Attorneys for Plaintiff

UNITED STATES DISTRICT COURT

DISTRICT OF OREGON

PORTLAND DIVISION

MELINDA RALL, an Oregon citizen, Plaintiff, v. **JOHNSON & JOHNSON**, a New Jersey corporation; and **ETHICON, INC.**, a New Jersey corporation; Defendants.	Case No.: _____ **COMPLAINT** Personal Injury; Products Liability; Negligence (28 U.S.C. §1332) **JURY TRIAL DEMANDED**

Comes now Melinda Rall (sometimes hereinafter referred to as "Plaintiff"), by and through undersigned counsel, and brings this action against Defendants Johnson & Johnson and Ethicon, Inc. (hereinafter "Defendants"), and alleges as follows:

Parties

1. Plaintiff Melinda Rall is, and was at all relevant times, a resident of Clackamas County in the State of Oregon and 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 incorporated in the State of New Jersey with its principal place of business in Somerville, New Jersey. Ethicon is a citizen of New Jersey. Ethicon transacts business within the State of Oregon.

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, 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 the Plaintiff for damages suffered by the 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.

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 the 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 the Oregon Long-Arm Statute, Or. R. Civ. Proc. 4. Defendants transact business within the State of Oregon, and Defendants committed tortious acts and omissions in Oregon. Defendants' tortious acts and omissions caused injury to Plaintiff in the State of Oregon. Defendants have

purposefully engaged in the business of developing, manufacturing, publishing information, marketing, distributing, promoting and/or selling, either directly or indirectly, medical devices including Physiomesh products in Oregon, for which they derived significant and regular income. The Defendants reasonably expected that that their defective mesh products, including Physiomesh, would be sold and implanted in Oregon.

11. Venue is proper in the District of Oregon pursuant to 28 USC 1391(b)(2) in that a substantial part of the events or omissions giving rise to the claim occurred in this District. Defendants designed, manufactured, marketed, and/or sold the subject Physiomesh in this District, received substantial compensation and profits from sales of Physiomesh in this District, and/or made material omissions and misrepresentations and breached warranties in this District.

Facts Common To All Counts

12. On or about September 3, 2015, Plaintiff Melinda Rall underwent surgery to implant a 25cm x 35cm Physiomesh device (PHY2535V) at OSV Providence St. Vincent Medical Center in Portland, Oregon, to attempt repair of a recurrent incisional hernia.

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

14. Subsequent to the implantation of the Physiomesh device, Plaintiff began to have severe pain and significant bleeding among other symptoms.

15. On or about September 4, 2015, the Plaintiff underwent wound exploration with evacuation of hematoma and cauterization of bleeding point.

16. On or about October 27, 2015, the Plaintiff was readmitted and underwent a CT guided aspiration of anterior abdominal wall seroma.

17. On or about September 28, 2016, Plaintiff was readmitted to OSV Providence St. Vincent Medical Center. The Plaintiff was found to have massive adherence of multiple loops of small bowel to the deep surface of her Physiomesh. Plaintiff underwent approximately two to three hours of dissection to free up enough bowel so that the Physiomesh implanted in Plaintiff could be removed. The disrupted portion of the Physiomesh was then excised and a new mesh was placed to repair the recurrent incisional hernia.

18. On or about February 24, 2017, Plaintiff was readmitted due to a recurrent incisional hernia, continued pain, nausea, and a bulge in her upper left quadrant. The Physiomesh implanted in Plaintiff appeared to have disintegrated or completely dissolved in the area of the hernia. The Physiomesh implanted in Plaintiff was also found to be disrupted with bowel bulging through. Plaintiff's Physiomesh was removed from the surface of the underlying bowel.

19. 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.

20. 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 the Plaintiff.

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

22. 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.

23. 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 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.

24. 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.

25. 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.

26. 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.

27. 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.

28. 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.

29. 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.

30. The manufacturing and design defects associated with the Physiomesh were directly and proximately related to the injuries suffered by the Plaintiff.

31. Neither the Plaintiff Melinda Rall nor her implanting physician were adequately warned or informed by Defendants of the defective and dangerous nature of Physiomesh. Moreover, neither the 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.

32. The Physiomesh implanted in Plaintiff Melinda Rall failed to reasonably perform as intended. The mesh failed, causing serious injury and had to be surgically revised via invasive surgery.

33. In May of 2016, Defendants issued an "Urgent: Field Safety Notice" relating to its Physiomesh Flexible Composite Mesh, the same product implanted in the Plaintiff, and sent such notification to hospitals and medical providers in various countries worldwide. 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. 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.

COUNT I
Strict Product Liability: Defective Design

34. Plaintiff incorporates herein by reference the allegations in all prior paragraphs as if fully set forth herein.

35. At the time the Physiomesh was implanted in the Plaintiff Melinda Rall'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.

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

37. The implantation of Physiomesh in the 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.

38. 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 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.

39. 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 in-growth 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 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.

40. 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.

41. 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 rupture and/or deformation.

42. 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.

43. 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.

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

45. 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.

46. The Physiomesh implanted in the Plaintiff failed to reasonably perform as intended, and had to be surgically revised necessitating further invasive surgery to repair the small bowel and hernia, and thus provided no benefit to her.

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

COUNT II
Strict Product Liability: Manufacturing Defect

48. Plaintiff incorporates herein by reference the allegations in all prior paragraphs as if fully set forth herein.

49. 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.

50. 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.

51. 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, supplied, distributed sold and/or otherwise placed in the stream of commerce.

52. 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.

53. 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.

54. The defective and unreasonably dangerous condition of the Physiomesh product was a proximate cause of damages and injuries suffered by Plaintiff.

55. 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.

COUNT III
Strict Product Liability: Failure to Warn

56. Plaintiff incorporates herein by reference the allegations in all prior paragraphs as if fully set forth herein.

57. At the time the Physiomesh was implanted in the 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.

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

59. The 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.

60. 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.

61. The Defendants' Instructions for Use for the Physiomesh failed to adequately warn the 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, or deformation or rupture of the mesh.

62. Defendants failed to adequately train or warn the 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.

63. Defendants failed to adequately train or warn the 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.

64. Defendants represented to physicians, including the 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 and would erode through adjacent tissue or organs.

65. 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.

66. If the 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, the 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 the Plaintiff.

67. As a direct and proximate result of the inadequate and defective warnings and instructions, the Plaintiff suffered injuries and damages as summarized herein.

COUNT IV
Negligence

68. Plaintiff incorporates herein by reference the allegations in all prior paragraphs as if fully set forth herein.

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

70. 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 the Plaintiff and the Plaintiff's physicians were unaware of the dangers and defects inherent in the Physiomesh.

71. As a direct and proximate result of Defendants' negligence in designing, testing, inspecting, manufacturing, packaging, labeling, marketing, distributing, training and preparing written instructions and warnings for Physiomesh, the Plaintiff suffered injuries and damages as summarized herein.

COUNT V
Breach of Express Warranty

72. Plaintiff incorporates herein by reference the allegations in all prior paragraphs as if fully set forth herein.

73. At all relevant and material times, Defendants manufactured, marketed, sold, distributed and otherwise placed in to the stream of commerce Physiomesh.

74. 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.

75. 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 hernias such as Plaintiff.

76. 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.

77. 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.

78. 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:

a. Defendants represented to Plaintiff and her physicians and healthcare providers through labeling, advertising, marketing 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.

79. 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.

80. 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 and Fitness

81. Plaintiff incorporates herein by reference the allegations in all prior paragraphs as if fully set forth herein.

82. 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.

83. 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.

84. 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.

85. 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.

86. 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
Misrepresentation

87. Plaintiff incorporates herein by reference the allegations in all prior paragraphs as if fully set forth herein.

88. Defendants misrepresented the mechanical soundness and reliability of Physiomesh devices to the general public through promotional and marketing campaigns. For example, Defendants' Instruction for Use provided with the Physiomesh expressly understated and misstated the risks known to be associated specifically with the Physiomesh by stating that potential adverse reactions are those typically associated with surgically implantable materials. But, 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.

89. Defendants continued this misrepresentation for an extended period of time, without disclosing material information regarding the defective, hazardous, and harmful complications relating to Physiomesh devices.

90. Defendants took advantage of the limited ability Plaintiff had to discover Defendants' strategic and intentional concealment of the defects in their Physiomesh devices.

91. Defendants concealed these design and/or manufacturing defects from the public by withholding information pertaining to the inherent design and/or manufacturing defects and high risks relating to the Physiomesh devices, and presenting the devices as sound and reliable.

92. Defendants' intentional misrepresentations and omissions were made willfully, wantonly, or recklessly to Plaintiff, the public at large, and Plaintiff's physicians and other health care providers to induce the purchase of Defendants' Physiomesh devices over other hernia mesh repair systems on the market.

93. Defendants knew or should have known of the high risk the Plaintiffs would encounter by unwillingly agreeing to have implanted one of Defendants' defectively designed and/or manufactured Physiomesh devices.

94. As a direct and proximate result of Defendant's negligence, Plaintiff suffered injuries and damages as summarized herein.

COUNT VIII
Punitive Damages

95. Plaintiff incorporates herein by reference the allegations in all prior paragraphs as if fully set forth herein.

96. 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.

97. Defendants' conduct in continuing to market, sell and distribute Physiomesh after obtaining knowledge it was failing and not performing as represented and intended, showed complete indifference to or a conscious disregard for the safety of others.

98. 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.

99. Defendants' willful, deliberate and complete indifference to or conscious disregard for the safety of others justifies an award of additional damages for aggravating circumstances in such a sum which will serve to deter Defendants and others from similar conduct in the future.

Prayer for Relief

WHEREFORE, as a result of the acts and omissions and conduct of Defendants set forth herein, the Plaintiff Melinda Rall is entitled to recover the following:

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 in an amount to be determined by the trier of fact as provided by law and to be supported by the evidence at trial; and

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

Jury Trial Demand

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: August 22, 2017.

[redacted]

Attorneys for Plaintiff

JS 44 (Rev. 06/17)

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. *(SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)*

I. (a) PLAINTIFFS

Melinda Rall

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

(c) Attorneys
[redacted]

DEFENDANTS

JOHNSON & JOHNSON, and
ETHICON, INC.

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

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

Attorneys *(If Known)*

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

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

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

(For Diversity Cases Only)

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

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

Click here for: Nature 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

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
- ❒ 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

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 - Transfer | ❒ 8 Multidistrict Litigation - Direct File

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing ***(Do not cite jurisdictional statutes unless diversity)***:
28 U.S.C. Sec 1332

Brief description of cause:
Product liability; Personal Injury based on Surgical Hernia Mesh Defect

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 Hon. Richard W. Story DOCKET NUMBER 1:17-md-2782

DATE
08/22/2017

SIGNATURE OF ATTORNEY OF RECORD
[redacted]

FOR OFFICE USE ONLY

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