

CIVIL COVER SHEET

JS 44 CAND (Rev. 12/11)

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

ELISA RISTER AND RICHARD RISTER,

(b) County of Residence of First Listed Plaintiff **San Bernardino County, CA**
(EXCEPT IN U.S. PLAINTIFF CASES)

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.

Attorney **CW**

(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

II. BASIS OF JURISDICTION (Place an "X" in One Box Only)

- 1 U.S. Government Plaintiff
- 2 U.S. Government Defendant
- 3 Federal Question (U.S. Government Not a Party)
- 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"/>	<input type="checkbox"/>	Incorporated or Principal Place of Business In This State	<input type="checkbox"/>	<input type="checkbox"/>
Citizen of Another State	<input type="checkbox"/>	<input type="checkbox"/>	Incorporated and Principal Place of Business In Another State	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Citizen or Subject of a Foreign Country	<input type="checkbox"/>	<input type="checkbox"/>	Foreign Nation	<input type="checkbox"/>	<input type="checkbox"/>

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

CONTRACT	TORTS	FORFEITURE/PENALTY	BANKRUPTCY	OTHER STATUTES
<input type="checkbox"/> 110 Insurance <input type="checkbox"/> 120 Marine <input type="checkbox"/> 130 Miller Act <input type="checkbox"/> 140 Negotiable Instrument <input type="checkbox"/> 150 Recovery of Overpayment & Enforcement of Judgment <input type="checkbox"/> 151 Medicare Act <input type="checkbox"/> 152 Recovery of Defaulted Student Loans (Excl. Veterans) <input type="checkbox"/> 153 Recovery of Overpayment of Veteran's Benefits <input type="checkbox"/> 160 Stockholders' Suits <input type="checkbox"/> 190 Other Contract <input type="checkbox"/> 195 Contract Product Liability <input type="checkbox"/> 196 Franchise	PERSONAL INJURY <input type="checkbox"/> 310 Airplane <input type="checkbox"/> 315 Airplane Product Liability <input type="checkbox"/> 320 Assault, Libel & Slander <input type="checkbox"/> 330 Federal Employers' Liability <input type="checkbox"/> 340 Marine <input type="checkbox"/> 345 Marine Product Liability <input type="checkbox"/> 350 Motor Vehicle <input type="checkbox"/> 355 Motor Vehicle Product Liability <input type="checkbox"/> 360 Other Personal Injury <input type="checkbox"/> 362 Personal Injury - Med. Malpractice	<input type="checkbox"/> 625 Drug Related Seizure of Property 21 USC 881 <input type="checkbox"/> 690 Other LABOR <input type="checkbox"/> 710 Fair Labor Standards Act <input type="checkbox"/> 720 Labor/Mgmt. Relations <input type="checkbox"/> 740 Railway Labor Act <input type="checkbox"/> 751 Family and Medical Leave Act <input type="checkbox"/> 790 Other Labor Litigation <input type="checkbox"/> 791 Empl. Ret. Inc. Security Act IMMIGRATION <input type="checkbox"/> 462 Naturalization Application <input type="checkbox"/> 463 Habeas Corpus - Alien Detainee (Prisoner Petition) <input type="checkbox"/> 465 Other Immigration Actions	<input type="checkbox"/> 422 Appeal 28 USC 158 <input type="checkbox"/> 423 Withdrawal 28 USC 157 PROPERTY RIGHTS <input type="checkbox"/> 820 Copyrights <input type="checkbox"/> 830 Patent <input type="checkbox"/> 840 Trademark SOCIAL SECURITY <input type="checkbox"/> 861 BIA (1395H) <input type="checkbox"/> 862 Black Lung (923) <input type="checkbox"/> 863 DIWC/DIWW (405(g)) <input type="checkbox"/> 864 SSID Title XVI <input type="checkbox"/> 865 RSI (405(g)) FEDERAL TAX SUITS <input type="checkbox"/> 870 Taxes (U.S. Plaintiff or Defendant) <input type="checkbox"/> 871 IRS -Third Party 26 USC 7609	<input type="checkbox"/> 375 False Claims Act <input type="checkbox"/> 400 State Reapportionment <input type="checkbox"/> 410 Antitrust <input type="checkbox"/> 430 Banks and Banking <input type="checkbox"/> 450 Commerce <input type="checkbox"/> 460 Deportation <input type="checkbox"/> 470 Racketeer Influenced and Corrupt Organizations <input type="checkbox"/> 480 Consumer Credit <input type="checkbox"/> 490 Cable/Sat TV <input type="checkbox"/> 850 Securities/Commodities/Exchange <input type="checkbox"/> 890 Other Statutory Actions <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
REAL PROPERTY <input type="checkbox"/> 210 Land Condemnation <input type="checkbox"/> 220 Foreclosure <input type="checkbox"/> 230 Rent Lease & Ejectment <input type="checkbox"/> 240 Torts to Land <input type="checkbox"/> 245 Tort Product Liability <input type="checkbox"/> 290 All Other Real Property	CIVIL RIGHTS <input type="checkbox"/> 440 Other Civil Rights <input type="checkbox"/> 441 Voting <input type="checkbox"/> 442 Employment <input type="checkbox"/> 443 Housing/Accommodations <input type="checkbox"/> 445 Amer. w. Disabilities - Employment <input type="checkbox"/> 446 Amer. w. Disabilities - Other <input type="checkbox"/> 448 Education	PRISONER PETITIONS <input type="checkbox"/> 510 Motions to Vacate Sentence Habeas Corpus: <input type="checkbox"/> 530 General <input type="checkbox"/> 535 Death Penalty <input type="checkbox"/> 540 Mandamus & Other <input type="checkbox"/> 550 Civil Rights <input type="checkbox"/> 555 Prison Condition <input type="checkbox"/> 560 Civil Detainee - Conditions of Confinement		

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 07/26/2012

SIGNATURE OF ATTORNEY OF RECORD

FILED
2012 JUL 26 AM 11:30
U.S. DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

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Attorneys for Plaintiff

**UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA**

ELISA RISTER AND RICHARD RISTER,

Plaintiffs,

vs.

INTUITIVE SURGICAL, INC.,

Defendant.

Case No. 12-333

**COMPLAINT
JURY TRIAL DEMANDED**

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

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THE PARTIES

1. The plaintiff, ELISA RISTER, is a resident of and domiciled in San Bernardino County, City of Fontana, and State of California.

2. The plaintiff, RICHARD RISTER, is a resident of and domiciled in San Bernardino County, City of Fontana, and State of California.

3. The defendant INTUITIVE SURGICAL, INC. (hereinafter "INTUITIVE") is a foreign business corporation, duly organized and existing under and by virtue of the laws of the State of Delaware.

JURISDICTION AND VENUE

4. Jurisdiction for this action in the United States District Court arises under 28 U.S.C. Sections 1332(a)(1) and 1332(c)(2) as this is a civil action based on complete diversity of citizenship in that the surgery performed on ELISA RISTER, a resident of California but a machine sold and distributed under the laws of Delaware. The amount in controversy exceeds \$75,000 exclusive of costs and interest.

GENERAL ALLEGATIONS

5. Plaintiff ELISA RISTER, a woman with a history of pain and irregular bleeding. Pursuant to evaluating ELISA RISTER, her Dr. informed ELISA RISTER that she needed to have a hysterectomy performed.

6. Her Dr. Nelson presented ELISA RISTER with information and materials propounding the benefit of da Vinci robotic hysterectomy over all other methods of hysterectomy. Specifically, her Dr. told ELISA RISTER that due to the da Vinci robotic approach she would heal faster, have a better outcome and have less

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pain.

7. Based on the representations made by her Dr. and the written materials provided to ELISA RISTER, the Plaintiff agreed to proceed with da Vinci robotic hysterectomy. Plaintiff ELISA RISTER underwent surgery which resulted in damage to her uterus

8. ELISA RISTER continues to suffer from abdominal pain, pelvic pain, dyspareunia, bloating, abdominal distention, fatigue and decreased energy and stamina. Through this time period ELISA RISTER has been unable to maintain normal intimate relationships with RICHARD RISTER and has suffered emotional distress.

9. Due to the injury sustained to her vaginal cuff and bowel during the da Vinci Robotic Hysterectomy, Plaintiff ELISA RISTER had to have multiple additional medical tests and physician consultations and has suffered pain, loss of function, emotional distress, and permanent injury. Plaintiff RICHARD RISTER has suffered the loss of Consortium.

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

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

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

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

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

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

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

17. Defendant 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.

18. Defendant 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 20 surgeries with the device.

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

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

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

22. On occasion these complications and injuries cause and/or contribute to

1 infectious processes from thermal injury causing abscess formation and can lead to the
2 untimely and premature death of the patient.

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

5 24. Defendant does not provide adequate warnings to physicians and
6 patients about the risks and complications associated with the use of its robotic device.
7

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

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

14 27. Defendant has not done, nor sponsored, any testing as to long-term
15 outcomes, in comparison to other surgical and laparoscopic methods.
16

17 28. Defendant has not revealed, through publications or reports to the Food
18 and Drug Administration and other governmental bodies, the true extent of
19 complications and injuries, which have occurred in actual practice.
20

21 29. Defendant has suppressed reports and complaints of complications and
22 performance errors due to the use of its said device.

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

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

3 32. Defendant has over-promoted its device to hospitals, physicians and the
4 public, including potential consumers, combined with minimizing the risks and
5 complications associated with its use.
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7 33. The device is defective in that it relies upon the use of monopolar
8 energy to cut, burn and cauterize tissue, whereas safer methods are available such as
9 bipolar energy and ultrasonic energy, which would reduce substantially the risk of
10 complications.
11

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

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

17 36. Defendant has failed to warn users and consumers of the said robotic
18 device about the inadequate insulation on the arms and the potential for electrical
19 current to pass into tissue outside of the operative field.
20

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

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

2 39. Defendant had specific knowledge and awareness of the dangers of
3 monopolar current and that there were safety modalities commercially available that
4 could have greatly diminished or eliminated some of these risks, yet the Defendant
5 elected not to include these safety features on the da Vinci Robotic Hysterectomy
6 platform.
7

8 40. Defendant has obtained and continues to maintain approval of the uses
9 of its device from the Food and Drug Administration by failing to fully inform them of
10 its knowledge of risks and complications associated with the use of its device.
11

12 **FIRST CAUSE OF ACTION – PRODUCT LIABILITY**

13 14 41. Plaintiffs incorporate by reference each and every paragraph of this
15 Complaint as though set forth in full in this cause of action.
16

17 42. Defendant placed into the stream of commerce its aforesaid device
18 which was defective in design, as previously pleaded.
19

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

23 44. At all relevant times to this action, Defendant owed a duty to properly
24 warn Plaintiff, the medical community, and the Public of the risks, dangers and
25 adverse side effects of the da Vinci Robotic hysterectomy platform.
26

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

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

6 b. failing to analyze properly and thoroughly the data resulting from the pre-
7 marketing tests of monopolar current used in the da Vinci Robotic Hysterectomy;

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

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

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

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

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

23 h. negligently continuing to manufacture, market, advertise, and
24

1 promote da Vinci Robotic Hysterectomy after Defendant knew or should have known
2 of the risks of serious injury and/or death associated with using monopolar current to
3 perform certain aspects of the surgery including the colpotomy incision;

4
5 i. failing to use due care in the preparation and development of the da Vinci
6 Robotic Hysterectomy to prevent the aforementioned risk of injuries to individuals
7 through the use of monopolar current;

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

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

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

5
6 m. failing to completely, accurately and in a timely fashion, disclose the results
7 of the pre-marketing testing of issues with monopolar energy and post-marketing
8 surveillance of monopolar energy related injuries and complications to Plaintiff,
9 consumers, the medical community, and the FDA;

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

13
14 o. failing to use due care in the manufacture, inspection, and safety evaluation
15 of the da Vinci Robotic Hysterectomy platform to prevent the aforementioned risk of
16 injuries to individuals who underwent a da Vinci Robotic Hysterectomy;

17 p. failing to use due care in the promotion of da Vinci Robotic Hysterectomy to
18 prevent the aforementioned risk of injuries to individuals when the drugs were
19 ingested;

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

23
24 r. failing to use due care in the selling of the monopolar scissors to prevent the
25 aforementioned risk of injuries to individuals who underwent da Vinci Robotic
26 Hysterectomy;

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

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

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

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

10 w. failing to give healthcare providers adequate information to weigh the risks
11 of serious injury and/or death for a given patient using the da Vinci Robotic
12 Hysterectomy platform and technique featuring the use of monopolar current; and,
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14 x. being otherwise reckless, careless and/or negligent.
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17 46. Defendant placed into the stream of commerce its aforesaid device,
18 which was defective in its labeling and warnings, as previously pleaded.

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

21 48. At the time the device left the possession of defendant it was in an
22 unreasonably dangerous and defective condition for application for robotic
23 hysterectomy using monopolar energy.
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25 49. Despite the fact that Defendant knew or should have known that the da
26 Vinci Robotic Hysterectomy platform using monopolar current had increased the risk
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1 of serious injury and/or death, Defendant continued to promote and market the da
2 Vinci Robotic Hysterectomy to consumers, including Plaintiff, when safer and more
3 effective methods of treatment were available.

4
5 50. The Defendant designed, tested, manufactured, packaged, marketed,
6 distributed, promoted, and sold the da Vinci Robot, placing the da Vinci Robotic
7 Hysterectomy into the stream of commerce.

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

12
13 52. The da Vinci Robot was expected to reach, and did reach, users and/or
14 consumers, including Plaintiff, without substantial change in the defective and
15 unreasonably dangerous condition in which it was manufactured and sold.

16 53. Plaintiff's surgeon used the da Vinci robotic Hysterectomy platform
17 including monopolar current as instructed by and certified by and in the foreseeable
18 manner normally intended, recommended, promoted, and marketed by Defendant.
19 Plaintiff's surgeon, Dr. Nelson, attended a surgical lab at Ochsner Hospital for hands-
20 on initial training and was proctored for three cases by Dr. Thomas Payne, a proctor
21 employed by INTUITIVE SURGICAL.

22
23 54. The da Vinci Robotic Hysterectomy platform was unreasonably
24 dangerous in that, as designed, it failed to perform safely when used by ordinary
25 consumers, including Plaintiff's surgeon, including when it was used as intended and
26 in a reasonably foreseeable manner.

1 60. In light of the potential and actual risk of harm associated with the use
2 of monopolar energy so close to bowel, bladder, ureter, vaginal cuff, and blood
3 vessels, a reasonable person who had actual knowledge of this potential and actual risk
4 of harm would have concluded that the da Vinci Robotic Hysterectomy platform
5 should not have been marketed in that condition.
6

7 61. Although Defendant knew or should have known of the defective
8 nature of its da Vinci Robotic Hysterectomy platform using monopolar current, it
9 continued to design, manufacture, market, and promote the use of it's da Vinci
10 Robotic Hysterectomy platform so as to maximize sales and profits at the expense of
11 the public health and safety. Defendant thus acted with conscious and deliberate
12 disregard of the foreseeable harm caused by the continued use of monopolar energy on
13 its robotic platform.
14

15 62. Plaintiff could not, through the exercise of reasonable care, have
16 discovered the risk of serious injury and/or death associated with and/or caused by the
17 da Vinci Robotic Hysterectomy platform featuring monopolar current. Plaintiff, if
18 aware of these additional risks, could have chosen surgical procedures with similar
19 efficacies but without these additional risks. As a result, Plaintiff suffered the personal
20 injuries described herein.
21

22 63. Information given by Defendant to the medical community and to the
23 consumers concerning the safety and efficacy of the da Vinci Robotic Hysterectomy
24 platform, especially the information contained in the advertising and promotional
25 materials, did not accurately reflect the serious and potentially fatal side effects.
26

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

3 65. As a direct and proximate consequence of Defendant's negligence,
4 willful, wanton, and/or intentional acts, omissions, misrepresentations and/or
5 otherwise culpable acts described herein, the Plaintiff, ELISA RISTER, sustained
6 injuries and damages alleged herein.
7

8 66. That by reason of the foregoing and defendant's aforesaid conduct,
9 among other things, the plaintiff ELISA RISTER suffered injuries which caused her to
10 undergo additional surgery and medical procedures, endured pain and suffering and
11 will continue to do so in the future, has suffered mental anguish and will continue to
12 do so in the future, has loss the pleasure of sexual activity, and has incurred medical
13 expenses.
14

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

18 68. As a result of its said conduct, Defendant has become strictly liable to
19 plaintiff.
20

21 69. Defendant's conduct in continuing to market, sell and distribute the
22 aforesaid devices after obtaining knowledge they were defective and not performing as
23 represented and intended, showed complete indifference to and/or a conscious
24 disregard for the safety of others justifying an award of punitive damages for
25 aggravating circumstances in such a sum which will serve to deter defendant and
26 others from similar conduct in the future.
27

1 **WHEREFORE**, Plaintiffs, demands judgment against Defendant and seeks
2 compensatory damages, and exemplary and punitive damages together with interest,
3 the costs of suit and attorneys' fees and such other and further relief as this Court
4 deems just and proper.
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7 **SECOND CAUSE OF ACTION – GENERAL NEGLIGENCE & NEGLIGENT**
8 **TRAINING & PROCTORING & NEGLIGENT CERTIFICATION**
9

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

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

16 72. In specific, defendant failed to warn users and consumers of the risk of
17 complications associated with the use of its said device, risks of monopolar current
18 use, including the damage to the bladder, bowel, ureter, vaginal cuff, and blood
19 vessels; the bladder and ureter which was a proximate cause of Plaintiff's ELISA
20 RISTER 'S additional surgery and medical treatments resulting in long term pain and
21 suffering.
22

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

4
5 74. Defendant did not properly proctor and/or properly instruct Plaintiff's
6 surgeons and attending staff as to the safe use of its device nor how to detect
7 complications which its said device causes and is known to cause.

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

11
12 **THIRD CAUSE OF ACTION – FRAUD**

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

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

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

23
24 79. Defendant was aware, or should have been aware, of the known
25 dangers of monopolar current in regard to unsuspected current leaving the shaft of a
26 poorly insulated instrument. Furthermore, Defendant suggested to Hospitals that
27

1 multiple uses of the robotic instruments could be done yet Defendant did so without
2 regard to re-testing of the insulation along the shaft of their robotic instruments or at
3 the wrist of the robotic instrument.

4
5 80. Defendant was aware, or should have been aware, of the known
6 dangers of monopolar current in regard to capacitive coupling, which like insulation
7 failure can cause a thermal injury to occur in adjacent structures like bowel, bladder,
8 ureter, vaginal cuff, or blood vessel. Defendant was aware, or should have been
9 aware, of the known increased incidence of vaginal cuff dehiscence, de-
10 vascularization and abscess formation due to the use of monopolar current while
11 performing the colpotomy portion of the da Vinci Robotic total laparoscopic
12 hysterectomy.

13
14 81. Defendant was aware that there were safer energy modalities including
15 ultrasonic energy and bipolar energy, yet maintained teaching the use of monopolar
16 current in the da Vinci Robotic Hysterectomy. Defendant did so based on not wanting
17 to pay for the cost of having to license these safer energy technologies.

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

26
27 83. Further, defendant concealed from consumers and users, including

1 those mentioned in the preceding paragraphs, the risks of complications of which it
2 was aware, which would have been material to consumers and users in making the
3 decision to use the said device.

4 84. Further, defendant suppressed reports of adverse outcomes with the use
5 of its device, which would have been material to consumers and users in making the
6 decision to use the said device.

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

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

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15 **FOURTH CAUSE OF ACTION - BREACH OF EXPRESS WARRANTY**

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

20 88. Defendant made express warranties of safety to the buyers and
21 consumers of the device utilized during Plaintiff's ELISA RISTER surgery, upon
22 which the buyers and users, as agents of Plaintiff ELISA RISTER , relied, to her
23 detriment. Defendant expressly represented to the Plaintiff ELISA RISTER (and to
24 other consumers and the medical community) that the da Vinci robotic hysterectomy
25 was safe, efficacious and fit for its intended purposes that it was of merchantable
26
27

1 quality, that it did not produce any unwarned-of dangerous side effects, and that it was
2 adequately tested.

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

5 a) Defendant represented through its labeling, advertising, marketing
6 materials, detail persons, seminar presentations, surgeon training sessions,
7 publications, notice letters, and regulatory submissions that the da Vinci Robotic
8 hysterectomy was safe, and fraudulently withheld and concealed information about the
9 substantial risks or serious injury and/or death associated with using monopolar
10 current on the existing da Vinci robotic platform;

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

15 c) defendant represented that the da Vinci Robotic Hysterectomy was
16 more efficacious than other alternative surgical methods, and fraudulently concealed
17 information that it was not more efficacious than alternative surgical methods.
18

19 90. Da Vinci Robotic Hysterectomy does not conform to Defendant's
20 express representations, because it is not safe, efficacious, has numerous serious
21 unwarned-of side effects, causes severe and permanent injuries including death, and
22 was not adequately tested.
23

24 91. The da Vinci Robotic Hysterectomy platform including the use of
25 monopolar current did not perform as safely as an ordinary physician, as an agent of
26
27

1 the patient, would have expected when used as intended or in a reasonably foreseeable
2 manner.

3 92. Plaintiff ELISA RISTER, her surgeon and other in the medical
4 community, relied upon Defendant's express warranties, resulting in the Plaintiff's da
5 Vinci Robotic Hysterectomy.
6

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

10 94. As a direct and proximate consequence of Defendant's breach of
11 express warranty and/or intentional acts, omissions, misrepresentations and/or
12 otherwise culpable acts described herein, the Plaintiffs sustained injuries and damages
13 alleged herein.
14

15 95. By selling the said device, defendant made implied warranties of
16 safety, merchantable quality, and fitness for use, which was breached when plaintiff
17 ELISA RISTER was injured during surgery.

18 96. As a further direct and proximate result of the acts of Defendant,
19 Plaintiff's suffered emotional distress.
20

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

25 ///

1 **FIFTH CAUSE OF ACTION – BREACH OF IMPLIED WARRANTY**

2
3 97. Plaintiffs incorporate by reference each and every paragraph of this
4 complaint as though set forth in full in this cause of action.
5

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

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

12 100. Defendant breached various implied warranties with respect to the da
13 Vinci Robot including the particulars:
14

15 a. Defendant represented through its labeling, advertising, marketing
16 materials, detail persons, seminar presentations, publications, notice letters, and
17 regulatory submissions that the da Vinci Robotic Hysterectomy platform was safe and
18 fraudulently withheld and concealed information about the substantial risks of serious
19 injury and/or death associated with using the da Vinci Robot with monopolar current;
20

21 b. Defendant represented that the da Vinci Robotic Hysterectomy with
22 monopolar current was as safe and/or safer than other alternative surgical approaches
23 that did not include the use of the da Vinci Robot, and fraudulently concealed
24 information, which demonstrated that the da Vinci Robotic Hysterectomy was not
25 safer than alternatives available on the market; and,
26

27 c. Defendant represented that the da Vinci Robotic Hysterectomy was as more
28

1 efficacious than other alternative surgical approaches and techniques and fraudulently
2 concealed information, regarding the true efficacy of the robotic hysterectomy with
3 monopolar current.
4

5
6 101. In reliance upon Defendant's implied warranty, Plaintiff's surgeon used
7 the da Vinci Robotic Hysterectomy platform as prescribed and in the foreseeable
8 manner normally intended, recommended, promoted, instructed, and marketed by
9 Defendant.

10 102. Defendant breached its implied warranty to Decedent in that the da
11 Vinci Robotic Hysterectomy platform with monopolar current was not of
12 merchantable quality, safe and fit for its intended use, or adequately tested.
13

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

18 104. As a further direct and proximate result of the acts of Defendant,
19 Plaintiffs suffered emotional distress and loss of consortium.
20

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

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SEVENTH CAUSE OF ACTION-LOSS OF CONSORTIUM

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

112. As a direct consequence of the injuries to the vaginal cuff and subsequent abscess and chronic inflammation and scarring sustained by ELISA RISTER while undergoing a da Vinci Robotic Hysterectomy, and the pelvic pain, formation of a large vaginal cuff abscess, bowel wall inflammation, pain with intercourse, permanent scarring, and the emotional consequences; Plaintiff RICHARD RISTER has been deprived the normal companionship, company, affection, regard, assistance, comfort, sexual relations, and emotional stability from his wife ELISA RISTER .

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

DEMAND FOR JURY TRIAL

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

GLOBAL PRAYER FOR RELIEF

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

1. On the First Cause of Action for Product Liability including personal injury and pain and suffering and emotional distress, the sum of \$10 million;
2. On the Second Cause of Action for Negligence, the sum of \$10 million;
3. On the Third Cause of Action for Fraud, the sum of \$10 million;
4. On the Fourth & Fifth Cause of Action for Breach Of Express Warranty and Breach of Implied Warranty, the sum of \$10 million;
5. On the Sixth Cause of Action for Unjust Enrichment, the sum of \$200 million
6. On the Seventh Count of Loss of Consortium, the sum of \$10 million.
7. On the claim for punitive damages in each cause of action, a total of \$20 million; and
8. Reasonable attorney's fees when recoverable
9. Such other additional and further relief to which Plaintiff may be justly entitled, in law or equity.

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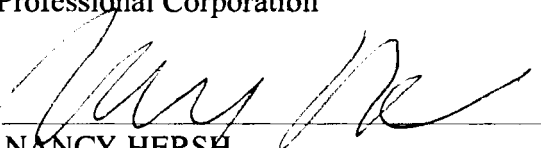
1 All together with the interest, costs and disbursements of this action.
2

3 Dated: San Francisco, California
4

5 JULY 26, 2012

6 Respectfully submitted,
7

8 HERSH & HERSH
9 A Professional Corporation

10
11 By 
12 NANCY HERSH
13 Attorneys for Plaintiffs
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HERSHANDHERSH
A Professional Corporation

AO 440 (Rev. 12/09) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

Northern District of California

ELISA RISTER AND RICHARD RISTER

Plaintiff

v.

INTUITIVE SURGICAL, INC.

Defendant

Civil Action No. 12-0333

JSC

SUMMONS IN A CIVIL ACTION

To: (Defendant's name and address)

INTUITIVE SURGICAL, INC.
c/o Agent for Service
CT Corporation System
818 W. Seventh Street
Los Angeles, CA 90017

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are:

Nancy Hersh
Hersh & Hersh
601 Van Ness Ave., Suite 2080
San Francisco, CA 94102

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

CLERK OF COURT

Simone Voltz

Signature of Clerk or Deputy Clerk

Date: