UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA

JOANNE QUINN,

Plaintiff,

v.

ETHICON, INC., a New Jersey Corporation and JOHNSON & JOHNSON, a New Jersey Corporation

Defendants.
_____/

CASE NO.: 6:16-CV-1663-ORL-40-DAB

JUDGE:

COMPLAINT AND DEMAND FOR JURY TRIAL

Plaintiff, JOANNE QUINN, by and through their undersigned counsel, sue Defendants, ETHICON, INC. and JOHNSON & JOHNSON and alleges as follows:

JURISDICTION, VENUE AND IDENTIFICATION OF PARTIES

1. This is an action for monetary damages in excess of Seventy-Five Thousand Dollars ($75,000).

2. The parties are citizens of different states and subject matter jurisdiction is proper in this Court pursuant to 28 U.S.C. §1332.

3. Plaintiff, JOANNE QUINN, is a resident of Brevard County, Florida.

4. Defendant, JOHNSON & JOHNSON is a New Jersey corporation with its corporate headquarters located in New Jersey. JOHNSON & JOHNSON is not registered to do business with the Florida Secretary of State, but may be served through its chief executive officer, Alex Gorsky, at One Johnson & Johnson Plaza, New Brunswick, NJ 08993.

5. Defendant, ETHICON, INC. is a New Jersey corporation with its corporate headquarters in New Jersey. ETHICON is not registered to do business with the Florida Secretary of State, but may be served through its officer Daniel G. Wildman at Route 22 West, Somerville, NJ 08876.

6. Defendants JOHNSON & JOHNSON and ETHICON, INC. are subject to *in personam* jurisdiction in the U.S. District Court for the Middle District of Florida because they placed a defective Product in the stream of commerce and that Product caused personal injuries to Plaintiff while she was residing in the State of Florida.

FACTUAL ALLEGATIONS

7. Defendants designed, manufactured, marketed, packaged, labeled and sold medical devices, including a medical device known as PHYSIOMESH™ flexible composite mesh for the repair of inguinal and incisional hernias.

8. On or about May 30, 2014, Plaintiff JOANNE QUINN was treated at Holmes Regional Hospital in Melbourne, Florida for repair of incisional hernias.

9. The surgeon, Emran Imami, M.D. used and implanted within JOANNE QUINN, ETHICON PHYSIOMESH™ hernia mesh, Product Code PHY2025V, (hereinafter "PHYSIOMESH" or "Product") which was designed, manufactured, tested, trained, marketed, promoted, packaged, labeled, and/or sold by the Defendants.

10. Plaintiff JOANNE QUINN's condition was not remedied by the procedure on May 30, 2014. In fact, her condition became steadily worse with persistent abdominal pain, diminished bowel motility and bowel obstruction.

11. On July 6, 2015, Plaintiff JOANNE QUINN underwent exploratory laparotomy, and extensive lysis of adhesions to remedy the complications caused by PHYSIOMESH. This surgery was performed by George Nassif, D.O. at Florida Hospital in Orlando, Florida.

12. Due to the severe adhesions to the bowels and abdominal wall caused by the defective PHYSIOMESH, Dr. Nassif ended up spending over two hours during the surgery to remove the defective PHYSIOMESH but was unable to remove all of the offending material.

13. Plaintiff JOANNE QUINN would not have agreed to the implantation of the PHYSIOMESH Product had she known of the potential complications.

14. As a result of these health complications caused by the implantation of the PHSYIOMESH Product, Plaintiff JOANNE QUINN has suffered and will continue to suffer pain and medical complications for the remainder of her life.

15. Plaintiff was implanted with a Product designed, manufactured, marketed, packaged, labeled sold and placed in the stream of commerce by Defendants.

16. Due to defective design, defective manufacturing, defective marketing, and negligence by Defendants, the Product has caused JOANNE QUINN severe and permanent bodily injuries and significant mental and physical pain and suffering, and economic loss.

17. The Product has numerous defects that create a high risk of unreasonable and dangerous injuries and side effects with severe permanent adverse health consequences. These defects include, but are not limited to the following:

a. The material used in the Product is not inert and therefore reacts to human tissues and /or other naturally occurring human bodily contents adversely affecting patient health;

b. The mesh material harbors infections that adversely affect human tissues and patient health;

c. The Product and mesh components migrate from the location of their implantation, adversely affecting tissues and patient health;

d. The Product and mesh components abrades tissues adversely affecting patient health;

e. The Product and the mesh components regularly fail to perform the purpose of their implantation such that the patient requires removal of the Product and repeated treatment and surgery.

f. Due to the various defects, the Product and the Product's mesh components regularly cause significant injury to patients such that the Product must be removed, resulting in additional surgery.

g. The Product and the Product's mesh components become embedded in human tissue over time such that when removal is required due its various defects, the removal causes damage to organs and tissues, adversely affecting patient health.

h. The Product is defective in shape, composition, weight, physical properties, chemical properties and mechanical properties and inappropriately designed and engineered for use in hernia repair.

18. Because of its numerous defects, the Product creates an unreasonable risk of injury and other adverse health consequences for patients, including, but not limited to, severe and chronic pain, infection, hernia recurrence, adhesions, intestinal blockage, mesh migration, mesh contraction and repeated surgeries.

19. Prior to the time that the Product was implanted into Plaintiff, Defendants were aware of numerous defects in the Product and its mesh components, including but not limited to the defects and unreasonable risks identified above.

20. Defendants manufactured, marketed and distributed the Product with the intent that it would be implanted in patients such as Plaintiff JOANNE QUINN.

21. Defendants were aware that implanting the Product in patients was likely to cause injury and harm to patients into whom the Product was implanted. Alternatively, Defendants failed to exercise reasonable care in determining the risks and potential adverse consequences of implanting the Product into patients.

22. Defendants made public statements in the form of written Product description, Product labels, promotional materials and other materials that asserted that implanting the Product in patients was safe and would not cause harm to patients.

23. These statements were made with the intent that medical professionals and members of the public would rely upon them, with the intent that members of the public would pay for the Product and that the Product would be implanted in patients.

24. When Defendants made these statements they knew that the statements were inaccurate. Alternatively, when Defendants made these statements they should have known the statements were inaccurate.

25. Representatives of Defendants also made statements to numerous individuals, including medical professionals, that implanting the Product in patients was safe and would not cause harm to patients. When Defendants' representatives made these statements, they knew that the statements were inaccurate. Alternatively, when Defendants' representatives made these statements, Defendants should have known these statements were inaccurate.

26. Defendants knowingly and deliberately made material representations to the Food and Drug Administration concerning the design, manufacture, safety, and efficacy of the Product.

27. Before Plaintiff JOANNE QUINN suffered the injuries complained of herein, Defendants were on notice of numerous bodily injuries caused by the Product, and based thereon, Defendants knew or should have known that the Product caused an unreasonably high rate of failure and injury to patients implanted with the Product.

28. Even though the Defendants knew or should have known that the Product created a foreseeable and unreasonable risk of harm to those patients it was implanted, Defendants continued to market the Product in the United States.

29. Defendants have sold thousands of the Product in the United States.

30. Defendants did not provide adequate warning or information as to the risks the Product carries including an unreasonably high rate of failure resulting in injury to bodily organs and corrective surgeries.

31. Plaintiff became obligated to retain the undersigned to pursue this action to compensate her for the damages caused to her by the Defendants and has obligated herself to pay the undersigned reasonable attorney's fees.

32. All conditions precedent to the filing of this action have been met or have been waived.

COUNT I - STRICT LIABILITY - DEFECTIVE MANUFACTURE

33. Plaintiff re-alleges and re-adopts the allegations set forth in paragraphs 1-32 above as if fully set forth herein, and further alleges:

34. One or more of the defects in the Product is the result of improper or incorrect manufacturing processes that result in the Product as manufactured deviating from its intended design.

35. The defects caused by manufacturing defect rendered the Product unreasonably dangerous to consumers and to Plaintiff.

36. The defects in the Product implanted in Plaintiff existed from its manufacture, therefore the defects were present when it left the possession and control of Defendants.

37. As a direct and proximate result of the defective manufacture of the Product, Plaintiff has suffered serious bodily injury, mental and physical pain and suffering, and has incurred economic loss.

WHEREFORE, Plaintiff, JOANNE QUINN demands judgment against Defendants for Strict Liability as to Defective Manufacture of the Product, for damages, injury, mental and physical pain and suffering and economic loss and further demands a trial by jury on all issues so triable.

COUNT II - STRICT LIABILITY - DEFECTIVE DESIGN

38. Plaintiff re-alleges and re-adopts the allegations set forth in paragraphs 1-37 above as if fully set forth herein, and further alleges:

39. The Product is unreasonably dangerous and dangerously defective as designed because as designed it has numerous defects that adversely affect patient health.

40. The defects in the Product existed from its inception, therefore the defects were present when it left the possession and control of Defendants.

41. The foreseeable risks of harm posed by the design of the Product could have been reduced and/or avoided by the adoption of a reasonable alternative design by Defendants, and the

failure of Defendants to adopt a safer alternative design rendered the Product unreasonably unsafe.

42. As a direct and proximate result of the defective design of the Product, Plaintiff has suffered serious bodily injury, mental and physical pain and suffering, and has incurred economic loss.

WHEREFORE, Plaintiff, JOANNE QUINN demands judgment against Defendants for Strict Liability as to Defective Design of the Product, for damages, injury, mental and physical pain and suffering and economic loss and further demands a trial by jury on all issues so triable.

COUNT III - STRICT LIABILITY - MARKETING DEFECT

43. Plaintiff re-alleges and re-adopts the allegations set forth in paragraphs 1-42 above as if fully set forth herein, and further alleges:

44. The Product was defective by reason of failure of Defendants to provide adequate warnings or instructions.

45. Defendants failed to provide such warning or instruction that a manufacturer exercising reasonable care would have provided to physicians who implanted the Product or to those patients who had been implanted with the Product, concerning the following risks, of which Defendants had actual or constructive knowledge at the time the Product left the Defendants' control:

a. the high failure rate of the Product;

b. the high rate of infections and abscesses caused by the Product;

c. the high rate of abdominal erosions and extrusions caused by the Product;

d. the high rate of chronic pain caused by the Product;

e. the high rate of migration of the Product;

f. the high rate of bowel obstruction caused by the Product;

g. the high rate of diminished bowel motility caused by the Product;

h. the high rate of corrective surgeries caused by the defective Product;

e. the high rate of patient injuries caused by the Product's migration, decomposition, infections, abscesses, erosion, extrusion, adhesion to bodily organs, and interference with normal bodily functions.

46. After receiving notice of numerous bodily injuries resulting from the Product, Defendants failed to timely provide such post-marketing or post-sale warnings or instructions that a manufacturer exercising reasonable care should have provided to physicians who implanted the Product or the persons who had been implanted with the Product that the Product was causing an unreasonably high rate of injury to patients and unreasonably high rate of corrective surgeries required to treat PHYSIOMESH™ related complications.

47. Furthermore Defendants failed to provide post-marketing or post-sale warnings or instructions concerning the necessity to remove the Product from the patient's body in the event of Product failure, migration, decomposition, adhesions to organs, infections, abscesses, erosion, or extrusion.

48. As a direct and proximate result of the inadequate warnings and instructions by Defendants, both at the time of marketing and after the sale of the Product, Plaintiff has suffered serious bodily injury, mental and physical pain and suffering, and has incurred economic loss.

WHEREFORE, Plaintiff, JOANNE QUINN demands judgment against Defendants for Strict Liability as to Defective Marketing of the Product, for damages, injury, mental and physical pain and suffering and economic loss and further demands a trial by jury on all issues so triable.

COUNT IV - NEGLIGENCE

49. Plaint Plaintiff re-alleges and re-adopts the allegations set forth in paragraphs 1-48 above as if fully set forth herein, and further alleges:

50. Defendants had a duty to Plaintiff JOANNE QUINN and other consumers to exercise reasonable care in designing, testing, manufacturing, labeling, packaging and selling or disturbing the Product.

51. Defendants failed to exercise ordinary and reasonable care in designing, manufacturing, testing, marketing, labeling, packaging, selling and/or distributing the Product and Defendants negligently failed to provide adequate warnings and instructions to JOANNE QUINN and/or to her physician regarding the Product. Further, Defendants failed to exercise ordinary and reasonable care by failing to warn patients and their physicians of the an unreasonably high rate of injury to patients and unreasonably high rate of corrective surgeries required to treat PHYSIOMESH™ related complications.

52. As a direct and proximate result of the negligence of Defendants, JOANNE QUINN has suffered serious bodily injury, mental and physical pain and suffering, and has incurred economic loss.

WHEREFORE, Plaintiff, JOANNE QUINN demands judgment against Defendants for Negligence, and for damages, injury, mental and physical pain and suffering and economic loss and further demands a trial by jury on all issues so triable.

COUNT V - BREACH OF EXPRESS WARRANTY

53. Plaintiff re-alleges and re-adopts the allegations set forth in paragraphs 1-52 above as if fully set forth herein, and further alleges:

54. Defendants expressly represented to Plaintiff JOANNE QUINN and her medical providers that the PHYSIOMESH™ Product was safe and fit for its intended purposes, that it was of merchantable quality, that it did not produce any dangerous side effects, and that it was adequately tested.

55. The PHYSIOMESH™ Product does not conform to Defendants' express representations because it is not safe, has numerous and serious side effects, and causes severe and permanent injuries, including but not limited to the risk of bowel adhesions, diminished bowel motility, bowel obstruction, chronic abdominal pain, and a high rate of corrective surgeries required to treat PHYSIOMESH™ related complications.

56. At all relevant times, the PHYSIOMESH™ Product did not perform as safely as an ordinary consumer would expect, when used as intended or in a reasonably foreseeable manner.

57. Plaintiff JOANNE QUINN and other consumers relied upon Defendants' express warranties.

58. As a direct and proximate result of Defendants' conduct, Plaintiff JOANNE QUINN suffered medical complications that included but were not limited to pain and suffering, disability, permanent scarring, mental anguish, loss of capacity for enjoyment of life, lost wages, loss of net accumulations, expense of hospitalization, extensive medical and nursing care and treatment in the past and in the future, and aggravations of pre-existing medical conditions.

WHEREFORE, Plaintiff, JOANNE QUINN demands judgment against Defendants for Breach of Express Warranty and for damages, injury, mental and physical pain and suffering and economic loss and further demands a trial by jury on all issues so triable.

COUNT VI - BREACH OF IMPLIED WARRANTY

59. Plaintiff re-alleges and re-adopts the allegations set forth in paragraphs 1-58 above as if fully set forth herein, and further alleges:

60. Defendants designed, manufactured, tested, trained, marketed, promoted, packaged, labeled, and/or sold the PHYSIOMESH™ Product.

61. At all relevant times, Defendants knew of the use for which the PHYSIOMESH™ Product was intended and impliedly warranted the Product to be of merchantable quality and safe and fit for such use.

62. Defendants were aware that consumers, including Plaintiff JOANNE QUINN would use the PHYSIOMESH™ Product for the treatment and repair of inguinal and incisional hernias.

63. Plaintiff JOANNE QUINN and other consumers reasonably relied upon the judgment and sensibility of Defendants to sell the PHYSIOMESH™ Product only if was indeed of merchantable quality and safe and fit for its intended use.

64. Defendants breached their implied warranty to consumers, including Plaintiff JOANNE QUINN; the PHYSIOMESH™ Product was not of merchantable quality or safe and fit for its intended use.

65. Consumers, including Plaintiff JOANNE QUINN, reasonably relied upon Defendants' implied warranty for the PHYSIOMESH™ Product.

66. The PHYSIOMESH™ Product reached consumers without substantial change in the condition in which it was designed, manufactured, tested, trained, marketed, promoted, packaged, labeled, and/or sold by Defendants.

67. As a direct and proximate result of Defendants' conduct, Plaintiff JOANNE QUINN suffered medical complications that included but were not limited to pain and suffering,

disability, permanent scarring, mental anguish, loss of capacity for enjoyment of life, lost wages, loss of net accumulations, expense of hospitalization, extensive medical and nursing care and treatment in the past and in the future, and aggravation of pre-existing medical conditions.

WHEREFORE, Plaintiff JOANNE QUINN demands judgment for damages against Defendants and further demands a trial by jury an all issues so triable.

DEMAND FOR JURY TRIAL

Plaintiff demands a trial by jury on all issues so triable.

Dated this 20 day of September, 2016.

Respectfully submitted by:

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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

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

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
Law Offices of Anna Lonchidis, Esq.
2385 NW Executive Center Dr., Suite 100
Boca Raton, FL 33431
Ph: 561-981-6118

DEFENDANTS

County of Residence of First Listed Defendant New Jersey
(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)*

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

TORTS

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
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury
- ☐ 362 Personal Injury - Medical Malpractice

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
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

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

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
- ☐ 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

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)*:

Brief description of cause:
This is a product liability case of a defective hernia mesh implanted into Plaintiff.

VII. REQUESTED IN COMPLAINT:

☐ CHECK IF THIS IS A CLASS ACTION UNDER RULE 23, F.R.Cv.P. DEMAND $

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

VIII. RELATED CASE(S) IF ANY

(See instructions): JUDGE _____ DOCKET NUMBER _____

DATE
September 20, 2016

SIGNATURE OF ATTORNEY OF RECORD

FOR OFFICE USE ONLY

RECEIPT # AMOUNT APPLYING IFP JUDGE MAG. JUDGE