UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

IN RE: ETHICON PHYSIOMESH FLEXIBLE COMPOSITE HERNIA MESH PRODUCTS LIABILITY LITIGATION	:	MDL DOCKET NO. 2782
This Document Relates to ALL CASES	:	CIVIL ACTION NO. 1:17-MD-02782-RWS

MASTER LONG FORM COMPLAINT

Come now Plaintiffs, by and through their counsel, and bring this Master Long Form Complaint as an administrative device to set forth potential claims individual Plaintiffs may assert against Defendants in this litigation. By operation of the Order of this Court, all allegations pled herein are deemed pled in any previously filed MDL constituent action where a Short-Form Complaint is filed in accordance with Practice and Procedure Order No. 2 and any Short-Form Complaint hereafter filed. Accordingly, Plaintiffs allege as follows:

I. PARTIES

PLAINTIFFS

1. Plaintiffs include men and women who were implanted with Defendants' Physiomesh Flexible Composite device ("Physiomesh") to treat

medical conditions, primarily for laparoscopic hernia repair. The Physiomesh device was often sold and/or implanted with a "SecureStrap" fixation device, also designed, manufactured, distributed and sold by Defendants, and use of the term "Physiomesh" includes the product with and without the SecureStrap fixation device.

2. Plaintiffs also include the spouses of the aforesaid individuals implanted with Physiomesh, as well as others with standing to file claims arising from Defendants' Physiomesh, as identified in the Short Form Complaint.

DEFENDANTS

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

4. 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.

5. Defendant Ethicon, Inc. 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.

6. Ethicon is a medical device company involved in the research, development, testing, manufacture, production, marketing, promotion and/or sale of medical devices including Physiomesh, with and without SecureStrap (hereinafter may be referred to as the "product," which term includes Physiomesh implanted with and without SecureStrap).

7. At all times relevant herein, Defendants were engaged in the business of placing medical devices into the stream of commerce by designing,

manufacturing, testing, training, marketing, promoting, packaging, labeling, and/or selling such devices including the Physiomesh. Defendants J&J, directly and/or through the actions of Defendant Ethicon, Inc., has at all pertinent times been responsible for the research, development, testing, manufacture, production, marketing, advertising, promotion, distribution and/or sale of Physiomesh worldwide. As a result of the coordinated activities of all Defendants named above, Plaintiffs were implanted with defective Physiomesh products.

8. Defendants are individually, jointly and severally liable to Plaintiffs for damages suffered by Plaintiffs arising from the Defendants' design, manufacture, marketing, labeling, distribution, sale and placement of its defective mesh products at issue in the instant action, effectuated directly and indirectly through their respective agents, servants, employees and/or owners, all acting within the course and scope of their representative agencies, services, employments and/or ownership.

9. 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.

10. Defendants had a legal duty to insure the safety and effectiveness of their Physiomesh by conducting adequate and well controlled studies on their products prior to marketing. Defendants deliberately chose to manipulate the only studies that were conducted on their products and by so doing provided doctors and patients with false and misleading information about the safety and effectiveness of the Physiomesh hernia mesh product. Furthermore, Defendants made a conscious decision to forego performing studies and creating registries that would have provided doctors and patients in the United States with accurate information regarding the lack of proof of the safety and effectiveness of their Physiomesh hernia mesh product.

II. JURISDICTION AND VENUE

11. The federal judicial district identified in the Short Form Complaint has subject-matter jurisdiction over this action pursuant to 28 U.S.C. § 1332(a) based on complete diversity of citizenship between Plaintiff or Plaintiffs and all Defendants. The amount in controversy exceeds $75,000.

12. Consistent with the Due Process Clause of the Fifth and Fourteenth Amendments, Defendants are subject to personal jurisdiction in the federal judicial district identified in the Short Form Complaint.

13. A substantial part of the events and omissions giving rise to Plaintiffs' causes of action occurred in the federal judicial district identified in the Short Form Complaint. Venue is proper in said district pursuant to 28 U.S.C. § 1391(a).

III. FACTS COMMON TO ALL COUNTS

14. Defendants manufactured, sold, and/or distributed the Physiomesh for use in the treatment and repair of hernias.

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

16. Plaintiffs were implanted with the Physiomesh to treat or repair hernias, the purposes for which Defendants designed, manufactured and sold Physiomesh.

17. Defendants represented to Plaintiffs and Plaintiffs' physicians that Physiomesh was a safe and effective product for use in hernia repairs.

18. Defendants' Physiomesh was defectively designed and/or manufactured, was not reasonably safe for its intended use in hernia repair, and the risks of the design outweighed any potential benefits associated with the design. As

a result of the defective design and/or manufacture of the Physiomesh, there was an unreasonable risk of severe adverse reactions to the mesh or mesh components including: chronic pain; recurrence of hernia; foreign body response; rejection; infection; inadequate or failure of incorporation/ingrowth; migration; scarification; deformation of mesh; improper wound healing; excessive and chronic inflammation; adhesions to internal organs; erosion; abscess; fistula formation; granulomatous response; seroma formation; nerve damage; tissue damage and/or death; and other complications.

19. Physiomesh has a unique design incorporating five (5) distinct layers: two layers of poliglecaprone-25 ("Monocryl") film covering two underlying layers of polydioxanone film ("PDS"), which in turn coat a polypropylene mesh. This design is not used in any other hernia repair product sold in the United States. The multi-layer coating was represented and promoted by the Defendants to prevent or minimize adhesion and inflammation and to facilitate incorporation of the mesh into the body, but it did not. Instead, the multi-layer coating prevented adequate incorporation of the mesh into the body and caused or contributed to an intense inflammatory and chronic foreign body response resulting in an adverse tissue

reaction including migration and damage to surrounding tissue in the form of sclerotic, granulomatous and/or fibrotic tissue and improper healing.

20. When 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 risks 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.

21. 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.

22. 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.

23. The multi-layer coating of 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.

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

25. 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.

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

27. When the multi-layer coating of the Physiomesh is disrupted and/or degrades, the "naked" polypropylene mesh is exposed to the adjoining tissue and viscera, and can become adhered to organs, and cause damage to organs, and potentiate fistula formation.

28. The Physiomesh device was often sold and/or implanted with a "SecureStrap" fixation device, also designed, manufactured, distributed and sold by Defendants, which exacerbated the risks, as well as the frequency, severity and duration of the risks, associated with the design of the Physiomesh product.

29. 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.

30. In May 2016, Defendants issued an "Urgent: Field Safety Notice" relating to the Physiomesh product, the same product implanted in Plaintiffs, 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 sales within the United States. Ethicon also knew or had reason to know that those implanted with the Ethicon Physiomesh Composite Mesh 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.

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

32. Neither Plaintiffs nor their implanting physicians were adequately warned or informed by Defendants of the defective and dangerous nature of Physiomesh. Moreover, neither Plaintiffs nor their 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.

33. The Physiomesh implanted in Plaintiffs failed to reasonably perform as intended. The mesh failed, caused serious injury and in some cases portions of the mesh or the entire mesh 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.

34. Plaintiffs' severe adverse reaction, and in some instances surgical removal of the Physiomesh, directly and proximately resulted from the defective and

dangerous condition of the product and Defendants' defective and inadequate warnings about the risks associated with the product, and the frequency, severity and duration of such risks. Plaintiffs have suffered, and will continue to suffer, both physical injury and pain and mental anguish, permanent and severe scarring and disfigurement, and have 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.

IV. CAUSES OF ACTION

COUNT I
Strict Product Liability: Defective Design

35. Plaintiffs hereby incorporate by reference each and every paragraph set forth in this Petition as if fully copied and set forth at length herein.

36. At the time the Physiomesh was implanted in Plaintiffs' 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.

37. The Physiomesh was defectively designed when supplied, sold, distributed and/or otherwise placed into the stream of commerce and when it was implanted in Plaintiffs.

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

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

40. 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, *inter alia*, encapsulation, chronic and excessive inflammatory response, deformation, scarification and contraction, migration, erosion and rejection. The impermeable multi-layer coating leads to seroma formation, and provides a potential breeding ground for infection, and protects bacteria from being eliminated by the body's natural immune response.

41. The multi-layer coating of the Physiomesh, which was marketed, promoted and intended as a barrier against adhesion to the internal organs, was only temporary; it was expected and intended to degrade over time inside the body. Thus, this coating prevented tissue ingrowth and incorporation in the short term, and degraded in the long-term, eventually leaving the unincorporated and "naked" polypropylene mesh exposed to the internal viscera and tissues. The degradation of this multi-layer coating caused or exacerbated an intense inflammatory and foreign body reaction. Once exposed to the viscera, the polypropylene mesh will inevitably adhere to the viscera, initiating a cascade of adverse consequences. Any purported beneficial purpose of the multi-layer coating (to prevent adhesion to the internal viscera and organs) was non-existent; the product provided no benefit while substantially increasing the risks to the patient.

42. 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.

43. 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.

44. The appropriate treatment for complications associated with Physiomesh involves additional invasive surgery to remove the mesh from the body, and to repair the damage caused by the failed Physiomesh, thus eliminating any purported benefit that the product was intended to provide to the patient.

45. Physiomesh was designed and intended for intraperitoneal implantation. 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 increased the risks of mesh deformation, adhesion, erosion, fistula formation, and other injuries. When implanted using an open surgical technique, the design of the Physiomesh provides no benefit, and the risks associated with the product are unreasonably and unnecessarily increased.

46. At the time the Physiomesh was implanted in Plaintiffs, there were safer feasible alternative designs for hernia mesh products that would have reduced the likelihood, severity, frequency and duration of the injuries Plaintiffs suffered.

47. 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.

48. The Physiomesh implanted in Plaintiffs failed to reasonably perform as intended, and had to be surgically removed necessitating further invasive surgery to repair the injuries caused by the defective product and to repair the very issue that the product was intended to repair, and thus provided no benefit to Plaintiffs.

49. Defendants are strictly liable to Plaintiffs for designing a defective product.

50. As a direct and proximate result of the defective and unreasonably dangerous condition of the product, Plaintiffs experienced significant mental and physical pain and suffering, have sustained permanent injury, have undergone medical treatment and will likely undergo future medical treatment and procedures,

have suffered financial or economic loss, including but not limited to, obligations for medical services and expenses, lost income, other damages and/or death.

COUNT II
Strict Product Liability: Failure to Warn

51. Plaintiffs hereby incorporate by reference each and every paragraph set forth in this Petition as if fully copied and set forth at length herein.

52. At the time the Physiomesh was implanted in Plaintiffs' bodies, 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.

53. The Defendants failed to properly and adequately warn and instruct the Plaintiffs and their health care providers as to the risks of the Physiomesh, given the Plaintiffs' conditions and need for information.

54. The Defendants failed to properly and adequately warn and instruct the Plaintiffs and their health care providers with regard to the inadequate research and

testing of the Physiomesh, and the complete lack of a safe, effective procedure for removal of the Physiomesh.

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

56. Plaintiffs and their physicians were unaware of the defects and dangers of Physiomesh, and were unaware of the frequency, severity and duration of the defects and risks associated with the Physiomesh.

57. The Defendants' Instructions for Use provided with the Physiomesh expressly understates and misstates the risks known to be associated specifically with the Physiomesh by stating that "Potential adverse reactions are those typically associated with surgically implantable materials." No other surgical mesh sold in the United States – and no other "surgically implantable material" – has the same design 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 Plaintiffs or their physicians about the risks or increased risks specifically

associated with the unique design of the Physiomesh. Defendants provided no warning to Plaintiffs or their physicians about the risks or increased risks specifically associated with use of the SecurStrap with the Physiomesh product, which was intended and sold by Defendants specifically for use in the implantation of Physiomesh.

58. The Defendants' Instructions for Use for the Physiomesh failed to adequately warn Plaintiffs or their physicians of numerous risks which Defendants knew or should have known were associated with the Physiomesh, including but not limited to the risks of the product's inhibition of tissue incorporation, pain, immunologic response, dehiscence, encapsulation, rejection, migration, scarification, shrinkage/contraction, degradation, deformation, 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/fracture of the mesh.

59. Defendants failed to adequately train or warn Plaintiffs or their physicians about the necessity for invasive surgical intervention in the event of complications, or how to properly treat such complications when they occurred.

60. Defendants failed to adequately warn Plaintiffs or their physicians that the necessary surgical removal of the Physiomesh in the event of complications would leave the hernia unrepaired, and would necessitate further medical treatment to attempt to repair the same hernia that the failed Physiomesh was intended to treat.

61. Defendants failed to adequately warn or train Plaintiffs or their physicians that the surgery required to remove the Physiomesh in the event of complications would obviate any purported benefit associated with laparoscopic implantation, and would involve additional, significant risks to the patient.

62. Defendants represented to physicians, including Plaintiffs' physicians, that the multi-layer coating would prevent or reduce adhesions 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.

63. 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.

64. If Plaintiffs and/or their 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, Plaintiffs would not have consented to allow the Physiomesh to be implanted in their body, and Plaintiffs' physicians would not have implanted the Physiomesh in Plaintiffs.

65. The Defendants are strictly liable in tort to the Plaintiffs for their wrongful conduct described herein.

66. As a direct and proximate result of the inadequate and defective warnings and instructions, Plaintiffs have been injured, sustained severe and permanent mental and physical pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort and consortium, economic loss and damages including, but not limited to medical expenses, lost income, other damages and/or death.

67. Defendants are equitably estopped from asserting a learned intermediary defense due to Defendants' fraudulent concealment, through affirmative misrepresentations and omissions, from Plaintiffs and Plaintiffs' physicians of the risks and defects associated with the Physiomesh, including the severity, duration and frequency of risks and complications. Defendants affirmatively withheld and/or misrepresented facts concerning the safety of the Physiomesh, including but not limited to adverse data and information from studies and testing conducted with respect to Physiomesh that showed the risks and dangers associated with Physiomesh were unreasonable, which were intentionally withheld from Plaintiffs and their physicians. As a result of Defendants' misrepresentations and concealment, Plaintiffs and Plaintiffs' physicians were unaware, and could not have known or have learned through reasonable diligence that Plaintiffs had been exposed to the risks alleged herein and that those risks were the direct and proximate result of the wrongful acts and/or omissions of the Defendant(s).

COUNT III
Strict Product Liability: Manufacturing Defect

68. Plaintiffs hereby incorporate by reference each and every paragraph set forth in this Petition as if fully copied and set forth at length herein.

69. At the time the Physiomesh was implanted in Plaintiffs' bodies, the Physiomesh was defective with respect to its manufacture, as described herein, in that Defendants deviated materially from their design and manufacturing specifications and/or such design and manufacture posed an unreasonable risk of harm to Plaintiffs in whom the Physiomesh was implanted.

70. As a direct and proximate result of the defective manufacture of the Physiomesh, the Physiomesh is unreasonably dangerous and defective, unfit and unsafe for its intended and reasonably foreseeable uses, and do not meet or perform to the expectations of patients and their health care providers.

71. The manufacturing defects associated with the Physiomesh device were not known, knowable or readily visible to Plaintiffs' physicians or to Plaintiffs, nor were they discoverable upon any reasonable examination by Plaintiffs' physicians or Plaintiffs. 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.

72. The Physiomesh implanted in Plaintiffs was different from the intended design and failed to perform as safely as products manufactured in accordance with the intended design would have performed.

73. The defective manufacture of the Physiomesh was a proximate cause of the damages and injuries suffered by the Plaintiff(s) named in the Short Form Complaint.

74. The Defendants are strictly liable in tort to the Plaintiffs for their wrongful conduct.

75. As a direct and proximate result of the Defendants' defective manufacture of the Physiomesh, Plaintiffs have been injured, sustained severe and permanent physical and mental pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort and consortium, economic loss and damages including, but not limited to medical expenses, lost income, other damages and/or death.

COUNT IV
Negligence

76. Plaintiffs hereby incorporate by reference each and every paragraph set forth in this Petition as if fully copied and set forth at length herein.

77. Defendants had a duty to individuals, including the Plaintiffs, to use reasonable and ordinary care in designing, testing, inspecting, manufacturing, packaging, labeling, marketing, distributing, training, and preparing written instructions and warnings for Physiomesh, as well as in the training of physicians to

implant the Physiomesh and/or to properly treat complications associated with the Physiomesh.

78. Defendants knew, or in the exercise of reasonable care should have known, that Physiomesh was defectively and unreasonably designed and/or manufactured, and was unreasonably dangerous and likely to injure patients in whom Physiomesh was implanted. Defendants knew or should have known that Plaintiff and Plaintiff's physicians were unaware of the dangers and defects inherent in the Physiomesh.

79. Defendants breached their duty of care and were negligent as described herein in the design, manufacture, labeling, warning, instruction, training, selling, marketing and distribution of the Physiomesh.

80. Defendants breached their duty of care by:

a. Failing to design the Physiomesh so as to avoid an unreasonable risk of harm to the patients in whom the Product was implanted, including the Plaintiffs;

b. Failing to manufacture the Physiomesh so as to avoid an unreasonable risk of harm to patients in whom the Physiomesh were implanted, including the Plaintiffs;

c. Failing to use reasonable care in the testing of the Physiomesh so as to avoid an unreasonable risk of harm to patients in whom the Physiomesh was implanted, including the Plaintiffs;

d. Failing to use reasonable care in inspecting the Physiomesh so as to avoid an unreasonable risk of harm to patients in whom the Products were implanted, including the Plaintiffs;

e. Withholding adverse information regarding Physiomesh within their knowledge, including but not limited to information from testing or study of the Physiomesh demonstrating unacceptable risks, and thereby preventing Plaintiffs and their physicians from understanding the risks associated with the Physiomesh;

f. Failing to adequately instruct, train or warn physicians regarding the use of the Physiomesh, the risks associated with the Physiomesh, including the frequency, severity and duration of such risks, and the appropriate treatment for complications associated with Physiomesh; and/or

g. Otherwise negligently or carelessly designing, manufacturing, marketing, labeling, packaging and/or selling the Physiomesh.

81. The reasons that Defendants' negligence caused the Physiomesh to be unreasonably dangerous and defective include those described hereinabove, which include but are not limited to:

a. 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.

b. 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.

c. 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.

d. The multi-layer coating of 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.

e. 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.

f. 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.

g. The polypropylene material used in the Physiomesh device is unreasonably susceptible to in vivo oxidative degradation, which causes or exacerbates an excessive and chronic inflammatory response, scarification, shrinkage and deformation of the mesh.

h. 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 increased the risks 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.

82. Defendants also negligently failed to warn or instruct Plaintiffs or their physicians regarding the risks and defects associated with the Physiomesh, including those described hereinabove, which include but are not limited to:

a. The Defendants failed to adequately warn Plaintiffs or their physicians that the multi-layer coating of the Physiomesh preventing adequate incorporation of the mesh resulting in an intense inflammatory and chronic foreign body response, adverse tissue reaction, migration, and damage to surrounding tissue in the form of sclerotic, granulomatous and/or fibrotic tissue and improper healing;

b. Defendants provided no warning to Plaintiffs or their physicians about the risks or increased risks specifically associated with the unique design of the Physiomesh. 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" – has the same design 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.

c. Defendants provided no warning to Plaintiffs or their physicians about the risks or increased risks specifically associated with use of the SecurStrap with the Physiomesh product, which was intended and sold by Defendants specifically for use in the implantation of Physiomesh.

d. The Defendants' Instructions for Use for the Physiomesh failed to adequately warn Plaintiffs or their physicians of numerous risks which Defendants knew or should have known were associated with the Physiomesh, including but not limited to the risks of the product's inhibition of tissue incorporation, pain, immunologic response, dehiscence, encapsulation, rejection, migration, scarification, shrinkage/contraction, degradation, deformation, 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/fracture of the mesh.

e. The Defendants failed to adequately warn Plaintiffs or their physicians of the unusually high rate of infection associated with the multi-layer coating;

f. The Defendants failed to adequately warn Plaintiffs or their physicians that the multi-layer coating of Defendants' Physiomesh is not biocompatible;

g. The Defendants failed to adequately warn Plaintiffs or their physicians that the polypropylene mesh portion of the Physiomesh had a propensity to cause recurrent hernia formation and/or rupture and curl, roll and deform;

h. The Defendants failed to adequately warn Plaintiffs or their physicians of the Physiomesh's propensity to shrink or contract within the body;

i. The Defendants failed to adequately warn Plaintiffs or their physicians of the risk of chronic inflammation associated with the Physiomesh;

j. The Defendants failed to adequately warn Plaintiffs or their physicians of the need for corrective surgery to adjust, remove or revise the Physiomesh;

k. The Defendants failed to adequately warn Plaintiffs or their physicians of the frequency, severity and duration of complications and risks associated with the Physiomesh;

l. The Defendants failed to adequately warn Plaintiffs or their physicians of the Physiomesh defects described hereinabove;

m. The Defendants failed to adequately warn Plaintiffs or their physicians that the Physiomesh exposes patients to more risks and different risks than those associated with safer feasible alternative products;

n. The Defendants failed to adequately warn Plaintiffs or their physicians that the risks associated with the Physiomesh device are more frequent, severe, longer lasting, and more difficult to treat than those associated with safer feasible alternative products;

o. The Defendants failed to adequately warn Plaintiffs or their physicians that Physiomesh is no more effective than feasible, available alternatives;

p. The Defendants failed to adequately warn Plaintiffs or their physicians that Physiomesh put patients at a greater risk of requiring additional surgery than feasible, available alternatives;

q. The Defendants failed to adequately warn Plaintiffs or their physicians that use of Physiomesh makes any future abdominal surgery on the patient much more complex and dangerous than feasible, available alternatives;

r. The Defendants failed to adequately warn Plaintiffs or their physicians of the inability to safely remove Physiomesh after injury, which increased risk of future injuries;

s. The Defendants failed to adequately warn Plaintiffs or their physicians that when the Physiomesh coating is disrupted and/or degrades, the "naked" polypropylene mesh may result in adherence to organs, damage or organs and potentiate fistula formation; and

t. The Defendants failed to adequately warn Plaintiffs or their physicians that removal of the Physiomesh due to complications may significantly impair the patients' quality of life and may not result in complete resolution of their injuries.

83. Defendants knew or should have known that its failure to exercise ordinary care in the manufacture, design, packaging, labeling, warnings, instructions, sale, marketing, distribution and training of physicians to implant the Physiomesh and/or to treat Physiomesh complications would cause foreseeable harm, injuries, and damages to individuals implanted with Physiomesh, including the Plaintiffs.

84. 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 in whom Physiomesh was implanted. Defendants knew or should have known that Plaintiffs and their physicians were unaware of the dangers and defects inherent in the Physiomesh.

85. Defendants' negligence was a proximate cause of the damages and injuries to Plaintiffs.

86. 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, Plaintiffs have been injured, sustained severe and permanent physical and mental pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort and consortium, economic loss, and damages including, but not limited to medical expenses, lost income, other damages and/or death.

COUNT V
Consumer Protection Laws

87. Plaintiffs hereby incorporate by reference each and every paragraph set forth in this Petition as if fully copied and set forth at length herein.

88. Plaintiffs purchased and used the Defendants' Physiomesh primarily for personal use and thereby suffered ascertainable losses as a result of Defendants' actions in violation of the consumer protection laws applicable in the state where their mesh was purchased and used.

89. Had Defendants properly advised patients, physicans and medical facilities of the defects and risks, including the frequency, severity and duration of

those risks, associated with the Physiomesh device, Plaintiffs would not have purchased and/or paid for the Physiomesh, would not have consented to allow Physiomesh to be implanted in their bodies, and would not have incurred related medical costs and injury.

90. Defendants engaged in wrongful conduct while at the same time obtaining, under false pretenses, moneys from Plaintiffs for the Physiomesh that would not have been paid had Defendants not engaged in unfair and deceptive conduct.

91. Unfair methods of competition or deceptive acts or practices that were proscribed by law, including the following:

a. Representing that goods or services have characteristics, ingredients, uses benefits or quantities that they do not have;

b. Advertising goods or services with the intent not to sell them as advertised; and,

c. Engaging in fraudulent or deceptive conduct that creates a likelihood of confusion or misunderstanding.

92. Plaintiffs were injured by the cumulative and indivisible nature of Defendants' conduct. The cumulative effect of Defendants' conduct directed at patients, physicians and consumers was to create demand for and sell the

Defendants' Physiomesh. Each aspect of Defendants' conduct combined to artificially create sales of the Defendants' Physiomesh.

93. Defendants have a statutory duty to refrain from unfair or deceptive acts or trade practices in the design, labeling, development, manufacture, promotion, and sale of the Physiomesh.

94. Defendants' deceptive, unconscionable, or fraudulent representations and material omissions to patients, physicians and consumers, including Plaintiffs, constituted unfair and deceptive acts and trade practices in violation of the state consumer protection statutes listed below. Defendants' actions, as complained of herein, constitute unfair competition or unfair, unconscionable, deceptive or fraudulent acts, or trade practices in violation of state consumer protection statutes in states where the purchase and/or implantation of the Physiomesh devices occurred.

95. Under the applicable statutes to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising, Defendants are the suppliers, manufacturers, advertisers, and sellers, which are subject to liability under such legislation for unfair, deceptive, fraudulent and unconscionable consumer sales practices.

96. Defendants violated the statutes that were enacted in these states to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising, by knowingly and falsely representing that the Physiomesh was fit to be used for the purpose for which the products were intended, when in fact they were defective and dangerous, and by other acts alleged herein.

97. The actions and omissions of Defendants alleged herein are uncured or incurable deceptive acts under the statutes enacted in the states to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising. Defendants had actual knowledge of the defective and dangerous condition of the Physiomesh and failed to take any action to cure such defective and dangerous conditions.

98. Plaintiffs, Plaintiffs' treating physicians, and the medical community relied upon Defendants' misrepresentations and omissions in determining to use the Physiomesh devices or in allowing the Physiomesh devices to be implanted in their bodies.

99. As a direct and proximate result of Defendants' violations of the states' consumer protection laws, Plaintiffs have sustained economic losses, injuries and

other damages and are entitled to statutory and compensatory damages in an amount to be proven at trial.

COUNT VI
Gross Negligence

100. Plaintiffs hereby incorporate by reference each and every paragraph set forth in this Petition as if fully copied and set forth at length herein.

101. The wrongs done by Defendants were aggravated by the kind of malice, fraud, and grossly negligent disregard for the rights of others, the public, and Plaintiffs for which the law would allow, and which Plaintiffs will seek at the appropriate time under governing law for the imposition of exemplary damages, in that Defendants' conduct was specifically intended to cause substantial injury to Plaintiffs; or when viewed objectively from Defendants' standpoint at the time of the conduct, involved an extreme degree of risk, considering the probability and magnitude of the potential harm to others, and Defendants were actually, subjectively aware of the risk involved, but nevertheless proceeded with conscious indifference to the rights, safety, or welfare of others; or included a material representation that was false, with Defendants, knowing that it was false or with

reckless disregard as to its truth and as a positive assertion, with the intent that the representation is acted on by Plaintiffs.

102. Plaintiffs relied on the representation and suffered injury as a proximate result of this reliance.

103. Plaintiffs therefore will seek to assert claims for exemplary damages at the appropriate time under governing law in an amount within the jurisdictional limits of the Court.

104. Plaintiffs also allege that the acts and omissions of named Defendants, whether taken singularly or in combination with others, constitute gross negligence that proximately caused the injuries to Plaintiffs. In that regard, Plaintiffs will seek exemplary damages in an amount that would punish Defendants for their conduct and which would deter other manufacturers from engaging in such misconduct in the future.

COUNT VII
Loss of Consortium

105. Plaintiffs hereby incorporate by reference each and every paragraph set forth in this Petition as if fully copied and set forth at length herein.

106. At all relevant times hereto, some Plaintiffs as specified in their Short Form Complaints had spouses (hereafter referred to as "Spouse Plaintiffs") and/or family members (hereafter referred to as "Family Member Plaintiffs") who have suffered injuries and losses as a result of Physiomesh and Plaintiffs' injuries. The Spouse Plaintiffs and Family Member Plaintiffs will be identified in the Short Form Complaint.

107. For the reasons set forth herein, Spouse Plaintiffs and/or Family Member Plaintiffs have suffered and will continue to suffer the loss of their loved one's support, companionship, services, society, love and affection as a result of the Physiomesh that was implanted in Plaintiffs.

108. For all Spouse Plaintiffs, Plaintiffs allege that their marital relationship was impaired and depreciated, and the marital association between husband and wife has been altered.

109. Spouse Plaintiffs and/or Family Member Plaintiffs have suffered great emotional pain and mental anguish.

110. As a direct and proximate result of Defendants' wrongful conduct, Spouse Plaintiffs and Family Member Plaintiffs of the aforesaid men and women, have sustained and will continue to sustain severe physical and mental injuries,

severe emotional distress, economic losses and other damages for which they are entitled to compensatory damages in an amount to be proven at trial. Defendants are liable to Spouse Plaintiffs and Family Member Plaintiffs, jointly and severally for all relief to which Spouse Plaintiffs and Family Member Plaintiffs are entitled by law.

Count VIII
Punitive Damages

111. Plaintiffs hereby incorporate by reference each and every paragraph set forth in this Petition as if fully copied and set forth at length herein.

112. Defendants failed to adequately test and study the Physiomesh to determine and ensure that the product was safe and effective prior to releasing the product for sale for permanent human implantation, and Defendants continued to manufacture and sell Physiomesh after obtaining knowledge and information that the product was defective and unreasonably unsafe. The limited testing and study that was undertaken by Defendants prior to release and after release of the Physiomesh device, including but not limited to animal studies and human clinical studies, revealed to Defendants that the risks associated with the Physiomesh were unreasonably frequent and severe and outweighed any purported benefit of the product. The adverse results of those tests and studies were intentionally concealed,

or else were misrepresented, by Defendants in order to continue to profit from sales of Physiomesh. Even though Defendants have other hernia repair mesh devices that do not present the same risks as the Physiomesh, Defendants developed, designed and sold Physiomesh, because the Physiomesh has a significantly higher profit margin than other hernia repair Physiomesh. 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 Plaintiffs. Defendants willfully and recklessly failed to avoid those consequences, and in doing so, Defendants acted intentionally, maliciously and recklessly with regard to the safety of those persons who might foreseeably have been harmed by the Physiomesh product, including Plaintiffs, justifying the imposition of punitive damages.

113. At all times relevant hereto, Defendants knew or should have known that the Defendants' Physiomesh was inherently dangerous with respect to the risks of failure, pain and suffering, loss of life's enjoyment, remedial surgeries and treatments, as well as other severe and personal injuries which are chronic or permanent in nature.

114. At all times material hereto, Defendants attempted to misrepresent and did misrepresent facts concerning the safety of the Defendants' Physiomesh,

including but not limited to adverse data and information from studies and testing conducted with respect to Physiomesh that showed the risks and dangers associated with Physiomesh were unreasonable.

115. Defendants' misrepresentations included knowingly withholding material information from the medical community and the public, including Plaintiffs, concerning the safety and efficacy of the Defendants' Physiomesh.

116. At all times material hereto, Defendants knew and intentionally and/or recklessly disregarded the fact that the Defendants' Physiomesh causes severe and potentially permanent complications with greater frequency than safer alternative devices or treatments.

117. At all times material hereto, Defendants intentionally misstated and misrepresented data and continue to misrepresent data so as to minimize the true and accurate risk of injuries and complications caused by the Physiomesh, including but not limited to data regarding the frequency, severity and duration of those risks and complications.

118. Notwithstanding their knowledge, Defendants continued to market the Defendants' Physiomesh to consumers without disclosing the true risk of side effects and complications, or the frequency, severity and duration of those risks.

119. Defendants knew of Physiomesh's defective and unreasonably dangerous nature, but continued to manufacture, produce, assemble, market, distribute, and sell the Defendants' Physiomesh so as to maximize sales and profits at the expense of the health and safety of the Public, including Plaintiffs, in conscious and/or reckless disregard of the foreseeable harm caused by the Physiomesh.

120. Defendants' conduct as described herein shows willful misconduct, malice, fraud, wantonness, oppression, or that entire want of care which raises the presumption of conscious indifference to consequences, thereby justifying an award of punitive damages.

Count IX
Discovery Rule, Equitable Tolling/Estoppel

121. Plaintiffs hereby incorporate by reference each and every paragraph set forth in this Petition as if fully copied and set forth at length herein.

122. Plaintiffs assert all applicable state statutory and common law rights and theories related to the tolling or extension of any applicable statute of limitations, including equitable tolling, delayed discovery, discovery rule, and/or fraudulent concealment.

123. The discovery rule applies to toll the running of the statute of limitations until Plaintiffs knew, or through the exercise of reasonable care and diligence should have known, of facts indicating either: that Plaintiffs had been injured; the cause of the injury; or the tortious nature of the wrongdoing that caused the injury.

124. The nature of Plaintiffs' injuries, damages, or their causal relationship to Defendants' conduct was not discovered, and through reasonable care and due diligence could not have been discovered, until a date within the applicable statute of limitations for filing Plaintiffs' claims.

125. The running of the statute of limitations in this cause is tolled due to equitable tolling. Defendants are equitably estopped from asserting a statute of limitations defense due to Defendants' fraudulent concealment, through affirmative misrepresentations and omissions, from Plaintiffs and Plaintiffs' physicians of the risks and defects associated with the Physiomesh, including the severity, duration and frequency of risks and complications. Defendants affirmatively withheld and/or misrepresented facts concerning the safety of the Defendants' Physiomesh, including but not limited to adverse data and information from studies and testing conducted with respect to Physiomesh that showed the risks and dangers associated

with Physiomesh were unreasonable, which were intentionally withheld from Plaintiffs and their physicians. As a result of Defendants' misrepresentations and concealment, Plaintiffs and Plaintiffs' physicians were unaware, and could not have known or have learned through reasonable diligence that Plaintiffs had been exposed to the risks alleged herein and that those risks were the direct and proximate result of the wrongful acts and/or omissions of the Defendant(s). Defendants are equitably estopped from asserting any statute of limitations defense based on their intentional conduct to withhold relevant information about the safety of the Physiomesh from Plaintiffs and their physicians.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs demand judgment against Defendants, and each of them, individually, jointly and severally, and Plaintiffs request compensatory damages, together with interest, cost of suit, attorneys' fees, and all such other relief as the Court deems just and proper as well as:

1. Compensatory damages to Plaintiffs for past, present and future damages, including, but not limited to, mental and physical pain and suffering for severe and permanent personal injuries sustained by Plaintiffs, health and medical care costs, lost wages or income, and loss of earning capacity, together with interest and costs as provided by law;

2. Restitution and disgorgement of profits;

3. Reasonable attorneys' fees;

4. The costs of these proceedings;

5. All ascertainable economic damages;

6. Punitive damages;

7. Survival damages (if applicable);

8. Wrongful death damages (if applicable); and

9. Such other and further relief as this Court deems just and proper.

This 6th day of September, 2017.

Co-Lead Counsel for Plaintiffs

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FONT CERTIFICATION

Pursuant to Local Rule 7.1 D, I hereby certify that foregoing document was prepared using Times New Roman 14 point type as provided in Local Rule 5.1.

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CO-LEAD COUNSEL FOR PLAINTIFFS

CERTIFICATE OF SERVICE

I hereby certify that on September 6, 2017, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

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