ATT: No

(Attachments: No)

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KAREN HAGER, 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**

COMPLAINT

Plaintiff Karen Hager, by and through her counsel, brings this suit against Johnson & Johnson ("J&J"), a New Jersey corporation; and its wholly owned subsidiary Ethicon, Inc. ("Ethicon"), a New Jersey corporation (collectively "Defendants").

NATURE OF THE ACTION

1. This is a products liability action against Defendants J&J and Ethicon brought by Plaintiff Karen Hager for injuries related to Defendants' Prolene (Polypropylene) Hernia System

("**Prolene Hernia System**"), a prosthetic mesh device marketed as and indicated for permanent reinforcement of surgical hernia repair.

2. Defendants J&J and Ethicon designed, manufactured, marketed, supplied, warranted, promoted, and sold to health care professionals and others, the Prolene Hernia System, which was implanted in Plaintiff Karen Hager.

3. The Prolene Hernia System created an unreasonable risk of harm to Karen Hager.

4. When implanted, 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 due to a prolonged and pronounced inflammatory response caused by the multiple mesh layers, degradation of polymers, non-conforming subcomponents, or some other mechanism—renders Defendants' Prolene Hernia System a defective product, unsafe for its intended use.

5. The selection and implantation of the Prolene Hernia System in Karen Hager by her surgeon was a result of Defendants' negligent misinformation, marketing, sales, promotion and direction.

JURISDICTION & VENUE

6. This is a lawsuit over a defective hernia mesh device, which Defendant Ethicon, Inc. and its parent company Defendant Johnson & Johnson designed, marketed, manufactured, warranted, promoted and sold within the United States, including the State of New Jersey.

7. Both Defendants conduct business in every county in the State of New Jersey.

8. Karen Hager currently resides in Ashland, Illinois and is a citizen and resident of Illinois.

9. Plaintiff underwent hernia repair surgery on or about March 25, 2004 at Springfield Clinic Surgery Center in Springfield, Illinois. At that time, the Prolene Hernia System that Defendants designed, marketed, manufactured, promoted, distributed, and sold, and warranted as safe and effective for use, was implanted into Plaintiff Karen Hager. Her implanting surgeon conformed to the accepted standard of care for hernia repair surgery.

10. Defendant J&J is a corporation incorporated in New Jersey. According to its website, J&J is 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.

11. Defendant J&J organizes its subsidiary businesses into individual Business Units, which coordinate the development, manufacture, testing, marketing, promotion, training, distribution, and sale of J&J products, including its hernia repair mesh devices such as the Prolene Hernia System at issue here. The corporate structure of J&J contains three sectors: (1) medical devices and diagnostics; (2) pharmaceutical; and (3) consumer.

12. Within the medical devices and diagnostic sector are "Business Units" as well, 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 device implanted in Plaintiff Karen Hager.

13. Gary Pruden, the Company Group Chairman and Worldwide Franchise Chairman for the Ethicon Franchise, is a J&J employee. The companies comprising the Ethicon Franchise are thus controlled by Defendant Johnson & Johnson, and include Defendant Ethicon, Inc.

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

15. Defendant Ethicon is a medical device company involved in the research, development, testing, manufacture, production, marketing, promotion or sale of medical devices, including the Prolene Hernia System.

16. Either directly or through the actions of its subsidiary Ethicon, J&J has at all material times been responsible for the research, development, testing, manufacture, production, marketing, promotion, distribution or sale of the Prolene Hernia System.

17. Either directly, or through their agents, apparent agents, servants or employees, Defendants at all material times sold, distributed and marketed the defective hernia repair devices in the State of New Jersey. Defendants derive substantial revenue from those products used or implanted in the State of New Jersey. Therefore, Defendants expected, or should have expected, that their business activities could or would subject them to legal action in the State of New Jersey.

18. Defendants were also involved in the business of monitoring and reporting adverse events concerning the Prolene Hernia System and having a role in the decision process and response related to any adverse events.

19. The 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, Middlesex County.

b. Defendants designed, manufactured, and placed into the stream of commerce their medical devices, including the Prolene Hernia System.

c. Defendants maintain offices within the State of New Jersey.

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

20. Defendants designed, manufactured, fabricated, marketed, promoted, distributed, advertised, and sold the Prolene Hernia System throughout the United States and worldwide, including in Middlesex County, State of New Jersey.

21. At all material times, Defendants developed, manufactured, advertised, promoted, marketed, and distributed their defective Prolene Hernia System throughout the United States, including within the State of New Jersey; and, specifically to Plaintiff Karen Hager and her implanting surgeon or practice groups, or to hospitals where Defendants' product was implanted.

22. Since Defendants J&J and Ethicon are both New Jersey corporations maintaining their principal places of business in New Jersey, Plaintiff's claims and causes of action are solely state-law claims. Any reference to a federal agency, regulation or rule is stated as background information only, and does not raise a federal question. Accordingly, this Court may rightfully exercise jurisdiction, and venue is proper.

23. Defendant Ethicon knowingly markets to, and derives income from, patients across the United States, including the State of New Jersey, from the sale of the Prolene Hernia System.

24. 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

25. The Prolene Hernia System, which was defectively designed and manufactured, left Defendants' hands in its defective condition and was delivered into the stream of commerce. Michael Fenner implanted the Prolene Hernia System in Plaintiff Karen Hager's groin to repair a right inguinal hernia with an open surgery on or about March 25, 2004 at Springfield Clinic

Surgery Center in Springfield, Illinois. Karen Hager was implanted with a Prolene Hernia System, Cat# PHSL, Lot# JBF1128L. After the implantation of the Prolene Hernia System, Karen Hager experienced severe and chronic pain.

26. On or around January 25, 2017, Karen Hager underwent an open surgery to remove the Prolene Hernia System due to severe and chronic pain and inguinal nerve entrapment.

27. Karen Hager is at a higher risk of severe complications during any subsequent inguinal surgery to the extent that future inguinal operations might be medically necessary.

28. The mechanism of failure in Plaintiff's device was a mechanism of failure that Defendants had marketed and/or warranted would not occur because of the Prolene Hernia System's design and composition. The implanted device that Defendants marketed and warranted (*i.e.*, the Prolene Hernia System) would not have failed but for the defective design and composition thereof.

29. As a direct and proximate result of Defendants' defective design, manufacturing, marketing, distribution, sale and warnings concerning the Prolene Hernia System, Plaintiff Karen Hager has suffered and continues to suffer injuries and damages, including: past, present and future physical and mental pain and suffering; physical disabilities; and past, present, and future medical, hospital, rehabilitative, and pharmaceutical expenses; as well as other related damages.

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

31. Defendants warranted the Prolene Hernia System as safe and effective for use; and placed the device into the U.S. stream of commerce.

32. The Prolene Hernia System has a unique design, which incorporates two distinct layers of polypropylene connected by a central polypropylene tube. This design is not used in any other hernia repair product sold in the United States.

33. Although Defendants represented and warranted the bi-layered polypropylene design of the Prolene Hernia System to prevent or minimize hernia recurrence and chronic pain, the design did not do so. Instead, the Prolene Hernia System occupied two inguinal compartments instead of one, increasing the intense inflammatory and chronic foreign body response, which resulted 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.

34. When an implanted Prolene Hernia System fails, the complications are more difficult to treat. Further, its eventual explantation results in large amounts of tissue loss due to the Prolene Hernia System's occupying of two inguinal compartments.

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

36. In 2018, the HerniaSurge Group published *International Guidelines for Groin Hernia Management*. The Guidelines were endorsed by the European Hernia Society, Americas Hernia Society, Asia Pacific Hernia Society, Afro Middle East Hernia Society, Australasian Hernia Society, International Endo Hernia Society, and European Associated for Endoscopic Surgery and Other Interventional Techniques. The HerniaSurge Group's Guidelines note the following: "three dimensional implants (plug-and-patch and bilayer) are not recommended because of the excessive

use of foreign material, the need to enter both the anterior and posterior planes and the additional cost."

THE FDA'S 510(k) CLEARANCE PROCESS

37. 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.

38. No clinical testing is required under this process.

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

40. 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.

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

42. 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.**

43. 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."

44. The Prolene Hernia System did not undergo premarket approval, but instead received 510(k) clearance on or about September 20, 1997. The Prolene Hernia System was initially approved for the intended use of repairing "indirect and direct inguinal hernia defects." However, in the Instructions for Use for the Prolene Hernia System, Defendants market the Prolene Hernia System as "indicated for the repair of inguinal (direct & indirect) and abdominal wall hernia defects."

DEFENDANTS' FAILURE TO WARN OF THE DANGERS ASSOCIATED WITH PROLENE HERNIA SYSTEM

45. Before placing the Prolene Hernia System on the market, Defendants were required to adequately test their product and mitigate its risks, including any design element which could cause the following: render the device ineffective, weaken the structural integrity of the device, prevent safe treatment when complications arise, increase complications, or increase or prolong inflammation after implantation. Such complications can 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.

46. Defendants designed, manufactured, promoted, marketed and sold the Prolene Hernia System, despite their long-standing knowledge that the material and design would cause dense adhesions, chronic pain, mesh shrinkage, mesh deformation, foreign body sensation, organ

complications, and hernia recurrence. Further, Defendants knew that treating such complications when they inevitably arose would result in even greater complications and a larger defect.

47. Defendants marketed the Prolene Hernia System to health care professionals, hospitals, and group purchasing organizations (GPOs).

48. Defendants had the ability to inform the above purchasers of developing problems or defects related to those products through varied communications, such as e-mails, letters, recalls, warnings in product inserts, and/or through product representatives who communicate, interact and work with surgeons, but failed to do so.

49. The multiple layers of the Prolene Hernia System increase the intensity and duration of the inflammatory response in host tissue. That response in turn increases dense adhesion formation from underlying structures and organs to the product, resulting in mesh contracture, mesh deformation, chronic pain, foreign body sensation, organ and tissue damage, hernia recurrence, and other complications.

50. The Prolene Hernia System IFU has a section for adverse reactions, which list "Potential adverse reactions are those typically associated with surgically implantable materials…" The polypropylene of the Prolene Hernia System 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 Prolene Hernia System further increase the inflammatory response and rate of infection, adhesion formation, chronic pain, seroma formation, fistula formation, hematomas, mesh contracture, hernia recurrence, mesh migration, bowel complications, foreign body response, extrusion, and other additional injuries.

51. There is not a contraindication section in the Prolene Hernia System IFU.

52. Defendants never performed any clinical trials and/or studies before marketing the Prolene Hernia System.

53. Defendants did not fully or adequately test the Prolene Hernia System which was implanted in Plaintiff Karen Hager.

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

55. Despite these reassurances, the defective design and manufacture of the Prolene Hernia System continued to elicit post-implant severe and chronic inflammatory responses. Such responses resulted in mesh contracture, mesh deformation, chronic pain, foreign body sensation, adhesion, seroma and fistula formation, organ injuries, hernia recurrence, infections, erosion, extrusion, and additional complications.

56. From the time Defendants first began selling the Prolene Hernia System in the U.S. through the present, their product labeling and product data have failed to contain adequate information, instructions, and warnings concerning the following: implantation of the mesh, explantation of the mesh, propensity of the mesh 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, hematoma and fistula formation, erosion, extrusion, infection, and other injuries occurring at a higher rate than other surgically implanted devices.

CAUSES OF ACTION PURSUANT TO NEW JERSEY LAW

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

57. Plaintiff Karen Hager incorporates by reference the allegations in all prior paragraphs, and further alleges as follows:

58. Defendants had a duty to design and manufacture, distribute, market, promote and sell the Prolene Hernia System so that it was neither defective nor unreasonably dangerous when put to the use for which they were designed, manufactured, distributed, marketed and sold.

59. In 1999, Defendants were engaged in the business of designing, manufacturing, marketing, distributing and selling various types of hernia mesh implant devices, and did design, manufacture, distribute, market and sell the Prolene Hernia System as one of those devices.

60. Defendants expected the Prolene Hernia System, which they were manufacturing, selling, distributing, supplying, and/or promoting, to reach—and it did in fact reach—health care professionals and consumers in the State of New Jersey and the United States, including Plaintiff and her implanting surgeon, without substantial change in its condition.

61. When the Prolene Hernia System left Defendants' possession and entered the stream of commerce in the State of New Jersey, it was in an unreasonably dangerous or defective condition. These defects include the following:

- The Prolene Hernia System was not reasonably safe as intended to be used;
- The Prolene Hernia System had an inadequate design for the purpose of hernia repair;
- The Prolene Hernia System, which utilized dual layers, contained unreasonably dangerous design defects, increasing and prolonging the inflammatory response;

- The Prolene Hernia System was not appropriately or adequately tested before distribution; and

- The Prolene Hernia System 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.

AND

- The Prolene Hernia System contained unreasonably dangerous design defects. Those included two connecting disc layers of polypropylene intended to occupy two inguinal compartments once implanted. But 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; and

- The Prolene Hernia System is unreasonably dangerous, due to the heavyweight polypropylene in it, which increases the inflammatory and foreign body response; the small pore size utilized, which increases inflammatory and foreign body response; the shrinkage and stiffening of the mesh over time; and degradation after implant.

62. When Defendants initially designed, manufactured, marketed, and sold the Prolene Hernia System, feasible, alternative safer designs were known and available, including a flat, single-layer, lightweight, large-pore mesh, or a fully resorbable mesh.

63. After Defendants' initial design and manufacture, marketing and sale of the Prolene Hernia System —but before Plaintiff Karen Hager underwent hernia surgery—Defendants had the ability to eliminate the unsafe character of the product without impairing its usefulness, but they did not.

64. Had Defendants properly and adequately tested the Prolene Hernia System, they would have discovered the following: multiple mesh layers increase and prolong the inflammatory response; the mesh experiences significant contraction and deformation over time; the mesh cannot

be safely removed; and these defects result in chronic and debilitating pain, foreign body sensation, a pronounced foreign body response, seroma and fistula formation, infections, erosion, and extrusion, among other complications.

65. Defendants' Prolene Hernia System were therefore defective in design, in that when the products left Defendants, the foreseeable risk of harm from them exceeded or outweighed the benefit or utility a consumer would expect, and/or they failed to comply with federal requirements for these medical devices.

66. As a direct and proximate result of Defendants' wrongful conduct—including their defective and dangerous design and inadequate warnings of the Prolene Hernia System, Plaintiff Karen Hager has sustained, and will continue to sustain, severe and debilitating injuries, economic loss, and other damages, including cost of medical care, rehabilitation, lost income, permanent instability and loss of balance, immobility, and pain and suffering, for which she is entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

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

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

68. Plaintiff Karen Hager incorporates by reference the allegations in all prior paragraphs, and further alleges as follows:

69. Defendants researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and otherwise released into the stream of commerce the Prolene Hernia System; and directly advertised or marketed their products to the FDA, health care professionals, GPOs, and consumers, including Plaintiff Karen Hager and her surgeon. Therefore, Defendants had a duty to warn of the risks associated with the use of their products.

70. Defendants distributed and sold their Prolene Hernia System, in its original form of manufacture, which included the defects described in this Complaint.

71. The products were expected to, and did reach Plaintiff and her implanting surgeon, without substantial change in their condition as manufactured and sold by Defendants.

72. The products that Defendants designed, developed, tested, manufactured, distributed, promoted, marketed, and/or sold or otherwise placed into the stream of commerce, were in dangerous and defective conditions, and posed a threat to any user/consumer.

73. At all material times, Plaintiff Karen Hager was the person Defendants should have considered to be subject to the harm caused by the defective nature of their products.

74. The Prolene Hernia System was implanted in Plaintiff Karen Hager and used in a manner for which it was intended.

75. Its use has resulted in severe physical, financial, emotional and other injuries to Plaintiff.

76. Defendants failed to adequately warn health care professionals and the public, including Plaintiff and her implanting surgeon, of the true risks of those products. The Prolene Hernia System was ineffective in reducing chronic pain or hernia recurrence, and would contract and deform significantly upon implantation, resulting in debilitating pain, organ complications, hernia recurrence, reoperation, infections, fistula, seroma and hematoma formation, erosion, extrusion, subsequent operations, and more.

77. Defendants failed to timely and reasonably warn of material adverse facts regarding the safety and efficacy of their Prolene Hernia System. Had they done so, proper warnings would have been heeded, Plaintiff's surgeon would not have used the hernia repair product, and no consumer, including Plaintiff, would have purchased and/or consented to its use.

78. Defendants failed to timely and reasonably provide adequate instructions and training concerning safe and effective use of the Prolene Hernia System.

79. The Prolene Hernia System, which Defendants researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold and released into the stream of commerce, were defective due to inadequate post-marketing warnings and/or instruction. Defendants knew or should have known that there was reasonable evidence of an association between their mesh products—including the Prolene Hernia System—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 public, including Plaintiff Karen Hager, and continued to aggressively promote their products.

80. The Prolene Hernia System, which Defendants researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold and otherwise released into the stream of commerce, were defective also due to inadequate post-marketing warnings and/or instructions regarding their increased risk of failure, resulting in revision surgery—although Defendants knew of safer alternative designs, including but not limited to a flat, lightweight, large-pore, single-layer mesh, or a fully resorbable mesh.

81. Defendants failed to perform or otherwise facilitate adequate testing on the products in question; failed to reveal and/or concealed their testing and research data; and selectively and misleadingly revealed and/or analyzed such testing and research data.

82. Plaintiff Karen Hager and her surgeon used the Prolene Hernia System for its intended purpose, *i.e.*, hernia repair.

83. Neither Plaintiff nor her surgeon could have discovered any defect in Defendants' product through the exercise of due care.

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

85. Neither Plaintiff nor her implanting surgeon had substantially the same knowledge about Defendants' product as Defendants did.

86. Defendants reasonably should have known that the Prolene Hernia System was unsuited to repair a hernia in Plaintiff Karen Hager.

87. As a direct and proximate result of Defendants' failure to adequately communicate a warning and/or their 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 described in this Complaint.

88. 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*.

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

89. Plaintiff Karen Hager incorporates by reference the allegations in all prior paragraphs, and further alleges as follows:

90. Defendants designed, developed, manufactured, tested, packaged, advertised, promoted, marketed, distributed, labeled and sold the Prolene Hernia System in a condition which rendered the products unreasonably dangerous due to their propensity to result in early failure after implant. Thus, the products were unreasonably dangerous in construction or composition.

91. The products Defendants manufactured, including their Prolene Hernia System, were defective in construction or composition in that, when they left Defendants' possession, they deviated in a material way from their manufacturing performance standards and/or differed from otherwise identical products manufactured to the same design formula. Defendants knew or should

have known that their products could fail in patients, thereby giving rise to pain and suffering, debilitation and the need for revision surgery to replace the devices—here, the Prolene Hernia System—with the attendant risk of complications and death from such further surgery. Nonetheless, Defendants continued to market their products as safe and effective.

92. As a direct and proximate result of the use of the products Defendants manufactured, designed, sold, supplied and introduced into the stream of commerce, Plaintiff Karen Hager suffered harm, damages and economic loss as previously described, and will continue to suffer such harm, damages and economic loss in the future.

93. 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*.

ASSERTION OF CLAIMS PURSUANT TO THE LAWS OF ILLINOIS

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

95. Plaintiff Karen Hager was injured from being implanted with the Prolene Hernia System outside the State of New Jersey. To the extent the Court chooses to apply the law of a state other than New Jersey, Plaintiff places Defendants on notice of her intention to plead and assert all claims available under Illinois law, or any other state law applied by this Court.

COUNT IV: NEGLIGENCE-
PURSUANT TO COMMON LAW

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

97. 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 Prolene Hernia System, they failed to adequately do so.

98. Defendants knew, or in the exercise of reasonable care should have known, that their products were defectively and unreasonably designed or manufactured, and were unreasonably dangerous and likely to injure patients like Plaintiff Karen Hager in whom the Prolene Hernia System was implanted. Defendants also knew or should have known that Plaintiff and her surgeon were unaware of the dangers and defects inherent in their products.

99. 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 Prolene Hernia System implanted in Plaintiff Karen Hager, she suffered injuries and damages as described in this Complaint.

COUNT V: STRICT LIABILITY – DESIGN DEFECT – PURSUANT TO COMMON LAW

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

101. When the Prolene Hernia System was implanted in Plaintiff, it was defectively designed. As described above, there was an unreasonable risk that the product would not perform safely and effectively for the purposes for which it was intended. Further, Defendants failed to design against such dangers, and failed to provide adequate warnings and instructions concerning the risks.

102. Defendants expected and intended the Prolene Hernia System to reach users such as Plaintiff in the condition in which it was sold.

103. The implantation of the Prolene Hernia System in Plaintiff was medically reasonable, and it was a type of use that Defendants intended and foresaw when they designed, manufactured and sold the device.

104. The risks of the Prolene Hernia System significantly outweigh any benefits Defendants contend could be associated with its design.

105. When the Prolene Hernia System was implanted in Plaintiff, it contained unreasonably dangerous design defects. Specifically, the dual layers of the Prolene Hernia System increase and prolong the inflammatory response; the mesh experiences significant contraction over time; and complication rates are unacceptably high. These defects result in mesh contraction, mesh deformation, chronic and debilitating pain, foreign body sensation, organ obstructions, seroma and fistula formation, infections, erosion, extrusion, a pronounced foreign body response, and an inability to safely remove the product, among other complications.

106. After Defendants' initial design and manufacture and marketing and sale of Prolene Hernia System —but before Plaintiff's surgery with the product—Defendants had the ability to eliminate the unsafe character of the products without impairing their usefulness, but they did not do so.

107. When the Prolene Hernia System was implanted in Plaintiff Karen Hager, Defendants' warnings and instructions for their product were inadequate and defective. As described above, there was an unreasonable risk that the product would not perform safely and effectively for the purposes for which it was intended. Defendants failed to design and manufacture against such dangers; and failed to provide adequate warnings and instructions concerning the risks.

108. When Defendants' Prolene Hernia System was implanted in Plaintiff, there were safer feasible alternative designs for hernia mesh products that would have prevented the injuries she suffered.

109. The hernia repair device implanted in Plaintiff failed to reasonably perform as intended and had to be surgically removed, necessitating further invasive surgery to repair the very issue the product was intended to repair. Thus, it provided no benefit to her.

110. As a direct and proximate result of the defective and unreasonably dangerous condition of Defendants' hernia mesh repair products, Plaintiff suffered injuries and damages as summarized in this Complaint.

COUNT VI: STRICT LIABILITY – FAILURE TO WARN – PURSUANT TO COMMON LAW

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

112. When the Prolene Hernia System was implanted in Plaintiff Karen Hager, Defendants' warnings and instructions were inadequate and defective. As described above, there was an unreasonable risk that the device would not perform safely and effectively for the purposes for which it was intended. Defendants failed to design or manufacture against such dangers, and failed to provide adequate warnings and instructions concerning the risks of the Prolene Hernia System.

113. Defendants expected and intended their products to reach users such as Plaintiff in the condition in which they were sold.

114. Plaintiff and her surgeon were unaware of the Prolene Hernia System's defects and dangers, and were unaware of the frequency, severity, and duration of the defects and risks associated with it.

115. Defendants failed to adequately warn health care professionals and the public, including Plaintiff and her implanting surgeon, of the true risks of the product. They did not warn that the Prolene Hernia System would contract significantly upon implantation, resulting in chronic

and debilitating pain, foreign body sensation, organ complications, hernia recurrence, reoperation, infections, fistula, seroma and hematoma formation, erosion, extrusion, subsequent operations, and more.

116. Defendants failed to timely and reasonably provide adequate instructions and training concerning the safe and effective use of their Prolene Hernia System.

117. Defendants failed to perform or otherwise facilitate adequate testing of the product; failed to reveal and/or concealed their testing and research data; and selectively and misleadingly revealed and/or analyzed such testing and research data.

118. The Prolene Hernia System —which Defendants researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and released into the stream of commerce—was defective due to inadequate post-marketing warnings and/or instruction. Defendants knew or should have known that there was reasonable evidence of an association between their devices 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 their hernia repair devices and the mesh they contained, including the Prolene Hernia System.

119. With respect to the complications listed in their warnings, Defendants provided inadequate information or warning regarding the frequency, severity and duration of those complications, although the associated complications were more frequent and severe, and lasted longer than those with safer feasible alternative hernia repair treatments.

120. If Plaintiff Karen Hager or her surgeon had been properly warned of the defects and dangers of the Prolene Hernia System, and of the frequency, severity and duration of the

associated risks, she would not have consented to allow it to be implanted in her body, and her surgeon would not have implanted the product.

121. As a direct and proximate result of the inadequate and defective warnings and instructions, Plaintiff suffered injuries and damages as described in this Complaint.

COUNT VII: STRICT LIABILITY – MANUFACTURING DEFECT – PURSUANT TO COMMON LAW

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

123. The Prolene Hernia System contained a manufacturing defect when it left Defendants' possession. The product differs from its intended result and/or from other ostensibly identical units of the same product line.

124. The manufacturing defects in Defendants' Prolene Hernia System were a producing cause of Plaintiff's injuries and damages, as described in this Complaint.

COUNT VIII: BREACH OF IMPLIED WARRANTY

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

126. Defendants designed, manufactured, produced, tested, studied, inspected, labeled, marketed, advertised, sold, promoted and distributed their Prolene Hernia System for use by Plaintiff Karen Hager and others. When they did so, Defendants knew of its intended use, and impliedly warranted it to be of merchantable quality, and safe and fit for its intended use.

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

128. In consenting to have the Prolene Hernia System implanted, Plaintiff, individually and/or by and through her surgeon, relied upon Defendants' implied warranties of merchantability.

129. But contrary to Defendants' implied warranties, the Prolene Hernia System was not of merchantable quality, and was not safe and/or was not fit for its intended use. Rather, it 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.

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

COUNT IX: BREACH OF EXPRESS WARRANTY

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

132. At all material times, Defendants manufactured, distributed, advertised, promoted, and sold the Prolene Hernia System.

133. At all material times, Defendants intended that the Prolene Hernia System be used in the manner Plaintiff used it. Further, they expressly warranted in their brochures and advertising that their 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.

134. At all material times, Defendants were aware that consumers, including Plaintiff Karen Hager, would use their Prolene Hernia System. Therefore, Plaintiff was a foreseeable user of Defendants' product.

135. Plaintiff and her implanting surgeon were at all material times in privity with Defendants.

136. Defendants' Prolene Hernia System was expected to reach, and did in fact reach consumers, including Plaintiff and her implanting surgeon, without substantial change in the condition in which Defendants manufactured and sold it.

137. Defendants breached various express warranties with respect to Prolene Hernia System, including the following:

- Defendants represented to Plaintiff and her surgeon or other health care providers, through their labeling, advertising marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions, that Prolene Hernia System was safe; but they fraudulently withheld and concealed information about substantial risks or serious injury and/or death associated with the use of the product or the hernia repair devices made from it;

- Defendants represented to Plaintiff and her surgeon or other health care providers that Prolene Hernia System was as safe and/or safer than other alternative procedures and devices; and they fraudulently concealed information demonstrating that the product was not safer than alternatives available on the market; and

- Defendants represented to Plaintiff and her surgeon or other health care providers that Prolene Hernia System was more efficacious than other alternatives; but they fraudulently concealed information regarding its lack of efficacy.

138. In reliance upon Defendants' express warranties, Plaintiff was implanted with the Prolene Hernia System as prescribed and directed; and therefore, in the foreseeable manner for which Defendants normally intended, recommended, promoted, and marketed it.

139. When they made such express warranties, Defendants knew or should have known that the Prolene Hernia System did not conform to their express representations because it was not safe and had numerous serious side effects. Defendants did not accurately warn about many of those side effects, thus making the product unreasonably unsafe for its intended purpose.

140. Members of the medical community, including physicians and other health care professionals, as well as Plaintiff and the public, relied upon Defendants' representations and warranties in connection with the use, recommendation, description, and/or dispensing of their Prolene Hernia System.

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

142. 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.

COUNT X: PUNITIVE DAMAGES

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

144. 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 their Prolene Hernia System; and by failing to provide adequate instructions and training concerning the use of their products. Defendants downplayed, understated, and/or disregarded their knowledge of the serious and permanent side effects and associated risks, despite available information demonstrating the following: the Prolene Hernia System 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, seroma and fistula formation,

infections, pain, and other harm to patients. Such risks and adverse effects could have been avoided had Defendants not concealed their knowledge of the serious and permanent side effects and risks associated with the use of Prolene Hernia System; or provided proper training and instruction to health care professionals regarding their use. Defendants' misrepresentations included knowingly withholding material information from the FDA, the medical community and the public, including Plaintiff, concerning the safety of their products.

145. Defendants were, or should have been, in possession of evidence demonstrating that the Prolene Hernia System caused serious side effects. Nevertheless, they continued to market the products by providing false and misleading information with regard to their safety and efficacy.

146. Defendants failed to provide warnings that would have dissuaded health care professionals from using their Prolene Hernia System devices, thus preventing health care professionals and consumers, including Plaintiff Karen Hager, from weighing the true risks against the benefits of using the products.

147. Defendants failed to provide adequate training, testing and instructions to health care professionals, which could have prevented the failure of hernia repair devices made with Prolene Hernia System, thus preventing serious harm and suffering to patients, including Plaintiff.

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

PRAYER FOR RELIEF

WHEREFORE, Plaintiff Karen Hager 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. costs of this action;

f. treble or punitive damages to Plaintiff; and

g. any and all such other and further legal and equitable relief as the Court deems necessary, just and proper.

DEMAND FOR TRIAL BY JURY

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

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

I hereby certify that there are related civil proceedings: Cottle v. Ethicon, Inc., et al, Docket No.: MID-L-6828-18; Bassett v. Ethicon, Inc., et al, Docket No.: MID-L-6788-18; Gold v. Ethicon, Inc., et al, Docket No.: MID-L-6852-18; Noakes v. Ethicon, Inc., et al, Docket No.: MID-L-6951-18; Fowler v. Ethicon, Inc., et al, Docket No.: MID-L-6845-18; Griffin v. Ethicon, Inc., et al, Docket No.: MID-L-6878-18; Linnenbrink v. Ethicon, Inc., et al, Docket No.: MID-L-6916-18; Campbell v. Ethicon, Inc., et al, Docket No.: MID-L-6812-18; Trebolo, Jr. v. Ethicon, Inc. et al, Docket No.: MID-L-7000-18; Gateley v. Ethicon, Inc., et al, Docket No.: MID-L-6849-18; Redding v. Ethicon, Inc., et al, Docket No.: MID-L-6957-18; Rice v. Ethicon, Inc., et al, Docket No.: MID-L-6960-18; Bean v. Ethicon, Inc., et al, Docket No.: MID-L-6789-18; Alumbaugh v. Ethicon, Inc., et al, Docket No.: MID-L-6782-18; Reynolds v. Ethicon, Inc., et al, Docket No.: MID-L-6959-18; Smith v. Ethicon, Inc., et al, Docket No.: MID-L-6990-18; Gaddis v. Ethicon, Inc., et al, Docket No.: MID-L-6846-18; Aaron v. Ethicon, Inc., et al, Docket No.: MID-L-6761-18; Diloreto v. Ethicon, Inc., et al, Docket No.: MID-L-6832-18; Pikulsky, et al v. Ethicon, Inc., et al, Docket No.: MID-L-6956-18; Lang v. Ethicon, Inc., et al, Docket No.: MID-L-6910-18; Gibson v. Ethicon, Inc., et al, Docket No.: MID-L-6850-18; Shackelford v. Ethicon, Inc., et al,

Docket No.: MID-L-6966-18; Lindsey v. Ethicon, Inc., et al, Docket No.: MID-L-6914-18; Mack, et al v. Ethicon, Inc., et al, Docket No.: MID-L-6932-18; Schriner v. Ethicon, Inc., et al, Docket No.: MID-L-6962-18; Alexander v. Ethicon, Inc., et al, Docket No.: MID-L-6780-18; Usey v. Ethicon, Inc., et al, Docket No.: MID-L-7002-18; Hart v. Ethicon, Inc., et al, Docket No.: MID-L-6880-18; Galvez v. Ethicon, Inc., et al, Docket No.: MID-L-6847-18; Lindly v. Ethicon, Inc., et al, Docket No.: MID-L-6913-18; Senkel v. Ethicon, Inc., et al, Docket No.: MID-L-6965-18; Maestas v. Ethicon, Inc., et al, Docket No.: MID-L-6934-18; Szaroleta v. Ethicon, Inc., et al, Docket No.: MID-L-6997-18; Krampen-Yerry v. Ethicon, Inc., et al, Docket No.: MID-L-6909-18; Lotridge v. Ethicon, Inc., et al, Docket No.: MID-L-6925-18; Dias v. Ethicon, Inc., et al, Docket No.: MID-L-6831-18; Alvarado, et al v. Ethicon, Inc., et al, Docket No.: MID-L-6783-18; Mountjoy, et al v. Ethicon, Inc., et al, Docket No.: MID-L-6946-18; Fontenot v. Ethicon, Inc., et al, Docket No.: MID-L-6844-18; Anawaty v. Ethicon, Inc., et al, Docket No.: MID-L-6784-18; Capshaw v. Ethicon, Inc., et al, Docket No.: MID-L-6814-18; Briscoe v. Ethicon, Inc., et al, Docket No.: MID-L-6806-18; Smith v. Ethicon, Inc., et al, Docket No.: MID-L-6991-18; Bradford v. Ethicon, Inc., et al, Docket No.: MID-L-6804-18; Johnson v. Ethicon, Inc., et al, Docket No.: MID-L-6890-18; Collier v. Ethicon, Inc., et al, Docket No.: MID-L-6826-18; Williams v. Ethicon, Inc., et al, Docket No.: MID-L-7006-18; Miller v. Ethicon, Inc., et al, Docket No.: MID-L-6940-18; Ward v. Ethicon, Inc., et al, Docket No.: MID-L-7004-18; Shepherd v. Ethicon, Inc., et al, Docket No.: MID-L-6967-18; Scobee v. Ethicon, Inc., et al, Docket No.: MID-L-6964-18; Snyder v. Ethicon, Inc., et al, Docket No.: MID-L-6993-18; Hodge v. Ethicon, Inc., et al, Docket No.: MID-L-6887-18; Trombley v. Ethicon, Inc., et al, Docket No.: MRS-L-750-18; Lloyd v. Ethicon, Inc., et al, Docket No.: MID-L-6917-18; Henley v. Ethicon, Inc., et al, Docket No.: MID-L-6883-18; Benton, et al v. Ethicon, Inc., et al, Docket No.: MID-L-6790-18; Jones v. Ethicon, Inc., et al,

Docket No.: MID-L-6906-18; Muniz v. Ethicon, Inc., et al, Docket No.: MID-L-6947-18; Deffenbaugh v. Ethicon, Inc., et al, Docket No.: MID-L-6830-18; Clulee v. Ethicon, Inc., et al, Docket No.: MID-L-6825-18; Johnson v. Ethicon, Inc., et al, Docket No.: MID-L-6889-18; Garrett v. Ethicon, Inc., et al, Docket No.: MID-L-6848-18; Hecker v. Ethicon, Inc., et al, Docket No.: MID-L-6881-18; Hendrix v. Ethicon, Inc., et al, Docket No.: MID-L-6882-18; Hinn v. Ethicon, Inc., et al, Docket No.: MID-L-6884-18; Holman, et al v. Ethicon, Inc., et al, Docket No.: MID-L-6888-18; Wolfe v. Ethicon, Inc., et al, Docket No.: MID-L-7008-18; Booth, et al v. Ethicon, Inc., et al, Docket No.: MID-L-6796-18; Jones v. Ethicon, Inc., et al, Docket No.: MID-L-6908-18; Brooks v. Ethicon, Inc., et al, Docket No.: MID-L-6808-18; Adams v. Ethicon, Inc., et al, Docket No.: MID-L-6779-18; Finotti v. Ethicon, Inc., et al, Docket No.: MID-L-6833-18; Mata v. Ethicon, Inc., et al, Docket No.: MID-L-6936-18; Darnell v. Ethicon, Inc., et al, Docket No.: MID-L-6829-18; Lynch v. Ethicon, Inc., et al, Docket No.: MID-L-6931-18; Parham v. Ethicon, Inc., et al, Docket No.: MID-L-6952-18; Tavian v. Ethicon, Inc., et al, Docket No.: MID-L-6998-18; Banks v. Ethicon, Inc., et al, Docket No.: MID-L-6787-18; Jones v. Ethicon, Inc., et al, Docket No.: MID-L-6892-18; Boston v. Ethicon, Inc., et al, Docket No.: MID-L-6799-18; Rivas v. Ethicon, Inc., et al, Docket No.: MID-L-6961-18; Perez v. Ethicon, Inc., et al, Docket No.: MID-L-6955-18; Austin v. Ethicon, Inc., et al, Docket No.: MID-L-6786-18; Rudenauer v. Ethicon, Inc., et al, Docket No.: MID-L-7050-18; Blackistone v. Ethicon, Inc., et al, Docket No.: MID-L-6794-18; Godfrey v. Ethicon, Inc., et al, Docket No.: MID-L-6851-18; McCutcheon v. Ethicon, Inc., et al, Docket No.: MID-L-6939-18; Soares v. Ethicon, Inc., et al, Docket No.: MID-L-6994-18; Woods v. Ethicon, Inc., et al, Docket No.: MID-L-7010-18; Perez v. Ethicon, Inc., et al, Docket No.: MID-L-6954-18; Chavira v. Ethicon, Inc., et al, Docket No.: MID-L-6822-18; Guidry v. Ethicon, Inc., et al, Docket No.: MID-L-6879-18; Newburn v. Ethicon, Inc., et al, Docket No.: MID-L-6949-18;

Cordova v. Ethicon, Inc., et al, Docket No.: MID-L-6827-18; Lecza v. Ethicon, Inc., et al, Docket No.: MID-L-6912-18; Taylor v. Ethicon, Inc., et al, Docket No.: MID-L-6999-18; Lowrey v. Ethicon, Inc., et al, Docket No.: MID-L-6930-18; Wilson, et al v. Ethicon, Inc., et al, Docket No.: MID-L-7007-18; Tyler v. Ethicon, Inc., et al, Docket No.: MID-L-7001-18; Whitfield, et al v. Ethicon, Inc., et al, Docket No.: MID-L-7005-18; Smith, et al v. Ethicon, Inc., et al, Docket No.: MID-L-6992-18; Moskowitz v. Ethicon, Inc., et al, Docket No.: MID-L-6945-18; Strauss v. Ethicon, Inc., et al, Docket No.: MID-L-7055-18; Masingo v. Ethicon, Inc., et al, Docket No.: MID-L-6935-18; Vinas v. Ethicon, Inc., et al, Docket No.: MID-L-7003-18; Morrone v. Ethicon, Inc., et al, Docket No.: MID-L-6942-18; Newman v. Ethicon, Inc., et al, Docket No.: MID-L-6950-18; Strawser v. Ethicon, Inc, et al, Docket No.: MID-L-6996-18; Johnson v. Ethicon, Inc., et al, Docket No.: MID-L-6891-18; Harding, et al v. Ethicon, Inc., et al, Docket No.: MID-L-7030-18; Brown, et al v. Ethicon, Inc., et al, Docket No.: MID-L-7017-18; Green v. Ethicon, Inc., et al, Docket No.: MID-L-6877-18; Bolyard v. Ethicon, Inc., et al, Docket No.: MID-L-6795-18; Bovino v. Ethicon, Inc., et al, Docket No.: MID-L-6800-18; Payne v. Ethicon, Inc., et al, Docket No.: MID-L-6953-18; Clements v. Ethicon, Inc., et al, Docket No.: MID-L-6824-18; Mosby v. Ethicon, Inc., et al, Docket No.: MID-L-6943-18; Mathews v. Ethicon, Inc., et al, Docket No.: MID-L-6937-18; Lowe v. Ethicon, Inc., et al, Docket No.: MID-L-6926-18; Gonzales v. Ethicon, Inc., et al, Docket No.: MID-L-6853-18; Abhold, et al v. Ethicon, Inc., et al, Docket No.: MID-L-6763-18; Warr v. Ethicon, Inc., et al, Docket No.: MID-L-7058-18; Ishii v. Ethicon, Inc., et al, Docket No.: MID-L-7034-18; Jacuzzi v. Ethicon, Inc., et al, Docket No.: MID-L-7035-18; McNally v. Ethicon, Inc., et al, Docket No.: MID-L-7040-18; McCutcheon v. Ethicon, Inc., et al, Docket No.: MID-L-7039-18; Newland v. Ethicon, Inc., et al, Docket No.: MID-L-7043-18; Johnson v. Ethicon, Inc., et al, Docket No.: MID-L-7036-18; Vaughan v. Ethicon, Inc., et al, Docket No.:

MID-L-7057-18; Shaw v. Ethicon, Inc., et al, Docket No.: MID-L-7051-18; Asturi v. Ethicon, Inc., et al, Docket No.: MID-L-7013-18; Brawley v. Ethicon, Inc., et al, Docket No.: MID-L-7016-18; Guy, et al v. Ethicon, Inc., et al, Docket No.: MID-L-7028-18; Mahne, et al v. Ethicon, Inc., et al, Docket No.: MID-L-7038-18; Pierce, et al v. Ethicon, Inc., et al, Docket No.: MID-L-7049-18; Classen, et al v. Ethicon, Inc., et al, Docket No.: MID-L-7019-18; Murphy v. Ethicon, Inc., et al, Docket No.: MID-L-7042-18; Thibodaux, et al v. Ethicon, Inc., et al, Docket No.: MID-L-7056-18; Nomikos v. Ethicon, Inc., et al, Docket No.: MID-L-7044-18; Nuri, et al v. Ethicon, Inc., et al, Docket No.: MID-L-7045-18; Corgan v. Ethicon, Inc., et al, Docket No.: MID-L-7020-18; Falcon v. Ethicon, Inc., et al, Docket No.: MID-L-7023-18; Frank v. Ethicon, Inc., et al, Docket No.: MID-L-7024-18; Moore v. Ethicon, Inc., et al, Docket No.: MID-L-7041-18; Hall v. Ethicon, Inc., et al, Docket No.: MID-L-7029-18; Lyon v. Ethicon, Inc., et al, Docket No.: MID-L-7037-18; Holland v. Ethicon, Inc., et al; Docket No.: MID-L-7032-18; Palka v. Ethicon, Inc., et al, Docket No.: MID-L-7047-18; Austin v. Ethicon, Inc., et al, Docket No.: MID-L-7014-18; Wetch v. Ethicon, Inc., et al, Docket No.: MID-L-7060-18; Waterfield, et al v. Ethicon, Inc., et al, Docket No.: MID-L-7059-18; Dill, et al v. Ethicon, Inc., et al; Docket No.: MID-L-7022-18; Blocker v. Ethicon, Inc., et al, Docket No.: MID-L-7015-18; Delph, et al v. Ethicon, Inc., et al, Docket No.: MID-L-7021-18; Rigney, et al v. Ethicon, Inc., et al, Docket No.: MID-L-7724-18; Henry v. Ethicon, Inc., et al, Docket No.: MID-L-7031-18; Skiba v. Ethicon, Inc., et al, Docket No.: MID-L-7052-18; Snyder v. Ethicon, Inc., et al, Docket No.: MID-L-7053-18; Alguacil v. Ethicon, Inc., et al, Docket No.: MID-L-7011-18; Perez v. Ethicon, Inc., et al, Docket No.: MID-L-7048-18; Hughey v. Ethicon, Inc., et al, Docket No.: MID-L-7033-18; White v. Ethicon, Inc., et al, Docket No.: MID-L-7061-18; Burns, et al v. Ethicon, Inc., et al, Docket No.: MID-L-7018-18; Spears v. Ethicon, Inc., et al, Docket No.: MID-L-7054-18; Hanson v. Ethicon, Inc., et al, Docket No.: MID-L-5813-18; Pepper,

et al v. Ethicon, Inc., et al, Docket No.: MID-L-7723-18; Varner v. Ethicon, Inc., et al, Docket No.: MID-L-5814-18; Reed v. Ethicon, Inc., et al, Docket No.: MID-L-6318-18; Matz v. Ethicon, Inc., et al, Docket No.: MID-L-6331-18; Vernick v. Ethicon, Inc., et al, Docket No.: MID-L-6368-18; Phillips v. Ethicon, Inc., et al, Docket No.: MID-L-6369-18; Eccles, et al v. Ethicon, Inc., et al, Docket No.: MID-L-6370-18; Williams v. Ethicon, Inc., et al, Docket No.: MID-L-6379-18; Favors, et al v. Ethicon, Inc., et al, Docket No.: MID-L-6386-18; Nelson, et al v. Ethicon, Inc., et al, Docket No.: MID-L-6420-18; Bennett v. Ethicon, Inc., et al, Docket No.: MID-L-6426-18; Greenklepper v. Ethicon, Inc., et al, Docket No.: MID-L-6687-18; Landers v. Ethicon, Inc., et al, Docket No.: MID-L-6760-18; Braden v. Ethicon, Inc., et al, Docket No.: MID-L-6805-18; Whipple v. Ethicon, Inc., et al, Docket No.: MID-L-7064-18; Blair v. Ethicon, Inc., et al, Docket No.: MID-L-7085-18; Carlson v. Ethicon, Inc., et al, Docket No.: MID-L-7086-18; Farmer v. Ethicon, Inc., et al, Docket No.: MID-L-7099-18; House v. Ethicon, Inc., et al, Docket No.: MID-L-7132-18; Lujan, et al v. Ethicon, Inc., et al, Docket No.: MID-L-7279-18; Gonzalez, et al v. Ethicon, Inc., et al, Docket No.: MID-L-7280-18; Piper v. Ethicon, Inc., et al, Docket No.: MID-L-7282-18; Oglesby v. Ethicon, Inc., et al, Docket No.: MID-L-7310-18; Kiger v. Ethicon, Inc., et al, Docket No.: MID-L-7325-18; Munoz v. Ethicon, Inc., et al, Docket No.: MID-L-7342-18; Coleman v. Ethicon, Inc., et al, Docket No.: MID-L-7400-18; Dorman v. Ethicon, Inc., et al, Docket No.: MID-L-7547-18; Mullins v. Ethicon, Inc., et al, Docket No.: MID-L-7548-18; Alcantara, et al v. Ethicon, Inc., et al, Docket No.: MID-L-7718-18; Davis, et al v. Ethicon, Inc., et al, Docket No.: MID-L-7719-18; Garner v. Ethicon, Inc., et al, Docket No.: MID-L-7720-18; Hickey, et al v. Ethicon, Inc., et al, Docket No.: MID-L-7721-18; Kinder, et al v. Ethicon, Inc., et al, Docket No.: MID-L-7722-18; Espino v. Ethicon, Inc., et al, Docket No.: MID-L-7957-18; Mangan v. Ethicon, Inc., et al, Docket No.: MID-L-7988-18; Cranwell v. Ethicon, Inc., et al,

Docket No.: MID-L-7989-18; Ransford v. Ethicon, Inc., et al, Docket No.: MID-L-7990-18; Cashe v. Ethicon, Inc., et al, Docket No.: MID-L-7992-18; Bailey, et al v. Ethicon, Inc., et al, Docket No.: MID-L-7993-18; Martinez v. Ethicon, Inc., et al, Docket No.: MID-L-8025-18; Grayson v. Ethicon, Inc., et al, Docket No.: MID-L-8101-18; Smith v. Ethicon, Inc., et al, Docket No.: MID-L-8102-18; Harris, et al v. Ethicon, Inc., et al, Docket No.: MID-L-8197-18; Holleran v. Ethicon, Inc., et al, Docket No.: MID-L-8198-18; Hooper, et al v. Ethicon, Inc., et al, Docket No.: MID-L-8199-18; Vautaw v. Ethicon, Inc., et al, Docket No.: MID-L-8313-18; Wilhelm v. Ethicon, Inc., et al, Docket No.: MID-L-8494-18; Akers v. Ethicon, Inc., et al, Docket No.: MID-L-8495-18; Wilson v. Ethicon, Inc., et al, Docket No.: MID-L-8497-18; Miller v. Ethicon, Inc., et al, Docket No.: MID-L-8498-18; Snader v. Ethicon, Inc., et al, Docket No.: MID-L-8526-18; Hausman v. Ethicon, Inc., et al, Docket No.: MID-L-8527-18; Fraser v. Ethicon, Inc., et al, Docket No.: MID-L-8642-18; Crockett v. Ethicon, Inc., et al, Docket No.: MID-L-8699-18; Williams v. Ethicon, Inc., et al, Docket No.: MID-L-8704-18; Galvez v. Ethicon, Inc., et al, Docket No.: MID-L-136-19; Lawen v. Ethicon, Inc., et al, Docket No.: MID-L-307-19; Blankenship v. Ethicon, Inc., et al, Docket No.: MID-L-329-19; McWilliams v. Ethicon, Inc., et al, Docket No.: MID-L-330-19; Kunes v. Ethicon, Inc., et al, Docket No.: MID-L-439-19; Simcox v. Ethicon, Inc., et al, Docket No.: MID-L-441-19; Kidwell v. Ethicon, Inc., et al, Docket No.: MID-L-743-19; and Skinner v. Ethicon, Inc., et al, Docket No.: MID-L-744-19. Beyond the Cottle, Bassett, Gold, Noakes, Fowler, Griffin, Linnenbrink, Campbell, Trebolo, Gateley, Redding, Rice, Bean, Alumbaugh, Reynolds, Gaddis, Aaron, Diloreto, Pikulsky, Lang, Gibson, Shackelford, Lindsey, Mack, Schriner, Alexander, Usey, Hart, Galvez, Lindly, Senkel, Maestas, Szaroleta, Krampen-Yerry, Lotridge, Dias, Alvarado, Mountjoy, Fontenot, Anawaty, Capshaw, Briscoe, Smith, Bradford, Johnson, Collier, Williams, Miller, Ward, Shepherd, Scobee, Snyder, Hodge, Trombley, Lloyd,

Henley, Benton, Jones, Muniz, Deffenbaugh, Clulee, Johnson, Garrett, Hecker, Hendrix, Hinn, Holman, Wolfe, Booth, Jones, Brooks, Adams, Finotti, Mata, Darnell, Lynch, Parham, Tavian, Banks, Jones, Boston, Rivas, Perez, Austin, Rudenauer, Blackistone, Godfrey, McCutcheon, Soares, Woods, Perez, Chavira, Guidry, Newburn, Cordova, Lecza, Taylor, Lowrey, Wilson, Tyler, Whitfield, Smith, Moskowitz, Strauss, Masingo, Vinas, Morrone, Newman, Strawser, Johnson, Harding, Brown, Green, Bolyard, Bovino, Payne, Clements, Mosby, Mathews, Lowe, Gonzales, Abhold, Warr, Ishii, Jacuzzi, McNally, McCutcheon, Newland, Johnson, Vaughan, Shaw, Asturi, Brawley, Guy, Mahne, Pierce, Classen, Murphy, Thibodaux, Nomikos, Corgan, Falcon, Frank, Moore, Hall, Lyon, Holland, Palka, Austin, Wetch, Waterfield, Dill, Blocker, Delph, Rigney, Henry, Skiba, Snyder, Alguacil, Perez, Hughey, White, Burns, Spears, Hanson, Pepper, Varner, Reed, Matz, Vernick, Phillips, Eccles, Williams, Favors, Nelson, Bennett, Greenklepper, Landers, Braden, Whipple, Blair, Carlson, Farmer, House, Lujan, Gonzalez, Piper, Oglesby, Kiger, Munoz, Coleman, Dorman, Mullins, Alcantara, Garner, Hickey, Kinder, Espino, Mangan, Cranwell, Ransford, Cashe, Bailey, Martinez, Grayson, Smith, Harris, Holleran, Hooper, Vautaw, Wilhelm, Akers, Wilson, Miller, Snader, Hausman, Fraser, Crockett, Williams, Galvez, Lawen, Blankenship, McWilliams, Kunes, Simcox, Kidwell, and Skinner cases, I am not aware of any other civil proceedings either pending or contemplated with respect to the matter in controversy herein, and that there are no other parties who shall be joined in this action at this time.

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

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

TRIAL COUNSEL DESIGNATION

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

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

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

Dated: January 24, 2019

Civil Case Information Statement

Case Details: MIDDLESEX | Civil Part Docket# L-000810-19

Case Caption: HAGER KAREN VS ETHICON, INC.
Case Initiation Date: 01/24/2019
Attorney Name: JOSHUA S KINCANNON
Firm Name: LOMURRO MUNSON COMER BROWN & SCHOTTLAND LLC
Address: 4 PARAGON WAY SUITE 100
FREEHOLD TWP NJ 07728
Phone:
Name of Party: PLAINTIFF : Hager, Karen
Name of Defendant's Primary Insurance Company (if known): Unknown

Case Type: PRODUCT LIABILITY
Document Type: Complaint with Jury Demand
Jury Demand: YES - 12 JURORS
Hurricane Sandy related? NO
Is this a professional malpractice case? NO
Related cases pending: YES
If yes, list docket numbers: Per Ravi at eCourts Help, please refer to the Notice of Other Actions paragraph for related actions
Do you anticipate adding any parties (arising out of same transaction or occurrence)? NO

THE INFORMATION PROVIDED ON THIS FORM CANNOT BE INTRODUCED INTO EVIDENCE

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

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

If yes, is that relationship:

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

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

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

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

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

01/24/2019
Dated

/s/ JOSHUA S KINCANNON
Signed