

Assigned for all purposes to: Spring Street Courthouse, Judicial Officer: Georgina Rizk

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8 **SUPERIOR COURT OF CALIFORNIA**

9 **COUNTY OF LOS ANGELES**

10 DAVID BAKOS,

11 Plaintiff,

12 v.

13 JOHNSON & JOHNSON, a New Jersey
14 Corporation; ETHICON, INC., a New Jersey
15 Corporation; ETHICON ENDO-SURGERY,
16 INC., an Ohio Corporation; JAMIE WELLS;
17 MAGGIE COX; JASON CLARKE; ISAAC
18 WOJCIK; ANNIE HENSON; and DOES 1
through 20 inclusive,

19 Defendants.

12 Case No.

13 **COMPLAINT FOR:**

14 **(1) PRODUCTS LIABILITY
(2) NEGLIGENCE
(3) INTENTIONAL
15 MISREPRESENTATION
(4) NEGLIGENT MISREPRESENTATION**

16 **JURY TRIAL DEMANDED**

21 Plaintiff DAVID BAKOS ("Plaintiff") alleges on information and belief against JOHNSON
22 & JOHNSON, ETHICON, INC., ETHICON ENDO-SURGERY, INC., JAMIE WELLS, MAGGIE
23 COX, JASON CLARKE, ISAAC WOJCIK, ANNIE HENSON, and DOES 1 through 20, inclusive
24 ("Defendants"), the following.

25 **INTRODUCTION AND SUMMARY OF ACTION**

26 1. Johnson & Johnson, Ethicon, Inc., Ethicon Endo-Surgery, Inc., Jamie Wells, Maggie
27 Cox, Jason Clarke, Isaac Wojcik, and Annie Henson (collectively hereafter "Defendants") are in the
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1 business of manufacturing and selling medical devices including curved intraluminal staplers,
2 which are medical devices used in invasive medical procedures within the human body. In or about
3 March 2018, a shift occurred in the manufacturing process for the CDH21A, CDH25A, CDH29A,
4 CDH33A, ECS21A, ECS25A, ECS29A, and ECS33A curved intraluminal staplers (or "staplers").
5 This shift, identified by Defendants in the U.S. Food & Drug Administration's ("FDA") May 16,
6 2019 recall notice, took place from March 6, 2018 until March 6, 2019. The shift rendered all of
7 these products defective and unsafe for use in patients.

8 2. The staplers were defective when used in patient procedures because, according to
9 the May 16, 2019 FDA recall notice, insufficient firing of the staplers will occur causing
10 malformed staples to eject and uncut washers, compromising staple integrity; and when used on
11 patients, leads to serious injuries or death. Possible injuries identified by the recall notice include
12 sepsis, bleeding, the need for an ostomy bag, lifelong nutritional and digestive problems,
13 anastomotic leaks, additional surgeries, need for additional closures (anastomoses), need for
14 antibiotics, and need for additional imaging studies.

15 3. Defendants never warned medical service providers or end users of a manufacturing
16 defect with its staplers until a recall notice issued. No warning was given to the public until the
17 May 16, 2019 FDA recall notice. Over 92,000 curved intraluminal staplers were affected by the
18 recall in the U.S. alone.

19 4. Any patient who underwent a medical procedure with one of the affected curved
20 intraluminal staplers manufactured by Defendants from March 6, 2018 to March 6, 2019 were
21 exposed to a serious risk of death or severe injuries. The staplers are used in the gastrointestinal
22 tract for creating connections between structures (anastomoses) in surgical procedures. Patients
23 with colorectal cancer and bariatric patients commonly undergo surgical procedures using the
24 affected staplers.

25 5. One of the defective curved intraluminal staplers manufactured by Defendants
26 (identified in paragraph 1) was used on Plaintiff David Bakos on April 9, 2019 at USC Norris
27 Comprehensive Cancer Center and Hospital (hereafter "USC Hospital") in Los Angeles, California

1 when he underwent surgery requiring the use of staples for closure, or anastomosis, after a surgical
2 procedure.

3 **PARTIES**

4 6. Plaintiff David Bakos is a citizen of the State of California and resides in Ventura
5 County.

6 7. Defendant Johnson & Johnson is the parent corporation of the Johnson & Johnson
7 family of companies, organized and existing under the laws of the State of New Jersey. Johnson &
8 Johnson's principal place of business is at 1 Johnson and Johnson Plaza, New Brunswick, New
9 Jersey. At all times relevant to this action, Johnson & Johnson has conducted substantial business
10 in California and regularly caused its products to be sold in California, including to USC Hospital
11 in Los Angeles, California. Plaintiff's causes of action also arise out of specific conduct occurring
12 in the County of Los Angeles, State of California. Therefore, personal jurisdiction is proper under
13 California Code of Civil Procedure § 410.10 and the Due Process Clauses of the Fifth and
14 Fourteenth Amendments to the Constitution of the United States of America.

15 8. Defendant Ethicon, Inc. (hereafter "Ethicon") is a subsidiary of Johnson & Johnson,
16 a corporation organized and existing under the laws of the State of New Jersey. Ethicon's principal
17 place of business is at Highway 22, Somerville, New Jersey. Among its business activities, Ethicon
18 is involved in the manufacture, distribution, sales, marketing, regulatory management, and services
19 related to Ethicon medical products in the United States, and in California where it maintains a
20 large sales operation selling Ethicon products all over the State of California, including the specific
21 curved intraluminal stapler involved in the subject incident. At all times relevant to this action,
22 Ethicon has conducted substantial business in California. Plaintiff's causes of action arise out of a
23 specific conduct committed in the County of Los Angeles, State of California. Therefore, personal
24 jurisdiction is proper under California Code of Civil Procedure § 410.10 and the Due Process
25 Clauses of the Fifth and Fourteenth Amendments to the Constitution of the United States of
26 America.

27 9. Defendant Ethicon Endo-Surgery, Inc. ("Ethicon Endo-Surgery") is a corporation
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1 organized and existing under the laws of the State of Ohio. Ethicon Endo-Surgery's principal place
2 of business is at 4545 Creek Road, Blue Ash, Ohio. Among its business activities, Ethicon Endo-
3 Surgery is involved in the manufacture, distribution, sales, marketing, regulatory management, and
4 services related to Ethicon medical products in the United States, and in California where it
5 maintains a large sales operation selling Ethicon products all over the State of California, including
6 the specific curved intraluminal stapler involved in the subject incident. At all times relevant to this
7 action, Ethicon Endo-Surgery has conducted substantial business in California. Plaintiff's causes of
8 action arise out of a specific conduct committed in the County of Los Angeles, State of California.
9 Therefore, personal jurisdiction is proper under California Code of Civil Procedure § 410.10 and
10 the Due Process Clauses of the Fifth and Fourteenth Amendments to the Constitution of the United
11 States of America.

12 10. Defendant Jamie Wells is an individual who, at all times herein relevant, is a sales
13 representative for Defendants for the greater Los Angeles Area. Defendant Jamie Wells is a citizen
14 of and resides in California. Defendant Jamie Wells is associated with Johnson & Johnson, Ethicon,
15 and Ethicon Endo-Surgery. All Defendants jointly maintain offices throughout the State of
16 California and specifically within the greater Los Angeles area for the purpose of marketing,
17 selling, and distributing their products to users in Southern California. Plaintiff is informed and
18 believes, and thereon alleges, Defendant Jamie Wells engages in the sales, marketing, and
19 distribution of Ethicon staplers, including the specific stapler involved in the subject incident.

20 11. Defendant Maggie Cox is an individual who, at all times herein relevant, is a sales
21 representative for Defendants for the greater Los Angeles Area. Defendant Maggie Cox is a citizen
22 of and resides in California. Defendant Maggie Cox is associated with Johnson & Johnson,
23 Ethicon, and Ethicon Endo-Surgery. All Defendants jointly maintain offices throughout the State of
24 California and specifically within the greater Los Angeles area for the purpose of marketing,
25 selling, and distributing their products to users in Southern California. Plaintiff is informed and
26 believes, and thereon alleges, Defendant Maggie Cox engages in the sales, marketing, and
27 distribution of Ethicon staplers, including the specific stapler involved in the subject incident.

1 12. Defendant Jason Clarke is an individual who, at all times herein relevant, is a sales
2 representative for Defendants for the greater Los Angeles Area. Defendant Jason Clarke is a citizen
3 of and resides in California. Defendant Jason Clarke is associated with Johnson & Johnson,
4 Ethicon, and Ethicon Endo-Surgery. All Defendants jointly maintain offices throughout the State of
5 California and specifically within the greater Los Angeles area for the purpose of marketing,
6 selling, and distributing their products to users in Southern California. Plaintiff is informed and
7 believes, and thereon alleges, Defendant Jason Clarke engages in the sales, marketing, and
8 distribution of Ethicon staplers, including the specific stapler involved in the subject incident.

9 13. Defendant Isaac Wojcik is an individual who, at all times herein relevant, is a sales
10 representative for Defendants for the greater Los Angeles Area. Defendant Isaac Wojcik is a citizen
11 of and resides in California. Defendant Isaac Wojcik is associated with Johnson & Johnson,
12 Ethicon, and Ethicon Endo-Surgery. All Defendants jointly maintain offices throughout the State of
13 California and specifically within the greater Los Angeles area for the purpose of marketing,
14 selling, and distributing their products to users in Southern California. Plaintiff is informed and
15 believes, and thereon alleges, Defendant Isaac Wojcik engages in the sales, marketing, and
16 distribution of Ethicon staplers, including the specific stapler involved in the subject incident.

17 14. Defendant Annie Henson is an individual who, at all times herein relevant, is a sales
18 representative for Defendants for the greater Los Angeles Area. Defendant Annie Henson is a
19 citizen of and resides in California. Defendant Annie Henson is associated with Johnson &
20 Johnson, Ethicon, and Ethicon Endo-Surgery. All Defendants jointly maintain offices throughout
21 the State of California and specifically within the greater Los Angeles area for the purpose of
22 marketing, selling, and distributing their products to users in Southern California. Plaintiff is
23 informed and believes, and thereon alleges, Defendant Annie Henson engages in the sales,
24 marketing, and distribution of Ethicon staplers, including the specific stapler involved in the subject
25 incident.

26 15. Defendants jointly designed, developed, manufactured, tested, inspected, assembled,
27 advertised, promoted, marketed, sold and/or distributed the defective curved intraluminal staplers
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throughout the United States.

16. Defendants Jamie Wells, Maggie Cox, Jason Clarke, Isaac Wojcik, and Annie Henson are employees, agents, joint-venturers, and/or representatives of Johnson & Johnson, Ethicon, and Ethicon Endo-Surgery in the advertisement, promotion, marketing, sales, and/or distribution of the curved intraluminal staplers in the State of California, and specifically in the greater Los Angeles area.

17. The true names and capacities of Does 1 through 20 are unknown to Plaintiff. Plaintiff is informed and believe and thereon allege that each of these Defendants are in some way liable for the events referred to in this Complaint and caused damage to Plaintiff. Plaintiff will amend this Complaint and insert the correct names and capacities of those Defendants when they are discovered.

18. At all times mentioned, each Defendant, including DOES 1 through 20, was the representative, agent, employee, joint venturer, or alter ego of each of the other defendants and in doing the things alleged herein was acting within the scope of its authority as such.

19. Johnson & Johnson, Ethicon, Ethicon Endo-Surgery, Jamie Wells, Maggie Cox, Jason Clarke, Isaac Wojcik, Annie Henson, and DOES 1 through 20 are collectively referred to herein as "Defendants."

GENERAL ALLEGATIONS

20. Defendants design, manufacture, and sell curved intraluminal staplers to be used by medical service providers in surgical procedures to enable surgeons to create a secure anastomosis (connection between two internal bodily structures) within the body.

21. Defendants designed, manufactured, and sold defective curved intraluminal staplers with the following product numbers: CDH21A, CDH25A, CDH29A, CDH33A, ECS21A, ECS25A, ECS29A, and ECS33A. Each stapler manufactured between March 6, 2018 and March 6, 2019 with these product numbers suffers from a manufacturing defect compromising staple integrity and can lead to serious injury or death when used by a surgeon as instructed in the device user manual.

1 22. On April 9, 2019, Plaintiff David Bakos' surgeon used one of the defective Ethicon
2 curved intraluminal staplers (identified in paragraphs 1 and 21) as intended by Defendants on the
3 Plaintiff to create an anastomosis following a procedure. The stapler caused severe injuries to
4 Plaintiff when it failed to create a proper anastomosis because of the ejection of a malformed staple
5 or uncut washer. Immediately following the procedure, Plaintiff suffered from unexpected
6 abdominal pain and fevers. It was soon discovered that there was a leak from the colorectal
7 anastomosis requiring corrective surgery.

8 23. Medical device manufacturers like Defendants must establish and follow quality
9 systems to help ensure that their products are manufactured as intended for use and can safely be
10 used in patient surgical procedures. The quality systems for FDA-regulated products, including
11 medical devices, are known as current good manufacturing practices ("CGMP's"). CGMP
12 requirements for medical device manufacturers are found in 21 C.F.R. sec. 820. The CGMP
13 requirements specify the framework that Defendants should have followed when developing and
14 manufacturing its curved intraluminal staplers. On information and belief, Defendants failed to
15 establish quality systems and CGMP's to ensure that its curved intraluminal staplers would not
16 feature any manufacturing defects and expose patients to risks of serious injury or death when the
17 device is used as intended by the surgeon. And as a result of its failure to establish and maintain
18 effective quality systems and CGMP's to ensure defect-free products, Plaintiff suffered severe
19 injuries.

20 24. Defendants failed to ensure that its curved intraluminal staplers manufactured
21 between March 6, 2018 and March 6, 2019 and sold in the U.S. were free of any manufacturing
22 defects. Defendants failed to exercise good judgment when establishing quality systems designed to
23 ensure safe medical device manufacturing in its facilities and sold staplers to medical providers in
24 the U.S. for at least an entire year before the FDA issued a mandatory recall of the affected lots of
25 staplers.

26 25. On information and belief, Defendants failed to establish and maintain a complaint
27 file and tracking system for the defective staplers to evaluate and review complaints it received
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1 from end users as required by 21 C.F.R. sec. 820.198. 21 C.F.R. sec. 820.198 requires a medical
2 device manufacturer like Defendants to receive, review, and evaluate or investigate complaints
3 received by end users for the purpose of timely identifying any problems with one of its devices
4 and either filing a Medical Device Report, publishing a safety letter, or taking other corrective
5 actions to ensure patient safety. As a result of its failure to establish and maintain a complaint unit
6 designed to ensure patient safety, Defendants allowed the defective staplers to remain on the
7 market causing severe injuries to Plaintiff.

8 26. The FDA regulates medical devices using a classification system (Class I, Class II,
9 and Class III) and puts a device into one of three categories; and each category carries different
10 disclosure and premarket review requirements based on the magnitude of potential risk of the
11 device. Curved intraluminal staplers, like the one used on Plaintiff, are Class I medical devices.
12 This means that the device was not subject to any premarket review by the FDA. As recently as
13 May 30, 2019, the FDA convened a discussion panel on the reclassification of surgical staplers for
14 internal use, including the subject defective staplers. Over the years, the devices have become much
15 more complex and have been associated with numerous reported cases of severe injuries and death.

16 27. Defendants have long known of the risks of serious injury and death associated with
17 its surgical staplers like the one used on Plaintiff. Between January 2011-March 2018, over 41,000
18 adverse events were reported with these devices—including over 360 deaths. One of the most
19 commonly reported problems with these devices is staple malformation—precisely the problem
20 with the stapler used on Plaintiff. The FDA's Draft Guidance for manufacturers of surgical staplers,
21 published on April 24, 2019, identified device malfunction as a primary root cause of the thousands
22 of patient events over the years associated with staplers—problems that the FDA believes could
23 have been prevented or mitigated by adequately warning end users or patients of the risks in the
24 directions for use in the labeling of the staplers.

25 28. On information and belief, due to the sheer volume of complaints and Medical
26 Device Reports associated with surgical staplers in 2018 and 2019 (in 2018 alone there were nearly
27 2,000 reported injuries), Defendants failure to establish effective complaint reporting and
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1 investigation units allowed a serious manufacturing defect to go unreported for over a year after the
2 defective lots of curved intraluminal staplers were released to the U.S. public.

3 29. During March 2018 and March 2019, Defendants intentionally or negligently failed
4 to warn users of a manufacturing defect with its curved intraluminal staplers. No warning was
5 issued to end users or patients before the FDA recall notice on May 16, 2019.

6 30. Despite the harm that can result from malformed staples or uncut washers,
7 Defendants negligently, recklessly, and with conscious disregard of the extreme risks to the public
8 of serious infection, pain, suffering, and death, aggressively marketed its curved intraluminal
9 staplers to medical service providers across the United States and in California, including USC
10 Hospital, claiming that the product was a safe and effective device.

11 31. Defendants knew that end users of its defective curved intraluminal staplers relied
12 on the manufacturer to provide timely warnings of any dangers associated with its product.
13 Defendants intended and expected the staplers to be used invasively by medical service providers.
14 Defendants sold the defective stapler used on Plaintiff David Bakos to USC Hospital with that
15 intention and expectation.

16 32. Defendants knew that end users of its defective curved intraluminal staplers relied
17 on the manufacturer to establish effective quality systems and CGMP's that could prevent a
18 manufacturing defect like the one present in the stapler used on the Plaintiff. Defendants sold the
19 defective stapler used on Plaintiff David Bakos to USC Hospital with that intention and
20 expectation.

21 33. Defendants represented to end users from March 6, 2018 until the time the subject
22 device was used in the plaintiff's surgical procedure that the device was safe and effective for use.

23 34. As a result of selling a defective stapler to USC Hospital before Plaintiff's April 9,
24 2019 procedure, Plaintiff's surgeon used one of the identified defective staplers causing him severe
25 injuries when the staple failed to make a safe anastomosis.

26 35. Plaintiff's surgeon used the defective stapler as intended and according to the
27 labeling of that device, yet the Plaintiff suffered severe injuries as a result of its use.

1 36. As a direct and proximate result of Defendants' failure to manufacture a stapler free
2 of defects, and of their fraudulent marketing and sale of the device as safe and effective, multiple
3 individuals, including Plaintiff, have suffered extraordinary pain and suffering, incurring both
4 general and special damages to be proven at trial.

FIRST CAUSE OF ACTION

STRICT PRODUCTS LIABILITY MANUFACTURING DEFECT

(Against All Defendants)

37. Plaintiff hereby incorporates by reference all preceding paragraphs of this Complaint as if fully set forth here.

38. Defendants designed, manufactured, inspected, tested, assembled, promoted, distributed, marketed, and sold the defective curved intraluminal stapler used on Plaintiff David Bakos.

39. At all times material hereto, the defective stapler that was designed, manufactured, inspected, tested, assembled, promoted, distributed, marketed, and sold by the Defendants, was expected to reach, and did reach, physicians and consumers, including Plaintiff, without substantial change to the condition in which it was sold.

40. At all times material hereto, the curved intraluminal stapler that was designed, manufactured, inspected, tested, assembled, promoted, distributed, marketed, and sold by the Defendants, contained a manufacturing defect, and did not conform to the Defendants' intended design, when it left the Defendants' possession.

41. The manufacturing defect affected the Ethicon curved intraluminal stapler used on the Plaintiff due to a self-described "shift" in the manufacturing process rendering all identified models different from the Defendants' intended result or from other identical units of the same product line by allowing the ejection of a malformed staple or uncut washer, which compromised staple integrity.

42. The manufacturing defect to the Ethicon curved intraluminal stapler used in Plaintiff's April 9, 2019 surgical procedure at USC Hospital was a substantial factor in producing

Plaintiff's severe injuries when the stapler ejected a malformed staple or uncut washer—failing to provide an effective anastomosis.

43. The Plaintiff's physician used the curved intraluminal stapler as directed for its intended purpose.

44. The curved intraluminal stapler used in Plaintiff's procedure had not been materially altered or modified prior to its use in Plaintiff.

45. As a direct and proximate result of the exposure to the defective Ethicon stapler, Plaintiff suffered injuries and damages as described herein.

SECOND CAUSE OF ACTION

NEGLIGENCE

(Against All Defendants)

46. Plaintiff hereby incorporates by reference all preceding paragraphs of this Complaint as if fully set forth here.

47. Defendants had a duty to exercise reasonable care when they designed, manufactured, inspected, tested, assembled, promoted, distributed, marketed, and sold the curved intraluminal stapler, including a duty to ensure that the stapler did not pose a significantly increased risk of adverse events.

48. Defendants failed to exercise reasonable care when they designed, manufactured, inspected, tested, assembled, promoted, distributed, marketed, and sold the curved intraluminal stapler used in Plaintiff's procedure. The stapler used in Plaintiff's procedure featured a manufacturing defect allowing the ejection of a malformed staple or uncut washer which prevented an effective anastomosis causing injuries during Plaintiff's procedure.

49. Defendants failed to exercise reasonable care in the following particulars:

a. Failure to establish and maintain effective quality systems and CGMP's ensuring a defect-free device;

b. Failure to establish and maintain a complaint reporting and tracking unit that could timely identify and report problems associated with Defendants' devices; and

- c. Failure to timely notify purchasers, end users, and patients of a defect associated with its curved intraluminal staplers.

3 50. Despite having defective quality systems, a defective complaint reporting and
4 tracking unit, and failing to timely notify relevant parties of a defect associated with its staplers,
5 Defendants continued to market those devices as safe and effective for use in patients until the May
6 16, 2019 recall notice.

7 51. In so doing, the Defendants failed to act as a reasonable manufacturer and distributor
8 of surgical staplers.

9 52. As a direct and proximate result of Defendants' negligence, Plaintiff has suffered
10 significant damages, including but not limited to physical injury, economic loss, pain and suffering,
11 and will continue to suffer such damages in the future.

THIRD CAUSE OF ACTION

FRAUD – INTENTIONAL MISREPRESENTATION

(Against All Defendants)

15 53. Plaintiff hereby incorporates by reference all preceding paragraphs of this
16 Complaint as if fully set forth here.

17 54. Defendants owed legal duties to Plaintiff to disclose important material facts
18 concerning the safety of the curved intraluminal stapler used in his procedure.

19 55. Defendants made false representations to Plaintiff and/or Plaintiff's physicians
20 concerning the safety of the curved intraluminal stapler used in his procedure. Specifically,
21 Defendants intentionally, knowingly, or recklessly without regard for the truth, misrepresented that
22 that the Ethicon curved intraluminal stapler used in Plaintiff's procedure was free of any defects,
23 that Defendants were not aware of any defects associated with that device, and that the stapler was
24 a safe and adequate means of performing anastomosis without unexpected complications and
25 injuries. Defendants made those false representations in an effort to mislead consumers into
26 purchasing and continued use of the curved intraluminal stapler and using it for medical
27 procedures, so that Defendants could profit. Through their agents, Defendants directly

1 | communicated these misrepresentations to Plaintiff and/or Plaintiff's physicians who were
2 | Plaintiff's fiduciaries.

3 56. Defendants' sales representatives, specifically Jamie Wells, Maggie Cox, Jason
4 Clarke, Isaac Wojcik, or Annie Henson made the representations described above to physicians and
5 staff at USC Hospital between March 2018 and April 2019.

6 57. At no time prior to the use of Defendants' curved intraluminal stapler in Plaintiff did
7 Defendants acknowledge that the device featured a manufacturing defect rendering it ineffective
8 and unsafe for use in any patient due to the ejection of malformed staples or uncut washers.

9 58. Defendants' representations to Plaintiff and/or Plaintiff's physicians were false
10 because the stapler was ineffective and unsafe for use in any patient due to the manufacturing
11 defect allowing ejection of malformed staples and uncut washers which could not safely render
12 anastomosis.

13 59. Defendants intended medical professionals, including Plaintiff's physicians, and
14 patients to rely on the Defendants' important material representations regarding the safety of the
15 curved intraluminal stapler.

16 60. Plaintiff and Plaintiff's physicians reasonably relied on Defendants'
17 misrepresentations to Plaintiff's detriment. During Plaintiff's procedure, the curved intraluminal
18 stapler ejected a malformed staple or uncut washer causing Plaintiff severe injuries.

19 61. As a direct and proximate result of Plaintiff and Plaintiff's physicians' detrimental
20 reliance on Defendants' false representations, Plaintiff was injured, thereby causing harm and
21 damage to Plaintiff.

FOURTH CAUSE OF ACTION

FRAUD – NEGLIGENT MISREPRESENTATION

(Against All Defendants)

25 62. Plaintiff hereby incorporates by reference all preceding paragraphs of this
26 Complaint as if fully set forth here.

27 63. Defendants owed legal duties to Plaintiff to disclose important material facts

1 concerning the safety of the curved intraluminal stapler used in his procedure.

2 64. Defendants made false representations to Plaintiff and/or Plaintiff's physicians
3 concerning the safety of the curved intraluminal stapler used in his procedure. Specifically,
4 Defendants intentionally, knowingly, or recklessly without regard for the truth, misrepresented that
5 that the Ethicon curved intraluminal stapler used in Plaintiff's procedure was free of any defects,
6 that Defendants were not aware of any defects associated with that device, and that the stapler was
7 a safe and adequate means of performing anastomosis without unexpected complications and
8 injuries. Defendants made those false representations in an effort to mislead consumers into
9 purchasing and continued use of the curved intraluminal stapler and using it for medical
10 procedures, so that Defendants could profit. Through their agents, Defendants directly
11 communicated these misrepresentations to Plaintiff and/or Plaintiff's physicians who were
12 Plaintiff's fiduciaries.

13 65. Defendants' sales representatives, specifically Jamie Wells, Maggie Cox, Jason
14 Clarke, Isaac Wojcik, or Annie Henson made the representations described above to physicians and
15 staff at USC Hospital between March 2018 and April 2019.

16 66. At no time prior to the use of Defendants' curved intraluminal stapler in Plaintiff did
17 Defendants acknowledge that the device featured a manufacturing defect rendering it ineffective
18 and unsafe for use in any patient due to the ejection of malformed staples or uncut washers.

19 67. Defendants' representations to Plaintiff and/or Plaintiff's physicians were false
20 because the stapler was ineffective and unsafe for use in any patient due to the manufacturing
21 defect allowing ejection of malformed staples and uncut washers which could not safely render
22 anastomosis.

23 68. Defendants intended medical professionals, including Plaintiff's physicians, and
24 patients to rely on the Defendants' important material representations regarding the safety of the
25 curved intraluminal stapler.

26 69. Plaintiff and Plaintiff's physicians reasonably relied on Defendants'
27 misrepresentations to Plaintiff's detriment. During Plaintiff's procedure, the curved intraluminal
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1 stapler ejected a malformed staple or uncut washer causing Plaintiff severe injuries.
2 As a direct and proximate result of Plaintiff and Plaintiff's physicians' detrimental reliance on
3 Defendants' false representations, Plaintiff was injured, thereby causing harm and damage to
4 Plaintiff.

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6 **PRAYER FOR RELIEF**

7 THEREFORE, Plaintiff demands judgment for the following:

- 8 1. Past and future medical and incidental expenses, according to proof;
9 2. Past and future loss of earnings and/or earning capacity, according to proof;
10 3. Past and future general damages, according to proof;
11 4. Punitive and exemplary damages in an amount to be determined at trial;
12 5. Prejudgment and post judgment interest;
13 6. Costs to bring this action; and
14 7. Such other and further relief as the court may deem just and proper.

15 DATED: July 9, 2019

16 PANISH SHEA & BOYLE LLP

17 By: _____
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19 Peter L. Kaufman
20 Attorneys for Plaintiff
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5 **DEMAND FOR JURY TRIAL**

6 Plaintiff hereby demands a trial by jury as to all causes of action.
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DATED: July 9, 2019

PANISH SHEA & BOYLE LLP

By: _____


Peter L. Kaufman
Attorneys for Plaintiff