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UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF CALIFORNIA

LISA NIELSEN, and KURT NIELSEN Plaintiffs, v. GYRUS ACMI, LP, a Minnesota Limited Partnership; GYRUS ACMI, LLC, a Minnesota Limited Liability Company; and DOES 1-50, Defendants.	Case No.: **COMPLAINT FOR:** **1. NEGLIGENCE** **2. STRICT PRODUCTS LIABILITY** **3. BREACH OF EXPRESS WARRANTY** **4. BREACH OF IMPLIED WARRANTY** **5. FRAUD** **6. LOSS OF SERVICES** **JURY TRIAL IS REQUESTED**

Plaintiffs LISA NIELSEN and KURT NIELSEN, complaining of the defendants and seeking a trial by jury of their claims, allege as follows:

I. INTRODUCTION

1. This action is being brought for injuries and damages caused to plaintiffs from the use of a product known as a power morcellator in connection with a hysterectomy on plaintiff LISA NIELSEN that was manufactured, sold and distributed by GYRUS ACMI, LP, GYRUS ACMI, LLC and as Does 1 though 50.

2. Plaintiff LISA NIELSEN had a surgical procedure known as a hysterectomy ("uterine morcellation") assisted by the use of a GYRUS ACMI, LP bipolar morcellator ("Gyrus Power Morcellator").

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II. JURISDICTION AND VENUE

3. This Court has original jurisdiction pursuant to 28 U.S.C. §1332, as the matter in controversy exceeds the sum or value of $75,000, exclusive of interest and costs, and is between citizens of different states as plaintiffs LISA NIELSEN and KURT NIELSEN are residents of the state of California and defendant GYRUS ACMI, LP is a limited partnership domiciled in the State of Minnesota and GYRUS ACMI, LLC is a limited liability company domiciled in the State of Delaware.

4. Venue in the Eastern District of California is proper under 28 U.S.C. §1391(b)(2) as a substantial part of the events or omissions giving rise to the claim occurred in this District.

III. PARTIES

5. Plaintiffs LISA NIELSEN and KURT NIELSEN are adult individuals residing in the city of Grass Valley, State of California.

6. Defendant GYRUS ACMI, LP is a Limited Partnership, organized and existing under the laws of the state of Minnesota, and at all times material and relevant hereto, was engaged in the business of designing, manufacturing, selling, supplying, distributing and marketing minimally invasive gynecological surgical products, including the Gyrus Power Morcellator. Defendant GYRUS ACMI, LLC is the general partner of GYRUS ACMI, LP.

7. Plaintiffs do not know the names and capacities, whether corporate, associate, or individual of defendants sued herein as DOES 1 through 50, inclusive, and therefore they sue these defendants by such fictitious names.

8. Plaintiffs are informed and believe, and thereon allege, that each of the fictitiously named DOE defendants is legally responsible in some manner for the wrongful events and occurrences herein alledged, and each of them was in some manner legally responsible for causing the injuries and damages to plaintiffs as described in this complaint. Plaintiffs will seek leave to amend this complaint to allege the true names and capacities of these Doe defendants when such information has been ascertained.

9. Plaintiffs are informed and believe, and thereon allege, that at all times herein

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mentioned, each of the defendants, whether specifically named or designated in this Complaint as a DOE defendant, was the agent, representative, joint-venture, co-conspirator, consultant, predecessor, successor, servant, or employee of each of the remaining defendants, and in doing the acts alleged herein, was acting in the course and scope of such agency, representation, joint venture, conspiracy, consultancy, predecessor agreement, successor agreement, service and employment with knowledge, acquiescence and ratification of each and every remaining defendant.

10. Defendants DOES 1 through 50, inclusive, were engaged in the business of manufacturing and/or selling and/or supplying and/or marketing and/or designing and/or distributing minimally invasive gynecological surgical products, specifically, the product(s) used upon Plaintiff LISA NIELSEN.

IV. BACKGROUND AND FACTS

11. Paragraphs 1 through 10 are incorporated by this reference into this cause of action as if they were set forth in full.

12. Plaintiff LISA NIELSEN underwent a surgical procedure known as a hysterectomy during which surgery the Gyrus Power Morcellator was used. This surgery took place in the city of Carmichael, California.

13. Prior to plaintiff LISA NIELSEN's surgery, she was unaware that she had cancer.

14. More than a year after the procedure, Plaintiff found out that she had seven cancerous in her abdomen. She thereafter underwent additional surgeries and chemotherapy, and continues to be actively monitored for new tumors.

15. Within the last two years, Plaintiff LISA NIELSEN learned that the tumors in her abdominal existed because the Gyrus Power Morcellator had been used during her hysterectomy. That surgery disseminated the cancer cells that were in her uterine fibroids, and that such dissemination could lead to metastatic disease at more locations.

16. Plaintiff LISA NIELSEN was never warned prior to her hysterectomy that there

was any chance that the "fibroids" could be cancerous, nor that using the Gyrus Power Morcellerator in the hysterectomy brought any chance of spreading cancer.

17. It is alleged that each and every defendant herein failed to warn that the use of the Gyrus Power Morcellerator increased the possibility of dissemination of cancer throughout Plaintiff's body.

18. Defendants knew or should have known of the risks, complications, and/or adverse events associated with their products used for uterine morcellation, but continued to sell them without disclosing the risk involved with the use of their products.

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FIRST CAUSE OF ACTION

NEGLEGENCE

19. Plaintiff incorporates paragraphs 1 to 18 herein by this reference.

20. Defendants GYRUS ACMI, LP, GYRUS ACMI, LLC and Does 1 through 50, inclusive, (hereafter collectively referred to as "Defendants"), owed a duty to design, manufacture, label, market, distribute, and supply and/or sell a product like the Gyrus Power Morcellator in such a way as to avoid harm to persons upon whom it was used, including plaintiff LISA NIELSEN, or to refrain from such activities following knowledge and/or constructive knowledge that such product is harmful to persons upon whom it is used.

21. Defendants owed a duty to warn of the hazards and dangers associated with the use of its product the Gyrus Power Morcellator and its associated minimally invasive gynecological products, for patients such as plaintiff herein, so as to avoid harm.

22. 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, minimally invasive gynecological products, including the Gyrus Power Morcellator, both generally, and in the following respects:

a. failing to conduct adequate and appropriate testing of minimally invasive

gynecological products, specifically including, but not limited to, products used for uterine morcellation;

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

c. putting products used for uterine morcellation 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, 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, 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;

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 are harmful to humans;

k. promoting, marketing, advertising and/or selling products used for uterine morcellation 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

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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 engaged in the manufacture of said products, specifically including products used for uterine morcellation;

n. placing and/or permitting the placement of the products used for uterine morcellation 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 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;

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

r. disregarding the safety and 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;

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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 of lesion removal;

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; and,

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

23. As a direct and proximate result of the negligent and/or recklessness and/or wanton acts and/or omissions of Defendants, Plaintiff LISA NIELSEN suffered serious physical injury, pain and suffering and severe mental and emotional distress and economic loss and harm.

WHEREFORE, Plaintiffs pray for relief as set forth below.

SECOND CAUSE OF ACTION

STRICT PRODUCTS LIABILITY

24. Plaintiff incorporates Paragraphs 1 to 23 above as though fully set forth herein.

25. As a result of the unreasonably dangerous and defective condition of the products used for uterine morcellation, including the Gyrus Power Morcellator, which Defendants manufactured, designed, labeled, marketed, distributed, supplied and/or sold, and/or placed into the stream of commerce, they are strictly liable to the Plaintiff LISA NIELSEN for her injuries which they directly and proximately caused, based on the following:

a. failing to properly and adequately design the products used for uterine morcellation,

b. failing to properly and adequately manufacture the products used for uterine morcellation; and,

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c. such other defects as shall be revealed in the course of discovery.

26. In addition, the aforesaid incident and Plaintiff LISA NIELSEN's injuries and losses were the direct and proximate result of the use the Gyrus Power Morcellerator in the way in which it was intended. Defendants manufactued, designed, labeled, marketed, distributed, supplied, sold and/or placed into the stream of commerce the products to be used for uterine morcellation, without proper and adequate warnings regarding the potential for said products' harm to humans and as otherwise set forth supra, when said Defendants knew or should have known of the need for such warnings and/or recommendations.

WHEREFORE, Plaintiff prays for relief as set forth below.

THIRD CAUSE OF ACTION

BREACH OF EXPRESS WARRANTY

27. Paragraphs 1 through 26 are incorporated by this reference into this cause of action as if they were set forth in full.

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

29. The aforesaid warranties were breached by Defendants in that the products used for uterine morcellation constituted a serious danger to user.

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 physical injury, pain and suffering and severe mental and emotional distress and economic loss and harm.

WHEREFORE, Plaintiff prays for relief as set forth below.

FOURTH CAUSE OF ACTION

BREACH OF IMPLIED WARRANTY

31. Paragraphs 1 through 30 are incorporated by this reference into this cause of

action as if they were set forth in full.

32. At all relevant and material times, Defendants manufactured, distributed, advertised, promoted, and sold the foregoing products used for uterine morcellation.

33. At all relevant times, Defendants intended that the products used for uterine morcellation be used in the manner that the Plaintiff's surgeons in fact used it and Defendants impliedly warranted that product to be of merchantable quality, safe and fit for such use, and was adequately tested.

34. Defendants breached various implied warranties with respect to the products used for uterine morcellation, including:

a. Defendants represented through their labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that the products used for uterine morcellation were safe, and withheld and concealed information about the substantial risks of serious injury and/or death associated with using the products used for uterine morcellation;

b. Defendants represented that the products used for uterine morcellation were as safe and/or safer than the alternative surgical approaches that did not include the use of the said products, and concealed information, which demonstrated that said products were not safer than alternatives available on the market; and,

c. Defendants represented that the products used for uterine morcellation were more efficacious than other alternative surgical approaches and techniques and concealed information, regarding the true efficacy of said products.

35. In reliance upon defendants' implied warranty, Plaintiff's surgeons used said products as prescribed and in the foreseeable manner normally intended, recommended, promoted, instructed, and marketed by Defendant.

36. Defendants breached their implied warranty to Plaintiff in that said products used for uterine morcellation were not of merchantable quality, safe and fit for their intended use, or adequately tested.

37. As a direct and proximate result of the negligent and/or reckless and/or wanton

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act and/or omissions of Defendants, plaintiff suffered serious physical injury, pain, and suffering and severe mental and emotional distress and economic loss and harm.

WHEREFORE, Plaintiff prays for relief as set forth below.

FIFTH CAUSE OF ACTION

FRAUDULENT MISREPRESENTATION AND OMISSION

38. Plaintiff incorporates by this reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs.

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

40. Prior to Plaintiff LISA NIELSEN undergoing her surgery, Defendants fraudulently misrepresented, that the use of their device for uterine morcellation was safe and effective.

41. Defendants had a duty to provide plaintiff LISA NIELSEN, physicians, and other customers with true and accurate information regarding the devices for uterine morcellation it manufactured, marketed, distributed and sold.

42. Defendants made representations and failed to disclose material facts with the intent to induce consumers, including plaintiff, LISA NIELSEN, and the medical community to act in reliance by purchasing and using the uterine morcellation sold by defendant.

43. Plaintiff LISA NIELSEN justifiably relied on her medical provider's use of the Gyrus Power Morcellator during plaintiff's hysterectomy due to Defendants' representations and omissions.

44. Defendants' representations and omissions regarding use of its uterine morcellation devices were a direct and proximate cause of plaintiff's injuries. Plaintiff did not discover Defendants' fraud until a date within the last three years.

45. As a direct and proximate result of the fraud of Defendants, plaintiff suffered serious physical injury, pain and suffering and severe mental and emotional distress and

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economic loss and harm.

46. Because of Defendants' fraud as described herein, plaintiff is entitled to an award of punitive damages against Defendants.

WHEREFORE, Plaintiff prays for relief as set forth below.

SIXTH CAUSE OF ACTION

LOSS OF SERVICES

47. Paragraphs 1 through 46 are incorporated by this reference into this cause of action as if they were set forth in full.

48. Plaintiff, KURT NIELSEN is the spouse of plaintiff LISA NIELSEN and as such is entitled to the services, society, companionship, consortium and support of the plaintiff LISA NIELSEN.

49. By reason of the foregoing acts and omission by the defendants, plaintiff KURT NIELSEN, was deprived of the services, society, companionship, consortium, and support of plaintiff, LISA NIELSEN.

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WHEREFORE, Plaintiffs pray for relief as follows:

a. Compensatory damages in excess of the jurisdictional amount, including, but not limited to pain, suffering, emotional distress, loss of enjoyment of life, loss of services, consortium, society and other non-economic damages in the amount of $5,000,000.00;

b. Economic damages in an amount to be determined at trial of this action;

c. Double or triple damages as allowed by law;

d. Restitution and disgorgement of profits;

e. Reasonable attorneys' fees

f. Punitive damages;

g. The costs of these proceedings;

h. Prejudgment interest; and

i. Such other and further relief as this Court deems just and proper

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DATED: September 19, 2014

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