### UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF NEW YORK

JOSEPH WASS,	Civil Action No.:
Plaintiff,	COMPLAINT
<b>v.</b>	JURY TRIAL DEMANDED
JOHNSON & JOHNSON and ETHICON, INC.,	
Defendant.	

Plaintiff, by and through the 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 Defendants' hernia mesh product. As a result, Plaintiff Joseph Wass 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. <u>STATEMENT OF PARTIES</u>

- 2. Plaintiff Joseph Wass ("Plaintiff") is, and was, at all relevant times, a citizen and resident of Pennsylvania and the United States.
- 3. Defendant Johnson & Johnson ("J&J") is a corporation incorporated in New Jersey, and according to its website, the world's largest and most diverse medical device and diagnostics company, with its principal place of business located at One Johnson & Johnson Plaza, New

Brunswick, New Jersey. Defendant J&J organizes its subsidiary businesses into individual Business Units to coordinate the development, manufacture, testing, marketing promotion, training, distribution and sale of its products, including but not limited to its hernia repair mesh products. Within J&J there are three sectors: medical devices and diagnostics, pharmaceutical, and consumer. Within the medical devices and diagnostic sector are "Business Units" including the "Ethicon Franchise." The Ethicon Franchise was charged by J&J with the design, development, promotion, marketing, testing, training, distribution and sale of the hernia repair mesh products at issue in this case. The Company Group Chairman and Worldwide Franchise Chairman for the Ethicon Franchise, Gary Pruden, is employed by J&J. The companies which comprise the Ethicon Franchise are thus controlled by J&J and include, but are not limited to, Ethicon Inc.

- 4. Defendant Ethicon, Inc. 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 authorized and registered to transact business within the State of New York. 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 Defendants were and still are a corporation authorized to do business in the State of New York.

- 7. At all times hereinafter mentioned, upon information and belief, Defendants were and still are business entities actually doing business in the State of New York.
- 8. At all times hereinafter mentioned, Defendants were, 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, transact business within the State of New York and contract to provide goods and services in the State of New York.
- 9. At all times hereinafter mentioned, upon information and belief, Defendants committed tortious acts inside and outside the State of New York, which caused injury to Plaintiff inside the State of New York.
- 10. At all times hereinafter mentioned, upon information and belief, Defendants expect or should reasonably expect its acts to have consequences in the State of New York, and derives substantial revenue from interstate or international commerce.

### II. <u>VENUE AND JURISDICTION</u>

- 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) Defendants' products are sold to and consumed by individuals in the State of New

York, 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 State of New York 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 State of New York through sales representatives conducting business in the State of New York 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 New York.
- 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 State of New York, such that requiring an appearance does not offend traditional notices of fair and substantial justice.

### III. <u>DEFENDANTS' HERNIA MESH PRODUCT</u>

- 17. In or about 2010, Defendants began to market and sell Physiomesh for the treatment of multiple medical conditions, primarily hernia repair.
- 18. Defendants' Hernia Mesh Products were designed, patented, manufactured, labeled, marketed, sold, and distributed by the Defendants at all relevant times herein.

- 19. Defendants' 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 Defendants' 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. Defendants' 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, Defendants use adulterated polypropylene in their Hernia Mesh Products.
- 23. Defendants failed to warn or notify doctors, regulatory agencies, and consumers of the Defendants' use of adulterated polypropylene in their Hernia Mesh Products.
- 24. The polypropylene component of Defendants' 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, Defendants 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. At all relevant times, Dr. Brent Matthews was a consultant for Ethicon. In addition, Dr. Matthews was receiving an honorarium as well as research and equipment support from Ethicon Endo-Surgery.
- 32. Dr. Matthews was a co-author of a study entitled "Ventralight ST and SorbaFix versus Physiomesh and Securestrap in a Porcine Model" (Deeken and Matthews 2013). Said study tested Physiomesh implant in pigs. The study found that after fourteen days of implantation:
  - a. 50% of the Physiomesh specimens experienced omental adhesions compared to only
     30% of the Ventralight specimens which experienced omental adhesions;
  - 50% of the Physiomesh specimens experienced incomplete integration of mesh and incomplete tissue coverage;

- c. Physiomesh specimens experienced more inflammation, hemorrhage, and angiogenesis
  as compared with Ventralight specimens;
- d. Physiomesh specimens had lesser strength of tissue ingrowth compared to Ventralights specimens.
- 33. At all relevant times during the pendency of and after the publication of the Matthews study, the Defendants knew or should have known Physiomesh demonstrated unacceptably high complication and failure rates.
- 34. At all relevant times, Dr. Maciej Stiemenstanski received consulting fees for serving on the Advisory Committee of Johnson and Johnson Medical products. Furthermore, Dr. Stienmenstankski co-authored the European Hernia Society Guidelines on Treatment of Inguinal Hernias, which was financed through grants from Ethicon.
- 35. Dr. Stienmenstankski co-authored a study entitled "Comparison of two different concepts of mesh and fixation technique in laparoscopic ventral hernia repair: a randomized controlled trial." (Palwak, Hilgers, Bury, Lehmann, Owczuk, and Smientanski 2015) The study, which began in November 2012, compared Physiomesh and Ventralight hernia mesh, and found:
  - a. 20% of Physiomesh participants experienced hernia recurrences within six months of implantation, requiring re-operation;
  - b. Physiomesh participants requiring reoperation experienced dense adhesions of the intestines and omentum directly to the Physiomesh;
  - c. None of the Ventralight participants experienced hernia recurrence;
  - d. The pain intensity was significantly higher across time for Physiomesh participants. At three months, fourteen Physiomesh participants reported experiencing pain while none of the Ventralight participants reported pain. At six months, eight Physiomesh

participants reported significantly higher pain compared to zero Ventralight participants.

- 36. The aforementioned study was terminated due to what the researchers considered serious adverse events. The high hernia recurrence rate, increased intensity of pain, and unexpected intestinal adhesions were deemed to be adverse to the participants.
- 37. At all relevant times during the pendency of and after the publication of the Stienmenstankski study, the Defendants knew or should have known Physiomesh demonstrated unacceptably high complication and failure rates.
- 38. 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.
- 39. Defendants failed to warn or notify doctor, regulatory agencies, and consumers of the known inflammatory properties of the Physiomesh.
- 40. 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.
- 41. 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.

- 42. Defendants' use of ETO on the Physiomesh Mesh results high infection rates due to inadequate moisture during the ETO cycle.
- 43. ETO is ineffective at sterilizing the Physiomesh Mesh due the poliglecaprone coating, multiple layers of the material, and mated surfaces of the Physiomesh.
- 44. 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.
- 45. Upon information and belief, Defendants paid researchers, doctors, clinicians, study designers, authors, and/or scientists to study the effectiveness of the Physiomesh, but did not disclose these relationships in the studies themselves.
- 46. Upon information and belief, Defendants paid doctors, surgeons, physicians, and/or clinicians to promote the Physiomesh, but did not readily disclose this information.
- 47. Defendants failed to implement adequate procedures and systems to report, track, and evaluate complaints and adverse events.
- 48. Between the 2010 and 2016, the FDA MAUDE Adverse Event Database received 156 reports of Physiomesh associated with complications or failures.
- 49. Defendants knew or should have known of these FDA MAUDE Physiomesh complications and failures demonstrated unacceptably high complication and failure rates.
- 50. Years after Defendants were aware or should have been aware of unacceptably high complication and failure rates associated with Physiomesh, Defendants published a Field Safety Notice on May 25, 2016. The Field Safety Notice was purportedly based on "unpublished data from two (2) large independent hernia registries (Herniamed German Registry and Danish Hernia Database-DHDB). The recurrence/reoperation rates (respectively) after laparoscopic ventral

hernia repair using ETHICON PHYSIOMESH™ Composite Mesh were higher than the average rates of the comparator set of meshes among patients in these registries."

- 51. The aforesaid Urgent Safety Field Notice did not refer to the published Matthews and Stienmenstankski journal articles, nor the FDA MAUDE database of known complications and failures associated with Physiomesh.
- 52. Defendants' Urgent Field Safety Notice was never sent to Physiomesh patients to notify them of potentially unacceptably high rates of complication and failure.
- 53. Defendants' Urgent Field Safety Notice did not advise surgeons to contact Physiomesh patients to notify them of potentially unacceptably high rates of complication and failure.
- 54. Defendants failed to employ an adequate number of staff to receive, process, investigate, document, and report adverse events.
- 55. 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. Defendants' deception through false advertising resulted in more physicians utilizing the Physiomesh.
- 56. 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.

- 57. 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.
- 58. 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 Defendants' Physiomesh product.
- 59. Defendants failed to design and establish a safe, effective procedure for removal of the Defendants' Physiomesh product; therefore, in the event of a failure, injury, or complications it is impossible to easily and safely remove the Defendants' Physiomesh product.
- 60. 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 Defendants' Physiomesh.
- 61. The Defendants' Physiomesh was at all times utilized and implanted in a manner foreseeable to the Defendants.
- 62. 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 Defendants' Physiomesh, and thus increase the sales of the Physiomesh, and also leading to the dissemination of inadequate and misleading information to patients, including Plaintiff.

- 63. 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.
- 64. 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.
- 65. As a direct, proximate, and foreseeable result of the Defendants' design, manufacture, labeling, marketing, sale, and distribution of the Physiomesh, the injuries, conditions, and complications suffered due to Defendants' 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

### IV. <u>FACTUAL BACKGROUND</u>

- 66. On or about February 20, 2013, Plaintiff underwent ventral hernia repair at Wayne Memorial Hospital in Homesdale, Pennslyvania by Dr. Brian Lenczewski. During this procedure, a 15 x 20 cm Physiomesh, model PHY1520V, was utilized for Plaintiff's hernia repair.
- 67. Defendant, manufactured, sold, and/or distributed the Physiomesh to Plaintiff, through his doctors, to be used for treatment of hernia repair.

- 68. On or about March 15, 2017, Plaintiff presented University of Pennslyvania Medical Center for excision of the Physiomesh due to chronic lower abdominal pain, bulge in the lower abdomen, and eventration of mesh. During the procedure, Dr. Jon Morris noted that "dense omental adhesions to the abdominal wall and the region of the mesh were identified". Dr. Morris also noted that "omentum had to be removed and dissected free from the overlying mesh'.
- 69. At all times, the Physiomesh was utilized and implanted in a manner foreseeable to Defendants, as Defendants generated the instructions for use and created procedures for implanting the mesh.
- 70. 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 Defendants.
- 71. Plaintiff and his physicians foreseeably used and implanted the Physiomesh, and did not misuse, or alter the Physiomesh in an unforeseeable manner.
- 72. Defendants advertised, promoted, marketed, sold, and distributed the Physiomesh as a safe medical device when Defendants knew or should have known the Physiomesh was not safe for its intended purposes and that the mesh product could cause serious medical problems.
- 73. Defendants had sole access to material facts concerning the defective nature of the products and their propensity to cause serious and dangerous side effects.
- 74. In reliance on Defendants' representations, Plaintiff's doctor was induced to, and did use the Physiomesh.
- 75. 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.

- 76. Defendants' 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.
- 77. The Defendants have marketed and sold the Defendants' 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.
- 78. 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 him until a date within the applicable statute of limitations.

### COUNT I NEGLIGENCE

- 79. Plaintiff re-alleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein.
- 80. At all relevant times, Defendants had a duty to exercise reasonable and ordinary care in the manufacture, design, labeling, instructions, warnings, sale, marketing, and distribution

of the Defendants' Physiomesh, and recruitment and training of physicians to implant the Physiomesh.

- 81. 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.
- 82. 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.
- 83. As a direct, proximate and foreseeable result of the Defendants' 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.
- 84. 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.

### <u>COUNT II</u> <u>STRICT LIABILITY – DESIGN DEFECT</u>

85. 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:

- 86. Defendants 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 Defendants, it was not safe for its anticipated use and safer, more reasonable alternative designs existed that could have been utilized by Defendants. A reasonably prudent medical device manufacturer would not have placed the Physiomesh with its defective design into the stream of commerce.
- 87. 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.
- 88. 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.
- 89. 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.
- 90. 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.
  - 91. The defective and unreasonably dangerous condition of the Physiomesh was the

proximate cause of the damages and injuries complained of by Plaintiff.

- 92. 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.
  - 93. 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

- 94. 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:
- 95. Defendants supplied, manufactured, sold, distributed and/or otherwise placed into the stream of commerce the Physiomesh implanted in Plaintiff. The Physiomesh was defective in its manufacture and construction when it left the hands of Defendants in that its manufacture and construction deviated from good manufacturing practices and/or manufacturing specifications as would be used and/or maintained by a reasonably prudent and careful medical device manufacturer.
- 96. 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.

- 97. 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.
- 98. The manufacturing defect in the Physiomesh implanted in Plaintiff was not known, knowable or readily visible to Plaintiff's physician or to Plaintiff nor was it discoverable upon any reasonable examination by Plaintiff's physician or Plaintiff. The Physiomesh was used and implanted in the very manner in which it was intended to be used and implanted by Defendants in accordance with the instructions for use and specifications provided by Defendants.
- 99. 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.
- 100. The defective and unreasonably dangerous condition of the Physiomesh product was a proximate cause of damages and injuries suffered by Plaintiff.
- 101. 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.
  - 102. Defendants are strictly liable to Plaintiff.

WHEREFORE, Plaintiff demands judgment against Defendants 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

- 103. 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:
- 104. Defendants manufactured, designed, marketed, sold and/or otherwise placed into the stream of commerce their Physiomesh surgical mesh product.
- 105. The Defendants failed to properly and adequately warn and instruct Plaintiff andhistreating 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 andhistreating physician with respect to the most effective proper technique and methods of implantation and/or the selection of appropriate candidates to receive Physiomesh.
- 106. The Defendants failed to properly and adequately warn and instruct Plaintiff andhistreating physician as to the risks and benefits of the Defendants' Physiomesh. To the contrary, Defendants withheld information from Plaintiff andhistreating physician regarding the true risks as relates to implantation of their Physiomesh.
- 107. The Defendants failed to properly and adequately warn and instruct Plaintiff andhistreating 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.
- 108. The Defendants 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.

- 109. As a direct and proximate result of the Defendants' 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.
- 110. 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

- 111. 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:
- 112. At all relevant and material times, Defendants manufactured, marketed, sold, distributed and otherwise placed in to the stream of commerce Physiomesh.
- 113. In advertising, marketing and otherwise promoting Physiomesh to physicians, hospitals and other healthcare providers, Defendants' expressly warranted that their Physiomesh was safe for use. In advertising, marketing and otherwise promoting Physiomesh, Defendants intended that physicians, hospitals and other healthcare providers rely upon their representations in an effort to induce them to use Physiomesh for their patients.

- 114. The Plaintiff was a person whom the Defendants could reasonably have expected to use, consume, or be affected by the Defendants' hernia mesh products as the Defendants specifically designed the Physiomesh for permanent implantation in patients exhibiting hernia such as Plaintiff.
- 115. With respect to Plaintiff, Defendants intended that Physiomesh be implanted in Plaintiff byhistreating 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.
- 116. 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 andhisphysicians and healthcare providers relied upon these express representations and warranties made by Defendants and consequently, Plaintiff was implanted with Defendants' Physiomesh.
- 117. Defendants breached express representations and warranties made to Plaintiff andhisphysicians and healthcare providers with respect to the Physiomesh implanted in Plaintiff including the following particulars:
  - A. Defendants represented to Plaintiff andhisphysicians and healthcare providers through labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions among other ways that the Defendants' Physiomesh was safe, meanwhile Defendants fraudulently withheld and concealed information about the substantial risks of

- serious injury associated with using Physiomesh;
- B. Defendants represented to Plaintiff andhisphysicians and healthcare providers that the Defendants' Physiomesh was as safe and/or safer than other alternative procedures and devices then on the market, meanwhile Defendants fraudulently concealed information that demonstrated that Physiomesh was not safer than alternative therapies and products available on the market; and
- C. Defendants represented to Plaintiff andhisphysicians and healthcare providers that the Defendants' Physiomesh was more efficacious than other alternative procedures, therapies and/or devices. Meanwhile Defendants fraudulently concealed information, regarding the true efficacy of Physiomesh.
- 118. At the time of making such express warranties, Defendants knew or should have known that Defendants' Physiomesh does not conform to the express warranties and Defendants' acts were motivated by financial gain while the adverse consequences of Defendants' conduct was outrageous, fraudulent, oppressive, done with malice or gross negligence and evidenced reckless indifference to Plaintiff's rights, health and safety.
- 119. As a direct and proximate result of Defendants' breaches of the aforementioned express warranties, Plaintiff was caused and in the future will be caused to suffer severe personal injuries, pain and suffering, severe emotional distress, financial or economic loss, including, but not limited to, obligations for medical services and expenses, impairment of personal relationships, and other damages.

WHEREFORE, Plaintiff demands judgment against Defendants 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

- 120. 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:
- 121. At all relevant and material times, Defendants manufactured, distributed, advertised, promoted, and sold the Defendants' Physiomesh.
- 122. 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 Defendants and Defendants 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.
- 123. The Plaintiff was a person whom the Defendants could reasonably have expected to use, consume, or be affected by the Defendants' hernia mesh products as the Defendants specifically designed the Physiomesh for permanent implantation in patients exhibiting hernia such as Plaintiff.
- 124. Defendants were 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 Defendants to Plaintiff's physicians. Plaintiff was a foreseeable user of Defendants' Physiomesh, and plaintiff was in privity with Defendants.

- 125. 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 Defendants' Physiomesh was of merchantable quality and safe when used for its intended purpose meanwhile Defendants fraudulently withheld and concealed information about the substantial risks of serious injury associated with using Physiomesh;
  - B. Defendants represented to Plaintiff and his physicians and healthcare providers that the Defendants' Physiomesh was safe, as safe as and/or safer than other alternative procedures and devices, meanwhile Defendants fraudulently concealed information, which demonstrated that the Physiomesh was not safe, as safe as or safer than alternatives and other products available on the market; and
  - C. Defendants represented to Plaintiff andhisphysicians and healthcare providers that the Defendants' Physiomesh were more efficacious than other alternative procedures and/or devices. Meanwhile Defendants fraudulently concealed information, regarding the true efficacy of Physiomesh.
- 126. In reliance upon Defendants' implied warranty, Plaintiff's implanting surgeon used Physiomesh to treat Plaintiff in the foreseeable manner normally intended, recommended, promoted, and marketed by Defendants and in accordance with the instructions for use and product specification provided by Defendants.
  - 127. Defendants breached their implied warranty to Plaintiff in that the Defendants'

Physiomesh was not of merchantable quality, safe and fit for its intended use nor was it adequately tested prior to being placed in the stream of commerce.

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

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

WHEREFORE, Plaintiff demands judgment against Defendants 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 CONSUMER FRAUD - VIOLATION OF GBL §§ 349 AND 350

- 130. Plaintiff incorporates all of the preceding paragraphs of this Complaint as if fully set forth here and further alleges as follows:
- 131. The Defendant acted, used and employed unconscionable commercial practices, deception, fraud, false pretenses, false promises and misrepresentations, and knowingly concealed, suppressed and omitted material facts with the intent that consumers, including Plaintiff and his prescriber, rely upon such concealment, suppression and omission, in connection with the sale, advertisement and promotion of its said hernia mesh product, in violation of all applicable state consumer fraud statutes, for the purpose of influencing and inducing physicians and medical

providers to prescribe it for patients/consumers such as the Plaintiff. By reason of the Defendant's unconscionable, deceptive and fraudulent acts and practices, and false pretenses, false promises and misrepresentations, reasonable patients/consumers acting reasonably, such as the Plaintiff, were caused to suffer ascertainable loss of money and property and actual damages.

- 132. The Defendant engaged in consumer-oriented, commercial conduct by selling and advertising the subject product.
- 133. The Defendant misrepresented and omitted material information regarding the subject product by failing to disclose known risks.
- 134. The Defendant's misrepresentations and concealment of material facts constitute unconscionable commercial practices, deception, fraud, false pretenses, misrepresentation, and/or the knowing concealment, suppression, or omission of materials facts with the intent that others rely on such concealment, suppression, or omission in connection with the sale and advertisement of the subject product, in violation of New York General Business Law ("GBL") §§ 349 and 350.
- 135. New York has enacted statutes to protect consumers from deceptive, fraudulent, and unconscionable trade and business practices. The Defendant violated these statutes by knowingly and falsely representing that the subject product was fit to be used for the purpose for which it was intended, when the Defendant knew it was defective and dangerous, and by other acts alleged herein.
- 136. The Defendant engaged in the deceptive acts and practices alleged herein in order to sell the subject product to the public, including Plaintiff.
- 137. As a direct and proximate result of the Defendant's violations of GBL §§ 349 and 350, Plaintiff has suffered damages, for which they are entitled to compensatory damages, equitable and declaratory relief, punitive damages, costs and reasonable attorneys' fees.

- 138. As a direct and proximate result of Defendant's conduct, Plaintiff used the said hernia mesh and suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.
- 139. Defendant's actions and omissions as alleged in this Complaint demonstrate a flagrant disregard for human life, so as to warrant the imposition of punitive damages.
  - 140. Plaintiffs seek actual and punitive damages from Defendant as alleged herein.

WHEREFORE, Plaintiff demands judgment against Defendant for compensatory, treble, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

### **COUNT VIII**

### GROSS NEGLIGENCE AND INTENTIONAL CONDUCT

- 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. The acts and omissions of Defendants 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.
- 143. The acts and omissions of Defendants, 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 Defendants 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

- 144. 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:
- 145. Defendants at all times were the manufacturers, sellers, and/or suppliers of Physiomesh.
- 146. Plaintiff was implanted with Defendants' 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.
- 147. Defendants have accepted payment by Plaintiff and/or by others on Plaintiff's behalf for the purchase of the Physiomesh with which Plaintiff was implanted.
- 148. Plaintiff was not implanted with nor did they receive the medical device that Defendants' represented and warranted to be safe, effective and efficacious and for which Plaintiff paid.
- 149. Equity demands that Defendants be required to disgorge any and all moneys, profits and/or any other thing of value received by Defendants on account of Plaintiff receiving a product that was substantially different than that which was represented and/or warranted and because of Defendants' conduct, acts and omissions as set out herein.

WHEREFORE, Plaintiff demands judgment against Defendants 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**

150. Whenever in this complaint it is alleged that Defendants did or omitted to do any act, it is meant that Defendants' 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 Defendants or was done in the normal and routine course and scope of employment of Defendants' officers, agents, servants, employees, and representatives.

## EQUITABLE TOLLING OF THE APPLICABLE STATUTE OF LIMITATIONS

- 151. The running of any statute of limitation has been tolled by reason of the Defendants' fraudulent conduct. Defendants, through their affirmative misrepresentations and omissions, actively concealed from Plaintiff and Plaintiff's treating physicians the true risks associated with Physiomesh.
- 152. As a result of the Defendants' 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 Defendants' acts and omissions.
- 153. Furthermore, Defendants 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. Defendants 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 Defendants knew that this information was not available to

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

154. The Plaintiff had no knowledge that Defendants were engaged in the wrongdoing alleged herein. Because of the fraudulent acts of concealment and wrongdoing by Defendants, 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 Defendants 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; and
  - 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 JOSEPH WASS By his attorneys,

/s/ David B. Rheingold

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JS 44C/SDNY REV. 06/01/17

**PLAINTIFFS** 

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

DEFENDANTS

Joseph Wass				Johnson & Johnson and Ethicon, INC.			
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Check YES only if demanded in complaint JURY DEMAND: ☑ YES ☐NO

NOTE: You must also submit at the time of filling the Statement of Relatedness form (Form IH-32).

### Case 1:17-cv-06667 Document 1-1 Filed 09/01/17 Page 2 of 2

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DEFENDANT(S) ADDRESS UNKNOWN REPRESENTATION IS HEREBY MADE THAT, AT THIS TIME, I HAVE BEEN UNABLE, WITH REASONABLE DILIGENCE, TO ASCERTAIN THE RESIDENCE ADDRESSES OF THE FOLLOWING DEFENDANTS:								
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