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

AMY FLOOD	§	
	§	
	§	
Plaintiff,	§	CIVIL ACTION NO. 2:17-cv-689
	§	
v.	§	JURY TRIAL DEMANDED
	§	
ETHICON, INC.,	§	
JOHNSON & JOHNSON, INC.	§	
	§	
	§	
Defendants.	§	

PLAINTIFF'S ORIGINAL COMPLAINT

COMES NOW Amy Flood, individually, by and through undersigned counsel, to complain of Ethicon, Inc. and Johnson & Johnson, Inc. (together, "Defendants") and respectfully show the Court and jury as follows:

I. PARTIES

- 1. Plaintiff is, and was, at all relevant times, a citizen and resident of Texas and the United States.
- 2. Defendant Johnson & Johnson ("J&J") is a corporation incorporated in New Jersey, with its principal place of business located at One Johnson & Johnson Plaza, New Brunswick, New Jersey. J&J maintains as its citizenship the State of 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. ("Ethicon") is a wholly owned subsidiary of Defendant Johnson & Johnson. Defendant Ethicon is a corporation incorporated in the State of New Jersey with its principal place of business in Somerville, New Jersey. Ethicon has as its citizenship the State of New Jersey.
- 5. Ethicon is a medical device company involved in the research, development, testing, manufacture, production, marketing, promotion and/or sale of medical devices including Physiomesh (hereinafter may be referred to as the "product").
- 6. J&J, directly and/or through the actions of Ethicon, has at all pertinent times been responsible for the research, development, testing, manufacture, production, marketing, promotion, distribution and/or sale of Physiomesh.
- 7. Defendants are individually, jointly and severally liable to Plaintiff for damages suffered by Plaintiff arising from the Defendants' design, manufacture, marketing, labeling, distribution, sale and placement of its defective mesh products at issue in the instant action, effectuated directly and indirectly through their respective agents, servants, employees and/or owners, all acting within the course and scope of their representative agencies, services, employments and/or ownership.

8. 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.

II. JURISDICTION AND VENUE

- 9. This Court has subject-matter jurisdiction over this action pursuant to 28 U.S.C. § 1332(a) based on complete diversity of citizenship between Plaintiff and all Defendants. The amount in controversy exceeds \$75,000, exclusive of interests and costs.
- 10. This Court has personal jurisdiction over each of the Defendants pursuant to Tex. Civ. Prac. & Rem. Code § 17.041, *et seq*. Defendants transact business within the State of Texas, and Defendants committed tortious acts and omissions in Texas. Defendants' tortious acts and omissions caused injury to Plaintiff in the State of Texas. Defendants have purposefully engaged in the business of developing, manufacturing, publishing information, marketing, distributing, promoting and/or selling, either directly or indirectly, through third parties, as successor in interest, or other related entities, medical devices including Physiomesh in Texas, for which they derived significant and regular income. The Defendants reasonably expected, and in fact anticipated, that that their defective mesh products, including Physiomesh, would be sold and implanted in Texas.
- 11. Defendant Ethicon is registered to transact business in Texas, and is thus also subject to personal jurisdiction.
 - 12. Venue is proper in this Court pursuant to 28 U.S.C. § 1391(b)(2).

III. FACTS COMMON TO ALL COUNTS

13. On or about October 14, 2015, Plaintiff had a 10x15 Physiomesh Composite mesh, catalog number PHY1015V, implanted laparoscopically to repair an incisional hernia.

- 14. Defendants manufactured, sold, and/or distributed the Physiomesh device to Plaintiff, through her doctors, to be used for treatment of hernia repair.
- 15. Plaintiff has suffered and will continue to suffer physical pain and mental anguish. Defendants were responsible for the research, design, development, testing, manufacture, production, marketing, promotion, distribution and sale of Physiomesh, including providing the warnings and instructions concerning the product.
- 16. Among the intended purposes for which Defendants designed, manufactured and sold Physiomesh was use by surgeons for hernia repair surgeries, the purpose for which the Physiomesh was implanted in Plaintiff.
- 17. Defendants represented to Plaintiff and Plaintiff's physicians that Physiomesh was a safe and effective product for hernia repair.
- 18. Defendants' 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 associated with the design. As a result of the defective design and/or manufacture of the Physiomesh, there was an unreasonable risk of severe adverse reactions to the mesh or mesh components including: chronic pain; recurrence of hernia; foreign body response; rejection; infection; inadequate or failure of incorporation/ingrowth; migration; scarification; deformation of mesh; improper wound healing; excessive and chronic inflammation; adhesions to internal organs; erosion; abscess; fistula formation; granulomatous response; seroma formation; nerve damage; tissue damage and/or death; and other complications.
- 19. Physiomesh has a unique design incorporating five (5) distinct layers: two layers of poliglecaprone-25 ("Monocryl") film covering two underlying layers of polydioxanone film ("PDS"), which in turn coat a polypropylene mesh. This design is not used in any other hernia

repair product sold in the United States. The multi-layer coating was represented and promoted by the Defendants to prevent or minimize adhesion and inflammation and to facilitate incorporation of the mesh into the body, but it did not. Instead, the multi-layer coating prevented adequate incorporation of the mesh into the body and caused or contributed to an intense inflammatory and chronic foreign body response resulting in an adverse tissue reaction including migration and damage to surrounding tissue in the form of sclerotic, granulomatous and/or fibrotic tissue and improper healing.

- 20. When affixed to the body's tissue, the impermeable multi-layer coating of the Physiomesh prevents fluid escape, which leads to seroma formation, and which in turn can cause infection, abscess formation and other complications.
- 21. The multi-layer coating provides a breeding ground for bacteria in which the bacteria cannot be eliminated by the body's immune response, which allows infection to proliferate.
- 22. The multi-layer coating of Defendants' Physiomesh is cytotoxic, immunogenic, and not biocompatible, which causes or contributes to complications such as delayed wound healing, inflammation, foreign body response, rejection, infection, and other complications.
- 23. Defendants knew or should have known of the cytotoxic and immunogenic properties of the multi-layer coating of the Physiomesh prior to introducing it into the stream of commerce.
- 24. When the multi-layer coating of the Physiomesh is disrupted and/or degrades, the "naked" polypropylene mesh is exposed to the adjoining tissue and viscera, and can become adhered to organs, and cause damage to organs, and potentiate fistula formation.

- 25. These manufacturing and design defects associated with the Physiomesh were directly and proximately related to the injuries suffered by Plaintiff.
- 26. Neither Plaintiff nor her implanting physician were adequately warned or informed by Defendants of the defective and dangerous nature of Physiomesh. Moreover, neither Plaintiff nor her implanting physician were adequately warned or informed by Defendants of the risks associated with the Physiomesh or the frequency, severity, or duration of such risks.
- 27. The Physiomesh implanted in Plaintiff failed to reasonably perform as intended. The mesh caused serious injury and may necessitate additional invasive surgery to repair the hernia that the Physiomesh was initially implanted to treat.
- 28. Plaintiff's severe adverse reaction, directly and proximately resulted from the defective and dangerous condition of the product and Defendants' defective and inadequate warnings about the risks associated with the product, and the frequency, severity and duration of such risks. Plaintiff has suffered, and will continue to suffer, both physical injury and pain and mental anguish, resulting from the defective and dangerous condition of the product and from Defendants' defective and inadequate warnings about the risks associated with the product.
- 29. On May 25, 2016, Defendants issued an "Urgent: Field Safety Notice" relating to its Physiomesh Flexible Composite Mesh, the same product implanted in Plaintiff, and sent such notification to hospitals and medical providers in various countries worldwide.
- 30. In this safety notice, Defendants advise these providers of "a voluntary product recall," citing two international device registries which reported data reflecting recurrence/reoperation rates after laparoscopic placement as being higher than that observed from a data set relating to patient outcomes after being implanted with other mesh. Defendants

attributed the high rate of recurrence to a "multifactorial issue" which could involve "possible product characteristics, operative, and patient factors."

31. However, in the United States, Defendants failed to issue a nationwide recall, opting instead to simply remove the product from shelves and cease further sales within the United States. This notice was not sent to patients implanted with the device, nor were physicians instructed to immediately remove the device. Instead, the recall instructed health care practitioners to "continue to follow those patients in the usual manner."

COUNT I

STRICT PRODUCT LIABILITY: DEFECTIVE DESIGN

- 32. At the time the Physiomesh was implanted in Plaintiff's body, the product was defectively designed. As described above, there was an unreasonable risk that the product would not perform safely and effectively for the purposes for which it was intended, and Defendants failed to design against such dangers, and failed to provide adequate warnings and instructions concerning these risks.
- 33. Defendants expected and intended the Physiomesh product to reach users such as Plaintiff in the condition in which the product was sold.
- 34. The implantation of Physiomesh in Plaintiff's body was medically reasonable, and was a type of use that Defendants intended and foresaw when it designed, manufactured and sold the product.
- 35. The risks of the Physiomesh significantly outweigh any benefits that Defendants contend could be associated with the product. The multi-layer coating, which is not used in any other hernia mesh product sold in the United States, prevents tissue from incorporating into the mesh, leading to encapsulation, deformation, scarification and contraction, migration, erosion

and rejection. The impermeable multi-layer coating leads to seroma formation, and provides a breeding ground for infection, and protects bacteria from being eliminated by the body's natural immune response.

- 36. The multi-layer coating of the Physiomesh, which was marketed, promoted and intended as a barrier against adhesion to the internal organs, was only temporary; it was expected and intended to degrade over time inside the body. Thus, this coating prevented tissue ingrowth in the short term, and degraded in the long-term, eventually leaving the "naked" polypropylene mesh exposed to the internal viscera and tissues. The degradation of this multi-layer coating caused or exacerbated an intense inflammatory and foreign body reaction. Once exposed to the viscera, the polypropylene mesh will inevitably adhere to the viscera, initiating a cascade of adverse consequences. Any purported beneficial purpose of the multi-layer coating (to prevent adhesion to the internal viscera and organs) was non-existent; the product provided no benefit while substantially increasing the risks to the patient.
- 37. The polypropylene mesh within the defective multi-layer coating of the Physiomesh was in itself dangerous and defective, particularly when used in the manner intended by Defendants in the Physiomesh. When implanted adjacent to the intestines and other internal organs, as Defendants intended for Physiomesh, polypropylene mesh is unreasonably susceptible to adhesion, bowel perforation or erosion, fistula formation and bowel strangulation or hernia incarceration, and other injuries.
- 38. The appropriate treatment for complications associated with Physiomesh involves additional invasive surgery to remove the mesh from the body, thus eliminating any purported benefit that the mesh was intended to provide to the patient.

- 39. Physiomesh was designed and intended for intraperitoneal implantation, which involved the product being implanted in contact with the intestines and/or other internal organs, which unnecessarily increased the risks of adhesion, erosion, fistula formation, and other injuries.
- 40. At the time the Physiomesh was implanted in Plaintiff, there were safer feasible alternative designs for hernia mesh products that would have prevented the injuries she suffered.
- 41. The Physiomesh product cost significantly more than competitive products because of its unique multi-layer coating, even though the multi-layer coating provided no benefit to consumers, and increased the risks to patients implanted with these devices.
- 42. The Physiomesh implanted in Plaintiff failed to reasonably perform as intended, and will likely need to be surgically removed necessitating further invasive surgery to repair the very issue that the product was intended to repair, and thus provided no benefit to her.
- 43. As a direct and proximate result of the defective and unreasonably dangerous condition of the product, Plaintiff suffered injuries and damages as summarized herein.

COUNT II

STRICT LIABILITY - MANUFACTURING DEFECT

- 44. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.
- 45. Defendants supplied, manufactured, sold, distributed and/or otherwise placed into the stream of commerce the Physiomesh implanted in Plaintiff. The Physiomesh was defective in its manufacture and construction when it left the hands of Defendants in that its manufacture and construction deviated from good manufacturing practices and/or manufacturing specifications as

would be used and/or maintained by a reasonably prudent and careful medical device manufacturer.

- 46. The Physiomesh as manufactured and constructed by Defendants was unreasonably dangerous to end consumers including Plaintiff and posed an unreasonable degree of risk, danger and harm to Plaintiff.
- 47. The Physiomesh was expected to reach and did reach Plaintiff's implanting surgeon and Plaintiff without substantial change in the condition in which it was manufactured, suppled, distributed sold and/or otherwise placed in the stream of commerce.
- 48. The manufacturing defect in the Physiomesh implanted in Plaintiff was not known, knowable or readily visible to Plaintiff's physician or to Plaintiff nor was it discoverable upon any reasonable examination by Plaintiff's physician or Plaintiff. The Physiomesh was used and implanted in the very manner in which it was intended to be used and implanted by Defendants in accordance with the instructions for use and specifications provided by Defendants.
- 49. The Physiomesh implanted in Plaintiff was different from its intended design and failed to perform as safely as a product manufactured in accordance with the intended design would have performed.
- 50. The defective and unreasonably dangerous condition of the Physiomesh product was a proximate cause of damages and injuries suffered by Plaintiff.
- 51. As a direct and proximate result of the Physiomesh's aforementioned manufacturing defect, Plaintiff was caused and in the future will be caused to suffer severe personal injuries, pain and suffering, severe emotional distress, financial or economic loss, including, but not limited to, obligations for medical services and expenses, and other damages.

52. Defendants are strictly liable to Plaintiff.

COUNT III

STRICT PRODUCT LIABILITY: FAILURE TO WARN

- 53. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.
- 54. At the time the Physiomesh was implanted in Plaintiff's body, the warnings and instructions provided by Defendants for the Physiomesh were inadequate and defective. As described above, there was an unreasonable risk that the product would not perform safely and effectively for the purposes for which it was intended, and Defendants failed to design and/or manufacture against such dangers, and failed to provide adequate warnings and instructions concerning these risks.
- 55. Defendants expected and intended the Physiomesh product to reach users such as Plaintiff in the condition in which the product was sold.
- 56. Plaintiff and her physicians were unaware of the defects and dangers of Physiomesh, and were unaware of the frequency, severity and duration of the defects and risks associated with the Physiomesh.
- 57. The Defendants' Instructions for Use provided with the Physiomesh expressly understates and misstates the risks known to be associated specifically with the Physiomesh by stating that "Potential adverse reactions are those typically associated with surgically implantable materials." No other surgical mesh sold in the United States and no other "surgically implantable material" suffers the same serious design flaws as Physiomesh. No other device or material contains the dangerous and defective multi-layer coating, which itself causes or

increases the risks of numerous complications, including prevention of incorporation, increased risk of seroma formation, immunologic response, increased risk for infection, and increased inflammatory reaction and foreign body response. Defendants provided no warning to physicians about the risks or increased risks specifically associated with the unique design of the Physiomesh.

- 58. The Defendants' Instructions for Use for the Physiomesh failed to adequately warn Plaintiff's physicians of numerous risks which Defendants knew or should have known were associated with the Physiomesh, including the risks of the product's inhibition of tissue incorporation, pain, immunologic response, dehiscence, encapsulation, rejection, migration, scarification, shrinkage/contraction, adhesion to internal organs and viscera, erosion through adjacent tissue and viscera, bowel obstruction, failure of repair/hernia recurrence, or hernia incarceration or strangulation.
- 59. Defendants failed to adequately train or warn Plaintiff or her physicians about the necessity for invasive surgical intervention in the event of complications, or how to properly treat such complications when they occurred.
- 60. Defendants failed to adequately warn Plaintiff or her physicians that the necessary surgical removal of the Physiomesh in the event of complications would leave the hernia unrepaired, and would necessitate further medical treatment to attempt to repair the same hernia that the failed Physiomesh was intended to treat.
- 61. Defendants represented to physicians, including Plaintiff's physician, that the multi-layer coating would prevent or reduce adhesion, and expressly intended for the Physiomesh to be implanted in contact with the intestines and internal organs and marketed and promoted the product for said purpose. Defendants failed to warn physicians that the multi-layer

coating prevented tissue ingrowth, which is the desired biologic response to an implantable mesh device. Defendants failed to warn physicians that the multi-layer coating was only temporary and therefore at best would provide only a temporary adhesion barrier, and when the coating inevitably degraded, the exposed polypropylene would become adhered to the organs or tissue.

- 62. With respect to the complications that were listed in the Defendants' warnings, Defendants provided no information or warning regarding the frequency, severity and duration of those complications, even though the complications associated with Physiomesh were more frequent, more severe and lasted longer than those with safer feasible alternative hernia repair treatments.
- 63. If Plaintiff and/or her physicians had been properly warned of the defects and dangers of Physiomesh, and of the frequency, severity and duration of the risks associated with the Physiomesh, Plaintiff would not have consented to allow the Physiomesh to be implanted in her body, and Plaintiff's physicians would not have implanted the Physiomesh in Plaintiff.
- 64. As a direct and proximate result of the inadequate and defective warnings and instructions, Plaintiff suffered injuries and damages as summarized herein.

COUNT IV

NEGLIGENCE

- 65. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.
- 66. Defendants had a duty to use reasonable care in designing, testing, inspecting, manufacturing, packaging, labeling, marketing, distributing, and preparing written instructions and warnings for Physiomesh, but failed to do so.

- 67. Defendants knew, or in the exercise of reasonable care should have known, that Physiomesh was defectively and unreasonably designed and/or manufactured, and was unreasonably dangerous and likely to injure patients in whom Physiomesh was implanted. Defendants knew or should have known that Plaintiff and Plaintiff's physicians were unaware of the dangers and defects inherent in the Physiomesh.
- 68. Defendants had a duty to continue to monitor Physiomesh after its introduction into the market to ensure potential consumers would be given proper warning of complications or dangers of the product, but failed to do so.
- 69. As a direct and proximate result of Defendants' negligence in designing, testing, inspecting, manufacturing, packaging, labeling, marketing, distributing, and preparing written instructions and warnings for Physiomesh, Plaintiff suffered injuries and damages as summarized herein.

COUNT V

BREACH OF EXPRESS WARRANTY

- 70. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.
- 71. At all relevant and material times, Defendants manufactured, marketed, sold, distributed and otherwise placed in to the stream of commerce Physiomesh.
- 72. In advertising, marketing and otherwise promoting Physiomesh to physicians, hospitals and other healthcare providers, Defendants expressly warranted that their Physiomesh was safe for use. In advertising, marketing and otherwise promoting Physiomesh, Defendants

intended that physicians, hospitals and other healthcare providers rely upon their representations in an effort to induce them to use Physiomesh for their patients.

- 73. The Plaintiff was a person whom the Defendants could reasonably have expected to use, consume, or be affected by the Defendants' hernia mesh products as the Defendants specifically designed the Physiomesh for permanent implantation in patients exhibiting hernia such as Plaintiff.
- 74. With respect to Plaintiff, Defendants intended that Physiomesh be implanted in Plaintiff by her treating surgeon in the reasonable and foreseeable manner in which it was implanted and in accordance with the instructions for use and product specifications provided by Defendants. Plaintiff was in privity with Defendants.
- 75. Defendants expressly warranted to physicians, hospitals, other healthcare providers and the general public including Plaintiff that Physiomesh was safe and fit for use by consumers including Plaintiff, that it was of merchantable quality, that its risks, side effects and potential complications are minimal and are comparable to other hernia mesh products, that it was adequately researched and tested and was fit for its intended use. Plaintiff and her physicians and healthcare providers relied upon these express representations and warranties made by Defendants and consequently, Plaintiff was implanted with Defendants' Physiomesh.
- 76. Defendants breached express representations and warranties made to Plaintiff and her physicians and healthcare providers with respect to the Physiomesh implanted in Plaintiff including the following particulars:
 - Defendants represented to Plaintiff and her physicians and healthcare providers through labeling, advertising, arketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions

- among other ways that the Defendants' Physiomesh was safe, meanwhile Defendants fraudulently withheld and concealed information about the substantial risks of serious injury associated with using Physiomesh;
- b. Defendants represented to Plaintiff and her physicians and healthcare providers that the Defendants' Physiomesh was as safe and/or safer than other alternative procedures and devices then on the market, meanwhile Defendants fraudulently concealed information that demonstrated that Physiomesh was not safer than alternative therapies and products available on the market; and
- c. Defendants represented to Plaintiff and her physicians and healthcare providers that the Defendants' Physiomesh was more efficacious than other alternative procedures, therapies and/or devices. Meanwhile Defendants fraudulently concealed information, regarding the true efficacy of Physiomesh.
- 77. At the time of making such express warranties, Defendants knew or should have known that Defendants' Physiomesh does not conform to the express warranties and Defendants' acts were motivated by financial gain while the adverse consequences of Defendants' conduct was outrageous, fraudulent, oppressive, done with malice or gross negligence and evidenced reckless indifference to Plaintiff's rights, health and safety.
- 78. As a direct and proximate result of Defendants' breaches of the aforementioned express warranties, Plaintiff was caused and in the future will be caused to suffer severe personal injuries, pain and suffering, severe emotional distress, financial or economic loss, including, but

not limited to, obligations for medical services and expenses, impairment of personal relationships, and other damages.

COUNT VI

BREACH OF IMPLIED WARRANTIES OF MERCHANTABILITY

- 79. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.
- 80. Defendants breached implied warranties with respect to the Physiomesh including the following particulars:
 - a. Defendants represented to Plaintiff and her physicians and healthcare providers through its labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that the Defendants' Physiomesh was of merchantable quality and safe when used for its intended purpose meanwhile Defendants fraudulently withheld and concealed information about the substantial risks of serious injury associated with using Physiomesh;
 - b. Defendants represented to Plaintiff and her physicians and healthcare providers that the Defendants' Physiomesh was safe, as safe as and/or safer than other alternative procedures and devices, meanwhile Defendants fraudulently concealed information, which demonstrated that the Physiomesh was not safe, as safe as or safer than alternatives and other products available on the market; and

- c. Defendants represented to Plaintiff and her physicians and healthcare providers that the Defendants' Physiomesh were more efficacious than other alternative procedures and/or devices. Meanwhile Defendants fraudulently concealed information, regarding the true efficacy of Physiomesh.
- 81. In reliance upon Defendants' implied warranty, Plaintiff's implanting surgeon used Physiomesh to treat Plaintiff in the foreseeable manner normally intended, recommended, promoted, and marketed by Defendants and in accordance with the instructions for use and product specification provided by Defendants.
- 82. Defendants breached their implied warranty to Plaintiff in that the Defendants' Physiomesh was not of merchantable quality, safe and fit for its intended use nor was it adequately tested prior to being placed in the stream of commerce.
- 83. Defendants' acts were motivated by financial gain while the adverse consequences of the conduct were actually known by Defendants. Defendants' conduct was outrageous, fraudulent, oppressive, done with malice and with gross negligence, and evidenced reckless disregard and indifference to Plaintiff's rights, health and safety.
- 84. As a direct and proximate result of Defendants' breach of the aforementioned implied warranties, Plaintiff was caused and in the future will be caused to suffer severe personal injuries, pain and suffering, severe emotional distress, financial or economic loss, including, but not limited to, obligations for medical services and expenses, impairment of personal relationships, and other damages.

COUNT VII

VICARIOUS LIABILITY

- 85. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.
- 86. Whenever in this Complaint it is alleged that Defendants did or omitted to do any act, it is meant that Defendants' officers, agents, servants, employees, or representatives did or omitted to do such act and that at the time such act or omission was done, it was done with the full authorization or ratification of Defendants or was done in the normal and routine course and scope of employment of Defendants' officers, agents, servants, employees, and representatives.

COUNT VIII

VIOLATION OF DECEPTIVE TRADE PRACTICES-CONSUMER PROTECTION ACT, § 17.41 et seq.

- 87. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.
- 88. As alleged herein, the conduct of Defendants constitutes unfair or deceptive acts or practices in trade or commerce as defined in, and in violation of the Deceptive Trade Practices-Consumer Protection Act, Tex. Bus. & Com. Code § 17.41, et seq.
- 89. The conduct of the Defendants impacted the public interest, had the capacity to deceive a substantial portion of the public, and, in fact, did deceive plaintiff.
- 90. As a direct and proximate result of these unfair or deceptive acts or practices, Plaintiff has been damaged in an amount to be determined with specificity at trial.

91. Plaintiff seeks both compensatory and punitive damages, and pursuant to Tex. Bus. & Com. Code § 17.50(d), the Plaintiff is entitled to reasonable attorneys' fees incurred in prosecuting this action.

COUNT IX

PUNITIVE DAMAGES

- 92. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.
- 93. Defendants continued to manufacture and sell Physiomesh after obtaining knowledge and information that the product was defective and unreasonably unsafe. Defendants were aware of the probable consequences of implantation of the dangerous and defective Physiomesh, including the risk of failure and serious injury, such as suffered by Plaintiff. Defendants willfully and deliberately failed to avoid those consequences, and in doing so, Defendants acted with conscious indifference, indifference to, and/or flagrant disregard of, the safety of those persons who might foreseeably have been harmed by the Physiomesh product, including Plaintiff, justifying the imposition of punitive damages to the full extent allowed by law.

IV. PRAYER FOR RELIEF

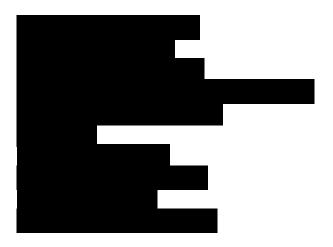
WHEREFORE, as a result of the acts and omissions and conduct of Defendants set forth herein, Plaintiff is entitled to recover for her personal injuries; past, present, and future medical and related expenses; past, present, and future lost wages; past, present and future loss of earning capacity; and past, present and future mental and physical pain and suffering; attorneys' fees to

the full extent permitted by law and Plaintiff is entitled to punitive damages in an amount sufficient to punish, penalize and deter Defendants from such conduct.

JURY TRIAL DEMANDED

Plaintiff demands trial by jury, judgment against Defendants, jointly and severally, for compensatory and punitive damages in an amount not less than \$75,000, as well as costs, attorney fees, interest, or any other relief, monetary or equitable, to which she is entitled.

DATED: October 9, 2017 Respectfully submitted,



Attorney for Plaintiff

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 purpose of initiating the civil de	This form, approved by the cocket sheet. (SEE INSTRUC	he Judicial Conference of th TIONS ON NEXT PAGE OF TH	ne United States in September 1 HIS FORM.)	974, is required for the use of	f the Clerk of Court for the	
I. (a) PLAINTIFFS			DEFENDANTS			
Amy Flood			Ethicon, Inc. and Johnson & Johnson, Inc.			
(b) County of Residence of First Listed Plaintiff Titus County, Texas (EXCEPT IN U.S. PLAINTIFF CASES)			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.			
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II. BASIS OF JURISDI	CTION (Place an "X" in C	ne Box Only)		RINCIPAL PARTIES	(Place an "X" in One Box for Plaints	
☐ 1 U.S. Government Plaintiff	☐ 3 Federal Question (U.S. Government)	Not a Party)		TF DEF 1		
☐ 2 U.S. Government Defendant	★ 4 Diversity (Indicate Citizensh	ip of Parties in Item III)	Citizen of Another State	2		
			Citizen or Subject of a Foreign Country	3 🗇 3 Foreign Nation	□ 6 □ 6	
IV. NATURE OF SUIT					of Suit Code Descriptions.	
CONTRACT 110 Insurance 120 Marine 130 Miller Act 140 Negotiable Instrument 150 Recovery of Overpayment & Enforcement of Judgment 151 Medicare Act 152 Recovery of Defaulted Student Loans (Excludes Veterans) 153 Recovery of Overpayment of Veteran's Benefits 160 Stockholders' Suits 190 Other Contract 195 Contract Product Liability 196 Franchise REAL PROPERTY 210 Land Condemnation 220 Foreclosure 230 Rent Lease & Ejectment 240 Torts to Land 245 Tort Product Liability 290 All Other Real Property	PERSONAL INJURY 310 Airplane 315 Airplane Product Liability 320 Assault, Libel & Slander 330 Federal Employers' Liability 340 Marine 345 Marine Product Liability 350 Motor Vehicle Product Liability 360 Other Personal Injury 362 Personal Injury Medical Malpractice CIVIL RIGHTS 440 Other Civil Rights 441 Voting 442 Employment 443 Housing/ Accommodations 445 Amer. w/Disabilities - Employment 446 Amer. w/Disabilities - Other 448 Education	PERSONAL INJURY 365 Personal Injury - Product Liability 367 Health Care/ Pharmaceutical Personal Injury Product Liability 368 Asbestos Personal Injury Product Liability PERSONAL PROPERTY 370 Other Fraud 371 Truth in Lending 180 Other Personal Property Damage Product Liability 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	CABOR CABO	422 Appeal 28 USC 158 423 Withdrawal 28 USC 157 PROPERTY RIGHTS 820 Copyrights 830 Patent 835 Patent - Abbreviated New Drug Application 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	375 False Claims Act 376 Qui Tam (31 USC 3729(a)) 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	
	moved from 3 the Court Cite the U.S. Civil Sta 28 U.S.C. Sec. 1	Appellate Court tute under which you are fi 332				
	Products Liability	- Personal Injury Base	ed on Failure of Surgical			
VII. REQUESTED IN COMPLAINT:	☐ CHECK IF THIS UNDER RULE 2	IS A CLASS ACTION 3, F.R.Cv.P.	DEMAND \$	CHECK YES only JURY DEMAND	y if demanded in complaint: o: ★ Yes □ No	
VIII. RELATED CASI IF ANY	E(S) (See instructions):	JUDGE Hon. Richa	ard W. Story	DOCKET NUMBER N	DGA 1:17-MD-2782 RWS	
DATE		SIGNATURE OF ATTOR	·	a committee in	,	
10/09/2017						
FOR OFFICE USE ONLY RECEIPT# AM	MOUNT	APPLYING IFP	JUDGE	MAG. JUI	DGE	

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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 there are multiple nature of suit codes associated with the case, pick the nature of suit code that is most applicable. Click here for: Nature of Suit Code Descriptions.
- V. Origin. Place an "X" in one of the seven 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 – Transfer. (6) Check this box when a multidistrict case is transferred into the district under authority of Title 28 U.S.C. Section 1407.

Multidistrict Litigation – Direct File. (8) Check this box when a multidistrict case is filed in the same district as the Master MDL docket. **PLEASE NOTE THAT THERE IS NOT AN ORIGIN CODE 7.** Origin Code 7 was used for historical records and is no longer relevant due to changes in statue.

- 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.