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Attorney for Plaintiffs
SARAH SALEM-ROBINSON
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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

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| SARAH SALEM-ROBINSON, and ALAN A. ROBINSON,<br>Plaintiffs,<br>vs.<br>RICHARD WOLF MEDICAL INSTRUMENTS CORPORATION, and DOES 1-50,<br>Defendants. | CASE NO. _____<br>COMPLAINT FOR NEGLIGENCE, STRICT PRODUCTS LIABILITY, BREACH OF EXPRESS WARRANTY, BREACH OF IMPLIED WARRANTY; FRAUD; LOSS OF SERVICES<br>JURY TRIAL IS REQUESTED |

Plaintiffs SARAH SALEM-ROBINSON and ALAN A. ROBINSON, 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 performed on plaintiff SARAH SALEM-ROBINSON that was manufactured, sold and distributed by Richard Wolf Medical Instruments Corporation (WOLF CORPORATION) and as Does 1 through 50.

2. Plaintiff SARAH SALEM-ROBINSON had a surgical procedure performed on her known as a supracervical hysterectomy assisted by the use of a Wolf Corporation solid tumor morcellator ("Wolf Power Morcellator") on May 18, 2012, at the Kaiser Santa Clara Medical Center Hospital located in Santa Clara, California.

## 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 plaintiff SARAH SALEM-ROBINSON and ALAN A. ROBINSON, are residents of the state of California and defendant WOLF CORPORATION is a resident of the State of Illinois.

4. Venue in the Northern 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 SARAH SALEM-ROBINSON and ALAN A. ROBINSON are adult individuals residing in the city of Los Altos, County of Santa Clara, state of California.

6. Defendant WOLF CORPORATION is a corporation, or other entity, organized and existing under the laws of the state of ILLINOIS, and who 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 Wolf Power Morcellator, with its principal place of business at 353 Corporate Woods Parkway, city of Vernon Hills, state of Illinois.

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 alleged, 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 mentioned, each of the defendants, whether specifically named or designated in this Complaint as a DOE defendant, was the agent, representative, joint venturer, 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.

## 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. On May 18, 2012 plaintiff SARAH SALEM-ROBINSON underwent a surgical procedure known as a supracervical hysterectomy during which surgery the Wolf Power Morcellator was used. This surgery took place at the Kaiser Santa Clara Medical Center hospital located in the city of Santa Clara, California.

13. Prior to plaintiff SARAH SALEM-ROBINSON's surgery of May 18th, 2012, there was no evidence that she had disseminated or metastatic cancer.

14. Following this procedure, on May 30, 2012, Plaintiff was informed that the one of the "fibroids" that had been removed during the surgery had been, in fact, not a benign fibroid but rather a cancerous tumor, specifically a leiomyosarcoma. Plaintiff was then informed that because the Wolf Power Morcellator had been used during her surgery there was significant risk that cancer cells had been disseminated within her peritoneum by the Wolf Power Morcellator and that such dissemination could lead to metastatic disease at more locations within plaintiff's body.

15. Because of the threat of dissemination of her cancer in her peritoneum and the threat that metastatic disease could occur, plaintiff began undergoing surveillance imaging. Initial imaging of plaintiff's lungs, abdomen and pelvis did not show any lesions or nodules that were consistent with possible metastatic disease.

16. Because of the risk of metastatic disease, plaintiff has undergone and continues to undergo aggressive treatment and therapy that has caused plaintiff injury and severe pain and

suffering. In addition, plaintiff subsequently developed 4 small lesions in one of her lungs that likely represent metastatic leiomyosarcoma which metastases are likely the result of the dissemination of plaintiff's cancer by the Wolf Power Morcellator.

17. It is alleged that each and every defendant herein failed to warn about the possibility of dissemination of an occult uterine leiomyosarcoma throughout the peritoneal cavity.

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

**FIRST CAUSE OF ACTION FOR NEGLIGENCE ON BEHALF OF PLAINTIFF SARAH SALEM-ROBINSON**

19. Paragraphs 1 through 18 are incorporated by this reference into this cause of action as if they were set forth in full.

20. Defendants WOLF CORPORATION 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 Wolf Power Morcellator in such a way as to avoid harm to persons upon whom it was used, including plaintiff Sarah Salem-Robinson, 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 Wolf Power Morcellator and its associated minimally invasive gynecologic 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 gynecologic products, including the Wolf Power Morcellator, both generally, and in the following particular respects:

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

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 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 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 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 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, plaintiffs pray for relief as set forth below.

**SECOND CAUSE OF ACTION FOR STRICT PRODUCTS LIABILITY**

**ON BEHALF OF SARAH SALEM-ROBINSON**

24. Paragraphs 1 through 23 are incorporated by this reference into this cause of action as if they were set forth in full.

25. As a result of the unreasonably dangerous and defective condition of the products used for uterine morcellation, including the Wolf 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 Plaintiffs for their 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,

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

26. In addition, the aforesaid incident and Plaintiffs' injuries and losses were the direct and proximate result of Defendants' manufacturing, designing, labeling, marketing, distributing,

supplying and/or selling and/or placing into the stream of commerce the products 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, plaintiffs pray for relief as forth below.

**THIRD CAUSE OF ACTION BREACH OF EXPRESS WARRANTY**

**ON BEHALF OF SARAH SALEM-ROBINSON**

27. Paragraphs 1 through 18 are incorporated by this reference into this cause of action as if they were set forth in full.

28. In the 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 for the 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 the 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 pray for relief as set forth below.

**FOURTH CAUSE OF ACTION FOR BREACH OF IMPLIED WARRANTY**

**ON BEHALF OF SARAH SALEM-ROBINSON**

31. Paragraphs 1 through 18 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 the 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. Defendant represented that the products used for uterine morcellation were as safe and/or safer than other 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 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, plaintiffs pray for relief as set forth below.

**FIFTH CAUSE OF ACTION FOR**

**FRAUDULENT MISREPRESENTATION AND OMISSION**

38. Plaintiffs incorporate 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 SARAH SALEM-ROBINSON 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 SARAH SALEM-ROBINSON, physicians, and other consumers 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, SARAH SALEM-ROBINSON, and the medical community to act in reliance by purchasing and using the uterine morcellator sold by defendant.

43. Plaintiff SARAH SALEM-ROBINSON and the medical community justifiably relied on Defendants' representations and omissions by purchasing and using the Wolf Power Morcellator during plaintiff's hysterectomy.

44. Defendants' representations and omissions regarding use of its uterine morcellation devices were a direct and proximate cause of plaintiffs' injuries.

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 economic loss and harm.

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

WHEREFORE, plaintiffs pray for relief as set forth below.

**SIXTH CAUSE OF ACTION FOR LOSS OF SERVICES**

**ON BEHALF OF ALAN A. ROBINSON**

47. Paragraphs 1 through 18 are incorporated by this reference into this cause of action as if they were set forth in full.

support of the plaintiff, SARAH SALEM-ROBINSON.

49. By reason of the foregoing acts and omissions by the defendants, plaintiff ALAN A. ROBINSON, was deprived of the services, society, companionship, consortium and support of plaintiff, SARAH SALEM-ROBINSON.

WHEREFORE, plaintiffs pray for relief as follows:

1. 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 an amount to be determined at trial of this action;

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

3. Double or triple damages as allowed by law;

4. Restitution and disgorgement of profits;

5. Reasonable attorneys' fees;

6. Punitive damages;

7. The costs of these proceedings;

8. Prejudgment interest; and

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

DATED: May 13, 2014

William Campisi Jr.
Attorney for Plaintiffs