UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO

1:14CV225

Civil Action No. _____

J. BARRETT

ERIKA STARR
1817 Bluefield Place, Apt. #1
Cincinnati, OH 45237

And

NICK GRIFFITH
1817 Bluefield Place, Apt. #1
Cincinnati, OH 45237

Plaintiffs,

v.

INTUITIVE SURGICAL, INC.
1266 Kifer Road
Sunnyvale, CA 94086

Serve: CT CORPORATION SYSTEM
150 West Market Street, Suite 800
Indianapolis, IN 46204

Defendant.

COMPLAINT AND
JURY TRIAL DEMAND

Plaintiffs, Erika Starr and Nick Griffith, by and through Counsel, hereby state their Complaint against Defendant Intuitive Surgical, Inc. as follows:

THE PARTIES

1. Plaintiff, Erika Starr, is a resident and citizen of Cincinnati, Hamilton County, Ohio.

2. Plaintiff, Nick Griffith, is a resident and citizen of Cincinnati, Hamilton County, Ohio.

3. Plaintiffs are a lawfully married couple and have three minor children.

4. Plaintiff, Erika Starr was 38 years of age at the time she sustained her injuries.

5. Plaintiffs are residents of Hamilton County, Ohio and are entitled to collect damages are a foreseeable result of Defendant Intuitive Surgical, Inc.'s (hereinafter "INTUITIVE") conduct.

6. Defendant INTUITIVE is a foreign business corporation, duly organized and existing under and by virtue of the laws of the State of Delaware with a principal place of business in the State of California at 1266 Kifer Road, Building 100, Sunnyvale, CA 94086-5304. Its registered agent for service is CT Corporation System, 450 West Market, Suite 800, Indianapolis, Indiana 46204.

JURISDICTION AND VENUE

7. At all times material to this Complaint, Defendant conducted and transacted business within the State of Indiana and in Hamilton County, by advertising, soliciting, selling, promoting, and distributing *da Vinci* ® Robotic Surgical System to hospitals, healthcare facilities, healthcare systems, healthcare providers, and ultimately to consumers, including Plaintiffs Heather and Matthew Bays.

8. Jurisdiction is conferred on this Court by the provisions of 28 U.S.C. § 1332 (a), *et seq.*, by virtue of diversity of citizenship where the matter in controversy, exclusive of interest and cost, exceeds $75,000.00.

9. Venue is appropriate in the Southern District of Indiana because the acts of negligence and the injuries sustained as a result of the negligence took place in Hamilton County within the State of Indiana.

FACTUAL ALLEGATIONS

A. Nature of the Case

10. Plaintiffs, Erika Starr and Nick Griffith, bring this case against Defendant INTUITIVE for damages associated with the use of the *da Vinci* ® Surgical System and its instrumentation, including but not limited to, the Monopolar Curved Scissors. Specifically, as a direct result of the use of the *da Vinci* ® Surgical System and its instrumentation, including the Monopolar Curved Scissors on or about March 13, 2013, Plaintiffs suffered physical and emotional injuries, including Plaintiff Erika Starr suffering a bowel perforation and/or thermal burns and subsequent infections that caused severe and permanent injuries, serious physical and mental pain and suffering, medical, hospital and surgical expenses, lost wages, and the impairment to earn money.

B. *da Vinci* ® Surgical System

11. Defendant INTUITIVE is a Delaware corporation with its principal place of doing business in Sunnyvale, California.

12. Defendant INTUITIVE is a publically traded company on the NASDAQ exchange, with a current market value of more than two billion dollars.

13. On its website Defendant INTUITIVE asserts that it is the global technology leader in surgical robotic products and promotes and advertises its products extensively.

14. Defendant INTUITIVE designed, manufactured, tested, marketed, distributed and aggressively sold, promoted and labeled the *da Vinci* ® Surgical System and its instrumentation, including but not limited to, the Intuitive Surgical EndoWrist Instrument Hot Shears Monopolar Curved Scissors (hereinafter "Monopolar Curved Scissors") to hospitals, healthcare facilities, healthcare systems, including but not limited Christ

Hospital, healthcare providers and ultimately to consumers, including Plaintiffs Erika Starr and Nick Griffith, in the State of Ohio.

15. Defendant INTUITIVE is the holder of the U.S. Food and Drug Administration (hereinafter "FDA") approved medical device, the *da Vinci* ® Surgical System and its instrumentation, including the Monopolar Curved Scissors.

16. The *da Vinci* ® Surgical System as manufactured by Defendant INTUITIVE is used to perform surgery, including cardiac, colorectal, general, gynecology, head and neck, thoracic and urology surgery throughout the United States, including in the State of Ohio.

17. At all relevant times, Defendant INTUITIVE performed pre and post market medical device surveillance in connection with the reporting of complaints and adverse events associated with the use of the *da Vinci* ® Surgical System and injuries and deaths that patients received while having surgery with the *da Vinci* ® Surgical System.

18. Defendant INTUITIVE has promoted its device as (a) safe and (b) safer than other comparative methods of surgery including, in the case of traditional laparoscopy and/or laparotomy.

19. The defects in Defendant INTUITIVE's products were inherent and existed at the time it left the Defendant INTUITIVE's facilities.

20. Defendant INTUITIVE utilizes prominent websites aimed at consumers, seeking to create demand and assurances for the use of its robotic device by patients who consult surgeons.

21. Defendant INTUITIVE sold its device through a calculated program of intimidation and market management, forcing hospitals and physicians to purchase it in order to appear to

be competitive, and creating a fear in their minds that if they did not have this technology they would lose business to competitors.

22. Defendant INTUITIVE reinforced its calculated program, as stated in the preceding paragraph, by placing, on its website for potential patients, names of certain physicians who had performed surgeries with this device.

23. Hospitals have paid in excess of $1.5 million dollars for the product, and more than 2,500 such machines have been marketed and sold by Defendant INTUITIVE and Defendant INTUITIVE has sold five (5) year maintenance contracts at a cost of approximately $100,000 per year per machine, and the *da Vinci* ® Surgical System has been used in over 400,000 surgeries.

24. On or about August 5, 2011, Defendant INTUITIVE submitted a Special 510(k) Device Modification for the Monopolar Curved Scissors Tip Cover Accessory, the description of which is, "an electrically isolating sleeve that is placed over the distal tip of the Monopolar Curved Scissors. The Tip Cover Accessory acts to isolate the metal parts of the instrument so that only the intended electrode (the scissor blades) is exposed for surgical application."

25. On October 7, 2011, the FDA responded to Defendant INTUITIVE's Special 510(k) Device Modification for the Monopolar Curved Scissors Tip Cover Accessory and permitted Defendant INTUITIVE to market the device.

26. In October 2011, as a response to complaints and medical device reports for arching through damaged tip covers that caused patient injuries, Defendant INTUITIVE initiated a field correction by sending letter to *da Vinci* ® Surgical System clients with suggestions

and recommendation for the proper use of the Tip Cover Accessory and for the correct generators that should be used with monopolar instruments.

27. In October 2011, Defendant INTUITIVE initiated a separate field correction by sending letters to *da Vinci* ® Surgical System clients with information for inspecting the instrument cannulas, proper flushing of the instruments and proper transportation of the *da Vinci* ® Surgical System between buildings.

28. In September 2012, Defendant INTUITIVE revised its medical device reporting practices, resulting in increased reports of device malfunction reports and administratively changed how medical device reports previously reported as adverse events were subcategorized resulting in an increase in events in the "serious injury" category.

29. Between 2011 and 2012, there was a spike in the number of adverse event reports filed with the FDA's Manufacturer and User Facility Experience (MAUDE) by 34% and during the same time period there was an increase with the number of procedures using the *da Vinci* ® Surgical System by 26%.

30. As of January 2013, Defendant INTUITIVE submitted additional 500 medical device reports to the FDA increasing the additional injuries and deaths reported.

31. As of January 2013, there were over 4,600 adverse events reported in the MAUDE database with the FDA, some of which contained information concerning patient injuries and deaths.

32. In January 2013, after an increase in adverse event reports and injuries, the FDA asked surgeons whose hospitals belong to the agency's Medical Product Safety Network to participate in a survey about the *da Vinci* ® Surgical System. Surgeons were asked about

user training, common equipment errors, patient selection and the complications they endured and how the complications with the *da Vinci* ® Surgical System compared with conventional surgeries, and what procedures are the best and least suited for the *da Vinci* ® Surgical System.

33. In March, 2013, the American College of Obstestricians and Gynecologists [hereinafter "ACOG"] declared, "Expertise with robotic surgery is limited and varies widely among hospitals and surgeons". ACOG further declared, "Studies have shown that adding this expensive technology [*da Vinci* ® robotic surgery] for routine surgical care does not improve patient outcomes. Consequently, there is no good data proving that robotic surgery is even as good as – let alone better – than existing, and far less costly, minimally invasive alternatives."

34. In March, 2013, ACOG concluded its statement, "Aggressive direct—to—consumer marketing of the latest medical technologies may mislead the public into believing that they are the best choice. Our patients deserve and need factual information about all of their treatment options, including costs, so that they can make truly informed healthcare decisions. Patients should be advised that robotic surgery is best used for unusual and complex clinical conditions in which improved outcomes over standard minimally invasive approaches have been demonstrated."

35. In March 2013, the Board of Registration in Medicine, Quality and Patient Safety Division in the Commonwealth of Massachusetts issued an Advisory on Robot-Assisted Surgery making recommendations on:

    a. Training, proctoring and assessment of proficiency with robotic surgery;

    b. Patient selection and risk assessment;

c. Informed decision making and noted that "Careful attention should be paid to the influences of direct to patient marketing and other factors that may introduce different dynamics into the patient selection process;" and

d. Perioperative considerations.

36. Prior to March 13, 2013, Defendant INTUITIVE was aware that patients had sustained bowel perforations, injuries and/or thermal burns and other injuries during the use of the *da Vinci* ® Surgical System and its instrumentation.

37. Prior to March 13, 2013, Defendant INTUITIVE was aware that patients with adhesions were at an increased risk to suffer bowel perforations when having surgery with the *da Vinci* ® robotic surgery and/or that intra-abdominal adhesions were a relative and/or absolute contraindication to having surgery via the *da Vinci* ® robot.

38. On March 13, 2013, Plaintiff Erika Starr had an exploratory laparoscopic *da Vinci* ® robotic surgery that included the removal of a left retroperitoneal cyst at Christ Hospital.

39. On or about April 19, 2013, Defendant INTUITIVE recalled the monoplar scissors because the instruments "may develop micro-cracks near the distal (scissor) end of the shaft following reprocessing. This may create a pathway for electrosurgical energy to leak to tissue during use and potentially cause thermal injury.... These micro-cracks may not be visible to the user."

40. On or about April 26, 2013, the FDA announced that it had launched an investigation into Defendant INTUITIVE and its medical device, the *da Vinci* ® Surgical System.

41. On or about May 2013, Defendant INTUITIVE started shipping a new revised version of the Monopolar Curved Scissors.

42. On July 16, 2013, the FDA issued a warning letter to Defendant INTUITIVE stating that Defendant INTUITIVE failed to do the following, including but not limited to:

a. Notify the FDA of the field correction letters Defendant INTUITIVE sent out to *da Vinci* ® Surgical System Clients in October 2011 concerning the monopolar scissors;

b. Notify the FDA of the field correction letters Defendant INTUITIVE sent out in October 2011 to *da Vinci* ® Surgical System clients concerning thyroidectomies indications not being cleared;

c. Notify the FDA of the field correction letters that Defendant INTUITIVE sent out in October 2011 to *da Vinci* ® Surgical System clients concerning the inspection of the instrument cannulas, proper flushing and transportation of the *da Vinci* ® Surgical System between buildings;

d. Take appropriate action despite having knowledge that patient injuries associated with intraoperative cleaning of energized instruments such as the Monopolar Curved Scissors and Fenestrated Bipolar Scissors.

43. Plaintiffs were advised that Plaintiff Erika Starr needed to have *da Vinci* ® robotic surgery.

44. Plaintiffs were presented with information promoting the benefit of a *da Vinci* ® robotic surgery over all other methods of surgery. Specifically, Plaintiffs were informed that due to the *da Vinci* ® robotic approach Erika Starr would heal faster, have a better outcome and have less pain.

45. Based on representations made and information provided to her, the Plaintiff agreed to proceed with the *da Vinci* ® robotic surgery.

46. During her *da Vinci* ® robotic surgery on March 13, 2013, PK gyrus biopolar grasper, a Prograf grapser and Monopolar Curved Scissors manufactured and distributed by Defendant INTUITIVE were used intraoperatively.

47. Plaintiff Erika Starr's surgery on March 13, 2013 resulted in her suffering a thermal injury and/or perforation to her small bowel, peritonitis, sepsis, pulmonary embolus, pericardial effusion and bilateral pleural effusions and additional surgeries, care and treatment, prolonged hospitalization and increased medical expenses, loss of wages, and loss of enjoyment of life.

48. Plaintiff continues to suffer from chronic abdominal pain, severe abdominal issues and other issues. Through this time period Erika Starr has been unable to maintain normal relationships and responsibilities and was totally dependent on her husband, Nick Griffith and she has suffered emotional distress and was unable to work for a period of time.

49. The use of Defendant INTUITIVE's robotic device in surgery presents substantial risks of complications and injuries, including, but not limited to, ureter injuries, thermal burns, de-vascularzation of the vaginal cuff impeding healing, partial thermal injury burns to bowel, post-surgical abscesses, tears, bleeding, hematomas, sepsis, fistulas and otherwise.

50. More specifically, Defendant INTUITIVE's robotic device can cause damage to the bowel, rectum, blood vessels, arteries, ureters, bladder and vaginal cuff.

51. On occasion these complications and injuries cause and/or contribute to infectious processes from thermal injury causing abscess formation and can lead to excessive pain, suffering and permanent emotional and physical disability.

52. Defendant INTUITIVE has been aware and was aware long before March 13, 2013 of the aforesaid risks and complications associated with the use of the *da Vinci* ® Surgical

System and the Monopolar Curved Scissors and its other assessories and has failed to take proper precautions including failure to make property notifications to hospitals, patients, doctors and the FDA.

53. Defendant INTUITIVE did not provide adequate warnings to physicians and patients about the risks and complications associated with the use of its robotic device, including but not limited to advising healthcare providers such as Dr. Marcia Bowling and Dr. Aparna Dacha of the increased risks of bowel perforations with patients with adhesions and/or the relative and/or absolute contraindication of the use of the *da Vinci* ® robot for surgery for patients with adhesions.

54. Defendant INTUITIVE has not done, nor sponsored any testing as to long-term outcomes in comparison to other surgical and laparoscopic methods.

55. Defendant INTUITIVE had not revealed timely, through publications or reports to the FDA and other governmental bodies, the true extent of complications and injuries, which then known to have been occurring in actual practice.

56. Defendant INTUITIVE had been suppressing reports and complaints of complications and performance errors due to the use of its said device prior to Plaintiff's surgery.

57. Defendant INTUITIVE does not adequately train physicians nor proctor them properly on the use of its device, thereby inducing them to cause complications and injuries, which would be avoided in the hands of properly trained physicians.

58. Defendant INTUITIVE represents that they will have skilled technicians in the operating room or on emergency call in the event of problems arising with its said device, but often has neglected to do so.

59. Defendant INTUITIVE has aggressively over-promoted its device to hospitals, physicians and the public, including potential consumers, combined with minimizing the risks and complications associated with its use.

60. The *da Vinci* ® surgical robot was defective in that it relied upon the use of monopolar energy to cut, burn, cauterize tissue, whereas safer methods were available.

61. The device has inadequate insulation for its arms thereby allowing electrical current to pass into tissue outside of the operative field thereby causing extensive injury.

62. The insulation on the shafts of the said device had become torn and worn in places, without the awareness of the physician user allowing electrical current to pass into tissue outside of the operative field causing damage.

63. Defendant INTUITIVE had failed to warn users and consumers of the said robotic device about the inadequate insulation on the arms and the potential for electrical current to pass into tissue outside of the operative field.

64. Due to design defects, Defendant INTUITIVE's devices had malfunctioned during the course of operative use causing injury, requiring additional surgeries and procedures to deal with complications of robotic use.

65. Defendant INTUITIVE had failed to warn users and consumers of its said device of the design flaws stated in the preceding paragraphs, although it has reached out directly to consumers to promote its asserted advantages.

66. Defendant INTUITIVE, in points of time, had specific knowledge and awareness of the dangers of monopolar current and that there were safety modalities commercially available that could have greatly diminished or eliminated some of these risks, yet the

Defendant INTUITIVE elected not to include these safety features on the *da Vinci* ® Robotic gynecology platform.

67. Defendant INTUITIVE had obtained and continued to maintain approval of the uses of its device from the FDA by failing to fully inform them of its knowledge of risks and complications associated with the use of its device.

68. As a direct result of Defendant INTUITIVE's conduct, Plaintiff Erika Starr has suffered and has had extensive surgeries and injuries and will be need in all likelihood care and treatment into the future.

FIRST CAUSE OF ACTION – STRICT LIABILITY

69. Plaintiffs incorporate by reference each and every paragraph of this Complaint as though set forth in full in this cause of action.

70. At the time of Plaintiff Erika Starr's injuries, Defendant INTUITIVE's *da Vinci* ® Surgical System and its instrumentation, including but not limited to, the Monopolar Curved Scissors, PK gyrus biopolar grapser, and/or the Prograf grasper were defective and unreasonably dangerous to foreseeable consumers, including Plaintiff.

71. The *da Vinci* ® Surgical System and its instrumentation, including but not limited to the Monopolar Curved Scissors, PK gyrus biopolar grapser and/or the Prograf grasper were in the same or substantially similar condition as it was when it left the possession of Defendants.

72. Plaintiffs did not misuse or materially alter the *da Vinci* ® Surgical System and/or its instrumentation.

73. Defendant INTUITIVE is strictly liable for Plaintiffs' injuries in the following ways:

a. The *da Vinci* ® Surgical System and its instrumentation as designed, manufactured, sold and supplied by Defendant, was defectively designed and placed into the stream of commerce by Defendants in a defective and unreasonably dangerous condition;

b. Defendant INTUITIVE failed to properly market, design, manufacture, distribute, supply and sell the *da Vinci* ® Surgical System and its instrumentation;

c. Defendant INTUITIVE failed to warn and place adequate warnings and instructions on the *da Vinci* ® Surgical System and its instrumentation, including but not limited to the Monopolar Curved Scissors, PK gyrus biopolar grapser and/or the Prograf grasper;

d. Defendant INTUITIVE failed to adequately test the *da Vinci* ® Surgical System and its instrumentation, including but not limited to, the Monopolar Curved Scissors PK gyrus biopolar grapser and/or the Prograf grasper;

e. Defendant INTUITIVE failed to provide timely and adequate post-market warnings and instructions after they knew of the risk of injury associated with the use of the *da Vinci* ® Surgical System and its instrumentation, including but not limited to, the Monopolar Curved Scissors; PK gyrus biopolar grapser and/or the Prograf grasper;

f. A Feasible alternative design existed that was capable of preventing Plaintiffs' injuries.

74. Defendant INTUITIVE's actions and omissions were the direct and proximate cause of Plaintiffs' injuries.

75. Defendant INTUITIVE's conduct as described above, was extreme and outrageous. Defendant INTUITIVE risked the lives of consumers and users of their products, including Plaintiff's, with the knowledge of the safety and efficacy problems and suppressed this knowledge from the general public. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendant's outrageous conduct warrants an award of punitive damages.

WHEREFORE, Plaintiffs demand judgment against Defendant INTUITIVE for compensatory, treble and punitive damages, together with interests, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

SECOND CAUSE OF ACTION - NEGLIGENCE

76. Plaintiffs incorporate by reference each and every paragraph of this Complaint as though set forth in full in this cause of action.

77. Defendant INTUITIVE had a duty to exercise reasonable care in the manufacture, labeling, sale and distribution of the *da Vinci* ® Surgical System and its instrumentation, including but not limited to, the Monopolar Curved Scissors, PK gyrus biopolar grapser and/or the Prograf grasper; including a duty to assure that the product did not cause unreasonable, dangerous injuries and/or deaths to patients.

78. Defendant INTUITIVE owed Plaintiffs a duty to exercise reasonable care when designing, testing, manufacturing, marketing, advertising, promoting, distributing, and/or selling *da Vinci* ® Surgical Systems and its instrumentation for surgery.

79. Defendant INTUITIVE failed to exercise ordinary care in the manufacture, sale, warnings, quality assurance, quality control and distribution of the *da Vinci* ® S urgical System and its instrumentation in that Defendant INTUITIVE knew or shown have

known that the *da Vinci* ® Surgical System and its instrumentation created a high risk of unreasonable harm.

80. Defendant INTUITIVE was negligent in the design, manufacture, advertising, warning, marketing and sale of the *da Vinci* ® Surgical System and its instrumentation, including but not limited to, the Monopolar Curved Scissors and violated R.C.§2307.74, R.C. § 2307.75, R.C. § 2307.76, R.C. § 2307.77 in that among other things Defendant:

a. Failed to use care in designing and manufacturing the *da Vinci* ® Surgical System its instrumentation so as to avoid the aforementioned risks to individuals;

b. Failed to accompany the *da Vinci* ® Surgical System and its instrumentation with proper warnings regarding all possible adverse events including injuries and deaths associated with its use, and the comparative severity and duration of such injuries and/or the complications of deaths. The warning given did not accurately reflect adequate instructions for use, potential complications, and potential known hazards and design defects that Defendant INTUITIVE was aware of prior to March 13, 2013 associated with the use of the *da Vinci* ® Surgical System and its instrumentation;

c. Failed to provide adequate training, proctoring and instruction to hospitals, healthcare systems and medical care providers as to the appropriate use of the *da Vinci* ® Surgical System and its instrumentation;

d. Placed unsafe products into the stream of commerce; and

e. Were otherwise careless or negligent.

81. At all relevant times to this action, Defendant INTUITIVE owed a duty to properly warn Plaintiffs, the healthcare community and the public of risks, dangers and adverse side effects of the *da Vinci* ® Robotic surgery platform as soon as it became known.

82. Defendant INTUITIVE breached its duty by failing to exercise ordinary care in the preparation, design, research, testing, development, manufacturing, inspection, labeling, marketing, promotion, advertising and selling of *da Vinci* ® Robotic Surgery, as set forth below:

a. Failing to test *da Vinci* ® robot properly and thoroughly before promoting the robotic surgical platform using monopolar energy and its instrumentation to the market;

b. Failing to analyze properly and thoroughly the data resulting from the pre-marketing tests of monopolar energy and its instrumentation used in the *da Vinci* ® robotic surgery.

c. Failing to report to the FDA, the healthcare community, and the general public those data resulting from pre-and-post marketing tests of the *da Vinci* ® Robotic surgery platform which indicated risks and relative and/or absolute contraindications associated with the use of the *da Vinci* ® robot;

d. Failing to conduct adequate post-market monitoring and surveillance of post-surgical complications, including the complications of bowel injuries, thermal burns and adhesions associated with the *da Vinci* ® robotic surgery using monopolar energy and its instrumentation;

e. Failing to conduct adequate analysis of adverse event reports and data maintained a conscious disregard for this data;

f. Designing, manufacturing, marketing advertising, distributing and promoting the *da Vinci* ® robotic surgery directly to consumers, including Plaintiff, without adequate warning of the significant and dangerous risks of monopolar current and the risks associated with the Monopolar Curved Scissors, PK gyrus biopolar grapser and/or the Prograf grasper and the *da Vinci* ® robotic surgery and without proper instructions to avoid the harm which could foreseeably occur as a result of using monopolar energy and its instrumentations on the existing *da Vinci* ® robotic surgery.

g. Failing to exercise due care when advertising and promoting *da Vinci* ® robotic surgery;

h. Negligently continuing to manufacture, market, advertise and promote *da Vinci* ® robotic surgery after Defendant INTUITIVE knew or could have known of the risks of serious injury and/or death associated with using monopolar current to perform certain aspects of the surgery;

i. Failing to use due care in the preparation and development of the *da Vinci* ® robotic surgery to prevent the aforementioned risk of injuries to individuals through the use of monopolar current;

j. Failing to use due care in the design of the *da Vinci* ® robot and its instrumentation with special regard to the insulation of the robotic arms and instruments to prevent the aforementioned risk of injuries to individuals during the routine course of surgery;

k. Failing to conduct adequate pre-clinical testing and research to determine the safety of the use of monopolar current and the insulation of the robotic

instruments to be used in robotic surgery, with special regard to the reusing of the instruments up to ten times in ten different patients;

l. Failing to conduct adequate pre-clinical testing and research and post marketing surveillance to determine the safety of the *da Vinci* ® robotic and its instruments to be used in robotic surgery with patients that have had previous abdominal surgeries and/or in patients that have adhesions.

m. Failing to conduct adequate intra-operative surveillance and post-operative complication studies to determine the safety of the use of monopolar energy and/or proper use of its instrumentation during the surgical robotic surgery procedure taught by Intuitive Surgical, Inc. while Defendant INTUITIVE knew or should have known that intra-operative surveillance and post-operative complication analysis would be the only means to determine the relative risk of using monopolar when performing a robotic surgery causing severe thermal injury to patients' bowel, in the absence of clinical trials which cannot be conducted for this purpose, and that such surveillance would be necessary for a due diligence program that would have altered Defendant INTUITIVE to the need to change the technique for the use of monopolar current or to withdraw it from the market altogether prior to this Plaintiff's surgery.

n. Failing to completely, accurately and in a timely fashion, disclose the results of the pre-marketing testing of issues with monopolar energy and post-marketing surveillance of monopolar energy, and the contraindications and increased risk for patients with adhesions related injuries and complications to Plaintiff, consumers, the medical community and the FDA.

o. Failing to accompany marketing materials promoting the *da Vinci* ® robotic surgery using monopolar current with proper warnings regarding all possible adverse side effects associated with the use of the same;

p. Failing to accompany marketing materials promoting the *da Vinci* ® robotic surgery with proper warnings regarding all possible adverse side effects associated with the use of the same, including but not limited to providing warnings and contraindications for use and increased bowel injuries for patients with prior surgeries and/or adhesions.

q. Failing to use due care in the manufacture, inspection and safety evaluation of the *da Vinci* ® robotic surgery to prevent the aforementioned risk of injuries to individuals who underwent a *da Vinci* ® robotic surgery;

r. Failing to use due care in the promotion of *da Vinci* ® robotic surgery to prevent the aforementioned risk of injuries to individuals;

s. Failing to use due care in the promotion of *da Vinci* ® robot to prevent the aforementioned risk of injuries to individuals who were to undergo robotic surgery;

t. Failing to use due care in the selling of the monopolar scissors to prevent the aforementioned risk of injuries to individuals who underwent *da Vinci* ® Robotic Surgery;

u. Failing to provide adequate and accurate training and information to the sales representatives who sold the *da Vinci* ® Robot;

v. Failing to provide adequate accurate training and information to healthcare providers for the appropriate use of the *da Vinci* ® Robot for surgery.

w. Failing to conduct or fund research into the development of safer robotic surgical instruments which would pose the least risk of causing severe thermal injury to bowel, bladder, ureter and blood vessels;

x. Failing to educate healthcare providers and the public about the safest use of the monopolar scissors and grasper instrumentation in *da Vinci* ® Robotic surgery;

y. Failing to give healthcare providers adequate information to weigh the risks of serious injury and/or death for a given patient using the *da Vinci* ® Robotic Surgery platform and technique featuring the use of monopolar current; and

z. Being otherwise reckless, careless and/or negligent.

83. Defendant INTUITIVE placed into the stream of commerce its aforesaid device, which was defective in its labeling and warnings, as previously pleaded.

84. Defendant INTUITIVE placed into the stream of commerce its aforesaid device, which was defective in its testing and approval, as previously pleaded and did not cause notification to Plaintiffd and others similarly situated until long after it had knowledge of the damages of the aforesaid robotic device and in this case not until after March 13, 2013 and after Plaintiff's surgical procedures.

85. At the time the device left the possession of Defendant INTUITIVE it was in an unreasonably dangerous and defective condition for application for robotic surgery using monopolar energy.

86. Despite the fact that Defendant INTUITIVE knew or should have known that the *da Vinci* ® robotic surgery platform using monopolar current had increased the risk of serious injury and/or death, Defendant INTUITIVE continued to promote and market the

da Vinci ® robotic surgery to consumers, including Plaintiffs Erika Starr and Nick Griffith, when safer and more effective methods of treatment were known to be available.

87. Defendant INTUITIVE designed, manufactured, packaged, marketed, distributed, promoted and sold the *da Vinci* ® Robot and its instrumentation, placing the *da Vinci* ® Robotic Surgical system and its instrumentation into the stream of commerce.

88. The *da Vinci* ® Robot was designed, tested, inspected, manufactured, assembled, developed, labeled, sterilized, licensed, marketed, advertised, promoted, sold, packaged, supplied and/or distributed by Defendant INTUITIVE in a defective and unreasonably dangerous condition to consumers, including Plaintiffs.

89. The *da Vinci* ® Robot was expected to reach, and did reach, users and/or consumers, including Plaintiffs, without substantial change in the defective and unreasonably dangerous condition in which it was manufactured and sold.

90. Plaintiff's surgeon used the *da Vinci* ® robot for gynecology and general surgery including monopolar current as instructed by and certified by and in the foreseeable manner normally intended, recommended, promoted and marketed by Defendant INTUITIVE. Upon information and belief, Plaintiff's surgeon attended a surgical lab for hands-on initial training and were proctored for by a proctor employed by Defendant INTUITIVE.

91. The *da Vinci* ® gynecological and general surgery platforms were unreasonably dangerous in that, as designed, it failed to perform safely when used by ordinary consumers, including Plaintiff's surgeon, including when it was used as intended and in a reasonably foreseeable manner.

92. The *da Vinci* ® robotic surgery was unreasonably dangerous, in that, as designed, the risks of serious injury and/or death, including bowel, rectum, bladder, ureter, abscess formation, permanent scarring or vascular injury, posed by its monopolar current risks exceeded any benefit the robotic approach was designed to or might in fact bestow.

93. The *da Vinci* ® robotic surgery was unreasonably dangerous, in that, as designed, it was dangerous to an extent beyond that contemplated by the medical community, and ordinary patients, including the Plaintiffs.

94. The *da Vinci* ® robot was defective in its design, in that, it neither bore nor was packaged with, nor accompanied by, warnings adequate to alert the medical community, including Plaintiff's surgeon, to the risks described herein, including, but not limited to, the risk of serious injury and/or death, including bowel, bladder or vascular injury posed by its monopolar current risks and the use of its instrumentation in general. The *da Vinci* ® Robot was not accompanied by adequate labeling, instructions for use and/or warning to fully apprise the medical, hospital, operating room and or scientific communities, and the potential patients, including Plaintiffs, or the potential risks and serious side effects associated with its use, thereby rendering Defendant INTUITIVE liable to the Plaintiff.

95. There were safer alternative energy modalities available including bipolar energy and ultrasonic energy and traditional laparoscopic and/or laparotomy surgery available.

96. Monopolar energy, as used and taught on the *da Vinci* ® robot, was unsafe for normal reasonably anticipated use in performing surgery and removal of cysts.

97. In light of the potential and actual risk of harm associated with the use of monopolar energy so close to bowel, bladder, ureter, vaginal cuff and blood vessels, a reasonable person who had actual knowledge of this potential and actual risk of harm would have

concluded that the *da Vinci* ® robotic surgery platform should not have been marketed in that condition.

98. Although Defendant INTUITIVE knew or should have known of the defective nature of its *da Vinci* ® robotic surgery platform using monopolar current, it continued to design, manufacture, market and promote the use of its *da Vinci* ® robotic surgery platform so as to maximize sales and profits at the expense of the public health and safety. Defendant INTUITIVE thus acted with conscious and deliberate disregard of the foreseeable harm caused by the continued use of monopolar energy on its robotic platform.

99. Plaintiffs could not, through the exercise of reasonable care, have discovered the risk of serious injury and/or death associated with and/or caused by the *da Vinci* ® robotic surgery platform featuring monopolar current. Plaintiffs, if aware of these additional risks could have chosen surgical procedures with similar efficacies but without these additional risks. As a result, Plaintiffs suffered the injuries as described herein.

100. Information given by Defendant INTUITIVE to the medical community and to the consumers concerning the safety and efficacy of the *da Vinci* ® robotic surgery platform, especially the information contained in the advertising and promotional materials, did not accurately reflect the serious and potentially fatal side effects and consequences.

101. Had adequate warnings and instructions been provided, Plaintiff's surgeon and doctors would not have suggested a robotic approach, and Plaintiff would have had a much lower risk of the harmful side effects described herein and/or could have made an informed judgment.

102. As a direct and proximate consequence of Defendant INTUITIVE's negligence, willful, wanton, and/or intentional acts, omissions, misrepresentations and/or otherwise culpable

acts described herein, the Plaintiffs Erica Starr and Nick Griffith sustained injuries and damages alleged herein.

103. As a direct and proximate cause of Defendant INTUITIVE's negligence, among other things, the Plaintiff Erica Starr suffered injuries which caused her to undergo additional surgeries and medical procedures, medical expenses, endured pain and suffering and will continue to do so in the future, lost wages, has suffered mental anguish and will continue to do so in the future, has incurred medical expenses and loss of enjoyment of life.

104. Plaintiff has incurred and Defendant INTUITIVE is liable for certain expenses, including hospital, surgical and medical treatment, transportation costs to various medical facilities as a result of, among other things, loss of income, pain and suffering as a result of Defendant INTUITIVE's conduct which was in conscious disregard of consequences.

105. As a result of its said conduct, Defendant INTUITIVE has become strictly liable to Plaintiff.

106. Defendant INTUITIVE's conduct in continuing to market, sell and distribute the aforesaid devices after obtaining knowledge and consciously disregarding they were defective and not performing as represented and intended, showed complete indifference to and/or a conscious, wanton disregard for the safety of others justifying an award of punitive damages for aggravating circumstances in such a sum which will serve to deter Defendant INTUITIVE and other from similar conduct in the future.

WHEREFORE, Plaintiffs demand judgment against Defendant INTUITIVE for compensatory, treble and punitive damages, together with interests, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

THIRD CAUSE OF ACTION – NEGLIGENT TRAINING & PROCTORING & NEGLIGENT CERTIFICATION

107. Plaintiffs repeat, reiterate and reallege each and every allegation and cause of action contained herein as if the same were set forth more fully at length herein.

108. Defendant INTUITIVE was negligent and careless in the design, testing, manufacturing, labeling and promotion of its aforesaid device, as pleaded in previous paragraphs.

109. In specific, Defendant INTUITIVE failed to warn users and consumers of the risk of complications associated with the use of its said device in patients with adhesions and the risks of monopolar current use, including the damage to the bladder, bowel, ureter, vaginal cuff, and blood vessels; the bladder and ureter which was a proximate cause of Plaintiff Erica Starr's additional surgery and medical treatments resulting in long term pain and suffering.

110. Upon information and belief, Defendant INTUITIVE took it upon itself to "train" and "certify" Plaintiff's surgeons on the use of the *da Vinci* ® robotic surgery platform using monopolar current. Upon information and belief, the Defendant INTUITIVE specifically trained Plaintiff's surgeons on the use of monopolar energy and the monopolar scissors.

111. Upon information and belief, Defendant INTUITIVE did not properly proctor and/or properly instruct Plaintiff's surgeons and attending staff as to the sage use of its device nor how to detect complications which its said device causes and is known to cause.

112. Defendant INTUITIVE had a financial incentive to promptly train, proctor and certify Plaintiff's surgeons without regard to whether or not Plaintiff's surgeons was truly skilled and competent on the *da Vinci* ® robotic surgery platform.

113. As a direct and proximate cause of Defendant INTUITIVE's negligence, among other things, the Plaintiff Erica Starr suffered injuries which caused her to undergo additional surgeries and medical procedures, medical expenses, endured pain and suffering and will continue to do so in the future, lost wages, has suffered mental anguish and will continue to do so in the future, has incurred medical expenses and loss of enjoyment of life.

114. Plaintiff has incurred and Defendant INTUITIVE is liable for certain expenses, including hospital, surgical and medical treatment, transportation costs to various medical facilities as a result of, among other things, loss of income, pain and suffering as a result of Defendant INTUITIVE's conduct which was in conscious disregard of consequences.

115. Defendant INTUITIVE'S negligence was a direct and proximate cause of all of the Plaintiffs' injuries.

WHEREFORE, Plaintiffs demand judgment against Defendant INTUITIVE for compensatory, treble and punitive damages, together with interests, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

FOURTH CAUSE OF ACTION – NEGLIGENT MISPRESENTATION

116. Plaintiffs repeat, reiterate and re-allege each and every allegation and cause of action set forth herein as if the same were set forth more fully at length herein.

117. Prior to the *da Vinci* ® surgical system and its instrumentation being used in Plaintiff Erica Starr's surgery and after her surgery, Defendant INTUITIVE misrepresented that the *da Vinci* ® surgical system and its instrumentation were safe and an effective and had medical benefits of shorten surgery time, less hospitalization time and fewer complications than traditional laparoscopy and/or laparotomy surgery.

118. Defendant INTUITIVE failed to disclose material facts regarding the safety and efficacy of having a surgery using the *da Vinci* ® surgical system, including information regarding the increased adverse events and injuries, including thermal burns, lacerations, perforations, bleeding, infections, additional surgeries and death.

119. Defendant INTUITIVE had a duty to provide Plaintiff Erica Starr's, physicians, and other consumers with true and accurate information and warning of any known risks and complications of the *da Vinci* ® surgical system and its instrumentation that it marketed, distributed and sold.

120. Defendant INTUITIVE knew or should have known, based on prior experience, adverse event reports, studies and knowledge as to the risks, complications and safety failures with the *da Vinci* ® surgical system and its instrumentation and that it had a duty to disclosure the dangers associated with the *da Vinci* ® surgical system and its instrumentation.

121. Defendant INTUITIVE made the representations and failed to disclose the material facts with the intent to induce consumers, including Plaintiff Erica Starr to act in reliance on undergoing surgery with the *da Vinci* ® surgical system.

122. Plaintiffs justifiably relied on Defendant's representations and nondisclosures by undergoing surgery with the *da Vinci* ® surgical system.

123. As a direct and proximate cause of Defendant INTUITIVE's negligence, among other things, the Plaintiff Erica Starr suffered injuries which caused her to undergo additional surgeries and medical procedures, medical expenses, endured pain and suffering and will continue to do so in the future, lost wages, has suffered mental anguish and will continue to do so in the future, has incurred medical expenses and loss of enjoyment of life.

124. Plaintiff has incurred and Defendant INTUITIVE is liable for certain expenses, including hospital, surgical and medical treatment, transportation costs to various medical facilities as a result of, among other things, loss of income, pain and suffering as a result of Defendant INTUITIVE's conduct which was in conscious disregard of consequences.

125. Defendant INTUITIVE's misrepresentations and omissions regarding the safety of the *da Vinci* ® surgical system and its instrumentation was the direct and proximate cause of Plaintiffs' injuries.

126. Defendant INTUITIVE's conduct, as described above, was extreme and outrageous. Defendant risked the lives of consumers and users of their product, including Plaintiff, with the knowledge of the safety and efficacy problems and suppressed this knowledge from the general public. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendant's outrageous conduct warrants an award of punitive damages.

127. As a direct and proximate cause of Defendant INTUITIVE's negligence, among other things, the Plaintiff Erica Starr suffered injuries which caused her to undergo additional surgeries and medical procedures, medical expenses, endured pain and suffering and will continue to do so in the future, lost wages, has suffered mental anguish and will continue to do so in the future, has incurred medical expenses and loss of enjoyment of life.

128. Plaintiff has incurred and Defendant INTUITIVE is liable for certain expenses, including hospital, surgical and medical treatment, transportation costs to various medical facilities as a result of, among other things, loss of income, pain and suffering as a result of Defendant INTUITIVE's conduct which was in conscious disregard of consequences.

129. Defendant INTUITIVE'S conduct was a direct and proximate cause of Plaintiffs' injuries.

WHEREFORE, Plaintiffs demand judgment against Defendant INTUITIVE for compensatory, treble and punitive damages, together with interests, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

FIFTH CAUSE OF ACTION-FRAUD

130. Plaintiffs repeat, reiterate and re-allege each and every allegation and cause of action set forth herein as if the same were set forth more fully at length herein.

131. Defendant INTUITIVE fraudently misrepresented the safety and comparative efficacy of its device, upon which Plaintiff's surgeons relied, to Plaintiff's detriment.

132. Defendant INTUITIVE misrepresented the safety and comparative efficacy of its device, upon which the hospital and surgery department where Plaintiff was operated on relied, in purchasing and using the device to Plaintiff's detriment.

133. Defendant INTUITIVE was aware and/or should have been aware, of the known dangers of monopolar current in regard to unsuspected current leaving the shaft of a poorly insulted instrument. Furthermore, Defendant INTUITIVE suggested to hospitals that multiple uses of the robotic instruments could be done yet Defendant INTUITIVE did so without regard to re-testing of the insulation along the shaft of their robotic instruments or at the wrist of the robotic instrument.

134. Defendant INTUITIVE was aware or should have been aware, of the known dangers of monopolar current in regard to capacitive coupling, which like insulation failure can cause a thermal injury to occur in adjacent structures like bowel, rectum, bladder, ureter,

vaginal cuff, or blood vessel. Defendant INTUITIVE was aware and with conscious disregard of the known increased incidence of ureter and other tissue damage as a result of thermal burns, de-vascularization and abscess formation due to the use of monopolar current while performing the *da Vinci* ® robotic total laparoscopic surgery.

135. Defendant INTUITIVE was aware that there were safer energy modalities yet caused to be maintained teaching and the use of the monopolar current in the *da Vinci* ® robotic surgery. Defendant INTUITIVE did so based on not wanting to pay for the cost of having to license these safer energy technologies.

136. Defendant INTUITIVE was also aware or should have been aware of the Active Electrode Monitoring System, or AEM Technology, which shields and monitors instruments continuously directing stray energy, the cause of stray electrosurgical burns, away from the patient. With the AEM system, the patient is never at risk for stray electrosurgical burns due to insulation failure and capacitive coupling. Despite having specific knowledge of this safety system the Defendant INTUITIVE chose not to purchase it for the *da Vinci* ® robotic surgery platform using monopolar current.

137. Defendant INTUITIVE concealed from consumers and users, including those mentioned in the preceding paragraphs, and the risks associated with adhesions and other risks of complications of which it was aware, which would have been material to consumers and users in making the decision to use the said device.

138. Defendant INTUITIVE suppressed reports of adverse outcomes with the use of its device, which would have been material to consumers and users in making the decision to use the said device.

139. Defendant INTUITIVE over-promoted its device and minimized the risks, for the purpose of making sale of its device, its maintenance and the use of replaceable parts and skewed the cost-benefit ratio inaccurately in its favor.

140. The said conduct was so willful, wanton, malicious and reckless that it merits the imposition of punitive damages.

141. As a direct and proximate cause of Defendant INTUITIVE's fraud, among other things, the Plaintiff Erica Starr suffered injuries which caused her to undergo additional surgeries and medical procedures, medical expenses, endured pain and suffering and will continue to do so in the future, lost wages, has suffered mental anguish and will continue to do so in the future, has incurred medical expenses and loss of enjoyment of life.

142. Plaintiff has incurred and Defendant INTUITIVE is liable for certain expenses, including hospital, surgical and medical treatment, transportation costs to various medical facilities as a result of, among other things, loss of income, pain and suffering as a result of Defendant INTUITIVE's conduct which was in conscious disregard of consequences.

143. Defendant INTUITIVE'S fraudulent conduct was a direct and proximate cause of Plaintiffs' injuries.

WHEREFORE, Plaintiffs demand judgment against Defendant INTUITIVE for compensatory, treble and punitive damages, together with interests, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

SIXTH CAUSE OF ACTION-FRAUDULENT CONCEALMENT

144. Plaintiffs hereby incorporate by reference all previous paragraphs of this complaint as if fully set forth herein and further alleges as follows:

145. Defendant INTUITIVE had the duty and obligation to disclose to Plaintiff and to her physicians the true facts concerning the *da Vinci* ® robotic surgery platform, that is, that the *da Vinci* ® robot was dangerous and defective and was likely to cause serious health consequences to users, including injuries as described in this complaint.

146. Defendant INTUITIVE concealed important facts from Plaintiffs and from Plaintiff's physicians which facts include, but are not limited to, that Defendant INTUITIVE had received numerous adverse events reports of serious injuries and/or death, including burns, tears, dehiscence, bleeding, hematomas, bowel injuries, sepsis and fistulas prior to Plaintiff's surgery on March 13, 2013.

147. Defendant INTUITIVE made affirmative representations to Plaintiffs and her physicians that the *da Vinci* ® robotic surgery platform was safe as set forth above while concealing the material facts set forth herein.

148. Defendant INTUITIVE had the duty and obligation to disclose to Plaintiffs and to her physicians the true facts concerning the *da Vinci* ® robotic surgery platform which facts include, but are not limited to, serious injuries and/or death including burns, tears, dehiscence, bleeding, hematomas, bowel injuries, sepsis and fistulas prior to Plaintiff's surgery.

149. At all times during the course of dealing between Defendant INTUITIVE and Plaintiffs, and/or Plaintiffs' healthcare providers, and/or the FDA, Defendant INTUITIVE misrepresentation the safety of the *da Vinci* ® Surgical System and its instrumentation.

150. At all times during the course of dealing between Defendant INTUITIVE and Plaintiffs, and/or Plaintiffs' healthcare providers, and/or the FDA, Defendant INTUITIVE

misrepresented the effectiveness and safety of the *da Vinci* ® Surgical System and its instrumentation.

151. Defendant INTUITIVE knew or were reckless in not knowing that its representations were false.

152. In representations to Plaintiffs, and/or Plaintiffs' healthcare providers, and/or the FDA, Defendant INTUITIVE fraudulently concealed and intentionally omitted the following material information:

a. That the *da Vinci* ® Surgical System was not as safe as other forms of surgery;

b. That the risks of adverse events with the *da Vinci* ® Surgical System was higher than other forms of surgery;

c. That the risks and complications associated with the *da Vinci* ® Surgical System were not adequately tested and/or known by Defendant;

d. That Defendant was aware of dangers, injuries and deaths occurring to other patients in otherwise routine surgeries when Defendant's product, the *da Vinci* ® Surgical System was used;

e. That the *da Vinci* ® Surgical System was defective and that it had instrumentation, including but not limited to, the Monopolar Curved Scissors that caused thermal injuries, burns, perforations, lacerations, bleeding, infections and death;

f. That healthcare providers throughout the country were not all receiving the same level of training and proctoring on the use of the *da Vinci* ® Surgical System;

g. That Defendant intentionally sought to reduce the number of proctored surgeries and the number of training hours of physicians before physicians operated on patients;

h. That physicians needed to be monitored more and needed additional training, including training on monopolar energy prior to operating with the *da Vinci* ® Surgical System;

i. That the *da Vinci* ® Surgical system and its instrumentation were manufactured negligently;

j. That the *da Vinci* ® Surgical system and its instrumentation were manufactured defectively;

k. That the *da Vinci* ® Surgical system and its instrumentation were manufactured improperly;

l. That the *da Vinci* ® Surgical system and its instrumentation were designed negligently;

m. That the *da Vinci* ® Surgical system and its instrumentation were designed defectively; and

n. That the *da Vinci* ® Surgical system and its instrumentation were designed improperly.

153. Defendant INTUITIVE was under a duty to disclose to Plaintiffs and their physicians, hospitals, healthcare providers, and/or the FDA the defective nature of the *da Vinci* ® Surgical System and its instrumentation.

154. Defendant INTUITIVE had sole access to material facts concerning the defective nature of its products and their propensity to cause serious and dangerous injuries and death and

caused damage to persons who had surgery with the *da Vinci* ® Surgical System, including the Plaintiffs.

155. Defendant INTUITIVE intentionally, willfully, and maliciously concealed or suppressed the facts set forth above from Plaintiff's physicians and Community Health Hospital and therefore from Plaintiff with the intent to defraud as alleged herein.

156. Neither Plaintiffs nor her physicians were aware of the concealed facts set forth herein. Had they been aware of those facts, they would not have acted as they did, that is, that the *da Vinci* ® robotic surgery platform would not have been the chosen surgical modality of Plaintiff and her physicians.

157. The Plaintiff was denied the right to be informed of the numerous adverse events including serious injuries including burns, tears, dehiscence, bleeding, hematomas, sepsis and fistulas associated with the *da Vinci* ® Robotic Surgery platform and Plaintiff would have opted for a different surgical procedure if put on notice of adverse events known to Defendant INTUITIVE.

158. As a proximate result of the concealment or suppression of the facts set forth above Plaintiff and her physicians' reasonably relied on Defendant INTUITIVE's deception, and Plaintiff underwent surgery utilizing the *da Vinci* ® robotic surgery platform and subsequently sustained injuries and damages as set forth in this complaint. Defendant INTUITIVE's concealment was a direct and proximate cause in causing all of Plaintiffs' injuries as stated herein.

159. In doing the acts here alleged, Defendant INTUITIVE acted with oppression, fraud and malice and Plaintiff is entitled to punitive damages in an amount reasonably related to Plaintiff's actual damages and to Defendant INTUITIVE's wealth and sufficiently large

to be an example to others and to deter Defendant INTUITIVE and others from engaging in similar conduct in the future.

WHEREFORE, Plaintiffs demand judgment against Defendant INTUITIVE for compensatory, treble and punitive damages, together with interests, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

SEVENTH CAUSE OF ACTION-BREACH OF EXPRESS WARRANTY

160. Plaintiffs repeat, reiterate and re-allege each and every allegations and cause of action set forth herein as if the same were set forth more fully at length herein.

161. Defendant INTUITIVE made express warranties of safety to the buyers and consumers of the device utilized during Plaintiff Erica Starr's surgery, upon which the buyers and users as agents of Plaintiff Erica Starr relied, to her detriment. Defendant INTUITIVE expressly caused to be represented to the Plaintiffs, Erica Starr and Nick Griffith (and to other consumers and the medical community) that the *da Vinci* ® robotic surgery was safe, efficacious and fit for its intended purposes that it was of merchantable quality, that it did not produce un-warned of dangerous side effects and that it was adequately tested.

162. Defendant INTUITIVE breached expressed warranties with respect to the *da Vinci* ® robotic surgery in the following ways:

a. Defendant INTUITIVE represented through its labeling, advertising, marketing materials, detail persons, seminar presentations, surgeon training sessions, publications, notice letters, and regulatory submissions that the *da Vinci* ® robotic surgery was safe, and fraudulently withheld and concealed information about the substantial risks or serious injury and/or death associated with using monopolar current on the existing *da Vinci* ® surgery platform;

b. Defendant INTUITIVE represented that the *da Vinci* ® robotic surgery was a safe and/or safer than alternative surgical methods, and fraudulently concealed information which demonstrated that the *da Vinci* ® robotic surgery approach was not safer than alternatives available on the market, and;

c. Defendant INTUITIVE represented that the *da Vinci* ® robotic surgery was more efficacious than other alternative surgical methods, and fraudulently concealed information that it was not more efficacious than alternative surgical methods.

163. The *da Vinci* ® robotic surgery does not confirm to Defendant INTUITIVE's express representations, because it is not safe, efficacious, has numerous serious un-warned of side effects, causes severe and permanent injuries including death, and was not adequately tested.

164. The *da Vinci* ® robotic surgery including the use of monopolar current did not perform as safely as an ordinary physician, as an agent of the patient, would have expected when used as intended or in a reasonably foreseeable manner.

165. Plaintiffs Erica Starr and Nick Griffith, and Plaintiff's surgeons and others in the medical community relied upon Defendant INTUITIVE's express warranties, resulting in the Plaintiff's *da Vinci* ® robotic surgery.

166. Plaintiff, after ascertaining through her own injuries that the *da vinci* ® robotic surgery violated express warranties, hereby supply notice to Defendant INTUITIVE of same through the filing of this lawsuit.

167. By selling the said device, Defendant INTUITIVE made implied warranties of safety, merchantable quality and fitness for use, which was breached when Plaintiffs were injured surgery.

168. As a direct and proximate consequence of Defendant INTUITIVE's breach of express warranty and/or intentional acts, omissions, misrepresentations and/or otherwise culpable acts described herein, the Plaintiffs sustained injuries and damages alleged herein.

WHEREFORE, Plaintiffs demand judgment against Defendant INTUITIVE for compensatory, treble and punitive damages, together with interests, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

EIGHTH CAUSE OF ACTION-BREACH OF IMPLIED WARRANTY

169. Plaintiffs incorporate by reference each and every paragraph of this complaint as though set forth in full in this cause of action.

170. At all time relevant and material times, Defendant INTUITIVE manufactured, distributed, advertised promoted and sold the *da Vinci* ® robot.

171. At all relevant times, Defendant INTUITIVE intended that the *da Vinci* ® robot be used in the manner that the Plaintiff's surgeon in fact used it and Defendant INTUITIVE impliedly warranted the product to be of merchantable quality, safe and fit for such use, and was adequately tested.

172. Defendant INTUITIVE breached various implied warranties with respect to the *da Vinci* ® robot including the particulars:

a. Defendant INTUITIVE represented through its labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters and regulatory submissions that the *da Vinci* ® robotic surgery platform was safe and fraudulently withheld and concealed information about the substantial risks of serious injury and/or death associated with the using of the *da Vinci* ® robot with monopolar current;

b. Defendant INTUITIVE represented that the *da Vinci* ® robotic surgery with monopolar current was as safe and/or safer than other alternative surgical approaches that did not include the use of *da Vinci* ® robot, and fraudulently concealed information, which demonstrated that the *da Vinci* ® robotic surgery was not safer than alternatives available on the market; and

c. Defendant INTUITIVE represented that the *da Vinci* ® robotic surgery was as more efficacious than other alternative surgical approaches and techniques and fraudulently concealed information, regarding the true efficacy of the robotic surgery with monopolar current.

173. In reliance upon Defendant INTUITIVE's implied warranty, Plaintiff's surgeon used the *da Vinci* ® robotic surgery platform as prescribed and in the foreseeable manner normally intended, recommended, promoted, instructed and marketed by Defendant INTUITIVE.

174. Defendant INTUITIVE breached its implied warranty to Plaintiffs in that the *da Vinci* ® robotic surgery platform with monopolar current was not merchantable quality, safe, and fit for its intended use, or adequately tested.

175. As a direct and proximate consequence of Defendant INTUITIVE's breach of implied warranty and/or intentional acts, omissions, misrepresentations and/or otherwise culpable acts described herein, the Plaintiffs sustained injuries and damages alleged herein including pain and suffering.

WHEREFORE, Plaintiffs demand judgment against Defendant INTUITIVE for compensatory, treble and punitive damages, together with interests, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

NINTH CAUSE OF ACTION-UNJUST ENRICHMENT

176. Plaintiffs incorporate by reference each and every paragraph of this complaint as though set forth in full in this cause of action.

177. At all times relevant to this action, Defendant INTUITIVE designed, advertised, marketed, promoted, manufactured, distributed, supplied, and/or sold the *da Vinci* ® robot for surgery use.

178. Christ Hospital in Cincinnati, Ohio purchased the *da Vinci* ® robot from the Defendant INTUITIVE for the purpose of using it for robotic surgery. Christ hospital purchased disposable and reusable instrument for the performing of Plaintiff Erica Starr's surgery.

179. Defendant INTUITIVE accepted payment from said aforementioned hospital for both the *da Vinci* ® robot used in Plaintiff Erica Starr's surgery, but also for the routine maintenance and per surgery cost of additional items including disposable items.

180. Erica Starr did not receive the safe and effective surgical product which she intended to have been purchased; nor did Christ Hospital where Plaintiff Erica Starr had her surgery.

181. It is inequitable and unjust for Defendant INTUITIVE to retain this money because the Plaintiff did not, in fact, receive the safe and efficacious surgical procedure Defendant INTUITIVE represented *da Vinci* ® robotic surgery to be.

WHEREFORE, Plaintiffs demand judgment against Defendant INTUITIVE fof compensatory, treble and punitive damages, together with interests, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

TENTH CAUSE OF ACTION – INFORMED CONSENT/FAILURE TO WARN/INADEQUATE WARNINGS AND INSTRUCTIONS

182. Plaintiffs incorporate by reference each and every paragraph of this Complaint as though set forth in full in this cause of action.

183. Defendant INTUITIVE violated R.C. §2307.76 failed to properly obtain informed Plaintiffs and failed to provide proper warnings, and/or provided inadequate warnings and instructions to physicians, healthcare providers, healthcare facilities and hospitals and consumers, including Plaintiffs of the risks associated with the use of the *da Vinci* ® robotic surgical system within surgeries, including the use within surgery surgeries.

184. Defendant INTUITIVE knew or, in the exercise of reasonable care, should have known about the risks associated with the *da Vinci* ® surgical system and its instrumentation and failed to properly inform Plaintiffs and failed to properly warn physicians, healthcare providers and consumers, including Plaintiffs of the risks associated with the use of the *da Vinci* ® robotic surgical system and the design defects within the *da Vinci* ® robotic instrumentation.

185. Defendant INTUITIVE failed to disclose these material risks to Plaintiffs and consumers, including the risks of thermal burns, tissue damage, infections, post-operative complications, additional surgeries and delayed healing.

186. Defendant INTUITIVE failed to provide post-marketing warnings, inadequate warnings and/or instructions concerning the risk of injuries, including but not limited bowel injuries, post-operative infections and additional surgeries and medical care and treatment, that a manufacturer exercising reasonable care would have provided concerning that risk, in light of the likelihood that the *da Vinci* ® surgical robot and its instrumentation would cause harm such as the harm suffered by Plaintiff and in light of the likely seriousness of that harm.

187. If Defendant INTUITIVE had disclosed such material risks, Plaintiffs would have sought a different method of surgery including traditional laparoscopic surgery and would not have sustained the injuries that Plaintiffs had endured.

188. Defendant INTUITIVE's failure to disclose these material risks was a direct and proximate cause of Plaintiffs' injuries.

WHEREFORE, Plaintiffs demand judgment against Defendant INTUITIVE for compensatory, treble and punitive damages, together with interests, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

ELEVENTH CAUSE OF ACTION – VIOLATION OF OHIO'S CONSUMER PROTECTION ACT

189. Plaintiffs incorporate by reference each and every paragraph of this Complaint as though set forth in full in this cause of action.

190. The State of Ohio prohibits unfair, false, misleading or deceptive acts or practices in trade and commerce.

191. Plaintiff, Erica Starr had a surgery with the *da Vinci* ® Surgical System and suffered ascertainable losses and injuries as a result of Defendant INTUITIVE's actions in violation of consumer protection laws.

192. Unfair methods of competition or deceptive acts or practices that were prescribed by law, including the following:

a. Representing that the goods or services have characteristics, ingredients, uses, benefits or quantities that they do not have;

b. Advertising goods or services with the intent not to sell them as advertised; and

c. Engaging in fraudulent or deceptive conduct that creates a likelihood of confusion or misunderstanding.

193. Defendant INTUITIVE'S conduct was the direct and proximate cause of Plaintiffs' injuries.

WHEREFORE, Plaintiffs demand judgment against Defendant INTUITIVE for compensatory, treble and punitive damages, together with interests, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

TWELFTH CAUSE OF ACTION – LOSS OF CONSORTIUM

194. Plaintiffs incorporate by reference each and every paragraph of this Complaint as though set forth in full in this cause of action.

195. Plaintiff, Nick Griffith, at all times herein was the lawfully married spouse of Plaintiff, Erica Starr.

196. As a direct and proximate cause of the negligence of Defendant INTUITIVE, Erica Starr sustained injuries to her ureter, the abdomen and subsequent abscess and chronic inflammation and scarring sustained by Erica Starr while undergoing a *da Vinci* ® Robotic Surgery and the pelvis pain, formation of intra-abdominal abscesses, sepsis, and pain, permanent scarring and the emotional consequences; Plaintiff and her husband have been deprived the normal companionship, company, affection, regard, assistance, comfort, personal relations and emotional stability from Erica Starr.

197. These physical and emotional consequences of the injuries have negatively impacted the quality and caused undue hardship to that relationship.

198. Defendant INTUITIVE'S conduct was the direct and proximate cause of Plaintiffs' injuries.

WHEREFORE, Plaintiffs demand judgment against Defendant INTUITIVE for compensatory, treble and punitive damages, together with interests, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

DEMAND FOR JURY TRIAL

Plaintiffs demand a trial by jury on all counts and issues contained herein.

GLOBAL PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully demand judgment against Defendant INTUITIVE for the following relief:

1. Judgment against Defendant INTUITIVE for compensatory damages in excess of the minimum dollar amount necessary to establish the jurisdiction of this Court, and for such amount as a jury may find fair and reasonable as shown by the evidence;

2. Punitive damages;

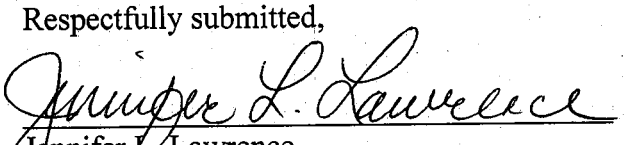
3. Plaintiffs' attorney fees and costs herein expended;

4. Pre- and post- judgment interest at the lawful rate;

5. Trial by jury; and

6. Any and all other relief to which they may be entitled.

Respectfully submitted,



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Dated: March 12, 2013

JS 44 (Rev. 12/12)

CIVIL COVER SHEET

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

Erika Starr
Nick Griffith
1817 Bluefield Place, Apt. #1, Cincinnati, OH 45237

(b) County of Residence of First Listed Plaintiff Hamilton
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
Jennifer L. Lawrence, Esq. and Anne L. Gilday, Esq., The Lawrence Firm, P.S.C., 606 Philadelphia Street, Covington, KY 41011
(859) 578-9130

DEFENDANTS

Intuitive Surgical, Inc., 1266 Kifer Road, Sunnyvale, CA 94086
Serve: CT Corporation System, 150 West Market Street, Suite 800, Indianapolis, IN 46204

County of Residence of First Listed Defendant _____
(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 USC 1332
Brief description of cause:
Product liability against Intuitive Surgical, Mfr. of da Vinci robot

VII. REQUESTED IN COMPLAINT:

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

DEMAND $

CHECK YES only if demanded in complaint:
JURY DEMAND: ☒ Yes ☐ No

VIII. RELATED CASE(S) IF ANY

(See instructions): JUDGE _____ DOCKET NUMBER _____

DATE 3-12-14

SIGNATURE OF ATTORNEY OF RECORD Jennifer L. Lawrence

FOR OFFICE USE ONLY

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

Court Name: US District Court SDO
Division: 1
Receipt Number: 100CIN021519
Cashier ID: kelseyl
Transaction Date: 03/12/2014
Payer Name: THE LAWRENCE FIRM

CIVIL FILING FEE
For: THE LAWRENCE FIRM
Case/Party: D-OHS-1-14-CV-000225-001
Amount: $400.00

CHECK
Remitter: THE LAWRENCE FIRM
Check/Money Order Num: 33636
Amt Tendered: $400.00

Total Due: $400.00
Total Tendered: $400.00
Change Amt: $0.00

A fee of $53.00 will be assessed on all returned checks.