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FRANKLIN C. ROBINSON,  
  
Plaintiff,

SUPERIOR COURT OF NEW JERSEY  
LAW DIVISION  
BERGEN COUNTY

v.

Docket No.:

JOHNSON & JOHNSON and  
ETHICON, INC.,

Defendants.

**CIVIL ACTION**

**COMPLAINT**

**JURY TRIAL DEMANDED**

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**COMPLAINT**

Plaintiff Franklin C. Robinson (“Franklin Robinson”), by and through his counsel, hereby  
sues JOHNSON & JOHNSON (“J&J”), a New Jersey corporation; and ETHICON, INC.  
(“Ethicon”), a New Jersey corporation (collectively “Defendants”).

**NATURE OF THE ACTION**

1. This is an action for strict products liability, failure to warn, and defective design,  
brought by Plaintiff Franklin Robinson for injuries arising out of the Physiomesh Flexible  
Composite Mesh (“Physiomesh” or “Ethicon Multi-Layered Hernia Mesh”) to treat an umbilical  
hernia from which he suffered.

2. Defendants J&J and Ethicon designed, manufactured, and supplied to doctors  
multi-layered hernia mesh, including the Ethicon Multi-Layered Hernia Mesh.

3. Ethicon Multi-Layered Hernia Mesh created an unreasonable risk of harm to Plaintiff Franklin Robinson .

4. The unreasonable risk of pain, dense adhesion formation, bowel complications, mesh shrinkage, hernia recurrence, seroma and fistula formation, and infection, whether from a prolonged and pronounced inflammatory response caused by the multiple layers, degradation of polymers due to exposure to gamma irradiation, non-conforming subcomponents, or some other mechanism, renders Ethicon Multi-Layered Hernia Mesh a defective product.

5. The selection and implantation of the Ethicon Multi-Layered Hernia Mesh by Plaintiff's surgeons were a result of the misinformation, marketing, sales, promotion, and direction by Defendants.

### **JURISDICTION AND VENUE**

6. This is a lawsuit over defective hernia mesh designed, marketed, manufactured, promoted, and sold within New Jersey and the United States by Defendant Ethicon and its parent company J&J.

7. Plaintiff Franklin Robinson currently resides in Brooklyn, NY and is a citizen and resident of New York. Plaintiff underwent hernia repair surgery on or about June 22, 2015 in Woodhull Medical and Mental Health Center. At that time, the Physiomesh that Defendants manufactured, distributed, and warranted was implanted into Plaintiff. Plaintiff Franklin Robinson's surgeon, medical staff, and other healthcare providers met or exceeded the standard of care applicable to the hernia surgery.

8. Defendant 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.

9. 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.” J&J charged the Ethicon Franchise with the design, development, promotion, marketing, testing, training, distribution and sale of the Physiomes, 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.

10. Defendant Ethicon is a wholly owned subsidiary of Defendant J&J. Defendant Ethicon is a corporation incorporated in the State of New Jersey with its principal place of business in Somerville, New Jersey. Defendants conduct business in every county in this State.

11. Defendant Ethicon is a medical device company involved in the research, development, testing, manufacture, production, marketing, promotion and/or sale of medical devices including Ethicon Multi-Layered Hernia Mesh.

12. J&J, directly and/or through the actions of Ethicon, has at all pertinent times been responsible for the research, development, testing, manufacture, production, marketing, promotion, distribution and/or sale of Ethicon Multi-Layered Hernia Mesh.

13. At all relevant times, Defendants either directly, or through their agents, apparent agents, servants or employees sold, distributed and marketed the defective Ethicon Multi-Layered Hernia Mesh in the State of New Jersey. Defendants derive substantial revenue from hernia mesh products used or implanted in the State of New Jersey. As such, Defendants expected or should

have expected that their business activities could or would subject them to legal action in the State of New Jersey.

14. All Defendants were also involved in the business of monitoring and reporting adverse events concerning the Ethicon Multi-Layered Hernia Mesh, and having a role in the decision process and response of Defendants, if any, related to these adverse events.

15. The Ethicon Multi-Layered Hernia Mesh Defendants are subject to jurisdiction within the State of New Jersey and this Court because:

- a. Defendants are engaged in substantial and not isolated business activity within the State of New Jersey, Bergen County.
- b. Defendants' hernia mesh products, including the subject Physiomesh, was designed, manufactured, and placed into the stream of commerce in State of New Jersey by the Defendants.
- c. Defendants maintain an office or agency within the State of New Jersey.
- d. Upon information and belief, at all relevant times, Defendants committed tortious acts within the State of New Jersey out of which these causes of action arise.

16. At all times relevant hereto, the Defendants developed, manufactured, advertised, promoted, marketed, sold and/or distributed the defective Ethicon Multi-Layered Hernia Mesh throughout the United States, including within the State of New Jersey and specifically including to Plaintiff Franklin Robinson's implanting physician or their practice group, or to the hospital where the Ethicon Multi-Layered Hernia Mesh was implanted.

17. Plaintiff has reviewed potential legal claims and causes of action against Defendants and has chosen to only pursue state-law claims. Any reference to any federal agency, regulation or rule is stated solely as background information and does not raise a federal question. Defendants J&J and Ethicon are both New Jersey corporations and both maintained their principal

place of Business in New Jersey. Accordingly, Plaintiff contends that this Court may rightfully exercise jurisdiction, and venue is proper in this case.

18. Defendants designed, manufactured, fabricated, marketed, packaged, advertised, and sold the Ethicon Multi-Layered Hernia Mesh throughout the world, including in Bergen County, State of New Jersey.

19. Ethicon knowingly markets to, and derives income from, patients in the State of New Jersey from the sale of Ethicon Multi-Layered Hernia Mesh.

20. This is an action for damages in excess of Fifteen Thousand Dollars (\$15,000.00), exclusive of interest and cost.

### **PHYSIOMESH HISTORY**

21. Defendants were the designers, manufacturers, distributors and suppliers of the Physiomesh at all material times.

22. Defendants warranted the Physiomesh and placed the device into the United States stream of commerce.

23. Physiomesh has a unique multi-layer design incorporating five (5) distinct layers: two layers of poliglecaprone-25 (“Monocryl”) film covering two underlying layers of polydioxanone film (“PDS”), which in turn coat a polypropylene mesh. This design is not used in any other hernia repair product sold in the United States.

24. 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.

25. When implanted intraperitoneally, which involves the abdomen being inflated and then deflated, and the product being implanted in contact with the intestines and/or other internal organs, the Physiomesh design unnecessarily increases the risk of mesh deformation, adhesion, erosion, fistula formation, and other injuries. When implanted using an open procedure, the Physiomesh design provides no benefit, and instead increases the risks associated with the product.

26. The multi-layer coating of the Defendants' Physiomesh is not biocompatible, which causes or contributes to complications such as delayed wound healing, inflammation, foreign body response, rejection, infection, and other complications.

27. 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.

28. The multi-layer Physiomesh coating provides a breeding ground for bacteria, in which the bacteria cannot be eliminated by the body's immune response. Thus, infection is allowed to proliferate.

29. Defendants knew or should have known of the lack of biocompatibility of the multi-layer coating of the Physiomesh prior to introducing it into the stream of commerce.

30. The polypropylene material used in the Physiomesh is unreasonably susceptible to in vivo oxidative degradation, which causes or exacerbates excessive inflammation and adverse foreign body reaction, leading to shrinkage, scarification, pain and mesh deformation.

31. The polypropylene mesh portion of the Physiomesh lacked sufficient strength to withstand normal abdominal forces, which results in recurrent hernia formation and/or rupture and deformation of the mesh itself.

32. One of the purported benefits of the Physiomesh design was implantation using laparoscopy, which involves minimally invasive surgery. However, treatment of complications associated with Physiomesh often requires open surgery, thus obviating any purported benefit from the intended laparoscopic implantation technique.

33. In May 2016, Defendants issued an “Urgent: Field Safety Notice” relating to the Physiomesh, the same product implanted in Plaintiff, and sent such notification to hospitals and medical providers in various countries worldwide. In this Urgent Field Safety Notice, Defendants advise these providers of “a voluntary product recall,” citing two international device registries which reported data reflecting recurrence/reoperation rates being higher than that observed from a data set relating to patient outcomes after being implanted with other mesh. Ethicon’s “Urgent: Field Safety Notice” stated Ethicon believed the higher rates to be a multifactorial issue, including possible product characteristics. However, in the United States, Defendants failed to issue a nationwide recall, opting instead to simply remove the product from the market and cease further sale within the United States. Ethicon also knew or had reason to know that those implanted with the Physiomesh were still at risk for adverse events since Ethicon stated in the Field Safety Notice that those implanted with Physiomesh should continue to be followed. Despite its knowledge, Ethicon did not issue any warning, caution or instruction to hospitals, physicians or patients regarding the importance of monitoring for potential complications.

**FAILURE TO WARN PHYSICIANS OF THE DANGERS ASSOCIATED  
WITH ETHICON MULTI-LAYERED HERNIA MESH**

35. Before placing Ethicon Multi-Layered Hernia Mesh on the market, Defendants

were required to mitigate risks of the product, including any element of design or sterilization which could render the device ineffective, weaken the structural integrity of the device, or increase or prolong inflammation once the device is implanted, which would result in an increase in adhesion formation, mesh shrinkage, pain, bowel complications, hernia recurrence, and/or the need for early surgical revision in patients-consumers.

36. Defendants designed, manufactured, and marketed the Ethicon Multi-Layered Hernia Mesh, despite long-standing knowledge that the materials utilized in Ethicon Multi-Layered Hernia Mesh would cause dense adhesions, chronic pain, mesh shrinkage, bowel obstructions, and early hernia recurrence.

37. When the multi-layer coating of Ethicon Multi-Layered Hernia Mesh is disrupted and/or degrades, the “naked” polypropylene mesh is exposed to the adjoining tissue and viscera, and can become adhered to organs, causing damage to organs and potential fistula formation.

38. The multi-layer coating of the Ethicon Multi-Layered Hernia Mesh is cytotoxic, immunogenic, and not biocompatible. The coating therefore causes or contributes to complications such as delayed wound healing, inflammation, foreign body response, rejection, infection, and other complications.

39. Defendants knew or should have known of the cytotoxic and immunogenic properties of the multi-layer coating of the Ethicon Multi-Layered Hernia Mesh prior to introducing it into the stream of commerce.

40. The polypropylene mesh portion of the Ethicon Multi-Layered Hernia Mesh was insufficient to withstand normal abdominal forces, resulting in recurrent hernia formation and/or rupture and deformation of the mesh itself.

41. Defendants marketed Ethicon Multi-Layered Hernia Mesh to general surgeons,

hospitals, and group purchasing organizations (GPOs), rather than end-user patients.

42. Defendants had the ability to inform surgeons, hospitals, or GPOs of developing problems or defects related to Ethicon Multi-Layered Hernia Mesh in its devices through e-mail, letter, recalls, warnings in product inserts, and/or through its product representatives, who work directly with the surgeon.

43. The multiple layers of Ethicon Multi-Layered Hernia Mesh increase the intensity and duration of the inflammatory response. That response in turn increases dense adhesion formation from underlying organs to the Ethicon Multi-Layered Hernia Mesh, resulting in bowel complications, mesh contracture, hernia recurrence, increased foreign body reaction, chronic severe pain, and more.

44. The Physiomesh IFU has a section for contraindications, which list “None known.”

45. The Physiomesh IFU has a section for adverse reactions, which list “Potential adverse reactions are those typically associated with surgically implantable materials...” The polypropylene base of Ethicon Multi-Layered Hernia Mesh carries many potential adverse reactions, such as a life-long inflammatory response that other surgically implantable materials do not present. Additionally, the multiple layers of Ethicon Multi-Layered Hernia Mesh further increase the inflammatory response and rate of infection, adhesion formation, chronic pain, seroma formation, fistula formation, hematomas, mesh contracture, hernia recurrence, mesh migration, bowel complications, foreign body response, extrusion, and other additional injuries.

46. Defendants failed to warn that Ethicon Multi-Layered Hernia Mesh creates a solid barrier preventing the body from adequately clearing or transporting fluid, which results in seroma formation, potentiating infections and fistula formation.

47. Defendants never performed any clinical trials and/or studies prior to marketing

Ethicon Multi-Layered Hernia Mesh.

48. Defendants did not fully and/or adequately test the configuration of these new, multi-layered barrier hernia meshes, that were implanted into Plaintiff.

49. Reassurances of device safety were made through direct promotional contact by Defendants' sales representatives and distributors, through word-of-mouth from Defendant's physician/technical consultants, and/or through industry targeted promotional materials.

50. Despite these reassurances, the defective design and manufacture of Ethicon Multi-Layered Hernia Mesh continued to elicit severe and chronic inflammatory responses, resulting in adhesion formation, bowel injuries, mesh contracture, pain, hernia recurrence, infections, seromas, fistulas, erosion, extrusion, and additional complications.

51. Defendants were aware that the Monocryl layer was ineffective at preventing adhesions to the polypropylene; the polypropylene utilized was too weak; the coating on both sides of the mesh would prevent incorporation; the barrier created by the Monocryl layer would prevent fluid clearance; and the multi-layered mesh would contract massively over time. Nonetheless, Defendants employed the design in its Ethicon Multi-Layered Hernia Mesh in a reckless disregard for the safety of patients, including Plaintiff.

52. From the time that Defendants first began selling Ethicon Multi-Layered Hernia Mesh in the United States through today, product labeling and product information failed to contain adequate information, instructions, and warnings concerning the following: implantation of the mesh, specifically its propensity to massively shrink, the increased duration and intensity of inflammation, and the elevated rate of adhesions, bowel complications, chronic pain, hernia recurrence, seroma formation, hematoma formation, fistula formation, erosion, extrusion, infection, and other injuries that occur at a higher rate than other surgically implanted devices.

53. Defendants J&J and Ethicon were responsible for the research, design, development, testing, manufacture, production, marketing, promotion, distribution, and sale of Ethicon Multi-Layered Hernia Mesh, including providing the warnings and instructions concerning the hernia mesh product.

54. Among the intended purposes for which Defendants J&J and Ethicon designed, manufactured, and sold Physiomesh was use by surgeons for hernia repair surgeries. That was the purpose for which the Physiomesh was implanted in Plaintiff Franklin Robinson.

55. Defendants represented to Plaintiff and his physicians that their Physiomesh was a safe and effective product for hernia repair.

56. 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.

#### **USE OF THE PRODUCT**

57. A defectively designed, manufactured, and marketed Physiomesh left the hands of Defendants in its defective condition, delivered into the stream of commerce. Dr. Adedayo Ojo implanted the Proceed Surgical Mesh in Franklin Robinson's abdomen to repair an umbilical hernia on or about June 22, 2015 at Woodhull Medical and Mental Health Center in Brooklyn,

New York. Plaintiff Franklin Robinson was implanted with a 25X20 cm Physiomesh, Cat # PHY2025V, Lot # ML8CTT0Q.

58. As a direct and proximate result of Defendants' defective design, manufacture, marketing, distribution, and/or sale of Ethicon Multi-Layered Hernia Mesh and placing the defective products into the stream of commerce, Plaintiff Franklin Robinson has been injured and damaged as follows:

- a. On or about February 29, 2016 Plaintiff Franklin Robinson underwent partial removal of the Ethicon Physiomesh at The Brooklyn Hospital Center, in Brooklyn, New York, by Dr. Sandeep Sirsi. Upon visualizing the Ethicon Physiomesh, Dr. Sirsi found extensive adhesiolyses.
- b. On or about June 20, 2016 Plaintiff Franklin Robinson again underwent partial removal of the Ethicon Physiomesh at The Brooklyn Hospital Center, in Brooklyn, New York, by Dr. Sandeep Sirsi. Upon visualizing the Ethicon Physiomesh, Dr. Sirsi found extensive adhesiolyses.
- c. Plaintiff Franklin Robinson experienced and/or continues to experience severe pain, nausea, diarrhea, chills, inflammation, loss of appetite, and extreme weight loss which have impaired his activities of daily living.
- d. Plaintiff Franklin Robinson continues to suffer complications as a result of his implantation with the Ethicon Physiomesh.
- e. Plaintiff Franklin Robinson is at a higher risk of severe complications during an abdominal surgery, to the extent that future abdominal operations might not be feasible.

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

60. Neither Plaintiff Franklin Robinson nor his implanting physician were adequately warned or informed by J&J or Ethicon of the defective and dangerous nature of Physiomesh.

Moreover, neither Plaintiff Franklin Robinson nor his implanting physician were adequately warned or informed by J&J or Ethicon of the risks associated with the Physiomesh or the frequency, severity, or duration of such risks.

61. The Physiomesh implanted in Plaintiff Franklin Robinson failed to reasonably perform as intended. The mesh caused serious injury and had to be surgically removed via invasive surgery, and necessitated additional invasive surgery to repair the hernia that the Physiomesh was initially implanted to treat.

62. Plaintiff Franklin Robinson's 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 defective and inadequate warnings by Defendants J&J and Ethicon about the risks associated with the product, and the frequency, severity and duration of such risks. Plaintiff Franklin Robinson has suffered, and will continue to suffer, both physical injury and pain and mental anguish, permanent and severe scarring and disfigurement, lost wages and earning capacity, 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 the product.

#### **THE FDA'S 510(k) CLEARANCE PROCESS**

63. The 510(k) clearance process refers to Section 510(k) of the Medical Device Amendments of 1976 MDA of the Federal Food, Drug and Cosmetic Act. Under this process, device manufacturers are only required to notify the FDA at least 90 days before they market a device claimed to be "substantially equivalent" to a device the FDA approved for sale prior to 1976, when the MDA was enacted.

64. No clinical testing is required under this process.

65. Subsequent amendments to the MDA allowed for 510(k) clearance of products deemed “substantially equivalent” to post-MDA, 510(k) cleared devices.

66. Through this domino effect, devices deemed “substantially equivalent” to devices previously deemed “substantially equivalent” to devices approved for sale by the FDA prior to 1976 could be sold to patients in a matter of 90 days without any clinical testing.

67. Clearance for sale under the 510(k) process does not equate to FDA approval of the cleared device.

68. In 2012, at the request of the FDA, the National Institute of Health (NIH) conducted a thorough review of the 510(k) process, coming to the following major conclusion:

**The 510(k) clearance process is not intended to evaluate the safety and effectiveness of medical devices with some exceptions. The 510(k) process cannot be transformed into a pre-market evaluation of safety and effectiveness so long as the standard for clearance is substantial equivalence to any previously cleared device.**

69. The NIH explained, “The assessment of substantial equivalence does not require an independent demonstration that the new device provides a ‘reasonable assurance of safety and effectiveness.’” Further, the NIH even pointed out that the classification of predicate devices approved for sale prior to the 1976 MDA “did not include any evaluation of the safety and effectiveness of individual medical devices . . . Thus is common for devices to be cleared through the 510(k) program by being found substantially equivalent to devices that were never individually evaluated for safety and effectiveness, either through the original device classification program or through the 510(k) process.”

70. On June 18, 2002, the Food and Drug Administration issued a document titled “Guidance for Resorbable Adhesion Barrier Devices for Use in abdominal and/or Pelvic Surgery; Guidance for Industry.” The 26 page document starts by explaining:

**FDA has determined that the resorbable adhesion barrier is a significant risk device as defined in 21 CFR 812.3(m)(4). The resorbable adhesion barrier is a class III device which is subject to premarket approval in accordance with section 515 of the Federal Food, Drug, and Cosmetics (FD&C) Act.**

71. The Physiomesh did not undergo premarket approval, but instead received 510(k) clearance on or about April 9, 2010. The Proceed was listed as a predicate device on the Physiomesh 510(k) application. Defendants did not claim that the Physiomesh was a resorbable adhesions barrier in their 510(k) application. However, after 510(k) clearance, Defendants marketed the Physiomesh as a resorbable adhesion barrier.

#### **CAUSES OF ACTION PURSUANT TO NEW JERSEY LAW**

#### **COUNT I: PRODUCTS LIABILITY ACT – STRICT PRODUCTS LIABILITY – DEFECTIVE DESIGN (N.J.S.A. 2A:58C-1, et seq.)**

72. Plaintiff realleges all previous paragraphs.

73. At the time the Physiomesh was implanted in Plaintiff Franklin Robinson, the mesh 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. Further, Defendants J&J and Ethicon failed to design against such dangers, and failed to provide adequate warnings and instructions concerning these risks.

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

75. The implantation of Physiomesh in Plaintiff was medically reasonable, and was a type of use that Defendants J&J and Ethicon intended and foresaw when they designed, manufactured and sold the product.

76. The risks of the Physiomesh design significantly outweigh any benefits that Defendants contend could be associated with the 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. Additionally, the impermeable multi-layer coating of the Physiomesh leads to seroma formation, provides a breeding ground for infection, and protects bacteria from being eliminated by the body's natural immune response.

77. 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, the 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 the multi-layer coating caused or exacerbated an intense inflammatory and foreign body reaction. Once exposed to the viscera, the polypropylene mesh will inevitably adhere to the viscera, initiating a cascade of adverse consequences. Any purported beneficial purpose of the multi-layer coating (to prevent adhesion to the internal viscera and organs) was non-existent. The product provided no benefit, while substantially increasing the risks to the patient.

78. The polypropylene mesh within the defective multi-layer coating of the Physiomesh was 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.

79. 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. That occurred with the Physiomesh implanted in Plaintiff Franklin Robinson.

80. 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. Plaintiff Franklin Robinson underwent additional invasive surgery.

81. Physiomesh was designed and intended for intraperitoneal implantation, which involved the product being implanted in contact with the intestines and/or other internal organs. The contact unnecessarily increased the risks of adhesion, erosion, fistula formation, and other injuries.

82. At the time the Physiomesh was implanted in Plaintiff, the warnings and instructions provided by J&J and Ethicon 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.

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

84. The Physiomesh product costs 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.

85. The Physiomesh implanted in Plaintiff Franklin Robinson failed to reasonably perform as intended and necessitated several additional surgeries and required that the Physiomesh be surgically removed, necessitating further invasive surgery to repair the very issue that the product was intended to repair. Thus, it provided no benefit to him.

86. As a direct and proximate result of the defective and unreasonably dangerous condition of the product, Plaintiff Franklin Robinson suffered injuries and damages as summarized in this Complaint.

87. Defendants are strictly liable in tort to Plaintiff Franklin Robinson for their wrongful conduct pursuant to the New Jersey Products Liability Act, N.J.S.A. 2A:58C-1 et seq.

**COUNT II: PRODUCTS LIABILITY ACT – STRICT PRODUCTS LIABILITY –  
FAILURE TO WARN (N.J.S.A. 2A:58C-1, et seq.)**

88. Plaintiff realleges all previous paragraphs.

89. At the time the Physiomesh was implanted in Plaintiff Franklin Robinson, the warnings and instructions Defendants J&J and Ethicon provided 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. Defendants failed to design and/or manufacture against such dangers, and failed to provide adequate warnings and instructions concerning these risks.

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

91. Plaintiff Franklin Robinson and his 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.

92. Defendants' Instructions for Use (IFU) provided with the Physiomesh expressly understated and misstated the risks known to be associated specifically with the Physiomesh. The IFUs stated that "Potential adverse reactions are those typically associated with surgically implantable materials." But Physiomesh contains a dangerous and defective multi-layer coating, which itself causes or increases the risks of numerous complications that are anything but "typical". Those complications include prevention of mesh 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 design of the Physiomesh.

93. The Physiomesh IFU failed to adequately warn Plaintiff Franklin Robinson's physicians of numerous risks which J&J and Ethicon knew or should have known were associated with the product. They include the risk of the Physiomesh'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 rupture of the mesh.

94. J&J and Ethicon failed to adequately warn Plaintiff Franklin Robinson or his physicians about the necessity for invasive surgical intervention in the event of complications.

Defendants also failed to train the physicians on how to properly treat such complications when they occurred.

95. Defendants failed to adequately warn Plaintiff Franklin Robinson or his physicians that the necessary surgical removal of the Physiomesb 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 Physiomesb was intended to treat.

96. J&J and Ethicon represented to physicians, including Plaintiff Franklin Robinson's physicians, that the multi-layer coating would prevent or reduce adhesion. They expressly intended for the Physiomesb to be implanted in contact with the intestines and internal organs and marketed and promoted the product for that purpose. But Defendants failed to warn them that the multi-layer coating prevented tissue ingrowth, which is the desired biologic response to an implantable mesh device. They further failed to warn physicians that the multi-layer coating was only temporary and therefore at best would provide only a temporary adhesion barrier. Thus, when the coating inevitably degraded, the exposed polypropylene would become adhered to the organs or tissue.

97. With respect to the complications listed in their warnings, J&J and Ethicon provided no information or warning regarding the frequency, severity and duration of those complications, although the complications associated with Physiomesb were more frequent and severe, and lasted longer than those with safer feasible alternative hernia repair treatments.

98. If Plaintiff Franklin Robinson or his physicians had been properly warned of the defects and dangers of Physiomesb, and of the frequency, severity and duration of the risks associated with the Physiomesb, he would not have consented to allow the Physiomesb to be implanted in his body, and his physicians would not have implanted the Physiomesb in Plaintiff.

99. As a direct and proximate result of the inadequate and defective warnings and instructions, Plaintiff Franklin Robinson suffered injuries and damages as summarized in this Complaint.

100. Defendants are strictly liable in tort to Plaintiff Franklin Robinson for their wrongful conduct pursuant to the New Jersey Products Liability Act, N.J.S.A. 2A:58C-1 et seq.

**COUNT III: PRODUCT LIABILITY ACT – STRICT PRODUCTS LIABILITY –  
MANUFACTURING DEFECT (N.J.S.A. 2A:58C-1, et seq.)**

101. Plaintiff realleges all previous paragraphs.

102. Defendants designed, developed, manufactured, tested, packaged, advertised, promoted, marketed, distributed, labeled and/or sold the Ethicon Multi-Layered Hernia Mesh, in a condition which rendered it unreasonably dangerous due to its propensity to result in early failure of the device. Ethicon Multi-Layered Hernia Mesh was unreasonably dangerous in construction or composition.

103. The Physiomesh contained a manufacturing defect when it left the possession of J&J and Ethicon. The Physiomesh differs from their intended result and/or from other ostensibly identical units of the same product line. Defendants knew or should have known that the Physiomesh could fail early in patients, thereby giving rise to pain and suffering, debilitation and the need for revision surgery to replace the device with the attendant risk of complications and death from such further surgery. Defendants continued to market Physiomesh as a safe and effective absorbable barrier hernia mesh.

104. The manufacturing defects in the Physiomesh were a producing cause of Plaintiff Franklin Robinson's injuries and damages specified in this Complaint.

105. Defendants are strictly liable in tort to Plaintiff Franklin Robinson for their wrongful conduct pursuant to the New Jersey Products Liability Act, N.J.S.A. 2A:58C-1 et seq.

**COUNT IV: NEGLIGENCE-PURSUANT TO COMMON LAW**

106. Plaintiff Franklin Robinson incorporates the allegations in all prior paragraphs, and further alleges as follows:

107. Although 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 the Physiomesh, they failed to do so.

108. Defendants knew, or in the exercise of reasonable care should have known, that the Physiomesh was defectively and unreasonably designed and/or manufactured and was unreasonably dangerous and likely to injure patients like Plaintiff Franklin Robinson in whom the Physiomesh was implanted. They also knew or should have known that Plaintiff and his physicians were unaware of the dangers and defects inherent in the Physiomesh.

109. 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 the Physiomesh, Plaintiff Franklin Robinson suffered injuries and damages as summarized in this Complaint.

**COUNT V: STRICT LIABILITY—DESIGN DEFECT-PURSUANT TO COMMON LAW**

110. Plaintiff Franklin Robinson incorporates the allegations in all prior paragraphs, and further alleges as follows:

111. At the time the Physiomesh was implanted in Plaintiff Franklin Robinson, the mesh 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. Further, Defendants J&J and Ethicon failed to design against such dangers, and failed to provide adequate warnings and instructions concerning these risks.

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

113. The implantation of Physiomesh in Plaintiff Franklin Robinson was medically reasonable, and was a type of use that Defendants intended and foresaw when they designed, manufactured and sold the product.

114. The risks of the Physiomesh design significantly outweigh any benefits that Defendants contend could be associated with the design.

115. 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, the 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 the multi-layer coating caused or exacerbated an intense inflammatory and foreign body reaction. Once exposed to the viscera, the polypropylene mesh will inevitably adhere to the viscera, initiating a cascade of adverse consequences. Any purported beneficial purpose of the multi-layer coating (to prevent adhesion to the internal viscera and organs) was non-existent. The product provided no benefit, while substantially increasing the risks to the patient.

116. At the time subsequent to Defendants’ initial design and manufacture and marketing and sale of the Physiomesh, including before Franklin Robinson’s hernia surgery, Defendants had the ability to eliminate the unsafe character of the Physiomesh without impairing its usefulness.

117. At the time the Physiomesh was implanted in Plaintiff Franklin Robinson, 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.

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

119. The Physiomesh implanted in Plaintiff Franklin Robinson 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. Thus, it provided no benefit to him.

120. As a direct and proximate result of the defective and unreasonably dangerous condition of the Physiomesh, Plaintiff Franklin Robinson suffered injuries and damages as summarized in this Complaint.

**COUNT VI: STRICT LIABILITY—FAILURE TO WARN-  
PURSUANT TO COMMON LAW**

121. Plaintiff Franklin Robinson incorporates the allegations in all prior paragraphs, and further alleges as follows:

122. At the time the Physiomesh was implanted in Plaintiff Franklin Robinson, the warnings and instructions Defendants provided 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. Defendants failed to design and/or manufacture against such dangers, and failed to provide adequate warnings and instructions concerning these risks.

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

124. Plaintiff Franklin Robinson and his physicians were unaware of the defects and dangers of the Physiomesh, and were unaware of the frequency, severity, and duration of the defects and risks associated with the Physiomesh.

125. Defendants failed to adequately warn health care professionals and the public, including Plaintiff Franklin Robinson and his implanting physician, of the true risks of the Physiomesh, which was ineffective at protecting underlying organs from adhesion formation and would contract significantly upon implantation, resulting in significant pain, bowel and other organ complications, hernia recurrence, reoperation, infections, fistulas, seromas, hematomas, erosion, extrusion, subsequent operations, and more.

126. Defendants failed to timely and reasonably provide adequate instructions and training concerning safe and effective use of the Physiomesh.

127. Defendants failed to perform or otherwise facilitate adequate testing; failed to reveal and/or concealed testing and research data; and selectively and misleadingly revealed and/or analyzed testing and research data.

128. The Physiomesh, which Defendants researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and otherwise released into the stream of commerce, was defective due to inadequate post-marketing warnings and/or instruction because Defendants knew or should have known that there was reasonable evidence of an association between the Physiomesh and dense adhesion formation, mesh contracture, and hernia recurrence, causing serious injury and pain. Nonetheless, Defendants failed to provide

adequate warnings to health care professionals and the consuming public, including Plaintiff Franklin Robinson, and continued to aggressively promote the Physiomesh.

129. With respect to the complications listed in their warnings, Defendants provided no information or warning regarding the frequency, severity and duration of those complications, although the complications associated with the Physiomesh were more frequent and severe, and lasted longer than those with safer feasible alternative hernia repair treatments.

130. If Plaintiff Franklin Robinson or his physician 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, he would not have consented to allow the Physiomesh to be implanted in his body, and his physician would not have implanted it in him.

131. As a direct and proximate result of the inadequate and defective warnings and instructions, Plaintiff Franklin Robinson suffered injuries and damages as summarized in this Complaint.

**COUNT VII: STRICT LIABILITY—MANUFACTURING DEFECT-  
PURSUANT TO COMMON LAW**

132. Plaintiff Franklin Robinson incorporates the allegations in all prior paragraphs, and further alleges as follows:

133. The Physiomesh contained a manufacturing defect when it left the possession of Defendants. The Physiomesh differs from their intended result and/or from other ostensibly identical units of the same product line.

134. The manufacturing defects in the Physiomesh were a producing cause of Plaintiff Franklin Robinson's injuries and damages as specified in this Complaint.

**COUNT VIII: BREACH OF IMPLIED WARRANTY**

135. Plaintiff realleges all previous paragraphs.

136. At the time Defendants J&J and Ethicon designed, manufactured, produced, tested, studied, inspected, labeled, marketed, advertised, sold, promoted and distributed the Physiomesh for use by Plaintiff Franklin Robinson, they knew of the intended use of the Physiomesh, and impliedly warranted their product to be of merchantable quality, and safe and fit for its intended use.

137. When the Physiomesh was implanted in Plaintiff to treat his hernia, the Physiomesh was being used for the ordinary purposes for which it was intended.

138. Plaintiff, individually and/or by and through his physicians, relied upon Defendants' implied warranties of merchantability in consenting to have the Physiomesh implanted in him.

139. Contrary to such implied warranties, the Physiomesh was not of merchantable quality, and was not safe and/or was not fit for its intended use. The Physiomesh was unreasonably dangerous and unfit for the ordinary purposes for which it was used. Defendants J&J and Ethicon failed to warn of known or reasonably scientifically knowable defects in the Physiomesh.

140. As a direct and proximate result of the conduct of Defendants J&J and Ethicon, Plaintiff Franklin Robinson suffered the injuries and damages described in this Complaint.

#### **COUNT IX: BREACH OF EXPRESS WARRANTY**

141. Plaintiff realleges all previous paragraphs.

142. Defendants advertised, labeled, marketed and promoted the Physiomesh, representing the quality to health care professionals, the FDA, Plaintiff, and the public in such a way as to induce its purchase or use, thereby making an express warranty that the Physiomesh would conform to the representations. More specifically, Defendants represented that the Physiomesh was safe and effective, that it was safe and effective for use by individuals such as

Plaintiff Franklin Robinson, and/or that it was safe and effective to treat Plaintiff Franklin Robinson's condition.

143. The representations, as set forth above, contained or constituted affirmations of fact or promises made by the seller to the buyer which related to the goods and became part of the basis of the bargain creating an express warranty that the goods shall conform to the affirmations of fact or promises.

144. The Physiomesh device did not conform to the representations made by Defendants in that the Physiomesh was not safe and effective, was not safe and effective for use by individuals such as Plaintiff Franklin Robinson, and/or was not safe and effective to treat in individuals, such as Plaintiff Franklin Robinson.

145. At all relevant times, Plaintiff used the Physiomesh for the purpose and in the manner intended by Defendants.

146. Plaintiff and Plaintiff's physicians, by the use of reasonable care, could not have discovered the breached warranty and realized its danger.

147. The breach of the warranty was a substantial factor in bringing about Plaintiff Franklin Robinson's injuries.

148. Within a reasonable time after Plaintiff Franklin Robinson knew or should have known of the failure of his Physiomesh, Plaintiff gave notice to Defendants of such failure.

149. Defendants breached the express warranty provided with the device.

150. As a direct and proximate result of Defendants' acts and omissions, including their failure to exercise ordinary care in the design, formulation, testing, manufacture, sale, and distribution of Physiomesh and, Plaintiff Franklin Robinson was implanted with Physiomesh and suffered severe and debilitating injuries, economic loss, and other damages, including but not

limited to, cost of medical care, rehabilitation, lost income, permanent instability and loss of balance, immobility, and pain and suffering, for which they are entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

### **COUNT X: PUNITIVE DAMAGES**

153. Plaintiff realleges all previous paragraphs.

154. Defendant J&J and Ethicon failed to adequately test and study the Physiomesh to determine and ensure that the product was safe and effective before releasing it for sale for permanent human implantation; and they continued to manufacture and sell Physiomesh after obtaining knowledge and information that the product was defective and unreasonably unsafe.

155. Even though Defendants have other hernia repair mesh devices that do not present the same risks as the Physiomesh, they developed, designed and sold Physiomesh, and continued to do so, because the Physiomesh has a significantly higher profit margin than other hernia repair products. Defendants J&J and Ethicon 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 Franklin Robinson. They willfully and recklessly failed to avoid those consequences, and in doing so, acted intentionally, maliciously and recklessly without regard to the safety of those persons who might foreseeably have been harmed by the Physiomesh product, including Plaintiff Franklin Robinson, justifying the imposition of punitive damages.

### **PRAYER FOR RELIEF**

WHEREFORE, Plaintiff Franklin Robinson seeks judgment against Defendants Johnson & Johnson and Ethicon, Inc., jointly and severally, as follows:

- a. special damages, to include past and future medical and incidental expenses, according to proof;
- b. past and future loss of earnings and/or earning capacity, according to proof;

- c. past and future general damages, to include pain and suffering, emotional distress and mental anguish, according to proof;
- d. pre-judgment and post-judgment interest;
- e. the costs of this action; and
- f. treble and/or punitive damages to Plaintiff; and
- g. granting any and all such other and further legal and equitable relief as the Court deems necessary, just and proper.

### **DEMAND FOR TRIAL BY JURY**

Plaintiff hereby demands a trial by jury to the full extent permitted by law.

### **NOTICE OF OTHER ACTIONS PURSUANT TO R. 4:5-1**

I hereby certify that there are related civil proceedings: Cottle v. Ethicon, Inc., et al, Docket No.: BER-L-7065-17; Bassett v. Ethicon, Inc., et al, Docket No.: BER-L-7836-17; Gold v. Ethicon, Inc., et al, Docket No.: BER-L-8037-17; Noakes v. Ethicon, Inc., et al, Docket No.: BER-L-8276-17; Fowler v. Ethicon, Inc., et al, Docket No.: BER-L-8572-17; Griffin v. Ethicon, Inc., et al, Docket No.: BER-L-8827-17; Linnenbrink v. Ethicon, Inc., et al, Docket No.: BER-L-8829-17; Campbell v. Ethicon, Inc., et al, Docket No.: BER-L-8998-17; Martin v. Ethicon, Inc., et al, Docket No.: BER-L-9127-17; Ruiz v. Ethicon, Inc., et al, Docket No.: BER-L-9130-17; Trebolo, Jr. v. Ethicon, Inc. et al, Docket No.: BER-L-9133-17; Gateley v. Ethicon, Inc., et al, Docket No.: BER-L-9151-17; Redding v. Ethicon, Inc., et al, Docket No.: BER-L-184-18; Rice v. Ethicon, Inc., et al, Docket No.: BER-L-197-18; Bean v. Ethicon, Inc., et al, Docket No.: BER-L-198-18; Alumbaugh v. Ethicon, Inc., et al, Docket No.: BER-L-207-18; Reynolds v. Ethicon, Inc., et al, Docket No.: BER-L-279-18; Smith v. Ethicon, Inc., et al, Docket No.: BER-L-652-18; Gaddis v. Ethicon, Inc., et al, Docket No.: BER-L-658-18; Clark v. Ethicon, Inc., et al, Docket No.: BER-L-691-18; Fielding v. Ethicon, Inc., et al, Docket No.: BER-L-693-18; Hollimon v. Ethicon, Inc., et al, Docket No.: BER-L-694-18; Miller v. Ethicon, Inc., et al, Docket No.: BER-L-695-18; Moore v. Ethicon, Inc., et al, Docket No.: BER-L-697-18; Rodriguez v. Ethicon, Inc., et al, Docket No.:

BER-L-699-18; Sollis v. Ethicon, Inc., et al, Docket No.: BER-L-703-18; Adams v. Ethicon, Inc., et al, Docket No.: BER-L-728-18; Crossland v. Ethicon, Inc., et al, Docket No.: BER-L-729-18; Denney v. Ethicon, Inc., et al, Docket No.: BER-L-732-18; Westerbeck v. Ethicon, Inc., et al, Docket No.: BER-L-733-18; Dollanmeyer v. Ethicon, Inc., et al, Docket No.: BER-L-774-18; Jarrell v. Ethicon, Inc., et al, Docket No.: BER-L-775-18; Jennings v. Ethicon, Inc., et al, Docket No.: BER-L-777-18; Johnson v. Ethicon, Inc., et al, Docket No.: BER-L-778-18; Kennedy v. Ethicon, Inc., et al, Docket No.: BER-L-779-18; McKinney v. Ethicon, Inc., et al, Docket No.: BER-L-780-18; Morgan v. Ethicon, Inc., et al, Docket No.: BER-L-781-18; Robins v. Ethicon, Inc., et al, Docket No.: BER-L-809-18; Aaron v. Ethicon, Inc., et al, Docket No.: BER-L-870-18; Diloreto v. Ethicon, Inc., et al, Docket No.: BER-L-1018-18; Pikulsky, et al v. Ethicon, Inc., et al, Docket No.: BER-L-1052-18; Lang v. Ethicon, Inc., et al, Docket No.: BER-L-1067-18; Gibson v. Ethicon, Inc., et al, Docket No.: BER-L-1110-18; Shackelford v. Ethicon, Inc., et al, Docket No.: BER-L-1200-18; Schriner v. Ethicon, Inc., et al, Docket No.: BER-L-1222-18; Alexander v. Ethicon, Inc., et al, Docket No.: BER-L-1241-18; Usey v. Ethicon, Inc., et al, Docket No.: BER-L-1244-18; Hart v. Ethicon, Inc., et al, Docket No.: BER-L-1349-18; Galvez v. Ethicon, Inc., et al, Docket No.: BER-L-1393-18; Lindly v. Ethicon, Inc., et al, Docket No.: BER-L-1402-18; Senkel v. Ethicon, Inc., et al, Docket No.: BER-L-1433-18; Maestas v. Ethicon, Inc., et al, Docket No.: BER-L-1456-18; Szaroleta v. Ethicon, Inc., et al, Docket No.: BER-L-1458-18; Krampen-Yerry v. Ethicon, Inc., et al, Docket No.: BER-L-1466-18; Lotridge v. Ethicon, Inc., et al, Docket No.: BER-L-1467-18; Dias v. Ethicon, Inc., et al, Docket No.: BER-L-1471-18; Alvarado, et al v. Ethicon, Inc., et al, Docket No.: BER-L-1479-18; Mountjoy, et al v. Ethicon, Inc., et al, Docket No.: BER-L-1480-18; Fontenot v. Ethicon, Inc., et al, Docket No.: BER-L-1513-18; Anawaty v. Ethicon, Inc., et al, Docket No.: BER-L-1516-18; Capshaw v. Ethicon, Inc., et al, Docket No.:

BER-L-1530-18; Bradford v. Ethicon, Inc., et al, Docket No.: BER-L-1806-18; Johnson v. Ethicon, Inc., et al, Docket No.: BER-L-2003-18; Collier v. Ethicon, Inc., et al, Docket No.: BER-L-2214-18; Williams v. Ethicon, Inc., et al, Docket No.: BER-L-2337-18; Miller v. Ethicon, Inc., et al, Docket No.: BER-L-2345-18; Ward v. Ethicon, Inc., et al, Docket No.: BER-L-2353-18; Shepherd v. Ethicon, Inc., et al, Docket No.: BER-L-2354-18; Scobee v. Ethicon, Inc., et al, Docket No.: BER-L-2355-18; and Wojtusiak, et al v. Ethicon, Inc., et al, Docket No.: BER-L-2456-18. Beyond the Cottle, Bassett, Gold, Noakes, Fowler, Griffin, Linnenbrink, Campbell, Martin, Ruiz, Trebolo, Gateley, Redding, Rice, Bean, Alumbaugh, Reynolds, Smith, Gaddis, Clark, Fielding, Hollimon, Miller, Moore, Rodriguez, Sollis, Adams, Crossland, Denney, Westerbeck, Dollanmeyer, Jarrell, Jennings, Johnson, Kennedy, McKinney, Morgan, Robins, Aaron, Diloreto, Pikulsky, Lang, Gibson, Shackelford, Schriener, Alexander, Usey, Hart, Galvez, Lindly, Senkel, Maestas, Szaroleta, Krampen-Yerry, Lotridge, Dias, Alvarado, Mountjoy, Fontenot, Anawaty, Capshaw, Bradford, Johnson, Collier, Williams, Miller, Ward, Shepherd, Scobee, and Wojtusiak cases, I am not aware of any other civil proceedings either pending or contemplated with respect to the matter in controversy herein, and that there are no other parties who shall be joined in this action at this time.

**CERTIFICATION PURSUANT TO R. 1:38-7(c)**

I hereby certify that confidential personal identifiers have been redacted from documents now submitted to the Court and will be redacted from all documents in the future in accordance with R. 1:38-8(b).

**TRIAL COUNSEL DESIGNATION**

Please take notice that pursuant to the provisions of R. 4:25-4, EDWARD RUFFO, ESQUIRE, is hereby designated as trial counsel on behalf of PLAINTIFF.

Attorney for Plaintiff,

/s/ Edward Ruffo

Edward Ruffo  
Rheingold, Giuffra, Ruffo & Plotlin, LLP  
551 Fifth Avenue, 29<sup>th</sup> Floor  
New York, NY 10017  
Phone: (212) 684-1880  
Fax: (212) 689-8156

Dated: April 20, 2018

**Edward Ruffo**  
**Attorney ID: 017131992**  
**Rheingold, Giuffra, Ruffo, & Plotkin, LLP**  
551 5<sup>th</sup> Ave, 29<sup>th</sup> Floor  
New York, NY 10176  
(212) 684-1880  
**Attorney for Plaintiff**

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FRANKLIN C. ROBINSON,  
  
Plaintiff,

SUPERIOR COURT OF NEW JERSEY  
LAW DIVISION  
BERGEN COUNTY

v.

Docket No.:

JOHNSON & JOHNSON and  
ETHICON, INC.,

Defendants.

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**CIVIL ACTION**

**SUMMONS**

From The State of New Jersey To the Defendant(s) Named Above:

From The State of New Jersey To The Defendant(s) Named Above: The plaintiff, named above, has filed a lawsuit against you in the Superior Court of New Jersey. The complaint attached to this summons states the basis for this lawsuit. If you dispute this complaint, you or your attorney must file a written answer or motion and proof of service with the deputy clerk of the Superior Court in the county listed above within 35 days from the date you received this summons, not counting the date you received it. (A directory of the addresses of each deputy clerk of the Superior Court is available in the Civil Division Management Office in the county listed above and online at [http://www.njcourts.gov/forms/10153\\_deptyclerklawref.pdf](http://www.njcourts.gov/forms/10153_deptyclerklawref.pdf).) If the complaint is one in foreclosure, then you must file your written answer or motion and proof of service with the Clerk of the Superior Court, Hughes Justice Complex, P.O. Box 971, Trenton, NJ 08625-0971. A filing fee payable to the Treasurer, State of New Jersey and a completed Case Information Statement (available from the deputy clerk of the Superior Court) must accompany your answer or motion when it is filed. You must also send a copy of your answer or motion to plaintiff's attorney whose name and address appear above, or to plaintiff, if no attorney is named above. A telephone call will not protect your rights; you must file and serve a written answer or motion (with fee of \$175.00 and completed Case Information Statement) if you want the court to hear your defense.

If you do not file and serve a written answer or motion within 35 days, the court may enter a judgment against you for the relief plaintiff demands, plus interest and costs of suit. If judgment is entered against you, the Sheriff may seize your money, wages or property to pay all or part of

the judgment.

If you cannot afford an attorney, you may call the Legal Services office in the county where you live or the Legal Services of New Jersey Statewide Hotline at 1-888-LSNJ-LAW (1-888-576-5529). If you do not have an attorney and are not eligible for free legal assistance, you may obtain a referral to an attorney by calling one of the Lawyer Referral Services. A directory with contact information for local Legal Services Offices and Lawyer Referral Services is available in the Civil Division Management Office in the county listed above and online at [http://www.njcourts.gov/forms/10153\\_deptyclerklawref.pdf](http://www.njcourts.gov/forms/10153_deptyclerklawref.pdf).

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Clerk of the Superior Court

DATED: \_\_\_\_\_

Defendant: Johnson & Johnson, a New Jersey Corporation  
Service Address: Law Department  
One Johnson & Johnson Plaza  
New Brunswick, NJ 08933

Defendant: Ethicon, Inc.  
Service Address: 555 US-22  
Sommerville, NJ 08876

**Appendix XII-B1**

	<b>CIVIL CASE INFORMATION STATEMENT (CIS)</b>		<b>FOR USE BY CLERK'S OFFICE ONLY</b>	
	Use for initial Law Division Civil Part pleadings (not motions) under <i>Rule 4:5-1</i> <b>Pleading will be rejected for filing, under <i>Rule 1:5-6(c)</i>,          if information above the black bar is not completed          or attorney's signature is not affixed</b>		PAYMENT TYPE: <input type="checkbox"/> CK <input type="checkbox"/> CG <input type="checkbox"/> CA	
			CHG/CK NO.	
			AMOUNT:	
			OVERPAYMENT:	
		BATCH NUMBER:		
ATTORNEY / PRO SE NAME Edward Ruffo		TELEPHONE NUMBER (212) 684-1880		COUNTY OF VENUE Bergen
FIRM NAME (if applicable) Rheingold, Giuffra, Ruffo & Plotkin, LLP			DOCKET NUMBER (when available)	
OFFICE ADDRESS 551 Fifth Avenue, 29th Floor New York, NY 10017			DOCUMENT TYPE Complaint	
			JURY DEMAND <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	
NAME OF PARTY (e.g., John Doe, Plaintiff) Franklin C. Robinson, Plaintiff		CAPTION Franklin C. Robinson v. Johnson & Johnson, et al.		
CASE TYPE NUMBER (See reverse side for listing) 606	HURRICANE SANDY RELATED? <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO	IS THIS A PROFESSIONAL MALPRACTICE CASE? <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO IF YOU HAVE CHECKED "YES," SEE N.J.S.A. 2A:53A-27 AND APPLICABLE CASE LAW REGARDING YOUR OBLIGATION TO FILE AN AFFIDAVIT OF MERIT.		
RELATED CASES PENDING? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No		IF YES, LIST DOCKET NUMBERS BER-L-7065-17; BER-L-7836-17; BER-L-8276-17; BER-L-8572-17		
DO YOU ANTICIPATE ADDING ANY PARTIES (arising out of same transaction or occurrence)? <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO		NAME OF DEFENDANT'S PRIMARY INSURANCE COMPANY (if known) <input type="checkbox"/> NONE <input checked="" type="checkbox"/> UNKNOWN		
<b>THE INFORMATION PROVIDED ON THIS FORM CANNOT BE INTRODUCED INTO EVIDENCE.</b>				
CASE CHARACTERISTICS FOR PURPOSES OF DETERMINING IF CASE IS APPROPRIATE FOR MEDIATION				
DO PARTIES HAVE A CURRENT, PAST OR RECURRENT RELATIONSHIP? <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO		IF YES, IS THAT RELATIONSHIP: <input type="checkbox"/> EMPLOYER/EMPLOYEE <input type="checkbox"/> FRIEND/NEIGHBOR <input type="checkbox"/> OTHER (explain) <input type="checkbox"/> FAMILIAL <input type="checkbox"/> BUSINESS		
DOES THE STATUTE GOVERNING THIS CASE PROVIDE FOR PAYMENT OF FEES BY THE LOSING PARTY? <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO				
USE THIS SPACE TO ALERT THE COURT TO ANY SPECIAL CASE CHARACTERISTICS THAT MAY WARRANT INDIVIDUAL MANAGEMENT OR ACCELERATED DISPOSITION				
 DO YOU OR YOUR CLIENT NEED ANY DISABILITY ACCOMMODATIONS? <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO		IF YES, PLEASE IDENTIFY THE REQUESTED ACCOMMODATION		
WILL AN INTERPRETER BE NEEDED? <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO		IF YES, FOR WHAT LANGUAGE?		
I certify that confidential personal identifiers have been redacted from documents now submitted to the court, and will be redacted from all documents submitted in the future in accordance with <i>Rule 1:38-7(b)</i> .				
ATTORNEY SIGNATURE 				

# Civil Case Information Statement

## Case Details: BERGEN | Civil Part Docket# L-003014-18

**Case Caption:** ROBINSON FRANKLIN VS JOHNSON & JOHNSON, I NC,

**Case Initiation Date:** 04/25/2018

**Attorney Name:** EDWARD A RUFFO

**Firm Name:** RHEINGOLD GIUFFRA RUFFO & PLOTKIN LLP

**Address:** 551 FIFTH AVENUE, 29TH FL  
NEW YORK NY 10176

**Phone:**

**Name of Party:** PLAINTIFF : Robinson, Franklin

**Name of Defendant's Primary Insurance Company**  
(if known): Unknown

**Case Type:** PRODUCT LIABILITY

**Document Type:** Complaint with Jury Demand

**Jury Demand:** YES - 12 JURORS

**Hurricane Sandy related?** NO

**Is this a professional malpractice case?** NO

**Related cases pending:** YES

**If yes, list docket numbers:** BER-L-7065-17

BER-L-7836-17

BER-L-8276-17

BER\_L-8572-17

**Do you anticipate adding any parties (arising out of same transaction or occurrence)?** NO

## THE INFORMATION PROVIDED ON THIS FORM CANNOT BE INTRODUCED INTO EVIDENCE

CASE CHARACTERISTICS FOR PURPOSES OF DETERMINING IF CASE IS APPROPRIATE FOR MEDIATION

**Do parties have a current, past, or recurrent relationship?** NO

**If yes, is that relationship:**

**Does the statute governing this case provide for payment of fees by the losing party?** NO

**Use this space to alert the court to any special case characteristics that may warrant individual management or accelerated disposition:**

**Do you or your client need any disability accommodations?** NO

**If yes, please identify the requested accommodation:**

**Will an interpreter be needed?** NO

**If yes, for what language:**

I certify that confidential personal identifiers have been redacted from documents now submitted to the court, and will be redacted from all documents submitted in the future in accordance with *Rule 1:38-7(b)*

04/25/2018

Dated

/s/ EDWARD A RUFFO

Signed