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VINCENT J. GRANT, JR., 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**

Plaintiff, Vincent J. Grant, Jr. ("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 a product liability action brought by Plaintiff for injuries arising out of the Prolene (Polypropylene) Hernia System ("Prolene Hernia System").

2. Defendants J&J and Ethicon designed, manufactured, marketed, supplied and sold to doctors a multi-layered hernia mesh "Ethicon Multi-Layered Hernia Mesh", including the Prolene Hernia System.

3. Ethicon Multi-Layered Hernia Mesh created an unreasonable risk of harm to Plaintiff.

4. The unreasonable risk of injury and harm, including pain, dense adhesion formation, organ 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, non-conforming subcomponents, or some other mechanism, renders Ethicon Multi-Layered Hernia Mesh a defective product, unsafe for its intended use.

5. The selection and implantation of the Ethicon Multi-Layered Hernia Mesh by Plaintiff's surgeons was a result of the negligent misinformation, marketing, sales, promotion and direction by Defendants.

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 Los Angeles, California and is a citizen and resident of California.

8. Plaintiff underwent hernia repair surgery on or about March 3, 2015, at the UCLA Medical Center in Santa Monica, California. At that time, the Prolene Hernia System product that Defendants manufactured, designed, distributed, and warranted by Defendants as safe and effective for use was implanted into Plaintiff. Plaintiff's implanting surgeon conformed to the accepted standard of care for hernia repair 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 Prolene Hernia System, the hernia repair products at issue in this case. The Company Group Chairman and Worldwide Franchise Chairman for the Ethicon Franchise, Gary Pruden, is employed by J&J. The companies which comprise the Ethicon Franchise are thus controlled by 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 Ethicon Multi-Layered Hernia Mesh.

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 Ethicon Multi-Layered Hernia Mesh.

14. At all relevant times, Defendants either directly, or through their agents, apparent agents, servants or employees sold, distributed and marketed the defective Ethicon Multi-Layered Hernia Mesh 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 Multi-Layered Hernia Mesh, and having a role in the decision process and response of Defendants, if any, related to these adverse events.

16. The Ethicon Multi-Layered Hernia Mesh Defendants are subject to jurisdiction within the State of New Jersey and this Court because:

a. Defendants are engaged in substantial business activity within the State of New Jersey, Bergen County.

b. Defendants' hernia mesh products, including the subject Prolene Hernia System, 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 tortious 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 defective Ethicon Multi-Layered Hernia Mesh throughout the United States, including within the State of New Jersey and specifically to Plaintiff and Plaintiff's implanting physicians or their practice groups, or to the hospitals where the Ethicon Multi-Layered Hernia Mesh was implanted.

18. Plaintiff's claims and causes of action are only 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 Ethicon Multi-Layered Hernia Mesh throughout the world, including in Bergen County, State of New Jersey.

20. Ethicon knowingly markets to, and derives income from, patients across the United Stated, including the State of New Jersey from the sale of Ethicon Multi-Layered Hernia Mesh.

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

FACTS COMMON TO ALL COUNTS

22. A defectively designed, manufactured and marketed Prolene Hernia System left the hands of Defendants in its defective condition, and was delivered into the stream of commerce. Tracey R. Childs, M.D., implanted the Prolene Hernia System in Plaintiff's abdomen to repair a right inguinal hernia on or about March 3, 2015, at the UCLA Medical Center in Santa Monica, California. Plaintiff was implanted with a Prolene Hernia System, Cat# PHSE, Lot 28383-24.

23. According to the medical records, on or about September 21, 2017, Dr. Chen at UCLA Medical Center in Santa Monica, California, performed on Plaintiff a laparoscopic and open hybrid right groin exploration and mesh removal, laparoscopic identification and neurectomy of the right genital branch of the genitofemoral nerve, open right groin exploration, identification and neurectomy of the right ilioinguinal nerve with intermuscular reimplantation, identification and neurectomy of the right iliohypogastric nerve with proximal intramuscular reimplantation, removal of anterior and posterior meshoma with tissue reconstruction of the floor of the inguinal canal, repair of recurrent direct inguinal hernia and extensive lysis of adhesions of colon and appendix to the previously placed mesh, with David Chen, M.D., at UCLA Medical Center in

Santa Monica, California. Upon visualizing the Prolene Hernia System, Dr. Chen noted a folded posterior leaflet of the bilayer mesh with entrapment of the appendix and colon adhesed to the mesh, present intra-abdominally and balled up and folded into a cup-like configuration. Dr. Chen further noted that the iliohypogastric and ilioinguinal nerves were entrapped with the mesh.

24. As a result of the defective Prolene Hernia Mesh System, Plaintiff experienced and/or continues to experience severe pain, nerve damage, mesh migration, meshoma, tissue reconstruction, neurectomy, mesh excision, stress and anxiety which have impaired his activities of daily living.

25. The mechanism of failure in Plaintiff's device was a mechanism of failure that Defendants had marketed and warranted would not occur because of Ethicon Multi-Layered Hernia Mesh design and composition.

26. As a direct and proximate result of Defendants' defective design, manufacturing, marketing, distribution, sale and warnings of the defective Ethicon Multi-Layered Hernia Mesh, 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.

27. Defendants were the designers, manufacturers, marketers, sellers, distributors and suppliers of the Prolene Hernia System at all material times.

28. Defendants warranted the Prolene Hernia System as safe and effective for use and placed the device into the United States stream of commerce.

29. Prolene Hernia System has a unique multi-layer design incorporating two (2) distinct layers of polypropylene together with a polypropylene tube. This design is not used in any

other hernia repair product sold in the United States.

30. The multi-layer polypropylene design was represented and promoted by the Defendants to prevent or minimize hernia recurrence and chronic pain, but it did not. Instead, the multi-layer polypropylene mesh occupied two inguinal compartments instead of one, increasing the intense inflammatory and chronic foreign body response, resulting in mesh stiffening, mesh hardening, mesh contracture, mesh deformation, mesh migration, granulomatous and/or fibrotic tissue, increased foreign body sensation, and increased chronic and debilitating pain.

31. When a Prolene Hernia System fails, the complications are harder to treat and the eventual explantation of the Prolene Hernia System results in large amounts of tissue loss due to the Prolene Hernia System occupying two inguinal compartments.

32. The polypropylene material used in the Prolene Hernia System is unreasonably susceptible to in vivo oxidative degradation, which causes or exacerbates excessive inflammation and adverse foreign body reaction, leading to shrinkage, scarification, pain and mesh deformation.

FAILURE TO WARN OF THE DANGERS ASSOCIATED WITH ETHICON MULTI-LAYERED HERNIA MESH

33. Before placing Ethicon Multi-Layered Hernia Mesh on the market, Defendants were required to adequately test the product and mitigate risks of the product, including any element of design which could render the device ineffective, weaken the structural integrity of the device, prevent safe treatment when complications arise, increase complications, or increase or prolong inflammation once the device is implanted, which would result in an increase in adhesion formation, mesh shrinkage, mesh deformation, pain, organ complications, hernia recurrence, and/or the need for early surgical revision in patients-consumers.

34. Defendants designed, manufactured, promoted, marketed and sold the Ethicon Multi-Layered Hernia Mesh, despite long-standing knowledge that the material and design utilized

in Ethicon Multi-Layered Hernia Mesh would cause dense adhesions, chronic pain, mesh shrinkage, mesh deformation, foreign body sensation, organ complications, and hernia recurrence, and that treating such complications when they inevitably arose would result in even greater complications and a larger defect.

35. Defendants marketed Ethicon Multi-Layered Hernia Mesh to general surgeons, hospitals, and group purchasing organizations (GPOs).

36. Defendants had the ability to inform surgeons, hospitals, or GPOs of developing problems or defects related to Ethicon Multi-Layered Hernia Mesh in its devices through communications, e-mails, letters, recalls, warnings in product inserts, and/or through its product representatives, who communicate, interact and work with the surgeon.

37. The multiple layers of Ethicon Multi-Layered Hernia Mesh increase the intensity and duration of the inflammatory response. That response in turn increases dense adhesion formation from underlying structures and organs to the Ethicon Multi-Layered Hernia Mesh, resulting in mesh contracture, mesh deformation, chronic pain, foreign body sensation, foreign body reaction, organ and tissue damage, hernia recurrence, and more.

38. Defendants never performed any clinical trials and/or studies prior to marketing Ethicon Multi-Layered Hernia Mesh.

39. Defendants did not fully and/or adequately test the configuration of these new, multi-layered hernia meshes, one of which was implanted into Plaintiff.

40. 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.

41. Despite these reassurances, the defective design and manufacture of Ethicon Multi-

Layered Hernia Mesh continued to elicit severe and chronic inflammatory responses, resulting in mesh contracture, mesh deformation, chronic pain, foreign body sensation, adhesion formation, organ injuries, hernia recurrence, infections, seromas, fistulas, erosion, extrusion, and additional complications.

42. From the time that Defendants first began selling Ethicon Multi-Layered Hernia Mesh 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 mesh, explantation of the mesh, its propensity to massively shrink and change shape, the increased duration and intensity of inflammation, and the elevated rate of adhesions, organ complications, chronic and debilitating pain, foreign body sensation, 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.

CAUSES OF ACTION

COUNT I: STRICT PRODUCTS LIABILITY – DEFECTIVE DESIGN UNDER NEW JERSEY PRODUCT LIABILTY ACT AND CALIFORNIA COMMON AND STATUTORY LAW

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

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

45. In and before 1999, 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 Prolene Hernia System.

46. Defendants expected the Ethicon Multi-Layered Hernia Mesh 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 Plaintiff's implanting physician, without substantial change in their condition.

47. At the time the Ethicon Multi-Layered Hernia Mesh left Defendants' possession and the time the Ethicon Multi-Layered Hernia Mesh 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:

- Ethicon Multi-Layered Hernia Mesh was not reasonably safe as intended to be used;
- Ethicon Multi-Layered Hernia Mesh had an inadequate design for the purpose of hernia repair;
- Ethicon Multi-Layered Hernia Mesh contained unreasonably dangerous design defects, utilizing multiple layers, which increases and prolongs the inflammatory response;
- Ethicon Multi-Layered Hernia Mesh was not appropriately or adequately tested before distribution; and
- Ethicon Multi-Layered Hernia Mesh had an unreasonably high propensity for adhesion formation, mesh contracture, mesh deformation, chronic pain, foreign body sensation, organ complications, seroma formation, fistula formation, hematoma formation, hernia recurrence, infection, erosion, and extrusion.
- the Prolene Hernia System contained unreasonably dangerous design defects, including two connecting disc layers of polypropylene, which were intended to

occupy two inguinal compartments once implanted. Due to the contours of the preperitoneal space, the deeper disc cannot be expected to be positioned flat, which results in increased complications and an inability to safely treat such complications.

- the Prolene Hernia System is unreasonably dangerous, due to the heavyweight polypropylene, which increases the inflammatory and foreign body response.
- the Prolene Hernia System is unreasonably dangerous, due to the small pore size utilized, which increases inflammatory and foreign body response.
- the Prolene Hernia System is unreasonably dangerous, due to the mesh shrinking and stiffening over time.
- the Prolene Hernia System is unreasonably dangerous, due to the mesh degrading after implantation.

48. At the time the Defendants' initial design, manufacture, marketing, and sale of Ethicon Multi-Layered Hernia Mesh, a feasible, alternative safer design was known and available, including, but not limited to, a flat, non-coated, single-layer, lightweight, large-pore mesh, or a fully resorbable mesh.

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

50. Had the Defendants properly and adequately tested Ethicon Multi-Layered Hernia Mesh, they would have discovered that multiple layers increase and prolong the inflammatory response; the mesh experiences significant contraction and deformation over time; the mesh cannot be safely removed; and that these defects result in chronic and debilitating pain, foreign body sensation, a pronounced foreign body response, seromas, fistulas, infections, erosion, and extrusion, among other complications.

51. Ethicon Multi-Layered Hernia Mesh, 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 from 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.

52. As a direct and proximate result of Defendants' wrongful conduct, including the defective and dangerous design and inadequate warnings of Ethicon Multi-Layered Hernia Mesh, 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 Plaintiff is entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

53. 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*. (herein after NJ PLA).

54. Defendants are strictly liable in tort to Plaintiff for their wrongful conduct pursuant to California common and statutory law.

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

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

56. Defendants researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and otherwise released into the stream of commerce Ethicon Multi-Layered Hernia Mesh; and directly advertised or marketed the product to the FDA,

health care professionals, GPOs, and consumers, including Plaintiff. Therefore, Defendants had a duty to warn of the risks associated with the use of Ethicon Multi-Layered Hernia Mesh.

57. Defendants distributed and sold Ethicon Multi-Layered Hernia Mesh in their original form of manufacture, which included the defects described herein.

58. Ethicon Multi-Layered Hernia Mesh was expected to and did reach Plaintiff and Plaintiff's implanting physician, without substantial change or adjustment in its condition as manufactured and sold by Defendants.

59. Each Ethicon Multi-Layered Hernia Mesh 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.

60. 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 Ethicon Multi-Layered Hernia Mesh.

61. Ethicon Multi-Layered Hernia Mesh was implanted in Plaintiff and used in a manner for which it was intended.

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

63. Defendants failed to adequately warn health care professionals and the public, including Plaintiff and Plaintiff's implanting physician, of the true risks of Ethicon Multi-Layered Hernia Mesh, which was ineffective at reducing chronic pain or hernia recurrence, and would contract and deform significantly upon implantation, resulting in debilitating pain, organ

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

64. Defendants failed to timely and reasonably warn of material facts regarding the safety and efficacy of Ethicon Multi-Layered Hernia Mesh. Had they done so, proper warnings would have been heeded and Plaintiff's physician, would not have used Ethicon Multi-Layered Hernia Mesh, or no consumer, including Plaintiff, would have purchased and/or consented to the use of Ethicon Multi-Layered Hernia Mesh.

65. Defendants failed to timely and reasonably provide adequate instructions and training concerning safe and effective use of Ethicon Multi-Layered Hernia Mesh.

66. Ethicon Multi-Layered Hernia Mesh, 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 Ethicon Multi-Layered Hernia Mesh 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 Ethicon Multi-Layered Hernia Mesh.

67. Ethicon Multi-Layered Hernia Mesh, 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 Ethicon Multi-Layered Hernia Mesh resulting in revision surgery, although Defendants knew of a safer alternative design

including, but not limited to, a flat, lightweight, large-pore, non-coated, single-layer mesh, or a fully resorbable mesh.

68. Defendants failed to perform or otherwise facilitate adequate testing on Ethicon Multi-Layered Hernia Mesh; failed to reveal and/or concealed such testing and research data; and selectively and misleadingly revealed and/or analyzed such testing and research data.

69. Plaintiff and Plaintiff's physicians used Ethicon Multi-Layered Hernia Mesh for its intended purpose, *i.e.*, hernia repair.

70. Plaintiff could not have discovered any defect in Ethicon Multi-Layered Hernia Mesh through the exercise of due care.

71. 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.

72. Neither Plaintiff nor Plaintiff's implanting physician had substantially the same knowledge about Ethicon Multi-Layered Hernia Mesh as Defendants.

73. Defendants reasonably should have known Ethicon Multi-Layered Hernia Mesh was unsuited to repair a hernia in Plaintiff.

74. 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.

75. 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*.

76. Defendants are strictly liable in tort to Plaintiff for their wrongful conduct pursuant to California common and statutory law.

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

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

78. Defendants designed, developed, manufactured, tested, packaged, advertised, promoted, marketed, distributed, labeled and/or sold Ethicon Multi-Layered Hernia Mesh, in a condition which rendered it unreasonably dangerous due to it propensity to result in early failure of the device. Ethicon Multi-Layered Hernia Mesh was unreasonably dangerous in construction or composition.

79. Ethicon Multi-Layered Hernia Mesh manufactured by Defendants 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 Ethicon Multi-Layered Hernia Mesh could fail 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 Ethicon Multi-Layered Hernia Mesh as a safe and effective hernia mesh.

80. 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.

81. 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*.

82. Defendants are strictly liable in tort to Plaintiff for their wrongful conduct pursuant to California common and statutory law.

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

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

84. 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 Prolene Hernia Mesh System, they failed to do so.

85. Defendants knew, or in the exercise of reasonable care should have known, that the Ethicon Prolene Hernia Mesh system was defectively and unreasonably designed and/or manufactured, and was unreasonably dangerous and likely to injure patients like Plaintiff in whom the Prolene Hernia System 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 Prolene Hernia System.

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

87. 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*.

88. 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.

89. Defendants are strictly liable in tort to Plaintiff for their wrongful conduct pursuant to California common law.

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

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

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

92. When the Ethicon Prolene Hernia System was implanted in Plaintiff, to treat his hernia, the Prolene Hernia System was being used for the ordinary purposes for which it was intended.

93. Plaintiff individually and/or by and through his physicians, relied upon Defendants' implied warranties of merchantability in consenting to have the Ethicon Prolene Hernia System implanted in him.

94. Contrary to such implied warranties, the Ethicon Prolene Hernia System was not of merchantable quality, and was not safe and/or was not fit for its intended use. The Prolene Hernia System 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 Prolene

Hernia System.

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

96. 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*.

97. Defendants are strictly liable in tort to Plaintiff for their wrongful conduct pursuant to California common and statutory law.

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

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

99. At all relevant times, Defendant manufactured, distributed, advertised, promoted, and sold the Ethicon Prolene Hernia System.

100. At all relevant times, Defendant intended the Ethicon Prolene Hernia System 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.

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

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

103. Defendants' Ethicon Prolene Hernia System 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.

104. Defendants breached various express warranties with respect to the Ethicon Prolene Hernia System, 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 Prolene Hernia System was safe and fraudulently withheld and concealed information about substantial risks or serious injury and/or death associated with using the Ethicon Prolene Hernia System.
- Defendants represented to Plaintiff, and his physicians and healthcare providers that their Ethicon Prolene Hernia System was as safe, and/or safer than other alternative procedures and devices and fraudulently concealed information, which demonstrated that the Ethicon Prolene Hernia System was not safer than alternatives available on the market; and
- Defendants represented to Plaintiff, and his physicians and healthcare providers that the Ethicon Prolene Hernia System was more efficacious than other alternatives and fraudulently concealed information regarding the true efficacy of the Ethicon Prolene Hernia System.

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

106. At the time of making such express warranties, Defendants knew or should have

known that the Ethicon Prolene Hernia System does not conform to these express representations because the Ethicon Prolene Hernia System was not safe and had numerous serious side effects, many of which Defendants did not accurately warn about, thus making the Ethicon Prolene Hernia System unreasonably unsafe for its intended purpose.

107. 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 Prolene Hernia System.

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

109. 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.

110. 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*.

111. Defendants are strictly liable in tort to Plaintiff for their wrongful conduct pursuant to California common and statutory law.

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

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

112. 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 Ethicon Multi-Layered Hernia Mesh 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 Ethicon Multi-Layered Hernia Mesh, despite available information demonstrating that Ethicon Multi-Layered Hernia Mesh lacked adequate testing, would significantly contract upon implantation, would cause an increased and prolonged inflammatory and foreign body response, high rates of chronic and debilitating pain, foreign body sensation, organ 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 Ethicon Multi-Layered Hernia Mesh or provided proper training and instruction to physicians regarding use of Ethicon Multi-Layered Hernia Mesh. Defendants' misrepresentations included knowingly withholding material information from the FDA, the medical community and the public, including Plaintiff, concerning the safety of Ethicon Multi-Layered Hernia Mesh.

113. Defendants were or should have been in possession of evidence demonstrating that Ethicon Multi-Layered Hernia Mesh caused serious side effects. Nevertheless, Defendants continued to market Ethicon Multi-Layered Hernia Mesh by providing false and misleading information with regard to its safety and efficacy.

114. Defendants failed to provide warnings that would have dissuaded health care professionals from using Ethicon Multi-Layered Hernia Mesh, thus preventing health care

professionals and consumers, including Plaintiff, from weighing the true risks against the benefits of using Ethicon Multi-Layered Hernia Mesh.

115. Defendants failed to provide adequate training, testing and instructions to physicians that could have prevented failure of Ethicon Multi-Layered Hernia Mesh causing serious harm and suffering to patients, including Plaintiff.

116. Defendants are liable for punitive damages pursuant to all applicable state law as a result of their wrongful, wanton, and reckless conduct as described above.

117. 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.

118. Defendants are liable in tort to Plaintiff for their wrongful conduct pursuant to California common and statutory law.

119. 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.*

120. Plaintiff is entitled to punitive damages as a result of Defendants' reckless conduct in wanton disregard of Plaintiff's safety pursuant to California Common 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 Ethicon Hernia Mesh Cases in exhibit A, attached hereto, I am not aware of any other civil 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/ Michael G. Daly
POGUST MILLROOD, LLC
Michael G. Daly, Esquire
NJ Attorney ID: 025812010
mdaly@pogustmillrood.com
Eight Tower Bridge, Suite 940
161 Washington Street
Conshohocken, Pennsylvania 19428
T: 610-941-4204
F: 610-941-4245

Attorney for Plaintiff, Vincent J. Grant, Jr.

Dated: August 2, 2019

SUMMONS

Attorney(s) Michael Daly
Office Address 161 Washington Street, Suite 940
Town, State, Zip Code Conshohocken, PA 19428

Telephone Number 610-941-4204
Attorney(s) for Plaintiff Vincent J. Grant, Jr.
Vincent J. Grant, Jr.

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: 8/2/2019

Name of Defendant to Be Served: Ethicon, Inc.

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

SUMMONS

Attorney(s) Michael G. Daly
Office Address 161 Washington Street, Suite 940
Town, State, Zip Code Conshohocken, PA 19428

Telephone Number (610) 941-4204
Attorney(s) for Plaintiff Vincent J. Grant, Jr.

Vincent J. Grant, Jr.

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.

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

DATED: 8/2/2019

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-005652-19

Case Caption: GRANT, JR. VINCENT VS ETHICON, INC.
Case Initiation Date: 08/02/2019
Attorney Name: MICHAEL G DALY
Firm Name: POGUST MILLROOD LLC
Address: EIGHT TOWER BRIDGE 161 WASHINGTON ST
STE 940
CONSHOHOCKEN PA 19428
Phone: 6109414204
Name of Party: PLAINTIFF : Grant, Jr., Vincent, J
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
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)

08/02/2019
Dated

/s/ MICHAEL G DALY
Signed