ATT: No

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

Plaintiff, John Schneider ("Plaintiff") 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, defective design,

brought by Plaintiff, John Schneider ("Plaintiff") for injuries arising out of the Proceed Surgical Mesh ("Ethicon Proceed" or "Proceed").

2. Defendant Ethicon manufactured and supplied to doctors a multi-layered hernia mesh known as the Proceed Surgical Mesh.

3. The Proceed Surgical Mesh created an unreasonable risk of harm to Plaintiff.

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

5. The selection and implantation of the Ethicon Proceed by Plaintiff's 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. Plaintiff currently resides in Austin, Texas. Plaintiff is a citizen and resident of Texas.

8. Plaintiff underwent hernia repair surgery on or about February 15, 2010 at University Medical Center at Brackenridge in Austin, Texas. At that time, the Ethicon Proceed mesh product that Defendants manufactured, designed, distributed, and warranted by Defendants was implanted into Plaintiff. Plaintiff's surgeon, medical staff, and other healthcare providers met

or exceeded the standard of care applicable to the hernia surgery.

9. 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.

10. Defendant J&J organizes its subsidiary businesses into individual Business Units to coordinate the development, manufacture, testing, marketing promotion, training, distribution and sale of its products, including but not limited to its hernia repair mesh products. Within J&J there are three sectors: medical devices and diagnostics, pharmaceutical, and consumer. Within the medical devices and diagnostic sector are "Business Units" including the "Ethicon Franchise." J&J charged the Ethicon Franchise with the design, development, promotion, marketing, testing, training, distribution and sale of the Proceed Surgical Mesh, the hernia repair 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 which comprise the Ethicon Franchise are thus controlled by Defendant J&J and include Ethicon, Inc.

11. 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.

12. 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.

13. 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.

14. 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.

15. All 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 response of Defendants, if any, related to these adverse events.

16. The Proceed 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, Middlesex County.

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

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

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

17. At all times relevant hereto, the 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 his practice group, or to the hospital where the Ethicon Proceed was implanted.

18. Plaintiff has reviewed potential legal claims and causes of action against

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

19. Defendants designed, manufactured, fabricated, marketed, packaged, advertised, and sold the Proceed throughout the world, including in Middlesex County, State of New Jersey.

20. Ethicon knowingly market to, and derive income from, patients in the State of New Jersey from the sale of Ethicon Proceed.

21. This is an action for damages in excess of Fifteen Thousand Dollars ($15,000.000), exclusive of interest and cost.

PROCEED HISTORY

22. Defendants were the designers, manufacturers, marketers, distributors and suppliers of the Ethicon Proceed Surgical Mesh at all material times.

23. Defendants warranted the Proceed Surgical Mesh and placed the device into the United States stream of commerce.

24. 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 the Defendants set out to design the Proceed Surgical Mesh in 2003.

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

26. Before 2003, Defendants were aware that increased adhesion formation would

result in increased mesh shrinkage.

27. Before 2003, Defendants were aware that Oxidized Regenerated Cellulose would result in dense adhesions in the presence of blood or fibrinous exudate.

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

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

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, which would result in an increase in adhesion formation, mesh shrinkage, pain, bowel complications, hernia recurrence, and/or the need for early surgical revision in patients-consumers.

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 sterilize the Proceed with gamma irradiation, despite long-standing knowledge that polypropylene will degrade and embrittle if exposed to any amount of gamma irradiation.

33. The Ethicon Proceed Surgical Mesh is made of the following, starting with the component which would be 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)

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 irradiation.

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

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

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

40. The polypropylene base is the only permanent, non-resorbable portion or 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, there were concerns in the medical community 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 utilized in the Proceed was ineffective

[1] U.S. Patent No. 3,943,933 (Issued Mar. 16, 1976).
[2] Proceed Surgical Mesh Instructions for Use, Status 04/2010.

at preventing adhesion formation to polypropylene over a decade before Defendants brought the Proceed to market.[3]

44. Despite significant evidence to 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.

FAILURE TO WARN PHYSICIANS OF THE DANGERS ASSOCIATED WITH PROCEED

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

46. 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 the surgeon.

47. The multiple 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.

48. Defendants state in the Ethicon Proceed IFU that "The PROLENE Soft Mesh component is 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 very least misleading, as the Proceed undergoes gamma irradiation that changes the composition of the polypropylene.

[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).

49. Defendants also state in the Ethicon Proceed IFU that the polypropylene material "when used as a suture, has been reported to be nonreactive 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 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.

50. The Ethicon Proceed IFU has a section for contraindications, which list "None known."

51. The Ethicon Proceed IFU has a section for adverse reactions, which list "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 multiple layers of the Ethicon Proceed further increases 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.

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

53. 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.

54. Defendants never performed any clinical trials and/or studies prior to marketing the Ethicon Proceed.

55. Defendants did not fully and/or adequately test the configuration of this new, multi-layered hernia mesh, designed with ORC, polypropylene, and PDS, that was implanted into Plaintiff.

56. 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.

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

58. 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.

59. Defendants were aware that the ORC layer was ineffective at preventing adhesions to the polypropylene; gamma irradiation would weaken the polypropylene; and the multi-layered mesh would contract massively over time. Nonetheless, Defendants employed the design in its Ethicon Proceed Surgical Mesh in a reckless disregard for the safety of patients, including Plaintiff.

60. 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.

61. From the time that Defendants first began selling the Ethicon Proceed in the United States through today, product labeling and product information failed to contain adequate information, instructions, and warnings concerning the following: implantation of the 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 that occur at a higher rate than other surgically implanted devices

USE OF THE PRODUCT

62. A defectively designed, manufactured and marketed Ethicon Proceed Surgical Mesh left the hands of Defendants in its defective condition, delivered into the stream of commerce. W. D. Fielder, MD implanted the Proceed Surgical Mesh in Plaintiff's abdomen to repair an incisional hernia on or about February 15, 2010. Plaintiff was implanted with a Proceed Surgical Mesh, Ref: PCDJ1, Lot: BGG307.

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

a. According to the medical records, on or about April 28, 2010 Plaintiff underwent an incision and drainage for an abdominal wound at the University Medical Center at Brackenridge in Austin, Texas with W.D. Fielder, MD. Some visible mesh was debrided and the area was copiously irrigated. The records further show that on or

about August 11, 2010, Plaintiff underwent removal of the infected mesh and abdominal wound VAC placement with W.D. Fielder, MD at the University Medical Center in Brackenridge in Austin, Texas. Dr. Fielder noted that all visible mesh was excised.

b. Plaintiff experienced and/or continues to experience severe pain, nausea, infection, recurrence, scarring, disfigurement, loss of appetite and stress and anxiety which have impaired his activities of daily living.

c. Plaintiff continues to suffer complications as a result of his implantation with the Ethicon Proceed.

d. Plaintiff is at a higher risk of severe complications during an abdominal surgery, to the extent that future abdominal operations might not be feasible.

64. The mechanism of failure in Plaintiff's device was exactly the same mechanism of failure that Defendants had marketed and 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.

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

66. Despite diligent investigation by Plaintiff into the cause of his injuries, including consultations with his medical providers, the nature of his injuries and damages and their relationship to the Proceed mesh was not discovered, and through reasonable care and diligence

could not have been discovered until a date within the applicable statute of limitations for filing Plaintiff's claims. Therefore, under appropriate application of the discovery rule, Plaintiff's suit was filed well within the applicable statutory limitations period.

67. Furthermore, in the existence of due diligence, Plaintiff could not have reasonably discovered the Defendants' fault or wrongful conduct, including, but not limited to, the defective design and/or manufacturing of the product until a date within the statute of limitations. Therefore, under appropriate application of the discovery rule, Plaintiff's suit was filed well within the statutory limitations period.

68. As a direct and proximate result of Defendants' defective design, manufacturing, marketing, distribution, sale and warnings of the defective Ethicon Proceed, Plaintiff has suffered and continues to suffer both injuries and damages, including, but not limited to: past, present and future physical and mental pain and suffering; physical disability, and past, present, and future medical, hospital, rehabilitative, and pharmaceutical expenses, and other related damages.

THE FDA'S 510(k) CLEARANCE PROCESS

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

70. No clinical testing is required under this process.

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

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

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

74. 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.**

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

76. Defendants cleared the Ethicon Proceed Surgical Mesh, 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.

77. 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.**

78. The 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 adhesions barrier in their 510(k) application. However, after 510(k) clearance, Defendants marketed the Proceed Surgical Mesh as a resorbable adhesion barrier.

79. 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.

CAUSES OF ACTION

COUNT I: STRICT PRODUCTS LIABILITY – DEFECTIVE DESIGN UNDER NEW JERSEY PRODUCT LIABILITY ACT (NJ PLA) AND TEXAS COMMON AND STATUTORY LAW

80. Plaintiff incorporates herein by reference the allegations in all prior paragraphs and further alleges as follows:

81. 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.

82. 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.

83. 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 and his implanting physician, without substantial change in their condition.

84. 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, but are not limited to 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 irradiation;
- the Ethicon Proceed contained unreasonably dangerous design defects, utilizing multiple layers, which increases and prolongs 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.

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

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

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

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

89. As a direct and proximate result of Defendants' wrongful conduct, including the defective and dangerous design and inadequate warnings or the Ethicon Proceed, Plaintiff has sustained and will continue to sustain severe and debilitating injuries, economic loss, and other damages including, but not limited to, cost of medical care, rehabilitation, lost income, permanent instability and loss of balance, immobility, and pain and suffering, for which he is entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

90. Defendants are strictly liable in tort to Plaintiff for their wrongful conduct pursuant to the New Jersey Products Liability Act, *N.J.S.A.* 2A:58C-1 *et seq*., (hereinafter NJ PLA).

91. Defendants are strictly liable in tort to Plaintiff for their wrongful conduct pursuant to Texas common and statutory law, including Tex. Civ. Prac. & Rem. Code Ann. §§ 82.001-82.008.

COUNT II: STRICT PRODUCTS LIABILITY – FAILURE TO WARN UNDER NJ PLA AND TEXAS COMMON AND STATUTORY LAW

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

93. 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. Therefore, Defendants had a duty to warn of the risks associated with the use of the Ethicon Proceed.

94. Defendants distributed and sold the Ethicon Proceed in their original form of manufacture, which included the defects described herein.

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

96. 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.

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

98. The Ethicon Proceed was implanted in Plaintiff and used in a manner for which it was intended.

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

100. Defendants failed to adequately warn health care professionals and the public, including Plaintiff 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.

101. 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's physician, would have used the Ethicon Proceed, or no consumer, including Plaintiff, would have purchased and/or consented to the use of the Ethicon Proceed.

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

103. 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, and continued to aggressively promote the Ethicon Proceed.

104. 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.

105. 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.

106. Both Plaintiff and his physician used the Ethicon Proceed for its intended purpose, *i.e.*, hernia repair.

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

108. 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.

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

110. Defendants reasonably should have known the Ethicon Proceed was unsuited to repair a hernia in Plaintiff.

111. 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 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.

112. Defendants are strictly liable in tort to Plaintiff for their wrongful conduct pursuant to the NJ PLA, *N.J.S.A.* 2A:58C-1 *et seq*.

113. Defendants are strictly liable in tort to Plaintiff for their wrongful conduct pursuant to Texas common and statutory law, including Tex. Civ. Prac. & Rem. Code Ann. §§ 82.001-82.008.

COUNT III: STRICT PRODUCTS LIABILITY – MANUFACTURING DEFECT UNDER NJ PLA AND TEXAS COMMON AND STATUTORY LAW

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

115. 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 it propensity to result in early failure of the device. The Ethicon Proceed was unreasonably dangerous in construction or composition.

116. The Ethicon Proceed Defendants manufacture 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, Defendants continued to market the Ethicon Proceed as a safe and effective absorbable barrier hernia mesh.

117. 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 suffered harm, damages and economic loss as previously described and will continue to suffer such harm, damages and economic loss in the future.

118. Defendants are strictly liable in tort to Plaintiff for their wrongful conduct pursuant to the NJ PLA, *N.J.S.A.* 2A:58C-1 *et seq*.

119. Defendants are strictly liable in tort to Plaintiff for their wrongful conduct pursuant to Texas common and statutory law, including Tex. Civ. Prac. & Rem. Code Ann. §§ 82.001-82.008.

COUNT IV: NEGLIGENCE-
PURSUANT TO NJ PLA, NEW JERSEY COMMON LAW, AND TEXAS COMMON LAW

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

121. 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.

122. 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 in whom the Proceed was implanted. They also knew or should have known that Plaintiff and his physicians were unaware of the dangers and defects inherent in the Ethicon Proceed.

123. 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 suffered injuries and damages as summarized in this Complaint.

124. Defendants are liable in tort to Plaintiff for their wrongful conduct pursuant to the NJ PLA, *N.J.S.A.* 2A:58C-1 *et seq*.

125. Defendants are similarly liable in tort to Plaintiff for their wrongful conduct, including but not limited to negligent marketing and negligent misrepresentations, pursuant to New Jersey common law.

126. Defendants are liable in tort to Plaintiff for their wrongful conduct, including but not limited to their negligent marketing and negligent design of the Proceed product, pursuant to any and all applicable Texas common law.

COUNT V: BREACH OF IMPLIED WARRANTY UNDER NJ PLA AND TEXAS COMMON AND STATUTORY LAW

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

128. At the time Defendants designed, manufactured, produced, tested, studied, inspected, labeled, marketed, advertised, sold, promoted and distributed the Ethicon Proceed for use by Plaintiff, 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.

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

130. Plaintiff, 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.

131. 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.

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

133. Defendants are liable in tort to Plaintiff for their wrongful conduct pursuant to the NJ PLA, *N.J.S.A.* 2A:58C-1 *et seq*.

134. Defendants are strictly liable in tort to Plaintiff for their wrongful conduct pursuant to Texas common and statutory law, including Tex. Civ. Prac. & Rem. Code Ann. §§ 82.001-82.008.

COUNT VI: BREACH OF EXPRESS WARRANTY UNDER NJ PLA AND TEXAS COMMON AND STATUTORY LAW

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

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

137. At all relevant times, Defendant intended the Ethicon Proceed be used in the manner that Plaintiff 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.

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

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

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

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

- Defendants represented to Plaintiff 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 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 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.

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

143. 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.

144. Members of the medical community, including physicians and other healthcare professionals, as well as Plaintiff 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.

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

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

147. Defendants are liable in tort to Plaintiff for their wrongful conduct pursuant to the

NJ PLA, *N.J.S.A.* 2A:58C-1 *et seq*.

148. Defendants are liable in tort to Plaintiff for their wrongful conduct pursuant to Texas common law and Texas statutory law, including Tex. Civ. Prac. & Rem. Code Ann. §§ 82.001-82.00.

COUNT VII: PUNITIVE DAMAGES UNDER NEW JERSEY COMMON LAW, TEXAS COMMON AND STATUTORY LAW, NEW JERSEY PUNITIVE DAMAGES ACT (N.J.S.A. 2A:15-5.9, *et seq*.) and NJ PLA (N.J.S.A. 2A:58C-1, *et seq*.)

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

150. Plaintiff 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, 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, concerning the safety of the Ethicon Proceed.

151. 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.

152. 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, from weighing the true risks against the benefits of using the Ethicon Proceed.

153. 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.

154. Defendants are liable in tort to Plaintiff for their wrongful conduct pursuant to the NJ PLA, *N.J.S.A.* 2A:58C-1 *et seq*., and New Jersey common law.

155. Plaintiff is entitled to punitive damages as a result of Defendants' reckless conduct in wanton disregard of Plaintiff's safety pursuant to *N.J.S.A.* 2A:15-5.9, *et seq.*

156. Plaintiff is entitled to punitive damages as a result of Defendants' reckless conduct in wanton disregard of Plaintiff's safety pursuant to any and all Texas common law and statutory law and liable in tort to Plaintiff for their wrongful conduct pursuant to the applicable Texas common and statutory law.

WHEREFORE, Plaintiff 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 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; 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, listed on Exhibit A. 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, Michael G. Daly, is hereby designated as trial counsel on behalf of Plaintiff.

/s/ Marc D. Grossman
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Dated: April 23, 2019

SUMMONS

Attorney(s) Marc Grossman
Office Address 100 Garden City Plaza, Suite 500
Town, State, Zip Code Garden City, NY 11530

Telephone Number (516) 741-5600
Attorney(s) for Plaintiff John Schneider
John Schneider

Plaintiff(s)

vs.

Johnson & Johnson, et al.

Defendant(s)

Superior Court of New Jersey

Middlesex County
Civil Law Division
Docket No:

CIVIL ACTION SUMMONS

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

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

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

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

/s/ Michelle M. Smith
Clerk of the Superior Court

DATED: 4/23/2019

Name of Defendant to Be Served: Ethicon, Inc.

Address of Defendant to Be Served: Route 22 West, Somerville, NJ 08876

SUMMONS

Attorney(s) Marc Grossman
Office Address 100 Garden City Plaza, Suite 500
Town, State, Zip Code Garden City, NY 11530

Telephone Number (516) 741-5600
Attorney(s) for Plaintiff John Schneider

John Schneider

Plaintiff(s)

vs.

Johnson & Johnson, et al.

Defendant(s)

Superior Court of New Jersey

Middlesex County
Civil Law Division
Docket No:

CIVIL ACTION SUMMONS

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

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

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

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/s/ Michelle M. Smith
Clerk of the Superior Court

DATED: 4/23/2019

Name of Defendant to Be Served: Johnson & Johnson

Address of Defendant to Be Served: One Johnson & Johnson Plaza, New Brunswick, New Jersey

Civil Case Information Statement

Case Details: MIDDLESEX | Civil Part Docket# L-003139-19

Case Caption: SCHNEIDER JOHN VS ETHICON, INC.
Case Initiation Date: 04/23/2019
Attorney Name: MARC DAVID GROSSMAN
Firm Name: SANDERS PHILLIPS GROSSMAN, LLC
Address: 100 GARDEN CITY PLAZA, STE 500
GARDEN CITY NY 11530
Phone:
Name of Party: PLAINTIFF : Schneider, John
Name of Defendant's Primary Insurance Company (if known): Unknown

Case Type: PROCEED MESH/PATCH
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: See exhibit A
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:

Please check off each applicable category: Putative Class Action? NO **Title 59?** NO

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)

04/23/2019
Dated

/s/ MARC DAVID GROSSMAN
Signed