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JAMES WILLIAMS, Plaintiff, v. JOHNSON & JOHNSON and ETHICON, INC., Defendants.	SUPERIOR COURT OF NEW JERSEY LAW DIVISION BERGEN COUNTY Docket No.: **CIVIL ACTION** **COMPLAINT** **JURY TRIAL DEMANDED**

COMPLAINT

Plaintiff James Williams by and through his counsel, hereby sues JOHNSON & JOHNSON ("J&J"), a New Jersey corporation; and ETHICON, INC. ("Ethicon"), a New Jersey corporation (collectively "Defendants").

NATURE OF THE ACTION

1. This is an action for strict products liability, failure to warn, and defective design, brought by Plaintiff James Williams for injuries arising out of the Proceed Ventral Patch ("Ethicon Proceed" or "Proceed").

2. Defendants manufactured and supplied to doctors a nine-layer hernia mesh patch

known as the Proceed Ventral Patch.

3. The Proceed Ventral Patch created an unreasonable risk of harm to Plaintiff James Williams.

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

5. The selection and implantation of the Ethicon Proceed by Plaintiff James Williams' surgeon was a result of the misinformation, marketing, sales, promotion and direction by Ethicon.

JURISDICTION & VENUE

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

7. James Williams currently resides in Laredo, Texas and is a citizen and resident of Texas. He underwent hernia repair surgery on July 28, 2014 at Laredo Medical Center in Laredo, Texas. At that time, the Ethicon Proceed mesh product that Defendants manufactured, designed, distributed, and warranted was implanted into him. His surgeon, medical staff, and other healthcare providers met or exceeded the standard of care applicable to the hernia surgery.

8. Defendant J&J is a corporation incorporated in New Jersey, and according to its website, the world's largest and most diverse medical device and diagnostics company, with its principal place of business located at One Johnson & Johnson Plaza, New Brunswick, New Jersey.

9. Defendant J&J organizes its subsidiary businesses into individual Business Units

to coordinate the development, manufacture, testing, marketing promotion, training, distribution and sale of its products, including its hernia repair mesh products. Within J&J there are three sectors: medical devices and diagnostics, pharmaceutical, and consumer. Within the medical devices and diagnostic sector are "Business Units" including the "Ethicon Franchise." J&J charged the Ethicon Franchise with the design, development, promotion, marketing, testing, training, distribution and sale of the Proceed Ventral Patch, the hernia repair mesh product 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 comprising the Ethicon Franchise are thus controlled by Defendant J&J and include Ethicon, Inc.

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

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

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

13. At all relevant times, Defendants either directly, or through their agents, apparent agents, servants or employees sold, distributed, and marketed the defective Ethicon Proceed in the State of New Jersey. Defendants derive substantial revenue from hernia mesh products used or implanted in the State of New Jersey. As such, Defendants expected or should have expected that their business activities could or would subject them to legal action in the State of New Jersey.

14. Defendants were also involved in the business of monitoring and reporting adverse events concerning the Ethicon Proceed, and having a role in the decision process and any response related to these adverse events.

15. Defendants are subject to jurisdiction within the State of New Jersey and this Court because:

a. Defendants are engaged in substantial and not isolated business activity within the State of New Jersey, Bergen County.

b. Defendants' hernia mesh products, including the subject Proceed Ventral Patch, were designed, manufactured, and placed into the stream of commerce in the State of New Jersey by Defendants.

c. Defendants maintain an office or agency within the State of New Jersey.

d. Upon information and belief, at all relevant times, Defendants committed tortious acts within the State of New Jersey out of which these causes of action arise.

16. At all material times, Defendants developed, manufactured, advertised, promoted, marketed, sold, and/or distributed the defective Ethicon Proceed throughout the United States, including within the State of New Jersey and specifically to Plaintiff's implanting physician or her practice group, or to the hospital where the Ethicon Proceed was implanted.

17. Plaintiff James Williams has reviewed potential legal claims and causes of action against Defendants and has chosen to only pursue state-law claims. Any reference to any federal agency, regulation, or rule is stated solely as background information and does not raise a federal question. Defendants J&J and Ethicon are both New Jersey corporations and both maintained their principal place of business in New Jersey. Accordingly, this Court may rightfully exercise jurisdiction, and venue is proper.

18. Defendants designed, manufactured, fabricated, marketed, packaged, advertised, and sold the Proceed device throughout the world, including in Bergen County, State of New

Jersey.

19. Defendants knowingly market to, and derive income from, patients in the State of New Jersey from the sale of the Proceed device.

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

PROCEED HISTORY

21. Defendants were the designers, manufacturers, marketers, distributors and suppliers of the Ethicon Proceed Ventral Patch at all material times.

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

23. Defendants knew that the oxidized regenerated cellulose layer of the Proceed was ineffective at preventing adhesion formation to the underlying polypropylene of the Proceed before Defendants set out to design the Proceed Ventral Patch in 2006, and even before Defendants set out to design the Proceed Surgical Mesh predicate device in 2003.

24. Before 2003, Defendants were aware that the Oxidized Regenerated Cellulose utilized in the Proceed had pores which were too large to prevent adhesion formation.

25. Before 2003, Defendants were aware that increased adhesion formation would result in increased mesh shrinkage.

26. Before 2003, Defendants were aware that utilizing Oxidized Regenerated Cellulose in their mesh products would result in dense adhesions in the presence of blood or fibrinous exudate.

27. Before 2003, Defendants were aware that polypropylene elicits a chronic, life-long inflammatory response that is accompanied by exudation of fibrinogen.

28. Before 2003, Defendants were aware that any exposure to gamma radiation would weaken and embrittle the polypropylene of the Proceed.

29. Before 2006, Defendants were aware that adding Vicryl and other additional layers to the Proceed Surgical Mesh to create the Proceed Ventral Patch, would increase the intensity and duration of inflammation and foreign body response (FBR), thus increasing fibrinous exudate.

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

31. Defendants designed, manufactured, and marketed the Proceed, despite long-standing knowledge that the materials utilized in the Proceed would cause dense adhesions, chronic pain, mesh shrinkage, bowel obstructions, and early hernia recurrence.

32. Defendants sterilized the Proceed with gamma radiation, despite long-standing knowledge that polypropylene will degrade and embrittle if exposed to any amount of gamma radiation.

33. The Ethicon Proceed Ventral Patch is made of the following, starting with the component placed closest to the bowel of the patient-consumer:

- Oxidized Regenerated Cellulose (ORC) barrier layer
- Polydioxanone (PDS) film layer
- Large pore polypropylene (Prolene soft mesh)
- PDS film layer
- PDS reinforcing element
- PDS ring
- PDS film layer
- Vicryl

- PDS film layer

34. Polypropylene hernia meshes are traditionally sterilized with ethylene oxide.

35. The ORC layer of the Ethicon Proceed will react and degrade in the presence of ethylene oxide.

36. Defendants sterilize the Ethicon Proceed with gamma radiation.

37. Gamma radiation degrades, weakens, and embrittles the polypropylene base of the Ethicon Proceed.

38. Decades before the release of the Ethicon Proceed, Defendants were aware that polypropylene degrades, weakens, and embrittles when exposed gamma radiation.[1]

39. The embrittled polypropylene of the Ethicon Proceed increases its propensity to tear away from the securing devices, such as sutures or tacks.

40. The polypropylene base is the only permanent, non-resorbable portion of the Ethicon Proceed.

41. Defendants designed, manufactured, promoted, sold and/or marketed the Ethicon Proceed to be utilized in anyone with a soft tissue defect, including, but not limited to: "infants, children, pregnant women, or women planning pregnancies…"[2]

42. For decades, the medical community had concerns about severe complications if polypropylene was placed too close to the bowel or other underlying organs, due to the formation of dense adhesions to the polypropylene.

43. Defendants were aware that the ORC layer in the Proceed was ineffective at preventing adhesion formation to polypropylene over a decade before Defendants brought the

[1] U.S. Patent No. 3,943,933 (Issued Mar. 16, 1976).
[2] Proceed Ventral Patch Instructions for Use, RMC 8550915, Status 9/08.

Proceed to market.[3]

44. Despite significant evidence to the contrary, Defendants marketed the Ethicon Proceed and its ORC layer as a tissue-separating barrier that would prevent adhesion formation from the underlying polypropylene to any nearby organs.

45. The following studies have investigated complications associated with the Ethicon Proceed:

a. In 2006, a study out of The Netherlands evaluating the use of new prosthetic meshes for ventral hernia repair was published in Surgical Endoscopy. **Proceed showed significantly less incorporation… Proceed composite has a smooth surface designed to prevent adhesion formation. However, it is less smooth than other composite meshes with antiadhesive barriers. Furthermore, the barrier applied is oxidized cellulose, which may not prevent mesh adhesions as effectively as anticipated or as reported previously.**

Burger, J.W. et al, *Evaluation of New Prosthetic Meshes for Ventral Hernia Repair*. Surg Endosc. 20:1320 – 1325 (2006). DOI: 10.1007/s00464-005-0706-4.

b. In 2009, a study out of The Netherlands on adhesions prevention during hernia mesh repair was published in the Annals of Biomedical Engineering. **The uncoated Prolene meshes were found to invoke a moderate inflammatory response in their immediate vicinity, characterized by the presence of active macrophages. A stronger inflammatory response was observed with the Proceed meshes, presumably due to ongoing phagocytosis of the oxidizing regenerated cellulose and polydioxanone coating… Most remarkable were adhesions with Proceed. Although adhesion scores were the lowest at day 7, they increased by day 30 and exceeded adhesion scores of NVP/BMA-coated Prolene mesh and Prolene.**

Emans, P. et al, *Polypropylene Meshes to Prevent Abdominal Herniation. Can Stable Coatings Prevent Adhesions in the Long Term?* Annals of Biomedical Engineering. 37(2):410 – 418 (2009). DOI: 10.1007/s10439-008-9608-7.

c. In 2009, a study out of Saint Louis, Missouri measuring adhesions and mesh contraction was published by Surgical Innovation. The data was

[3] Robert J. Fitzgibbons, Jr., M.D. et al., *A Laparoscopic Intraperitoneal Onlay Mesh Technique for the Repair of an Indirect Inguinal Hernia*, 219-2 ANNALS OF SURGERY 114 (1994).

previously presented at the American Hernia Society, Third International Hernia Congress on June 9, 2006. **The highest degrees of mesh contraction occurred with DualMesh and Proceed… Proceed exhibited the greatest surface area of adhesion coverage and the highest-grade adhesions.**

Pierce, R. et al, *120-Day Comparative Analysis of Adhesion Grade and Quantity, Mesh Contraction, and Tissue Response to a Novel Omega-3 Fatty Acid Bioabsorbable Barrier Macroporous Mesh After Intraperitoneal Placement*. Surg Innov. (2009). DOI: 10.1177/1553350608330479.

d. In 2010, a study out of Saint Louis, Missouri on adhesion related complications associated with intraperitoneal mesh was published in Surgical Endoscopy. **Nevertheless, there appears to be some differentiation in the adhesion characteristics of the absorbable-barrier-coated meshes… We noticed a similar increase in the adhesion tenacity score of PROCEED in a preclinical study of intraperitoneal placement f absorbable-barrier-coated meshes in a rabbit model.**

Jenkins, E. et al, *Prospective Evaluation of Adhesion Characteristics to Intraperitoneal Mesh and Adhesiolysis-Related Complications During Laparoscopic Re-Exploration After Prior Ventral Hernia Repair*. Surg Endosc. 24:3002 – 3007. DOI: 10.1007/s00464-010-1076-0.

e. In 2010, a study out of Belgium on the lack of convincing data in medical literature regarding to use of intraperitoneal hernia mesh was published in The World Journal of Hernia and Abdominal Wall Surgery. The content of the paper was presented during the 32nd International Congress of the European Hernia Society, in Istanbul, on October 6-8, 2010. **After release of the omental adhesions, we found the [Proceed] mesh to have shrunk and folded up, to a dimension of approximately 3.0 cm in diameter. This means a shrinkage from a circle of diameter 6.4 cm (surface: 3.14 x 3.2^2 = 32.2 cm^2) to a "circle" of diameter 3.0 cm (surface: 3.14 x 1.5^2 = 7.1 cm^2), equivalent to a mesh surface shrinkage of 77.9%... There is a complete lack of convincing data on these mesh devices in the medical literature.**

Muysoms, F.E. et al, *Complications of Mesh Devices for Intraperitoneal Umbilical Hernia Repair: A Word of Caution*. Journal of Hernia. 15:463-468 (2011). DOI: 10.1007/s10029-010-0692-x.

f. In 2012, a study out of Saint Louis, Missouri on the effectiveness of barrier hernia mesh was published in Surgical Endoscopy. **This study also demonstrated increased adhesion formation for all of the barrier mesh prostheses between 7 and 30 days, which the authors attributed to increased inflammation related to the degradation and resorption of**

the barrier layer components, which were ongoing between 7 and 30 days. This effect was most pronounced in PROCEED Surgical Mesh materials, which again highlights the influence that the chemistry of the particular barrier components may have over the inflammatory response and subsequent adhesion formation.

Deeken, C. et al, *A Review of the Composition, Characteristics, and Effectiveness of Barrier Mesh Prostheses Utilized for Laparoscopic Ventral Hernia Repair*. Surg Endosc. 26:566-575 (2012). DOI: 10.1007/s00464-011-1899-3.

g. In 2014, a study out of Belgium on the Proceed Ventral Patch (PVP) was published in The World Journal of Hernia and Abdominal Wall Surgery. **Polypropylene meshes, like the PVP, have demonstrated an in vivo centripetal shrinkage percentage of up to 77% in some patients. This finding of mesh contraction was confirmed in those patients. This finding of mesh contraction was confirmed in those patients that were re-operated for recurrence in 21% of the patients where the radiologist was able to visualize the mesh. The overlap obtained with a mesh of 6.4 cm in diameter is in sufficient with hernias larger than 2 cm. Therefore, we recommend not to use PVP in hernias of 2cm or more.**

Bontinck, J. et al, *Single Centre Observational Study to Evaluate the Safety and Efficacy of the Proceed Ventral Patch to Repair Small Ventral Hernias*. Journal of Hernia. 18:671 – 680 (2014). DOI: 10.1007/s10029-013-1140-5.

h. In 2015, a study out of Belgium on the Proceed (PP/ORC) was published in The World Journal of Hernia and Abdominal Wall Surgery. **In our opinion, there are several factors contributing to the extensive FBR and shrinkage/mesh contraction of the PP/ORC device. First, the composition of the PP/ORC device out of nine different layers will lead to a more extensive FBR. Second, absorption of 8 of these 9 layers will create a severe inflammatory reaction as, e.g.. shown with vicryl mesh absorption, also being one of the components of the PP/ORC device. A third possible explanation is delamination of the device.**

Reynvoet, E. et al, *Intraperitoneal Mesh Devices for Small Midline Hernias: Mesh Behavior in a Porcine Model*. Journal of Hernia. 19:955 – 963 (2015). DOI: 10.1007/s10029-015-1368-3.

i. In 2016, a study out of Bosnia and Herzegovina was published by The Royal Belgian Society for Surgery. **The extent of [adhesion] site involvement after 28 days was statistically significantly greater in the Proceed group.**

Delibegovic, S. et al, *Formation of Adhesions After Intraperitoneal*

Applications of TiMesh: Experimental Study on a Rodent Model. The Royal Belgian Society for Surgery. (2016). DOI 10.1080/00015458.2016.1179513

j. In 2016, a study out of Germany on the adhesion prevention efficacy of Proceed (PCM) was published in International Journal of Medical Sciences. **PCM does not provide significant adhesion prevention.**

Winny, M. et al, *Adhesions Prevention Efficacy of Composite Meshes Parietex, Proceed, and 4DryField PH Covered Polypropylene Meshes in an IPOM Rat Model*. Int. J. Med. Sci. 13:936 – 941 (2016). DOI: 10.7150/ijms.16215.

k. In 2017, a Proceed (PVP) randomized controlled trial out of The Netherlands was published in the World Journal of Surgery. **At this point, PVP device usage shows an easier and faster operating procedure. Nevertheless, this advantage is outweighed by the significantly higher incidence of early re-operations due to early complications.**

Ponten, J.E. et al, *Mesh Versus Patch Repair for Epigastric and Umbilical Hernia (MORPHEUS Trial); One-Year Results of a Randomized Controlled Trial*. World J. Surg. (2017). DOI: 10.1007/s00268-017-4297-8.

l. In 2017, a study out of Brazil was published on adhesions and collagen formation following mesh implantation. **The study follow-up time, 90 days, was established because there were no articles in the literature with prolonged follow-up… What we can formulate is that absorption of the regenerated oxidized cellulose exposes the polypropylene layer to the abdominal visceral content and that this consequently led to the adhesions found… The adhesion formation is a complex process and is basically started by the tissue injury process which breaks down the balance between coagulation and fibrinolysis. Fibrin deposition results in a matrix where the fibroblasts produce extracellular matrix. The end process generates various degrees of adhesion… In the present study, type III collagen was expressed more in the coated group and based on the result of the research this could increase hernia formation.**

Rossi, L. et al, *Peritoneal Adhesions Type I, III and Total Collagen on Polypropylene and Coated Polypropylene Meshes: Experimental Study in Rats*. ABCD Arq Bras Cir Dig 30(2):77 – 82 (2017). DOI: 10.1590/0102-6720201700020001.

FAILURE TO WARN PHYSICIANS OF THE DANGERS ASSOCIATED WITH PROCEED

46. Defendants marketed the Ethicon Proceed to general surgeons, hospitals, and group purchasing organizations (GPOs), rather than end-user patients.

47. Defendants had the ability to inform surgeons, hospitals, or GPOs of developing problems or defects in its devices through e-mail, letter, recalls, warnings in product inserts, and/or through its product representatives, who work directly with surgeons.

48. The nine layers of the Ethicon Proceed increase the intensity and duration of the inflammatory response. That response in turn increases dense adhesion formation from underlying organs to the Ethicon Proceed, resulting in bowel complications, mesh contracture, hernia recurrence, increased foreign body reaction, chronic severe pain, and more.

49. Defendants downplayed the intensity of the inflammatory reaction caused by Vicryl by stating in the Ethicon Proceed Instructions for Use (IFU) that the Vicryl elicits "only a mild tissue reaction during absorption."

50. Defendants state in the Ethicon Proceed IFU that "The PROLENE Soft Mesh components are constructed of knitted filaments of extruded polypropylene, identical in composition to that used in PROLENE Polypropylene Suture, Nonabsorbable Surgical Suture, U.S.P." This statement is false, or at the very least misleading, as the Proceed undergoes gamma irradiation that changes the composition of the polypropylene.

51. Defendants also state in the Ethicon Proceed IFU that the polypropylene material "when used as a suture, has been reported to be non-reactive and to retain its strength indefinitely in clinical use. The PROLENE Soft Mesh affords excellent strength, durability and surgical adaptability, with a porous structure to enable mesh incorporation into surrounding tissues." This statement is false, or at the very least misleading, as Defendants are aware that the Ethicon Proceed

is reactive and does not retain its strength. Furthermore, Defendants are aware of reports that the small polypropylene sutures do elicit a small reaction, and increasing amounts of polypropylene greatly increase such reaction. The very reason the Defendants added the ORC layer to the Prolene Soft Mesh was to protect organs from reacting with the polypropylene of the Prolene Soft Mesh.

52. The Ethicon Proceed IFU has a section for contraindications, which lists "None known."

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

54. The Ethicon Proceed IFU notes that "Selected mesh size should allow for adequate overlap of the fascial defect on all sides." The IFU never defines what constitutes "adequate overlap." Defendants are aware that the Ethicon Proceed shrinks over time, with reports of the Ethicon Proceed shrinking as much as 77%.

55. Defendants failed to warn that the Ethicon Proceed will elicit a fibrinous exudate.

56. Defendants failed to warn that the Ethicon Proceed creates a solid barrier preventing the body from adequately clearing or transporting fluid, which results in seroma formation, potentiating infections and fistula formation.

57. Defendants never performed any clinical trials and/or studies before marketing the

Ethicon Proceed.

58. Defendants did not fully and/or adequately test the configuration of its new, nine-layer hernia mesh patch design with ORC, polypropylene, Vicryl, and six layers of PDS, that was implanted into Plaintiff James Williams.

59. Although the United States does not have a complete and accurate database to track problems with hernia mesh implants, controlled studies have investigated the problems with the Ethicon Proceed.

60. A single center study was conducted in Belgium, where three surgeons implanted only the Ethicon Proceed in 101 patients between April 2009 and December 2011. The Ethicon Proceed was able to be visualized by ultrasound in 47 patients. Of those 47 patients, 10 were noted to have mesh contraction. The Ethicon Proceed "was removed during the operation in four patients and important centripetal contraction of the mesh, diminishing the surface area, was observed in all cases." The authors concluded the Proceed has "demonstrated an in vivo centripetal shrinkage percentage of up to 77% in some patients. This finding of mesh contraction was confirmed in those patients that were reoperated for recurrence and in 21% of the patients where the radiologist was able to visualize the mesh. The overlap obtained with a mesh of 6.4cm in diameter was insufficient with hernias larger than 2 cm. Therefore, we recommend not to use PVP (Proceed Ventral Patch) in hernias of 2 cm or more." The authors go on to note that their study is likely underpowered as "Most recurrences after ventral hernia repair occur within 2 years after the operation. Since our study had a mean follow-up of 16 months, it is likely that a longer follow-up would yield a higher recurrence rate."[4]

61. In 2015, another study in Belgium confirmed "massive shrinkage" with the Ethicon

[4] J. Bontinck, Single Centre Observational Study to Evaluate the Safety and Efficacy of the Proceed Ventral Patch to Repair Small Ventral Hernias, 18 Hernia 671, Clinical.Trials.gov: NCT01307696 (2013).

Proceed. The authors concluded that "This can however not be considered the ideal indication for a mesh device repair with a suggested mesh overlap of at least 5 cm for incisional hernias."[5]

62. Defendants continue to market the Ethicon Proceed without warning of the massive mesh shrinkage or the necessary overlap to prevent early hernia recurrence due to mesh shrinkage.

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

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

65. Defendants were aware that the ORC layer was ineffective in preventing adhesions to the polypropylene; gamma irradiation would weaken the polypropylene; and the nine-layer mesh would contract massively over time. Nonetheless, Defendants employed the design in the Ethicon Proceed Ventral Patch in reckless disregard for the safety of patients, including Plaintiff James Williams.

66. Moreover, despite direct knowledge of significant adverse events reported by patients and physicians, as well as awareness of failures that have been reported in literature and published clinical trials, Defendants have continued to market the Ethicon Proceed as being safe and effective for hernia repair.

67. From the time Defendants first began selling the Ethicon Proceed in the United States through today, product labeling and the product information failed to contain adequate

[5] E. Reynvoet, Intraperitoneal Mesh Devices for Small Midline Hernias: Mesh Behavior in a Porcine Model, 19 Hernia 955 (2015).

information, instructions, and warnings concerning the following: implantation of the Proceed, specifically its propensity to massively shrink, the increased in duration and intensity of inflammation, and the elevated rate of adhesions, bowel complications, chronic pain, hernia recurrence, seroma formation, hematoma formation, fistula formation, erosion, extrusion, infection, and other injuries occurring at a higher rate than other surgically implanted devices.

USE OF THE PRODUCT

68. A defectively designed, manufactured and marketed Ethicon Proceed Ventral Patch left the hands of Defendants in its defective condition, and was delivered into the stream of commerce. Dr. Ivan Mederos implanted the Proceed Ventral Patch in James Williams' abdomen to repair an umbilical hernia on or about July 28, 2014 at Laredo Medical Center in Laredo, Texas. James Williams was implanted with a medium Proceed Ventral Patch, Cat No. PVPM, Lot No. hd8gxzzo.

69. As a direct and proximate result of Defendants' defective design, manufacture, marketing, distribution, and/or sale of the Ethicon Proceed, and their placing of their defective product into the stream of commerce, Plaintiff James Williams has been injured and damaged as follows:

a. On April 5, 2016, James Williams underwent removal of the Ethicon Proceed at Laredo Medical Center in Laredo, Texas, by Dr. Michael Morris.
b. James Williams experienced and/or continues to experience severe pain, nausea, diarrhea, chills, inflammation, and loss of appetite, which have impaired his activities of daily living.
c. James Williams continues to suffer complications as a result of his implantation with the Ethicon Proceed.
d. James Williams is at a higher risk of severe complications during an abdominal surgery, to the extent that future abdominal operations might not be feasible.

70. The mechanism of failure in Plaintiff James Williams device was a mechanism of failure that Defendants warranted would not occur because of the Ethicon Proceed design and composition. It was also the same failure mechanism that the medical and scientific community had been studying and documenting since the 1990s, *i.e.,* ORC was ineffective at preventing adhesions to polypropylene, and polypropylene contracts when dense adhesions form to it.

71. Moreover, the symptoms and findings associated with Ethicon Proceed product failures that have been reported in the literature are identical to those Plaintiff James Williams suffered.

72. As a direct and proximate result of Defendants' defective design, manufacturing, marketing, distribution, sale and warnings of the Ethicon Proceed, Plaintiff James Williams has suffered and continues to suffer injuries and damages, including: past, present and future physical and mental pain and suffering; physical disability; past, present, and future medical, hospital, rehabilitative, and pharmaceutical expenses; and other related damages.

THE FDA'S 510(k) CLEARANCE PROCESS

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

73. No clinical testing is required under this process.

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

75. Through this domino effect, devices deemed "substantially equivalent" to devices

previously deemed "substantially equivalent" to devices approved for sale by the FDA before 1976 could be sold to patients in a matter of 90 days without any clinical testing.

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

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

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

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

79. Defendants cleared the Ethicon Proceed Ventral Patch, and its related components, under the 510(k) Premarket Notification. Under Section 510(k) of the Federal Food, Drug and Cosmetic Act, a medical device does not have to go through the rigors of a clinical study to gain approval by the FDA. Instead, the device was supposed to demonstrate substantial equivalence to a predicate medical device.

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

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

81. The first Proceed Surgical Mesh did not undergo premarket approval, but instead received 510(k) clearance on or about September 17, 2003. The only predicate device listed on the 510(k) application is the Prolene Soft Polypropylene Mesh, a non-barrier hernia mesh. Defendants did not claim that the Proceed Surgical Mesh was a resorbable adhesion barrier in their 510(k) application. However, after 510(k) clearance, Defendants marketed the Proceed Surgical Mesh as a resorbable adhesion barrier.

82. Defendants applied for 510(k) clearance for the Proceed Surgical Mesh again in May of 2006. The only predicate device listed on the 510(k) application is the prior Proceed Surgical Mesh. In this 510(k) application, Defendants did not claim the intended use of the Proceed was a resorbable adhesion barrier; however, in the device description Defendants note that the "ORC side provides a bioresorbable layer that physically separates the polypropylene mesh from underlying tissue and organ surfaces during the wound-healing period to minimize tissue attachment to the mesh." Defendants continued to market the Proceed Surgical Mesh as a resorbable adhesion barrier.

83. Defendants applied for 510(k) clearance for the Proceed Ventral Patch in December of 2006. Defendants do not mention in the 510(k) application for the Proceed Ventral Patch that the mesh is intended to act as a resorbable adhesion barrier. After 510(k) clearance, Defendants

marketed and continue to market the Proceed Ventral Patch as a resorbable adhesion barrier. Even the Ethicon Proceed IFU notes "The ORC side of the patch provides a bioresorbable layer that physically separates the polypropylene mesh form underlying tissue and organ surfaces while minimizing tissue attachment to the polypropylene mesh during the critical wound healing period."

CAUSES OF ACTION PURSUANT TO NEW JERSEY LAW

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

84. Plaintiff James Williams incorporates by reference the allegations in all prior paragraphs and further alleges as follows:

85. Defendants had a duty to design and manufacture, distribute, market, promote and sell, the Ethicon Proceed so that it was neither defective nor unreasonably dangerous when put to the use for which it was designed, manufactured, distributed, marketed and sold.

86. In and before 2003, Defendants were engaged in the business of designing, manufacturing, marketing, distributing and selling hernia mesh implants, and did design, manufacture, distribute, market and sell the Ethicon Proceed.

87. Defendants expected the Ethicon Proceed Devices they were manufacturing, selling, distributing, supplying, and/or promoting to reach, and they did in fact reach, implanting physicians and consumers in the State of New Jersey and the United States, including Plaintiff James Williams and his implanting physician, without substantial change in their condition.

88. At the time the Ethicon Proceed left Defendants' possession and the time the Ethicon Proceed entered the stream of commerce in the State of New Jersey, it was in an unreasonably dangerous or defective condition. These defects include the following:

- the Ethicon Proceed was not reasonably safe as intended to be used;
- the Ethicon Proceed had an inadequate design for the purpose of hernia repair;

- the Ethicon Proceed contained unreasonably dangerous design defects, including a large pore ORC layer that is ineffective at preventing adhesion formation to the underlying polypropylene;
- the Ethicon Proceed is unreasonably dangerous, due to the degraded state of the polypropylene utilized, which has been exposed to gamma radiation;
- the Ethicon Proceed contained unreasonably dangerous design defects, utilizing nine layers, which increase and prolong the inflammatory response;
- the Ethicon Proceed was not appropriately or adequately tested before distribution; and
- the Ethicon Proceed had an unreasonably high propensity for adhesion formation, mesh contracture, hernia recurrence, chronic pain, bowel complications, seroma formation, fistula formation, hematoma formation, infection, erosion, and extrusion.

89. At the time of Defendants' initial design, manufacture, marketing, and sale of the Ethicon Proceed, a feasible, safer alternative design was known and available, including, but not limited to, a flat, non-coated, single-layer mesh placed away from the bowel.

90. At the time subsequent to Defendants' initial design and manufacture and marketing and sale of the Ethicon Proceed, including before Plaintiff James Williams' hernia surgery, Defendants had the ability to eliminate the unsafe character of the Ethicon Proceed without impairing its usefulness.

91. Had Defendants properly and adequately tested the Ethicon Proceed, they would have discovered the following: the ORC layer was ineffective at preventing adhesion formation to the polypropylene; the nine layers would increase and prolong the inflammatory response; the mesh experiences significant contraction over time; recurrence rates are unacceptably high; the polypropylene was too weak; and the defects result in bowel obstructions, seromas, fistulas, infections, erosion, extrusion, and a pronounced foreign body response, among other complications.

92. The Ethicon Proceed, manufactured, supplied, distributed, marketed, promoted and sold by Defendants, was therefore defective in design and formulation in that, when it left Defendants, the foreseeable risk of harm from the product exceeded or outweighed the benefit or utility the consumer would expect, and/or it failed to comply with federal requirements for these medical devices.

93. As a direct and proximate result of Defendants' wrongful conduct, including the defective and dangerous design and inadequate warnings of the Ethicon Proceed, Plaintiff James Williams has sustained and will continue to sustain severe and debilitating injuries, economic loss, and other damages including cost of medical care, rehabilitation, lost income, immobility, and pain and suffering, for which he is entitled to compensatory and equitable damages and declaratory relief, in an amount to be proven at trial.

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

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

95. Plaintiff James Williams incorporates the allegations in all prior paragraphs, and further alleges as follows:

96. Defendants researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and otherwise released into the stream of commerce the Ethicon Proceed; and directly advertised or marketed the product to the FDA, health care professionals, and consumers, including Plaintiff James Williams. Therefore, Defendants had a duty to warn of the risks associated with the use of the Ethicon Proceed.

97. Defendants distributed and sold the Ethicon Proceed in its original form of manufacture, which included the defects described in this Complaint.

98. The Ethicon Proceed was expected to and did reach Plaintiff James Williams and his implanting physician, without substantial change or adjustment in its condition as manufactured and sold by Defendants.

99. Each Ethicon Proceed designed, developed, tested, manufactured, distributed, promoted, marketed, and/or sold or otherwise placed into the stream of commerce by Defendants, was in a dangerous and defective condition and posed a threat to any user or consumer.

100. At all material times, Plaintiff James Williams was a person Defendants should have considered to be subject to the harm caused by the defective nature of the Ethicon Proceed.

101. The Ethicon Proceed was implanted in Plaintiff James Williams, and used in a manner for which it was intended.

102. This use has resulted in severe physical, financial, emotional and other injuries to Plaintiff James Williams.

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

104. Defendants failed to timely and reasonably warn of material facts regarding the safety and efficacy of the Ethicon Proceed. Had they done so, proper warnings would have been heeded and no health care professional, including Plaintiff James Williams' physician, would have used the Ethicon Proceed, or no consumer, including Plaintiff James Williams, would have purchased and/or consented to the use of the Ethicon Proceed.

105. Defendants failed to timely and reasonably provide adequate instructions and training concerning safe and effective use of the Ethicon Proceed.

106. The Ethicon Proceed, which Defendants researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and otherwise released into the stream of commerce, was defective due to inadequate post-marketing warnings and/or instruction because Defendants knew or should have known that there was reasonable evidence of an association between the Ethicon Proceed and dense adhesion formation, mesh contracture, and hernia recurrence, causing serious injury and pain. Nonetheless, Defendants failed to provide adequate warnings to health care professionals and the consuming public, including Plaintiff James Williams, and continued to aggressively promote the Ethicon Proceed.

107. The Ethicon Proceed, which Defendants researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and otherwise released into the stream of commerce, was defective due to inadequate post-marketing warnings and/or instruction regarding the increased risk of failure of the Ethicon Proceed resulting in revision surgery, although Defendants knew of a safer alternative design including, but not limited to, a flat, non-coated, single-layer mesh placed away from the bowel.

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

109. Plaintiff James Williams and his physician used the Ethicon Proceed for its intended purpose, *i.e.,* hernia repair.

110. Plaintiff James Williams could not have discovered any defect in the Ethicon Proceed through the exercise of due care.

111. Defendants, as designers, manufacturers, distributors, promoters, marketers and/or sellers of medical devices are held to the level of knowledge of experts in their field.

112. Neither Plaintiff James Williams nor his implanting physician had substantially the same knowledge about the Ethicon Proceed as Defendants.

113. Defendants reasonably should have known the Ethicon Proceed was unsuitable to repair a hernia defect in patients like Plaintiff James Williams.

114. As a direct and proximate result of Defendants' failure to adequately communicate a warning and/or failure to provide an adequate warning and other wrongful conduct, Plaintiff James Williams has sustained and will continue to sustain severe physical injuries, severe emotional distress, mental anguish, economic losses, and other damages, as set forth in this Complaint.

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

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

116. Plaintiff James Williams incorporates the allegations in all prior paragraphs, and further alleges as follows:

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

118. The Ethicon Proceed Defendants manufactured was defective in construction or composition in that, when it left the hands of Defendants, it deviated in a material way from their manufacturing performance standards and/or it differed from otherwise identical products

manufactured to the same design formula. Defendants knew or should have known that the Ethicon Proceed could fail early in patients, thereby giving rise to pain and suffering, debilitation and the need for revision surgery to replace the device with the attendant risk of complications and death from such further surgery. Nonetheless, Defendants continued to market the Ethicon Proceed as a safe and effective absorbable barrier hernia mesh.

119. As a direct and proximate result of the use of the subject product as manufactured, designed, sold, supplied and introduced into the stream of commerce by Defendants, Plaintiff James Williams suffered harm, damages and economic loss as previously described and will continue to suffer such harm, damages and economic loss in the future.

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

ASSERTION OF CLAIMS PURSUANT TO THE LAWS OF TEXAS

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

122. Plaintiff James Williams was injured outside the state of New Jersey as a result of being implanted with the Ethicon Proceed. To the extent the Court chooses to apply the law of a state other than New Jersey, Plaintiff James Williams hereby places Defendants on notice of his intention to plead and assert all claims available under the state's law applied by this Court.

COUNT IV: NEGLIGENCE-
PURSUANT TO COMMON LAW

123. Plaintiff James Williams incorporates the allegations in all prior paragraphs, and further alleges as follows:

124. Although Defendants had a duty to use reasonable care in designing, testing, inspecting, manufacturing, packaging, labeling, marketing, distributing, training, and preparing

written instructions and warnings for the Ethicon Proceed, they failed to do so.

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

126. As a direct and proximate result of Defendants' negligence in designing, testing, inspecting, manufacturing, packaging, labeling, marketing, distributing, training and preparing written instructions and warnings for the Ethicon Proceed, Plaintiff James Williams suffered injuries and damages as summarized in this Complaint.

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

127. Plaintiff James Williams incorporates the allegations in all prior paragraphs, and further alleges as follows:

128. At the time the Ethicon Proceed was implanted in Plaintiff James Williams, the mesh product was defectively designed. As described above, there was an unreasonable risk that the product would not perform safely and effectively for the purposes for which it was intended. Further, Defendants failed to design against such dangers, and failed to provide adequate warnings and instructions concerning these risks.

129. Defendants expected and intended the Ethicon Proceed product to reach users such as Plaintiff James Williams in the condition in which the product was sold.

130. The implantation of Ethicon Proceed in Plaintiff James Williams was medically reasonable, and was a type of use that Defendants intended and foresaw when they designed, manufactured and sold the product.

131. The risks of the Ethicon Proceed design significantly outweigh any benefits that Defendants contend could be associated with the design.

132. At the time the Ethicon Proceed was implanted in Plaintiff James Williams, it contained unreasonably dangerous design defects. Specifically, the ORC layer is ineffective at preventing adhesion formation to the polypropylene; the nine layers increase and prolong the inflammatory response; the mesh experiences significant contraction over time; recurrence rates are unacceptably high; the polypropylene is too weak. These defects result in bowel obstructions, seromas, fistulas, infections, erosion, extrusion, mesh contraction, and a pronounced foreign body response, among other complications.

133. At the time subsequent to Defendants' initial design and manufacture and marketing and sale of the Ethicon Proceed, including before Plaintiff James Williams's hernia surgery, Defendants had the ability to eliminate the unsafe character of the Ethicon Proceed without impairing its usefulness.

134. At the time the Ethicon Proceed was implanted in Plaintiff James Williams, the warnings and instructions provided by Defendants for the Proceed were inadequate and defective. As described above, there was an unreasonable risk that the product would not perform safely and effectively for the purposes for which it was intended, and Defendants failed to design and/or manufacture against such dangers, and failed to provide adequate warnings and instructions concerning these risks.

135. At the time the Ethicon Proceed was implanted in Plaintiff James Williams, there were safer feasible alternative designs for hernia mesh products that would have prevented the injuries he suffered.

136. The Ethicon Proceed implanted in Plaintiff James Williams failed to reasonably

perform as intended and had to be surgically removed, necessitating further invasive surgery to repair the very issue that the product was intended to repair. Thus, it provided no benefit to him.

137. As a direct and proximate result of the defective and unreasonably dangerous condition of the Ethicon Proceed, Plaintiff James Williams suffered injuries and damages as summarized in this Complaint.

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

138. Plaintiff James Williams incorporates the allegations in all prior paragraphs, and further alleges as follows:

139. At the time the Ethicon Proceed was implanted in Plaintiff James Williams, the warnings and instructions Defendants provided for the Proceed were inadequate and defective. As described above, there was an unreasonable risk that the product would not perform safely and effectively for the purposes for which it was intended. Defendants failed to design and/or manufacture against such dangers, and failed to provide adequate warnings and instructions concerning these risks.

140. Defendants expected and intended the Ethicon Proceed to reach users such as Plaintiff James Williams in the condition in which the product was sold.

141. Plaintiff James Williams and his physicians were unaware of the defects and dangers of the Ethicon Proceed, and were unaware of the frequency, severity, and duration of the defects and risks associated with the Proceed.

142. Defendants failed to adequately warn health care professionals and the public, including Plaintiff James Williams and his implanting physician, of the true risks of the Ethicon Proceed, which was ineffective at protecting underlying organs from adhesion formation and would contract significantly upon implantation, resulting in significant pain, bowel and other organ

complications, hernia recurrence, reoperation, infections, fistulas, seromas, hematomas, erosion, extrusion, subsequent operations, and more.

143. Defendants failed to timely and reasonably provide adequate instructions and training concerning safe and effective use of the Ethicon Proceed.

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

145. The Ethicon Proceed, which Defendants researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and otherwise released into the stream of commerce, was defective due to inadequate post-marketing warnings and/or instruction because Defendants knew or should have known that there was reasonable evidence of an association between the Ethicon Proceed and dense adhesion formation, mesh contracture, and hernia recurrence, causing serious injury and pain. Nonetheless, Defendants failed to provide adequate warnings to health care professionals and the consuming public, including Plaintiff James Williams, and continued to aggressively promote the Ethicon Proceed.

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

147. If Plaintiff James Williams or his physician had been properly warned of the defects and dangers of Ethicon Proceed, and of the frequency, severity and duration of the risks associated with the Proceed, he would not have consented to allow the Proceed to be implanted in his body, and his physician would not have implanted it in him.

148. As a direct and proximate result of the inadequate and defective warnings and instructions, Plaintiff James Williams suffered injuries and damages as summarized in this Complaint.

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

149. Plaintiff James Williams incorporates the allegations in all prior paragraphs, and further alleges as follows:

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

151. The manufacturing defects in the Ethicon Proceed were a producing cause of Plaintiff James Williams injuries and damages as specified in this Complaint.

COUNT VIII: BREACH OF IMPLIED WARRANTY

152. Plaintiff James Williams incorporates the allegations in all prior paragraphs, and further alleges as follows:

153. At the time Defendants designed, manufactured, produced, tested, studied, inspected, labeled, marketed, advertised, sold, promoted and distributed the Ethicon Proceed for use by Plaintiff James Williams, they knew of the intended use of the Proceed, and impliedly warranted their product to be of merchantable quality, and safe and fit for its intended use.

154. When the Ethicon Proceed was implanted in Plaintiff James Williams to treat his hernia, the Proceed was being used for the ordinary purposes for which it was intended.

155. Plaintiff James Williams, individually and/or by and through his physicians, relied upon Defendants' implied warranties of merchantability in consenting to have the Ethicon Proceed implanted in him.

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

157. As a direct and proximate result of the conduct of Defendants, Plaintiff James Williams suffered the injuries and damages described in this Complaint.

COUNT IX: BREACH OF EXPRESS WARRANTY

158. Plaintiff James Williams incorporates the allegations in all prior paragraphs, and further alleges as follows:

159. At all relevant times, Defendant manufactured, distributed, advertised, promoted, and sold the Ethicon Proceed.

160. At all relevant times, Defendant intended the Ethicon Proceed be used in the manner that Plaintiff James Williams in fact used it and Defendants expressly warranted in its brochures and advertising that each product was safe and fit for use by consumers, that it was of merchantable quality, that its side effects were minimal and comparable to other mesh products, and that it was adequately tested and fit for its intended use.

161. At all relevant times, Defendants were aware that consumers, including Plaintiff James Williams, would use the Ethicon Proceed. Therefore, Plaintiff James Williams was a foreseeable user of Defendants' Ethicon Proceed.

162. Plaintiff James Williams and/or his implanting physician were at all relevant times in privity with Defendants.

163. Defendants' Ethicon Proceed was expected to reach and did in fact reach consumers, including Plaintiff James Williams and his implanting physician, without substantial change in the condition in which it was manufactured and sold by Defendants.

164. Defendants breached various express warranties with respect to the Ethicon Proceed, including the following particulars:

- Defendants represented to Plaintiff James Williams and his physicians and healthcare providers through their labeling, advertising marketing materials, detail persons, seminar presentations publications, notice letters, and regulatory submissions that the Ethicon Proceed was safe and fraudulently withheld and concealed information about substantial risks or serious injury and/or death associated with using the Ethicon Proceed.
- Defendants represented to Plaintiff James Williams and his physicians and healthcare providers that their Ethicon Proceed was as safe, and/or safer than other alternative procedures and devices and fraudulently concealed information, which demonstrated that the Ethicon Proceed was not safer than alternatives available on the market; and
- Defendants represented to Plaintiff James Williams and his physicians and healthcare providers that the Ethicon Proceed was more efficacious than other alternatives and fraudulently concealed information regarding the true efficacy of the Ethicon Proceed.

165. In reliance upon Defendants' express warranty, Plaintiff James Williams was implanted with Defendants' Ethicon Proceed as prescribed and directed, and therefore, in the foreseeable manner normally intended, recommended, promoted, and marketed by Defendants.

166. At the time of making such express warranties, Defendants knew or should have known that the Ethicon Proceed does not conform to these express representations because the Ethicon Proceed was not safe and had numerous serious side effects, many of which Defendants did not accurately warn about, thus making the Ethicon Proceed unreasonably unsafe for its intended purpose.

167. Members of the medical community, including physicians and other healthcare professionals, as well as Plaintiff James Williams and the public, relied upon the representations and warranties of Defendants in connection with the use recommendation, description, and/or dispensing of the Ethicon Proceed.

168. Defendants breached their express warranties to Plaintiff James Williams in that the Ethicon Proceed was not of merchantable quality, safe, and fit for its intended purpose, nor was it adequately tested.

169. As a direct and proximate result of Defendants' conduct, Plaintiff James Williams has sustained and will continue to sustain severe physical injuries, severe emotional distress, mental anguish, economic losses, and other damages.

COUNT X: PUNITIVE DAMAGES

170. Plaintiff James Williams incorporates the allegations in all prior paragraphs, and further alleges as follows:

171. Plaintiff James Williams is entitled to punitive damages because Defendants' wrongful acts and/or omissions were wanton or in conscious disregard of the rights of others. Defendants misled both the medical community and the public at large, including Plaintiff James Williams, by making false representations about the safety and efficacy of the Ethicon Proceed and by failing to provide adequate instructions and training concerning its use. Defendants downplayed, understated, and/or disregarded their knowledge of the serious and permanent side effects and risks associated with the use of the Ethicon Proceed, despite available information demonstrating that the Ethicon Proceed lacked adequate testing, was ineffective at preventing adhesion formation of polypropylene, would significantly contract upon implantation, would fail early, and would cause an increased and prolonged inflammatory and foreign body response, high

rates of bowel complications, seromas, infections, fistulas, pain, and other harm to patients. Such risk and adverse effects could easily have been avoided had Defendants not concealed knowledge of the serious and permanent side effects and risks associated with the use of the Ethicon Proceed or provided proper training and instruction to physicians regarding use of the Ethicon Proceed. Defendants' misrepresentations included knowingly withholding material information from the FDA, the medical community and the public, including Plaintiff James Williams, concerning the safety of the Ethicon Proceed.

172. Defendants were or should have been in possession of evidence demonstrating that the Ethicon Proceed caused serious side effects. Nevertheless, Defendants continued to market the Ethicon Proceed by providing false and misleading information with regard to its safety and efficacy.

173. Defendants failed to provide warnings that would have dissuaded health care professionals from using the Ethicon Proceed, thus preventing health care professionals and consumers, including Plaintiff James Williams, from weighing the true risks against the benefits of using the Ethicon Proceed.

174. Defendants failed to provide adequate training, testing and instructions to physicians that could have prevented failure of the Ethicon Proceed causing serious harm and suffering to patients, including Plaintiff Shackelford.

WHEREFORE, James Williams demands judgment against Defendants for compensatory damages and punitive damages, together with interest, cost of suit and attorney's fees and such other relief as the Court deems proper.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff James Williams prays for judgment and an award of damages

against Defendants, as follows:

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

DEMAND FOR TRIAL BY JURY

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

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

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

691-18; Fielding v. Ethicon, Inc., et al, Docket No.: BER-L-693-18; Hollimon v. Ethicon, Inc., et al, Docket No.: BER-L-694-18; Miller v. Ethicon, Inc., et al, Docket No.: BER-L-695-18; Moore v. Ethicon, Inc., et al, Docket No.: BER-L-697-18; Rodriguez v. Ethicon, Inc., et al, Docket No.: BER-L-699-18; Sollis v. Ethicon, Inc., et al, Docket No.: BER-L-703-18; Adams v. Ethicon, Inc., et al, Docket No.: BER-L-728-18; Crossland v. Ethicon, Inc., et al, Docket No.: BER-L-729-18; Denney v. Ethicon, Inc., et al, Docket No.: BER-L-732-18; Westerbeck v. Ethicon, Inc., et al, Docket No.: BER-L-733-18; Dollanmeyer v. Ethicon, Inc., et al, Docket No.: BER-L-774-18; Jarrell v. Ethicon, Inc., et al, Docket No.: BER-L-775-18; Jennings v. Ethicon, Inc., et al, Docket No.: BER-L-777-18; Johnson v. Ethicon, Inc., et al, Docket No.: BER-L-778-18; Kennedy v. Ethicon, Inc., et al, Docket No.: BER-L-779-18; McKinney v. Ethicon, Inc., et al, Docket No.: BER-L-780-18; Morgan v. Ethicon, Inc., et al, Docket No.: BER-L-781-18; Robins v. Ethicon, Inc., et al, Docket No.: BER-L-809-18; Aaron v. Ethicon, Inc., et al, Docket No.: BER-L-870-18; Diloreto v. Ethicon, Inc., et al, Docket No.: BER-L-1018-18; Pikulsky, et al v. Ethicon, Inc., et al, Docket No.: BER-L-1052-18; Lang v. Ethicon, Inc., et al, Docket No.: BER-L-1067-18; Gibson v. Ethicon, Inc., et al, Docket No.: BER-L-1110-18; Shackelford v. Ethicon, Inc., et al, Docket No.: BER-L-1200-18; Schriner v. Ethicon, Inc., et al, Docket No.: BER-L-1222-18; Alexander v. Ethicon, Inc., et al, Docket No.: BER-L-1241-18; Usey v. Ethicon, Inc., et al, Docket No.: BER-L-1244-18; Hart v. Ethicon, Inc., et al, Docket No.: BER-L-1349-18; Galvez v. Ethicon, Inc., et al, Docket No.: BER-L-1393-18; Lindly v. Ethicon, Inc., et al, Docket No.: BER-L-1402-18; Senkel v. Ethicon, Inc., et al, Docket No.: BER-L-1433-18; Maestas v. Ethicon, Inc., et al, Docket No.: BER-L-1456-18; Szaroleta v. Ethicon, Inc., et al, Docket No.: BER-L-1458-18; Krampen-Yerry v. Ethicon, Inc., et al, Docket No.: BER-L-1466-18; Lotridge v. Ethicon, Inc., et al, Docket No.: BER-L-1467-18; Dias v. Ethicon, Inc., et al, Docket No.: BER-L-1471-18; Alvarado, et al v.

Ethicon, Inc., et al, Docket No.: BER-L-1479-18; Mountjoy, et al v. Ethicon, Inc., et al, Docket No.: BER-L-1480-18; Fontenot v. Ethicon, Inc., et al, Docket No.: BER-L-1513-18; Anawaty v. Ethicon, Inc., et al, Docket No.: BER-L-1516-18; Capshaw v. Ethicon, Inc., et al, Docket No.: BER-L-1530-18; Bradford v. Ethicon, Inc., et al, Docket No.: BER-L-1806-18; Johnson v. Ethicon, Inc., et al, Docket No.: BER-L-2003-18; and Collier v. Ethicon, Inc., et al, Docket No.: BER-L-2214-18. Beyond the Cottle, Bassett, Gold, Noakes, Fowler, Griffin, Linnenbrink, Campbell, Martin, Ruiz, Trebolo, Gateley, Redding, Rice, Bean, Alumbaugh, Reynolds, Smith, Gaddis, Clark, Fielding, Hollimon, Miller, Moore, Rodriguez, Sollis, Adams, Crossland, Denney, Westerbeck, Dollanmeyer, Jarrell, Jennings, Johnson, Kennedy, McKinney, Morgan, Robins, Aaron, Diloreto, Pikulsky, Lang, Gibson, Shackelford, Schriner, Alexander, Usey, Hart, Galvez, Lindly, Senkel, Maestas, Szaroleta, Krampen-Yerry, Lotridge, Dias, Alvarado, Mountjoy, Fontenot, Anawaty, Capshaw, Bradford, Johnson, and Collier cases, I am not aware of any other civil proceedings either pending or contemplated with respect to the matter in controversy herein, and that there are no other parties who shall be joined in this action at this time.

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

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

TRIAL COUNSEL DESIGNATION

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

LOMURRO, MUNSON, COMER, BROWN & SCHOTTLAND, LLC
Attorneys for Plaintiff

/s JOSHUA S. KINCANNON
JOSHUA S. KINCANNON, ESQ.

Dated: April 3, 2018

Civil Case Information Statement

Case Details: BERGEN | Civil Part Docket# L-002337-18

Case Caption: WILLIAMS JAMES VS ETHICON, INC.
Case Initiation Date: 04/03/2018
Attorney Name: JOSHUA S KINCANNON
Firm Name: LOMURRO MUNSON COMER BROWN & SCHOTTLAND LLC
Address: 4 PARAGON WAY SUITE 100
FREEHOLD TWP NJ 07728
Phone:
Name of Party: PLAINTIFF : Williams, James
Name of Defendant's Primary Insurance Company (if known): Unknown

Case Type: PRODUCT LIABILITY
Document Type: Complaint with Jury Demand
Jury Demand: YES - 12 JURORS
Hurricane Sandy related? NO
Is this a professional malpractice case? NO
Related cases pending: YES
If yes, list docket numbers: 2017: 7065, 7836, 8037, 8276, 8572, 8827, 8829, 8998, 9127, 9130, 9133, 9151
2018: 184, 197, 198, 207, 279, 652, 658, 691, 693, 694, 695, 697, 699, 703, 728, 729, 732, 733, 774, 775, 777, 778, 779, 780, 781, 809, 870, 1018, 1052, 1067, 1110, 1200, 1222, 1241, 1244, 1393, 1402, 1433, 1456, 1458, 1466, 1467, 1471, 1479, 1480, 1513, 1516, 1530, 1806, 2003, 2214
Do you anticipate adding any parties (arising out of same transaction or occurrence)? NO

THE INFORMATION PROVIDED ON THIS FORM CANNOT BE INTRODUCED INTO EVIDENCE

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

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

If yes, is that relationship:

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

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

Do you or your client need any disability accommodations? NO
If yes, please identify the requested accommodation:

Will an interpreter be needed? NO
If yes, for what language:

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

04/03/2018
Dated

/s/ JOSHUA S KINCANNON
Signed