE OF ACTION

Design Defect

77. Plaintiff adopts and re-alleges each of the foregoing paragraphs as if fully restated in this sentence and further state as follows:

78. Defendants manufactured, designed, marketed, distributed, and sold the power morcellator device.

79. When Defendants manufactured, designed, marketed, distributed, and sold the power morcellator device, they had a duty to ensure the design was not unreasonably dangerous and to ensure there were not design assembly, or manufacturing defects.

80. The power morcellator device manufactured by Defendants was expected to and did reach consumers, including Plaintiff Marguerite Wilson, without any alterations or changes.

81. The power morcellator device manufactured, designed, marketed, distributed, and sold by Defendants was defective in design, because when it left the hands of the Defendant, the foreseeable risks of the product exceeded the benefits associated with its design or formulation.

82. The power morcellator device manufactured, designed, marketed, distributed, and sold by Defendants was defective in design, because when it left the Defendants' hands, it was more dangerous than an ordinary consumer would expect.

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

84. The fact that such harm as that suffered by Plaintiff Marguerite Wilson will occur in a percentage of women upon whom a power morcellator devices are used is completely foreseeable because (1) there are no pathognomonic symptoms or accurate preoperative diagnostic tests available for uterine sarcomas, which are therefore usually discovered postoperatively; (2) as a result, there is no reliable way for physicians to know, pre-operatively, that they are using the device on malignant tissue; (3) physicians are encouraged to use the device even when they do suspect malignancy, through language in the product labeling suggesting that a tissue extraction bag can make the device safe in the

setting of malignancy; (4) evidence shows that malignant tissue can still be disseminated even with the proper use of a tissue extraction bag; and (5) once it has been disseminated by tissue morcellation, uterine sarcoma spreads and upstages rapidly, carries a poor prognosis, and is typically inoperable.

85. At the time Defendants manufactured, designed, marketed, distributed, and sold its power morcellator devices, safer, more practical, alternative treatment options were available to remove Plaintiff's uterus, including but not limited to vaginal or traditional laparotomy approaches to surgery, both of which pose much less risk of dissemination of malignant tissue with comparable efficacy.

86. As a direct and proximate result of the unreasonably dangerous and defective condition of the power morcellator devices, which Defendants manufactured, designed, labeled, marketed, distributed, supplied, or sold, or otherwise placed into the stream of commerce, Defendants are liable to the Plaintiff, Ms. Wilson's estate, and her survivors for her injuries and losses, which Defendants directly and proximately caused, based on the failure to properly and adequately design the power morcellator devices.

87. In addition, as a direct and proximate result of Defendants' manufacturing, designing, labeling, marketing, distributing, supplying, or selling or otherwise placing into the stream of commerce the power morcellator devices used for uterine morcellation, without proper and adequate warnings regarding the potential for those product's to cause harm to humans and, when Defendant knew or should have known of the need for such warnings or recommendations, Ms. Wilson, her estate, the Plaintiff, and Ms. Wilson's other survivors suffered serious injuries and financial losses and other harms, including Ms. Wilson's death, and as further set forth above.

WHEREFORE, on behalf of the survivors and estate of the deceased, Marguerite Wilson, Plaintiff respectfully requests that this Honorable Court enter judgment in their favor and against Defendants, in an amount in excess of \$75,000, plus interest, costs, punitive damages, and attorney's fees.

IV. SECOND CAUSE OF ACTION

Inadequate Warning or Failure to Warn

88. Plaintiff adopts and re-alleges each of the foregoing paragraphs as if fully restated in this sentence and further state as follows:

89. Defendants manufacture, design, market, and sell their power morcellator devices.

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

91. The power morcellator device manufactured, designed, marketed, distributed, and sold by Defendants was defective due to inadequate warning or instruction because at the time it left the control of Defendant and was placed into the stream of commerce, Defendants knew or should have known that their product was unreasonably dangerous, because it substantially and significantly increases the risk of spreading and rapidly upstaging undiagnosed cancer as compared to other treatment options for hysterectomy or myomectomy.

92. Despite the fact that Defendants knew or should have known about the increased risk of dissemination of malignant tissue associated with its power morcellator

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

93. When Defendants manufactured, designed, marketed, distributed, and sold the power morcellator device, they had a duty to ensure the adequate warnings of its dangerous or hazardous properties.

94. At all relevant times, Defendants knew or had reason to know that their product was dangerous or was likely to be dangerous for the use for which it was supplied.

95. At all relevant times, Defendants had no reason to believe that those for whose use their product was supplied would realize its dangerous condition.

96. At all relevant times, Defendants failed to exercise reasonable care to inform users of their product's dangerous condition or the facts that make it likely to be dangerous.

97. As a direct and proximate result of the unreasonably dangerous and defective condition of the power morcellator device used for uterine morcellation, which Defendants manufactured, designed, labeled, marketed, distributed, supplied, or sold, or otherwise placed into the stream of commerce, Defendants are liable to the Plaintiff, Ms. Wilson's estate and her survivors pursuant to §388 of the Restatement (Second) of Torts for her injuries and losses, which Defendants directly and proximately caused, based on

Defendants' failure to properly and adequately manufacture their power morcellator device used for uterine morcellation.

98. In addition, as a direct and proximate result of Defendant's manufacturing, designing, labeling, marketing, distributing, supplying, or selling or otherwise placing into the stream of commerce the power morcellator device used for uterine morcellation, without proper and adequate warnings regarding the potential for said product's harm to humans and as otherwise set forth herein, when said Defendants knew or should have known of the need for such warnings or recommendations, Ms. Wilson, her estate, the Plaintiff, and Ms. Wilson's other survivors suffered serious injuries and financial losses and other harms, including Ms. Wilson's death, and as further set forth above.

WHEREFORE, on behalf of the survivors and estate of the deceased, Marguerite Wilson, Plaintiff respectfully requests that this Honorable Court enter judgment in their favor and against Defendants, in an amount in excess of \$75,000 plus interest, costs, punitive damages, and attorney's fees.

V. THIRD CAUSE OF ACTION

Negligence

99. Plaintiff adopts and re-alleges all foregoing paragraphs as if fully restated in this sentence and further state as follows:

100. Defendants owed a duty of reasonable care to design, manufacture, label, market, distribute, and supply or sell products, including its power morcellator device used for uterine morcellation in such a way as to avoid harm to persons upon whom they are used, such as Plaintiff Marguerite Wilson, and to refrain from such activities following knowledge or constructive knowledge that such product is harmful to persons upon whom it is used.

101. Defendant knew or should have known that in a certain percentage of women, uterine or fibroid cancer exists in a state that is not only undiagnosed before hysterectomy is contemplated, but also undiagnosable.

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

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

104. Defendants therefore owed a duty to warn of the hazards and dangers associated with the use of their power morcellator device for patients such as Plaintiff, so as to avoid exactly this type of harm.

105. Defendants failed to exercise ordinary care in the design, formulation, manufacture, design, distribution, marketing, labeling, and sale of their power morcellator device in that Defendants knew, or should have known, that their product caused such significant bodily harm or death and was not safe for use by consumers.

106. Defendants also failed to exercise ordinary care in the labeling of their power morcellator device, and failed to issue, to consumers and their health care providers, adequate warnings of the increased risk of serious bodily injury or death due to the use of their power morcellator device, as compared to other alternative treatments.

107. Despite the fact that Defendants knew or should have known that their power morcellator device posed a serious and increased risk of bodily harm to consumers,

Defendants continued to manufacture and market the device for use by consumers, including women such as Plaintiff Marguerite Wilson, and continued to knowingly withhold critical safety information, such as the increased risk of dissemination of malignant tissue as compared to other surgical approaches.

108. Defendants knew or should have known that women with undiagnosed uterine sarcoma would undergo surgery in which their power morcellator device was used, and in so doing, would suffer the immediate spread and rapid upstaging of cancer with poor prognosis for survival.

109. 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, or selling or otherwise placing into the stream of commerce, minimally invasive gynecologic products, including their power morcellator device used for uterine morcellation, both generally, and in the following particular respects:

- a. failing to conduct adequate and appropriate testing of their power morcellator device;
- b. putting their power morcellator device on the market without first conducting adequate testing to determine possible side effects;
- c. putting their power morcellator device on the market without adequate testing of its dangers to humans;
- d. failing to recognize the significance of their own and others' testing of, and information regarding, products used for uterine morcellation, including their

- power morcellator device, which testing evidenced their own and similar devices' potential harm to humans;
- e. failing to respond promptly and appropriately to their own and others' testing of, and information regarding products used for uterine morcellation, including their power morcellator device, which indicated their own and similar devices' potential harm to humans;
 - f. failing to promptly and adequately warn of the potential for their power morcellator device to be harmful to humans in violation of Restatement (Second) of Torts, §388;
 - g. failing to promptly and adequately warn of the potential for the metastases of cancer when using their power morcellator device in violation of Restatement (Second) of Torts, §388.
 - h. failing to promptly, adequately, and appropriately recommend testing and monitoring of patients upon whom their power morcellator device was used, in light of such products' potential harm to humans;
 - i. failing to properly, appropriately, and adequately monitor the post-market performance of their power morcellator device and the device's effects on patients;
 - j. concealing from the FDA, National Institutes of Health, the general medical community, and physicians, Defendants' full knowledge and experience regarding the potential that their power morcellator device is harmful to humans;

- k. promoting, marketing, advertising, or selling their power morcellator device for use on patients given Defendants' knowledge and experience of the device's potential harmful effects;
- l. failing to timely withdraw their power morcellator device from the market or warn of its potential dangers, given Defendant's knowledge of the potential for the device to harm humans;
- m. failing to fulfill the standard of care required of a reasonable, prudent, minimally invasive gynecological surgical products manufacturer engaged in the manufacture of those products, specifically Defendants' power morcellator device used for uterine morcellation;
- n. placing or permitting the placement of the power morcellator device into the stream of commerce without warnings of the potential for the product to be harmful to humans or without properly warning of said product's dangerousness;
- o. failing to disclose to the medical community in an appropriate and timely manner facts within Defendants' knowledge relevant to the potential of their power morcellator device to be harmful to humans;
- p. failing to respond or react promptly and appropriately to reports that their power morcellator device, and other similar devices, were causing harm to patients;
- q. disregarding the safety of users and consumers such as Marguerite Wilson, by failing adequately to warn of their power morcellator device's potential to harm humans;
- r. disregarding the safety of users and consumers, such as Marguerite Wilson, by failing to timely withdraw their power morcellator device from the market;

- s. disregarding publicity, government or industry studies, information, documentation and recommendations, consumer complaints, and reports or other information regarding the hazards of the products used for uterine morcellation, including Defendants' own power morcellator device, and the device's potential to harm humans;
- t. failing to exercise reasonable care in informing physicians or hospitals using Defendants' power morcellator device for uterine morcellation about Defendants' own knowledge regarding that product's potential to harm humans;
- u. promoting their device as safe or safer than other comparable methods of tissue removal;
- v. promoting their device on websites aimed at creating user and consumer demand;
- w. such other acts or omissions constituting negligence and carelessness as may appear during the course of discovery or at the trial of this matter.

110. As a direct and proximate result of the negligent, reckless, or wanton acts or omissions of Defendant, Ms. Wilson, her estate, the Plaintiff, and Ms. Wilson's other survivors suffered serious injuries and financial losses and other harms, including Ms. Wilson's death, and as further set forth above.

WHEREFORE, on behalf of the survivors and estate of the deceased, Marguerite Wilson, Plaintiff respectfully requests that this Honorable Court enter judgment in her favor and against Defendants, in an amount in excess of \$75,000 plus interest, costs, punitive damages, and attorney's fees.

VI. FOURTH CAUSE OF ACTION

Breach of Express Warranty

111. Plaintiff adopts and re-alleges all foregoing paragraphs as if fully restated in this sentence and further state as follows:

112. In the advertising and marketing of the products used for uterine morcellation, which was directed to both physicians and hospitals, Defendants warranted that their power morcellator device product or products, were safe for use, which had the natural tendency to induce physicians and hospitals to use the products for patients and for patients to want to be treated with the products.

113. Defendants breached those warranties since their products used for uterine morcellation constituted a serious danger to the user.

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

115. As a direct and proximate result of Defendants' breach of express warranty, Ms. Wilson, her estate, the Plaintiff, and Ms. Wilson's other survivors suffered serious injuries and financial losses and other harms, including Ms. Wilson's death, and as further set forth above.

WHEREFORE, on behalf of the survivors and estate of the deceased, Marguerite Wilson, Plaintiff respectfully requests that this Honorable Court enter judgment in her favor and against Defendants, in an amount in excess of \$75,000, plus interest, costs, punitive damages, and attorney's fees.

VII. FIFTH CAUSE OF ACTION

Breach of Implied Warranty of Merchantability

116. Plaintiff adopts and re-alleges all foregoing paragraphs as if fully restated in this sentence and further state as follows:

117. At all relevant times, Defendants manufactured, distributed, advertised, promoted, and sold the power morcellator device.

118. At all relevant times, Defendants intended that the power morcellator device would be used in the manner that Marguerite Wilson's surgeon in fact used it and Defendants impliedly warranted the product to be of merchantable quality, safe and fit for such use, and was adequately tested.

119. Defendants breached various implied warranties with respect to the power morcellator device, including:

- a. Defendants represented through their labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that the power morcellator device was safe, meanwhile Defendants withheld and concealed information about the substantial risks of serious injury or death associated with using the power morcellator device;
- b. Defendants represented that the power morcellator device was as safe or safer than other alternative surgical approaches that did not include the use of the device, meanwhile Defendants concealed information, which demonstrated that the power morcellator device was not safer than alternatives available on the market; and,

c. Defendants represented that the power morcellator device was more efficacious than other alternative surgical approaches and techniques, while Defendants concealed information regarding the true efficacy of their products.

120. Additionally, Defendants' failure to adequately warn consumers and users of the product of its dangers rendered the product unreasonably dangerous for its intended purposes, including uterine morcellation.

121. In reliance upon Defendants' implied warranty, Marguerite Wilson's surgeon used Defendants' products as prescribed and in the foreseeable manner normally intended, recommended, promoted, instructed, and marketed by Defendant.

122. Defendants breached their implied warranty to Marguerite Wilson since their power morcellator device was not of merchantable quality, safe, and fit for its intended use, nor was it adequately tested.

123. As a direct and proximate consequence of Defendants' breach of implied warranty or intentional acts, omissions, misrepresentations, or other culpable acts described in this Complaint, Ms. Wilson, her estate, the Plaintiff, and Ms. Wilson's other survivors suffered serious injuries and financial losses and other harms, including Ms. Wilson's death, and as further set forth above.

WHEREFORE, on behalf of the survivors and estate of the deceased, Marguerite Wilson, Plaintiff respectfully requests that this Honorable Court enter judgment in her favor and against Defendants, in an amount in excess of \$75,000, plus interest, costs, punitive damages, and attorney's fees.

VIII. SIXTH CAUSE OF ACTION

Breach of Implied Warranty of Fitness

124. Plaintiff adopts and re-alleges all foregoing paragraphs as if fully restated in this sentence and further state as follows:

125. At the time Defendants manufactured, designed, marketed, sold, or distributed the power morcellator device, Defendants had actual or constructive knowledge that consumers would choose Defendants' product for its ordinary purpose (the minimally invasive removal of uterus or fibroids).

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

127. Contrary to this implied warranty of fitness, the Defendants' power morcellator device was not fit or safe for Marguerite Wilson's use, because the power morcellator device was unreasonably dangerous compared to other available surgical approaches to hysterectomy as previously described.

128. As a direct and proximate result Defendants' breach of implied warranty of fitness or failure to comply with applicable federal requirements, Ms. Wilson, her estate, the Plaintiff, and Ms. Wilson's other survivors suffered serious injuries and financial losses and other harms, including Ms. Wilson's death, and as further set forth above.

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

WHEREFORE, on behalf of the survivors and estate of the deceased, Marguerite Wilson, Plaintiff respectfully requests that this Honorable Court enter judgment in her favor and against Defendants, in an amount in excess of \$75,000, plus interest, costs, punitive damages, and attorney's fees.

IX. PRAYER FOR RELIEF

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

- i. Compensatory damages in excess of the minimum jurisdictional amount, including but not limited to compensation for injury, pain, suffering, mental anguish, emotional distress, loss of enjoyment of life, and other non-economic damages in an amount to be determined by the trier of fact in this action;
- ii. Economic damages in the form of medical expenses, out-of-pocket expenses, child care expenses, life care expenses, lost earnings, and other economic damages in an amount to be determined by the trier of fact in this action;
- iii. Damages for impairment and disfigurement, or both, in an amount to be determined by the trier of fact in this action;
- iv. Attorneys' fees, expenses, and costs of this action;
- v. Interest on all damages as allowed by law;
- vi. Punitive damages; and
- vii. Such further relief as this Honorable Court deems necessary, just, and proper.

Respectfully submitted this 28th day of December 2015.

BURG, SIMPSON
ELDREDGE, HERSH & JARDINE, P.C.

/s/Rick D. Bailey

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Englewood, Virginia 80112
(303) 792-5595
Fax: (303) 708-0527
rbailey@burgsimpson.com
COUNSEL FOR PLAINTIFF

X. DEMAND FOR JURY TRIAL

Plaintiff demands trial by jury as to all issues so triable.

/s/ Rick Bailey

CIVIL COVER SHEET

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

I. (a) PLAINTIFFS

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

(c) Attorneys (Firm Name, Address, and Telephone Number)

DEFENDANTS

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, 2 U.S. Government Defendant, 3 Federal Question (U.S. Government Not a Party), 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)

- Citizen of This State, Citizen of Another State, Citizen or Subject of a Foreign Country, PTF DEF, Incorporated or Principal Place of Business In This State, Incorporated and Principal Place of Business In Another State, Foreign Nation

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

Table with 5 columns: CONTRACT, REAL PROPERTY, TORTS, CIVIL RIGHTS, PRISONER PETITIONS, FORFEITURE/PENALTY, LABOR, IMMIGRATION, BANKRUPTCY, SOCIAL SECURITY, FEDERAL TAX SUITS, OTHER STATUTES. Contains various legal categories and checkboxes.

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 (Enter U.S. Civil Statute under which you are filing and write a brief statement of cause.)

VII. Previous Bankruptcy Matters (For nature of suit 422 and 423, enter the case number and judge for any associated bankruptcy matter previously adjudicated by a judge of this Court. Use a separate attachment if necessary.)

VIII. REQUESTED IN COMPLAINT: CHECK IF THIS IS A CLASS ACTION UNDER RULE 23, F.R.Cv.P.

DEMAND \$

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

IX. RELATED CASE(S) IF ANY

(See instructions):

JUDGE

DOCKET NUMBER

X. This case (check one box) Is not a refiling of a previously dismissed action is a refiling of case number previously dismissed by Judge

DATE

SIGNATURE OF ATTORNEY OF RECORD

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. Previous Bankruptcy Matters For nature of suit 422 and 423 enter the case number and judge for any associated bankruptcy matter previously adjudicated by a judge of this court. Use a separate attachment if necessary.

VIII. 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.

IX. 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.

X. Refiling Information. Place an "X" in one of the two boxes indicating if the case is or is not a refiling of a previously dismissed action. If it is a refiling of a previously dismissed action, insert the case number and judge.

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