UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

BOSTON DIVISION

DAVID WATRING,	)	**Civil Action No.:**
	)	
Plaintiff,	)	
	)	
v.	)	**COMPLAINT AND JURY DEMAND**
	)	
	)	
Ethicon, Inc.,	)	
	)	
Defendant.	)	
	)	
	)	
	)	
	)	

Plaintiff, by and through his undersigned counsel, bring this Complaint for damages against Defendants and in support thereof state the following:

1. This is a device tort action brought on behalf of the above named Plaintiff arising out of the failure of Defendant's hernia mesh product. As a result, Plaintiff DAVID WATRING suffered permanent injuries and significant pain and suffering, emotional distress, lost wages and earning capacity, and diminished quality of life. The Plaintiff respectfully seeks all damages to which he may be legally entitled.

I. STATEMENT OF PARTIES

2. Plaintiff David Watring ("Plaintiff") is, and was, at all relevant times, a citizen and resident of Massachusetts and the United States.

3. Defendant Ethicon, Inc. ("Ethicon") is a foreign corporation licensed to do business in the Commonwealth of Massachusetts who identifies as its registered agent for the service of process as CT Corporation System at 155 Federal St., Suite 700 in Boston Massachusetts.

4. At all relevant times, each of the Defendants designed, developed, manufactured, licensed, marketed, distributed, sold and/or placed Hernia Mesh Products in the stream of commerce, including the Physiomesh surgical mesh product that is at issue in this lawsuit.

5. All acts and omissions of each Defendant as described herein were done by its agents, servants, employees, representatives, and/or owners, acting in the course and scope of their respective agencies, services, employments and/or ownership.

6. At all relevant times, each of the Defendant, was and still is a corporation authorized to do business in the Commonwealth of Massachusetts.

7. At all times hereinafter mentioned, upon information and belief, Defendant was and still is a business entity actually doing business in the Commonwealth of Massachusetts.

8. At all times hereinafter mentioned, Defendant was, and are currently, engaged in the business of designing, manufacturing, advertising, marketing, and selling Hernia Mesh Products including the Physiomesh (referred to herein, at times as "Physiomesh" or "Hernia Mesh Product"), and in pursuance of this business, transacts business within the Commonwealth of Massachusetts and contracts to provide goods and services in the Commonwealth of Massachusetts.

9. At all times hereinafter mentioned, upon information and belief, Defendant committed tortious acts inside and outside the Commonwealth of Massachusetts, which caused injury to Plaintiff inside the Commonwealth of Massachusetts.

10. At all times hereinafter mentioned, upon information and belief, Defendants expect or should reasonably expect its acts to have consequences in the Commonwealth of Massachusetts, and derives substantial revenue from interstate or international commerce.

II. VENUE AND JURISDICTION

11. Damages sought in this matter are in excess of $75,000.00. Subject matter jurisdiction is proper pursuant to 28 U.S.C. §1332(a)-(c).

12. This Court has subject matter jurisdiction over the parties pursuant to 28 U.S.C. §1332(a) because the parties are citizens of different states and the amount in controversy exceeds $75,000.00, exclusive of interest and cost.

13. Venue is proper in this Court pursuant to 28 U.S.C. §1332(a)-(c) by virtue of the facts that (a) a substantial part of the events or omissions giving rise to the claims occurred in this District and (b) Defendant's products are sold to and consumed by individuals in the Commonwealth of Massachusetts, thereby subjecting Defendants to personal jurisdiction in this action and making them all "residents" of this judicial District.

14. Defendants have and continue to conduct substantial business in the Commonwealth of Massachusetts and in this District, distribute Hernia Mesh Products in this District, receive substantial compensation and profits from sales of Hernia Mesh Products in this District, and made material omissions and misrepresentations and breaches of warranties in this District, so as to subject them to *in personam* jurisdiction in this District.

15. Defendants conducted business in the Commonwealth of Massachusetts through sales representatives conducting business in the Commonwealth of Massachusetts and because Defendants were engaged in testing, developing, manufacturing, labeling, marketing, distributing, promoting and/or selling, either directly or indirectly, and/or through third parties or related entities, Hernia Mesh Products in Massachusetts.

16. Consistent with the Due Process Clause of the Fifth and Fourteenth Amendments, this Court has *in personam* jurisdiction over Defendants, because Defendants are present in the Commonwealth of Massachusetts, such that requiring an appearance does not offend traditional notices of fair and substantial justice.

III. DEFENDANT'S HERNIA MESH PRODUCT

17. In or about 2010, Defendants began to market and sell Physiomesh for the treatment of multiple medical conditions, primarily hernia repair.

18. Defendant's Hernia Mesh Products were designed, patented, manufactured, labeled, marketed, sold, and distributed by the Defendants at all relevant times herein.

19. Defendant's Products contain polypropylene mesh. Despite claims that this material is inert, a substantial body of scientific evidence shows that this mesh material is biologically incompatible with human tissue and promotes and immune response in a large subset of the population receiving Defendant's Products. This immune response promotes degradation of the polypropylene mesh, as well as the surrounding tissue, and can contribute to the formation of severe adverse reactions to the mesh.

20. Defendant's polypropylene based Hernia Mesh Products are designed, intended, and utilized for permanent implantation into the human body.

21. Defendants failed to warn or notify doctors, regulatory agencies, and consumers of the known severe and life-threatening risk associated with polypropylene.

22. Upon information and belief, Defendant's use adulterated polypropylene in their Hernia Mesh Products.

23. Defendant's failed to warn or notify doctors, regulatory agencies, and consumers of the Defendant's use of adulterated polypropylene in their Hernia Mesh Products.

24. The polypropylene component of Defendant's Physiomesh product is laminated between two layers of poliglecaprone, a bioresorbable polymer used to form an anti-adhesion barrier between the polypropylene and the host tissue.

25. Utilizing an anti-adhesion barrier on the parietal side of a polypropylene hernia mesh graft increases the risk that the graft will not incorporate into the abdominal wall, causing the graft to fold, buckle and migrate, posing a threat to adjacent organs.

26. Poliglecaprone is known to incite an inflammatory response in soft tissue. When poliglecaprone is implanted in a patient's abdominal cavity, an inflammatory response occurs, causing complications including but not limited to pain, graft rejection, graft migration, organ damage, adhesions, complex seroma, fistula, sinus tract formation, delayed wound closure, infection, sepsis, and death.

27. The inflammatory reaction to a mesh implant is increased when the mesh has folded or deformed.

28. Upon information and belief, Defendant's utilized non-conforming goods in the production of the Physiomesh, including accepting goods without the required documentation to verify the source, quality, authenticity, or chain of custody of the goods.

29. Upon information and belief, Defendants had actual knowledge of the inflammatory properties of the poliglecaprone component of the Physiomesh prior to introducing it into the stream of commerce.

30. Upon information and belief, Defendants had actual knowledge of the substantial risk that Physiomesh implants will fail to incorporate into the abdominal walls of patients, requiring additional surgery.

31. Defendants failed to adequately test the effects of the known inflammatory properties of the Physiomesh in animals and humans, both before and after the product entered the stream of commerce.

32. Defendant's failed to warn or notify doctor, regulatory agencies, and consumers of the known inflammatory properties of the Physiomesh.

33. Defendants utilize Ethylene Oxide ("ETO") in an attempt to sterilize the Physiomesh. ETO is an effective disinfectant; however, dry spores are highly resistant to ETO. Moisture must be present to eliminate spores using ETO. Presoaking the product to be sterilized is most desirable, but high levels of humidity during the ETO process can also be effective in eliminating spores. Physiomesh implanted with spores will result in an infection. The spores can remain dormant for extended periods of time, resulting in infections months or years after implantation with the Physiomesh.

34. Moisture and high humidity levels are not utilized in the sterilization process for the Physiomesh, as it would result in the degradation of the poliglecaprone coating prior to implant.

35. Defendant's use of ETO on the Physiomesh Mesh results high infection rates due to inadequate moisture during the ETO cycle.

36. ETO is ineffective at sterilizing the Physiomesh Mesh due the poliglecaprone coating, multiple layers of the material, and mated surfaces of the Physiomesh.

37. Upon information and belief, Defendants manipulated, altered, skewed, slanted, misrepresented, and/or falsified pre-clinical and/or clinical studies to bolster the perceived performance of the Physiomesh.

38. Upon information and belief, Defendants paid researchers, doctors, clinicians, study designers, authors, and/or scientist to study the effectiveness of the Physiomesh, but did not disclose these relationships in the studies themselves.

39. Upon information and belief, Defendant's paid doctors, surgeons, physicians, and/or clinicians to promote the Physiomesh, but did not readily disclose this information.

40. Defendants failed to implement adequate procedures and systems to report, track, and evaluate complaints and adverse events.

41. Defendants failed to employ an adequate number of staff to receive, process, investigate, document, and report adverse events.

42. Defendants marketed the Physiomesh to the medical community and to patients as safe, effective, reliable, medical devices for the treatment of hernia repair, and as safer and more effective as compared to the traditional products and procedures for treatment, and other

competing mesh products. Defendants have made claims that the Physiomesh is superior in a variety of ways, but have never conducted a single clinical study on the Physiomesh implanted in humans. Defendant's deception through false advertising resulted in more physicians utilizing the Physiomesh.

43. Defendants marketed and sold the Physiomesh to the medical community at large and patients through carefully planned, multifaceted marketing campaigns and strategies. These campaigns and strategies include, but are not limited to, aggressive marketing to health care providers at medical conferences, hospitals, and private offices, and include the provision of valuable benefits to health care providers. Also utilized were documents, patient brochures, and websites.

44. Prior to the introduction of the Physiomesh to the market, Defendants had been notified and warned about the risk of widespread and sometimes catastrophic complications associated with the Physiomesh by leading hernia repair specialists, surgeons, hospitals, patients, internal consultants, and employees. Instead of improving the design of Physiomesh, Defendants chose to push Physiomesh to market while misrepresenting the efficacy and safety of the Physiomesh through various means and media, actively and intentionally misleading the medical community, patients, and the public at large.

45. Defendants failed to perform or rely on proper and adequate testing and research in order to determine and evaluate the risks and benefits of the Defendant's Physiomesh product.

46. Defendants failed to design and establish a safe, effective procedure for removal of the Defendant's Physiomesh product; therefore, in the event of a failure, injury, or complications it is impossible to easily and safely remove the Defendant's Physiomesh product.

47. Feasible and suitable alternative procedures and instruments, as well as suitable alternative designs for implantation and treatment of hernias and soft tissue repair have existed at all times relevant as compared to the Defendant's Physiomesh.

48. The Defendant's Physiomesh was at all times utilized and implanted in a manner foreseeable to the Defendants.

49. The Defendants have at all times provided incomplete, insufficient, and misleading training and information to physicians, in order to increase the number of physicians utilizing the Defendant's Physiomesh, and thus increase the sales of the Physiomesh, and also leading to the dissemination of inadequate and misleading information to patients, including Plaintiff.

50. The Physiomesh implanted into the Plaintiff was in the same or substantially similar condition as when it left the possession of the Defendants, and in the condition directed by and expected by the Defendants.

51. Defendants withdrew Physiomesh from the market in May of 2016, after studies began to reveal the higher rate or complication and reoperation associated with Physiomesh.

IV. FACTUAL BACKGROUND

52. On April 11, 2013, Plaintiff underwent parastomal hernia repair at Falmouth Hospital, where he was implanted with a 15 x 20 cm Physiomesh.

53. Defendant, manufactured, sold, and/or distributed the Physiomesh to Plaintiff, through his doctors, to be used for treatment of hernia repair.

54. On November 14, 2013, Plaintiff presented to Falmouth Hospital for recurrence of his parastomal hernia, which contained loops of small bowel.

55. On March 30, 2016, Plaintiff presented to Falmouth Hospital with a symptomatic recurrent hernia. There were several loops of small bowel contained within the hernia, with dense adhesions between the loops of bowel. An extensive amount of time performing adhesiolysis was required in order to reduce them, as well as the adhesions between the fascial defect and the small bowel.

56. Following this procedure, Plaintiff developed yet another hernia at the implant site of the Physiomesh and is currently awaiting consultation to determine whether further surgery is feasible.

57. At all times, the Physiomesh was utilized and implanted in a manner foreseeable to Defendant, as Defendant generated the instructions for use and created procedures for implanting the mesh.

58. Other than any degradation caused by faulty design, manufacturing, or faulty packaging**,** the Physiomesh implanted into the Plaintiff was in the same or substantially similar condition as when it left the possession of Defendants, and in the condition directed by and expected by Defendant.

59. Plaintiff and his physicians foreseeably used and implanted the Physiomesh, and did not misuse, or alter the Physiomesh in an unforeseeable manner.

60. Defendants advertised, promoted, marketed, sold, and distributed the Physiomesh as a safe medical device when Defendant knew or should have known the Physiomesh was not safe for its intended purposes and that the mesh product could cause serious medical problems.

61. Defendants had sole access to material facts concerning the defective nature of the products and their propensity to cause serious and dangerous side effects.

62. In reliance on Defendant's representations, Plaintiff's doctor was induced to, and did use the Physiomesh.

63. As a result of having the Physiomesh implanted, Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury, permanent and substantial physical deformity, has undergone and will undergo corrective surgery or surgeries, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, and present and future lost wages.

64. Defendant's Physiomesh was marketed to the medical community and to patients as safe, effective, reliable, medical devices; implanted by safe and effective, minimally invasive surgical techniques for the treatment of medical conditions, primarily hernia repair and soft tissue repair, and as a safer and more effective as compared to the traditional products and procedures for treatment, and other competing hernia mesh products.

65. The Defendants have marketed and sold the Defendant's Physiomesh to the medical community at large and patients through carefully planned, multifaceted marketing campaigns and strategies. These campaigns and strategies include, but are not limited to, direct to consumer advertising, aggressive marketing to health care providers at medical conferences, hospitals, private offices, and/or group purchasing organizations, and include a provision of valuable consideration and benefits to the aforementioned.

66. The injuries, conditions, and complications suffered due to Defendant's Physiomesh include but are not limited to foreign body reaction, rashes, infection, adhesions, organ perforation, inflammation, fistula, mesh erosion, scar tissue, blood loss, dyspareunia, neuropathic and other acute and chronic nerve damage and pain, abdominal pain, nausea,

vomiting, kidney failure, and in many cases the patients have been forced to undergo intensive medical treatment, including but not limited to operations to locate and remove the Physiomesh, operations to attempt to repair abdominal organs, tissue, and nerve damage, the use of narcotics for pain control and other medications, and repeat operations to remove various tissues that are contaminated with the Physiomesh.

67. Plaintiff in the exercise of due diligence, could not have reasonably discovered the cause of his injuries including but not limited to the defective design and/or manufacturing the Physiomesh implanted inside of his until a date within the applicable statute of limitations.

COUNT I

NEGLIGENCE

68. Plaintiff re-alleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein.

69. At all relevant times, Defendant had a duty to exercise reasonable and ordinary care in the manufacture, design, labeling, instructions, warnings, sale, marketing, and distribution of the Defendant's Physiomesh, and recruitment and training of physicians to implant the Physiomesh.

70. Defendants breached the duty of care to the Plaintiff, as aforesaid, in the manufacture, design, labeling, warnings, instructions, sale, marketing, distribution, and recruitment and training of physicians to implant the Physiomesh.

71. Defendants knew or should have known that its failure to exercise ordinary care in the manufacture, design, labeling, warnings, instructions, sale, marketing, distribution and

recruitment and training of physicians to implant the Physiomesh would cause foreseeable harm, injuries and damages to individuals such as Plaintiff who are implanted with Physiomesh.

72. As a direct, proximate and foreseeable result of the Defendant's design, manufacture, labeling, marketing, sale, and distribution of the Physiomesh, Plaintiff has been injured, sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and consortium, and economic damages.

73. Each act or omission of negligence was a proximate cause of the damages and injuries to Plaintiff.

WHEREFORE, Plaintiff demands judgment against Defendant, and requests compensatory damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT II

STRICT LIABILITY – DESIGN DEFECT

74. Plaintiff re-alleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein and additionally or in the alternative, if same be necessary, allege as follows:

75. Defendant supplied, manufactured, sold, distributed and/or otherwise placed into the stream of commerce the Physiomesh implanted into Plaintiff. The mesh was defective in its design in that when it left the hands of Defendant, it was not safe for its anticipated use and safer, more reasonable alternative designs existed that could have been utilized by Defendant. A reasonably prudent medical device manufacturer would not have placed the Physiomesh with its defective design into the stream of commerce.

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

77. The Physiomesh was unreasonably dangerous, taking into consideration the utility of said product and the risks involved in its use. The foreseeable risks associated with the design of the mesh were more dangerous than a reasonably prudent consumer such as Plaintiff and/or his physician would expect when the mesh was used for its normal and intended purpose.

78. The Physiomesh reached Plaintiff's implanting surgeon and was implanted in Plaintiff without any substantial change in the condition in which it was supplied, distributed, sold and/or otherwise placed into the stream of commerce.

79. The Physiomesh failed to perform as safely as an ordinary consumer and/or his physician would expect when used as intended or when used in a manner reasonably foreseeable by the manufacturer, and the risks and dangers of the Physiomesh outweigh its benefits. The design defects in the Physiomesh were not known, knowable and/or reasonably visible to Plaintiff and/or his physician or discoverable upon any reasonable examination. The Physiomesh was used and implanted in the manner in which it was intended to be used and implanted by Defendants pursuant to the instructions for use and the product specifications provided by Defendants.

80. The defective and unreasonably dangerous condition of the Physiomesh was the proximate cause of the damages and injuries complained of by Plaintiff.

81. As a direct and proximate result of the Physiomesh's aforementioned design defects, Plaintiff was caused and in the future will be caused to suffer severe personal injuries, pain and suffering, severe emotional distress, financial or economic loss, including, but not

limited to, obligations for medical services and expenses, and other damages.

82. Defendants are strictly liable to Plaintiff.

WHEREFORE, Plaintiff demands judgment against Defendant and requests compensatory damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT III

STRICT LIABILITY – MANUFACTURING DEFECT

83. Plaintiff re-alleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein and additionally or in the alternative, if same be necessary, allege as follows:

84. Defendants supplied, manufactured, sold, distributed and/or otherwise placed into the stream of commerce the Physiomesh implanted in Plaintiff. The Physiomesh was defective in its manufacture and construction when it left the hands of Defendant in that its manufacture and construction deviated from good manufacturing practices and/or manufacturing specifications as would be used and/or maintained by a reasonably prudent and careful medical device manufacturer.

85. The Physiomesh as manufactured and constructed by Defendants was unreasonably dangerous to end consumers including Plaintiff and posed an unreasonable degree of risk, danger and harm to Plaintiff.

86. The Physiomesh was expected to reach and did reach Plaintiff's implanting surgeon and Plaintiff without substantial change in the condition in which it was manufactured, suppled, distributed sold and/or otherwise placed in the stream of commerce.

87. The manufacturing defect in the Physiomesh implanted in Plaintiff was not known, knowable or readily visible to Plaintiff's physician or to Plaintiff nor was it discoverable upon any reasonable examination by Plaintiff's physician or Plaintiff. The Physiomesh was used and implanted in the very manner in which it was intended to be used and implanted by Defendant in accordance with the instructions for use and specifications provided by Defendants.

88. The Physiomesh implanted in Plaintiff was different from its intended design and failed to perform as safely as a product manufactured in accordance with the intended design would have performed.

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

90. As a direct and proximate result of the Physiomesh's aforementioned manufacturing defect, Plaintiff was caused and in the future will be caused to suffer severe personal injuries, pain and suffering, severe emotional distress, financial or economic loss, including, but not limited to, obligations for medical services and expenses, and other damages.

91. Defendant is strictly liable to Plaintiff.

WHEREFORE, Plaintiff demands judgment against Defendant and requests compensatory damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT IV

STRICT LIABILITY – FAILURE TO WARN

92. Plaintiff realleges and incorporates by reference every allegation of this Complaint

as if each were set forth fully and completely herein and additionally or in the alternative, if same be necessary, allege as follows:

93. Defendant manufactured, designed, marketed, sold and/or otherwise placed into the stream of commerce their Physiomesh surgical mesh product.

94. The Defendants failed to properly and adequately warn and instruct Plaintiff and his treating physician that Physiomesh was designed and/or manufactured in a way that could cause injuries and damages including lasting and permanent injuries. Defendants further failed to inform and further warn Plaintiff and his treating physician with respect to the most effective proper technique and methods of implantation and/or the selection of appropriate candidates to receive Physiomesh.

95. The Defendants failed to properly and adequately warn and instruct Plaintiff and his treating physician as to the risks and benefits of the Defendant's Physiomesh. To the contrary, Defendants withheld information from Plaintiff and his treating physician regarding the true risks as relates to implantation of their Physiomesh.

96. The Defendants failed to properly and adequately warn and instruct Plaintiff and his treating physician that inadequate research and testing of the Physiomesh was done prior to Physiomesh being placed on the market and in the stream of commerce and that Defendants lacked a safe, effective procedure for removal of the Physiomesh once complications from same arise.

97. The Defendant intentionally, recklessly, and maliciously misrepresented the efficacy, safety, risks, and benefits of Physiomesh, understating the risks and exaggerating the benefits in order to advance its own financial interest, with wanton and willful disregard for the

rights, safety and health of Plaintiff.

98. As a direct and proximate result of the Defendant's design, manufacture, marketing, sale, and distribution of the Physiomesh, Plaintiff has been injured and sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and economic damages.

99. The Defendants are strictly liable in tort to the Plaintiff for their wrongful conduct in failing to properly warn Plaintiff.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory damages, interest, attorneys' fees, costs of suit, and such further relief as the Court deems equitable and just.

COUNT V

BREACH OF EXPRESS WARRANTY

100. Plaintiff re-alleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein and additionally or in the alternative, if same be necessary, allege as follows:

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

102. In advertising, marketing and otherwise promoting Physiomesh to physicians, hospitals and other healthcare providers, Defendant's expressly warranted that their Physiomesh was safe for use. In advertising, marketing and otherwise promoting Physiomesh, Defendant intended that physicians, hospitals and other healthcare providers rely upon their representations in an effort to induce them to use Physiomesh for their patients.

103. The Plaintiff was a person whom the defendants could reasonably have expected to use, consume, or be affected by the Defendant' hernia mesh products within the meaning of Massachusetts General Laws ch. 106, §2-3l8, as the Defendant specifically designed the Physiomesh for permanent implantation in patients exhibiting hernia such as Plaintiff.

104. With respect to Plaintiff, Defendant intended that Physiomesh be implanted in Plaintiff by his treating surgeon in the reasonable and foreseeable manner in which it was implanted and in accordance with the instructions for use and product specifications provided by Defendants. Plaintiff was in privity with Defendants.

105. Defendants expressly warranted to physicians, hospitals, other healthcare providers and the general public including Plaintiff that Physiomesh was safe and fit for use by consumers including Plaintiff, that it was of merchantable quality, that its risks, side effects and potential complications are minimal and are comparable to other hernia mesh products, that it was adequately researched and tested and was fit for its intended use. Plaintiff and his physicians and healthcare providers relied upon these express representations and warranties made by Defendants and consequently, Plaintiff was implanted with Defendant's Physiomesh.

106. Defendants breached express representations and warranties made to Plaintiff and his physicians and healthcare providers with respect to the Physiomesh implanted in Plaintiff including the following particulars:

A. Defendant represented to Plaintiff and his physicians and healthcare providers through labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions among other ways that the Defendant's Physiomesh was safe, meanwhile Defendant

fraudulently withheld and concealed information about the substantial risks of serious injury associated with using Physiomesh;

B. Defendant represented to Plaintiff and his physicians and healthcare providers that the Defendant's Physiomesh was as safe and/or safer than other alternative procedures and devices then on the market, meanwhile Defendant fraudulently concealed information that demonstrated that Physiomesh was not safer than alternative therapies and products available on the market; and

C. Defendant represented to Plaintiff and his physicians and healthcare providers that the Defendant's Physiomesh was more efficacious than other alternative procedures, therapies and/or devices. Meanwhile Defendant fraudulently concealed information, regarding the true efficacy of Physiomesh.

107. At the time of making such express warranties, Defendants knew or should have known that Defendant's Physiomesh does not conform to the express warranties and Defendant's acts were motivated by financial gain while the adverse consequences of Defendant's conduct was outrageous, fraudulent, oppressive, done with malice or gross negligence and evidenced reckless indifference to Plaintiff's rights, health and safety.

108. As a direct and proximate result of Defendant's breaches of the aforementioned express warranties, Plaintiff was caused and in the future will be caused to suffer severe personal injuries, pain and suffering, severe emotional distress, financial or economic loss, including, but not limited to, obligations for medical services and expenses, impairment of personal relationships, and other damages.

WHEREFORE, Plaintiff demands judgment against Defendant and requests

compensatory damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT VI

BREACH OF IMPLIED WARRANTIES OF MERCHANTABILITY

AND FITNESS OF PURPOSE

109. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein and additionally or in the alternative, if same be necessary, allege as follows:

110. At all relevant and material times, Defendant manufactured, distributed, advertised, promoted, and sold the Defendant's Physiomesh.

111. At all relevant times, Defendants intended that its Physiomesh be implanted for the purposes and in the manner that Plaintiff's implanting surgeon did in fact implant it in accordance with the instructions for use and product specifications provided by Defendant and Defendant impliedly warranted that their Physiomesh was of merchantable quality, safe and fit for its intended use of implantation in Plaintiff and was properly and adequately tested prior to being placed in the stream of commerce.

112. The Plaintiff was a person whom the defendants could reasonably have expected to use, consume, or be affected by the Defendant' hernia mesh products within the meaning of Massachusetts General Laws ch. 106, §2-3l8, as the Defendant specifically designed the Physiomesh for permanent implantation in patients exhibiting hernia such as Plaintiff.

113. the insulation, construction and/or ship building industry and that individuals such as the plaintiff would come in contact with such asbestos materials.

114. Defendant was aware that consumers such as Plaintiff would be implanted with Physiomesh by their treating physicians in accordance with the instructions for use and product specifications provided by Defendant to Plaintiff's physicians. Plaintiff was a foreseeable user of Defendant's Physiomesh, and plaintiff was in privity with Defendants.

115. Defendants breached implied warranties with respect to the Physiomesh including the following particulars:

A. Defendants represented to Plaintiff and his physicians and healthcare providers through its labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that the Defendant's Physiomesh was of merchantable quality and safe when used for its intended purpose meanwhile Defendant fraudulently withheld and concealed information about the substantial risks of serious injury associated with using Physiomesh;

B. Defendant represented to Plaintiff and his physicians and healthcare providers that the Defendant's Physiomesh was safe, as safe as and/or safer than other alternative procedures and devices, meanwhile Defendant fraudulently concealed information, which demonstrated that the Physiomesh was not safe, as safe as or safer than alternatives and other products available on the market; and

C. Defendants represented to Plaintiff and his physicians and healthcare providers that the Defendant's Physiomesh were more efficacious than other alternative procedures and/or devices. Meanwhile Defendant fraudulently concealed

information, regarding the true efficacy of Physiomesh.

116. In reliance upon Defendant's implied warranty, Plaintiff's implanting surgeon used Physiomesh to treat Plaintiff in the foreseeable manner normally intended, recommended, promoted, and marketed by Defendants and in accordance with the instructions for use and product specification provided by Defendants.

117. Defendants breached their implied warranty to Plaintiff in that the Defendant's Physiomesh was not of merchantable quality, safe and fit for its intended use nor was it adequately tested prior to being placed in the stream of commerce.

118. Defendant's acts were motivated by financial gain while the adverse consequences of the conduct were actually known by Defendant. Defendant's conduct was outrageous, fraudulent, oppressive, done with malice and with gross negligence, and evidenced reckless disregard and indifference to Plaintiff's rights, health and safety.

119. As a direct and proximate result of Defendant's breach of the aforementioned implied warranties, Plaintiff was caused and in the future will be caused to suffer severe personal injuries, pain and suffering, severe emotional distress, financial or economic loss, including, but not limited to, obligations for medical services and expenses, impairment of personal relationships, and other damages.

WHEREFORE, Plaintiff demands judgment against Defendant and requests compensatory damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT VII

VIOLATION OF CONSUMER PROTECTION LAWS

120. Plaintiff re-alleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein and additionally or in the alternative, if same be necessary, allege as follows:

121. Plaintiff by and through his treating physician was implanted with Defendant's Physiomesh for the sole, primary and personal use and purpose of treating his physical medical condition and thereby suffered ascertainable losses as a result of Defendant's actions in violation of the consumer protection laws.

122. Had Defendants not engaged in the deceptive conduct described herein, Plaintiff would not have purchased and/or otherwise been implanted with Physiomesh, and would not have suffered permanent physical injury as described herein and incurred medical costs and expenses.

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

124. Defendants engaged in unfair methods of competition and/or deceptive acts or practices that were prescribed by law, including the following:

A. Representing that goods or services have characteristics, ingredients, uses, benefits or qualities 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.

125. Plaintiff was injured by the cumulative and indivisible nature of Defendant's conduct. The cumulative effect of Defendant's conduct directed at patients, physicians and consumers was to create demand for and sell the Defendant's Physiomesh. Each aspect of Defendant's conduct combined to artificially create sales of Defendant's Physiomesh.

126. Defendants have a statutory duty to refrain from unfair or deceptive acts or trade practices in the design, labeling, marketing and sale of surgical mesh products.

127. Defendant's deceptive, unconscionable and/or fraudulent representations and material omissions to patients, physicians and consumers, including Plaintiff, constituted unfair and deceptive acts and trade practices in violation of state and federal consumer protection statutes listed.

128. Defendant's actions, as complained of herein, constitute unfair competition or unfair, unconscionable, deceptive or fraudulent acts, or trade practices in violation of federal and state consumer protection statues, as listed below.

129. Defendants have engaged in unfair competition or unfair or deceptive acts or trade practices or have made false representations.

- 15 U.S.C. §§ 2301-2312 (1982)
- Massachusetts Consumer Protection Law (MGL Ch. 93A)

130. Under the statutes listed above to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising, Defendant is the suppliers, manufacturers, advertisers, and sellers, who are subject to liability under such legislation for unfair, deceptive, fraudulent and unconscionable consumer sales practices.

131. Defendant violated the statutes that were enacted in Massachusetts to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising, by knowingly and falsely representing that the Defendant's Physiomesh was fit to be used for the purpose for which it was intended while in fact it was defective and dangerous, and by other acts alleged herein. These representations were made in marketing and promotional materials.

132. The actions and omissions of Defendant alleged herein are uncured or incurable deceptive acts under the statutes enacted in Massachusetts and other states to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising.

133. Defendant had actual knowledge of the defective and dangerous condition of Defendant's Physiomesh and failed to take any action to cure such defective and dangerous conditions to the detriment of Plaintiff and other consumers.

134. The medical community including Plaintiff's physician and other health care providers relied upon Defendant's misrepresentations and omissions in determining whether to use Defendant's Physiomesh.

135. Defendant's deceptive, unconscionable or fraudulent representations and material omissions to patients, physicians and consumers, constituted unfair and deceptive acts and practices.

136. By reason of the unlawful acts engaged in by Defendants, and as a direct and proximate result thereof, Plaintiff has suffered ascertainable losses and damages.

137. As a direct and proximate result of Defendant's violations of the Massachusetts

consumer protection laws, Plaintiff has sustained economic losses and other damages and is entitled to statutory and compensatory damages in an amount to be proven at trial.

WHEREFORE, Plaintiff demands judgment against Defendant and requests restitution and disgorgement of profits, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems just and proper.

COUNT VIII

GROSS NEGLIGENCE AND INTENTIONAL CONDUCT

138. Plaintiff re-alleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein and additionally or in the alternative, if same be necessary, allege as follows:

139. The acts and omissions of Defendant as alleged herein are of a character and nature that is outrageous, fraudulent, oppressive, done with malice and evidenced reckless disregard for Plaintiff's rights, health and safety and constitute gross negligence and/or willful or intentional indifference or conduct.

140. The acts and omissions of Defendant, whether taken singularly or in combination with others, constitute gross negligence or willful and/or intentional conduct that proximately caused injuries to Plaintiff.

WHEREFORE, Plaintiff demands judgment against Defendant and requests compensatory damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT IX

UNJUST ENRICHMENT

141. Plaintiff re-alleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein and additionally or in the alternative, if same be necessary, allege as follows:

142. Defendant at all times was the manufacturer, seller, and/or supplier of Physiomesh.

143. Plaintiff was implanted with Defendant's Physiomesh for the purpose of treatment for hernia repair and/or a soft tissue injury and Defendants were paid for Plaintiffs use of said product.

144. Defendant have accepted payment by Plaintiff and/or by others on Plaintiff's behalf for the purchase of the Physiomesh with which Plaintiff was implanted.

145. Plaintiff was not implanted with nor did he receive the medical device that Defendant's represented and warranted to be safe, effective and efficacious and for which Plaintiff paid.

146. Equity demands that Defendant be required to disgorge any and all moneys, profits and/or any other thing of value received by Defendant on account of Plaintiff receiving a product that was substantially different than that which was represented and/or warranted and because of Defendant's conduct, acts and omissions as set out herein.

WHEREFORE, Plaintiff demands judgment against Defendant and requests compensatory damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

VICARIOUS LIABILITY

147. Whenever in this complaint it is alleged that Defendant did or omitted to do any act, it is meant that Defendant's officers, agents, servants, employees, or representatives did or omitted to do such act and that at the time such act or omission was done, it was done with the full authorization or ratification of Defendant or was done in the normal and routine course and scope of employment of Defendant's officers, agents, servants, employees, and representatives.

EQUITABLE TOLLING OF THE APPLICABLE STATUTE OF LIMITATIONS

148. The running of any statute of limitation has been tolled by reason of the Defendant's fraudulent conduct. Defendant, through its affirmative misrepresentations and omissions, actively concealed from Plaintiff and Plaintiff's treating physicians the true risks associated with Physiomesh.

149. As a result of the Defendant's actions, Plaintiff and Plaintiff's treating physicians were unaware, and could not reasonably know or have learned through reasonable diligence that Plaintiff had been exposed to the risks alleged herein and that those risks were the direct and proximate result of Defendant's acts and omissions.

150. Furthermore, Defendant's are estopped from relying on any statute of limitations defense because of their fraudulent concealment of the truth regarding the quality and nature of Physiomesh. Defendant had a duty to disclose the true character, quality and nature of Physiomesh because this was non-public information over which Defendant had and continued to have exclusive control, and because Defendant knew that this information was not available to the

Plaintiff, medical providers and/or to health facilities. Defendant is estopped from relying on any statute of limitation because of their intentional concealment of these facts.

151. The Plaintiff had no knowledge that Defendant was engaged in the wrongdoing alleged herein. Because of the fraudulent acts of concealment and wrongdoing by Defendant, Plaintiff could not have reasonably discovered the wrongdoing until less than the applicable limitations period prior to the filing of this action.

PRAYER FOR RELIEF

Plaintiff demands judgment against Defendant and prays for the following relief in accordance with applicable law and equity:

i. Compensatory damages to Plaintiff for past, present, and future damages, including, but not limited to, pain and suffering for severe and permanent personal injuries sustained by Plaintiff, permanent impairment, mental pain and suffering, loss of enjoyment of life, past and future health and medical care costs and economic damages including past and future lost earnings and/or earning capacity together with interest and costs as provided by law;

ii. Reasonable attorneys' fees as provided by law;

iii. The costs of these proceedings, including past a future cost of the suit incurred herein;

iv. Prejudgment interest on all damages as is allowed by law;

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

JURY TRIAL DEMANDED

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

Respectfully submitted,

PLAINTIFF DAVID WATRING
By his attorneys,

/s/ Robert T. Naumes, Jr.
Robert T. Naumes, Jr.
MA BBO# 664826
Law Offices of Jeffrey Glassman
1 International Place, 18th Floor
Boston, MA 02110
P: (617) 367-2900
F: (617) 722-9999
bnaumes@jeffreysglassman.com

Adam M. Evans
Hollis Law Firm, P.A.
5100 W. 95th St.
Prairie Village, KS 66207
P: (913) 385-5400
F: (913) 385-5402
adam@hollislawfirm.com
Pro Hac Vice Pending

JS 44 (Rev. 12/07)

CIVIL COVER SHEET

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

I. (a) PLAINTIFFS

David Watring

(b) County of Residence of First Listed Plaintiff Barnstable Cty., MA
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorney's (Firm Name, Address, and Telephone Number)

Law Offices of Jeffrey Glassman, 1 International Place
18th Floor Boston, MA 02110, (617) 367-2900

DEFENDANTS

ETHICON, INC.

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

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

Attorneys (If Known)

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

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

III. CITIZENSHIP OF PRINCIPAL PARTIES (Place an "X" in One Box for Plaintiff and One Box for Defendant)
(For Diversity Cases Only)

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

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

CONTRACT
- ☐ 110 Insurance
- ☐ 120 Marine
- ☐ 130 Miller Act
- ☐ 140 Negotiable Instrument
- ☐ 150 Recovery of Overpayment & Enforcement of Judgment
- ☐ 151 Medicare Act
- ☐ 152 Recovery of Defaulted Student Loans (Excl. Veterans)
- ☐ 153 Recovery of Overpayment of Veteran's Benefits
- ☐ 160 Stockholders' Suits
- ☐ 190 Other Contract
- ☐ 195 Contract Product Liability
- ☐ 196 Franchise

REAL PROPERTY
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

TORTS

PERSONAL INJURY
- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers' Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury

PERSONAL INJURY
- ☐ 362 Personal Injury - Med. Malpractice
- ☒ 365 Personal Injury - Product Liability
- ☐ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

CIVIL RIGHTS
- ☐ 441 Voting
- ☐ 442 Employment
- ☐ 443 Housing/ Accommodations
- ☐ 444 Welfare
- ☐ 445 Amer. w/Disabilities - Employment
- ☐ 446 Amer. w/Disabilities - Other
- ☐ 440 Other Civil Rights

PRISONER PETITIONS
- ☐ 510 Motions to Vacate Sentence

Habeas Corpus:
- ☐ 530 General
- ☐ 535 Death Penalty
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Condition

FORFEITURE/PENALTY
- ☐ 610 Agriculture
- ☐ 620 Other Food & Drug
- ☐ 625 Drug Related Seizure of Property 21 USC 881
- ☐ 630 Liquor Laws
- ☐ 640 R.R. & Truck
- ☐ 650 Airline Regs.
- ☐ 660 Occupational Safety/Health
- ☐ 690 Other

LABOR
- ☐ 710 Fair Labor Standards Act
- ☐ 720 Labor/Mgmt. Relations
- ☐ 730 Labor/Mgmt.Reporting & Disclosure Act
- ☐ 740 Railway Labor Act
- ☐ 790 Other Labor Litigation
- ☐ 791 Empl. Ret. Inc. Security Act

IMMIGRATION
- ☐ 462 Naturalization Application
- ☐ 463 Habeas Corpus - Alien Detainee
- ☐ 465 Other Immigration Actions

BANKRUPTCY
- ☐ 422 Appeal 28 USC 158
- ☐ 423 Withdrawal 28 USC 157

PROPERTY RIGHTS
- ☐ 820 Copyrights
- ☐ 830 Patent
- ☐ 840 Trademark

SOCIAL SECURITY
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

FEDERAL TAX SUITS
- ☐ 870 Taxes (U.S. Plaintiff or Defendant)
- ☐ 871 IRS—Third Party 26 USC 7609

OTHER STATUTES
- ☐ 400 State Reapportionment
- ☐ 410 Antitrust
- ☐ 430 Banks and Banking
- ☐ 450 Commerce
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced and Corrupt Organizations
- ☐ 480 Consumer Credit
- ☐ 490 Cable/Sat TV
- ☐ 810 Selective Service
- ☐ 850 Securities/Commodities/ Exchange
- ☐ 875 Customer Challenge 12 USC 3410
- ☐ 890 Other Statutory Actions
- ☐ 891 Agricultural Acts
- ☐ 892 Economic Stabilization Act
- ☐ 893 Environmental Matters
- ☐ 894 Energy Allocation Act
- ☐ 895 Freedom of Information Act
- ☐ 900Appeal of Fee Determination Under Equal Access to Justice
- ☐ 950 Constitutionality of State Statutes

V. ORIGIN (Place an "X" in One Box Only)

☒ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from another district (specify) ☐ 6 Multidistrict Litigation ☐ 7 Appeal to District Judge from Magistrate Judgment

VI. CAUSE OF ACTION

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

Brief description of cause:
Personal injury based on surgical mesh product

VII. REQUESTED IN COMPLAINT:

☐ CHECK IF THIS IS A CLASS ACTION UNDER F.R.C.P. 23

DEMAND $ 75,001.00

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

VIII. RELATED CASE(S) IF ANY (See instructions): JUDGE _____ DOCKET NUMBER _____

DATE
11/11/2016

SIGNATURE OF ATTORNEY OF RECORD
/s/ Robert T. Naumes, Jr.

FOR OFFICE USE ONLY

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