UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF LOUISIANA

BYRONE GOUGISHA, **Plaintiff,** **v.** **JOHNSON & JOHNSON, ETHICON, INC., ETHICON ENDO-SURGERY, INC., and DOES 1 – 20,** **Defendants.**	**Civil Action No.: _____** **COMPLAINT AND JURY TRIAL DEMAND**

COMPLAINT

Plaintiff, BYRONE GOUGISHA, by and through the undersigned counsel, brings this Complaint seeking judgment against Defendants Johnson & Johnson, Ethicon, Inc., Ethicon Endo-Surgery, Inc. and Does 1 – 20 (collectively "Defendants") for personal injuries sustained from Defendants' defective and unreasonably dangerous product, the curved intraluminal staplers (hereinafter sometimes "staplers"). At all relevant times, the curved intraluminal staplers were manufactured, designed, formulated, tested, packaged, labeled, produced, created, made, constructed, assembled, marketed, advertised, promoted, distributed, and/or sold by Defendants.

PARTIES

1. Plaintiff Byrone Gougisha is a citizen of New Orleans, Orleans Parish, Louisiana.

2. Defendant Johnson & Johnson is the parent corporation of the Johnson & Johnson family of companies, organized and existing under the laws of the State of New Jersey. Johnson & Johnson's principal place of business is at 1 Johnson and Johnson Plaza, New Brunswick, New Jersey.

3. Defendant Ethicon, Inc. (hereinafter sometimes "Ethicon") is a subsidiary of Johnson & Johnson, a corporation organized and existing under the laws of the State of New Jersey. Ethicon's principal place of business is at Highway 22, Somerville, New Jersey. Among its business activities, Ethicon is involved in the manufacture, distribution, sales, marketing, regulatory management, and service related to Ethicon medical products in the United States, including the stapler involved in this subject incident.

4. Defendant Ethicon Endo-Surgery, Inc. (hereinafter sometimes "Ethicon Endo-Surgery") is a corporation organized and existing under the laws of the State of Ohio. Ethicon Endo-Surgery's principal place of business is at 4545 Creek Road, Blue Ash, Ohio. Among its business activities, Ethicon Endo-Surgery is involved in the manufacture, distribution, sales, marketing, regulatory management, and services related to Ethicon medical products in the United States, including the stapler involved in the subject incident.

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

6. The true names and capacities of Does 1 – 20 are unknown to Plaintiff. Upon information and belief, Plaintiff alleges 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 these Defendants when they are discovered.

JURISDICTION AND VENUE

7. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1332 because the amount in controversy as to Plaintiff exceeds $75,000.00, exclusive of interest and costs, and because Defendants are citizens of states other than the state in which Plaintiff is a citizen.

8. Personal jurisdiction over Defendants is proper in the United States District Court for the Eastern District of Louisiana because Defendants: (a) conducted business in the state of Louisiana; (b) regularly conducted and solicited business in the state of Louisiana; (c) specifically transacted and conducted business in the state of Louisiana with respect to their curved intraluminal staplers; (d) have substantial and continuing contact with the state of Louisiana; (e) derive substantial revenue from goods used and consumed within the state of Louisiana; (f) purposefully directed their business activities, particularly with respect to their curved intraluminal staplers, to the state of Louisiana; (g) purposely placed their curved intraluminal staplers into the stream of commerce in the state of Louisiana; (h) expected or reasonably should have expected that their curved intraluminal staplers would reach the state of Louisiana and be purchased and used by individuals in the state of Louisiana; (i) anticipated or reasonably should have anticipated that their curved intraluminal staplers would reach the state of Louisiana and be purchased and used by individuals in the state of Louisiana; (j) engaged in a persistent course of conduct in the state of Louisiana with respect to their curved intraluminal staplers; (k) have committed a tort in whole or in part in the state of Louisiana; (l) reasonably expected or should

have expected their acts and omissions to have consequences within the state of Louisiana; and (m) intended to serve the Louisiana market, thereby purposely availing themselves to jurisdiction in the state of Louisiana and submitting to the authority of the state of Louisiana.

9. Plaintiff's claims arise out of Defendants' purposeful contacts and business conducted within the state of Louisiana. Plaintiff was a citizen of New Orleans, Orleans Parish, Louisiana at all relevant times.

FACTUAL ALLEGATIONS

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

11. The staplers are used in the gastrointestinal tract for creating connections between structures (anastomoses) in surgical procedures. Patients with colorectal cancer and bariatric patients commonly undergo surgical procedures using the affected staplers.

12. In or about March 2018, a shift occurred in the manufacturing process for the CDH21A, CDH25A, CDH29A, CDH33A, ECS21A, ECS25A, ECS29A, and ECS33A curved intraluminal staplers.

13. This shift, identified by Defendants in the U.S. Food & Drug Administration's ("FDA") May 16, 2019 recall notice, took place from March 6, 2018 until March 6, 2019. The shift rendered all staplers manufactured by Defendants from March 6, 2018 to March 6, 2019 defective and unsafe for use in patients.

14. The staplers with the following product numbers: CDH21A, CHD25A, CDH29A, CDH33A, ECS21A, ECS25A, ECS29A, and ECS33A were defective when used in patient procedures because, according to the May 16, 2019 FDA recall notice insufficient firing of the

staplers will occur causing malformed staples to eject and uncut washers, compromising staple integrity; and when used on patients, leads to serious injuries or death.

15. Possible injuries identified in the recall notice include sepsis, bleeding, the need for an ostomy bag, lifelong nutritional and digestive problems, anastomotic leaks, additional surgeries, need for additional closures (anastomoses), need for antibiotics, and need for additional imaging studies.

16. Any patient who underwent a medical procedure with one of the affected staplers manufactured by Defendants from March 6, 2018 to March 6, 2019 was exposed to a serious risk of death or severe injuries.

17. Upon information and belief, one of the defective staplers manufactured by Defendants was used on Plaintiff Byrone Gougisha on August 27, 2018 at Ochsner Medical Center – West Bank when he underwent a laparoscopic extended right colectomy.

18. Upon information and belief, the defective stapler caused severe injuries to Plaintiff when it failed to create a proper anastomosis because of the ejection of a malformed staple or uncut washer.

19. After the procedure, it was discovered that Plaintiff suffered from an anastomotic leak requiring additional corrective surgeries.

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

21. During March 2018 and March 2019, Defendants intentionally or negligently failed to warn users of a manufacturing defect with its curved intraluminal staplers.

22. No warning was issued to the public before the FDA recall notice on May 16, 2019.

23. Defendants knew that healthcare providers and patients relied on the manufacturer to provide timely warnings of any dangers associated with its defective curved intraluminal staplers.

24. Defendants intended and expected the staplers to be used invasively by healthcare providers.

25. Defendants knew that healthcare providers and patients relied on the manufacturer to establish effective quality systems and CGMP's that could prevent a manufacturing defect like the one present in the stapler used on the Plaintiff.

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

CAUSES OF ACTION

COUNT I
Unreasonable Dangerous in Construction or Composition Pursuant to La. R.S. 9:2800.55

27. At all times relevant to this action, Defendants had a duty to manufacture, design, formulate, test, package, label, produce, create, make, construct, assemble, market, advertise, promote, distribute, and sell the staplers with reasonable and due care for the safety and wellbeing of its end users.

28. At all times relevant to this action, Defendants' curved intraluminal staplers were expected to reach, and did reach, end users in the State of Louisiana and throughout the United States, including Plaintiff without substantial change in the condition in which it was sold.

29. At the time curved intraluminal staplers left Defendants' possession, the staplers were defective and were in a condition that made them unreasonably dangerous.

30. The manufacturing defect affected the curved intraluminal staplers due to a self-described "shift" in the manufacturing process rendered all identified models different from 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.

31. The curved intraluminal staplers manufactured from March 6, 2018 until March 6, 2019 were not made in accordance with the Defendants' specification or performance standards.

32. At the time the curved intraluminal staplers left Defendants' control, the staplers deviated in a material way from the manufacturer's specifications and/or performance standards.

33. At the time the curved intraluminal staplers left Defendants' control, the staplers deviated in a material way from the otherwise identical products manufactured by Defendants.

34. As a direct and proximate result of Defendant's defective design of the curved intraluminal staplers, Plaintiff was caused to suffer serious and dangerous side effects, including an anastomotic leak and additional corrective surgeries, and has further suffered the injuries and damages as alleged herein.

35. As a direct and proximate result of Defendants' defective design of the staplers, Plaintiff requires and/or will require more healthcare and services and did incur medical, health, incidental and related expenses.

COUNT II
Unreasonably Dangerous in Design
Pursuant to La. R.S. 9:2800.56

36. At all times relevant to this action, Defendants had a duty to manufacture, design, formulate, test, package, label, produce, create, make, construct, assemble, market, advertise, promote, distribute, and sell the staplers with reasonable and due care for the safety and well-being of its end users.

37. At all times relevant to this action, Defendants knew that the curved intraluminal staplers would be used by healthcare providers in invasive medical procedures, including Plaintiff's surgeon.

38. At all times relevant to this action, Plaintiff was a foreseeable end user of curved intraluminal staplers.

39. At the time the curved intraluminal staplers left Defendants' control, the staplers were defective and were in a condition that made them unreasonably dangerous.

40. The curved intraluminal staplers are defective in that the design of curved intraluminal staplers causes them to eject malformed staples or uncut washers.

41. The curved intraluminal staplers are defective because their risks and dangers outweighed any purported benefit.

42. At the time the curved intraluminal staplers left Defendants' control, Defendants knew that the defective condition of the curved intraluminal staplers made them unreasonably dangerous.

43. The curved intraluminal staplers were unreasonably dangerous when used by healthcare providers who used it as it was intended to be used, including Plaintiff's surgeon.

44. Plaintiff could not, by the exercise of reasonable care, have discovered Xarelto's defects herein mentioned and perceived its danger.

45. At the time the stapler used by Plaintiff's surgeon left the Defendants' control, there existed an alternative design for the product that was capable of preventing the Plaintiff's damages, and the gravity of the damage outweighed the minimal burden on Defendant of adopting such an alternative design.

46. As a direct and proximate result of Defendant's defective design of the staplers, Plaintiff was caused to suffer serious and dangerous side effects, including an anastomotic leak and additional corrective surgeries, and has further suffered the injuries and damages as alleged herein.

47. As a direct and proximate result of Defendants' defective design of the curved intraluminal staplers, Plaintiff requires and/or will require more healthcare and services and did incur medical, health, incidental and related expenses.

JURY DEMAND

Plaintiff hereby demands a trial by jury as to all claims in this action.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays as follows:

i. That process issue according to law;

ii. That Defendants be duly served and cited to appear and answer herein, and that after due proceedings are had, that there be judgment in favor of Plaintiff and against Defendants for the damages set forth below, along with court costs, pre-judgment and post-judgment interest at the legal rate;

iii. Pain and suffering (past and future);

iv. Medical expenses (past and future);

v. Loss of enjoyment of life (past and future);

vi. Mental anguish and distress (past and future);

vii. Physical impairment (past and future);

viii. Awarding Plaintiff the taxable costs of these proceedings; and

ix. Awarding Plaintiff such other and further relief as may be just and proper.

Dated this 27th day of August 2019.

Respectfully submitted

/s/ Claire E. Berg

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