

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

LAWANDA SALISBURY,
Plaintiff,

v.

INTUITIVE SURGICAL, INC.
Defendants.

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Christina Kovacs (P75687)
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COMPLAINT AND JURY DEMAND

NOW COMES Plaintiff, Lawanda Salisbury, by and through her attorney, Oliver Law Group, P.C., and in her complaint against Defendants, states as follows:

PARTIES AND JURISDICTION

1. Plaintiff is a resident of the county of Wayne, State of Michigan.
2. Defendant is a Delaware corporation, licensed to do business in the State of Michigan, with a principal place of business in Sunnyvale, California.
3. This Court has diversity jurisdiction over this case pursuant to 28 U.S.C. § 1332, as the parties are citizens of different states and the matter in controversy exceeds \$75,000.00.

4. Venue is proper pursuant to 28 U.S.C. §1391 as a substantial part of the events giving rise to this case occurred in the Eastern District of Michigan. Additionally, Defendant conducts significant business in the Eastern District of Michigan.

GENERAL FACTUAL ALLEGATIONS

1. On, November 06, 2009, Plaintiff underwent a surgical procedure known as a robotic assisted laparoscopic total hysterectomy, at Henry Ford Hospital.
2. After Plaintiff's surgeons began the minimally invasive procedure, defects in the robot caused Plaintiff's surgeons to suddenly and unexpectedly abandon the minimally invasive procedure and engage in an open abdominal total hysterectomy.
3. This procedure utilizes the da Vinci robot system allowing the surgical procedure to be minimally invasive.
4. The da Vinci robot utilizes a number of interchangeable component instruments, designed, manufactured and sold by Defendant.
5. One of the instruments, used with the robot in Plaintiff's surgery was the *Hot Shears*TM Monopolar Curved Scissors. (EXHIBIT A & B).
6. Defendant recommends this instrument for use in hysterectomy procedures.
7. Defendant recommends this instrument be used up to 30 times and warrants this instrument for 30 uses and/or 1-year from the shipment date. (EXHIBIT B).
8. Henry Ford Hospital programs the da Vinci robot to only allow one set of monopolar scissors to be used 10 times prior to replacement. (EXHIBIT B).
9. During Plaintiff's robotic assisted laparoscopic hysterectomy, one of the blades on the monopolar scissors broke off and became lost.

10. After commencing the procedure, Plaintiff's attending surgeon, Dr. Evan Theoharis and assistant Surgeon, Dr. David Eisenstein, noticed the robot's monopolar scissors was missing one of the two blades. (EXHIBIT C).
11. After the surgeons discovered this blade detached from the robot, they were concerned the blade remained inside of the patient, and decided to "explore" the patient's upper abdomen for the blade. (EXHIBIT C).
12. The blade is metallic and only half a centimeter in length. The small size of the blade caused the surgeons difficulty in ascertaining the blades location. (EXHIBIT C).
13. The search ended upon retrieval of the blade. This allowed the surgeons to close up the patient.
14. Plaintiff's surgeons used this instrument in accordance with the recommended usage and in a foreseeable manner.
15. At the time they broke, the monopolar scissors had been used less than 10 times.
16. Plaintiff consented to the robotic assisted laparoscopic total hysterectomy because the benefits of minimally invasive surgery included a faster recover time, a shorter hospital stay and less scarring.
17. Plaintiff's desire to return to work and passion for dancing increased the value of the faster recovery time offered by the minimally invasive surgery.
18. The defective scissors caused Plaintiff to endure a more invasive and extensive procedure than she originally consented to and anticipated, requiring Plaintiff's surgeons to explore her upper abdomen for a sharp piece of metal, only a half centimeter in length.
19. The more invasive procedure exposed Plaintiff to higher risk of death and/or injury and increased Plaintiff's recovery time, hospital stay, and scarring.

20. Defendant represented the usage of the da Vinci robot allowed for a minimally invasive procedure, resulting in significantly less pain, minimal blood loss, fewer complications, and quicker recovery times.
21. In this case, the usage of the da Vinci robot resulted in an invasive procedure with a longer recovery time, greater blood loss and greater complications than a traditional hysterectomy.
22. The failure of the da Vinci robot's monopolar curved scissors caused great bodily harm to Plaintiff. Plaintiff lost a significant amount of blood, endured a longer recovery, and was unable to return to work and unable to engage in her true passion for dancing, for several weeks following the procedure.

HISTORY OF THE DA VINCI SYSTEM

23. In July 2000, the FDA cleared the da Vinci robot for laparoscopic surgery. (EXHIBIT D)
24. In 2003, Intuitive Surgical offered the first major upgrade to the da Vinci system by offering a 4th instrument arm. (EXHIBIT D)
25. In 2006, the da Vinci system was upgraded to offer high definition vision to the surgeon and integrated patient vital signs into the robot. The 2006 upgrades also increased instrument reach and arm movement. (EXHIBIT D)
26. The final improvement in the 2006 upgrades was to streamline the operating room set-up by offering a simplified set up and few pieces to coordinate. (EXHIBIT D).
27. The robot still relied upon the usage of interchangeable and replaceable instruments, such as the monopolar scissors.

COUNT ONE: STRICT LIABILITY- MANUFACTURING DEFECT

28. Plaintiff incorporates all preceding paragraphs by reference and further states as follows:

29. Defendant designed, developed, manufactured, tested, packaged, advertised, promoted, marketed, distributed, labeled and sold component parts for the da Vinci robot, including the monopolar scissors, in a condition which rendered them unreasonably dangerous due to the propensity to result in failure of the device. The robot and component parts were unreasonably dangerous in construction and/or composition.

30. The component part of the robot, the monopolar scissors, were defective in manufacture, construction and compositions, causing them to deviate in a material way from Defendant's manufacturing standards and differentiate from otherwise identical products manufactured to the same design formula, when they left Defendant's control.

31. Surgeons used the monopolar scissors in a reasonably foreseeable way, at the time the scissors failed.

32. The scissors failed when a blade broke off and got lost inside the patient during surgery.

33. As a direct and proximate result of the use of the monopolar scissors with the da Vinci robot, as manufactured, designed, sold and supplied by Defendant, Plaintiff suffered harm, damages, and economic loss, as previously described.

34. The defects in the monopolar scissors caused physical, economical and emotional harm to Plaintiff.

COUNT II: STRICT LIABILITY- DESIGN DEFECT

35. Plaintiff incorporate by reference the preceding paragraphs and further states as follows:

36. At all relevant times, Defendants engaged in the development, testing, manufacturing, and sales of the monopolar scissors for use with the da Vinci robot.
37. Defendant knew the scissors would be used in hysterectomies when they designed, tested, manufactured and sold the scissors.
38. The scissors were defective and unreasonably dangerous when they left the control of Defendant, because they had a propensity to break, failed to include any mechanism for alerting the surgeon upon breaking during usage, and failed to include technology allowing for the surgeon to locate the broken instrument inside of a patient.
39. The defects in the scissors harmed Plaintiff by forcing her surgeons to search for a sharp piece of metal within her body cavity, without any knowledge of when they broke and where the scissors were located, these actions, caused additional trauma to the patient by changing the nature of the procedure from minimally invasive to invasive and by causing exploratory surgery to locate the missing device.
40. The propensity of the scissors to break, increases the risks of the da Vinci robot procedure over traditional surgery without offering substantial benefits to the patient to justify this risk.
41. Defendant failed to warn Plaintiff and her doctors about the risk of failure associated with the monopolar scissors component used with the da Vinci robot.
42. As a result of Defendant's failures and the product's defects, Plaintiff suffered physical, emotional and economic harm.

COUNT III: NEGLIGENCE

43. Plaintiff incorporates the previous paragraphs by reference and continues to state as follows:

44. Defendants had a duty to exercise reasonable care in the design, manufacture, testing, marketing, sales and distribution of the da Vinci robot component instruments, including the monopolar scissors.
45. Defendants breached this duty of care by designing, manufacturing, selling and distributing a defective pair of monopolar scissors, which broke in the course of reasonable and foreseeable usage, got lost in a patient, and caused injury to the patient.
46. This resulted from Defendant's careless design and manufacturing of the scissors, which failed to include reasonable warnings and safeguards, which could alert surgeons when the scissors break during surgery and implement technology to prevent the scissors from getting lost in a patient.
47. Defendant knew or should have known would result in harm to Plaintiff.
48. Defendant's careless design and manufacturing of the monopolar scissors caused Plaintiff's surgeons to abruptly change surgical procedures, abandon the minimally invasive technique, and explore Plaintiff's upper abdomen for a missing piece of a robot instrument.
49. Defendant's conduct set forth in the previous paragraphs resulted in physical, mental and economic damages to Plaintiff.

COUNT IV: NEGLIGENT MISREPRESENTATION

50. Plaintiff incorporates the previous paragraphs by reference and continues to state as follows:
51. Defendant misrepresented the efficacy and safety of the monopolar scissors by their statements warranting the monopolar scissors for 30 uses.

52. Defendant failed to disclose the propensity of the scissors to break when used less than 10 times, and failed to disclose the lack of warnings and safeguards implemented to prevent the scissors from getting lost in a patient.
53. Defendants had a duty to provide Plaintiff and surgeons with true and accurate information of any known risks and harmful side effects of the medical device they marketed and sold.
54. Defendant breached this duty with their omissions of harmful information and their misleading warranty statements which lead an ordinary consumer to believe the instrument was safe and effective.

WHEREFORE Plaintiff requests an award of damages against Defendant to compensate her for the physical, emotional, and economic injuries caused by the defective product, along with any other relief this court determines is equitable and just.

Date: July 6, 2012

OLIVER LAW GROUP, P.C.

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