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11 UNITED STATES DISTRICT COURT
12 NORTHERN DISTRICT OF CALIFORNIA

13 DANIELLE COOK AND EVAN COOK,

14 Plaintiffs,

15 v.

16 INTUITIVE SURGICAL, INC.

17 Defendant.

18 Civil Action No. **C 12 6363**

19 **COMPLAINT**

20 **JURY TRIAL DEMANDED**

21 Plaintiffs, complaining of the Defendant by their attorneys, respectfully allege, upon
22 information and belief, the following:

23 **THE PARTIES**

24 1. The Plaintiff, DANIELLE COOK, is a resident of and domiciled in Mesa,
25 Arizona.

26 2. The Plaintiff, EVAN COOK, is the husband of DANIELLE COOK and a
27 resident of and domiciled in Mesa, Arizona

28 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 with a principle place of business in the State of California.

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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 DANIELLE COOK, a resident of Arizona but a machine sold and distributed under the laws of Delaware by a corporation with its principle place of business in the State of California. The amount in controversy exceeds \$75,000 exclusive of costs and interest.

GENERAL ALLEGATIONS

5. Plaintiff DANIELLE COOK, was advised that she needed to have a hysterectomy performed.

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

7. Based on the representations made by her physicians and the written materials provided to her, the Plaintiff agreed to proceed with da Vinci robotic hysterectomy. Plaintiff DANIELLE COOK underwent surgery on December 17, 2010 which resulted in damage, including significant post-operative intra-abdominal bleeding, thermal burning, severe infection with intra-abdominal abscesses, and septic shock.

8. DANIELLE COOK continues to suffer from chronic abdominal pain and severe bowel issues. Through this time period DANIELLE COOK has been unable to maintain normal intimate relationships with EVAN COOK and has suffered emotional distress.

9. Due to the injuries sustained during the da Vinci Robotic hysterectomy, Plaintiff DANIELLE COOK had to have multiple painful additional medical tests and procedures and physician consultations and additional surgery and has suffered pain, loss of function, emotional distress, and permanent injury. Plaintiff EVAN COOK has suffered loss of Consortium.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

4 33. The da Vinci surgical robot is defective in that it relies upon the use of
5 monopolar energy to cut, burn and cauterize tissue, whereas safer methods are available such as
6 bipolar energy and ultrasonic energy, which would reduce substantially the risk of
7 complications.

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

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

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

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

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

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

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

1 **FIRST CAUSE OF ACTION- PRODUCT LIABILITY**

2 41. Plaintiff incorporates by reference each and every paragraph of this Complaint as
3 though set forth in full in this cause of action.

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

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

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

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

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

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

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

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

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

26 f. designing, manufacturing, marketing, advertising, distributing and promoting the
27 da Vinci Robotic Hysterectomy directly to consumers, including Plaintiff, without adequate
28 warning of the significant and dangerous risks of monopolar current and the da Vinci Robotic

1 Hysterectomy Platform and without proper instructions to avoid the harm which could foresee
2 ably occur as a result of using monopolar energy on the existing da Vinci Robotic Hysterectomy
3 platform;

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

6 h. negligently continuing to manufacture, market, advertise, and promote da Vinci
7 Robotic Hysterectomy after Defendant knew or should have known of the risks of serious injury
8 and/or death associated with using monopolar current to perform certain aspects of the surgery;

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

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

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

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

1 m. failing to completely, accurately and in a timely fashion, disclose the results of
2 the pre-marketing testing of issues with monopolar energy and post-marketing surveillance of
3 monopolar energy related injuries and complications to Plaintiff, consumers, the medical
4 community, and the FDA;

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

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

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

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

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

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

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

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

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

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

1 x. being otherwise reckless, careless and/or negligent.

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

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

6 48. At the time the device left the possession of Defendant it was in an unreasonably
7 dangerous and defective condition for application for robotic hysterectomy using monopolar
8 energy.

9 49. Despite the fact that Defendant knew or should have known that the da Vinci
10 Robotic Hysterectomy platform using monopolar current had increased the risk of serious injury
11 and/or death, Defendant continued to promote and market the da Vinci Robotic Hysterectomy to
12 consumers, including Plaintiff Danielle Cook, when safer and more effective methods of
13 treatment were available.

14 50. The Defendant designed, tested, manufactured, packaged, marketed distributed,
15 promoted, and sold the da Vinci Robot, placing the da Vinci Robotic Hysterectomy into the
16 stream of commerce.

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

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

24 53. Plaintiff's surgeon used the da Vinci Robotic Hysterectomy platform including
25 monopolar current as instructed by and certified by and in the foreseeable manner normally
26 intended, recommended, promoted, and marketed by Defendant. Plaintiff's surgeons, attended a
27 surgical lab for hands-on initial training and were proctored for by a proctor employed by
28 INTUITIVE SURGICAL.

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

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

9 56. The da Vinci Robotic Hysterectomy platform was unreasonably dangerous in
10 that, as designed, it was dangerous to an extent beyond that contemplated by the medical
11 community, and ordinary regulars, including the Plaintiff Danielle Cook.

12 57. The da Vinci Surgical Robot was defective in its design in that it neither bore,
13 nor was packaged with, nor accompanied by, warnings adequate to alert the medical
14 community, including Plaintiff's surgeon, to the risks described herein, including, but not
15 limited to, the risk of serious injury and/or death, including bowel, bladder, ureteral, vaginal cuff
16 de-vascularization, or vascular injury, posed by its monopolar current risks. The da Vinci Robot
17 was not accompanied by adequate labeling, instructions for use and/or warnings to fully apprise
18 the medical, hospital, operating room and/or scientific communities, and potential patients,
19 including Plaintiff, of the potential risks and serious side effects associated with its use, thereby
20 rendering Defendant liable to the Plaintiff.

21 58. There were safer alternative energy modalities available including bipolar energy
22 and ultrasonic energy.

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

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

1 have concluded that the da Vinci Robotic Hysterectomy platform should not have been
2 marketed in that condition.

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

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

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

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

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

25 66. That by reason of the foregoing and Defendant's aforesaid conduct, among other
26 things, the Plaintiff DANIELLE COOK suffered injuries which caused her to undergo
27 additional surgeries and medical procedures, endured pain and suffering and will continue to do
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1 so in the future, has suffered mental anguish and will continue to do so in the future, has loss the
2 pleasure of sexual activity, and has incurred medical expenses.

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

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

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

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

15 **SECOND CAUSE OF ACTION- GENERAL NEGLIGENCE &**
16 **NEGLIGENT TRAINING & PROCTORING & NEGLIGENT CERTIFICATION**

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

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

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

26 73. Defendant took it upon itself to "train" and "certify" Plaintiff's surgeon on the use
27 of the da Vinci Robotic Hysterectomy platform using monopolar current. Upon belief the
28 Defendant specifically trained Plaintiff's surgeon on the use of monopolar current via operative

1 endo-shear scissors during the dissection of the bladder and the colpotomy incision causing
2 thermal injury and devascularization of the vaginal cuff leading to increased tissue damage,
3 abscesses, and chronic inflammatory changes.

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

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

10 **THIRD CAUSE OF ACTION- FRAUD**

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

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

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

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

23 80. Defendant was aware, or should have been aware, of the known dangers of
24 monopolar current in regard to capacitive coupling, which like insulation failure can cause a
25 thermal injury to occur in adjacent structures like bowel, bladder, ureter, vaginal cuff, or blood
26 vessel. Defendant was aware, or should have been aware, of the known increased incidence of
27 vaginal cuff dehiscence, de-vascularization and abscess formation due to the use of monopolar
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1 current while performing the colpotomy portion of the da Vinci Robotic total laparoscopic
2 hysterectomy.

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

7 82. Defendant was also aware, or should have been aware, of the Active Electrode
8 Monitoring System, or AEM Technology, which shields and monitors instruments continuously
9 directing stray energy, the cause of stray electrosurgical burns, away from the patient. With the
10 AEM system, the patient is never at risk for stray electrosurgical burns due to insulation failure
11 and capacitive coupling. Despite having specific knowledge of this safety system the Defendant
12 chose not to purchase it for the da Vinci Robotic Hysterectomy platform using monopolar
13 current.

14 83. Further, Defendant concealed from consumers and users, including those
15 mentioned in the preceding paragraphs, the risks of complications of which it was aware, which
16 would have been material to consumers and users in making the decision to use the said device.

17 84. Further, Defendant suppressed reports of adverse outcomes with the use of its
18 device, which would have been material to consumers and users in making the Decision to use
19 the said device.

20 85. Further, Defendant over-promoted its device and minimized its risks, for the
21 purpose of making sales of its device, its maintenance, and the use of replaceable parts, and
22 skewed the cost-benefit ratio inaccurately in its favor.

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

25 **FOURTH CAUSE OF ACTION- FRAUDULENT CONCEALMENT**

26 87. Plaintiff hereby incorporates by reference all previous paragraphs of this
27 Complaint as if fully set forth herein and further alleges as follows:
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1 88. Defendant Intuitive Surgical had the duty and obligation to disclose to Plaintiff
2 and to her physicians, the true facts concerning the da Vinci Robotic Hysterectomy platform,
3 that is, that the da Vinci Robot was dangerous and defective, and likely to cause serious health
4 consequences to users, including injuries as described in this Complaint.

5 89. Defendant INTUITIVE SURGICAL concealed important facts from Plaintiff and
6 from Plaintiff's physicians which facts include, but are not limited to, that Defendant Intuitive
7 Surgical had received numerous adverse events reports of serious injuries and/or death,
8 including burns, tears, dehiscences, bleeding, hematomas, sepsis and fistulas prior to Plaintiff's
9 surgery in December 2010.

10 90. Defendant INTUITIVE SURGICAL made affirmative representations to Plaintiff
11 and her physicians that the da Vinci Robotic Hysterectomy platform was safe as set forth above
12 while concealing the material facts set forth herein.

13 91. Defendant INTUITIVE SURGICAL had the duty and obligation to disclose to
14 Plaintiff and to her physicians the true facts concerning the da Vinci Robotic Hysterectomy
15 platform, which facts include, but are not limited to, serious injuries and/or death including
16 burns, tears, dehiscences, bleeding, hematomas, sepsis and fistulas prior to Plaintiff's surgery in
17 December 2010.

18 92. Defendant INTUITIVE SURGICAL intentionally, willfully, and maliciously
19 concealed or suppressed the facts set forth above from Plaintiff's physicians, and therefore from
20 Plaintiff, with the intent to defraud as alleged herein.

21 93. Neither Plaintiff nor her physicians were aware of the concealed facts set forth
22 herein. Had they been aware of those facts, they would not have acted as they did, that is, that
23 the da Vinci Robotic Hysterectomy platform would not have been the chosen surgical modality
24 of Plaintiff and her physicians.

25 94. Had Plaintiff been informed of the numerous adverse events including serious
26 injuries including burns, tears, dehiscences, bleeding, hematomas, sepsis and fistulas associated
27 with the da Vinci Robotic Hysterectomy platform, Plaintiff would have opted for a different
28 surgical procedure.

1 95. As a proximate result of the concealment or suppression of the facts set forth
2 above, Plaintiff and her physicians' reasonably relied on Defendant INTUITIVE SURGICAL's
3 deception and, Plaintiff underwent surgery utilizing the da Vinci Robotic Hysterectomy
4 platform and subsequently sustained injuries and damages as set forth in this Complaint.
5 Defendant INTUITIVE SURGICAL's concealment was a substantial factor in causing
6 Plaintiff's injuries.

7 96. In doing the acts herein alleged, Defendant INTUITIVE SURGICAL acted with
8 oppression, fraud, and malice and Plaintiff is entitled to punitive damages in an amount
9 reasonably related to Plaintiff's actual damages, and to Defendant INTUITIVE SURGICAL's
10 wealth, and sufficiently large to be an example to others, and to deter Defendant INTUITIVE
11 SURGICAL and others from engaging in similar conduct in the future.

12 **FIFTH CAUSE OF ACTION- BREACH OF EXPRESS WARRANTY**

13 97. Plaintiff repeats, reiterates and re-alleges each and every allegation and cause of
14 action set forth herein as if the same were set forth more fully at length herein.

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

22 99. Defendant breached expressed warranties with respect to the da Vinci robotic
23 hysterectomy in the following ways:

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

1 b. Defendant represented that the da Vinci Robotic Hysterectomy was as safe
2 and/or safer than alternative surgical methods, and fraudulently concealed information which
3 demonstrated that the da Vinci robotic hysterectomy approach was not safer than alternatives
4 available on the market; and,

5 c. Defendant represented that the da Vinci Robotic Hysterectomy was more
6 efficacious than other alternative surgical methods, and fraudulently concealed information that
7 it was not more efficacious than alternative surgical methods.

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

11 101. The da Vinci Robotic Hysterectomy platform including the use of monopolar
12 current did not perform as safely as an ordinary physician, as an agent of the patient, would have
13 expected when used as intended or in a reasonably foreseeable manner.

14 102. Plaintiff DANIELLE COOK, her surgeons and other in the medical community,
15 relied upon Defendant's express warranties, resulting in the Plaintiff's da Vinci Robotic
16 Hysterectomy.

17 103. Plaintiff, after ascertaining through her own injuries that the da Vinci Robotic
18 Hysterectomy violated express warranties, hereby supply notice to Defendant INTUITIVE
19 SURGICAL INC. of same through the filing of this lawsuit.

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

23 105. By selling the said device, Defendant made implied warranties of safety,
24 merchantable quality, and fitness for use, which was breached when Plaintiff DANIELLE
25 COOK was injured during surgery.

26 106. As a further direct and proximate result of the acts of Defendant, Plaintiff's
27 suffered emotional distress.

28 **WHEREFORE**, Plaintiffs demand judgment against Defendant and seeks compensatory

1 damages, and exemplary and punitive damages together with interest, the costs of suit and
2 attorneys' fees and such other and further relief as this Court deems just and proper.

3 **SIXTH CAUSE OF ACTION- BREACH OF IMPLIED WARRANTY**

4 107. Plaintiff incorporates by reference each and every paragraph of this Complaint as
5 though set forth in full in this cause of action.

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

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

11 110. Defendant breached various implied warranties with respect to the da Vinci
12 Robot including the particulars:

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

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

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

25 111. In reliance upon Defendant's implied warranty, Plaintiffs surgeon used the da
26 Vinci Robotic Hysterectomy platform as prescribed and in the foreseeable manner normally
27 intended, recommended, promoted, instructed, and marketed by Defendant.

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

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

8 114. As a further direct and proximate result of the acts of Defendant, Plaintiffs
9 suffered emotional distress and loss of consortium.

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

13 **SEVENTH CAUSE OF ACTION- UNJUST ENRICHMENT**

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

16 116. At all times relevant to this action, Defendant designed, advertised, marketed,
17 promote, manufactured, distributed, supplied, and/or sold the da Vinci Robot for hysterectomy
18 use.

19 117. Plaintiff DANIELLE COOK's surgeon's hospital purchased the da Vinci Robot
20 from the Defendant for the purpose of using it for Robotic Hysterectomy. Same hospital
21 purchased disposable and reusable instrument for the performing of DANIELLE COOK'S
22 surgery.

23 118. Defendant has accepted payment from said aforementioned hospital for both the
24 da Vinci robot used in DANIELLE COOK'S surgery, but also for the routine maintenance and
25 per surgery cost of additional items including disposable items.

26 119. DANIELLE COOK did not receive the safe and effective surgical product which
27 she intended to purchase; nor did the hospital where DANIELLE COOK had her surgery.
28

1 120. It is inequitable and unjust for Defendant to retain this money because the
2 Plaintiff did not in fact receive the safe and efficacious surgical procedure Defendant
3 represented da Vinci Robotic Hysterectomy to be.

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

7 **EIGHTH CAUSE OF ACTION-LOSS OF CONSORTIUM**

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

10 122. As a direct consequence of the injuries to the abdomen and subsequent abscess
11 and chronic inflammation and scarring sustained by DANIELLE COOK while undergoing a da
12 Vinci Robotic Hysterectomy, and the pelvic pain, formation of intra-abdominal abscesses, septic
13 shock, pain with intercourse, permanent scarring, and the emotional consequences; Plaintiff
14 EVAN COOK has been deprived the normal companionship, company, affection, regard,
15 assistance, comfort, sexual relations, and emotional stability from his wife DANIELLE COOK.

16 123. These physical and emotional consequences of the injuries have negatively
17 impacted the quality and caused undue hardship to the marriage relationship.

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

21 **DEMAND FOR JURY TRIAL**

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

23 **GLOBAL PRAYER FOR RELIEF**

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

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

28 2. On the Second Cause of Action for Negligence, the sum of \$10 million;

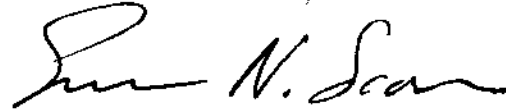
- 1 3. On the Third Cause of Action for Fraud, the sum of \$10 million;
2 4. On the Fourth Cause of Action for Fraudulent Concealment, the sum of \$10
3 million;
4 5. On the Fifth & Sixth Cause of Action for Breach Of Express Warranty and
5 Breach of Implied Warranty, the sum of \$10 million;
6 6. On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

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

13 Dated: San Francisco, California

14 December 14, 2012

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