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

ROMONA YVETTE GOURDINE and RANDOLPH GOURDINE, JR., Plaintiffs, v. **KARL STORZ ENDOSCOPY-AMERICA, INC., a California Corporation; KARL STORZ ENDOVISION, INC., a Massachusetts Corporation; and KARL STORZ GMBH & CO. KG, organized in Germany,** Defendants.	**CIVIL ACTION NO.:** 2:14-cv-04839-RMG **COMPLAINT AND JURY DEMAND**

COME NOW, Plaintiffs Romona Yvette Gourdine and Randolph Gourdine, Jr., wife and husband, by and through the undersigned counsel, and hereby alleges against Karl Storz Endoscopy-American, Inc., Karl Storz Endovision, Inc., and Karl Storz GMBH & Co. KG (collectively "Defendants"), as follows:

1. The Plaintiff is entitled to the relief she seeks because the Defendants (a) negligently failed to warn Plaintiff and her doctor about the true risks of the Storz Rotocut G1 Morcellator, (b) made the instrument unsafe for its intended use, and are strictly liable for placing the Rotocut G1 Morcellator on the market, and (d) fraudulently misrepresented the risks of the instrument. These acts and omissions of the Defendants injured the Plaintiff, exposing her to risks of her cancer spreading throughout her body and causing her to endure painful and expensive radiation treatment.

PARTIES, JURISDICTION AND CITIZENSHIP

2. Plaintiffs Romona Yvette Gourdine (hereinafter "Mrs. Gourdine") and Plaintiff Randolph Gourdine, Jr. (collectively "Plaintiffs") are, and at the times mentioned in this Complaint were, husband and wife.

3. The Plaintiffs are and were at the times mentioned in this Complaint residents of Summerville, South Carolina, and are citizens of the State of South Carolina.

4. Upon information and belief, the Storz Morcellator was approved for sale and use in the U.S.A. on application to the Food and Drug Administration (FDA) by Defendants. The Defendants applied for the approval pursuant to Section 510(k) of the Food, Drug, and Cosmetic Act (FDCA), 52 Stat. 1040, as amended, 21 U.S.C. '301 et seq.

5. Defendants Karl Storz Endoscopy-America, Inc. (hereinafter "KS Endoscopy"), is incorporated in the state of California, and together with the other Defendants, it is responsible for the sale, marketing, promotion, and distribution of Storz instruments, including the Storz Morcellator, in the United States. It maintains its principal place of business in El Segundo, California, and is a citizen of the state of California, according to 28 U.S.C. 1332. Defendants Karl Storz Endoscopy-America, Inc., is the entity listed as the Applicant on the 510(k) form for the Storz Morcellator.

6. Defendants Karl Storz Endovision, Inc. (hereinafter "KS Endovision"), is incorporated in the state of Massachusetts, and it manufactures Storz instruments distributed in the United States. It maintains its principal place of business in Charlton, Massachusetts, and is a citizen of the state of Massachusetts, according to 28 U.S.C. 1332.

7. Defendants Karl Storz GMBH & Co. KG, (hereinafter "Karl Storz") is organized in Germany and maintains its principal place of business in Tuttlingen, Germany. It is the parent

company of Karl Storz Endovision, Inc., and Karl Storz Endoscopy-America, Inc. Together with the other Defendants, Karl Storz is responsible for the design, production, marketing, and sale of the Storz Morcellator, and for all information about the Storz Morcellator product, including warnings and instructions to surgeons about its use and risks. In an adverse event reported by Defendants to the FDA on May 26, 2011, Defendants Karl Storz is the entity listed as the manufacturer of the defective Storz Morcellator, rather than Defendants KS Endoscopy, the applicant on the 510(k) form for the Storz Morcellator.

8. Upon information and belief, Defendants Karl Storz directs and controls Defendants KS Endoscopy and KS Endovision. Upon information and belief, there is significant overlap between the executive leadership of all three Defendants, including but not limited to Karl-Christian Storz, Sybill Storz, and Eric Schmiler. Upon information and belief, this shared executive leadership allows Defendants Karl Storz to dominate Defendants KS Endoscopy and KS Endovision to such an extent that the activities and contacts of Defendants KS Endoscopy and KS Endovision should be imputed to their parent corporation, Defendants Karl Storz, as they are nothing more than the alter egos of Karl Storz.

9. Upon information and belief, Defendants KS Endoscopy and KS Endovision have purposefully availed themselves of the benefits of doing business in South Carolina through manufacturing, designing, labeling, marketing, distributing, supplying and/or selling, the Storz 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 Ms. Gourdine in South Carolina. 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.

10. All Defendants are diverse from the Plaintiff and are subject to service of process. This

Court properly may exercise personal jurisdiction over them. Each Defendant has sufficient minimum contacts with the state of South Carolina to be sued and be required to defend here.

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

ALLEGATIONS

12. Ms. Gourdine, on or about December 28, 2011, underwent a surgical procedure known as a supra-cervical hysterectomy. During this procedure the surgeon removed one or more fibroids from her uterus and broad ligament using a powered surgical instrument known as a Storz Rotocut G1 Morcellator ("Storz Morcellator").

13. The surgeon who performed the surgery utilized the Storz Morcellator to cut, shred, and remove Ms. Gourdine's fibroid and uterus. Pathology of the fibroid tissue was found to be leiomyosarcoma. The use of the Storz Morcellator in cutting, shredding, and removing the uterus and fibroid(s) from Ms. Gourdine created the potential for dissemination of cancerous cells throughout her abdominal cavity. This potential dissemination worsened her long-term prognosis for the course of this cancer.

14. As a result of the use of the Storz Morcellator on Ms. Gourdine, she was required to undergo radiation therapy to prevent the potential spread of cancer throughout her abdomen. Fibroid removal surgery without use of a morcellator generally poses almost no danger of dissemination and/or upstaging of cancer.

15. Defendants knew, or should have known, of the risk of disseminating unsuspected/undiagnosed cancers with the normal and customary use of the Storz Morcellator and failed to properly communicate those risks to physicians and/or patients.

16. Ms. Gourdine’s aggressive radiation therapy included months of radiation treatments.

She has experienced and may continue to experience the following adverse effects of radiation: fatigue, joint pain, inflammation, swelling, insomnia, and gastrointestinal distress. Without the morcellation of her cancer by the Storz Morcellator, she would not have required this extensive and debilitating radiation treatment.

17. The Plaintiff, as a result of the having to undergo this radiation treatment, has incurred out of pocket expenses for treatment, and has lost employment compensation. Ms. Gourdine will also have to visit her oncologist, and have to undergo a battery of tests, several times annually for the reminder of her life, as a result of the fear of the potential dissemination of her cancer.

18. Despite Defendants' knowledge of the risks of morcellation surgery, they failed to adequately warn about the true risk of dissemination of cancer and the possibility that preventative radiation may be required following the use of the Storz Morcellator.

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

20. The Defendants designed, manufactured, marketed, and sold the Storz 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 Ms. Gourdine's surgery. The 510(k) Summary of Safety and Effectiveness submitted to the FDA by Defendants on or about July 27, 2006, states:

> Indication: The ROTOCUT G1 Electromechanical Morcellator in conjunction with the UNIDRWE GYN control unit is a motorized unit for morcellating and extracting tissue during laparoscopic procedures in general surgery, *gynecology including the removal or myomas [fibroids] and hysterectomy, and in urology including nephrectomy. (emphasis added)*

21. Defendants also failed to require the use of a closed system tissue bag in conjunction with morcellation of fibroid tissue to capture any extraneous morcellated tissue that may contain

cancerous cells.

22. The Defendants' instructions about use of the Storz Morcellator accompanying the device state that "use of a tissue extraction bag is advised for the morcellation of malignant tumors or tissue suspected of being malignant, and for tissue that the surgeon may consider to be harmful if disseminated in a body cavity." That statement is insufficient, negligent, and in that it wrongly conveys that detection of cancerous tissue by conventional procedures and techniques prior to morcellation is feasible and likely. It is not. In at least 1 in 350 cases, Ms. Gourdine's included, detection of such cancerous tissue is not feasible or likely, as Defendants knew or should have known.

23. The surgical tissue bag and method has been available since 1991, long before the Storz 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 may result in the dissemination of cancerous cells throughout the body.

24. 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 Storz Morcellator to prevent dissemination of an unsuspected cancer, Ms. Gourdine required radiation treatment. These events, which were completely avoidable, have significantly decreased Ms. Gourdine's quality of life and may have shortened her life expectancy.

25. Had Ms. Gourdine known that she may potentially have had to undergo radiation after her surgery due to the morcellation surgery, she would not have chosen to undergo morcellation.

AS A FIRST CAUSE OF ACTION: NEGLIGENCE

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

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

28. Defendants owed a duty to warn of the hazards and dangers associated with the use of its products for patients such as Plaintiff herein, so as to avoid harm.

29. Defendants, acting by and through their authorized divisions, subsidiaries, agents, servants, and employees, were guilty of carelessness, recklessness, negligence, gross negligence and willful, wanton, outrageous and reckless disregard for human life and safety in manufacturing, designing, labeling, marketing, distributing, supplying and/or selling and/or placing into the stream of commerce, the Storz Morcellator, both generally and in the following particular respects:

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

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

c. putting products used for uterine morcellation such as the Storz Morcellator on the market without adequate testing of its dangers to humans;

d. failing to recognize the significance of their own and other testing of, and information regarding, products used for uterine morcellation, such as the Storz Morcellator, which

testing evidenced such products potential harm to humans;

e. failing to respond promptly and appropriately to their own and other testing of, and information regarding products used for uterine morcellation, such as the Storz Morcellator which indicated such products potential harm to humans;

f. failing to promptly and adequately warn of the potential of the products used for uterine morcellation to be harmful to humans;

g. failing to promptly and adequately warn of the potential for the metastases of cancer when using products used for uterine morcellation, such as the Storz Morcellator;

h. failing to promptly, adequately, and appropriately recommend testing and monitoring of patients upon whom products used for uterine morcellation in light of such products potential harm to humans;

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

j. concealing from the FDA, National Institutes of Health, the general medical community and/or physicians, their full knowledge and experience regarding the potential that products used for uterine morcellation, specifically the Storz Morcellator, are harmful to humans;

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

l. failing to withdraw products used for uterine morcellation from the market, restrict its use and/or warn of such products' potential dangers, Given their knowledge of the potential for its harm to humans;

m. failing to fulfill the standard of care required of a reasonable, prudent, minimally invasive gynecological surgical products manufacturer engaged in the manufacture of said products, specifically including products used for uterine morcellation such as the Storz Morcellator;

n. placing and/or permitting the placement of the products used for uterine morcellation, specifically the Storz Morcellator, into the stream of commerce without warnings of the potential for said products to be harmful to humans and/or without properly warning of said products' dangerousness;

o. failing to disclose to the medical community in an appropriate and timely manner, facts relative to the potential of the products used for uterine morcellation, including the Storz Morcellator, to be harmful to humans;

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

q. disregarding the safety of users and consumers of products used for uterine morcellation, including plaintiff herein, under the circumstances by failing adequately to warn of said products' potential harm to humans;

r. disregarding the safety of users and consumers of the products used for uterine morcellation, including plaintiff herein, and/or her physicians' and/or hospital, under the circumstances by failing to withdraw said products from the market and/or restrict their usage;

s. disregarding publicity, government and/or industry studies, information, documentation and recommendations, consumer complaints and reports and/or other information

regarding the hazards of the products used for uterine morcellation and their potential harm to humans;

t. failing to exercise reasonable care in informing physicians and/or hospitals using the products used for uterine morcellation about their own knowledge regarding said products' potential harm to humans;

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

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

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

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

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

z. failing to use due care under the circumstances;

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

bb. failing to monitor, analyze and report adverse post-surgical outcomes stemming from the use of the Storz Morcellator for disseminated cancer;

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

dd. failing to respond to multiple published studies describing the risk of disseminated cancer and up-staging of cancer with morcellator use;

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

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

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

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

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

AS A SECOND CAUSE OF ACTION: DEFECTIVE MANUFACTURING

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

32. Defendants were and are engaged in the business of selling the Storz Morcellator in the State of South Carolina.

33. The Storz Morcellator manufactured, marketed, promoted and sold by Defendants was expected to, and did, reach Plaintiff Romona Yvette Gourdine without substantial change in the condition in which it was sold.

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

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

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

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

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

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

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

41. There are comparative products on the market with safer alternative designs in that they provide equal or greater efficacy and far less risk.

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

AS A THIRD CAUSE OF ACTION: DESIGN DEFECT

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

44. Defendants were and are engaged in the business of selling Storz Morcellator in the State of South Carolina.

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

46. The foreseeable risks associated with the design or formulation of the Storz Morcellator include, but are not limited to, the fact that the design or formulation of Storz Morcellator is

more dangerous than a reasonably prudent consumer would expect when used in an intended or reasonably foreseeable manner.

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

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

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

50. There are products on the market with safer alternative designs in that they provide equal or greater efficacy and far less risk.

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

AS A FOURTH CAUSE OF ACTION:
FAILURE TO WARN

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

60. The Storz Morcellator is a defective and therefore unreasonably dangerous product, because its labeling fails to adequately warn consumers and prescribers of, among other things, the risk of migration of the product post-insertion, development of endometriosis resulting from uterine perforation, or possibility that device complication may necessitate hysterectomy.

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

62. The Storz Morcellator was under the exclusive control of Defendants and was unaccompanied by appropriate warnings regarding all of the risks associated with its use. The warnings given did not accurately reflect the risk, incidence, symptoms, scope or severity of such injuries to the consumer or physicians. The promotional activities of Defendants further diluted or minimized the warnings given with the product.

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

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

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

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

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

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

69. Defendants had a continuing duty to warn consumers, including Plaintiff, her physicians, and the medical community of the dangers associated with the Storz Morcellator, and by negligently and/or wantonly failing to adequately warn of the dangers associated with its use, Defendants breached their duty.

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

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

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

AS A FIFTH CAUSE OF ACTION:
STRICT LIABILITY

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

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

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

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

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

77. The Storz Morcellator was defective due to inadequate pre-marketing testing.

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

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

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

AS A SIXTH CAUSE OF ACTION:
BREACH OF IMPLIED WARRANTY

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

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

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

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

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

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

AS A SEVENTH CAUSE OF ACTION:
PERSONAL INJURY – ROMONA GOURDINE

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

86. Plaintiff underwent a hysterectomy wherein a Storz Morcellator manufactured by the Defendants was utilized on December 28, 2011.

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

88. Shortly after this procedure Ms. Gourdine learned that the fibroid tumors were leiomyosarcoma, a rare cancer.

89. Plaintiff was forced to undergo months of radiation therapy in order to stop the potential spread of morcellated cancer cells.

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

91. Plaintiff was unaware, and did not have the capacity to be aware, of the connection between the Storz Morcellator and the potential dissemination of cancer at the time the Storz Morcellator was used in her procedure.

92. As a result of her medical problems, Plaintiff Romona Gourdine:

a. Suffered severe pain;

b. Underwent surgical procedures;

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

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

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

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

AS A EIGHTH CAUSE OF ACTION:
BREACH OF EXPRESS WARRANTY

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

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

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

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

WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory,

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

AS A NINTH CAUSE OF ACTION:
NEGLIGENT MISREPRESENTATION

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

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

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

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

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

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

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

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

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

AS A TENTH CAUSE OF ACTION:
FRAUDULENT MISREPRESENTATION AND OMISSION

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

106. Upon information and belief, the Defendants' statements about the Storz Morcellator, as they appear in the manual which accompanied the device used for Ms. Gourdine's surgery in December 2011, wrongly and falsely convey that the device may be used safely in surgeries of the type performed on Ms. Gourdine without a tissue bag to contain fragmented tissue. The Defendants knew or should have known that (a) the device is unsafe for use without containment of tissue fragments even when cancer is not suspected and detected by standard procedures prior to the morcellation surgery, and (b) in at least 1 in 350 cases, the device will disseminate cancer which is not suspected and detected prior to the surgery.

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

108. Defendants, having undertaken design, formulation, testing, manufacture, marketing, sale, and distribution of devices used for uterine morcellation, including the Storz

Morcellator, owed a duty to monitor, analyze and report adverse outcomes stemming from the use of the Storz Morcellator.

109. Defendants, having undertaken design, formulation, testing, manufacture, marketing, sale, and distribution of devices used for uterine morcellation, including the Storz Morcellator, owed a duty to monitor and respond to multiple published studies that describe the risk of disseminated cancer and up-staging of cancer with morcellator use.

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

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

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

AS AN ELEVENTH CAUSE OF ACTION:
FRAUD BY CONCEALMENT

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

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

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

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

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

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

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

AS A TWELTH CAUSE OF ACTION: LOSS OF CONSORTIUM

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

122. Plaintiff Randolph Gourdine, Jr. is the husband of Romona Yvette Gourdine.

123. As a result of the medical conditions developed by his wife and the medical treatment and hospitalizations that she endured, Plaintiff Randolph Gourdine, Jr. :

a. Lost a substantial measure of his wife's household services;

b. has lost, and will continue to lose in the future, a substantial measure of his wife's consortium; and

c. had to take time away from work and consequently lost wages.

124. As a direct and proximate result of one or more of these wrongful acts or omissions of the Defendants, Plaintiff Randolph Gourdine, Jr. suffered injuries.

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

REQUEST FOR PUNITIVE DAMAGES

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

125. At all times relevant herein, Defendants:

a. knew that Storz Morcellator was dangerous and ineffective;

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

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

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

126. 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.

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

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

PRAYER FOR RELIEF

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

JURY DEMAND

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

Respectfully submitted this the 23rd day of December, 2014.

MOTLEY RICE LLC

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