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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

VIVIANA RUSCITTO, Plaintiff, -vs- THE VALLEY HOSPITAL, INC., HOWARD H. JONES, M.D., EUGENIA C. KUO, M.D., CELESTE A. TELFEYAN, D.O., KARL STORZ ENDOSCOPY-AMERICA, INC., KARL STORZ ENDOVISION, INC., KARL STORZ GMBH & CO.KG, and JOHN DOES (1-10) AND XYZ CORP (1-10) (such names and corporations being fictitious) Defendants.	CIVIL CASE NO.: Civil Action **COMPLAINT AND JURY DEMAND**

Plaintiff, VIVIANA RUSCITTO, residing at 107 Birchwood Avenue in Upper Nyack, New York, 10960 by way of Complaint against the Defendants, says:

NATURE OF THE ACTION

1. This is an action brought by Plaintiff, VIVIANA RUSCITTO for damages suffered as a direct and proximate result of the defective and unreasonably dangerous surgical instrument, the # Unidrive GYN 20711120 ("Unidrive") power morcellator, used during her laparoscopic supracervical hysterectomy and bilateral salpingectomy procedures for the treatment of uterine fibroids. At all times relevant hereto, the # Unidrive GYN 20711120 ("Unidrive") was manufactured, designed, tested, packaged, labeled, produced,created, made, constructed, assembled, marketed, advertised, distributed and sold by Defendants KARL STORZ ENDOSCOPY-AMERICA, INC., KARL STORZ ENDOVISION, INC., KARL STORZ GMBH & CO.KG (collectively "KARL STORZ").

2. As a result of the use of the # Unidrive GYN 20711120 ("Unidrive") on Plaintiff, she suffered injuries to her person including metastasized Stage 4 cancer. She must undergo extensive and difficult treatments for her advanced-stage cancer, including daily medications, regular injections and multiple rounds of radiation therapy. Plaintiff has experienced the ill-effects

of both her cancer and cancer treatments including, but not limited to, fatigue, body pain, joint pain, stiffness, inflammation, swelling, insomnia, and gastrointestinal distress.

PARTIES

3. At all times relevant hereto, Plaintiff, VIVIANA RUSCITTO was residing at 107 Birchwood Avenue in Upper Nyack, New York, 10960
4. Defendant Karl Storz Endoscopy-America, Inc. (hereinafter "KS Endoscopy"), is a California corporation with its principal place of business at 2151 E. Grand Avenue, El Segundo, CA, 0245. Upon information and belief, Defendant KS Endoscopy is responsible for the sales, marketing and distribution of products in the United States for the manufacturer Defendant Karl Storz GMBH & Co.KG, including the # Unidrive GYN 20711120 ("Unidrive") power morcellator.
5. At all relevant times, Defendant KS Endoscopy has transacted and conducted business in the State of New Jersey and derived substantial revenue from interstate commerce.
6. Defendant Karl Storz Endovision, Inc. (hereinafter "KS Endovision"), is a Massachusetts corporation with its principal place of business at 91 Carpenter Hill, Charlton, MA, 01507. Upon information and belief, Defendant KS Endovision is responsible for the manufacturing of Karl Storz

instruments distributed in the United States, including the # Unidrive GYN 20711120 ("Unidrive") power morecellator.

7. At all relevant times, Defendant KS Endovision has transacted and conducted business in the State of New Jersey and derived substantial revenue from interstate commerce.

8. Defendant Karl Storz GMBH & Co. KG, (hereinafter "Karl Storz") is a foreign entity organized in Germany with its principal place of business at Dr. Karl-Storz-Straße 34, 78532 Tuttlingen, Germany. Upon information and belief, Defendant Karl Storz is the parent company of Karl Storz Endovision, Inc., and Karl Storz Endoscopy-America, Inc. and together with the other Defendants, Karl Storz is responsible for the design, production, marketing, manufacturing, and sale of all information for Karl Storz products, including the # Unidrive GYN 20711120 ("Unidrive") power morcellator.

9. At all relevant times, Defendant Karl Storz has transacted and conducted business in the State of New Jersey and derived substantial revenue from interstate commerce.

10. Upon information and belief, Defendants Karl Storz have purposefully availed themselves of the benefits of doing business in New Jersey through manufacturing, designing, labeling, marketing, distributing, supplying and/or

selling, the # Unidrive GYN 20711120 ("Unidrive") power morcellator, and by placing it into the stream of commerce for those purposes, and by promoting, selling and intending its use for the surgery of Plaintiff in New Jersey. As Defendants KS Endoscopy and KS Endovision are the alter egos of Defendants Karl Storz, all of the above activities are imputed to Defendants Karl Storz as well.

11. That at all times hereinafter mentioned, Defendant HOWARD H. JONES, M.D. ("JONES") was and is an obstetrician and gynecological doctor duly licensed to practice medicine in the State of New Jersey.

12. That at all times hereinafter mentioned, Defendant JONES specialized and specializes in the field of gynecological surgery.

13. That at all times hereinafter mentioned, Defendant JONES maintained and maintains an office for the practice of medicine at 1 Valley Health Plaza Paramus, New Jersey 07652.

14. That at all times hereinafter mentioned, Defendant EUGENIA C. KUO ("KUO") was and is a physician duly licensed to practice medicine in the State of New Jersey.

15. That at all times hereinafter mentioned, Defendant KUO specialized and specializes in the field of gynecological surgery.

16. That at all times hereinafter mentioned, Defendant KUO was a resident and

an employee of the Valley Hospital, and maintained and maintains an office for the practice of medicine at 223 N. Van Dien Avenue Ridgewood, New Jersey 07450.

17. That at all times hereinafter mentioned, Defendant CELESTE A. TELFEYAN ("TELFEYAN") was and is a physician duly licensed to practice medicine in the State of New Jersey.

18. That at all times hereinafter mentioned, Defendant TELFEYAN specialized and specializes in the field of anesthesiology.

19. That at all times hereinafter mentioned, Defendant TELFEYAN, maintained and maintains an office for the practice of medicine at Valley Hospital at 223 N. Van Dien Avenue Ridgewood, New Jersey 07450.

20. That at all times hereinafter mentioned, Defendant THE VALLEY HOSPITAL, INC. ("VALLEY") is and was a domestic corporation, duly incorporated and existing by virtue of the Laws of the State of New Jersey with a principal place of business located at 223 N. Van Dien Avenue Ridgewood, New Jersey 07450.

21. Upon information and belief, Defendants John Does (1 through 10) and XYZ Corporations (1-10) (the "Doe Defendants") are corporations or other business entities, the names and addresses of which are unknown, who were involved in the business of developing, designing, licensing, manufacturing,

distributing, selling, marketing, promotion and/or introducing into interstate commerce, either directly or indirectly through third parties, subsidiaries or related entities, the # Unidrive GYN 20711120 ("Unidrive") power morecellator.

22. In the interest of clarity, this complaint refers to Defendant KS Endoscopy, Defendant KS Endovision, Defendant Karl Storz as "Defendants Karl Storz."

23. Defendants do business in New Jersey, where Plaintiff underwent her operation during which the # Unidrive GYN 20711120 ("Unidrive") power morecellator was used, through the sales of the # Unidrive GYN 20711120 ("Unidrive") and other medical devices and instruments in the state.

24. At all times relevant, Defendants were engaged in the business of developing, designing, licensing, manufacturing, distributing, selling, marketing, promoting and/or introducing into interstate commerce, either directly or indirectly through third parties, subsidiaries or related entities, the power morcellator.

25. At all times alleged herein, Defendants include and included any and all parents, subsidiaries, affiliates, divisions, franchises, partners, joint venturers, and organizational units of any kind, their predecessors,

successors and assigns and their officers, directors, employees, agents, representatives and any and all other persons acting on their behalf.

26. At all times herein mentioned, each of the Defendants, Defendant Karl Storz GMBH & Co. KG, Karl Storz Endovision, Inc., and Karl Storz Endoscopy-America, Inc., was the agent, servant, partner, predecessors in interest, aider and abettor, co-conspirator and joint venturer of eachother and was at all times operating and acting with the purpose and scope of said agency, service, employment, partnership, conspiracy and joint venture.

JURISDICTION AND VENUE

27. This Court has jurisdiction over this action pursuant to 28 U.S.C.A. § 1332, as there is complete diversity of citizenship between Plaintiff and Defendants, and the amount in controversy exceeds $75,000, exclusive of interest and costs.

28. Venue is proper in the District of New Jersey pursuant to 28 U.S.C.A. § 1391, as a substantial part of the events giving rise to these claims occurred within this district, including the sale and use of the power morcellator on the Plaintiff, as well as Plaintiff's resulting injuries.

29. The Court has personal jurisdiction over Defendants consistent with the New Jersey and United States Constitutions because Defendants transacted business in New Jersey and caused tortious injury in New Jersey by an act or

omission outside New Jersey by virtue of Defendants' regularly conducted business in New Jersey from which they respectively derive substantial revenue. Defendants do substantial business in the State of New Jersey, advertise in this district, and receive substantial compensation and profits from sales of the power morcellator within this District.

30. Defendants expected or should have expected that their business activities could or would have consequences within the State of New Jersey, as well as throughout the United States.

FACTS COMMON TO ALL COUNTS

22. On October 17, 2014, Plaintiff VIVIANA RUSCITTO ("PLAINTIFF") underwent a robotic assisted laparoscopic supracervical hysterectomy and bilateral salpingectomy, with the removal of the umbilical hernia sac procedure at defendant, The Valley Hospital in Ridgewood, New Jersey.

23. On October 17, 2014, Plaintiff's surgery at The Valley Hospital ("HOSPITAL") was performed by Howard H. Jones, M.D ("JONES"); Eugenia C. Kuo, M.D. ("KUO") who assisted; and Celeste A. Telfeyan, D.O. ("TELFEYAN"), as the anesthesiologist. Defendants JOHN DOES (1-10) and XYZ CORP (1-10) (such names and corporations being fictitious) were individuals or corporations otherwise involved in the surgery on the

PLAINTIFF or the manufacture and distribution of the power morcellator described below.

24. Prior to Plaintiff's surgery on October 17, 2014, she had no known evidence of cancer.

25. On or before October 17, 2014, PLAINTIFF was never warned of the danger and likelihood that the use of a laparoscopic power morcellator device could disseminate and upstage unsuspected cancer. In fact, PLAINTIFF was specifically concerned about ovarian cancer, and verbally communicated her concerns to her surgeon, JONES who duly documented the Plaintiff's concerns.

26. During the surgery, JONES used a power morcellator produced and sold by Karl Storz Endoscopy-America Inc.("KARL STORZ ENDOSCOPY"), model # Unidrive GYN 20711120 ("Unidrive") and manufactured Karl Storz Endovision, Inc.("KARL STORZ ENDOVISION"), to assist in the removal of Plaintiff's uterus.

27. On October 22, 2014, a Dr. Christiano of the Pathology Department of the HOSPITAL diagnosed PLAINTIFF with leiomyosarcoma. This diagnosis was confirmed by Dr. Young of Massachusetts General Hospital on October 29, 2014.

28. Plaintiff began cancer treatment at Memorial Sloan Kettering ("MSK"), and

MSK discovered through a CT Scan that the HOSPITAL failed to diagnose an ovarian vein clot in the PLAINITFF and which clot now requires that the PLAINTIFF inject herself daily with Lovenox, a blood thinner, to prevent serious injury.

29. On November 28, 2014, Plaintiff underwent a total open hysterectomy, exploratory surgery and a total abdominal pelvic wash by Carol M. Brown, M.D. at MSK, and the procedures required PLAINTIFF to remain in MKS as an inpatient for four full days.

30. Plaintiff has suffered multiple metastases, including the right side of her abdomen, two pelvic lesions and multiple lung lesions.

31. On or about December 22, 2014, Plaintiff began chemotherapy treatment at MSK under the supervision and care of Martee Hensley, M.D. The chemotherapy treatment is expected to continue until February 2016. Plaintiff has received 9 cycles of a total of 21 cycles of chemotherapy to the present date.

32. Plaintiff receives chemotherapy for two weeks, then has one week off. She arrives at MSK on Mondays at 7:45 a.m. to have lab work to clear her and her blood for chemotherapy, and then she meets with the doctor. She begins receiving chemotherapy through an IV from about 10 a.m. to about 12 p.m. For the first week of the cycle, she receives Gemicitabine and during the

second, she receives Gemicitabine and Doxitaxale. Due to an allergy to Gemicitabine, Plaintiff also receives Benadryl via IV during her treatments. On Tuesdays, following her chemotherapy, Plaintiff receives an injection of Meulasta, which is used to promote blood cell growth, as chemotherapy is killing her white blood cells.

33. The doctors at MSK surgically installed a Mediport, which was a same day surgery, so that Plaintiff can have IVs without inserting a needle into her arm for each treatment day.

34. Each and every Defendant herein failed to warn Plaintiff or her physician about the possibility of dissemination of an occult uterine leiomyosarcoma throughout the abdomen.

35. Defendants were each aware of the risks, complications, and/or adverse events associated with the products used for uterine morcellation.

36. Had the laparoscopic power morcellator used on Plaintiff not released and disseminated cancerous tissue, she would not have been diagnosed with an advanced Stage IV metastatic cancer and/or would not have suffered and been diagnosed with leiomyosarcoma.

37. The laparoscopic power morcellator used on Plaintiff during her October 17, 2014 surgery caused Plaintiff's current cancerous condition, and it has profoundly and gravely injured Plaintiff.

38. As a result of the conduct alleged herein by Defendants, Plaintiff suffered serious bodily injury and is likely to die from her condition. In addition to the medical bills that Plaintiff has and will continue to incur, she will also continue to suffer severe physical and mental pain as a result of her terminal condition.

BACKGROUND ON LAPAROSCOPIC POWER MORCELLATOR

39. In the United States, it is estimated that 600,000 women a year will undergo a surgical myomectomy or hysterectomy for the management of symptomatic uterine fibroids.

40. In conventional, non-power morecellator hysterectomies, the women's entire uterus is removed essentially intact and in conventional myomectomies, the uterine fibroid are removed essential intact and the women's uterus is left intact.

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

42. Laparoscopic Power Morcellators are electronically 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.

43. 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.

44. 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.

45. 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 cancerous cells can travel to remote areas of the body through the vasculature or lymphatic systems.

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

47. As a result, use of a Laparoscopic Power Morcellator can spread and upstage a women's undetected cancer, changing the stage of the cancer from an early stage cancer into a much higher stage cancer and significantly worsening a woman's prognosis.

48. Defendants promoted their device as a safe and effective tool for its intended

use, including the treatment of uterine fibroids. Defendants, however, knew or should have known of about the risks of morcellation surgery, including subsequent development of cancer outside the uterus.

49. On April 17, 2014, the FDA issued a safety communication discouraging the use of laparoscopic power morcellation during hysterectomy or myomectomy for uterine fibroids, stating that "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." The FDA discouraged this practice because of this risk and the fact that "there is no reliable method for predicting whether a women with fibroids may have a uterine sarcoma."

50. On November 24, 2014, the FDA updated its prior safety communication regarding power morcellators. Rather than merely discouraging power morcellation in the treatment of uterine fibroids, the FDA now warns against "the use of laparoscopic power morcellators in the majority of women undergoing myectomy or hysterectomy for treatment of fibroids."

51. The FDA stated that "if laparoscopic power morcellation is performed in women with unsuspected uterine sarcoma [a type of cancer], there is a risk that the procedure will spread the cancerous tissue within the abdomen and

pelvis**, significantly worsening the patient's long-term survival**." [emphasis added]

52. Despite Defendants' knowledge of the risks of morcellation surgery, they failed to adequately warn about the true risk of dissemination of cancerous cells, subsequent development of cancer outside the uterus and the possible need for radiation treatment and chemotherapy treatment following the use of the power morcellator.

53. Defendants also failed to provide and manufacture an instrument safe for its intended use.

54. The Defendants designed, manufactured, marketed, and sold the power morcellator for uterine surgery, specifically for cuffing, shredding, and removing the uterus and uterine fibroids. Defendants therefore knew of and intended the use of their morcellator for surgical cases such as Plaintiff's surgery. Reasonable and feasible alternative designs existed, including the surgical tissue bag and method, which has been available since 1991, long before the power morcellator was marketed and used. Defendants knew or should have known that use of the tissue bag could prevent the spread of malignant cells to healthy tissue in the body cavity, yet failed to require concomitant use of the bag, or warn that failure to use the tissue bag can lead to subsequent development of cancer outside the uterus.

55. Because of Defendants' failure to adequately warn surgeons of the risk of morcellator use and Defendants' failure to adequately recommend, require or provide a safe, closed system tissue bag for use with the power morcellator to prevent dissemination of an unsuspected cancer, Plaintiff suffered injury, including metastasized cancer.

COUNT 1: MEDICAL MALPRACTICE

56. That at all times hereinafter mentioned, Defendant HOWARD H. JONES, M.D. ("JONES") was and is an obstetrician and gynecological doctor duly licensed to practice medicine in the State of New Jersey.

57. That at all times hereinafter mentioned, Defendant JONES specialized and specializes in the field of gynecological surgery.

58. That at all times hereinafter mentioned, Defendant JONES maintained and maintains an office for the practice of medicine at 1 Valley Health Plaza Paramus, New Jersey 07652.

59. That at all times hereinafter mentioned, Defendant EUGENIA C. KUO ("KUO") was and is a physician duly licensed to practice medicine in the State of New Jersey.

60. That at all times hereinafter mentioned, Defendant KUO specialized and specializes in the field of gynecological surgery.

61. That at all times hereinafter mentioned, Defendant KUO was a resident and

an employee of the Valley Hospital, and maintained and maintains an office for the practice of medicine at 223 N. Van Dien Avenue Ridgewood, New Jersey 07450.

62. That at all times hereinafter mentioned, Defendant CELESTE A. TELFEYAN ("TELFEYAN") was and is a physician duly licensed to practice medicine in the State of New Jersey.

63. That at all times hereinafter mentioned, Defendant TELFEYAN specialized and specializes in the field of anesthesiology.

64. That at all times hereinafter mentioned, Defendant TELFEYAN, maintained and maintains an office for the practice of medicine at Valley Hospital at 223 N. Van Dien Avenue Ridgewood, New Jersey 07450.

65. That at all times hereinafter mentioned, Defendant THE VALLEY HOSPITAL, INC. ("VALLEY") is and was a domestic corporation, duly incorporated and existing by virtue of the Laws of the State of New Jersey with a principal place of business located at 223 N. Van Dien Avenue Ridgewood, New Jersey 07450.

66. That at all times hereinafter mentioned, Defendant VALLEY owns, operates, controls, and maintains surgical suites and/or operating rooms, which physicians, including Defendants JONES, KUO, and TELFEYAN, used and use in connection with the surgery performed on Plaintiff on

October 17, 2014.

67. That at all times hereinafter mentioned, Defendant VALLEY supplied, permitted, allowed, used and/or provided Defendant Karl Storz GMBH & Co. KG, Karl Storz Endovision, Inc., and Karl Storz Endoscopy-America, Inc.'s Unidrive power morcellator to Defendants JONES, KUO and TELFEYAN in connection with Plaintiff's October 17, 2014 gynecological surgery.

68. That Defendants JONES, KUO and TELFEYAN undertook to and did render certain medical care, diagnosis, and/or treatment to Plaintiff on or before October 17, 2014.

69. That on or before October 17, 2014, Defendant JONES met with and performed a physical examination of Plaintiff VIVIANA RUSCITTO, including of her lower abdomen.

70. That on or before October 17, 2014, Defendant JONES took a history from Plaintiff VIVIANA RUSCITTO of her physical condition.

71. That on or before October 17, 2014, Defendant JONES reviewed the results of an abdominal MRI that showed "a large 8 cm posterior submucosal fibroid that is degenerating."

72. That on or before October 17, 2014, Defendant JONES also noted that Plaintiff had fibroids, menorrhagia, and that she was noted to have heavier

bleeding that had been increasing over the last year.

73. That on or before October 17, 2014, Defendant JONES neither requested nor sought a biopsy of Plaintiff's large 8 cm posterior submucosal degenerating fibroid.

74. That on or before October 17, 2014, Defendant JONES did not consider or schedule Plaintiff for a Dilation and Curettage (D&C).

75. That on October 17, 2014, Defendants JONES, KUO, and TELFEYAN, under general endotracheal anesthesia, performed on the Plaintiff a robotic assisted laparoscopic supracervical hysterectomy, bilateral salpingectomy, with the removal of the umbilical hernia sac at Defendant VALLEY (hereinafter described as "the surgery").

76. That on October 17, 2014, Defendants JONES, KUO, and TELFEYAN discovered that the uterus had multiple large fibroids, several anterior and several large posterior lower uterine segment fibroids.

77. That on October 17, 2014, Defendants JONES, KUO, and TELFEYAN, introduced the Defendant Karl Storz GMBH & Co. KG, Karl Storz Endovision, Inc., and Karl Storz Endoscopy-America, Inc.'s Unidrive power morcellator through the left lower quadrant port, and then proceeded to serially morcellate the Plaintiff's uterus intra-abdominally.

78. That on October 17, 2014, the post-operative pathology report on portions of

the uterus indicated leiomyoscarcoma.

79. That on or before October 17, 2014, Defendant JONES knew, and Plaintiff specifically told him, that she had tremendous anxiety of ovarian cancer.

80. That Defendants VALLEY, JONES, KUO, TELFEYAN, their agents, servants, and/or employees, held themselves out to the public, and specifically to Plaintiff VIVIANA RUSCITTO, as utilizing and employing medical personnel possessing the proper degree of learning and skill necessary to render proper medical care, perform a hysterectomy, and a salpingectomy in accordance with good and accepted medical practices, and that they undertook to use reasonable care and diligence in the treatment of patients, especially Plaintiff VIVIANA RUSCITTO, herein.

81. That Defendants VALLEY, JONES, KUO, and TELFEYAN, their agents, servants, and/or employees, were negligent and careless in failing to perform a pre-operative and/or inter-operative biopsy on Plaintiff's large 8 cm posterior submusocal degenerating fibroid; in negligently using or employing a power morcellator in connection with Plaintiff's hysterectomy and salpingectomy and intentionally shredding and spreading the leiomyosarcoma all over Plaintiff's abdomen; in negligently failing to use a bag or sac internally to prevent the spread and contamination of the internal abdominal cavity with leiomyosarcoma; in failing to convert Plaintiff's

laparoscopic hysterectomy into an open procedure and simply removing the uterus in its entirety;) in failing to perform a limited open procedure to remove plaintiff's uterus, or alteratively removing the uterus via her vagina, and thus avoiding morcellation completely; in failing to follow and adhere to previous well-publicized and commonly disseminated FDA warnings, which strongly advised against using power morcellators and required that patients be fully advised of the risks associated with using a power morcellator, including the spreading of leiomyosarcoma throughout the abdominal cavity, and potential upstaging a patient's cancer; in failing to advise Plaintiff of any risks associated with the power morcellator, including but not limited to the risk that the large fibroid could contain leiomyosarcoma, and that the cancer could be spread throughout her abdominal cavity, thus increasing staging and decreasing Plaintiff's best chance of survival; in failing to advise Plaintiff of alternative procedures available to the power morcellator, including an open hysterectomy, which were substantially safer to the patient; in the hospital failing to ensure the safety of the patient by prohibiting the use of the power morcellator during the laparoscopic hysterectomy, insisting that a bag be used to isolate any potentially cancerous tissue; and/or securing the patient's informed written consent regarding the increased risks of spreading her cancer and decreasing her

chances of survival; in the hospital, through its CEO, in failing to develop policies and safeguards to ensure that all patients, including Plaintiff VIVIANA RUSCITTO, were adequately informed and protected from doctors using power morcellators; in failing to obtain valid informed consent from Plaintiff, including ensuring that the scope of surgery agreed to by the Plaintiff was what the Defendants intended to perform, thus deviating from the standard of care; in failing to implement a "time out procedure," as indicated by community standards, ensuring that the surgical team members understand the scope and limitations of the procedure, and in failing to have the members of the surgical team sign off on the verification form; in failing to file a Sentinel Event Report, which is required by community standards when an unanticipated outcome of significant injury or death occurs; in failing to supervise, hire, train, retain, and employ competent staff at the hospital, to monitor FDA warnings, and disseminate that information to hospital staff to ensure compliance by its attending physicians who perform surgeries at its facilities; in failing to update hospital policy and protocols in response to the Society of Gynecological Oncology's December 2013 Position Statement, outlining the risks, hazards and dangers of power morcellation, and indicating that all risks, benefits and alternatives to such a procedure should be discussed with a patient so that "an informed and

voluntary decision" may be made; in failing to update hospital policy and protocols in response to the FDA's April 17, 2014 Safety Communication, which discourages the use of "laparoscopic power morcellation during hysterectomy or myomectomy for uterine fibroids" and which encouraged health care providers to "thoroughly discuss the benefits and risks of all treatments with patients," as well as informing patients that unknown cancer may spread and worsen their prognosis; in failing to update hospital policy and protocols in response to the FDA's April 17, 2014 Media Release, which discouraged the use of laparoscopic power morcellators for hysterectomies and myomectomies, as well as recommending that health care professionals "carefully consider all available treatment options" for women with uterine fibroids, and to discuss all benefits and risks associated with the use of power morcellation; in failing to update hospital policy and protocols in response to the American College of Obstetricians and Gynecologists' May 2014 Special Report, which discouraged the use of power morcellation, and stated that "alternative treatment options as well as risks and benefits should be discussed" with patients and that patients must also be advised that "if occult cancer is present and morcellation is used…there is a risk that the cancer may spread and worsen the patient's outcome;" in failing to update hospital policy and protocols in response to a

manufacturer's warning and notification of the aforementioned FDA pronouncements, and the dangers of the use of power morcellation in hysterectomies and myomectomies; in failing to make use of the best medical judgments available, in that the Defendants were guilty of negligence and malpractice, both active and passive, in the care and treatment of Plaintiff VIVIANA RUSCITTO, and also guilty of negligence and malpractice under the theory of res ipsa loquitur, and in otherwise being careless and negligent at or about the aforesaid time and place.

82. That as a result of the foregoing, the Defendants caused Plaintiff VIVIANA RUSCITTO's leiomyocarcoma to be substantially upstaged, and she sustained an extension and spreading of her cancer, and has been caused to suffer severe physical injuries, including a surgery in an attempt to remove all of her uterus that was morcellated by Defendants intra-abdominally, as well as a complete abdominal body wash, extensive chemotherapy treatments, pain and mental anguish, severe shock, and a decrease in her life expectancy; has been caused to incur certain expenses for medical attention and surgery; and has been caused to abstain from the duties of her vocation. Plaintiff is also expected to have a substantial future lost wage claim.

83. The amount of damages herein exceeds the jurisdictional limit of all lower courts, which would otherwise have jurisdiction in this matter.

84. As a result of the foregoing, Plaintiff sustained injuries and demands damages against THE VALLEY HOSPITAL, INC., HOWARD H. JONES, M.D., EUGENIA C. KUO, M.D., and CELESTE A. TELFEYAN, D.O. in an unspecified amount, together with costs and disbursements of this action to be determined by a jury at the time of trial.

COUNT 2: LACK OF INFORMED CONSENT

85. Plaintiff VIVIANA RUSCITTO repeats, reiterates and re-alleges each and every allegation contained in paragraphs "1" through "84" as is set forth herein at length.

86. That there were certain risks, hazards, and dangers with respect to the course of treatment and lack thereof undertaken by the Defendants.

87. That Defendant failed to warn and advise Plaintiff VIVIANA RUSCITTO of the risks, hazards, and dangers of aforesaid course of treatment.

88. That Plaintiff VIVIANA RUSCITTO had the right to know the risks, hazards, and dangers of the aforesaid course of treatment and the available alternatives to it.

89. That had the Plaintiff VIVIANA RUSCITTO known of the risks, hazards, and dangers of the aforesaid course of treatment, she would not have consented.

90. That had the Plaintiff VIVIANA RUSCITTO, or any reasonable person, been informed of the risks, hazards, and dangers with respect to the aforesaid course of treatment, they would not have consented to it.

91. That as a result of the foregoing, Plaintiff's leiomyosarcoma of the fibroid uterus was substantially upstaged, and she sustained an extension and spreading of her cancer; she also lost her best chances for survival and has been caused to suffer severe physical injuries, including unnecessary surgical procedures, extensive chemotherapy, pain and mental anguish, severe shock, and a decrease in life expectancy; has been caused to incur certain expenses for medical attention and surgery; and has been caused to abstain from the duties of her vocation presently and in the future.

92. The amount of damages herein exceeds the jurisdictional limit of all lower courts, which would otherwise have jurisdiction in this matter.

93. As a result of the foregoing, Plaintiff sustained injuries and demands damages against THE VALLEY HOSPITAL, INC., HOWARD H. JONES, M.D., EUGENIA C. KUO, M.D., and CELESTE A. TELFEYAN, D.O. in an unspecified amount, together with costs and disbursements of this action to be determined by a jury at the time of trial.

COUNT 3:PRODUCTS LIABILITY AND DEFECTIVE DESIGN

94. Plaintiff, VIVIANA RUSCITTO, repeats, reiterates, and re-alleges each and every allegation contained in paragraphs "1" through "93" as set forth herein at length.

95. That Defendant KARL STORZ ENDOSCOPY-AMERICA, INC. ("KARL STORZ ENDOSCOPY") is and was a foreign for-profit corporation duly incorporated and existing under the Laws of the State of California, and duly filed and existing as a foreign for-profit corporation under the Laws of the State of New Jersey with a principal place of business at 600 Corporate Pointe Culver City, California 90230.

96. That Defendant, KARL STORZ ENDOVISION, INC., ("KARL STORZ ENDOVISION") is and was a foreign for-profit corporation duly incorporated and existing under the Laws of the State of Massachusetts, with a principal place of business at 91 Carpenter Road Charlton, Mass 01507.

97. Defendant Karl Storz GMBH & Co. KG, (hereinafter "Karl Storz") is a foreign entity organized in Germany with its principal place of business at Dr. Karl-Storz-Straße 34, 78532 Tuttlingen, Germany and is the parent company of Karl Storz Endovision, Inc., and Karl Storz Endoscopy-America, Inc. and together with the other Defendants, Karl Storz is responsible for the design, production, marketing, manufacturing, and sale of all information for Karl Storz products, including the # Unidrive GYN

20711120 ("Unidrive") power morcellator.

98. That Defendant, KARL STORZ ENDOVISION was and is a manufacturer of the laparoscopic power morcellators.

99. Defendant KARL STORZ ENDOSCOPY was responsible for designing, researching, developing, testing, manufacturing, packaging, labeling, marketing, promoting, distributing and/or selling laparoscopic power morcellators.

100. Defendant, KARL STORZ ENDOVISION, was responsible for designing, researching, developing, testing, manufacturing, packaging, labeling, marketing, promoting, distributing and/or selling laparoscopic power morcellators.

101. That prior to Plaintiff VIVIANA RUSCITTO's October 17, 2014 surgery, Defendants KARL STORZ knew or should have known that their laparoscopic power morcellators could cause occult malignant tissue fragments to be disseminated and implanted in the body, upstaging cancer and significantly decreasing the best chance of survival for a patient.

102. Defendants KARL STORZ failed to respond to published and well-publicized reports warning of the risks, hazards, and dangers of using laparoscopic power morcellators during hysterectomies and myomectomies by either changing the design of their product or taking it off the market.

103. On information and belief, that Defendant, KARL STORZ ENDOSCOPY, in accordance with industry practice, monitors medical and lay media channels for issues concerning their products.

104. On information and belief, that Defendant KARL STORZ, in accordance with industry practice, monitors medical and lay media channels for issues concerning their products.

105. That Defendants, KARL STORZ knew or should have known that laparoscopic power morcellators, specifically model Unidrive GYN 20711120 SN# (LB 2459) & (HB 2392), could cause the spread of occult malignant cancer based on the well-publicized April 17, 2014 Media Release and Safety Communication issued by the FDA.

106. That Defendants, KARL STORZ knew or should have known that 1 in 350 women undergoing hysterectomies or myomectomies have unsuspected uterine sarcomas.

107. That Defendants, KARL STORZ knew or should have known that there are "no preoperative diagnostic tests…that reliably detect uterine sarcoma."

108. That Defendants, KARL STORZ knew or should have known that the use of a laparoscopic power morcellator on women with unsuspected uterine sarcoma carries a risk of significantly worsening the patient's long-term

survival.

109. The evidence set forth herein should have placed Defendants on notice that their laparoscopic power morcellators could cause the dissemination and/or upstaging of patient's undetected uterine cancer.

110. As designed and marketed, Defendants KARL STORZ's laparoscopic power morcellator model Unidrive GYN 20711120 SN# (LB 2459) & (HB 2392), supplied to Defendant VALLEY and used by Defendants JONES, KUO and TELFEYAN was unsafe for its intended purpose and defective in design in that it subjected Plaintiff VIVIANA RUSCITTO to certain risks, including but not limited to dissemination and implantation of cancerous tissue throughout the abdominal cavity and pelvic region; upstaging of Plaintiff's cancer to Stage IV; and decreasing Plaintiff's best chance of survival.

111. That the knowledge Defendants, KARL STORZ had, or should have had, as to the risks associated with the use of their laparoscopic power morcellator should have prompted them to put the institutions and doctors they supplied with this product, specifically Defendants VALLEY, JONES, KUO and TELFEYAN , on notice of the risks, hazards, and dangers associated with the product.

112. That Defendants, KARL STORZ failed to design, develop,

manufacture and sell the laparoscopic power morcellator used in Plaintiff's October 17, 2014 surgery with a containment bag or other such system to minimize the risk of spreading such cancerous tissue and that such failure was negligent, as it fell below the standard of care expected of a reasonable medical device manufacturer.

COUNT 4: INADEQUATE WARNING

113. Plaintiff repeats the allegations of paragraphs 1 through 112 as if set forth herein at length.

114. That Defendants, KARL STORZ failed to provide reasonable and adequate warning about the risks, hazards, and dangers associated with the use of model Unidrive GYN 20711120 SN# (LB 2459) & (HB 2392).

115. That Defendants, KARL STORZ has and had an ongoing duty of medical device surveillance and is and was under a continuing duty to inform surgeons, regulatory agencies, and the public of new safety information they learn, or should have learned, about their marketed devices once that information becomes available to Defendant.

116. That Defendants, KARL STORZ knew or should have known that the FDA guidelines indicate that manufacturers provide an appropriate warning if there is reasonable evidence of an association of a serious hazard with the use of the device.

117. That Defendants, KARL STORZ failed to disclose the difficulty of diagnosing uterine sarcomas prior to or during surgery; the actual prevalence of undiagnosed uterine sarcomas in women undergoing surgeries using morcellation; actual rates at which the use of laparoscopic power morcellators disseminate and/or upstage occult cancer; that laparoscopic power morcellators can worsen long-term medical outcomes when compared with other fibroid treatments; and that the use of laparoscopic power morcellators can increase staging and impede prognosis and actually worse a patient's prognosis.

118. That Unidrive, the device used on Plaintiff VIVANA RUSCITTO, failed to contain a warning regarding the potential dissemination of occult cancer.

119. That Unidrive, the laparoscopic power morcellator used on Plaintiff, failed to contain a recommendation to use a bag to minimize the risk of disseminating cancerous tissue.

120. Neither the 510(k) submissions, nor Defendnat's inadequate warnings concerning their laparoscopic power morcellators, adequately instructed Plaintiff, the Hospital, or her surgeon that an appropriate tissue bag to contain shredded tissue fragments should be used to prevent or minimize the risk of disseminating and worsening occult uterine cancer.

121. Defendant, KARL STORZ also failed to adequately warn of the risks associated with their laparoscopic power morcellators, including, but not limited to, the failure to adequately warn because any warnings given were not commensurate with the risks involved; the failure to adequately warn because the warnings contained no information about the risk of disseminating and upstaging a patient's occult cancer; the failure to timely include a Black Box Warning regarding the risks of disseminating and upstaging a patient's occult cancer; and the failure to timely include a Contraindication regarding the risks of disseminating and upstaging a patient's occult or known cancer.

122. That Defendants, KARL STORZ failure to adequately warn the Plaintiff of the risks, hazards, and dangers associated with the use of their laparoscopic power morcellator model Unidrive GYN 20711120 SN# (LB 2459) & (HB 2392) prevented her from fully evaluating the risks and benefits of undergoing surgery with such a device.

123. That because of Defendants KARL STORZ negligence in failing to adequately warn the Plaintiff of the risks, hazards, and dangers described herein, Plaintiff was caused severe and permanent injuries including, but not limited to, a surgery in an attempt to remove all of the uterus that was morcellated by Defendants JONES, KUO and TELFEYAN, intra-

abdominally, as well as a complete abdominal body wash, extensive chemotherapy treatments, pain and mental anguish, severe shock, and a decrease in her life expectancy; has been caused to incur certain expenses for medical attention and surgery; and has been caused to abstain from the duties of her vocation.

COUNT 5: NEGLIGENCE

124. Plaintiff VIVIANA RUSCITTO repeats, reiterates and re-alleges each and every allegation contained in paragraphs "1" through "123" as is set forth herein at length.

125. That Defendants KARL STORZ is and was regularly engaged in the business of designing, researching, developing, testing, manufacturing, packaging, labeling, marketing, promoting, distributing, and/or selling laparoscopic power morcellators, specifically model Unidrive GYN 20711120 SN# (LB 2459) & (HB 2392), which are medical devices used in gynecological surgeries such as hysterectomies and myomectomies.

126. That Defendants KARL STORZ owed a duty to design, research, develop, test, manufacture, package, label, market, promote, distribute, sell, and/or supply products, including gynecological products such as laparoscopic power morcellators, in such a way as to avoid harm to persons,

including Plaintiff VIVIANA RUSCITTO, upon whom they are used by adequately warning of the risks, hazards, and dangers associated with using such products.

127. That Defendants KARL STORZ their authorized divisions, subsidiaries, agents, servants, and/or employees were careless, reckless or otherwise negligent in manufacturing, designing, labeling, marketing, distributing, supplying, and/or selling laparoscopic power morcellators including model Unidrive GYN 20711120 SN# (LB 2459) & (HB 2392) in failing to design their power morcellators for safe use in hysterectomies and myomectomies; in failing to conduct adequate and proper testing of their laparoscopic power morcellators; in marketing model Unidrive GYN 20711120 SN# (LB 2459) & (HB 2392) without doing adequate research to discover possible side effects of use of such a product; in failing to monitor data concerning their devices and promptly report safety concerns that arise from that data; in failing to remain informed of the community standards and opinions concerning laparoscopic power morcellators, such as those of the FDA, the American College of Obstetricians and Gynecologists (ACOG), and the Society of Gynecological Oncology (SCO), which provided Defendant with notice of the risks now commonly associated with laparoscopic power morcellator usage; in failing to respond to testing of, and

information readily available regarding, laparoscopic power morcellators, indicating potential harm to humans; in failing to monitor adverse events and complications reported about model Unidrive GYN 20711120 SN# (LB 2459) & (HB 2392) and its effects on patients; in failing to adequately provide safety information to buyers when they knew or should have known of the risks, hazards and dangers associated with model Unidrive GYN 20711120 SN# (LB 2459) & (HB 2392); in failing to adequately warn of the actual potential for the spreading and/or upstaging of undetected uterine sarcomas when using laparoscopic power morcellators; in failing to reveal their full knowledge and experience regarding the risk that laparoscopic power morcellators, including model Unidrive GYN 20711120 SN# (LB 2459) & (HB 2392), would spread cancer; in promoting, marketing, advertising, and/or selling their laparoscopic power morcellators, given their knowledge of the risks, hazards, and dangers associated therein; in failing to timely withdraw their laparoscopic power morcellators from the market, restrict their uses, and adequately warn of the potential risks, hazards, and dangers known to be associated with such products; in failing to fulfill the standard of care required of a reasonably prudent medical device manufacturer; in disregarding well-publicized and commonly distributed studies, information, documentation and recommendations, consumer

complaints and reports, and/or other information regarding the risks, hazards, and dangers of laparoscopic power morcellator use during hysterectomies and myomectomies; in failing to provide updated safety information to physicians, hospitals, and other healthcare entities; in promoting the product on websites aimed at creating user and consumer demand; in advertising and promoting their laparoscopic power morcellators, including model Unidrive GYN 20711120 SN# (LB 2459) & (HB 2392) as safe and/or safer than other methods of uterine fibroid removal; and in otherwise being careless and negligent.

128. That Defendants, KARL STORZ knew or should have known that their laparoscopic power morcellators carried certain risks, hazards, and dangers, including the spreading and/or upstaging of undetected cancer, but continued to market, manufacture, distribute, and/or make available their laparoscopic power morcellators to patients.

129. That Defendants, KARL STORZ their sales staff, agents, and/or employees made false material representations and/or omissions through the course of aggressive sales and marketing operations that implemented false or misleading statements by sales representatives, Defendant sponsored literatures, events and conferences, online and/or video marketing, or other promotional material to promote and sell laparoscopic power morcellators

while omitting material facts regarding the device's known risks, harzards, and dangers.

130. That Defendants, Defendants KARL STORZ knew or should have known that consumers, like Plaintiff VIVANA RUSCITTO, would foreseeably suffer injury as a result of the Defendant's failure to exercise ordinary care, as set forth herein.

131. That Defendants, KARL STORZ ENDOSCOPY and KARL STORZ ENDOVISION's negligence and/or recklessness was the cause of and a substantial factor in bringing about Plaintiff's injuries.

132. That Defendants, KARL STORZ acted in conscious disregard of, or indifference to, the high degree of risk of physical harm to women undergoing surgery with their laparoscopic power morcellators, including Plaintiff herein, of which Defendant knew or had reason know, giving rise to punitive damages.

133. That Defendants, KARL STORZ knew or should have known of the danger associated with the use of laparoscopic power morcellators, specifically model Unidrive GYN 20711120 SN# (LB 2459) & (HB 2392), 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.

134. That Defendants, KARL STORZ is doing business in New Jersey.

135. That Defendants, KARL STORZ carried on solicitation or service activities in New Jersey.

136. That Defendants, KARL STORZ laparoscopic power morcellators are used within New Jersey in the ordinary course of trade.

137. That Defendants, KARL STORZ derives and derived substantial revenue from interstate commerce.

138. That as a result of the foregoing, Plaintiff's leiomyosarcoma of the fibroid uterus was substantially upstaged, and she sustained an extension and spreading of her cancer; she also lost her best chances for survival and has been caused to suffer severe physical injuries, including unnecessary surgical procedures, extensive chemotherapy, pain and mental anguish, severe shock, and a decrease in life expectancy; has been caused to incur certain expenses for medical attention and surgery; and has been caused to abstain from the duties of her vocation presently and in the future.

139. The amount of damages herein exceeds the jurisdictional limit of all lower courts, which would otherwise have jurisdiction in this matter.

140. As a result of the foregoing, Plaintiff sustained injuries and demands damages Defendants KARL STORZ, in an unspecified amount, together

with costs and disbursements of this action to be determined by a jury at the time of trial.

COUNT 6: STRICT PRODUCTS LIABILITY

141. Plaintiff VIVIANA RUSCITTO repeats, reiterates and re-alleges each and every allegation contained in paragraphs "1" through "140" as is set forth herein at length.

142. That Defendants, KARL STORZ laparoscopic power morcellators, including model Unidrive GYN 20711120 SN# (LB 2459) & (HB 2392), 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, sold, labeled, distributed, and/or marketed by Defendant.

143. That Defendants KARL STORZ laparoscopic power morcellators, including model Unidrive GYN 20711120 SN# (LB 2459) & (HB 2392), 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 exceeded the benefits associated with their design.

144. That Defendants, KARL STORZ laparoscopic power morcellators were defective in design or formulation in that they lacked efficacy, posed a greater likelihood of injury, and were more dangerous than other available

surgical treatment options indicated for the same conditions and uses.

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

146. That Defendants, KARL STORZ laparoscopic power morcellators, as designed, pose and posed a substantial and unavoidable likelihood of harm and it was feasible to design said products in a safer manner.

147. That Defendants, KARL STORZ laparoscopic power morcellators, including model Unidrive GYN 20711120 SN# (LB 2459) & (HB 2392), were defective in design or formulation in that the risks, hazards, and dangers associated with their use were unknowable and unacceptable to the average or ordinary consumer.

148. That Defendants, KARL STORZ laparoscopic power morcellators failed to comply with state and federal standards when sold.

149. That at the time of Plaintiff's October 17, 2014 surgery, the laparoscopic power morcellator was being used for its advertised and

intended purpose, and in the manner Defendants, KARL STORZ s intended.

150. As a foreseeable, direct, and proximate result of the aforementioned wrongful acts and omissions of Defendant, Plaintiff VIVIANA RUSCITTO was caused to suffer from the aforementioned injuries and damages.

151. Due to the aforesaid condition of the laparoscopic power morcellator used on Plaintiff during her surgery, Defendant is strictly liable to Plaintiff, VIVANA RUSCITTO.

152. That as a result of the foregoing, the Defendants caused Plaintiff VIVIANA RUSCITTO's leiomyocarcoma to be substantially upstaged, and she sustained an extension and spreading of her cancer, and has been caused to suffer severe physical injuries, including a surgery in an attempt to remove all of the uterus that was morcellated by Defendants intra-abdominally, as well as a complete abdominal body wash, extensive chemotherapy treatments, pain and mental anguish, severe shock, and a decrease in her life expectancy; has been caused to incur certain expenses for medical attention and surgery; and has been caused to abstain from the duties of her vocation. Plaintiff is also expected to have a substantial future lost wage claim.

153. The amount of damages herein exceeds the jurisdictional limit of all lower courts, which would otherwise have jurisdiction in this matter.

154. By reason of the foregoing, Plaintiff VIVIANA RUSCITTO demands judgment against the Defendants KARL STORZ for compensatory damages in a sum that exceeds the jurisdictional limits of all lower courts that otherwise might have jurisdiction, and punitive damages, together with interest, costs, and attorney's fees of this case, and all such other further and different relief as the Court deems proper.

COUNT 7: STRICT PRODUCTS LIABILTY (FAILURE TO WARN)

155. Plaintiff VIVIANA RUSCITTO repeats, reiterates and re-alleges each and every allegation contained in paragraphs "1" through "154" as is set forth herein at length.

156. That Defendants KARL STORZ was 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.

157. That Defendants KARL STORZ failed to adequately warn health care professionals and the public, specifically Plaintiff VIVIANA RUSCITTO and her surgeon, with the risks associated with use of the laparoscopic power morcellators, all of which were known or scientifically knowable to Defendant prior to the October 17, 2014 surgery of Plaintiff, including, but

not limited to, the risk of spreading unsuspected cancerous tissue beyond the uterus; the risk of upstaging undetected cancer; in failing to provide accurate warnings regarding the inadequacy of pre-operative screening for the presence of unsuspected uterine sarcomas; in failing to provide accurate rates of the prevalence of unsuspected malignant tissue in women undergoing uterine morcellation; in failing to advise the Hospital and Surgeon to use a bag to isolate the shredded uterus intra-abdominally; and in failing to advise doctors to carefully monitor patients following laparoscopic power morcellator surgery to evaluate for the presence of uterine cancer at an earlier date and to allow for appropriate treatment in the event of such a finding.

158. That Defendants, KARL STORZ failure to adequately warn Plaintiff VIVANA RUSCITTO and her surgeon of the risks associated with laparoscopic power morcellators prevented Plaintiff and her surgeon from correctly and fully evaluating the risks and benefits of undergoing surgery with the Defendant's device.

159. That Defendants, KARL STORZ failed to timely include a Black Box Warning regarding the risks of dissemination of occult malignancy and the upstaging of a patient's occult cancer.

160. That Defendants, KARL STORZ ENDOSCOPY and, KARL STORZ

ENDOVISION, failed to timely include a Contraindication that laparoscopic power morcellators should not be used in women with tissue of unsuspected, occult, or known malignancy.

161. That had Defendants, KARL STORZ timely and adequately warned of the risks of the laparoscopic power morcellator used during Plaintiff's October 17, 2014 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 risk to the Plaintiff prior to the surgery, not using the power morcellator, and/or selecting an alternative and safer treatment option for Plaintiff.

162. That if Plaintiff had been adequately warmed of the life-threatening risks of the use of the laparoscopic power morcellators, as stated herein, she would have chosen an alternative treatment, one that did not carry the avoidable risks of spreading and/or upstaging occult cancer, and, therefore, would have avoided the injuries described herein.

163. That Defendants KARL STORZ failure to adequately warn about the risks of their laparoscopic power morcellators was a substantial and contributing factor in causing Plaintiff VIVANA RUSCITTO's injuries.

164. That as a foreseeable, direct, and proximate result of the

aforementioned wrongful acts and omissions of Defendants, KARL STORZ Plaintiff VIVANA RUSCITTO was caused to suffer from the aforementioned injuries and damages.

165. That as a result of the foregoing, the Defendants caused Plaintiff VIVIANA RUSCITTO's leiomyocarcoma to be substantially upstaged, and she sustained an extension and spreading of her cancer, and has been caused to suffer severe physical injuries, including a surgery in an attempt to remove all of the uterus that was morcellated by Defendants intra-abdominally, as well as a complete abdominal body wash, extensive chemotherapy treatments, pain and mental anguish, severe shock, and a decrease in her life expectancy; has been caused to incur certain expenses for medical attention and surgery; and has been caused to abstain from the duties of her vocation. Plaintiff is also expected to have a substantial future lost wage claim.

166. The amount of damages herein exceeds the jurisdictional limit of all lower courts, which would otherwise have jurisdiction in this matter.

167. By reason of the foregoing, Plaintiff VIVIANA RUSCITTO demands judgment against the Defendants KARL STORZ, for compensatory damages in a sum that exceeds the jurisdictional limits of all lower courts that otherwise might have jurisdiction, and punitive damages, together with

interest, costs, and attorney's fees of this case, and all such other further and different relief as the Court deems proper.

COUNT 8: BREACH OF EXPRESS WARRANTIES

168. Plaintiff VIVIANA RUSCITTO repeats, reiterates and re-alleges each and every allegation contained in paragraphs "1" through "167" as is set forth herein at length.

169. That Defendants, KARL STORZ expressly warranted, through their labeling, advertising, marketing, materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that the laparoscopic power morcellators, including the model Unidrive GYN 20711120 SN# (LB 2459) & (HB 2392), were safe, and withheld and concealed information from Plaintiff and her surgeon about the substantial risks of serious injury and/or death associated with using the products used for uterine morcellation.

170. That Defendants, KARL STORZ expressly warranted that their laparoscopic power morcellators were safe for their intended use and as otherwise described herein.

171. 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.

172. That Defendants, KARL STORZ represented that the products used for uterine morcellation were safer and more efficacious than other alternative surgical approaches and techniques.

173. That Defendants, KARL STORZ further concealed information, regarding the true efficacy of said products.

174. That Defendants, KARL STORZ 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 spreading cancerous tissue beyond the uterus and/or upstaging or worsening a women's cancer, degrading Plaintiff's health, and decreasing her life expectancy and best chance of survival.

175. That Defendants, KARL STORZ 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 Plaintiff with intent to induce medical and healthcare providers and patients to dispense, provide, prescribe, accept, and/or

purchase their laparoscopic power morcellators.

176. That Defendants, KARL STORZ 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 literate, 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.

177. That the express warranties represented by the Defendant were a part of the basis of Plaintiff and her surgeon's consent to permit the use of the laparoscopic power morcellator on Plaintiff during her October 17, 2014 surgery.

178. That Plaintiff and her surgeon relied on said express warranties in deciding to use the laparoscopic power morcellator as a treatment option.

179. That at the time of the making of the express warranties, the Defendants, KARL STORZ had knowledge of the purpose for which the laparoscopic power morcellators were to be used, and expressly warranted the same to be in all respects safe, effective, and proper for such purpose.

180. That as a result of the foregoing breach of express warranty, Plaintiff was caused to suffer serious and dangerous side effects including the

spreading and worsening of cancer, increasing the likelihood of her death, physical pain and mental anguish, including diminished enjoyment of life, and any and all life complications caused by Plaintiff's injuries.

181. That as a result of the foregoing, the Defendants caused Plaintiff VIVIANA RUSCITTO's leiomyocarcoma to be substantially upstaged, and she sustained an extension and spreading of her cancer, and has been caused to suffer severe physical injuries, including a surgery in an attempt to remove all of the uterus that was morcellated by Defendants intra-abdominally, as well as a complete abdominal body wash, extensive chemotherapy treatments, pain and mental anguish, severe shock, and a decrease in her life expectancy; has been caused to incur certain expenses for medical attention and surgery; and has been caused to abstain from the duties of her vocation. Plaintiff is also expected to have a substantial future lost wage claim.

182. The amount of damages herein exceeds the jurisdictional limits of all lower courts, which would otherwise have jurisdiction in this matter.

183. By reason of the foregoing, Plaintiff VIVIANA RUSCITTO demands judgment against the Defendants KARL STORZ, for compensatory damages in a sum that exceeds the jurisdictional limits of all lower courts that otherwise might have jurisdiction, and punitive damages, together with

interest, costs, and attorney's fees of this case, and all such other further and different relief as the Court deems proper.

COUNT 9: BREACH OF IMPLIED WARRANTY FOR A PARTICULAR PURPOSE

184. Plaintiff VIVIANA RUSCITTO repeats, reiterates and re-alleges each and every allegation contained in paragraphs "1" through "183" as is set forth herein at length.

185. That Defendants, KARL STORZ impliedly represented and warranted to the users of their laparoscopic power morcellators and parties undergoing surgery with their laparoscopic power morcellators that said devices were safe and fit for the particular purpose for which said products were to be used, namely for the safe removal of uterine tissue and uterine fibroids.

186. That the aforementioned representations and warranties were false, misleading, and inaccurate in that Defendant's laparoscopic power morcellators were unsafe, degraded Plaintiff VIVANA RUSCITTO's health, and shortened her life expectancy.

187. That Plaintiff relied on the implied warranty for fitness for a particular use and purpose.

188. That Plaintiff and her surgeon reasonably relied upon the skill and

judgment of Defendants, KARL STORZ as to whether the Defendant's laparoscopic power morcellator was safe and fit for its intended use, including the removal of uterine tissue and uterine fibroids in the course of hysterectomies and myomectomies, among other indications.

189. That Defendants, KARL STORZ 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.

190. That Defendants, KARL STORZ breached the aforesaid implied warranty, as their laparoscopic power morcellators, including model Unidrive GYN 20711120 SN# (LB 2459) & (HB 2392) used on Plaintiff VIVIANA RUSCITTO, were not reasonably fit for their intended purposes and uses.

191. That as a result of the foregoing, the Defendant caused Plaintiff VIVIANA RUSCITTO's leiomyocarcoma to be substantially upstaged, and she sustained an extension and spreading of her cancer, and has been caused to suffer severe physical injuries, including a surgery in an attempt to remove all of the uterus that was morcellated by Defendants intra-

abdominally, as well as a complete abdominal body wash, extensive chemotherapy treatments, pain and mental anguish, severe shock, and a decrease in her life expectancy; has been caused to incur certain expenses for medical attention and surgery; and has been caused to abstain from the duties of her vocation. Plaintiff is also expected to have a substantial future lost wage claim.

192. The amount of damages herein exceeds the jurisdictional limits of all lower courts, which would otherwise have jurisdiction in this matter.

193. By reason of the foregoing, Plaintiff VIVIANA RUSCITTO demands judgment against the Defendants KARL STORZ for compensatory damages in a sum that exceeds the jurisdictional limits of all lower courts that otherwise might have jurisdiction, and punitive damages, together with interest, costs, and attorney's fees of this case, and all such other further and different relief as the Court deems proper.

COUNT 10: BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY

194. Plaintiff VIVIANA RUSCITTO repeats, reiterates and re-alleges each and every allegation contained in paragraphs "1" through "193" as is set forth herein at length.

195. That Defendants, KARL STORZ manufactured, compounded, portrayed, distributed, recommended, merchandized, advertised, promoted, and/or sold their laparoscopic power morcellators for the purpose of removing uterine tissue.

196. That Defendants, KARL STORZ knew and promoted the use of their laparoscopic power morcellators for the use for which said device was to be used on Plaintiff, namely treating uterine fibroids, improving health, maintaining health, and potentially prolonging life.

197. That Defendants, KARL STORZ impliedly warranted to Plaintiff and her surgeon that their laparoscopic power morcellators, specifically model Unidrive GYN 20711120 SN# (LB 2459) & (HB 2392), were of merchantable quality for the purposes for which they were to be used.

198. That these aforementioned representations and warranties were false, misleading, and inaccurate in that the laparoscopic power morcellator used on Plaintiff was unsafe, degraded Plaintiff's health and shortened her life expectancy.

199. That Plaintiff, the hospital, 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.

200. That 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 were intended.

201. That as a direct and proximate result of the foregoing, Plaintiff was caused bodily injury increasing the likelihood of her death, pain, suffering, and economic loss.

202. That as a result of the foregoing, the Defendants caused Plaintiff VIVIANA RUSCITTO's leiomyocarcoma to be substantially upstaged, and she sustained an extension and spreading of her cancer, and has been caused to suffer severe physical injuries, including a surgery in an attempt to remove all of the uterus that was morcellated by Defendants intra-abdominally, as well as a complete abdominal body wash, extensive chemotherapy treatments, pain and mental anguish, severe shock, and a decrease in her life expectancy; has been caused to incur certain expenses for medical attention and surgery; and has been caused to abstain from the duties of her vocation. Plaintiff is also expected to have a substantial future lost wage claim.

203. The amount of damages herein exceeds the jurisdictional limits of all lower courts, which would otherwise have jurisdiction in this matter.

204. By reason of the foregoing, Plaintiff VIVIANA RUSCITTO demands judgment against the Defendant KARL STORZ for compensatory damages in a sum that exceeds the jurisdictional limits of all lower courts that otherwise might have jurisdiction, and punitive damages, together with interest, costs, and attorney's fees of this case, and all such other further and different relief as the Court deems proper.

COUNT 11: FRAUDULENT MISREPRESENTATION AND OMISSION

205. Plaintiff VIVIANA RUSCITTO repeats, reiterates and re-alleges each and every allegation contained in paragraphs "1" through "204" as is set forth herein at length.

206. That Defendants, KARL STORZ having undertaken design, formulation, testing, manufacture, marketing, sale and distribution of devices used for uterine morcellation, including the model Unidrive GYN 20711120 SN# (LB 2459) & (HB 2392) owed a duty to provide accurate and complete information regarding said devices.

207. That prior to Plaintiff undergoing her surgery, Defendants, KARL STORZ, fraudulently misrepresented that the use of their model Unidrive GYN 20711120 SN# (LB 2459) & (HB 2392) morcellator for uterine

morcellation was safe and effective.

208. That Defendants, KARL STORZ had a duty to provide Plaintiff, physicians, and other consumers with true and accurate information regarding the devices for uterine morcellation it manufactured, marketed, distributed and sold.

209. That Defendants, KARL STORZ made representations and failed to disclose material facts with the intent to induce customers, including Plaintiff VIVIANA RUSCITTO, and the medical community to act in reliance by purchasing and using model Unidrive GYN 20711120 SN# (LB 2459) & (HB 2392) uterine morcellator sold by Defendant.

210. That Plaintiff and the medical community justifiably relied on Defendants, KARL STORZ s representations and omissions by purchasing and using the uterine morcellator during Plaintiff's October 17, 2014 surgery.

211. That Defendants, KARL STORZ's representations and omissions regarding use of its uterine morcellation devices were a direct and proximate cause of Plaintiff's injuries.

212. That as a result of the foregoing, the Defendants caused Plaintiff VIVIANA RUSCITTO's leiomyocarcoma to be substantially upstaged, and she sustained an extension and spreading of her cancer, and has been caused

to suffer severe physical injuries, including a surgery in an attempt to remove all of the uterus that was morcellated by Defendants intra-abdominally, as well as a complete abdominal body wash, extensive chemotherapy treatments, pain and mental anguish, severe shock, and a decrease in her life expectancy; has been caused to incur certain expenses for medical attention and surgery; and has been caused to abstain from the duties of her vocation. Plaintiff is also expected to have a substantial future lost wage claim.

213. The amount of damages herein exceeds the jurisdictional limits of all lower courts, which would otherwise have jurisdiction in this matter.

214. By reason of the foregoing, Plaintiff VIVIANA RUSCITTO demands judgment against the Defendants KARL STORZ, for compensatory damages in a sum that exceeds the jurisdictional limits of all lower courts that otherwise might have jurisdiction, and punitive damages, together with interest, costs, and attorney's fees of this case, and all such other further and different relief as the Court deems proper.

WHEREFORE, the Plaintiff VIVIANA RUSCITTO, demands judgment against Defendants THE VALLEY HOSPITAL, INC., HOWARD H. JONES, M.D., EUGENIA C. KUO, M.D., and CELESTE A. TELFEYAN , D.O., on her First and Second Causes of Action, and against Defendant KARL STORZ GMBH

& CO. KG, KARL STORZ ENDOVISION, INC., and KARL STORZ ENDOSCOPY-AMERICA, INC. on her Third, Fourth, Fifth, Sixth, Seventh, Eighth, Ninth, Tenth, and Eleventh Causes of Action, for damages together with interest, costs and disbursements of this action, and such other, further and different relief that this Court deems just and proper.

REQUEST FOR PUNITIVE DAMAGES

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

216. At all times relevant herein, Defendants:

a. knew that power morcellator was dangerous and ineffective;

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

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

d. with full knowledge of the health risks associated with the power morcellator and without adequate warnings of the same,

manufactured, marketed, promoted, developed, sold and/or distributed power morcellator for routine use.

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

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

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

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment against the Defendants, jointly and severally, as follows:

a. For an award of compensatory damages, including damages against Defendants and each of them for pain and suffering, medical and hospital

expenses, loss of income, permanent disability, and other damages according to proof at trial in excess of $75,000;

b. For an award of punitive or exemplary damages against Defendants and each of them in excess of $75,000;

c. For reasonable attorneys' fees and costs;

d. For pre-judgment interest; and

e. For such further and other relief the court deems just, equitable, and proper.

Dated: July 22, 2015

s/ Demetrios K. Stratis
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**Pro hac vice application forthcoming*

JURY DEMAND

Plaintiff hereby demands a trial by jury on all issues so triable.

Dated: July 22, 2015

s/ *Demetrios K. Stratis*

DEMETRIOS K. STRATIS, ESQ.

CERTIFICATION OF OTHER ACTIONS

The undersigned hereby certifies that the matter in controversy is not the subject of any other action pending in any court, arbitration, or administrative proceeding.

s/ Demetrios K. Stratis
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