IN THE UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
JACKSONVILLE DIVISION

SHERI ANNE JAMES	)	
	)	
and	)	
	)	
ALFRED GEORGE JAMES	)	
	)	
Plaintiffs,	)	**Civil Action No.** 3:17-cv-759-J-39JRK
	)	
v.	)	**JURY TRIAL DEMANDED**
	)	
JOHNSON & JOHNSON and ETHICON, INC.,	)	
	)	
Defendants.	)	
	)	

PLAINTIFFS' COMPLAINT FOR DAMAGES

Comes now Plaintiffs, Sheri Anne James and Alfred George James (hereinafter "Plaintiffs"), by and through undersigned counsel, and brings this action against Defendants, Johnson & Johnson and Ethicon, Inc. (hereinafter "Defendants"), and alleges as follows:

Statement of Parties

1. Plaintiffs are and at all relevant times have been a citizen and resident of the state of Florida and of the United States.

2. Defendant, Johnson & Johnson ("J&J") is a corporation incorporated in New Jersey, and according to its website, the world's largest and most diverse medical device and diagnostics company, with its principal place of business located at One Johnson & Johnson Plaza, New Brunswick, New Jersey. Defendant J&J is a citizen 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, Inc. is a corporation s

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 Flexible Composite hernia repair mesh (hereinafter may be referred to as "Physiomesh" or "the product").

6. J&J, directly and/or through the actions of Ethicon, Inc., 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 Plaintiffs for damages suffered by Plaintiffs 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 respective 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.

Statement of 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, a citizen of Florida, and both Defendants, who are citizens of New Jersey. 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 the Florida Long-Arm Statute, *Fla. Stat. § 48.193.* Defendants transact business within the State of Florida, and Defendants committed tortious acts and omissions in Florida. Defendants' tortious acts and omissions caused injury to Plaintiff in the State of Florida. Defendants have purposefully engaged in the business of publishing information, marketing, distributing, promoting and/or selling, either directly or indirectly, medical devices including Physiomesh mesh products in Florida, for which they derived significant and regular income. The Defendants reasonably expected that their defective mesh products, including Physiomesh, would be sold, used and/or implanted in the State of Florida. Accordingly, the exercise of jurisdiction over these Defendants under these circumstances is consistent with federal and state constitutional due-process guarantees.

11. Venue is proper in this Court pursuant to 28 U.S.C. § 1391(b)(2).

Statement of Facts Common to All Counts

12. Plaintiff, Sheri James, was implanted with a 15 x 25 cm Physiomesh device (PHY2325V, Lot DH5CJWAG) during a procedure to repair a massive multiple anterior abdominal wall recurrent incisional ventral hernia at Memorial Hospital on or about May 9, 2012. This operation included a laparotomy with adhesiolysis and reduction of incarcerated small bowel and omentum, and resection of multiple hernia sacs and previously placed failed synthetic mesh.

13. Defendants manufactured, sold, and/or distributed the Physiomesh device to Plaintiff Sheri James, through her physicians, to be used for treatment of hernia repair.

14. Plaintiff experienced pelvic pain, urinary frequency, and a fistula was confirmed by cystoscopy. On or about December 10, 2012, Plaintiff underwent a procedure of over 3 hours in duration at St. Vincent's Medical Center Southside, which included laparoscopic lysis of adhesions, laparoscopic removal of bladder from hernia and abdominal wall, and mesh repair of the abdominal wall hernia. A 10 x 15 cm Physiomesh device (PHY1015V, Lot EA8KPQA0) was used to repair the hernia.

15. On or about July 17, 2013, Plaintiff Sheri James underwent an open repair of recurrent incisional hernia with mesh and bladder repair. Some of the previously-placed Physiomesh was explanted during this procedure

16. Since the failure of Defendants' Physiomesh implants, Plaintiff has suffered and been treated for additional pain, hernia recurrence and additional adhesion and scarification which may require additional surgery to repair.

17. Defendants were responsible for the research, design, development, testing, manufacture, production, marketing, promotion, distribution and sale of Physiomesh including providing the warnings and instruction for use of the product.

18. 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.

19. Defendants represented to Plaintiff and Plaintiff's physicians that Physiomesh was a safe and effective product for hernia repair.

20. Defendants' Physiomesh was defectively designed, 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 of 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; infection; rejection; inadequate or failure of incorporation/in-growth; 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 complication.

21. Physiomesh has a unique design incorporating five (5) distinct layers; two layers of polyglecaprone-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 products 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.

22. 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.

23. 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.

24. 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.

25. Defendants knew of 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.

26. The polypropylene mesh portion of the Physiomesh was insufficient to withstand normal abdominal forces, which resulted in recurrent hernia formation and/or rupture and deformation of the mesh itself.

27. 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 or tissue, and cause damage to organs or tissue and potentiate fistula formation.

28. These design defects associated with the Physiomesh were directly and proximately related to the injuries suffered by Plaintiff Sheri James.

29. Neither Plaintiff Sheri James 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.

30. The Physiomesh implanted in Plaintiff Sheri James failed to reasonably perform as intended. The mesh failed, caused serious injury including formation of fluid and infection around the mesh, and required that the mesh be removed by and through another serious invasive surgery.

31. Plaintiff Sheri James' severe adverse reaction, and the necessity for surgical removal of the Physiomesh, 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 bodily injury and pain and mental anguish, permanent and severe scarring and disfigurement, and has incurred substantial medical bills and other expenses, resulting from the defective and dangerous condition of the product and from Defendants' defective and inadequate warnings about the risks associated with Physiomesh.

COUNT I

Strict Product Liability: Defective Design

32. Plaintiffs incorporate herein by reference the allegations in paragraph 12 through 31 as if fully set forth herein.

33. At the time the Physiomesh was implanted in Plaintiff Sheri James' 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.

34. Defendants expected and intended the Physiomesh product to reach users such as Plaintiff in the condition in which the product was sold.

35. The implantation of Physiomesh in Plaintiff Sheri James' body was medically reasonable and was a type of use that Defendants intended and foresaw when it designed, manufactured and sold the product.

36. The risks of the Physiomesh design significantly outweigh any benefits that Defendants contend could be associated with the product's design. The multi-layer coating, which is not used in any other hernia mesh product sold in the United States, prevents tissue from incorporating in to the mesh, leading to encapsulation, deformation, scarification and contraction, migration, erosion and rejection. The impermeable multi-layer coating lead to seroma formation, and provides a breeding ground for infection and protects bacteria from being eliminated by the body's natural immune response.

37. The Physiomesh device implanted in Plaintiff Sheri James was used in a reasonably foreseeable manner, but failed to perform as an ordinary consumer would expect.

38. The multi-layer coating of the Physiomesh, which was marketed, promoted and intended as a barrier against adhesion to the internal organs, as 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 in the Physiomesh will inevitably adhere to and can erode into and through 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.

39. 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 the Physiomesh, polypropylene mesh is unreasonably susceptible to adhesion, bowel perforation or erosion, fistula formation and bowel strangulation or hernia incarceration, seroma formation, infection and other injuries.

40. The polypropylene mesh used in the Physiomesh device was insufficient in strength to withstand the internal forces of the abdomen after implantation, which made the device susceptible to deformation and rupture.

41. 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.

42. Physiomesh was designed and intended for intra-peritoneal implantation, which involved the product being implanted in contact with the intestines and/or other internal organs which unnecessarily increased the risk of adhesion, erosion, fistula formation, seroma formation, infection and other injuries.

43. At the time the Physiomesh was implanted in Plaintiff Sheri James, there were safer feasible alternative designs for hernia mesh products that would have prevented the injuries he suffered.

44. 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 the product.

45. The Physiomesh implanted in Plaintiff Sheri James failed to reasonably perform as intended, and had 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.

46. As a direct and proximate result of the defective and unreasonably dangerous condition of the product, Plaintiff sSheri James suffered injuries and damages as summarized herein.

COUNT II

Strict Product Liability: Failure to Warn

47. Plaintiffs incorporate herein by reference the allegations in paragraphs 12 through 46 as if fully set forth herein.

48. At the time the Physiomesh was implanted in Plaintiff Sheri James' 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.

49. Defendants expected and intended that Physiomesh product to reach users such as Plaintiff Sheri James in the condition in which the product was sold.

50. Plaintiff Sheri James 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.

51. 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 of 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.

52. 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, intestinal obstruction, failure of repair/hernia recurrence, hernia incarceration or strangulation, infection, seroma, deformation or rupture of the mesh.

53. Defendants failed to adequately train or warn Plaintiff Sheri James 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.

54. Defendants failed to adequately train or warn Plaintiff Sheri James 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 and/or require significant and ongoing medical treatment for complications.

55. Defendants represented to physicians, including Plaintiff Sheri James' 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 in-growth, 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 temporary adhesion barrier, and when the coating inevitably degraded, the exposed polypropylene would become adhered to the organs or tissue and would erode through adjacent tissue or organs.

56. Defendants failed to warn Plaintiff Sheri James or her physicians that Physiomesh created an increased risk of immunologic and foreign body response, fluid collection, seroma and infection that would necessitate the removal of the Physiomesh device and further necessitate future and ongoing medical treatment including additional invasive surgery.

57. 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.

58. If Plaintiff Sheri James 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 Physiomesh in Plaintiff.

59. As a direct and proximate result of the inadequate and defective warnings and instructions associated with Physiomesh, Plaintiff Sheri James suffered injuries and damages as summarized herein.

COUNT III

Negligence

60. Plaintiffs incorporate herein by reference the allegations of paragraphs 12 through 59 as if fully set forth herein.

61. Defendants had a duty to use reasonable care in designing, testing, inspecting, manufacturing, packaging, labeling, marketing, distributing, training and preparing appropriate written instructions and warning for Physiomesh, but failed to do so.

62. 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 Sheri James and Plaintiff's physician were unaware of the dangers and defects inherent with the Physiomesh.

63. As a direct and proximate result of Defendants' negligence in designing, testing, inspecting, manufacturing, packaging, labeling, marketing, distributing, training and preparing written instruction and warning for Physiomesh, Plaintiff Sheri James suffered injuries and damages as summarized herein.

COUNT IV

Loss of Consortium

64. Plaintiffs incorporate herein by reference the allegations in paragraphs 12 through 63 as if fully set forth herein.

65. As a direct and proximate result of the Defendants' negligence and conduct as detailed above, Plaintiff Alfred James was caused to lose the consortium and society of the Plaintiff's spouse, Sheri James.

COUNT V

Punitive Damages

66. Plaintiffs incorporate herein by reference the allegations in paragraphs 12 through 65 as if fully set forth herein.

67. Defendants failed to adequately test and study the Physiomesh to determine and ensure that the product was safe and effective prior to releasing the product for sale for permanent human implantation, and Defendants continued to manufacture and sell Physiomesh after obtaining knowledge and information that the product was defective and unreasonably unsafe. Even though Defendants have other hernia repair mesh devices that do not present the same risks as Physiomesh, Defendants developed, designed and sold Physiomesh because the Physiomesh has a significantly higher profit margin than other hernia repair products. 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, recklessly and without consideration for the health and welfare of Plaintiff and the general public failed to avoid those consequences, and in doing so, Defendants acted intentionally, maliciously and recklessly with regard to the safety of those persons including Plaintiff, who it was foreseeable would be harmed by the Physiomesh product. Defendants intentional, malicious and reckless conduct as described herein justifies the imposition of punitive damages in an amount to deter Defendants from engaging in such conduct in the future.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs demand judgment in her favor and seeks the following relief against Defendants:

A. Compensatory damages in excess of $75,000, exclusive of interest and costs;

B. Costs of suit;

C. Pre-judgment and post-judgment interest;

D. Punitive damages; and

E. Such other relief as this Court deems just and proper under the circumstances

JURY DEMAND

Plaintiffs demand trial by jury on all issues so triable.

Dated: 6/29/2017

By: _____

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JS 44 (Rev 09/10)

UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA

CIVIL COVER SHEET

This automated JS-44 conforms generally to the manual JS-44 approved by the Judicial Conference of the United States in September 1974. The data is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. The information contained herein neither replaces nor supplements the filing and service of pleadings or other papers as required by law.

Plaintiff(s):

First Listed Plaintiff:
Plaintiff Sheri Anne James ;
1 Citizen of This State;
County of Residence: Duval County

Additional Plaintiff(s):
Plaintiff Alfred George James ;
1 Citizen of This State;

Defendant(s):

First Listed Defendant:
Johnson & Johnson ;
5 Incorporated and Principal Place of Business in Another State; New Jersey
County of Residence: Outside This District

Additional Defendants(s):
Ethicon, Inc. ;
5 Incorporated and Principal Place of Business in Another State; New Jersey

County Where Claim For Relief Arose: Duval County

Plaintiff's Attorney(s):

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Defendant's Attorney(s):

Basis of Jurisdiction: 4. Diversity of Citizenship

Citizenship of Principal Parties (Diversity Cases Only)

Plaintiff: 1 Citizen of This State

Defendant: 5 Incorporated and Principal Place of Business in Another State

Origin: 1. Original Proceeding

Nature of Suit: 365 Other Personal Injury Product Liability
Cause of Action: 28 U.S.C. 1332
Requested in Complaint

Class Action: Not filed as a Class Action

Monetary Demand (in Thousands): >$75,000

Jury Demand: Yes

Related Cases: Is NOT a refiling of a previously dismissed action

JAX024537 $400 / 39 JRK

Signature: /s/ Joseph A Osborne

Date: 6/29/2017

If any of this information is incorrect, please close this window and go back to the Civil Cover Sheet Input form to make the correction and generate the updated JS44. Once corrected, print this form, sign and date it, and submit it with your new civil action.