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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

ANNA LERHAUPT AND BENJAMIN
LERHAUPT,

Plaintiffs,

vs.

INTUITIVE SURGICAL, INC.,

Defendant.

C 12 5959

Case No.

COMPLAINT

JURY TRIAL DEMANDED

HRL

Plaintiffs, complaining of the defendant by their attorney, respectfully allege,
upon information and belief, the following:

THE PARTIES

1. The plaintiff, ANNA LERHAUPT, is a resident of and domiciled
Cincinnati Ohio.

2. The plaintiff, BENJAMIN LERHAUPT, is a resident of and domiciled
in Cincinnati Ohio.

COMPLAINT AND DEMAND FOR JURY TRIAL

HERSHANDHERSH
A Professional Corporation

1 3. The defendant INTUITIVE SURGICAL, INC. (hereinafter
2 "INTUITIVE") is a foreign business corporation, duly organized and existing under
3 and by virtue of the laws of the State of Delaware with a principle place of business in
4 the State of California.
5

6 **JURISDICTION AND VENUE**

7 4. Jurisdiction for this action in the United States District Court arises
8 under 28 U.S.C. Sections 1332(a)(1) and 1332(c)(2) as this is a civil action based on
9 complete diversity of citizenship in that the surgery performed on ANNA
10 LERHAUPT, a resident of Ohio but a machine sold and distributed under the laws of
11 Delaware by a corporation with its principle place of business in the State of
12 California. The amount in controversy exceeds \$75,000 exclusive of costs and
13 interest.
14

15 **GENERAL ALLEGATIONS**

16 5. Plaintiff ANNA LERHAUPT, was advised that she needed to have a
17 hysterectomy performed and gall bladder removal.
18

19 6. Her physician presented her with information and materials promoting
20 the benefit of da Vinci robotic hysterectomy and gall bladder surgery over all other
21 methods of surgery. Specifically, her physicians told her that due to the da Vinci
22 robotic approach she would heal faster, have a better outcome and have less pain.

23 7. Based on the representations made by her physicians and the written
24 materials provided to her, the Plaintiff agreed to proceed with da Vinci robotic
25 hysterectomy and gall bladder removal. Plaintiff ANNA LERHAUPT underwent
26 surgery which resulted in damage including infection and vesicovaginal fistula.
27

1 8. ANNA LERHAUPT continues to suffer from cramping and bladder
2 problems. Through this time period ANNA LERHAUPT has been unable to maintain
3 normal intimate relationships with BENJAMIN LERHAUPT and has suffered
4 emotional distress.
5

6 9. Due to the injuries sustained during the da Vinci Robotic hysterectomy,
7 and gall bladder surgery, Plaintiff ANNA LERHAUPT had to have multiple painful
8 additional medical tests and procedures and physician consultations and additional
9 surgery and has suffered pain, loss of function, emotional distress, and permanent
10 injury. Plaintiff BENJAMIN LERHAUPT has suffered loss of Consortium.
11

12 10. Defendant INTUITIVE is a Delaware corporation with its principal
13 place of doing business in Sunnyvale, CA.

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

16 12. Defendant designed, manufactured, tested, sold, promoted and labeled
17 the da Vinci surgical robot.

18 13. On its website defendant asserts that it is the global technology leader
19 in surgical robotic products.
20

21 14. The said robotic device is used in hospitals for a variety of surgeries,
22 including gynecological, and including therein hysterectomies.

23 15. Defendant has promoted its device as (a) safe, and (b) safer than other
24 comparative methods of surgery including, in the case of hysterectomies, laparoscopy,
25 vaginal surgery and open surgery.
26

27 16. Defendant utilizes prominent websites aimed at consumers, seeking to
28

1 create demand for the use of its robotic device by patients who consult surgeons.

2 17. Defendant sold its device through a calculated program of intimidation
3 and market management, forcing hospitals and physicians to purchase it in order to
4 appear to be competitive, and creating a fear in their minds that if they did not have
5 this technology they would lose business to competitors.
6

7 18. Defendant reinforced its calculated program, as stated in the preceding
8 paragraph, by placing, on its website for potential patients, names of certain physicians
9 who had performed 20 surgeries with the device.

10 19. The use of defendant's robotic device in surgery presents substantial
11 risks of complications and injuries, including de-vascularization of the vaginal cuff
12 impeding healing, partial thermal injury burns to bowel, post-surgical abscesses, tears,
13 dehiscences, bleeding, hematomas, sepsis, and fistulas.
14

15 20. More specifically, defendant's robotic device can cause damage to the
16 bowel, blood vessels, arteries, ureters, bladder and vaginal cuff.

17 21. In addition, due to lengthened time of surgery, patients are
18 unnecessarily exposed to anesthesia for a dangerous period of time.
19

20 22. On occasion these complications and injuries cause and/or contribute to
21 infectious processes from thermal injury causing abscess formation and can lead to the
22 untimely and premature death of the patient.

23 23. Defendant is aware of the aforesaid risks and complications associated
24 with the use of the said robotic device.

25 24. Defendant does not provide adequate warnings to physicians and
26 patients about the risks and complications associated with the use of its robotic device.
27
28

1 25. Defendant has not done, nor sponsored, adequate testing on its said
2 device before and after marketing it to determine whether in random tests its said
3 device is either safer or more effective or otherwise superior to other surgical and
4 laparoscopic methods to which it compares itself.

5
6 26. Defendant has not done adequate post marketing surveillance of
7 complications and injuries that have occurred in actual practice.

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

10 28. Defendant has not revealed, through publications or reports to the Food
11 and Drug Administration and other governmental bodies, the true extent of
12 complications and injuries, which have occurred in actual practice.

13
14 29. Defendant has suppressed reports and complaints of complications and
15 performance errors due to the use of its said device.

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

19
20 31. Defendant represents that they will have skilled technicians in the
21 operating room or on emergency call in the event of problems arising with its said
22 device, but often has neglected to do so.

23 32. Defendant has over-promoted its device to hospitals, physicians and the
24 public, including potential consumers, combined with minimizing the risks and
25 complications associated with its use.

26 33. The device is defective in that it relies upon the use of monopolar
27

1 energy to cut, burn and cauterize tissue, whereas safer methods are available such as
2 bipolar energy and ultrasonic energy, which would reduce substantially the risk of
3 complications.
4

5 34. The device has inadequate insulation for its arms thereby allowing
6 electrical current to pass into tissue outside of the operative field.

7 35. The insulation on the shafts of the said device becomes torn and worn
8 in places, without the awareness of the physician user, allowing electrical current to
9 pass into tissue outside of the operative field, causing damage.

10 36. Defendant has failed to warn users and consumers of the said robotic
11 device about the inadequate insulation on the arms and the potential for electrical
12 current to pass into tissue outside of the operative field.

13 37. Due to design defects, defendant's devices have malfunctioned during
14 the course of operative use causing injury, including the necessity of converting the
15 procedure into open surgery, or often requiring subsequent surgeries to deal with
16 complications of robotic use.

17 38. Defendant has failed to warn users and consumers of its said device of
18 the design flaws stated in the preceding paragraphs, although it has reached out
19 directly to consumers to promote its asserted advantages.
20

21 39. Defendant had specific knowledge and awareness of the dangers of
22 monopolar current and that there were safety modalities commercially available that
23 could have greatly diminished or eliminated some of these risks, yet the Defendant
24 elected not to include these safety features on the da Vinci Robotic Hysterectomy
25 platform.
26
27
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1 40. Defendant has obtained and continues to maintain approval of the uses
2 of its device from the Food and Drug Administration by failing to fully inform them of
3 its knowledge of risks and complications associated with the use of its device.
4

5
6 **FIRST CAUSE OF ACTION – PRODUCT LIABILITY**
7

8 41. Plaintiffs incorporate by reference each and every paragraph of this
9 Complaint as though set forth in full in this cause of action.
10

11 42. Defendant placed into the stream of commerce its aforesaid device
12 which was defective in design, as previously pleaded.
13

14 43. Defendant owed Plaintiffs a duty to exercise reasonable care when
15 designing, testing, manufacturing, marketing, advertising, promoting, distributing,
16 and/or selling da Vinci Robots for hysterectomy.
17

18 44. At all relevant times to this action, Defendant owed a duty to properly
19 warn Plaintiff, the medical community, and the Public of the risks, dangers and
20 adverse side effects of the da Vinci Robotic hysterectomy platform.
21

22 45. Defendant breached its duty by failing to exercise ordinary care in the
23 preparation, design, research, testing, development, manufacturing, inspection,
24 labeling, marketing, promotion, advertising and selling of da Vinci Robotic Surgery,
25 as set forth below:
26

27 a. Failing to test da Vinci Robotic Hysterectomy properly and thoroughly
28 before promoting the robotic surgical platform using monopolar current to the market;

 b. failing to analyze properly and thoroughly the data resulting from the pre-

1 marketing tests of monopolar current used in the da Vinci Robotic Hysterectomy;

2 c. failing to report to the FDA, the medical community, and the general public
3 those data resulting from pre- and post-marketing tests of the da Vinci Robotic
4 Hysterectomy platform which indicated risks associated with its use;

5 d. failing to conduct adequate post-market monitoring and surveillance of post-
6 surgical complications associated with the da Vinci Robotic Hysterectomy platform
7 using monopolar current;

8 e. failing to conduct adequate analysis of adverse event reports;

9 f. designing, manufacturing, marketing, advertising, distributing and promoting
10 the da Vinci Robotic Hysterectomy directly to consumers, including Plaintiff, without
11 adequate warning of the significant and dangerous risks of monopolar current and the
12 da Vinci Robotic Hysterectomy Platform and without proper instructions to avoid the
13 harm which could foresee ably occur as a result of using monopolar energy on the
14 existing da Vinci Robotic Hysterectomy platform;

15 g. failing to exercise due care when advertising and promoting da Vinci
16 Robotic Hysterectomy;

17 h. negligently continuing to manufacture, market, advertise, and promote da
18 Vinci Robotic Hysterectomy after Defendant knew or should have known of the risks
19 of serious injury and/or death associated with using monopolar current to perform
20 certain aspects of the surgery including the colpotomy incision;

21 i. failing to use due care in the preparation and development of the da Vinci
22 Robotic Hysterectomy to prevent the aforementioned risk of injuries to individuals
23 through the use of monopolar current;

1 j. failing to use due care in the design of the da Vinci Robotic Hysterectomy
2 platform with special regard to the insulation of the robotic arms and instruments to
3 prevent the aforementioned risk of injuries to individuals during the routine course of
4 surgery;

5
6 k. failing to conduct adequate pre-clinical testing and research to determine the
7 safety of the use of monopolar current and the insulation of the robotic instruments to
8 be used in robotic hysterectomy, with special regard to the reusing of the instruments
9 up to ten times in ten different patients;

10 l. failing to conduct adequate intra-operative surveillance and post operative
11 complication studies to determine the safety of the use of monopolar energy during the
12 surgical robotic hysterectomy procedure taught by INTUITIVE SURGICAL INC.,
13 while defendant knew or should have known that intra-operative surveillance and
14 post-operative complication analysis would be the only means to determine the
15 relative risk of using monopolar during important surgical steps when performing a
16 robotic hysterectomy with specific attention to the risks of performing a colpotomy
17 incision or an amputation of the uterus, causing severe thermal injury to bladder,
18 ureter, bowel, vaginal cuff, and blood vessels, in the absence of clinical trials which
19 cannot be conducted for this purpose, and that such surveillance would be necessary
20 for a due diligence program that would alert defendant to the need to change the
21 technique for the use of monopolar current or to withdraw it from the market
22 altogether;

23
24 m. failing to completely, accurately and in a timely fashion, disclose the results
25 of the pre-marketing testing of issues with monopolar energy and post-marketing
26
27

1 surveillance of monopolar energy related injuries and complications to Plaintiff,
2 consumers, the medical community, and the FDA;

3 n. failing to accompany marketing materials promoting the da Vinci Robotic
4 Hysterectomy platform using monopolar current with proper warnings regarding all
5 possible adverse side effects associated with the use of the same;
6

7 o. failing to use due care in the manufacture, inspection, and safety evaluation
8 of the da Vinci Robotic Hysterectomy platform to prevent the aforementioned risk of
9 injuries to individuals who underwent a da Vinci Robotic Hysterectomy;

10 p. failing to use due care in the promotion of da Vinci Robotic Hysterectomy to
11 prevent the aforementioned risk of injuries to individuals when the drugs were
12 ingested;
13

14 q. failing to use due care in the sale and marketing of the da Vinci Robot
15 to prevent the aforementioned risk of injuries to individuals who were to undergo
16 robotic hysterectomy;

17 r. failing to use due care in the selling of the monopolar scissors to prevent the
18 aforementioned risk of injuries to individuals who underwent da Vinci Robotic
19 Hysterectomy;
20

21 s. failing to provide adequate and accurate training and information to the sales
22 representatives who sold the da Vinci Robot;

23 t. failing to provide adequate and accurate training and information to
24 healthcare providers for the appropriate use of the da Vinci Robot for hysterectomy;

25 u. failing to conduct or fund research into the development of safer robotic
26 surgical instruments which would pose the least risk of causing severe thermal injury
27
28

1 to bowel, bladder, ureter, and blood vessels;

2 v. failing to educate healthcare providers and the public about the safest use of
3 the monopolar scissors in da Vinci Robotic surgery;

4 w. failing to give healthcare providers adequate information to weigh the risks
5 of serious injury and/or death for a given patient using the da Vinci Robotic
6 Hysterectomy platform and technique featuring the use of monopolar current; and,

7 x. being otherwise reckless, careless and/or negligent.
8

9
10 46. Defendant placed into the stream of commerce its aforesaid device,
11 which was defective in its labeling and warnings, as previously pleaded.

12 47. Defendant placed into the stream of commerce its aforesaid device,
13 which was defective in its testing and approval, as previously pleaded.

14 48. At the time the device left the possession of defendant it was in an
15 unreasonably dangerous and defective condition for application for robotic
16 hysterectomy using monopolar energy.

17 49. Despite the fact that Defendant knew or should have known that the da
18 Vinci Robotic Hysterectomy platform using monopolar current had increased the risk
19 of serious injury and/or death, Defendant continued to promote and market the da
20 Vinci Robotic Hysterectomy to consumers, including Plaintiff, when safer and more
21 effective methods of treatment were available.

22 50. The Defendant designed, tested, manufactured, packaged, marketed,
23 distributed, promoted, and sold the da Vinci Robot, placing the da Vinci Robotic
24 Hysterectomy into the stream of commerce.
25
26
27
28

1 51. The da Vinci Robot was designed, tested, inspected, manufactured,
2 assembled, developed, labeled, sterilized, licensed, marketed, advertised, promoted,
3 sold, packaged, supplied and/or distributed by Defendant in a defective and
4 unreasonably dangerous condition to consumers, including the Plaintiff.
5

6 52. The da Vinci Robot was expected to reach, and did reach, users and/or
7 consumers, including Plaintiff, without substantial change in the defective and
8 unreasonably dangerous condition in which it was manufactured and sold.

9 53. Plaintiff's surgeon used the da Vinci robotic Hysterectomy platform
10 including monopolar current as instructed by and certified by and in the foreseeable
11 manner normally intended, recommended, promoted, and marketed by Defendant.
12 Plaintiff's surgeons, attended a surgical lab for hands-on initial training and were
13 proctored for by a proctor employed by INTUITIVE SURGICAL.
14

15 54. The da Vinci Robotic Hysterectomy platform was unreasonably
16 dangerous in that, as designed, it failed to perform safely when used by ordinary
17 consumers, including Plaintiff's surgeon, including when it was used as intended and
18 in a reasonably foreseeable manner.
19

20 55. The da Vinci Robotic Hysterectomy was unreasonably dangerous in
21 that, as designed, the risks of serious injury and/or death, including bowel, bladder,
22 ureteral, vaginal cuff, abscess formation, permanent scarring, or vascular injury, posed
23 by its monopolar current risks exceeded any benefit the Robotic approach was
24 designed to or might in fact bestow.

25 56. The da Vinci Robotic Hysterectomy platform was unreasonably
26 dangerous in that, as designed, it was dangerous to an extent beyond that contemplated
27

1 by the medical community, and ordinary regulars, including the Plaintiff.

2 57. The da Vinci Surgical Robot was defective in its design in that it
3 neither bore, nor was packaged with, nor accompanied by, warnings adequate to alert
4 the medical community, including Plaintiff's surgeon, to the risks described herein,
5 including, but not limited to, the risk of serious injury and/or death, including bowel,
6 bladder, ureteral, vaginal cuff devascularization, or vascular injury, posed by its
7 monopolar current risks. The da Vinci Robot was not accompanied by adequate
8 labeling, instructions for use and/or warnings to fully apprise the medical, hospital,
9 operating room and/or scientific communities, and potential patients, including
10 Plaintiff, of the potential risks and serious side effects associated with its use, thereby
11 rendering Defendant liable to the Plaintiff.
12

13 58. There were safer alternative energy modalities available including
14 bipolar energy and ultrasonic energy.
15

16 59. Monopolar energy, as used and taught on the da Vinci Robotic
17 Hysterectomy platform, was unsafe for normal or reasonably anticipated use in
18 performing the colpotomy incision or the amputation of the uterus.
19

20 60. In light of the potential and actual risk of harm associated with the use
21 of monopolar energy so close to bowel, bladder, ureter, vaginal cuff, and blood
22 vessels, a reasonable person who had actual knowledge of this potential and actual risk
23 of harm would have concluded that the da Vinci Robotic Hysterectomy platform
24 should not have been marketed in that condition.

25 61. Although Defendant knew or should have known of the defective
26 nature of its da Vinci Robotic Hysterectomy platform using monopolar current, it
27

1 continued to design, manufacture, market, and promote the use of it's da Vinci
2 Robotic Hysterectomy platform so as to maximize sales and profits at the expense of
3 the public health and safety. Defendant thus acted with conscious and deliberate
4 disregard of the foreseeable harm caused by the continued use of monopolar energy on
5 its robotic platform.
6

7 62. Plaintiff could not, through the exercise of reasonable care, have
8 discovered the risk of serious injury and/or death associated with and/or caused by the
9 da Vinci Robotic Hysterectomy platform featuring monopolar current. Plaintiff, if
10 aware of these additional risks, could have chosen surgical procedures with similar
11 efficacies but without these additional risks. As a result, Plaintiff suffered the personal
12 injuries described herein.
13

14 63. Information given by Defendant to the medical community and to the
15 consumers concerning the safety and efficacy of the da Vinci Robotic Hysterectomy
16 platform, especially the information contained in the advertising and promotional
17 materials, did not accurately reflect the serious and potentially fatal side effects.
18

19 64. Had adequate warnings and instructions been provided, Plaintiff's
20 surgeon would not have suggested a robotic approach, and Plaintiff would have had at
21 a much lower risk of the harmful side effects described herein.

22 65. As a direct and proximate consequence of Defendant's negligence,
23 willful, wanton, and/or intentional acts, omissions, misrepresentations and/or
24 otherwise culpable acts described herein, the Plaintiff, ANNA LERHAUPT, sustained
25 injuries and damages alleged herein.
26

27 66. That by reason of the foregoing and defendant's aforesaid conduct,
28

1 among other things, the plaintiff ANNA LERHAUPT suffered injuries which caused
2 her to undergo additional surgery and medical procedures, endured pain and suffering
3 and will continue to do so in the future, has suffered mental anguish and will continue
4 to do so in the future, has loss the pleasure of sexual activity, and has incurred medical
5 expenses.
6

7 67. Plaintiff has incurred and Defendant is liable for certain expenses,
8 including hospital, surgical and medical treatment, transportation costs to University
9 Centers, as a result of, among other things, defendant's conduct.

10 68. As a result of its said conduct, Defendant has become strictly liable to
11 plaintiff.
12

13 69. Defendant's conduct in continuing to market, sell and distribute the
14 aforesaid devices after obtaining knowledge they were defective and not performing as
15 represented and intended, showed complete indifference to and/or a conscious
16 disregard for the safety of others justifying an award of punitive damages for
17 aggravating circumstances in such a sum which will serve to deter defendant and
18 others from similar conduct in the future.

19 **WHEREFORE**, Plaintiffs, demands judgment against Defendant and seeks
20 compensatory damages, and exemplary and punitive damages together with interest,
21 the costs of suit and attorneys' fees and such other and further relief as this Court
22 deems just and proper.
23

24 ///

25 ///

**SECOND CAUSE OF ACTION – GENERAL NEGLIGENCE & NEGLIGENT
TRAINING & PROCTORING & NEGLIGENT CERTIFICATION**

70. Plaintiff repeats, reiterates and realleges each and every allegation and cause of action contained herein as if the same were set forth more fully at length herein.

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

72. In specific, defendant failed to warn users and consumers of the risk of complications associated with the use of its said device, 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's ANNA LERHAUPT 'S additional surgery and medical treatments resulting in long term pain and suffering.

73. Defendant took it upon itself to "train" and "certify" Plaintiff's surgeon on the use of the da Vinci Robotic Hysterectomy platform using monopolar current. Upon belief the Defendant specifically trained Plaintiff's surgeon on the use of monopolar current via operative endoshear scissors during the dissection of the bladder and the colpotomy incision causing thermal injury and devascularization of the vaginal cuff leading to increased tissue damage, abscess, and chronic inflammatory changes.

74. Defendant did not properly proctor and/or properly instruct Plaintiff's surgeons and attending staff as to the safe use of its device nor how to detect

1 complications which its said device causes and is known to cause.

2 75. Defendant had a financial incentive to promptly train, proctor, and
3 certify Plaintiff's surgeon without regard to whether or not Plaintiff's surgeon was
4 truly skilled and competent on the da Vinci Robotic Hysterectomy platform.
5

6
7 **THIRD CAUSE OF ACTION – FRAUD**
8

9 76. Plaintiff repeats, reiterates and realleges each and every allegation and
10 cause of action set forth herein as if the same were set forth more fully at length
11 herein.
12

13 77. Defendant misrepresented the safety and comparative efficacy of its
14 device, upon which decedent's surgeons relied, to decedent's detriment.

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

18 79. Defendant was aware, or should have been aware, of the known
19 dangers of monopolar current in regard to unsuspected current leaving the shaft of a
20 poorly insulated instrument. Furthermore, Defendant suggested to Hospitals that
21 multiple uses of the robotic instruments could be done yet Defendant did so without
22 regard to re-testing of the insulation along the shaft of their robotic instruments or at
23 the wrist of the robotic instrument.
24

25 80. Defendant was aware, or should have been aware, of the known
26 dangers of monopolar current in regard to capacitive coupling, which like insulation
27

1 failure can cause a thermal injury to occur in adjacent structures like bowel, bladder,
2 ureter, vaginal cuff, or blood vessel. Defendant was aware, or should have been
3 aware, of the known increased incidence of vaginal cuff dehiscence, de-
4 vascularization and abscess formation due to the use of monopolar current while
5 performing the colpotomy portion of the da Vinci Robotic total laparoscopic
6 hysterectomy.
7

8 81. Defendant was aware that there were safer energy modalities including
9 ultrasonic energy and bipolar energy, yet maintained teaching the use of monopolar
10 current in the da Vinci Robotic Hysterectomy. Defendant did so based on not wanting
11 to pay for the cost of having to license these safer energy technologies.
12

13 82. Defendant was also aware, or should have been aware, of the Active
14 Electrode Monitoring System, or AEM Technology, which shields and monitors
15 instruments continuously directing stray energy, the cause of stray electrosurgical
16 burns, away from the patient. With the AEM system, the patient is never at risk for
17 stray electrosurgical burns due to insulation failure and capacitive coupling. Despite
18 having specific knowledge of this safety system the Defendant choose not to purchase
19 it for it's da Vinci Robotic Hysterectomy platform using monopolar current.
20

21 83. Further, defendant concealed from consumers and users, including
22 those mentioned in the preceding paragraphs, the risks of complications of which it
23 was aware, which would have been material to consumers and users in making the
24 decision to use the said device.

25 84. Further, defendant suppressed reports of adverse outcomes with the use
26 of its device, which would have been material to consumers and users in making the
27

1 decision to use the said device.

2 85. Further, defendant over-promoted its device and minimized its risks,
3 for the purpose of making sales of its device, its maintenance, and the use of
4 replaceable parts, and skewed the cost-benefit ratio inaccurately in its favor.
5

6 86. The said conduct was so willful, wanton, malicious and reckless that it
7 merits the imposition of punitive damages.
8

9 **FOURTH CAUSE OF ACTION - BREACH OF EXPRESS WARRANTY**
10

11 87. Plaintiff repeats, reiterates and realleges each and every allegation and
12 cause of action set forth herein as if the same were set forth more fully at length
13 herein.
14

15 88. Defendant made express warranties of safety to the buyers and
16 consumers of the device utilized during Plaintiff's ANNA LERHAUPT surgery, upon
17 which the buyers and users, as agents of Plaintiff ANNA LERHAUPT, relied, to her
18 detriment. Defendant expressly represented to the Plaintiff ANNA LERHAUPT (and
19 to other consumers and the medical community) that the da Vinci robotic
20 hysterectomy was safe, efficacious and fit for its intended purposes that it was of
21 merchantable quality, that it did not produce any unwarned-of dangerous side effects,
22 and that it was adequately tested.
23

24 89. Defendant breached expressed warranties with respect to the da Vinci
25 robotic hysterectomy in the following ways:

26 a) Defendant represented through its labeling, advertising, marketing
27
28

1 materials, detail persons, seminar presentations, surgeon training sessions,
2 publications, notice letters, and regulatory submissions that the da Vinci Robotic
3 hysterectomy was safe, and fraudulently withheld and concealed information about the
4 substantial risks or serious injury and/or death associated with using monopolar
5 current on the existing da Vinci robotic platform;
6

7 b) Defendant represented that the da Vinci Robotic Hysterectomy was as
8 safe and/or safer than alternative surgical methods, and fraudulently concealed
9 information which demonstrated that the da Vinci robotic hysterectomy approach was
10 not safer than alternatives available on the market; and,
11

12 c) defendant represented that the da Vinci Robotic Hysterectomy was
13 more efficacious than other alternative surgical methods, and fraudulently concealed
14 information that it was not more efficacious than alternative surgical methods.

15 90. Da Vinci Robotic Hysterectomy does not conform to Defendant's
16 express representations, because it is not safe, efficacious, has numerous serious
17 unwarned-of side effects, causes severe and permanent injuries including death, and
18 was not adequately tested.

19 91. The da Vinci Robotic Hysterectomy platform including the use of
20 monopolar current did not perform as safely as an ordinary physician, as an agent of
21 the patient, would have expected when used as intended or in a reasonably foreseeable
22 manner.
23

24 92. Plaintiff ANNA LERHAUPT, her surgeons and other in the medical
25 community, relied upon Defendant's express warranties, resulting in the Plaintiff's da
26 Vinci Robotic Hysterectomy.
27

1 93. Plaintiff, after ascertaining through her own injuries that the da Vinci
2 Robotic Hysterectomy violated express warranties, hereby supply notice to Defendant
3 INTUITIVE SURGICAL INC. of same through the filing of this lawsuit.

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

8 95. By selling the said device, defendant made implied warranties of
9 safety, merchantable quality, and fitness for use, which was breached when plaintiff
10 ANNA LERHAUPT was injured during surgery.

11 96. As a further direct and proximate result of the acts of Defendant,
12 Plaintiff's suffered emotional distress.

13 **WHEREFORE**, Plaintiffs demand judgment against Defendant and seeks
14 compensatory damages, and exemplary and punitive damages together with interest,
15 the costs of suit and attorneys' fees and such other and further relief as this Court
16 deems just and proper.

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18
19
20 **FIFTH CAUSE OF ACTION – BREACH OF IMPLIED WARRANTY**

21
22 97. Plaintiffs incorporate by reference each and every paragraph of this
23 complaint as though set forth in full in this cause of action.

24 98. At all relevant and material times, Defendant manufactured, distributed,
25 advertised, promoted, and sold the da Vinci Robot.

1 99. At all relevant times, Defendant intended that the da Vinci Robot be
2 used in the manner that the Plaintiff's surgeon in fact used it and Defendant impliedly
3 warranted the product to be of merchantable quality, safe and fit for such use, and was
4 adequately tested.
5

6 100. Defendant breached various implied warranties with respect to the da
7 Vinci Robot including the particulars:

8 a. Defendant represented through its labeling, advertising, marketing
9 materials, detail persons, seminar presentations, publications, notice letters, and
10 regulatory submissions that the da Vinci Robotic Hysterectomy platform was safe and
11 fraudulently withheld and concealed information about the substantial risks of serious
12 injury and/or death associated with using the da Vinci Robot with monopolar current;
13

14 b. Defendant represented that the da Vinci Robotic Hysterectomy with
15 monopolar current was as safe and/or safer than other alternative surgical approaches
16 that did not include the use of the da Vinci Robot, and fraudulently concealed
17 information, which demonstrated that the da Vinci Robotic Hysterectomy was not
18 safer than alternatives available on the market; and,
19

20 c. Defendant represented that the da Vinci Robotic Hysterectomy was as more
21 efficacious than other alternative surgical approaches and techniques and fraudulently
22 concealed information, regarding the true efficacy of the robotic hysterectomy with
23 monopolar current.
24

25 101. In reliance upon Defendant's implied warranty, Plaintiff's surgeon used
26 the da Vinci Robotic Hysterectomy platform as prescribed and in the foreseeable
27

1 manner normally intended, recommended, promoted, instructed, and marketed by
2 Defendant.

3 102. Defendant breached its implied warranty to Decedent in that the da
4 Vinci Robotic Hysterectomy platform with monopolar current was not of
5 merchantable quality, safe and fit for its intended use, or adequately tested.
6

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

11 104. As a further direct and proximate result of the acts of Defendant,
12 Plaintiffs suffered emotional distress and loss of consortium.

13 **Wherefore,** Plaintiffs demand judgment against Defendant and seeks compensatory
14 damages, and exemplary and punitive damages together with interest, the costs of suit
15 and attorneys' fees and such other and further relief as this Court deems just and
16 proper.
17

18 **SIXTH CAUSE OF ACTION - UNJUST ENRICHMENT**
19

20 105. Plaintiffs incorporate by reference each and every paragraph of this
21 complaint as though set forth in full in this cause of action.
22

23 106. At all times relevant to this action, Defendant designed, advertised,
24 marketed, promoted, manufactured, distributed, supplied, and/or sold the da Vinci
25 Robot for hysterectomy use.

26 107. Plaintiff ANNA LERHAUPT'S surgeon's hospital purchased the da
27

1 Vinci Robot from the Defendant for the purpose of using it for Robotic Hysterectomy.
2 Same hospital purchased disposable and reusable instrument for the performing of
3 ANNA LERHAUPT'S surgery.
4

5 108. Defendant has accepted payment from said aforementioned hospital for
6 both the da Vinci robot used in ANNA LERHAUPT'S surgery, but also for the routine
7 maintenance and per surgery cost of additional items including disposable items.

8 109. ANNA LERHAUPT did not receive the safe and effective surgical
9 product which she intended to purchase; nor did the hospital where ANNA
10 LERHAUPT had her surgery.
11

12 110. It is inequitable and unjust for Defendant to retain this money because
13 the Plaintiff did not in fact receive the safe and efficacious surgical procedure
14 Defendant represented da Vinci Robotic Hysterectomy to be.

15 **WHEREFORE**, Plaintiffs demand judgment against Defendant and seeks equitable
16 relief, the costs of suit and attorneys' fees, and such other and further relief as this
17 Court deems just and proper.
18

19
20 **SEVENTH CAUSE OF ACTION-LOSS OF CONSORTIUM**
21

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

24 112. As a direct consequence of the injuries to the vaginal cuff and
25 subsequent abscess and chronic inflammation and scarring sustained by ANNA
26 LERHAUPT while undergoing a da Vinci Robotic Hysterectomy, and the pelvic pain,
27
28

1 formation of a large vaginal cuff abscess, bowel wall inflammation, pain with
2 intercourse, permanent scarring, and the emotional consequences; Plaintiff
3 BENJAMIN LERHAUPT has been deprived the normal companionship, company,
4 affection, regard, assistance, comfort, sexual relations, and emotional stability from his
5 wife ANNA LERHAUPT.
6

7 113. These physical and emotional consequences of the injuries have
8 negatively impacted the quality and caused undo hardship to the marriage relationship.
9 **Wherefore**, Plaintiffs demand judgment against Defendant and seeks compensatory
10 damages, and exemplary and punitive damages together with interest, the costs of suit
11 and attorneys' fees and such other and further relief as this Court deems just and
12 proper.
13

14 **DEMAND FOR JURY TRIAL**
15

16 Plaintiffs demand a trial by jury on all counts and issues so triable.
17

18 **GLOBAL PRAYER FOR RELIEF**
19

20
21 WHEREFORE, Plaintiffs respectfully demand judgment against Defendant on each
22 count as follows:

- 23 1. On the First Cause of Action for Product Liability including
24 personal injury and pain and suffering and emotional distress, the
25 sum of \$10 million;
- 26 2. On the Second Cause of Action for Negligence, the sum of \$10
27

HERSHANDHERSH
A Professional Corporation

1 million;

2 3. On the Third Cause of Action for Fraud, the sum of \$10 million;

3 4. On the Fourth & Fifth Cause of Action for Breach Of Express
4 Warranty and Breach of Implied Warranty, the sum of \$10
5 million;

6 5. On the Sixth Cause of Action for Unjust Enrichment, the sum of
7 \$200 million

8 6. On the Seventh Count of Loss of Consortium, the sum of \$10
9 million.

10 7. On the claim for punitive damages in each cause of action, a total
11 of \$20 million; and

12 8. Reasonable attorney's fees when recoverable

13 9. Such other additional and further relief to which Plaintiff may be
14 justly entitled, in law or equity.

15 All together with the interest, costs and disbursements of this action.

16 Dated: San Francisco, California

17 JULY 26, 2012

18 Respectfully submitted,

19 HERSH & HERSH
20 A Professional Corporation

21 By _____
22 NANCY HERSH
23 Attorneys for Plaintiffs

CIVIL COVER SHEET

The JL 14 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

ANNA LERHAUPT AND BENJAMIN LERHAUPT

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

(c) Attorneys (Firm Name, Address, and Telephone Number)
Nancy Hersh, Esq.; Mark Burton, Esq.
Hersh & Hersh, 601 Van Ness Ave., Suite 2080
San Francisco, CA 94102; Tel: (415) 441-5544

DEFENDANTS

INTUITIVE SURGICAL, INC.,

County of Residence of First Listed Defendant Santa Clara
(IN U.S. PLAINTIFF CASES ONLY)

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

Attorneys (If Known)

HRL

ADR

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)

- | | PTF | DEF | | PTF | DEF |
|---|---------------------------------------|----------------------------|---|----------------------------|---------------------------------------|
| Citizen of This State | <input checked="" type="checkbox"/> 1 | <input type="checkbox"/> 1 | Incorporated or Principal Place of Business In This State | <input type="checkbox"/> 4 | <input type="checkbox"/> 4 |
| Citizen of Another State | <input type="checkbox"/> 2 | <input type="checkbox"/> 2 | Incorporated and Principal Place of Business In Another State | <input type="checkbox"/> 5 | <input checked="" type="checkbox"/> 5 |
| Citizen or Subject of a Foreign Country | <input type="checkbox"/> 3 | <input type="checkbox"/> 3 | Foreign Nation | <input type="checkbox"/> 6 | <input type="checkbox"/> 6 |

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

CONTRACT	PERSONAL INJURY	PRODUCT LIABILITY	FORFEITURE/PENALTY	BANKRUPTCY	OTHER STATUTES
<input type="checkbox"/> 110 Insurance	<input type="checkbox"/> 310 Airplane	<input checked="" type="checkbox"/> 365 Personal Injury - Product Liability	<input type="checkbox"/> 625 Drug Related Seizure of Property 21 USC 881	<input type="checkbox"/> 422 Appeal 28 USC 158	<input type="checkbox"/> 375 False Claims Act
<input type="checkbox"/> 120 Marine	<input type="checkbox"/> 315 Airplane Product Liability	<input type="checkbox"/> 367 Health Care/Pharmaceutical Personal Injury Product Liability	<input type="checkbox"/> 690 Other	<input type="checkbox"/> 423 Withdrawal 28 USC 157	<input type="checkbox"/> 400 State Reapportionment
<input type="checkbox"/> 130 Miller Act	<input type="checkbox"/> 320 Assault, Libel & Slander	<input type="checkbox"/> 368 Asbestos Personal Injury Product Liability			<input type="checkbox"/> 410 Antitrust
<input type="checkbox"/> 140 Negotiable Instrument	<input type="checkbox"/> 330 Federal Employers' Liability				<input type="checkbox"/> 430 Banks and Banking
<input type="checkbox"/> 150 Recovery of Overpayment & Enforcement of Judgment	<input type="checkbox"/> 340 Marine				<input type="checkbox"/> 450 Commerce
<input type="checkbox"/> 151 Medicare Act	<input type="checkbox"/> 345 Marine Product Liability				<input type="checkbox"/> 460 Deportation
<input type="checkbox"/> 152 Recovery of Defaulted Student Loans (Excl. Veterans)	<input type="checkbox"/> 350 Motor Vehicle				<input type="checkbox"/> 470 Racketeer Influenced and Corrupt Organizations
<input type="checkbox"/> 153 Recovery of Overpayment of Veteran's Benefits	<input type="checkbox"/> 355 Motor Vehicle Product Liability				<input type="checkbox"/> 480 Consumer Credit
<input type="checkbox"/> 160 Stockholders' Suits	<input type="checkbox"/> 360 Other Personal Injury				<input type="checkbox"/> 490 Cable/Sat TV
<input type="checkbox"/> 190 Other Contract	<input type="checkbox"/> 362 Personal Injury - Med. Malpractice				<input type="checkbox"/> 490 Securities/Commodities/Exchange
<input type="checkbox"/> 195 Contract Product Liability					<input type="checkbox"/> 890 Other Statutory Actions
<input type="checkbox"/> 196 Franchise					<input type="checkbox"/> 891 Agricultural Acts
					<input type="checkbox"/> 893 Environmental Matters
					<input type="checkbox"/> 895 Freedom of Information Act
					<input type="checkbox"/> 896 Arbitration
					<input type="checkbox"/> 899 Administrative Procedure Act/Review or Appeal of Agency Decision
					<input type="checkbox"/> 950 Constitutionality of State Statutes

V. ORIGIN

(Place an "X" in One Box Only)

- ☒ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from another district (specify) ☐ 6 Multidistrict Litigation

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing. (Do not cite jurisdictional statutes unless diversity):
28 U.S.C. Sections 1332(a)(1) and 1332(c)(2)

Brief description of cause:

Personal injury, Product Liability, Negligence, Fraud, Breach of Express and Implied Warranty, Unjust Enrichment

VII. REQUESTED IN COMPLAINT:

☐ CHECK IF THIS IS A CLASS ACTION UNDER F.R.C.P. 23 DEMAND \$

CHECK YES only if demanded in complaint:

JURY DEMAND: ☒ Yes ☐ No

VIII. RELATED CASE(S) IF ANY

(See instructions):

JUDGE

DOCKET NUMBER

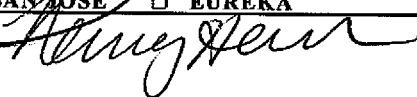
IX. DIVISIONAL ASSIGNMENT (Civil L.R. 3-2)

(Place an "X" in One Box Only)

☐ SAN FRANCISCO/OAKLAND ☒ SAN JOSE ☐ EUREKA

DATE 11/20/2012

SIGNATURE OF ATTORNEY OF RECORD



INSTRUCTIONS FOR ATTORNEYS COMPLETING CIVIL COVER SHEET FORM JS 44

Authority For Civil Cover Sheet

The JS 44 civil cover sheet and the information contained herein neither replaces nor supplements the filings and service of pleading 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. Consequently, a civil cover sheet is submitted to the Clerk of Court for each civil complaint filed. The attorney filing a case should complete the form as follows:

I. (a) Plaintiffs-Defendants. Enter names (last, first, middle initial) of plaintiff and defendant. If the plaintiff or defendant is a government agency, use only the full name or standard abbreviations. If the plaintiff or defendant is an official within a government agency, identify first the agency and then the official, giving both name and title.

(b) County of Residence. For each civil case filed, except U.S. plaintiff cases, enter the name of the county where the first listed plaintiff resides at the time of filing. In U.S. plaintiff cases, enter the name of the county in which the first listed defendant resides at the time of filing. (NOTE: In land condemnation cases, the county of residence of the "defendant" is the location of the tract of land involved.)

(c) Attorneys. Enter the firm name, address, telephone number, and attorney of record. If there are several attorneys, list them on an attachment, noting in this section "(see attachment)".

II. Jurisdiction. The basis of jurisdiction is set forth under Rule 8(a), F.R.C.P., which requires that jurisdictions be shown in pleadings. Place an "X" in one of the boxes. If there is more than one basis of jurisdiction, precedence is given in the order shown below.

United States plaintiff. (1) Jurisdiction based on 28 U.S.C. 1345 and 1348. Suits by agencies and officers of the United States are included here.

United States defendant. (2) When the plaintiff is suing the United States, its officers or agencies, place an "X" in this box.

Federal question. (3) This refers to suits under 28 U.S.C. 1331, where jurisdiction arises under the Constitution of the United States, an amendment to the Constitution, an act of Congress or a treaty of the United States. In cases where the U.S. is a party, the U.S. plaintiff or defendant code takes precedence, and box 1 or 2 should be marked.

Diversity of citizenship. (4) This refers to suits under 28 U.S.C. 1332, where parties are citizens of different states. When Box 4 is checked, the citizenship of the different parties must be checked. (See Section III below; federal question actions take precedence over diversity cases.)

III. Residence (citizenship) of Principal Parties. This section of the JS 44 is to be completed if diversity of citizenship was indicated above. Mark this section for each principal party.

IV. Nature of Suit. Place an "X" in the appropriate box. If the nature of suit cannot be determined, be sure the cause of action, in Section VI below, is sufficient to enable the deputy clerk or the statistical clerks in the Administrative Office to determine the nature of suit. If the cause fits more than one nature of suit, select the most definitive.

V. Origin. Place an "X" in one of the seven boxes.

Original Proceedings. (1) Cases which originate in the United States district courts.

Removed from State Court. (2) Proceedings initiated in state courts may be removed to the district courts under Title 28 U.S.C., Section 1441. When the petition for removal is granted, check this box.

Remanded from Appellate Court. (3) Check this box for cases remanded to the district court for further action. Use the date of remand as the filing date.

Reinstated or Reopened. (4) Check this box for cases reinstated or reopened in the district court. Use the reopening date as the filing date.

Transferred from Another District. (5) For cases transferred under Title 28 U.S.C. Section 1404(a). Do not use this for within district transfers or multidistrict litigation transfers.

Multidistrict Litigation. (6) Check this box when a multidistrict case is transferred into the district under authority of Title 28 U.S.C. Section 1407. When this box is checked, do not check (5) above.

Appeal to District Judge from Magistrate Judgment. (7) Check this box for an appeal from a magistrate judge's decision.

VI. Cause of Action. Report the civil statute directly related to the cause of action and give a brief description of the cause. Do not cite jurisdictional statutes unless diversity.

Example: U.S. Civil Statute: 47 USC 553

Brief Description: Unauthorized reception of cable service

VII. Requested in Complaint. Class Action. Place an "X" in this box if you are filing a class action under Rule 23, F.R.Cv.P.

Demand. In this space enter the dollar amount (in thousands of dollars) being demanded or indicate other demand such as a preliminary injunction.

Jury Demand. Check the appropriate box to indicate whether or not a jury is being demanded.

VIII. Related Cases. This section of the JS 44 is used to reference related pending cases if any. If there are related pending cases, insert the docket numbers and the corresponding judge names for such cases.

IX. Divisional Assignment. In accordance with Civil L.R. 3-2(c) - (f), select the appropriate venue based upon the county in which a substantial part of the events or omissions which give rise to the claim occurred or in which a substantial part of the property that is the subject of the action is situated.

Date and Attorney Signature. Date and sign the civil cover sheet.