IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF MICHIGAN

DENISE WHITFIELD Plaintiff, v. **KARL STORZ ENDOSCOPY-AMERICA, INC.,** **KARL STORZ ENDOVISION, INC.,** **AND** **KARL STORZ GMBH & CO. KG** Defendants.	§	Case No.: 2:15-cv-10352 Judge: _____ **COMPLAINT WITH JURY DEMAND ENDORSED HEREON** Carasusana B. Wall (0090234) ZOLL, KRANZ & BORGESS, LLC 6620 W. Central Ave., Suite 100 Toledo, OH 43617 Tel. (419) 841-9623 Fax. (419) 841-9719 Email: cara@zkblaw.com *Counsel for Plaintiff*

Now comes Plaintiff Denise Whitfield, 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:

NATURE OF THE ACTION

1. This is an action brought by Plaintiff Denise Whitfield for damages suffered as a direct and proximate result of the defective and unreasonably dangerous surgical instrument, the Rotocut G1 power morcellator, used during her laparoscopic supracervical hysterectomy and bilateral salpingectomy procedures for the treatment of uterine fibroids. At all times relevant

hereto, the Rotocut G1 was manufactured, designed, tested, packaged, labeled, produced, created, made, constructed, assembled, marketed, advertised, distributed and sold by Defendants.

2. As a result of the use of the Rotocut G1 on Plaintiff, she suffered injuries to her person including metastasized Stage 4 bone and breast. 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 Denise Whitfield resided at 2797 West 8 Mile Road, Detroit, MI, 48203.

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 Defendant Karl Storz GMBH & Co.KG, including the Rotocut G1 power morcellator.

5. At all relevant times, Defendant KS Endoscopy has transacted and conducted business in the State of Michigan 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 Rotocut G1 power morecellator.

7. At all relevant times, Defendant KS Endovision has transacted and conducted business in the State of Michigan 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, and sale and all information for Karl Storz products, including the Rotocut G1 power morcellator.

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

10. Upon information and belief, Defendants KS Endoscopy and KS Endovision have purposefully availed themselves of the benefits of doing business in Michigan through manufacturing, designing, labeling, marketing, distributing, supplying and/or selling, the Rotocut G1 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 Michigan. 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. Upon information and belief, Defendants John Doe Entities 1 through 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 Rotocut G1 power morecellator.

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

13. Defendants do business in Michigan, where Plaintiff underwent her operation during which the Rotocut G1 power morecellator was used, through the sales of the Rotocut G1 and other medical devices and instruments in the state.

14. 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 Rotocut G1 power morcellator.

15. 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.

16. At all times herein mentioned, each of the Defendants was the agent, servant, partner, predecessors in interest, aider and abettor, co-conspirator and joint venturer of each of the remaining Defendants herein 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

17. 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.

18. Venue is proper in the Eastern District of Michigan 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 Rotocut G1 power morcellator on the Plaintiff, as well as Plaintiff's resulting injuries.

19. The Court has personal jurisdiction over Defendants consistent with the Michigan and United States Constitutions and pursuant to Michigan Compiled Law 600.705, because Defendants transacted business in Michigan and caused tortious injury in Michigan by an act or omission outside Michigan by virtue of Defendants' regularly conducted business in Michigan from which they respectively derive substantial revenue. Defendants do substantial business in the State of Michigan and within the Eastern District of Michigan, advertise in this district, and receive substantial compensation and profits from sales of the Rotocut G1 power morcellator within this District.

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

FACTS

21. Power morcellators are medical instruments used in different types of laparoscopic surgeries, including procedures to treat uterine fibroids. Power morcellators are used to cut and shred tissue to facilitate the tissue's removal through small incisions.

22. On July 27, 2006, Defendants received 510(k) clearance by the FDA for its Rotocut G1 Electromechanical Morcellator, describing it as a "motorized, reusable surgical device system, intended for the morcellation and extracting tissue during laparoscopic procedures in general surgery, gynecology and urology."

23. 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.

24. 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."

25. 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."

26. 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]

27. 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 following the use of the Rotocut G1 power morcellator.

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

29. The Defendants designed, manufactured, marketed, and sold the Rotocut G1 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. 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)*

30. Reasonable and feasible alternative designs existed, including the surgical tissue bag and method, which has been available since 1991, long before the Rotocut G1 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.

31. 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 Rotocut G1 power morcellator to prevent dissemination of an unsuspected cancer, Plaintiff suffered injury, including metastasized bone and breast cancer.
32. Upon information and believe, as of the current date, Defendants' Rotocut G1 power morcellator remains on the market and in use.
33. On June 14, 2011, Plaintiff underwent surgical procedures known as laparoscopic supracervical hysterectomy and bilateral salpingectomy for the treatment of uterine fibroids. Upon information and belief, during this procedure the surgeon used the Rotocut G1 power morcellator on the Plaintiff for tissue morcellation.
34. The surgeon who performed the surgery utilized the Rotocut G1 power morcellator to cut, shred, and remove Plaintiff's fibroid and uterus. The use of the Rotocut G1 power morcellator in cutting, shredding, and removing the uterus and fibroid(s) from Plaintiff resulted in the development of cancer outside the uterus.
35. Upon information and belief, Plaintiff underwent a mammogram examination in 2013 that did not show any signs of cancer.
36. On or about July 17, 2014, Plaintiff was admitted to the hospital through the emergency room for spinal surgery. However, during this stay, Plaintiff's cancer was discovered and she was diagnosed with Stage 4, metastasized bone and breast cancer.
37. As a result of the use of the Rotocut G1 power morcellator, Plaintiff developed Stage 4 bone and breast cancer, and has had to undergo extensive and intensive therapies for the treatment and management of her advanced-stage cancer. This treatment includes daily hormone medications, regular injections of medications by her physicians and multiple ten-week

rounds of radiation therapy. Fibroid removal surgery without use of a morcellator generally poses almost no danger of dissemination of cancerous cells, subsequent development of cancer outside the uterus and/or upstaging of cancer.

38. Defendants knew, or should have known, of the risk of disseminating unsuspected/undiagnosed cancerous cells and subsequent development of cancer outside the uterus with the normal and customary use of the Rotocut G1 power morcellator and failed to properly communicate those risks to physicians and/or patients.

39. Plaintiff has experienced the ill-effects of both her cancer and the cancer treatments including, but not limited to, fatigue, body pain, joint pain, stiffness, inflammation, swelling, insomnia, and gastrointestinal distress. Without the Rotocut G1 power morcellator, she would not have developed Stage 4 bone and breast cancer.

40. The Plaintiff, as a result of the having to undergo this radiation treatment, has incurred out of pocket expenses for treatment. Not only does Plaintiff now face a shortened life-expectancy, but she must also regularly visit her oncologist and physicians to undergo a battery of treatment and tests for the remainder of her life.

41. Had Plaintiff known that she would develop Stage 4, metastasized breast and bone cancer, she would not have chosen to undergo morcellation.

COUNT ONE: NEGLIGENCE

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

43. The Defendants owed a duty to manufacture, compound, label, market, distribute, and supply and/or sell products, including instruments for uterine morcellation, specifically the Rotocut G1 power 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.

44. 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.

45. Defendants placed Rotocut G1 power morcellator into the stream of commerce with wanton and reckless disregard for the public safety.

46. Defendants knew and, in fact, advertised and promoted the use of Rotocut G1 power 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.

47. Despite the fact that evidence existed that the use of Rotocut G1 power 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 Rotocut G1 power morcellator and in fact acted to deceive the medical community and public at large, including all potential users of Rotocut G1 power morcellator by promoting it as safe and effective for its intended use.

48. 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.

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

50. 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 Rotocut G1 power morcellator, both generally and in the following particular respects:

a. failing to conduct adequate and appropriate testing of instruments such as the Rotocut G1 power morcellator, specifically including, but not limited to, products used for uterine morcellation;

b. putting products used for uterine morcellation such as the Rotocut G1 power morcellator on the market without first conducting adequate testing to determine possible side effects;

c. putting products used for uterine morcellation such as the Rotocut G1 power 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 Rotocut G1 power 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 Rotocut G1 power 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 Rotocut G1 power 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 their full knowledge and experience regarding the potential that products used for uterine morcellation, specifically the Rotocut G1 power morcellator, are harmful to humans;

k. promoting, marketing, advertising and/or selling products used for uterine morcellation such as the Rotocut G1 power 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 Rotocut G1 power morcellator;

n. placing and/or permitting the placement of the products used for uterine morcellation, specifically the Rotocut G1 power 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 Rotocut G1 power 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 Rotocut G1 power 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 Rotocut G1 power morcellator.

bb. failing to monitor, analyze and report adverse post-surgical outcomes stemming from the use of the Rotocut G1 power morcellator for cancer developed outside the uterus;

cc. failing to monitor, analyze and report adverse post-surgical outcomes stemming from the use of the Rotocut G1 power morcellator;

dd. failing to respond to multiple published studies describing the risk of disseminated cancer cells, subsequently developing cancer outside the uterus and up-staging of cancer with morcellator use;

ee. 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 developing outside the uterus when such data because available; and,

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

51. 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.

52. 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.

COUNT TWO: DESIGN DEFECT

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

54. Defendants were and are engaged in the business of selling the Rotocut G1 power morcellator in the State of Michigan.

55. The Rotocut G1 power morcellator manufactured, marketed, promoted and sold by Defendants was expected to, and did, reach Plaintiff Denise Whitfield without substantial change in the condition in which it was sold.

56. Defendants have introduced a product into the stream of commerce which is dangerous and unsafe in that the harm of the Rotocut G1 power morcellator outweighs any benefit derived therefrom. The unreasonably dangerous nature of Rotocut G1 power morcellator caused serious harm to Plaintiff.

57. 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.

58. As a direct and proximate result of the subject product's defective design, Plaintiff suffered severe and permanent physical injuries, including Stage 4 metastasized cancer. 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

59. Defendants placed Rotocut G1 power morcellator into the stream of commerce with wanton and reckless disregard for the public safety.

60. Defendants knew and, in fact, advertised and promoted the use of Rotocut G1 power 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.

61. Despite the fact that evidence existed that the use of Rotocut G1 power 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 Rotocut G1 power morcellator and in fact acted to deceive the medical community and public at large, including all potential users of Rotocut G1 power morcellator by promoting it as safe and effective.

62. 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.

63. There was both technical and economic feasibility, at the time the Rotocut G1 power morcellator left Defendants' control, of using an alternative design that would not cause the risks described herein.

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

65. 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.

COUNT THREE: MANUFACTURING DEFECT

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

67. Defendants were and are engaged in the business of selling Rotocut G1 power morcellator in the State of Michigan.

68. The Rotocut G1 power 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.

69. The foreseeable risks associated with the design or formulation of the Rotocut G1 power morcellator include, but are not limited to, the fact that the design or formulation of Rotocut G1 power morcellator is more dangerous than a reasonably prudent consumer would expect when used in an intended or reasonably foreseeable manner.

70. 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.

71. Defendants placed Rotocut G1 power morcellator into the stream of commerce with wanton and reckless disregard for the public safety.

72. 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.

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

74. The instrument utilized in Plaintiff's surgery was unreasonably safe at the time it left the Defendants' control.

75. 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.

COUNT FOUR: FAILURE TO WARN

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

77. The Rotocut G1 power 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 developing cancer outside of the uterus.

78. Defendants researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and otherwise released into the stream of commerce

the pharmaceutical, Rotocut G1 power 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 Rotocut G1 power morcellator.

79. The Rotocut G1 power 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.

80. Defendants downplayed the serious and dangerous side effects of Rotocut G1 power morcellator to encourage sales of the product; consequently, Defendants placed its profits above its customers' safety.

81. The Rotocut G1 power 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 Rotocut G1 power morcellator, they still failed to provide warnings that accurately reflected the signs, symptoms, incident, scope, or severity of the risks associated with the product.

82. Plaintiff used Rotocut G1 power morcellator as intended and as indicated by the package labeling and instructions or in a reasonably foreseeable manner.

83. Plaintiff could not have discovered any defect in Rotocut G1 power morcellator through the exercise of reasonable care.

84. Defendants, as manufacturers of medical devices and instruments, 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 Rotocut G1 power morcellator.

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

86. Defendants had a continuing duty to warn consumers, including Plaintiff, her physicians, and the medical community, of the dangers associated with the Rotocut G1 power morcellator, and by negligently and/or wantonly failing to adequately warn of the dangers associated with its use, Defendants breached their duty.

87. Although Defendants knew, or were reckless in not knowing, of the defective nature of the Rotocut G1 power 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 Rotocut G1 power morcellator.

88. 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.

89. 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.

COUNT FIVE: STRICT LIABILITY

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

91. Defendants are manufacturers and/or suppliers of Rotocut G1 power morcellator and are strictly liable to Plaintiffs for designing, creating, manufacturing, distributing, selling and placing Rotocut G1 power morcellator into the stream of commerce.

92. The Rotocut G1 power 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 alternatives.

93. The Rotocut G1 power morcellator was defective in design in that, when it left the hands of the manufacturer and/or suppliers, the foreseeable risks exceeded the benefits associated with the product design.

94. The Rotocut G1 power morcellator was also defective due to inadequate warnings or instructions because the manufacturer knew or should have known that Rotocut G1 power morcellator created, among other things, a risk of dissemination of cancerous tissue, subsequent development of cancer outside the uterus and resulting treatment, and the Defendants failed to adequately warn of these risks.

95. The Rotocut G1 power morcellator was defective due to inadequate pre-marketing testing.

96. 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 Rotocut G1 power morcellator and continues to promote and sell the Rotocut G1 power morcellator in the absence of those adequate warnings.

97. 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.

98. 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.

COUNT SIX: BREACH OF IMPLIED WARRANTY

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

100. Defendants marketed, manufactured, promoted, distributed and/or sold Rotocut G1 power morcellator as safe for use by the public at large, including Plaintiff, who underwent a procedure involving the Rotocut G1 power 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.

101. Plaintiff reasonably relied on the skill and judgment of the Defendants, and as such their implied warranty, in undergoing a procedure involving the Rotocut G1 power morcellator.

102. Contrary to same, Rotocut G1 power 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.

103. 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.

104. 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.

COUNT SEVEN: BREACH OF EXPRESS WARRANTY

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

106. The aforementioned manufacturing, designing, distributing, marketing, and promoting of Rotocut G1 power 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 Rotocut G1 power morcellator was to be used and Defendants warranted the Rotocut G1 power morcellator to be in all respects safe, effective and proper for such purposes.

107. The Rotocut G1 power morcellator does not conform to these express warranties and representations because Rotocut G1 power morcellator is not safe or effective and produces serious side effects. 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.

108. 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.

COUNT NINE: NEGLIGENT MISREPRESENTATION

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

110. Defendants, having undertaken the designing, manufacturing, marketing, distribution and/or promotion of Rotocut G1 power morcellator, owed a duty to provide accurate and complete information regarding Rotocut G1 power morcellator.

111. Defendants falsely represented that Rotocut G1 power morcellator was a safe and effective surgical tool. The representations by Defendants were in fact false, as Rotocut G1 power morcellator is not safe and is dangerous to the health of its users.

112. At the time the aforesaid representations were made, Defendants concealed from Plaintiff and health care providers information about the propensity of Rotocut G1 power morcellator to cause great harm. Defendants negligently misrepresented claims regarding the safety and efficacy of Rotocut G1 power morcellator despite the lack of information regarding same.

113. These misrepresentations were made by Defendants with the intent to induce Plaintiff's surgeons to perform, and Plaintiff to undergo, a procedure using the Rotocut G1 power morcellator, which caused her injury.

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

115. 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 Rotocut G1 power morcellator. 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.

116. 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.

COUNT TEN: FRAUDULENT MISREPRESENTATION AND OMISSION

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

118. Upon information and belief, the Defendants' statements about the Rotocut G1 power morcellator, wrongly and falsely convey that the device may be used safely in surgeries of the type performed on Plaintiff. 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.

119. Defendants, having undertaken design, formulation, testing, manufacture, marketing, sale, and distribution of devices used for uterine morcellation, including the Rotocut G1 power morcellator, owed a duty to provide accurate and complete information regarding said instruments.

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

G1 power morcellator, owed a duty to monitor, analyze and report adverse outcomes stemming from the use of the Rotocut G1 power morcellator.

121. Defendants, having undertaken design, formulation, testing, manufacture, marketing, sale, and distribution of devices used for uterine morcellation, including the Rotocut G1 power morcellator, owed a duty to monitor and respond to multiple published studies that describe the risk of disseminated cancerous cells, the subsequent development of cancer outside the uterus and up-staging of cancer with morcellator use.

122. 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 Rotocut G1 power morcellator. They failed to perform that duty, omitting material information about the instrument's risks.

123. 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 Rotocut G1 power 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 Rotocut G1 power morcellator.

124. Defendants' representations and omissions regarding use of its uterine morcellation device were a direct and proximate cause of the Plaintiffs injuries, specifically the development of cancer outside her uterus, 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.

REQUEST FOR PUNITIVE DAMAGES

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

126. At all times relevant herein, Defendants:

a. knew that Rotocut G1 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 Rotocut G1 power morcellator;

d. with full knowledge of the health risks associated with the Rotocut G1 power morcellator and without adequate warnings of the same, manufactured, marketed, promoted, developed, sold and/or distributed Rotocut G1 power morcellator for routine use.

127. 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.

128. 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.

129. 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: January 26, 2015

Respectfully Submitted,

/s/Carasusana B. Wall

Carasusana B. Wall (0090234)
ZOLL, KRANZ & BORGESS, LLC
6620 W. Central Ave., Suite 100
Toledo, OH 43617
Tel. (419) 841-9623
Fax: (419) 841-9719
Email: cara@zkblaw.com
Counsel for Plaintiff

JURY DEMAND

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

/s/ Carasusana B. Wall
Carasusana B. Wall (0090234)

JS 44 (Rev. 12/12)

CIVIL COVER SHEET

County in which action arose: Wayne County

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

I. (a) PLAINTIFFS

DENISE WHITFIELD

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

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

Zoll, Kranz & Borgess, LLC,
6620 West Central Ave., Suit 100, Toledo, OH 43617
(419) 841-9623

DEFENDANTS

KARL STORZ ENDOSCOPY-AMERICA INC., KARL STORZ ENDOVISION INC., KARL STROZ GMBH & CO. KG

County of Residence of First Listed Defendant: Los Angeles County, CA
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys *(If Known)*

II. BASIS OF JURISDICTION *(Place an "X" in One Box Only)*

- ❒ 1 U.S. Government Plaintiff
- ❒ 3 Federal Question *(U.S. Government Not a Party)*
- ❒ 2 U.S. Government Defendant
- ☒ 4 Diversity *(Indicate Citizenship of Parties in Item III)*

III. CITIZENSHIP OF PRINCIPAL PARTIES *(Place an "X" in One Box for Plaintiff and One Box for Defendant)*

(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☒ 1	❒ 1	Incorporated *or* Principal Place of Business In This State	❒ 4	❒ 4
Citizen of Another State	❒ 2	❒ 2	Incorporated *and* Principal Place of Business In Another State	❒ 5	☒ 5
Citizen or Subject of a Foreign Country	❒ 3	❒ 3	Foreign Nation	❒ 6	❒ 6

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

CONTRACT
- ❒ 110 Insurance
- ❒ 120 Marine
- ❒ 130 Miller Act
- ❒ 140 Negotiable Instrument
- ❒ 150 Recovery of Overpayment & Enforcement of Judgment
- ❒ 151 Medicare Act
- ❒ 152 Recovery of Defaulted Student Loans (Excludes Veterans)
- ❒ 153 Recovery of Overpayment of Veteran's Benefits
- ❒ 160 Stockholders' Suits
- ❒ 190 Other Contract
- ❒ 195 Contract Product Liability
- ❒ 196 Franchise

REAL PROPERTY
- ❒ 210 Land Condemnation
- ❒ 220 Foreclosure
- ❒ 230 Rent Lease & Ejectment
- ❒ 240 Torts to Land
- ❒ 245 Tort Product Liability
- ❒ 290 All Other Real Property

TORTS

PERSONAL INJURY
- ❒ 310 Airplane
- ❒ 315 Airplane Product Liability
- ❒ 320 Assault, Libel & Slander
- ❒ 330 Federal Employers' Liability
- ❒ 340 Marine
- ❒ 345 Marine Product Liability
- ❒ 350 Motor Vehicle
- ❒ 355 Motor Vehicle Product Liability
- ❒ 360 Other Personal Injury
- ❒ 362 Personal Injury - Medical Malpractice

PERSONAL INJURY
- ❒ 365 Personal Injury - Product Liability
- ☒ 367 Health Care/ Pharmaceutical Personal Injury Product Liability
- ❒ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ❒ 370 Other Fraud
- ❒ 371 Truth in Lending
- ❒ 380 Other Personal Property Damage
- ❒ 385 Property Damage Product Liability

CIVIL RIGHTS
- ❒ 440 Other Civil Rights
- ❒ 441 Voting
- ❒ 442 Employment
- ❒ 443 Housing/ Accommodations
- ❒ 445 Amer. w/Disabilities - Employment
- ❒ 446 Amer. w/Disabilities - Other
- ❒ 448 Education

PRISONER PETITIONS

Habeas Corpus:
- ❒ 463 Alien Detainee
- ❒ 510 Motions to Vacate Sentence
- ❒ 530 General
- ❒ 535 Death Penalty

Other:
- ❒ 540 Mandamus & Other
- ❒ 550 Civil Rights
- ❒ 555 Prison Condition
- ❒ 560 Civil Detainee - Conditions of Confinement

FORFEITURE/PENALTY
- ❒ 625 Drug Related Seizure of Property 21 USC 881
- ❒ 690 Other

LABOR
- ❒ 710 Fair Labor Standards Act
- ❒ 720 Labor/Management Relations
- ❒ 740 Railway Labor Act
- ❒ 751 Family and Medical Leave Act
- ❒ 790 Other Labor Litigation
- ❒ 791 Employee Retirement Income Security Act

IMMIGRATION
- ❒ 462 Naturalization Application
- ❒ 465 Other Immigration Actions

BANKRUPTCY
- ❒ 422 Appeal 28 USC 158
- ❒ 423 Withdrawal 28 USC 157

PROPERTY RIGHTS
- ❒ 820 Copyrights
- ❒ 830 Patent
- ❒ 840 Trademark

SOCIAL SECURITY
- ❒ 861 HIA (1395ff)
- ❒ 862 Black Lung (923)
- ❒ 863 DIWC/DIWW (405(g))
- ❒ 864 SSID Title XVI
- ❒ 865 RSI (405(g))

FEDERAL TAX SUITS
- ❒ 870 Taxes (U.S. Plaintiff or Defendant)
- ❒ 871 IRS—Third Party 26 USC 7609

OTHER STATUTES
- ❒ 375 False Claims Act
- ❒ 400 State Reapportionment
- ❒ 410 Antitrust
- ❒ 430 Banks and Banking
- ❒ 450 Commerce
- ❒ 460 Deportation
- ❒ 470 Racketeer Influenced and Corrupt Organizations
- ❒ 480 Consumer Credit
- ❒ 490 Cable/Sat TV
- ❒ 850 Securities/Commodities/ Exchange
- ❒ 890 Other Statutory Actions
- ❒ 891 Agricultural Acts
- ❒ 893 Environmental Matters
- ❒ 895 Freedom of Information Act
- ❒ 896 Arbitration
- ❒ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ❒ 950 Constitutionality of State Statutes

V. ORIGIN *(Place an "X" in One Box Only)*

☒ 1 Original Proceeding | ❒ 2 Removed from State Court | ❒ 3 Remanded from Appellate Court | ❒ 4 Reinstated or Reopened | ❒ 5 Transferred from Another District *(specify)* | ❒ 6 Multidistrict Litigation

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing ***(Do not cite jurisdictional statutes unless diversity)***:
28 U.S.C §1332

Brief description of cause:
This action involves a product liability claim arising out of the use of a power morcellator

VII. REQUESTED IN COMPLAINT:

❒ CHECK IF THIS IS A **CLASS ACTION** UNDER RULE 23, F.R.Cv.P.

DEMAND $ 75,000.00

CHECK YES only if demanded in complaint:

JURY DEMAND: ☒ Yes ❒ No

VIII. RELATED CASE(S) IF ANY

(See instructions): JUDGE _____ DOCKET NUMBER _____

DATE: January 26, 2015

SIGNATURE OF ATTORNEY OF RECORD: /s/ Carasusana B. Wall

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____

PURSUANT TO LOCAL RULE 83.11

1. Is this a case that has been previously dismissed?

☐ Yes
☒ No

If yes, give the following information:

Court: n/a

Case No.: n/a

Judge: n/a

2. Other than stated above, are there any pending or previously discontinued or dismissed companion cases in this or any other court, including state court? (Companion cases are matters in which it appears substantially similar evidence will be offered or the same or related parties are present and the cases arise out of the same transaction or occurrence.)

☐ Yes
☒ No

If yes, give the following information:

Court: n/a

Case No.: n/a

Judge: n/a

Notes :