IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
SHERMAN DIVISION

LIZZEY ANNETT, an individual	)	
Plaintiff,	)	Case No.
v.	)	
JOHNSON & JOHNSON, a multinational corporation; and ETHICON, INC., a New Jersey corporation,	)	**PLAINTIFF DEMANDS TRIAL BY STRUCK JURY**
Defendants.	)	

COMPLAINT

Plaintiff, Lizzey Annett, by and through the undersigned attorneys, hereby submits the within complaint against the above-named Defendants. In support hereof, Plaintiff states the following:

PARTIES

1. Plaintiff Lizzey Annett is a citizen of the State of Texas, County of Dallas, City of Desoto. Lizzy Annett is referred to herein as "Plaintiff".
2. Defendant Johnson & Johnson ("J&J") is a multinational corporation with its worldwide headquarters located at One Johnson & Johnson Plaza, New Brunswick, New Jersey.
3. Defendant J&J organizes its subsidiary businesses into individual business units to coordinate the development, manufacture, testing, marketing promotion, training, distribution, and sale of its products, including but not limited to its hernia repair mesh products. Within J&J there are three sectors: medical devices and diagnostics, pharmaceutical, and consumer. Within the medical devices and diagnostic sector are

"Business Units" including the "Ethicon Franchise." The Ethicon Franchise was charged by J&J with the design, development, promotion, marketing, testing, training, distribution and sale of the hernia repair mesh products at issue in this case. The Company Group Chairman and Worldwide Franchise Chairman for the Ethicon Franchise, Gary Pruden, is employed by J&J. The companies which comprise the Ethicon Franchise are thus controlled by J&J and include, but are not limited to, Ethicon Inc.

4. Defendant Ethicon, Inc., is a wholly owned subsidiary of Defendant Johnson & Johnson with its corporate headquarters in Somerville, New Jersey. Defendants Johnson & Johnson and Ethicon, Inc., are collectively referred to herein as "Defendants". Further, as described herein, all acts and omissions of Defendants were done by their agents, servants, employees and/or owners while acting in the course and scope of their respective agencies, services, employments and/or ownership.
5. Defendants are individually, jointly, and severally liable to Plaintiff for damages arising from the Defendants' design, manufacture, marketing, labeling, distribution, sale and placement of its defective mesh products at issue here.
6. Defendants are vicariously liable for the acts and/or omissions of its employees and/or agents who were at all times relevant hereto acting on behalf of Defendants and within the scope of their employment or agency with Defendants.

NATURE OF THE ACTION

7. This is an action at law for negligence, strict product liability, and breach of warranty. The action arises out of serious personal injuries sustained by Plaintiff and caused by Defendants' product, Ethicon Physiomesh™ Flexible Composite Mesh (hereinafter referred to as "Physiomesh™" or the "product").

8. Defendants designed, manufactured, packaged, labeled, marketed, sold, distributed, and placed into the stream of commerce Physiomesh™, including the specific line of the product implanted in Plaintiff; to wit, product code nos. "PHY2025V" and "PHY1520V".

JURISDICTION

9. There is complete diversity of citizenship between Plaintiff and Defendants. In addition, the amount in controversy exclusive of interest and costs exceeds $75,000. This Court may therefore exercise subject matter jurisdiction of this action under 28 U.S.C. § 1332.

VENUE

10. Because a substantial portion of the events giving rise to Plaintiff's cause of action accrued in the Eastern District of Texas, venue is proper and maintainable in the Eastern District of Texas under 28 U.S.C. § 1391(b)(2). Specifically, Defendants designed, manufactured, packaged, labeled, marketed, sold, distributed, and placed into the stream of commerce the product(s) at issue within the State of Texas and the Eastern District thereof. Furthermore, the product failed and Plaintiff underwent corrective surgery within the Eastern District of Texas. As such, a substantial portion of the events giving rise to Plaintiff's claims herein accrued within the Eastern District of Texas. Venue is therefore proper under § 1391(b)(2).

FACTUAL ALLEGATIONS

11. Defendants designed, manufactured, packaged, labeled, marketed, sold, distributed, and placed into the stream of commerce medical devices, including Ethicon Physiomesh™ Flexible Composite Mesh. The product at issue here is a hernia repair mesh designed for laparoscopic ventral and inguinal hernia repair ("LVIHR").

12. There is compelling clinical and scientific evidence probative of the assertion that Physiomesh™ is biologically incompatible with human tissue[1], and the risks of the Physiomesh™ design outweigh any potential benefit.[2] This biological incompatibility exists because, *inter alia*, Defendants' design and manufacture of the mesh utilizes polypropylene material. Defendants designed Physiomesh™ with monofilament polypropylene mesh coated with a monocryl (polyglecaprone 25) absorbable barrier layers, one to each side of the polypropylene mesh. An undyed polydioxanone film provides the bond between the polyglecaprone-25 film and polypropylene mesh. Physiomesh™ is thus comprised of inelastic properties, and clinical and scientific data suggests the inelasticity creates the biological incompatibility with human tissue.

13. Defendants designed, manufactured, packaged, labeled, marketed, sold, and distributed Physiomesh™ despite its biological incompatibility with human tissue. In fact, Defendants withdrew the product from the global market in response to the dissemination of unpublished data from two (2) large independent hernia registries in Europe.[3] This data, furthermore, concludes that hernia recurrence and reoperation rates after LVIHR in patients implanted with Physiomesh™ or other similar polypropylene mesh are substantially higher than the average rates of comparator sets of meshes. The reoperation and recurrence rates are higher because, among other things, Physiomesh™ substantially consists of inelastic properties biologically incompatible with human tissue. Both clinical and scientific studies

[1] *See* Pawlak, Maciej., et al., *Comparison of two different concepts of mesh and fixation technique in laparoscopic ventral hernia repair: a randomized controlled trial*. Surg Endosc (2016) 30:1188-1197 (Attached hereto as "Exhibit A").
[2] Baumann, Donald, et al, *Bioprosthetic Mesh in Abdominal Wall Reconstruction*, Semin Plast Surg 2012;26:18-24. (Attached herto as "Exhibit B").
[3] *See* Urgent Field Safety Notice Ethicon Physiomesh™ Flexible Composite Mesh (May 25, 2016) (Attached hereto as "Exhibit C").

have found that the inelastic mesh may break down in its structure and allow the hernia to recur or cause bacterial infections and swelling at the surgical site. Summarily, patients implanted with Physiomesh™ are at a substantially greater risk of needing further surgery due to the product's complications concerning design, manufacture, safety, and efficacy. The foregoing complications include but are not limited to chronic pain, infection, greater risk for hernia recurrence and reoperation, adhesion, intestinal blockage, bowel obstruction, mesh migration, mesh contraction, bleeding, perforation, inadequate or failure of incorporation/ingrowth, scarification, deformation of mesh, improper wound healing, chronic inflammation, erosion, abscess, fistula formation, granulomatous response, seroma formation, nerve damage, and tissue damage.

14. Defendants represented and promoted the multilayer design, alleging it would prevent or minimize adhesion and inflammation and facilitate incorporation of the mesh into the body. Instead, the multi-layer coating prevents adequate incorporation of the mesh into the body and causes or contributes to intense inflammatory and chronic foreign body response; the result is adverse tissue reaction, including migration and damage to surrounding tissue in the form of sclerotic, granulomatous and/or fibrotic tissue and improper healing. Moreover, the impermeable multilayer coating prevents fluid escape and leads to seroma formation, which may cause, *inter alia*, infection and abscess formation. Furthermore, the multilayer coating is a nidus for bacteria—i.e., after implantation, bacteria multiplies and the body's immune response cannot eliminate the same, and, as a result, infection advances.

15. The multilayer coating is cytotoxic, immunogenic, and not biocompatible, causing and/or contributing to complications such as, *inter alia*, delayed wound healing, inflammation, foreign body response, rejection, and infection.

16. Defendants learned of the product's high failure rate through, *inter alia*, the serious adverse events reported to the Food and Drug Administration (FDA). These adverse events were experienced by patients who were implanted with the product shortly after Physiomesh™ was cleared under the 510(k) fast-tracked approval process. Due to clear patient safety issues presented by the adverse events and thereby imputed to Defendants, Defendants knew or should have known Physiomesh™ was defectively designed and/or manufactured, was not reasonably safe for its intended use in hernia repair, and the risks of the design outweighed any potential benefits flowing therefrom. Nonetheless, Defendants continued to manufacture, package, label, market, sell, distribute, and place into the stream of commerce Physiomesh™ Flexible Composite Mesh.
17. Neither Plaintiff nor her implanting physician were adequately warned or informed by Defendants of the patient safety risks associated with Physiomesh™, nor the frequency, severity, or duration of said risks.
18. The FDA's fast-tracked 510(k) clearance process does not require clinical trials for safety and efficacy. Defendants received 510(k) clearance in April 2010. Within the same year of approval, Defendants became aware through adverse event reports that the product presents significant complications concerning design, safety, manufacture, and efficacy. Despite receiving the foregoing adverse event reports, Defendants decided to keep the product within the global market and did not remove Physiomesh™ from the market until the dissemination of unfavorable clinical data from two European hernia registries, *supra*.
19. Defendants were aware of the product's complications concerning design, manufacture, safety, and efficacy after Defendants placed the product into the stream of commerce and before Plaintiff suffered the injuries stated herein, *infra*. But Defendants nonetheless failed

to warn both surgeons and consumers about the product's complications concerning safety and efficacy, including but not limited to the following: chronic pain, infection, greater risk for hernia recurrence and reoperation, adhesion, intestinal blockage, bowel obstruction, mesh migration, mesh contraction, bleeding, perforation, inadequate or failure of incorporation/ingrowth, scarification, deformation of mesh, improper wound healing, chronic inflammation, erosion, abscess, fistula formation, granulomatous response, seroma formation, nerve damage, and tissue damage.

20. On or about July 30 2014, Plaintiff Lizzey Annett underwent incisional hernia repair at Medical City Dallas Hospital ("MCDH"), Dallas, Texas. Medical imaging showed Ms. Annett had developed incisional hernia secondary to her history of abdominal surgery. Dr. Jeffrey Henke MD performed the hernia repair procedure and used a piece of 20 x 25 cm Physiomesh™.

21. Ms. Annett's condition, however, was not remedied by the procedure and mesh placement; she presented for follow up to Dr. Henke, whose examination revealed an enlarging bulge along the area superior to the placement of the Physiomesh™. Medical imaging revealed the presence of recurrent hernia. After discussion, Ms. Annett consented to abdominal hernia repair surgery.

22. On or about February 25, 2015, Ms. Annett underwent recurrent hernia repair; Dr. Henke performed the procedure. During the procedure, Dr. Henke recognized an 8-cm fascial defect and repaired it using a 15 x 20 cm piece of Physiomesh™, product code no. PHY1520V. The dictated operative report states the following:

> [u]pon inspection of the abdominal cavity, I was able to quickly visualized [sic] a large ventral hernia urging [sic] superior to her previous hernia repair with dense small bowel adhesions, so we placed another 5 trocar and began enterolysis, take down the small

> bowel adhesions as it continued to get more dense in the lower abdominal wall to the previous mesh.

23. Unfortunately, Ms. Annett's condition did not improve but steadily worsened after the February 2015 procedure. Due to chronic pain and suspected recurrent hernia, Plaintiff again presented for CT scan, which demonstrated evidence of recurrent incisional hernia.

24. On or about October 19, 2016, Plaintiff again underwent surgery to repair recurrent hernia. This surgery was performed by Dr. Dean Anthony Cione, MD AT Texas Health Presbyterian Hospital of Plano, Plano, TX. Dr. Cione began the procedure robotically but found dense small bowel adhesions to the implanted Physiomesh™; he then performed lysis of adhesions robotically, but was ultimately required to abort the robotic procedure and convert to open laparotomy. The operative note, in pertinent part, states the following:

> Patient had small bowel and omental adhesions with 2 large incisional hernias and 3 smaller incisional hernias superiorly. The 3 smaller ones superiorly had incarcerated omentum. They were slightly enlarged, and then the omentum was reduced. We released small bowel adhesions to the anterior abdominal wall. There were small bowel adhesions into the 2 larger hernias and the hernia sac. These we easily released with sharp Metzenbaum dissection. As we released this, it became evident that the old mesh repair had come apart, and there were 2 loops of small bowel in the upper incisional hernia which were densely adherent to the mesh. We freed as much as we could, and the mesh and the bowel in 2 areas had become one. Just inferior to the lower-most incisional hernia, there was another area of mesh where the bowel in a longer segment had become densely adhesed [sic] to the mesh. It became clear that we were not going to be able to get the small bowel free from the mesh, and so we decided to abort the robotic procedure and perform an exploratory laparotomy.

25. Due to the presence of severe small bowel and omental adhesions, Dr. Cione was unable to remove all of the offending inelastic material. Moreover, a significant amount of operating room time was required to take down the adhesions, and Dr. Cione was also

required to perform two distinct small bowel resections. Dr. Cione dictated, in pertinent part, the following:

> Once we had the 2 larger incisional hernias visualized, open, the upper one had the 2 loops of small bowel side by side, densely adhesed, [sic] one with the mesh. We freed the mesh from the abdominal wall and pulled this up in the wound. There was no way to get the mesh off the small bowel. It would require a small bowel resection of about 10 inches to incorporate both loops […] From the upper incisional hernia, a segment was then excised that was a little farther downstream of the jejunum. Probably 10 inches or so of small bowel was resected here for a total of 16 inches between the 2 resections.

26. Based on Dr. Cione's dictated operative note, it is clear that Physiomesh™ failed to achieve its marketed purpose. Instead, Physiomesh™ caused Plaintiff severe pain and suffering, mental anguish, and economic loss.

27. But for the existence of Physiomesh™ within the global market and Defendants' failure to warn both surgeons and consumers of the medically significant complications surrounding Physiomesh™, Plaintiff would not have elected to be implanted with Defendants' product.

28. As a direct result of being implanted with Physiomesh™, Plaintiff has suffered and will continue to suffer severe and permanent bodily injuries, significant mental and physical pain and suffering, and economic loss.

29. The product at issue here has numerous defects creating unreasonable risks of dangerous injuries, side effects, and severe, permanent adverse health consequences to ordinary persons. These defects include but are not limited to the following:

    a. the material used is not inert and thus promotes a negative reaction to human tissue and/or other natural human bodily contents;

    b. the mesh material harbors infections that adversely affect patient health;

    c. the product and mesh components migrate from the location of implantation;

d. the product and mesh components abrade human tissue;

e. the product and mesh components regularly fail to perform their intended medical purpose, and are associated with an elevated risk of removal and recurrent reparative treatment and/or surgery;

f. the product's defects cause significant complications requiring removal and recurrent reparative treatment and/or surgery;

g. subsequent to implantation, the product and mesh components become embedded in human tissue, the abdominal wall, and organs, such that when the product's complications require removal, the removal then causes significant and potentially irreparable damage to organs and tissues; and

h. the product is defective in shape, composition, weight, physical properties, chemical properties, mechanical properties, and improperly designed and engineered for its ostensible clinical indications.

30. Because of the product's numerous defects, Physiomesh™ creates an unreasonable risk of injury and adverse health consequences to ordinary patients, including but not limited to the following: chronic pain, infection, greater risk for hernia recurrence and reoperation, adhesion, intestinal blockage, bowel obstruction, mesh migration, mesh contraction, bleeding, perforation, inadequate or failure of incorporation/ingrowth, scarification, deformation of mesh, improper wound healing, chronic inflammation, erosion, abscess, fistula formation, granulomatous response, seroma formation, nerve damage, and tissue damage.

31. Before Plaintiff was implanted with the product, Defendants gained actual knowledge of its aforesaid numerous defects, including but not limited to those stated herein.

32. Defendants designed, manufactured, packaged, labeled, marketed, sold, distributed, and placed into the stream of commerce Physiomesh™, with the intent it be implanted in patients such as Plaintiff who were clinically indicated for the product's ostensible benefits.

33. Defendants were aware that implanting the product in clinically indicated patients carried a substantial likelihood of injury and harm. In the alternative, Defendants failed to exercise reasonable care in determining the risks and potential adverse consequences of the widespread implantation of Physiomesh™ in patients worldwide.
34. Defendants made public representations in the form of written product descriptions, product labels, package inserts, and promotional materials that contended implantation of the product in clinically indicated patients was safe and would not cause harm.
35. Defendants affirmatively misrepresented facts concerning the product's benefits, potential complications/adverse health consequences, and contraindications, with the intent that the misrepresentations be relied upon by members of the public.
36. When Defendants and/or their agents, employees, or servants made these misrepresentations, they knew the same was false, inaccurate, or misleading. In the alternative, Defendants and/or their agents, employees, or servants knew or should have known the statements are misrepresentations of material fact or are otherwise false, inaccurate, or misleading.
37. Defendants knowingly made material misrepresentations to the FDA both before, during and after the 510(k) approval process concerning the design, manufacture, safety, and efficacy of the product.
38. Defendants held actual knowledge of the product's defects and adverse health implications before both Plaintiff and other patients worldwide were respectively implanted with the product. Nonetheless, Defendants did not remove the product from the global market.
39. Defendants failed to provide adequate warnings concerning the products complications and adverse health implications, including but not limited to an unreasonable risk of failure to

perform its intended purpose and concomitant adverse health consequences stated herein, such as recurrent corrective surgery to repair the hernia and/or other consequences of the mesh.

40. Plaintiff became obligated to retain the undersigned attorneys to pursue this action in order to compensate the same for damages and personal injuries sustained as a result of Defendants' egregious conduct.

COUNT ONE—STRICT LIABILITY—MANUFACTURING DEFECT

41. Plaintiff re-alleges and incorporates by reference the allegations set forth above in each and every paragraph herein as if fully set forth herein.
42. One or more of the product's defects is the result of an improper manufacturing process which caused a deviation from the product's intended design.
43. The manufacturing defect(s) rendered the product unreasonably dangerous to consumers and ordinary persons/patients such as Plaintiff.
44. The defects in the product existed when said products left the possession and control of Defendants.
45. As a direct and proximate consequence of the product's defective manufacture, Plaintiff has suffered and will continue to suffer serious bodily injury, physical and mental pain and suffering, and economic loss.

WHEREFORE, Plaintiff demands judgment against Defendants on the basis of damages, personal injury, mental and physical pain and suffering, and economic loss caused by Defendants' defective manufacture of the product.

COUNT II—STRICT LIABILITY—DEFECTIVE DESIGN

46. Plaintiff re-alleges and incorporates by reference each and every paragraph hereinabove as if fully set forth herein.

47. This product has defects creating unreasonable risks of bodily harm to ordinary patients, persons, and/or consumers.

48. The risks of Physiomesh™ substantially outweigh any potential benefits. The multilayer coating, which is not utilized in any other hernia repair mesh product sold in the United States, prevents tissue from incorporating into the mesh, leading to encapsulation, deformation, scarification, contraction, migration, erosion and rejection. The impermeable multilayer coating leads to seroma formation and both provides a nidus for bacteria and protects bacteria from being eliminated by the body's natural immune response, thus promoting infection

49. The multilayer coating, which was marketed, promoted, and intended to serve as a barrier against adhesion to the internal organs, is temporary; it degrades over time inside the body and prevents tissue ingrowth in the short term. Eventually, the polypropylene material becomes exposed to the internal viscera and tissues. The degradation of this multilayer coating causes or exacerbates intense inflammatory and foreign body reaction. Once exposed to the viscera, the polypropylene mesh will inexorably adhere to the viscera, initiating a series of adverse consequences. Simply put, the clinic and scientific data now available confutes any purported beneficial purpose of the multilayer coating.

50. When implanted adjacent to the intestines and other internal organs, as Defendants designed, the polypropylene mesh is unreasonably susceptible to, *inter alia*, adhesion,

bowel perforation and/or erosion, fistula formation, bowel strangulation, hernia incarceration.

51. The defects stated herein exist because the product is defective in design.

52. The defects in design were present when the product left Defendants' possession and control.

53. The product's design posed and poses foreseeable risks of harm to ordinary patients such as Plaintiff. These foreseeable risks of harm, moreover, could have been eliminated, reduced, and/or avoided with the adoption of a reasonable alternative design. Defendants' failure to adopt a reasonable alternative design renders the product unreasonably safe to ordinary patients, persons, and/or consumers.

54. Plaintiff has suffered as a direct and proximate consequence of the defective design serious bodily injury, mental and physical pain and suffering, and economic loss.

WHEREFORE, Plaintiff demands judgments against Defendants for damages sustained as a result of Defendants' defective design of Physiomesh™.

COUNT III—STRICT LIABILITY—FAILURE TO WARN

55. Plaintiff re-alleges and incorporates by reference each and every paragraph herein as if fully set forth herein.

56. Defendants failed to provide adequate warnings regarding product health risks, complications, safety, and efficacy. Defendants' failure to provide adequate warnings, furthermore, renders the product unreasonably dangerous to ordinary patients, persons, and/or consumers.

57. Defendants had actual or constructive knowledge of the aforesaid product risks and complications concerning safety and efficacy when said product left Defendants'

possession and control. Nonetheless, Defendants failed to exercise reasonable care in providing adequate warning to both physicians who implant the product and patients/consumers clinically indicated for its purported benefits. Defendants failed to warn both surgeons and consumers of product risks and complications, including but not limited to the following:

i. the product has an unreasonably elevated failure rate;

j. the product carries an increased risk of causing infections and abscesses;

k. the product carries an increased risk of causing abdominal erosions and extrusions;

l. the product has a high rate of causing chronic pain;

m. the product carries an increased risk of migration;

n. the product carries an increased risk of bowel obstruction;

o. the product has a high rate of causing diminished bowel motility;

p. the product and implantation thereof in patients carries an increased risk of requiring corrective surgery due to mesh complications, including but not limited to hernia recurrence and the need for repair/reoperation; and

q. there is an unreasonably elevated rate of patient injury associated with complications in use of the product, including but not limited to chronic pain, infection, greater risk for hernia recurrence and reoperation, adhesion, intestinal blockage, bowel obstruction, mesh migration, mesh contraction, bleeding, perforation, inadequate or failure of incorporation/ingrowth, scarification, deformation of mesh, improper wound healing, chronic inflammation, erosion, abscess, fistula formation, granulomatous response, seroma formation, nerve damage, and tissue damage.

58. Defendants failed to provide adequate and timely postmarketing warnings of the aforesaid product risks and complications. A similarly situated manufacturer exercising reasonable care would have provided timely postmarketing warnings of the aforesaid product risks and complications.

59. Defendants, furthermore, failed to provide adequate instructions to surgeons concerning the necessity to remove the product from patients in the event of migration, decomposition, adhesion, infection, abscess, erosion, or extrusion.

60. As a direct and proximate consequence of Defendants' inadequate warnings and instructions, at both the time of marketing and sale, Plaintiff has suffered serious bodily injury, both mental and physical pain and suffering, and economic loss.

WHEREFORE, Plaintiff demands judgment for damages against Defendants for strict liability based on failure to warn.

COUNT IV—NEGLIGENCE

61. Plaintiff re-alleges and incorporates by reference the allegations set forth in each and every paragraph herein above as if fully set forth herein.

62. Defendants owed a duty to both Plaintiff and other foreseeable plaintiffs to exercise reasonable care in the design, test, manufacture, labeling, packaging, sale, and distribution of the product.

63. Defendants failed to exercise the standard of care owed to Plaintiff and other foreseeable plaintiffs in the design, manufacture, testing, marketing, labeling, packaging, distribution, and sale of the product. Defendants further failed to provide adequate warnings to both patients and physicians regarding product use, risks, complications, safety, and efficacy—

including but not limited to the unreasonably high rate of corrective surgeries for hernia repair and recurrence.

64. Plaintiff suffered damages as a direct and proximate consequence of Defendants' conduct, including but not limited to serious bodily injury, mental and physical pain and suffering, and economic loss.

WHEREFORE, Plaintiff demands judgment for damages against Defendants on the basis of negligence.

COUNT V—BREACH OF EXPRESS WARRANTY

65. Plaintiff re-alleges and incorporates by reference the allegations set forth in each and every paragraph hereinabove as if fully set forth herein.

66. Defendants expressly represented to both Plaintiff and her medical providers that the product was safe and fit for its intended purposes, of merchantable quality, that it did not present any serious health risk or complication, and that it was adequately tested.

67. Physiomesh™ does not conform to Defendants' express representations because it is not reasonably safe and fit for its intended purpose, nor is it of merchantable quality. Moreover, the product presents serious health risks and complications, including but not limited to an unreasonably high rate of requiring corrective surgery to repair the mesh or hernia recurrence/reoperation.

68. The product did not perform in a reasonably safe manner expected by ordinary consumers.

69. Plaintiff and other foreseeable plaintiffs reasonably and justifiably relied on Defendants' express representations.

70. As a direct and proximate consequence of Defendants' conduct, Plaintiff suffered severe medical complications, including but not limited to physical and mental pain and suffering,

serious bodily injury, disability, permanent scarring, mental anguish, diminished enjoyment of life, lost wages, medical expenses, past and future medical care and expenses, and aggravation of preexisting conditions.

WHEREFORE, Plaintiff demands judgment for damages against Defendants based on breach of express warranty.

COUNT VI—BREACH OF IMPLIED WARRANTY

71. Plaintiff re-alleges and incorporates by reference each and every paragraph hereinabove as if fully set forth herein.
72. At all relevant times hereto, Defendants knew the use for which the product was intended. Defendants impliedly warranted the product to be of merchantable quality and safe and fit for its ordinary, intended purpose.
73. Defendants marketed the product for LVIHR and knew it would be used and implanted in patients such as Plaintiff for its marketed purpose.
74. Plaintiff and other ordinary patients and/or consumers reasonably and justifiably relied on Defendants' merchant status, judgment, and sensibility to sell the product only if it was of merchantable quality and safe and fit for its ordinary, intended purpose.
75. Defendants breached their implied warranties as the product is not safe nor fit for its ordinary, intended purpose.
76. The product left the possession and control of Defendants and reached Plaintiff in an unaltered, unmodified, and/or unchanged condition form which it was designed, marketed, and intended.
77. As a direct and proximate consequence of Defendants' conduct, Plaintiff suffered severe medical complications, including but not limited to physical and mental pain and suffering,

serious bodily injury, disability, permanent scarring, mental anguish, diminished enjoyment of life, lost wages, medical expenses, past and future medical care and expenses, and aggravation of preexisting conditions.

WHEREFORE, Plaintiff demands judgment for damages against Defendants based on breach of implied warranty.

PLAINTIFF DEMANDS TRIAL BY STRUCK JURY AS TO ALL ISSUES

Respectfully submitted: March 16, 2017

FERRER, POIROT & WANSBROUGH

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CERTIFICATE OF SERVICE

I hereby certify that on March 16, 2017, I electronically filed the foregoing with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the following:

Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, New Jersey 08933

Ethicon Inc
Route 22 West
Somerville, NJ 08876

/s/John T. Kirtley, III
John T. Kirtley, III

JS 44 (Rev. 12/12)

CIVIL COVER SHEET

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

Lizzey Annett

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

(c) Attorneys *(Firm Name, Address, and Telephone Number)*

Heninger Garrison Davis LLC
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DEFENDANTS

Johnson & Johnson; Ethicon Inc.

County of Residence of First Listed Defendant Middlesex County, NJ
(IN U.S. PLAINTIFF CASES ONLY)

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

Attorneys *(If Known)*

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

- ❒ 1 U.S. Government Plaintiff
- ❒ 3 Federal Question *(U.S. Government Not a Party)*
- ❒ 2 U.S. Government Defendant
- ☒ 4 Diversity *(Indicate Citizenship of Parties in Item III)*

III. CITIZENSHIP OF PRINCIPAL PARTIES *(Place an "X" in One Box for Plaintiff and One Box for Defendant)*

(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☒ 1	❒ 1	Incorporated *or* Principal Place of Business In This State	❒ 4	❒ 4
Citizen of Another State	❒ 2	❒ 2	Incorporated *and* Principal Place of Business In Another State	❒ 5	☒ 5
Citizen or Subject of a Foreign Country	❒ 3	❒ 3	Foreign Nation	❒ 6	❒ 6

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

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- ❒ 442 Employment
- ❒ 443 Housing/ Accommodations
- ❒ 445 Amer. w/Disabilities - Employment
- ❒ 446 Amer. w/Disabilities - Other
- ❒ 448 Education

PRISONER PETITIONS

Habeas Corpus:
- ❒ 463 Alien Detainee
- ❒ 510 Motions to Vacate Sentence
- ❒ 530 General
- ❒ 535 Death Penalty

Other:
- ❒ 540 Mandamus & Other
- ❒ 550 Civil Rights
- ❒ 555 Prison Condition
- ❒ 560 Civil Detainee - Conditions of Confinement

FORFEITURE/PENALTY
- ❒ 625 Drug Related Seizure of Property 21 USC 881
- ❒ 690 Other

LABOR
- ❒ 710 Fair Labor Standards Act
- ❒ 720 Labor/Management Relations
- ❒ 740 Railway Labor Act
- ❒ 751 Family and Medical Leave Act
- ❒ 790 Other Labor Litigation
- ❒ 791 Employee Retirement Income Security Act

IMMIGRATION
- ❒ 462 Naturalization Application
- ❒ 465 Other Immigration Actions

BANKRUPTCY
- ❒ 422 Appeal 28 USC 158
- ❒ 423 Withdrawal 28 USC 157

PROPERTY RIGHTS
- ❒ 820 Copyrights
- ❒ 830 Patent
- ❒ 840 Trademark

SOCIAL SECURITY
- ❒ 861 HIA (1395ff)
- ❒ 862 Black Lung (923)
- ❒ 863 DIWC/DIWW (405(g))
- ❒ 864 SSID Title XVI
- ❒ 865 RSI (405(g))

FEDERAL TAX SUITS
- ❒ 870 Taxes (U.S. Plaintiff or Defendant)
- ❒ 871 IRS—Third Party 26 USC 7609

OTHER STATUTES
- ❒ 375 False Claims Act
- ❒ 400 State Reapportionment
- ❒ 410 Antitrust
- ❒ 430 Banks and Banking
- ❒ 450 Commerce
- ❒ 460 Deportation
- ❒ 470 Racketeer Influenced and Corrupt Organizations
- ❒ 480 Consumer Credit
- ❒ 490 Cable/Sat TV
- ❒ 850 Securities/Commodities/ Exchange
- ❒ 890 Other Statutory Actions
- ❒ 891 Agricultural Acts
- ❒ 893 Environmental Matters
- ❒ 895 Freedom of Information Act
- ❒ 896 Arbitration
- ❒ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ❒ 950 Constitutionality of State Statutes

V. ORIGIN *(Place an "X" in One Box Only)*

☒ 1 Original Proceeding ❒ 2 Removed from State Court ❒ 3 Remanded from Appellate Court ❒ 4 Reinstated or Reopened ❒ 5 Transferred from Another District *(specify)* ❒ 6 Multidistrict Litigation

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing ***(Do not cite jurisdictional statutes unless diversity)***:
28 USC s1332

Brief description of cause:

VII. REQUESTED IN COMPLAINT:

❒ CHECK IF THIS IS A **CLASS ACTION** UNDER RULE 23, F.R.Cv.P.

DEMAND $ 1,000,000.00

CHECK YES only if demanded in complaint:
JURY DEMAND: ☒ Yes ❒ No

VIII. RELATED CASE(S) IF ANY

(See instructions): JUDGE _____ DOCKET NUMBER MDL#2782 (not yet formed)

DATE 03/15/2017

SIGNATURE OF ATTORNEY OF RECORD /s/ W. Lewis Garrison, Jr.

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____

INSTRUCTIONS FOR ATTORNEYS COMPLETING CIVIL COVER SHEET FORM JS 44

Authority For Civil Cover Sheet

The JS 44 civil cover sheet and the information contained herein neither replaces nor supplements the filings and service of pleading or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. Consequently, a civil cover sheet is submitted to the Clerk of Court for each civil complaint filed. The attorney filing a case should complete the form as follows:

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

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

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

II. Jurisdiction. The basis of jurisdiction is set forth under Rule 8(a), F.R.Cv.P., which requires that jurisdictions be shown in pleadings. Place an "X" in one of the boxes. If there is more than one basis of jurisdiction, precedence is given in the order shown below.
United States plaintiff. (1) Jurisdiction based on 28 U.S.C. 1345 and 1348. Suits by agencies and officers of the United States are included here.
United States defendant. (2) When the plaintiff is suing the United States, its officers or agencies, place an "X" in this box.
Federal question. (3) This refers to suits under 28 U.S.C. 1331, where jurisdiction arises under the Constitution of the United States, an amendment to the Constitution, an act of Congress or a treaty of the United States. In cases where the U.S. is a party, the U.S. plaintiff or defendant code takes precedence, and box 1 or 2 should be marked.
Diversity of citizenship. (4) This refers to suits under 28 U.S.C. 1332, where parties are citizens of different states. When Box 4 is checked, the citizenship of the different parties must be checked**.** (See Section III below**; NOTE: federal question actions take precedence over diversity cases.**)

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

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

V. Origin. Place an "X" in one of the six boxes.
Original Proceedings. (1) Cases which originate in the United States district courts.
Removed from State Court. (2) Proceedings initiated in state courts may be removed to the district courts under Title 28 U.S.C., Section 1441. When the petition for removal is granted, check this box.
Remanded from Appellate Court. (3) Check this box for cases remanded to the district court for further action. Use the date of remand as the filing date.
Reinstated or Reopened. (4) Check this box for cases reinstated or reopened in the district court. Use the reopening date as the filing date.
Transferred from Another District. (5) For cases transferred under Title 28 U.S.C. Section 1404(a). Do not use this for within district transfers or multidistrict litigation transfers.
Multidistrict Litigation. (6) Check this box when a multidistrict case is transferred into the district under authority of Title 28 U.S.C. Section 1407. When this box is checked, do not check (5) above.

VI. Cause of Action. Report the civil statute directly related to the cause of action and give a brief description of the cause. **Do not cite jurisdictional statutes unless diversity.** Example: U.S. Civil Statute: 47 USC 553 Brief Description: Unauthorized reception of cable service

VII. Requested in Complaint. Class Action. Place an "X" in this box if you are filing a class action under Rule 23, F.R.Cv.P.
Demand. In this space enter the actual dollar amount being demanded or indicate other demand, such as a preliminary injunction.
Jury Demand. Check the appropriate box to indicate whether or not a jury is being demanded.

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

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