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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

RICHARD POTTER **Plaintiff,** **v.** **C.R. BARD and DAVOL, INC.,** **Defendants.**	)	**Civil Action No.:** **COMPLAINT** **JURY TRIAL DEMANDED**

Plaintiff RICHARD POTTER (hereinafter "Plaintiff"), by and through his undersigned counsel, brings this Complaint for damages against Defendants C.R. Bard and Davol Inc., and in support thereof states the following:

1. This is a device tort action brought on behalf of the above-named Plaintiff arising out of the failure of the Defendants' hernia mesh product. As a result, Plaintiff RICHARD POTTER suffered permanent injuries and significant pain and suffering, emotional distress, lost wages and earning capacity, and diminished quality of life. Plaintiff respectfully seeks all damages to which he may be legally entitled.

STATEMENT OF PARTIES

2. Plaintiff is, and was, at all relevant times, a citizen and resident of Florida and Tennessee and the United States.

3. C.R. Bard, Inc. ("Bard") is incorporated and based in New Jersey. Bard is a multinational marketer, promoter, seller, producer, manufacturer, and developer of medical devices. Bard controls the largest market share of the hernia mesh market. Bard is the parent company of Davol.

4. Bard controls the largest market share of the hernia mesh market. Bard is the parent company of Davol. Bard controls the largest market share of the hernia mesh market. Bard is the corporate parent/stockholder of Davol and participates in the manufacture and distribution of ePTFE Bard Mesh. It also manufactures and supplies Davol with material that forms part of the ePTFE Bard Mesh.

5. Davol, Inc. ("Davol") is incorporated in Delaware and has its principal place of business in Rhode Island. Davol is a medical device company involved in the research, development, testing, manufacture, production, marketing, promotion and/or sale of medical devices including hernia meshes composed of polypropylene, and polyglycolic acid (PGA) fibers coated with Sepra Technology, a bioresorbable, chemically modified sodium

hyalurnate, carboxymethylcellulose, and polyethylene glycol based hydrogel (hereinafter "ST Bard Mesh" or "product").

6. Davol is a medical device company involved in the research, development, testing, manufacture, production, marketing, promotion and/or sale of medical devices including a hernia mesh patch composed of an absorbable polydioxanone (PDO) recoil ring concealed between two layers of polypropylene mesh, and an expanded polytetrafluoroethylene (ePTFE) sheet, which attached to one side the polypropylene mesh (hereinafter "ePTFE Bard Mesh" or "product").

7. Bard was, at all times relevant hereto, responsible for the actions of Davol and exercised control over Davol's functions specific to the oversight and compliance with applicable safety standards relating to and including ePTFE Bard Mesh sold in the United States. In such capacity, they committed or allowed to be committed tortious and wrongful acts, including the violation of numerous safety standards relating to device manufacturing, quality assurance/control, and conformance with design and manufacturing specifications. Their misfeasance and malfeasance caused Plaintiff to suffer injury and damages.

8. Defendants are individually, jointly and severally liable to Plaintiff for damages suffered by Plaintiff arising from the Defendants' design, manufacture, marketing, labeling, distribution, sale and placement of its defective ST Bard Mesh at issue in the instant suit, effectuated directly and indirectly through their respective agents, servants, employees and/or owners, all acting within the course and scope of their representative agencies, services, employments and/or ownership.

9. Defendants are individually, jointly and severally liable to Plaintiff for damages suffered by Plaintiff arising from the Defendants' design, manufacture, marketing, labeling, distribution, sale and placement of its defective ePTFE Bard Mesh at issue in the instant suit,

effectuated directly and indirectly through their respective agents, servants, employees and/or owners, all acting within the course and scope of their representative agencies, services, employments and/or ownership.

10. Defendants are vicariously liable for the acts and/or omissions of their employees and/or agents who were at all times relevant hereto acting on behalf of Defendants and within the scope of their employment or agency with Defendants.

VENUE AND JURISDICTION

11. This Court has subject-matter jurisdiction over this action pursuant to 28 U.S.C. § 1332(a) based on complete diversity of citizenship between Plaintiff and all Defendants. The amount in controversy exceeds $75,000.00.

12. Venue is proper in this Court pursuant to 28 U.S.C. § 1332(a)-(c) by virtue of the fact that (a) a substantial part of the events or omissions giving rise to Plaintiff's claims occurred in this District and (b) Defendants' products are sold to and consumed by individuals in the State of New Jersey, thereby subjecting Defendants to personal jurisdiction in this action and making them all "residents" of this judicial District.

13. Defendants have and continue to conduct substantial business in the State of New Jersey and in this District, distribute ST Bard Mesh and ePTFE Bard Mesh in this District, receive substantial compensation and profits from sales of ST Bard Mesh and ePTFE Bard Mesh in this District, and made material omissions and misrepresentations and breaches of warranties in this District, so as to subject them to *in personam* jurisdiction in this District.

14. Defendants conducted business in the State of New Jersey through sales representatives conducting business in the State of New Jersey and because Defendants were engaged in testing, developing, manufacturing, labeling, marketing, distributing, promoting and/or

selling, either directly or indirectly, and/or through third parties or related entities, ST Bard Mesh and ePTFE Bard Mesh in New Jersey.

15. Consistent with the Due Process Clause of the Fifth and Fourteenth Amendments, this Court has *in personam* jurisdiction over Defendants, because Defendants are present in the State of New Jersey, such that requiring an appearance does not offend traditional notices of fair and substantial justice.

FACTS COMMON TO ALL COUNTS

16. On or about December 7, 2009, Plaintiff RICHARD POTTER underwent repair of multiple abdominal wall incarcerated hernias by Dr. Roshan Singh, MD at Lawnwood Regional Medical Center & Heart Institute, Fort Pierce, Florida. A Ventrio Mesh patch 13.8 cm x 17.8 cm, Cat No. 0010212, Lot No. DATB0001 was implanted in Plaintiff RICHARD POTTER during this repair (hereinafter "Ventrio" or "ePTFE Bard Mesh").

17. Defendants, manufactured, sold, and/or distributed the ePTFE Bard Mesh to Plaintiff, through Plaintiff's doctors, to be used for treatment of hernia repair.

18. On or about August 25, 2017, Plaintiff RICHARD POTTER underwent surgery by Dr. Thomas S. Layman, MD to surgically fix a recurrent ventral incisional hernia with incarcerated omentum due to recurring pain where the Ventrio mesh was fixated. During this procedure, Dr. Layman implanted a Ventralex ST Hernia Patch (Medium Circle with Strap, 2.5" diameter), Cat No. 5950008, Lot No. HUAZ0317 in Plaintiff.

19. Defendants, manufactured, sold, and/or distributed the ST Bard Mesh to Plaintiff, through his doctors, to be used for treatment of hernia repair.

20. On or about February 22, 2018, Plaintiff RICHARD POTTER underwent an open repair of a recurrent incarcerated ventral hernia with mesh, removal of old mesh from previous

surgeries, and lysis of extensive intra-abdominal adhesions between the bowel and mesh by Dr. Ramon Villanueva, MD at Sweetwater Hospital Association, Sweetwater, Tennessee. Upon entering the Plaintiff's abdomen, Dr. Villanueva made the following findings: "He was taken to the operating room and unfortunately found to have a conglomeration of mesh and adhesions and bowel wall mangled together under the incision. The procedure was very difficult to do. It was basically separating bowel from mesh without causing major injuries. "

21. Plaintiff RICHARD POTTER continues to experience complications and chronic pain related to the ePTFE Bard Mesh and ST Bard Mesh and will likely require additional surgeries to repair the damage from the ePTFE Bard Mesh and ST BARD Mesh.

22. Bard was, at all times relevant hereto, responsible for the actions of Davol and exercised control over Davol's functions specific to the oversight and compliance with applicable safety standards relating to and including ST Bard Mesh sold in the United States. In such capacity, they committed or allowed to be committed tortious and wrongful acts, including the violation of numerous safety standards relating to device manufacturing, quality assurance/control, and conformance with design and manufacturing specifications. Their misfeasance and malfeasance caused Plaintiff to suffer injury and damages.

23. Defendants were responsible for the research, design, development, testing, manufacture, production, marketing, promotion, distribution and sale of ST Bard Mesh and ePTFE Bard Mesh, including providing the warnings and instructions concerning the ST Bard Mesh and ePTFE Bard Mesh.

24. Among the intended purposes for which Defendants designed, manufactured and sold ePTFE Bard Mesh was use by surgeons for hernia repair surgeries, the purpose for which the ePTFE Bard Mesh was implanted in Plaintiff.

25. The ePTFE Bard Mesh is composed of the following layers:

a. ePTFE sheet
b. Polypropylene mesh
c. PDO absorbable recoil ring
d. Polypropylene mesh

26. The polypropylene side of the ePTFE Bard Mesh was intended to promote incorporation (scarring into the abdominal wall), while the ePTFE side was intended to prevent adhesion formation from the polypropylene being exposed to underlying organs. However, the utilization of ePTFE results in the product being highly prone to infection, while the utilization of polypropylene results in the product being extremely difficult to remove once the ePTFE Bard Mesh becomes infected.

27. For decades, there were concerns in the medical community about severe complications if a foreign object, such as a mesh, was placed too close to the bowel or other underlying organs, due to inflammation in the presence of sensitive organs and the formation of dense adhesions to the device.

28. Among the intended purposes for which Defendants designed, manufactured and sold ST Bard Mesh was use by surgeons for hernia repair surgeries, the purpose for which the ST Bard Mesh was implanted in Plaintiff RICHARD POTTER.

29. Defendants represented to Plaintiff RICHARD POTTER and his physicians that ST Bard Mesh and ePTFE Bard Mesh were safe and effective products for hernia repair.

THE FDA'S 510(k) CLEARANCE PROCESS

30. The 510(k) clearance process refers to Section 510(k) of the Medical Device Amendments of 1976 MDA of the Federal Food, Drug and Cosmetic Act. Under this process, device manufacturers are only required to notify the FDA at least 90 days before they market a

device claimed to be "substantially equivalent" to a device the FDA had approved for sale before 1976, when the MDA was enacted.

31. No clinical testing is required under this process.

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

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

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

35. 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.**

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

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

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

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

ESTOPPEL AND TOLLING OF STATUTE OF LIMITATIONS

39. Defendants are estopped from relying on any statues of limitations or repose by virtue of their acts of fraudulent concealment, which include the Defendants' intentional concealment from Plaintiff and the general public that the ST Bard Mesh and ePTFE Bard Mesh are defective, while continually marketing the ST Bard Mesh and ePTFE Bard Mesh with the effects described herein.

40. Given the Defendants' affirmative actions of concealment by failing to disclose this known but non-public information about the defects – information over which the Defendants had exclusive control – and because Plaintiff could not reasonably have known the ST Hernia Mesh and ePTFE Bard Mesh were defective, Defendants are estopped from relying on any statutes of limitations that might overwise be applicable to the claims asserted herein.

CAUSES OF ACTION RELATED TO THE VENTRIO MESH PRODUCT

COUNT I: STRICT LIABILITY – MANUFACTURING DEFECT

41. Plaintiff incorporates herein by reference the allegations in all prior paragraphs as if fully set forth herein.

42. Defendants expected and intended the ePTFE Bard Mesh product to reach users such as Plaintiff in the condition in which the product was sold.

43. The implantation of ePTFE Bard Mesh in Plaintiff's body was medically reasonable, and was a type of use that Defendants intended and foresaw when it designed, manufactured and sold the product.

44. At the time the ePTFE Bard Mesh that was implanted in Plaintiff's body, the product was defectively manufactured.

45. Defendants' poor quality control and general non-compliance resulted in the non-conformance of the ePTFE Bard Mesh implanted in Plaintiff. The ePTFE Bard Mesh implanted in Plaintiff did not conform to the Defendants' intended manufacturing and design specifications.

46. Upon information and belief, Defendants utilized substandard and adulterated polypropylene and raw materials used to make the ePTFE Bard Meshes, which deviated from Defendants' material and supply specifications.

47. As a direct and proximate result of the defective manufacture of the ePTFE Bard Mesh, Plaintiff suffered injuries and damages as summarized herein.

COUNT II: STRICT LIABILITY – DESIGN DEFECT

48. Plaintiff incorporates herein by reference the allegations in all prior paragraphs as if fully set forth herein.

49. Defendants' ePTFE Bard Mesh was defectively designed and/or manufactured, was not reasonably safe for its intended use in hernia repair, and the risks of the design outweighed any potential benefits associated with the design. As a result of the defective design and/or manufacture of the ePTFE Bard Mesh, there was an unreasonable risk of severe adverse reactions to the mesh or mesh components including: chronic infections; chronic pain; recurrence of hernia; foreign body response; rejection; infection; scarification; improper wound healing; excessive and chronic inflammation; allergic reaction; adhesions to internal organs; erosion; abscess; fistula formation; granulomatous response; seroma formation; nerve damage; tumor formation, cancer, tissue damage and/or death; and other complications.

50. When affixed to the body's tissue, the impermeable ePTFE layer prevents fluid escape, which leads to seroma formation, and which in turn can cause infection or abscess formation and other complications.

51. The smooth surface of the ePTFE Bard Mesh provides an ideal bacteria breeding ground in which the bacteria cannot be eliminated by the body's immune response, which allows bacteria to lie dormant and infection to eventually proliferate.

52. The ePTFE Bard Mesh is defective in its design in part because of a material mismatch. ePTFE shrinks at a significantly faster rate than polypropylene. This material mismatch results in the ePTFE Bard Mesh curling after implantation.

53. ePTFE contracts due to the body's inflammatory and foreign body response. Polypropylene incites a greater inflammatory and foreign body response than ePTFE alone. Defendants' ePTFE and polypropylene combination design results in the ePTFE layer shrinking faster than ePTFE not in the presence of polypropylene would.

54. Defendants utilize Ethylene Oxide ("ETO") in an attempt to sterilize the ePTFE Bard Mesh ETO is an effective disinfectant; however, dry spores are highly resistant to ETO. Moisture must be present to eliminate spores using ETO. Presoaking the product to be sterilized is most desirable, but high levels of humidity during the ETO process can also be effective in eliminating spores. ePTFE Bard Mesh implanted with spores will eventually result in an infection. The spores can remain dormant for extended periods of time, resulting in infections months or years after implantation with the ePTFE Bard Mesh. The following non-exhaustive literature discusses the necessity of moisture during ETO sterilization:

> a. In January of 1989, a review on sterilization methods of medical devices was published in the Journal of Biomaterials Applications. ETO was among the sterilization methods reviewed. **ETO was noted to be highly resistant to dry spores, moisture must be present; presoaking most desirable. Experiments demonstrated the importance of the state of humidification of organisms at the time of their exposure to ETO. Desiccation of the spores prior to ETO exposure produces a small but significant percentage of organisms which are highly resistant to the sterilization process. Similar resistance to destruction by ETO occurs in desiccated staphylococcus aureus. Rehumidification of such organisms can require prolonged exposure to an atmosphere having a 50 to 90 percent relative humidity. Moisture has been found to be a critical factor in achieving sterility with gaseous ETO. No gas sterilizer can effectively kill desiccated spores.**
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> Dempsey, D.J. and Thirucote, R.R., *Sterilization of medical devices: A Review*. Journal of Biomaterials Applications, 3(3), pp. 454-523 (1988). DOI: 10.1177/088532828800300303

55. The multi-layer design of the ePTFE Bard Mesh results in ineffective sterilization more often.

56. The Defendants' ePTFE Bard Mesh is cytotoxic, immunogenic, and not biocompatible, which causes or contributes to complications such as delayed wound healing, inflammation, foreign body response, rejection, infection, and other complications.

57. The solid, flat, relatively smooth and continuous surface of the ePTFE Bard Mesh inhibits the body's ability to clear toxins.

58. These manufacturing and design defects associated with the ePTFE Bard Mesh were directly and proximately related to the injuries suffered by Plaintiff.

59. Neither Plaintiff nor Plaintiff's implanting physician were adequately warned or informed by Defendants of the defective and dangerous nature of ePTFE Bard Mesh. Moreover, neither Plaintiff nor Plaintiff's implanting physician were adequately warned or informed by Defendants of the risks associated with the ePTFE Bard Mesh.

60. The ePTFE Bard Mesh implanted in Plaintiff failed to reasonably perform as intended. The ePTFE Bard Mesh caused serious injury and had to be surgically removed via invasive surgery, and necessitated additional invasive surgery to repair the hernia that the ePTFE Bard Mesh was initially implanted to treat.

61. At the time the ePTFE Bard Mesh that was implanted in Plaintiff's body, the product was defectively designed. As described above, there was an unreasonable risk that the ePTFE Bard Mesh would not perform safely and effectively for the purposes for which it was intended, and Defendants failed to design against such dangers, and failed to provide adequate warnings and instructions concerning these risks.

62. Defendants expected and intended the ePTFE Bard Mesh product to reach users such as Plaintiff in the condition in which the product was sold.

63. The implantation of ePTFE Bard Mesh in Plaintiff's body was medically reasonable, and was a type of use that Defendants intended and foresaw when it designed, manufactured and sold the product.

64. The risks of the ePTFE Bard Mesh significantly outweigh any benefits that Defendants contend could be associated with the product. The ePTFE Bard Mesh incites an intense inflammatory response, leading to encapsulation, deformation, scarification and contraction, migration, erosion and rejection. The impermeable ePTFE layer leads to seroma formation, and provides a breeding ground for infection, and protects bacteria from being eliminated by the body's natural immune response.

65. The polypropylene mesh patch was in itself dangerous and defective, particularly when used in the manner intended by Defendants in the ePTFE Bard Mesh. The particular polypropylene material used in the ePTFE Bard Mesh was substandard, adulterated and non-medical grade, and was unreasonably subject to oxidative degradation within the body, further exacerbating the adverse reactions caused by the product. As the ePTFE layer quickly contracts, the ePTFE Bard Mesh curls, exposing the underlying polypropylene. When implanted adjacent to the bowel and other internal organs, as Defendants intended for ePTFE Bard Mesh, polypropylene mesh is unreasonably susceptible to adhesion, bowel perforation or erosion, fistula formation and bowel strangulation or hernia incarceration, and other injuries.

66. Bacterial adherence is increased due to the interstitial porosity, surface tension, and electronegativity of ePTFE.

67. ePTFE undergoes irreversible structural changes in the presence of microorganisms. The structural changes that ePTFE undergoes provides protection to the microorganisms, allowing them to flourish and necessitating the total removal of ePTFE Bard Mesh.

68. The appropriate treatment for complications associated with ePTFE Bard Mesh involves additional invasive surgery in an attempt to remove the mesh from the body, thus eliminating any purported benefit that the mesh was intended to provide to the patient.

69. The ePTFE Bard Mesh was designed and intended for intraperitoneal implantation, which required the product to be placed in contact with internal organs, which unnecessarily increased the risks of adhesion, erosion, fistula formation, and other injuries.

70. At the time the ePTFE Bard Mesh was implanted in Plaintiff, there were safer feasible alternative designs for hernia mesh products, including but not limited to, a flat, non-coated, light-weight, large-pore, single-layer mesh placed away from the bowel.

71. The ePTFE Bard Mesh product cost significantly more than competitive products because of its unique design, even though the ePTFE Bard Mesh provided no benefit to consumers over other mesh types, and increased the risks to patients implanted with these devices.

72. The ePTFE Bard Mesh has a solid, flat, relatively smooth and continuous surface. Medical devices which utilize this design greatly increase the risk of tumor and cancer formation via the "Oppenheimer Effect":

> a. In 1958, a study supported by a research grant from the National Cancer Institute titled The Latent Period in Carcinogenesis by Plastics in Rats and its Relation to the Presarcomatous Stage was published in the Journal of Cancer. **The presence of polymer in a sheet form appears to be of primary importance, as shown by the manifold increase in the percentage of tumors induced by this form, as opposed to textiles, sponges, powders, etc. This may act in some way as a block to the free interchange of tissue constituents, subjecting some cells to an altered environment and changing their pattern of growth. Whether the primary cause is lack of nutrients or oxygen, or the accumulation of products of metabolism, or even a freeing of the cell from some hormonal control, is not a present clear, but undoubtedly the cell is placed under conditions that are favorable to autonomous, unregulated growth. Plastics embedded subcutaneously in rodents in film or sheet form induce malignant tumors in significant numbers (up to 50%), but**

> **embedded in other forms, such as textiles, sponges, or powders, they induce tumors only rarely.**
>
> Oppenheimer, B.S. et al, *The Latent Period in Carcinogenesis by Plastics in Rats and its Relations to the Presearcomatous Stage*. Journal of Cancer 1(11). 204 – 213 (1958).
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> b. In 1999, the World Health Organization's International Agency for Research on Cancer published *Surgical implants and Other Foreign Bodies*, which evaluated the carcinogenic risks of various surgical implants in humans. **Polymeric implants prepared as thin smooth films are possibly carcinogenic to humans.**
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> *Surgical Implants and Other Foreign Bodies*. IARC Monogr Eval Carcinog Risks Hum 74:1-409 (1999).

73. Plaintiff was implanted with a Ventrio mesh patch, which also includes an inner ring of PDO, to aid in the short-term memory and stability of the device. The inner PDO ring is called SorbaFlex Memory Technology.

74. The PDO ring breaks down via hydrolysis over a period of at least 6 to 8 months once implanted. The PDO ring elicits an intense inflammatory response during absorption.

75. The Ventrio mesh patch is vulnerable to buckling, folding, and/or migrating once the PDO ring has absorbed.

76. The numerous layers utilized to create the ePTFE Bard Mesh increases the intensity and duration of inflammation and foreign body response.

77. The ePTFE Bard Mesh implanted in Plaintiff failed to reasonably perform as intended, and had to be surgically removed necessitating further invasive surgery to repair the very issue that the product was intended to repair, and thus provided no benefit to him.

78. As a direct and proximate result of the defective and unreasonably dangerous condition of the product, Plaintiff suffered injuries and damages as summarized herein.

COUNT III: STRICT LIABILITY – FAILURE TO WARN

79. Plaintiff incorporates herein by reference the allegations in all prior paragraphs as if fully set forth herein.

80. At the time the ePTFE Bard Mesh that was implanted in Plaintiff's body, the warnings and instructions provided by Defendant for the ePTFE Bard Mesh were inadequate and defective. As described above, there was an unreasonable risk that the product would not perform safely and effectively for the purposes for which it was intended, and Defendants failed to design and/or manufacture against such dangers, and failed to provide adequate warnings and instructions concerning these risks.

81. Defendants expected and intended the ePTFE Bard Mesh product to reach users such as Plaintiff in the condition in which the product was sold.

82. Plaintiff and Plaintiff's physicians were unaware of the defects and dangers of ePTFE Bard Mesh, and were unaware of the frequency, severity and duration of the risks associated with the ePTFE Bard Mesh.

83. The Defendants' Instructions for Use provided with the EPTFE Bard Mesh expressly understates and misstates the risks known to be associated specifically with the EPTFE Bard Mesh by representing that the complications such as inflammation associated with the EPTFE Bard Mesh as "possible complications." The EPTFE Bard Mesh will always incite severe inflammation once implanted. The inflammation caused by the EPTFE Bard Mesh is chronic in nature and systemic, not acute localized inflammation. Defendants provided no warning to physicians about the risks or increased risks specifically associated with the unique design of the ePTFE Bard Mesh.

84. The Defendants' Instructions for Use for the ePTFE Bard Mesh failed to adequately warn Plaintiff's physicians of numerous risks which Defendants knew or should have known were associated with the ePTFE Bard Mesh, including the risks of the product's immunologic response, infection, pain, dehiscence, encapsulation, rejection, migration, scarification, contraction, erosion through adjacent tissue and viscera, bowel obstruction, and tumor or cancer formation.

85. The Defendants' Instructions for Use for the ePTFE Bard Mesh failed to instruct physicians how much larger than the hernia defect the ePTFE Bard Mesh needed to be for an effective repair.

86. The Defendants' Instructions for Use for the ePTFE Bard Mesh failed to disclose the extent the ePTFE Bard Mesh would shrink, or that it would even shrink at all.

87. Defendants failed to adequately train or warn Plaintiff or Plaintiff's physicians about the necessity for invasive surgical intervention in the event of complications, or how to properly treat such complications when they occurred.

88. Defendants failed to adequately warn Plaintiff or Plaintiff's physicians that the surgical removal of the ePTFE Bard Mesh in the event of complications would leave the hernia unrepaired, the resulting hernia would be much larger than the original, and would necessitate further, more complicated medical treatment to attempt to repair the same hernia that the failed ePTFE Bard Mesh was intended to treat.

89. Defendants failed to adequately warn Plaintiff or Plaintiff's physicians that in the event of complications, the ePTFE Bard Mesh is more difficult to fully remove than other feasible hernia meshes that at all relevant times have been available.

90. Defendants failed to warn Plaintiff or Plaintiff's physicians that as a result of being implanted with the ePTFE Bard Mesh, Plaintiff would be at a higher risk of infection for the remainder of Plaintiff's life.

91. With respect to the complications that were listed in the Defendants' warnings, Defendants provided no information or warning regarding the frequency, severity and duration of those complications, even though the complications associated with ePTFE Bard Mesh were more frequent, more severe and lasted longer than those with safer feasible alternative hernia repair treatments.

92. If Plaintiff and/or Plaintiff's physicians had been properly warned of the defects and dangers of ePTFE Bard Mesh, and of the frequency, severity and duration of the risks associated with the ePTFE Bard Mesh, Plaintiff would not have consented to allow the ePTFE Bard Mesh to be implanted, and Plaintiff's physicians would not have implanted the ePTFE Bard Mesh in Plaintiff.

93. As a direct and proximate result of the inadequate and defective warnings and instructions, Plaintiff suffered injuries and damages as summarized herein.

COUNT IV: NEGLIGENCE

94. Plaintiff incorporates herein by reference the allegations in all prior paragraphs as if fully set forth herein.

95. Defendants had a duty to use reasonable care in designing, testing, inspecting, manufacturing, packaging, labeling, marketing, distributing, and preparing written instructions and warnings for ePTFE Bard Mesh, but failed to do so.

96. Defendants knew, or in the exercise of reasonable care should have known, that ePTFE Bard Mesh was defectively and unreasonably designed and/or manufactured, and was

unreasonably dangerous and likely to injure patients in whom ePTFE Bard Mesh was implanted. Defendants knew or should have known that Plaintiff and Plaintiff's physicians were unaware of the dangers and defects inherent in the ePTFE Bard Mesh.

97. Defendants knew or should have known that the MSDS for the polypropylene used to manufacturer its ePTFE Bard Mesh prohibited permanently implanting the polypropylene into the human body.

98. Defendants utilized non-medical grade polypropylene.

99. Defendants knew or should have known that polypropylene is not inert and would degrade, flake, chip, and disperse throughout the body once implanted.

100. Defendants knew or should have known that polypropylene incites a severe inflammatory response once implanted and continues to incite a severe inflammatory response indefinitely or until removed.

101. Defendants knew or should have known that every piece of polypropylene that flakes off and migrates throughout the body also incites its own chronic inflammatory response wherever it embeds.

102. Defendants knew or should have known that ePTFE is associated with high rates of severe, chronic infections.

103. Defendants knew or should have known that ePTFE degrades in the presence of bacteria.

104. Defendants knew or should have known that once ePTFE is infected, it is nearly impossible to permanently rid the infection and salvage the mesh.

105. Defendants knew or should have known that ePTFE is not inert and would degrade, flake, chip, and disperse throughout the body once implanted.

106. Defendants knew or should have known that implanting a solid, flat, relatively smooth and continuous disc shaped object would increase the rate of tumor formation and other adverse events.

107. Defendants knew or should have known that all subsequent operations carry a greater risk of infection after the patient has been implanted with ePTFE.

108. As a direct and proximate result of Defendants' negligence in designing, testing, inspecting, manufacturing, packaging, labeling, marketing, distributing, and preparing written instructions and warnings for ePTFE Bard Mesh, Plaintiff suffered injuries and damages as summarized herein.

COUNT V: BREACH OF EXPRESS WARRANTY

109. Plaintiff incorporates herein by reference the allegations in all prior paragraphs as if fully set forth herein.

110. At all relevant and material times, Defendants manufactured, marketed, sold, distributed and otherwise placed in to the stream of commerce ePTFE Bard Mesh.

111. In advertising, marketing and otherwise promoting ePTFE Bard Mesh to physicians, hospitals and other healthcare providers, Defendants expressly warranted that their ePTFE Bard Mesh was safe for use and reasonably fit for their intended purposes. In advertising, marketing and otherwise promoting ePTFE Bard Mesh, Defendants' intended that physicians, hospitals and other healthcare providers rely upon their representations regarding safety and fitness in an effort to induce them to implant ePTFE Bard Mesh in their patients.

112. With respect to the Plaintiff, Defendants intended that ePTFE Bard Mesh be implanted by Plaintiff's treating surgeon in a reasonable and foreseeable manner in which it was

implanted and in accordance with the instructions for use and product specifications provided by Defendants. The Plaintiff was in privity with Defendants.

113. Defendants expressly warranted to physicians, hospitals, other healthcare providers and the general public including Plaintiffs that ePTFE Bard Mesh was safe and fit for use by consumers, that it was of merchantable quality, that its risks, side effects and potential complications were minimal and comparable to other hernia mesh products, that it was adequately researched and tested, and that it was fit for its intended use. Plaintiff and Plaintiff's physicians and healthcare providers reasonably relied upon Defendants' express representations and warranties, and consequently, Plaintiff was implanted with Defendants' ePTFE Bard Mesh.

114. The ePTFE Bard Mesh was manufactured from polypropylene, ePTFE, and PDO. The ePTFE was represented by the Defendants to decrease complications, but it did not. Instead, the ePTFE harbors and protects bacteria, resulting in a severe, chronic infection, that can take years to manifest.

115. Defendant breached these express warranties because the ePTFE Bard Mesh implanted in Plaintiff was unreasonably dangerous, defective, and not as Defendants had represented.

116. Defendants breached express representations and warranties made to the Plaintiff, as well as Plaintiff's physicians and healthcare providers, with respect to the ePTFE Bard Mesh, including, but not limited to, the following particulars:

a. Defendants represented to Plaintiff and Plaintiff's physicians and healthcare providers through labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions among other ways that the Defendants' ePTFE Bard Mesh was safe, meanwhile Defendants fraudulently withheld and concealed information about the substantial risks of serious injury associated with using ePTFE Bard Mesh.

b. Defendants represented to Plaintiff and Plaintiff's physicians and healthcare providers that the Defendants' ePTFE Bard Mesh was as safe and/or safer than other alternative procedures and devices on the market, meanwhile Defendants fraudulently concealed information that demonstrated that ePTFE Bard Mesh was not safer than alternative therapies and products available on the market; and

c. Defendants represented to Plaintiff and Plaintiff's physicians and healthcare providers that the Defendants' ePTFE Bard Mesh was more efficacious than other alternative procedures, therapies and/or devices, meanwhile Defendants fraudulently concealed information, regarding the true efficacy of ePTFE Bard Mesh.

117. Defendants' breach of their express warranties resulted in the implantation of an unreasonably dangerous and defective product into the Plaintiff, placing Plaintiff's health and safety in jeopardy.

118. At the time of making such express warranties, Defendants knew or should have known that Defendants' ePTFE Bard Mesh does not conform to the express warranties and Defendants' acts were motivated by financial gain while the adverse consequences of Defendants' conduct was outrageous, fraudulent, oppressive, done with malice or gross negligence and evidenced reckless indifference to Plaintiff's rights, health and safety so as to warrant the imposition of punitive damages.

COUNT VI: BREACH OF IMPLIED WARRANTY

119. Plaintiff incorporates herein by reference the allegations in all prior paragraphs as if fully set forth herein.

120. At all relevant and material times, Defendants manufactured, marketed, sold, distributed and otherwise placed in to the stream of commerce ePTFE Bard Mesh.

121. At all material times, Defendants intended that the product be implanted for the purposes and in the manner that Plaintiff and/or his implanting physicians in fact used them; and

Defendants impliedly warranted each ePTFE Bard Mesh and its component parts to be of merchantable quality, safe and fir for such use, and adequately tested.

122. Defendants were aware that consumers, including Plaintiff or Plaintiff's physicians, would implant their ePTFE Bard Mesh in the manner directed by the instructions for use. Thus, Plaintiff was a foreseeable user of the product.

123. Plaintiff and/or Plaintiff's physicians were at all material times in privity with Defendants.

124. The ePTFE Bard Mesh was expected to reach, and did in fact reach consumers, including Plaintiff or Plaintiff's physicians, without substantial change in the condition in which Defendants manufactured and sold it.

125. Defendants breached various implied warranties made to the Plaintiff, as well as Plaintiff's physicians and healthcare providers, with respect to the ePTFE Bard Mesh, including, but not limited to, the following particulars:

a. Defendants represented through labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that the ePTFE Bard Mesh was safe; but fraudulently withheld and concealed information about the substantial risks of serious injury associated with using the product;

b. Defendants represented that the ePTFE Bard Mesh was safe, and/or safer than other alternative procedures and devices; but fraudulently concealed information demonstrating that the product was no safer than alternatives available on the market; and

c. Defendants represented that the ePTFE Bard Mesh was more efficacious than other alternative procedures and/or devices; but fraudulently concealed information regarding the true efficacy of the ePTFE Bard Mesh.

126. In reliance upon Defendants' implied warranties, Plaintiff individually and/or by and through his physician, used the ePTFE Bard Mesh as prescribed and in the foreseeable manner normally intended, recommended, promoted, and marketed by Defendants.

127. Defendants breached their implied warranty to Plaintiff in that the ePTFE Bard Mesh was not of merchantable quality, safe and fit for its intended use, or adequately tested.

128. As a direct and proximate result of Defendants' breaches of implied warranties, Plaintiff was caused to suffer, and did suffer, severe personal injuries, pain and suffering, severe emotional distress, financial or economic loss, including obligations for medical services and expenses, impairment of personal relationships, and other damages.

COUNT VII: VIOLATION OF CONSUMER PROTECTION LAWS

129. Plaintiff incorporates herein by reference the allegations in all prior paragraphs as if fully set forth herein.

130. Plaintiff purchased and used the Defendants' ePTFE Bard Mesh primarily for personal use and thereby suffered ascertainable losses as a result of Defendants' actions in violation of the consumer protection laws.

131. Had Defendants not engaged in the deceptive conduct described herein, Plaintiff would not have purchased and/or paid for the Defendants' ePTFE Bard Mesh, and would not have incurred related medical cost and injury.

132. Defendants engaged in wrongful conduct while at the same time obtaining, under false pretenses, moneys from Plaintiff for the ePTFE Bard Mesh that would not have been paid had Defendants not engaged in unfair and deceptive conduct.

133. Unfair methods of competition or deceptive acts or practices that were proscribed by law, including the following:

a. representing that goods or services have characteristics, ingredients, uses, benefits or qualities that they do not have;
b. advertising goods or services with the intent not to sell them as advertised; and
c. engaging in fraudulent or deceptive conduct that creates a likelihood of confusion or misunderstanding.

134. Plaintiff was injured by the cumulative and indivisible nature of Defendants' conduct. The cumulative effect of Defendants' conduct directed at patients, physicians and consumers was to create demand for and sell the Defendants' ePTFE Bard Mesh. Each aspect of Defendants' conduct combined to artificially create sales of the Defendants' ePTFE Bard Mesh.

135. Defendants have a statutory duty to refrain from unfair or deceptive acts or trade practices in the design, labeling, development, manufacture, promotion, and sale of the Defendants' ePTFE Bard Meshes.

136. Had Defendants not engaged in the deceptive conduct described above, Plaintiff would not have purchases and/or paid for the ePTFE Bard Mesh, and would not have incurred related medical costs.

137. Defendants' deceptive, unconscionable, or fraudulent representations and material omissions to patients, physicians and consumers, including Plaintiff, constituted unfair and deceptive acts and trade practices in violation of the state consumer protection statutes listed.

138. Defendants' actions, as complained of herein, constitute unfair competition or unfair, unconscionable, deceptive or fraudulent acts, or trade practices in violation of state consumer protection statues, as listed below.

139. Defendants have engaged in unfair competition or unfair or deceptive acts or trade practices or have made false representations.

a. 15 U.S.C. §§ 2301-2312 (1982)
b. R.I. Gen. Laws §§ 6-13.1, et. seq.

c. N.J. Stat. Ann §§ 56:8-1, et seq.
d. §§ 501.201-501.213, Fla. Stat.
e. Tenn. Code Ann. §§ 47-18-101 et seq.

140. Under the statutes listed above to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising, Defendants are the suppliers, manufacturers, advertisers, and sellers, who are subject to liability under such legislation for unfair, deceptive, fraudulent and unconscionable consumer sales practices.

141. Defendants violated the statutes that were enacted in these states to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising, by knowingly and falsely representing that the Defendants' ePTFE Bard Mesh was fit to be used for the purpose for which it was intended, when in fact it was defective and dangerous, and by other acts alleged herein. These representations were made in marketing and promotional materials.

142. The actions and omissions of Defendants alleged herein are uncured or incurable deceptive acts under the statutes enacted in the states to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising.

143. Defendants had actual knowledge of the defective and dangerous condition of the Defendants' ePTFE Bard Mesh and failed to take any action to cure such defective and dangerous conditions.

144. Plaintiff and the medical community relied upon Defendants' misrepresentations and omissions in determining which product and/or procedure to undergo and/or perform (if any).

145. Defendants' deceptive, unconscionable or fraudulent representations and material omissions to patients, physicians and consumers, constituted unfair and deceptive acts and practices.

146. By reason of the unlawful acts engaged in by Defendants, and as a direct and proximate result thereof, Plaintiff has suffered ascertainable losses and damages.

147. As a direct and proximate result of Defendants' violations of the states; consumer protection laws, Plaintiff has sustained economic losses and other damages and is entitled to statutory and compensatory damages in an amount to be proven at trial.

COUNT VIII: GROSS NEGLIGENCE

148. Plaintiff incorporates herein by reference the allegations in all prior paragraphs as if fully set forth herein.

149. Defendants' acts or omissions were aggravated by the kind of malice, fraud, and grossly negligent disregard for the rights of others, the public, and Plaintiff for which the law would allow, and which Plaintiff will seek at the appropriate time under governing law for the imposition of exemplary damages, in that Defendants' conduct, including the failure to comply with applicable Federal standards: was specifically intended to cause substantial injury to Plaintiff; or when viewed objectively from Defendants' standpoint at the time of the conduct, involved an extreme degree of risk, considering the probability and magnitude of the potential harm to others, and Defendants were actually, subjectively aware of the risk involved, but nevertheless proceeded with conscious indifference to the rights, safety, or welfare of others; or included a material representation that was false, with Defendants, knowing that it was false or with reckless disregard as to its truth and as a positive assertion, with the intent that the representation is acted on by Plaintiff.

150. Plaintiff relied on the representation and suffered injury as a proximate result of this reliance.

151. Plaintiff therefore will seek to assert claims for exemplary damages at the appropriate time under governing law in an amount within the jurisdictional limits of the Court.

152. Plaintiff also alleges that the acts and omissions of named Defendants, whether taken singularly or in combination with others, constitute gross negligence that proximately caused the injuries to Plaintiff. In that regard, Plaintiff will seek exemplary damages in an amount that would punish Defendants for their conduct and which would deter other manufacturers from engaging in such misconduct in the future.

COUNT IX: NEGLIGENT INFLICTION OF EMOTIONAL DISTRESS

153. Plaintiff incorporates herein by reference the allegations in all prior paragraphs as if fully set forth herein.

154. Defendants carelessly and negligently manufactured, designed, developed, tested, labeled, marketed and sold the Defendants' ePTFE Bard Mesh to Plaintiff.

155. Defendants carelessly and negligently concealed the harmful effects of the Defendants' ePTFE Bard Mesh from Plaintiff individually and/or Plaintiff's physician on multiple occasions and continue to do so to this day.

156. Defendants carelessly and negligently misrepresented the quality, safety and efficacy of the ePTFE Bard Mesh to Plaintiff individually and/or Plaintiff's physician on multiple occasions and continue to do so to this day.

157. Plaintiff was directly impacted by Defendants' carelessness and negligence, in that Plaintiff has sustained and will continue to sustain emotional distress, severe physical injuries, economic losses, and other damages as a direct result of the decision to purchase the ePTFE Bard Mesh sold and distributed by Defendants.

158. Defendants continued to carelessly and negligently misrepresent the quality, safety, efficacy, dangers and contraindications of the ePTFE Bard Mesh to Plaintiff individually and/or Plaintiff's physician after Plaintiff sustained emotional distress, severe physical injuries, and economic loss.

159. Defendants continued to carelessly and negligently misrepresent the quality, safety, efficacy, dangers and contraindications of the ePTFE Bard Mesh to Plaintiff individually and/or Plaintiff's physician knowing that doing so would cause the Plaintiff to suffer additional and continued emotional distress, severe physical injuries, and economic loss.

160. As a proximate result of the Defendants' conduct, Plaintiff has been injured, sustained severe and permanent pain, suffering, anxiety, depression, disability, impairment, loss of enjoyment of life, loss of care, comfort, and economic damages.

COUNT X: FRAUDULENT CONCEALMENT

161. Plaintiff incorporates herein by reference the allegations in all prior paragraphs as if fully set forth herein.

162. At all times relevant hereto, it was known or knowable to Defendants that their Products caused large numbers of complications. Moreover, it was known or knowable to Defendants that the surgical technique and training of implanting physicians was not the cause of the adverse events associated with these devices. It was known or knowable to Defendants that the safety and efficacy of its Products had not been proven with respect to, among other things, the product, its components, its performance, and its method of insertion. It was known or knowable to Defendants that the Products were not safe and effective. Defendants continued to represent that its Products were safe and effective.

163. Despite what was known or knowable to Defendants about the lack of safety and efficacy of its Products, Defendants failed to disclose this information to the Plaintiff, to Plaintiff's physicians, and to the public at large.

164. At all times relevant hereto, Defendants had the duty and obligation to disclose to Plaintiff and Plaintiff's physicians the true facts concerning the Products, that is, that said Products were dangerous and defective, lacking efficacy for its purported use and lacking safety in normal use, and how likely it was to cause serious consequences to users, including permanent and debilitating injuries. Defendants concealed these material facts prior to the time that Plaintiff was implanted with Defendants' Products.

165. Defendants were under a duty to Plaintiff to disclose and warn of the defective nature of the ePTFE Bard Mesh because:

a. Defendants were in a superior position to know the true quality, safety, and efficacy of its Products;

b. Defendants knowingly made false claims about the safety and quality of its ePTFE Bard Mesh in documents and marketing materials; and

c. Defendants fraudulently and affirmatively concealed the defective nature of the ePTFE Bard Mesh from Plaintiff.

166. The facts concealed and/or not disclosed by Defendants to Plaintiff were material facts that a reasonable person would have considered to be important in deciding whether or not to purchase and/or use the Defendants' Products.

167. At all times relevant hereto, Defendants and each of them, willfully, intentionally, and maliciously concealed facts as set forth above from Plaintiff and his physicians with the intent to defraud, as alleged herein.

168. Defendants intentionally concealed and/or failed to disclose the true defective nature of ePTFE Bard Mesh so that Plaintiff would request and purchase the Defendants' ePTFE Bard Mesh, and Plaintiff's healthcare providers would dispense, prescribe, and recommend the Defendants' ePTFE Bard Mesh, and Plaintiff justifiably acted or relied upon the concealed and/or non-disclosed facts to his detriment.

169. At all times relevant hereto, neither Plaintiff nor his physicians were aware of the facts set forth above, and had they been aware of said facts, they would not have acted as they did, that is, would not reasonably relied upon said representations of safety and efficacy and utilized Defendants' Products in their treatment. Defendants' failure to disclose this information was a substantial factor in Plaintiff's physicians selecting Defendants' Products. The failure to disclose also resulted in the provision of incorrect and incomplete information to Plaintiff, as a patient.

170. As a direct and proximate result of Defendants' conduct, Plaintiff was injured.

COUNT XI: NEGLIGENT MISREPRESENTATION

171. Plaintiff incorporates herein by reference the allegations in all prior paragraphs as if fully set forth herein.

172. Defendants had a duty to accurately and truthfully represent to the medical and healthcare community, Plaintiff, and the public, that its ePTFE Bard Mesh had not been adequately tested and found to be a safe and effective treatment. The representations made by Defendants were, in fact, false.

173. Defendants failed to exercise ordinary care in the representations concerning the Products while they were involved in their manufacture, sale, testing, quality assurance, quality control, and distribution in interstate commerce, because Defendants negligently misrepresented the ePTFE Bard Mesh's high risk of unreasonable and dangerous adverse side effects.

174. Defendants breached their duty in representing that the Defendants' ePTFE Bard Mesh has no serious side effects different from older generations of similar products and/or procedures to Plaintiff, Plaintiff's physicians, and the medical community.

175. As a foreseeable, direct, and proximate result of the negligent misrepresentation of Defendants, as set forth herein, Defendants knew, and had reason to know, that the ePTFE Bard Mesh had been insufficiently tested, or had not been tested at all, and that they lacked adequate and accurate warnings, and that they created a high risk—and/or higher than acceptable risk, and/or higher than reported and represented risk—of adverse side effects, including, but not limited to, pain, graft rejection, graft migration, organ damage, complex seroma, fistula, sinus tract formation, delayed wound closure, infection, sepsis, and death.

176. As a direct and proximate result of the Defendants' conduct, Plaintiff has been injured and sustained past and future severe pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and economic damages.

CAUSES OF ACTION RELATED TO THE VENTRALEX ST MESH PRODUCT

COUNT XII: STRICT LIABILITY – MANUFACTURING DEFECT

177. Plaintiff incorporates herein by reference the allegations in all prior paragraphs as if fully set forth herein.

178. Defendants expected and intended the ST Bard Mesh product to reach users such as Plaintiff in the condition in which the product was sold.

179. The implantation of ST Bard Mesh in Plaintiff RICHARD POTTER's body was medically reasonable, and was a type of use that Defendants intended and foresaw when it designed, manufactured and sold the product.

180. At the time the ST Bard Mesh was implanted in Plaintiff RICHARD POTTER's body, the product was defectively manufactured.

181. Defendants' poor quality control and general non-compliance resulted in the non-conformance of the ST Bard Mesh implanted in Plaintiff RICHARD POTTER. The ST Bard Mesh implanted in Plaintiff did not conform to the Defendants' intended manufacturing and design specifications.

182. Upon information and belief, Defendants utilized substandard and adulterated polypropylene and raw materials used to make the ST coating on their finished ST Bard Meshes, which deviated from Defendants' material and supply specifications.

183. As a direct and proximate result of the defective manufacture of the ST Bard Mesh, Plaintiff suffered injuries and damages as summarized herein.

COUNT XIII: STRICT LIABILITY – DESIGN DEFECT

184. Plaintiff incorporates herein by reference the allegations in all prior paragraphs as if fully set forth herein.

185. Defendants' ST Bard Mesh was defectively designed and/or manufactured, was not reasonably safe for its intended use in hernia repair, and the risks of the design outweighed any potential benefits associated with the design. As a result of the defective design and/or manufacture of the ST Bard Mesh, there was an unreasonable risk of severe adverse reactions to the mesh or mesh components including: chronic pain; recurrence of hernia; foreign body response; rejection; infection; scarification; improper wound healing; excessive and chronic inflammation; allergic reaction; adhesions to internal organs; erosion; abscess; fistula formation; granulomatous response; seroma formation; nerve damage; tumor formation, cancer, tissue damage and/or death; and other complications.

186. When affixed to the body's tissue, the impermeable coating of the ST Mesh prevents fluid escape, which leads to seroma formation, and which in turn can cause infection or abscess formation and other complications.

187. The ST coating provides an ideal bacteria breeding ground in which the bacteria cannot be eliminated by the body's immune response, which allows infection to proliferate.

188. Defendants utilize Ethylene Oxide ("ETO") in an attempt to sterilize the ST Mesh. ETO is an effective disinfectant; however, dry spores are highly resistant to ETO. Moisture must be present to eliminate spores using ETO. Presoaking the product to be sterilized is most desirable, but high levels of humidity during the ETO process can also be effective in eliminating spores. ST Mesh implanted with spores will eventually result in an infection. The spores can remain dormant for extended periods of time, resulting in infections months or years after implantation with the ST Mesh. The following non-exhaustive literature discusses the necessity of moisture during ETO sterilization:

> a. In January of 1989, a review on sterilization methods of medical devices was published in the Journal of Biomaterials Applications. ETO was among the sterilization methods reviewed. **ETO was noted to be highly resistant to dry spores, moisture must be present; presoaking most desirable. Experiments demonstrated the importance of the state of humidification of organisms at the time of their exposure to ETO. Desiccation of the spores prior to ETO exposure produces a small but significant percentage of organisms which are highly resistant to the sterilization process. Similar resistance to destruction by ETO occurs in desiccated staphylococcus aureus. Rehumidification of such organisms can require prolonged exposure to an atmosphere having a 50 to 90 percent relative humidity. Moisture has been found to be a critical factor in achieving sterility with gaseous ETO. No gas sterilizer can effectively kill desiccated spores.**
>
> Dempsey, D.J. and Thirucote, R.R., *Sterilization of medical devices: A Review*. Journal of Biomaterials Applications, 3(3), pp. 454-523 (1988). DOI: 10.1177/088532828800300303

189. The ST Bard Mesh is acidic, causing bacteriostasis (inhibition of the growth of bacteria without killing the bacteria), which results in the inability to properly validate sterilization.

190. The coating on the Defendants' ST Bard Mesh is cytotoxic, immunogenic, and not biocompatible, which causes or contributes to complications such as delayed wound healing, inflammation, foreign body response, rejection, infection, and other complications.

191. The ST coating is designed and intended to resorb in less than 30 days.

192. When the ST coating is disrupted, degrades, and/or resorbs, the "naked" polypropylene mesh and PGA is exposed to the adjoining tissue and viscera, and can become adhered to organs, and cause incarceration of organs, and fistula formation.

193. The solid, flat, relatively smooth and continuous surface of the ST Bard Mesh inhibits the body's ability to clear toxins.

194. These manufacturing and design defects associated with the ST Bard Mesh were directly and proximately related to the injuries suffered by Plaintiff.

195. Neither Plaintiff RICHARD POTTER nor his implanting physician were adequately warned or informed by Defendants of the defective and dangerous nature of ST Bard Mesh. Moreover, neither Plaintiff RICHARD POTTER nor his implanting physician were adequately warned or informed by Defendants of the risks associated with the ST Bard Mesh.

196. The ST Bard Mesh implanted in Plaintiff RICHARD POTTER failed to reasonably perform as intended. The ST Bard Mesh caused serious injury and had to be surgically removed via invasive surgery, and necessitated additional invasive surgery to repair the hernia that the ST Bard Mesh was initially implanted to treat.

197. At the time the ST Bard Mesh that was implanted in Plaintiff RICHARD POTTER's body, the product was defectively designed. As described above, there was an

unreasonable risk that the ST Bard Mesh would not perform safely and effectively for the purposes for which it was intended, and Defendants failed to design against such dangers, and failed to provide adequate warnings and instructions concerning these risks.

198. Defendants expected and intended the ST Bard Mesh product to reach users such as Plaintiff in the condition in which the product was sold.

199. The implantation of ST Bard Mesh in Plaintiff RICHARD POTTER's body was medically reasonable, and was a type of use that Defendants intended and foresaw when it designed, manufactured and sold the product.

200. The risks of the ST Bard Mesh significantly outweigh any benefits that Defendants contend could be associated with the product. The ST coating, which is not used in any other hernia mesh product sold in the United States, incites an intense inflammatory response, leading to encapsulation, deformation, scarification and contraction, migration, erosion and rejection. The impermeable ST coating leads to seroma formation, and provides a breeding ground for infection, and protects bacteria from being eliminated by the body's natural immune response. This ST coating also caused immunogenic response, and was known to be cytotoxic.

201. The coating of the ST Bard Mesh, which was marketed, promoted and intended as a barrier against adhesion to the bowel, was only temporary; it was expected and intended to degrade over time inside the body. Thus, this coating prevented tissue ingrowth in the short term, and degraded in the long-term, eventually leaving the "naked" polypropylene mesh and PGA exposed to the internal viscera and tissues. Once exposed to the viscera, the polypropylene and PGA will inevitably adhere to the viscera, initiating a cascade of adverse consequences. Any purported beneficial purpose of the coating (to prevent adhesion to the bowel and internal viscera)

was non-existent; the product provided no benefit while substantially increasing the risks to the patient.

202. The polypropylene mesh within the defective coating of the ST Mesh was in itself dangerous and defective, particularly when used in the manner intended by Defendants in the ST Bard Mesh. The particular polypropylene material used in the ST Bard Mesh was substandard, adulterated and non-medical grade, and was unreasonably subject to oxidative degradation within the body, further exacerbating the adverse reactions to the product once the ST coating degraded. When implanted adjacent to the bowel and other internal organs, as Defendants intended for ST Bard Mesh, polypropylene mesh is unreasonably susceptible to adhesion, bowel perforation or erosion, fistula formation and bowel strangulation or hernia incarceration, and other injuries.

203. The appropriate treatment for complications associated with ST Bard Mesh involves additional invasive surgery to remove the mesh from the body, thus eliminating any purported benefit that the mesh was intended to provide to the patient.

204. The ST Bard Mesh was designed and intended for intraperitoneal implantation, which required the product to be placed in contact with internal organs, which unnecessarily increased the risks of adhesion, erosion, fistula formation, and other injuries.

205. At the time the ST Bard Mesh was implanted in Plaintiff RICHARD POTTER, there were safer feasible alternative designs for hernia mesh products, including but not limited to, a flat, non-coated, single-layer mesh placed away from the bowel.

206. The ST Bard Mesh product cost significantly more than competitive products because of its unique ST coating, even though the ST coating provided no benefit to consumers, and increased the risks to patients implanted with these devices.

207. The ST Bard Mesh has a solid, flat, relatively smooth and continuous surface. Medical devices which utilize this design greatly increase the risk of tumor and cancer formation via the "Oppenheimer Effect":

> a. In 1958, a study supported by a research grant from the National Cancer Institute titled *The Latent Period in Carcinogenesis by Plastics in Rats and its Relation to the Presarcomatous Stage* was published in the Journal of Cancer. **The presence of polymer in a sheet form appears to be of primary importance, as shown by the manifold increase in the percentage of tumors induced by this form, as opposed to textiles, sponges, powders, etc. This may act in some way as a block to the free interchange of tissue constituents, subjecting some cells to an altered environment and changing their pattern of growth. Whether the primary cause is lack of nutrients or oxygen, or the accumulation of products of metabolism, or even a freeing of the cell from some hormonal control, is not at present clear, but undoubtedly the cell is placed under conditions that are favorable to autonomous, unregulated growth. Plastics embedded subcutaneously in rodents in film or sheet form induce malignant tumors in significant numbers (up to 50%), but embedded in other forms, such as textiles, sponges, or powders, they induce tumors only rarely.**
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> Oppenheimer, B.S. et al, *The Latent Period in Carcinogenesis by Plastics in Rats and its Relations to the Presearcomatous Stage*. Journal of Cancer 1(11). 204 – 213 (1958).
>
> b. In 1999, the World Health Organization's International Agency for Research on Cancer published *Surgical implants and Other Foreign Bodies*, which evaluated the carcinogenic risks of various surgical implants in humans. **Polymeric implants prepared as thin smooth films are possibly carcinogenic to humans.**
>
> Surgical Implants and Other Foreign Bodies. IARC Monogr Eval Carcinog Risks Hum 74:1-409 (1999).

208. The ST Bard Mesh implanted in Plaintiff RICHARD POTTER failed to reasonably perform as intended, and had to be surgically removed necessitating further invasive surgery to repair the very issue that the product was intended to repair, and thus provided no benefit to him.

209. As a direct and proximate result of the defective and unreasonably dangerous condition of the product, Plaintiff suffered injuries and damages as summarized herein.

COUNT XIV: STRICT LIABILITY – FAILURE TO WARN

210. Plaintiff incorporates herein by reference the allegations in all prior paragraphs as if fully set forth herein.

211. At the time the ST Bard Mesh that was implanted in Plaintiff RICHARD POTTER's body, the warnings and instructions provided by Defendant for the ST Bard Mesh were inadequate and defective. As described above, there was an unreasonable risk that the product would not perform safely and effectively for the purposes for which it was intended, and Defendants failed to design and/or manufacture against such dangers, and failed to provide adequate warnings and instructions concerning these risks.

212. Defendants expected and intended the ST Bard Mesh product to reach users such as Plaintiff in the condition in which the product was sold.

213. Plaintiff and Plaintiff's physicians were unaware of the defects and dangers of ST Bard Mesh, and were unaware of the frequency, severity and duration of the risks associated with the ST Bard Mesh.

214. The Defendants' Instructions for Use provided with the ST Bard Mesh expressly understates and misstates the risks known to be associated specifically with the ST Bard Mesh by representing that the complications such as inflammation associated with the ST Bard Mesh as "possible complications." The ST Bard Mesh will always incite severe inflammation once implanted. The inflammation caused by the ST Bard Mesh is chronic in nature and systemic, not acute localized inflammation. No other surgical mesh sold in the United States has the dangerous and defective ST coating, which itself causes or increases the risks of numerous complications,

including increased risk of seroma formation, immunologic response, increased risk for infection, and increased inflammatory reaction and foreign body response. Defendants provided no warning to physicians about the risks or increased risks specifically associated with the unique design of the ST Mesh.

215. The Defendants' Instructions for Use for the ST Mesh failed to adequately warn Plaintiff's physicians of numerous risks which Defendants knew or should have known were associated with the ST Mesh, including the risks of the product's immunologic response, pain, dehiscence, encapsulation, rejection, migration, scarification, contraction, adhesion to internal organs and viscera, erosion through adjacent tissue and viscera, bowel obstruction, or hernia incarceration or strangulation.

216. Defendants failed to adequately train or warn Plaintiff or Plaintiff's physicians about the necessity for invasive surgical intervention in the event of complications, or how to properly treat such complications when they occurred.

217. Defendants failed to adequately warn Plaintiff or Plaintiff's physicians that the surgical removal of the ST Bard Mesh in the event of complications would leave the hernia unrepaired, the resulting hernia would be much larger than the original, and would necessitate further, more complicated medical treatment to attempt to repair the same hernia that the failed ST Mesh was intended to treat.

218. Defendants represented to physicians, including Plaintiff's physician, that the ST coating would prevent or reduce adhesions, and expressly intended for the ST Mesh to be implanted in contact with the bowel and internal organs and marketed and promoted the product for said purpose. Defendants failed to warn physicians that the ST coating was only temporary and therefore at best would provide only a temporary adhesion barrier, and when the coating

inevitably degraded, the exposed polypropylene and PGA would become adhered to the bowel or tissue.

219. Defendants failed to warn Plaintiff and Plaintiff's physicians that the ST Bard Mesh was considered a significant risk device by the FDA.

220. Defendants marketed and continue to market the ST Bard Mesh in brochures and online without disclosing or making evident that PGA is utilized in the ST Bard Mesh.

221. With respect to the complications that were listed in the Defendants' warnings, Defendants provided no information or warning regarding the frequency, severity and duration of those complications, even though the complications associated with ST Bard Mesh were more frequent, more severe and lasted longer than those with safer feasible alternative hernia repair treatments.

222. If Plaintiff and/or Plaintiff's physicians had been properly warned of the defects and dangers of ST Bard Mesh, and of the frequency, severity and duration of the risks associated with the ST Bard Mesh, Plaintiff would not have consented to allow the ST Bard Mesh to be implanted, and Plaintiff's physicians would not have implanted the ST Bard Mesh in Plaintiff.

223. As a direct and proximate result of the inadequate and defective warnings and instructions, Plaintiff suffered injuries and damages as summarized herein.

COUNT XV: NEGLIGENCE

224. Plaintiff incorporates herein by reference the allegations in all prior paragraphs as if fully set forth herein.

225. Defendants had a duty to use reasonable care in designing, testing, inspecting, manufacturing, packaging, labeling, marketing, distributing, and preparing written instructions and warnings for ST Bard Mesh, but failed to do so.

226. Defendants knew, or in the exercise of reasonable care should have known, that ST Bard Mesh was defectively and unreasonably designed and/or manufactured, and was unreasonably dangerous and likely to injure patients in whom ST Bard Mesh was implanted. Defendants knew or should have known that Plaintiff and Plaintiff's physicians were unaware of the dangers and defects inherent in the ST Bard Mesh.

227. Defendants knew or should have known that the Material Safety Data Sheet for the polypropylene used to manufacturer its ST Mesh prohibited permanently implanting the polypropylene into the human body.

228. Defendants utilized non-medical grade polypropylene.

229. Defendants knew or should have known that polypropylene is not inert and would degrade, flake, chip, and disperse throughout the body once implanted.

230. Defendants knew or should have known that polypropylene incites a severe inflammatory response once implanted and continues to incite a severe inflammatory response indefinitely or until removed.

231. Defendants knew or should have known that every piece of polypropylene that flakes off and migrates throughout the body also incites its own chronic inflammatory response wherever it embeds.

232. Defendants knew or should have known that PGA induces an intense local inflammatory response following implantation.

233. Defendants knew or should have known that carboxymethylcellulose induces an intense local inflammatory response following implantation.

234. Defendants knew or should have known of the cytotoxic and immunogenic properties of the coating on the ST Mesh prior to introducing it into the stream of commerce.

235. As a direct and proximate result of Defendants' negligence in designing, testing, inspecting, manufacturing, packaging, labeling, marketing, distributing, and preparing written instructions and warnings for ST Bard Mesh, Plaintiff suffered injuries and damages as summarized herein.

COUNT XVI: BREACH OF EXPRESS WARRANTY

236. Plaintiff incorporates herein by reference the allegations in all prior paragraphs as if fully set forth herein.

237. At all relevant and material times, Defendants manufactured, marketed, sold, distributed and otherwise placed in to the stream of commerce ST Bard Mesh.

238. In advertising, marketing and otherwise promoting ST Bard Mesh to physicians, hospitals and other healthcare providers, Defendants expressly warranted that their ST Bard Mesh was safe for use and reasonably fit for their intended purposes. In advertising, marketing and otherwise promoting ST Bard Mesh, Defendants' intended that physicians, hospitals and other healthcare providers rely upon their representations regarding safety and fitness in an effort to induce them to implant Bard ST Mesh in their patients.

239. Examples of affirmations of fact and statements which were communicated to the plaintiff both directly and via his doctors, and which became the basis of the bargain include but are not limited to:

a. Defendants' Instructions for Use claims that the ST coating minimizes adhesion formation: "[t]he visceral side of the mesh is a bioresorbable coating, separating the mesh from underlying tissue and organ surfaces to minimize tissue attachment to the mesh."

b. Defendants' Brochure states:

i. "Hydrogel barrier minimizes tissue attachment to the visceral side of the mesh."

ii. "An extensively studied barrier with more than 10 publications and used clinically since 2007."
iii. "Both materials have been used in general surgery for years with demonstrated clinical success."
iv. "Monofilament polypropylene mesh… it is completely inert, resists infections, and sinus tract formation, has rapid fibrinous fixation, becomes completely incorporated into the host tissue."

240. With respect to the Plaintiff, Defendants intended that ST Bard Mesh be implanted by Plaintiff's treating surgeon in a reasonable and foreseeable manner in which it was implanted and in accordance with the instructions for use and product specifications provided by Defendants. Plaintiff was in privity with Defendants.

241. Defendants expressly warranted to physicians, hospitals, other healthcare providers and the general public, including Plaintiff, that ST Bard Mesh was safe and fit for use by consumers, that it was of merchantable quality, that its risks, side effects and potential complications were minimal and comparable to other hernia mesh products, that it was adequately researched and tested, and that it was fit for its intended use. Plaintiff and Plaintiff's physicians and healthcare providers reasonably relied upon Defendants' express representations and warranties, and consequently, Plaintiff was implanted with Defendants' ST Bard Mesh.

242. The ST Bard Mesh was manufactured from polypropylene, polyglycolic acid fibers coated with a bioresorbable, chemically modified sodium hyalurnate, carboxymethylcellulose, and polyethylene glycol based hydrogel. The ST coating was represented by the Defendants to prevent or minimize adhesion and inflammation and to facilitate incorporation of the mesh into the body, but it did not. Instead, the ST coating caused an intense systemic inflammatory and chronic foreign body response, resulting in an adverse tissue reaction including damage to surrounding tissue in the form of sclerotic, granulomatous and/or fibrotic tissue and improper or delayed healing.

243. Defendant breached these express warranties because the ST Bard Mesh implanted in Plaintiff was unreasonably dangerous, defective, and not as Defendants had represented.

244. Defendants breached express representations and warranties made to the Plaintiff, as well as Plaintiff's physicians and healthcare providers, with respect to the ST Bard Mesh, including, but not limited to, the following particulars:

a. Defendants represented to Plaintiff and Plaintiff's physicians and healthcare providers through labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions among other ways that the Defendants' ST Bard Mesh was safe, meanwhile Defendants fraudulently withheld and concealed information about the substantial risks of serious injury associated with using ST Bard Mesh;

b. Defendants represented to Plaintiff and their physicians and healthcare providers that the Defendants' ST Bard Mesh was as safe and/or safer than other alternative procedures and devices on the market, meanwhile Defendants fraudulently concealed information that demonstrated that ST Bard Mesh was not safer than alternative therapies and products available on the market; and

c. Defendants represented to Plaintiff and Plaintiff's physicians and healthcare providers that the Defendants' ST Bard Mesh was more efficacious than other alternative procedures, therapies and/or devices, meanwhile Defendants fraudulently concealed information, regarding the true efficacy of ST Bard Mesh.

245. Defendants' breach of their express warranties resulted in the implantation of an unreasonably dangerous and defective product into the Plaintiff, placing Plaintiff's health and safety in jeopardy.

246. At the time of making such express warranties, Defendants knew or should have known that Defendants' ST Bard Mesh does not conform to the express warranties and Defendants' acts were motivated by financial gain while the adverse consequences of Defendants' conduct were outrageous, fraudulent, oppressive, done with malice or gross negligence and

evidenced reckless indifference to Plaintiff's rights, health and safety so as to warrant the imposition of punitive damages.

COUNT XVII: BREACH OF IMPLIED WARRANTY

247. Plaintiff incorporates herein by reference the allegations in all prior paragraphs as if fully set forth herein.

248. At all relevant and material times, Defendants manufactured, marketed, sold, distributed and otherwise placed in to the stream of commerce ST Bard Mesh.

249. At all material times, Defendants intended that the product be implanted for the purposes and in the manner that Plaintiff and/or his implanting physicians in fact used them; and Defendants impliedly warranted each ST Bard Mesh and its component parts to be of merchantable quality, safe and fir for such use, and adequately tested.

250. Defendants were aware that consumers, including Plaintiff or Plaintiff's physicians, would implant their ST Bard Mesh in the manner directed by the instructions for use. Thus, Plaintiff was a foreseeable user of the product.

251. Plaintiff and/or Plaintiff's physicians were at all material times in privity with Defendants.

252. The ST Bard Mesh was expected to reach, and did in fact reach consumers, including Plaintiff or Plaintiff's physicians, without substantial change in the condition in which Defendants manufactured and sold it.

253. Defendants breached various implied warranties made to the Plaintiff, as well as Plaintiff's physicians and healthcare providers, with respect to the ST Bard Mesh, including, but not limited to, the following particulars:

a. Defendants represented through labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory

submissions that the ST Bard Mesh was safe; but fraudulently withheld and concealed information about the substantial risks of serious injury associated with using the product;

b. Defendants represented that the ST Bard Mesh was safe, and/or safer than other alternative procedures and devices; but fraudulently concealed information demonstrating that the product was no safer than alternatives available on the market; and

c. Defendants represented that the ST Bard Mesh was more efficacious than other alternative procedures and/or devices; but fraudulently concealed information regarding the true efficacy of the ST Bard Mesh.

254. In reliance upon Defendants' implied warranties, Plaintiff individually and/or by and through his physician, used the ST Bard Mesh as prescribed and in the foreseeable manner normally intended, recommended, promoted, and marketed by Defendants.

255. Defendants breached their implied warranty to Plaintiff in that the ST Bard Mesh was not of merchantable quality, safe and fit for its intended use, or adequately tested.

256. As a direct and proximate result of Defendants' breaches of implied warranties, Plaintiff was caused to suffer, and did suffer, severe personal injuries, pain and suffering, severe emotional distress, financial or economic loss, including obligations for medical services and expenses, impairment of personal relationships, and other damages.

COUNT XVIII: GROSS NEGLIGENCE

257. Plaintiff incorporates herein by reference the allegations in all prior paragraphs as if fully set forth herein.

258. The wrongs done by Defendants were aggravated by the kind of malice, fraud, and grossly negligent disregard for the rights of others, the public, and Plaintiff for which the law would allow, and which Plaintiff will seek at the appropriate time under governing law for the imposition of exemplary damages, in that Defendants' conduct, including the failure to comply

with applicable Federal standards: was specifically intended to cause substantial injury to Plaintiff; or when viewed objectively from Defendants' standpoint at the time of the conduct, involved an extreme degree of risk, considering the probability and magnitude of the potential harm to others, and Defendants were actually, subjectively aware of the risk involved, but nevertheless proceeded with conscious indifference to the rights, safety, or welfare of others; or included a material representation that was false, with Defendants, knowing that it was false or with reckless disregard as to its truth and as a positive assertion, with the intent that the representation is acted on by Plaintiff.

259. Plaintiff relied on the representation and suffered injury as a proximate result of this reliance.

260. Plaintiff therefore will seek to assert claims for exemplary damages at the appropriate time under governing law in an amount within the jurisdictional limits of the Court.

261. Plaintiff also alleges that the acts and omissions of named Defendants, whether taken singularly or in combination with others, constitute gross negligence that proximately caused the injuries to Plaintiff. In that regard, Plaintiff will seek exemplary damages in an amount that would punish Defendants for their conduct and which would deter other manufacturers from engaging in such misconduct in the future.

COUNT XIX: UNJUST ENRICHMENT

262. Plaintiff incorporates herein by reference the allegations in all prior paragraphs as if fully set forth herein.

263. Defendants are and at all times were the manufacturers, sellers, and/or suppliers of the Defendants' ST Bard Mesh.

264. Plaintiff paid for the Defendants' ST Bard Mesh for the purpose of treatment for hernia repair and/or a soft tissue injury or other similar condition.

265. Defendants have accepted payment by Plaintiff, and others on Plaintiff's behalf, for the purchase of the Defendants' ST Bard Mesh.

266. Plaintiff has not received the safe and effective medical device for which Plaintiff paid.

267. It would be inequitable for Defendants to keep this money, because Plaintiff did not in fact receive a safe and effective medical device.

COUNT XX: NEGLIGENT INFLICTION OF EMOTIONAL DISTRESS

268. Plaintiff incorporates herein by reference the allegations in all prior paragraphs as if fully set forth herein.

269. Defendants carelessly and negligently manufactured, designed, developed, tested, labeled, marketed and sold the Defendants' ST Bard Mesh to Plaintiff.

270. Defendants carelessly and negligently concealed the harmful effects of the Defendants' ST Bard Mesh from Plaintiff individually and/or Plaintiff's physician on multiple occasions and continue to do so to this day.

271. Defendants carelessly and negligently misrepresented the quality, safety and efficacy of the ST Bard Mesh to Plaintiff individually and/or Plaintiff's physician on multiple occasions and continue to do so to this day.

272. Plaintiff was directly impacted by Defendants' carelessness and negligence, in that Plaintiff has sustained and will continue to sustain emotional distress, severe physical injuries, economic losses, and other damages as a direct result of the decision to purchase the ST Bard Mesh sold and distributed by Defendants.

273. Defendants continued to carelessly and negligently misrepresent the quality, safety, efficacy, dangers and contraindications of the ST Bard Mesh to Plaintiff individually and/or Plaintiff's physician after Plaintiff sustained emotional distress, severe physical injuries, and economic loss.

274. Defendants continued to carelessly and negligently misrepresent the quality, safety, efficacy, dangers and contraindications of the ST Bard Mesh to Plaintiff individually and/or Plaintiff's physician knowing that doing so would cause the Plaintiff to suffer additional and continued emotional distress, severe physical injuries, and economic loss.

275. As a proximate result of the Defendants' conduct, Plaintiff has been injured, sustained severe and permanent pain, suffering, anxiety, depression, disability, impairment, loss of enjoyment of life, loss of care, comfort, and economic damages.

COUNT XXI: FRAUDULENT CONCEALMENT

276. Plaintiff incorporates herein by reference the allegations in all prior paragraphs as if fully set forth herein.

277. At all times relevant hereto, it was known or knowable to Defendants that their ST Bard Mesh caused large numbers of complications. Moreover, it was known or knowable to Defendants that the surgical technique and training of implanting physicians was not the cause of the adverse events associated with these devices. It was known or knowable to Defendants that the safety and efficacy of its ST Bard Mesh had not been proven with respect to, among other things, the ST Bard Mesh, its components, its performance, and its method of insertion. It was known or knowable to Defendants that the ST Bard Mesh was not safe and effective. Defendants continued to represent that its Products were safe and effective.

278. Despite what was known or knowable to Defendants about the lack of safety and efficacy of the ST Bard Mesh, Defendants failed to disclose this information to the Plaintiff, to Plaintiff's physicians, and to the public at large.

279. At all times relevant hereto, Defendants had the duty and obligation to disclose to Plaintiff and Plaintiff's physicians the true facts concerning the ST Bard Mesh, that is, that said Products were dangerous and defective, lacking efficacy for its purported use and lacking safety in normal use, and how likely it was to cause serious consequences to users, including permanent and debilitating injuries. Defendants concealed these material facts prior to the time that Plaintiff was implanted with Defendants' ST Bard Mesh.

280. Defendants were under a duty to Plaintiff to disclose and warn of the defective nature of the Products because:

a. Defendants were in a superior position to know the true quality, safety, and efficacy of its ST Bard Mesh;

b. Defendants knowingly made false claims about the safety and quality of its ST Bard Mesh in documents and marketing materials; and

c. Defendants fraudulently and affirmatively concealed the defective nature of the ST Bard Mesh from the Plaintiff.

281. The facts concealed and/or not disclosed by Defendants to Plaintiff were material facts that a reasonable person would have considered to be important in deciding whether or not to purchase and/or use the Defendants' ST Bard Mesh.

282. At all times relevant hereto, Defendants and each of them, willfully, intentionally, and maliciously concealed facts as set forth above from Plaintiff and his physicians with the intent to defraud, as alleged herein.

283. Defendants intentionally concealed and/or failed to disclose the true defective nature of the ST Bard Mesh so that Plaintiff would request and purchase the Defendants' ST Bard Mesh, and their healthcare providers would dispense, prescribe, and recommend the Defendants' ST Bard Mesh, and Plaintiff justifiably acted or relied upon the concealed and/or non-disclosed facts to their detriment.

284. At all times relevant hereto, neither Plaintiff nor his physicians were aware of the facts set forth above, and had they been aware of said facts, they would not have acted as they did, that is, would not have reasonably relied upon said representations of safety and efficacy and utilized Defendants' ST Bard Mesh in their treatment. Defendants' failure to disclose this information was a substantial factor in Plaintiff's physicians selecting Defendants' ST Bard Mesh. The failure to disclose also resulted in the provision of incorrect and incomplete information to Plaintiff, as a patient.

285. As a direct and proximate result of this conduct, Plaintiff was injured.

COUNT XXII: CONSTRUCTIVE FRAUD

286. Plaintiff incorporates herein by reference the allegations in all prior paragraphs as if fully set forth herein.

287. Defendants are in a unique position of knowledge concerning the quality, safety, and efficacy of the Defendants' ST Bard Mesh; knowledge that is not possessed by Plaintiff or Plaintiff's physicians. Defendants thereby hold a position of superiority over Plaintiff and Plaintiff's physicians.

288. Despite their unique and superior knowledge regarding the defective nature of the ST Bard Mesh, Defendants continue to suppress, conceal, omit, and/or misrepresent information to Plaintiff, the medical community, and the public concerning the severity and frequency of risks

and dangerous inherent in the intended use of its ST Bard Mesh, as compared to other products and forms of treatment.

289. Defendants have concealed and suppressed material information that would reveal that the ST Bard Mesh had a higher risk of adverse effects, in addition to, and exceeding those associated with alternative procedures and available devices. Instead, Defendants have misrepresented the safety and efficacy of the ST Bard Mesh.

290. Upon information and belief, Defendants' misrepresentations are designed to induce physicians to prescribe, dispense, recommend, and/or purchase the Defendants' ST Bard Mesh. Plaintiff and the medical community have relied upon Defendants' misrepresentations.

291. Defendants took unconscionable advantage of their dominant position of knowledge with regard to Plaintiff and Plaintiff's healthcare providers, and engaged in constructive fraud in their relationship with Plaintiff and Plaintiff's medical providers. Plaintiff reasonably relied on Defendants' representations.

292. As a proximate cause of the Defendants' conduct, Plaintiff has been injured and sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and economic damages.

COUNT XXIII: DISCOVERY RULE, TOLLING, AND FRAUDULENT CONCEALMENT

293. Plaintiff incorporates herein by reference the allegations in all prior paragraphs as if fully set forth herein.

294. Plaintiff asserts all applicable state statutory and common law rights and theories related to the tolling or extension of any applicable statute of limitations, including equitable tolling, class action tolling, delayed discovery, discovery rule, and fraudulent concealment.

295. Plaintiff pleads that the discovery rule should be applied to toll the running of the statute until Plaintiff knew, or through the exercise of reasonable care and diligence should have known, of facts indicated that Plaintiff had been injured, the cause of the injury, and the tortious nature of the wrongdoing that caused the injury.

296. Despite diligent investigation by Plaintiff into the cause of Plaintiff's injuries, including consultations with Plaintiff's medical providers, the nature of Plaintiff's injuries and damages, and their relationship to the ST Bard Mesh was not discovered, and through reasonable care and diligence could not have been discovered until a date within the applicable statute of limitations for filing Plaintiff's claims. Therefore, under appropriate application of the discovery rule, Plaintiff's suit was filed well within the applicable statutory limitations period.

297. The running of the statute of limitations in this cause of action is tolled due to equitable tolling. Defendants are estopped from asserting a statute of limitations defense due to Defendants' fraudulent concealment, through misrepresentations and omissions, from Plaintiff and Plaintiff's physicians of the true risks associated with the ST Bard Mesh. As a result of Defendants' fraudulent concealment, Plaintiff and Plaintiff's physicians were unaware, and could not have known or have learned through reasonable diligence that Plaintiff had been exposed to the risks alleged herein and that those risks were the direct and proximate result of the wrongful acts and omissions of the Defendants.

COUNT XXIV: NEGLIGENT MISREPRESENTATION

298. Plaintiff incorporate herein by reference the allegations in all prior paragraphs as if fully set forth herein.

299. Defendants had a duty to accurately and truthfully represent to the medical and healthcare community, Plaintiff, and the public, that its ST Bard Mesh had not been adequately

tested and found to be a safe and effective treatment. The representations made by Defendants were, in fact, false.

300. Defendants failed to exercise ordinary care in the representations concerning the ST Bard Mesh while they were involved in their manufacture, sale, testing, quality assurance, quality control, and distribution in interstate commerce, because Defendants negligently misrepresented the ST Bard Mesh's high risk of unreasonable and dangerous adverse side effects.

301. Defendants breached their duty in representing that the Defendants' ST Bard Meshes have no serious side effects different from older generations of similar products and/or procedures to Plaintiff, Plaintiff's physicians, and the medical community.

302. As a foreseeable, direct, and proximate result of the negligent misrepresentation of Defendants, as set forth herein, Defendants knew, and had reason to know, that the ST Bard Mesh had been insufficiently tested, or had not been tested at all, and that they lacked adequate and accurate warnings, and that they created a high risk—and/or higher than acceptable risk, and/or higher than reported and represented risk—of adverse side effects, including, but not limited to, pain, graft rejection, graft migration, organ damage, complex seroma, fistula, sinus tract formation, delayed wound closure, infection, sepsis, and death.

303. As a proximate cause of the Defendants' conduct, Plaintiff has been injured and sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and economic damages.

COUNT XXV: PUNITIVE OR ENHANCED COMPENSATORY DAMAGES

304. Plaintiff incorporates herein by reference the allegations in all prior paragraphs as if fully set forth herein.

305. Defendants failed to adequately test and study the ST Bard Mesh and ePTFE Bard Mesh to determine and ensure that the ST Bard Mesh and ePTFE Bard Mesh were safe and effective prior to releasing the products for sale for permanent human implantation, and Defendants continued to manufacture and sell ST Bard Mesh and ePTFE Bard Mesh after obtaining knowledge and information that the product was defective and unreasonably unsafe.

306. Even though Defendants have other hernia repair mesh devices that do not present the same risks as the ST Bard Mesh and ePTFE Bard Mesh, Defendants developed, designed and sold ST Bard Mesh and ePTFE Bard Mesh, and continue to do so, because the ST Bard Mesh and ePTFE Bard Mesh have significantly higher profit margin than other hernia repair products. Defendants were aware of the probable consequences of implantation of the dangerous and defective ST Bard Mesh and ePTFE Bard Mesh, including the risk of failure and serious injury, such as suffered by Plaintiff.

307. At all times relevant hereto, Defendants knew or should have known that ST Bard Mesh and ePTFE Bard Mesh were inherently more dangerous with respect to the risk of foreign body response, allergic reactions, rejection, infection, failure, erosion, pain and suffering, organ perforation, dense adhesions, tumor or cancer formation, loss of life's enjoyment, remedial surgeries and treatments in an effort to cure the conditions proximately related to the use of the product, as well as the other severe and personal injuries which are permanent and lasting in nature.

308. Defendants' misrepresentation included knowingly withholding material information from the medical community and the public, including Plaintiff, concerning the safety and efficacy of the ST Bard Mesh and ePTFE Bard Mesh, which deprived Plaintiff and Plaintiff's implanting physicians of vitally necessary information with which to make a fully informed decision about whether to use ST Bard Mesh and ePTFE Bard Mesh.

309. At all times material hereto, Defendants knew and recklessly and/or intentionally disregarded the fact that the Defendants' ST Bard Mesh and ePTFE Bard Mesh can cause debilitating and potentially life-threatening side effects with greater frequency than safer alternative methods, products, procedures, and/or treatment.

310. At all times material hereto, Defendants knew and recklessly and/or intentionally disregarded the fact that ST Bard Mesh and ePTFE Bard Mesh can cause debilitating and potentially life-threatening side effects with greater frequency than safer alternative products and/or methods of treatment and recklessly failed to advise the medical community and the general public, including Plaintiff, of the same.

311. At all times material hereto, Defendants intentionally misstated and misrepresented data and continue to misrepresent data so as to minimize the perceived risk of injuries and the rate of complications caused by the associated with ST Bard Mesh and ePTFE Bard Mesh.

312. Notwithstanding the foregoing and the growing body of knowledge and information regarding the true and defective nature of ST Bard Mesh and ePTFE Bard Mesh with its increased risk of side effects and serious complications, Defendants continue to aggressively market the ST Bard Mesh and ePTFE Bard Mesh to the medical community and to consumers without disclosing the true risk of such complications.

313. At the time of the Plaintiff was implanted with the ST Bard Mesh and ePTFE Bard Mesh and since that time, Defendants knew that ST Bard Mesh and ePTFE Bard Mesh was defective and unreasonably dangerous but continued to manufacture, produce, assemble, market, distribute, and sell ST Bard Mesh and ePTFE Bard Mesh so as to maximize sales and profits at the expense of the health and safety of the public in a conscious, reckless and/or intentional disregard

of the likely and foreseeable harm caused by ST Bard Mesh and ePTFE Bard Mesh to members of the public including Plaintiff.

314. At all times material, Defendants have concealed and/or failed to disclose to the public the serious risks and the potential complications associated with ST Hernia Mesh and ePTFE Bard Mesh in order to ensure continued and increased sales and profits and to the detriment of the public, including Plaintiff.

315. Defendants' conduct, acts and omissions, as described herein, are of such character and nature so as to entitle Plaintiff to an award of punitive damages in accordance with applicable statutory and common law. Defendants' conduct shows willful misconduct, malice, fraud, wantonness, oppression, or that entire want of care which raises the presumption of conscious indifference to consequences, thereby justifying an award of punitive damages.

PRAYER FOR RELIEF

Plaintiff demands judgment against Defendants, individually, jointly and severally, and prays for the following relief in accordance with applicable law and equity:

i. compensatory damages to Plaintiff for past, present, and future damages, including but not limited to, pain and suffering for severe and permanent personal injuries sustained by Plaintiff, permanent impairment, mental pain and suffering, loss of enjoyment of life, health and medical care costs, economic damages, together with interest and costs as provided by law;
ii. restitution and disgorgement of profits;
iii. punitive or enhanced compensatory damages;
iv. reasonable attorneys' fees as provided by law;
v. costs of these proceedings, including past and future cost of the suit incurred herein;
vi. all ascertainable economic damages;
vii. prejudgment interest on all damages as allowed by law; and
viii. such other and further relief as this Court deems just and proper.

DEMAND FOR JURY TRIAL

Plaintiff hereby demands a trial by jury on all issues so triable.

Respectfully submitted,

LOMURRO, MUNSON, COMER, BROWN & SCHOTTLAND, LLC
4 Paragon Way, Suite 100
Freehold, New Jersey 07728
Phone: (732) 414-0300
Fax: (732) 431-4043
jkincannon@lomurrofirm.com
Attorneys for Plaintiff

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

Dated: August 24, 2018

JS 44 (Rev. 06/17)

CIVIL COVER SHEET

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

I. (a) PLAINTIFFS

RICHARD POTTER

(b) County of Residence of First Listed Plaintiff INDIAN RIVER
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys *(Firm Name, Address, and Telephone Number)*

JOSHUA S. KINCANNON, ESQ.
LOMURRO, MUNSON, COMER, BROWN & SCHOTTLAND, LLC
4 PARAGON WAY, SUITE 100
FREEHOLD, NJ 07728
(732) 414-0300

DEFENDANTS

C.R. BARD and DAVOL, INC.

County of Residence of First Listed Defendant UNION
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys *(If Known)*

II. BASIS OF JURISDICTION *(Place an "X" in One Box Only)*

- ❒ 1 U.S. Government Plaintiff
- ❒ 3 Federal Question *(U.S. Government Not a Party)*
- ❒ 2 U.S. Government Defendant
- ☒ 4 Diversity *(Indicate Citizenship of Parties in Item III)*

III. CITIZENSHIP OF PRINCIPAL PARTIES *(Place an "X" in One Box for Plaintiff and One Box for Defendant)*

(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	❒ 1	❒ 1	Incorporated *or* Principal Place of Business In This State	❒ 4	☒ 4
Citizen of Another State	☒ 2	❒ 2	Incorporated *and* Principal Place of Business In Another State	❒ 5	❒ 5
Citizen or Subject of a Foreign Country	❒ 3	❒ 3	Foreign Nation	❒ 6	❒ 6

IV. NATURE OF SUIT *(Place an "X" in One Box Only)*

Click here for: Nature of Suit Code Descriptions.

CONTRACT	TORTS		FORFEITURE/PENALTY	BANKRUPTCY	OTHER STATUTES
❒ 110 Insurance	PERSONAL INJURY	PERSONAL INJURY	❒ 625 Drug Related Seizure of Property 21 USC 881	❒ 422 Appeal 28 USC 158	❒ 375 False Claims Act
❒ 120 Marine	❒ 310 Airplane	☒ 365 Personal Injury - Product Liability	❒ 690 Other	❒ 423 Withdrawal 28 USC 157	❒ 376 Qui Tam (31 USC 3729(a))
❒ 130 Miller Act	❒ 315 Airplane Product Liability	❒ 367 Health Care/ Pharmaceutical Personal Injury Product Liability		PROPERTY RIGHTS	❒ 400 State Reapportionment
❒ 140 Negotiable Instrument	❒ 320 Assault, Libel & Slander	❒ 368 Asbestos Personal Injury Product Liability		❒ 820 Copyrights	❒ 410 Antitrust
❒ 150 Recovery of Overpayment & Enforcement of Judgment	❒ 330 Federal Employers' Liability	PERSONAL PROPERTY	LABOR	❒ 830 Patent	❒ 430 Banks and Banking
❒ 151 Medicare Act	❒ 340 Marine	❒ 370 Other Fraud	❒ 710 Fair Labor Standards Act	❒ 835 Patent - Abbreviated New Drug Application	❒ 450 Commerce
❒ 152 Recovery of Defaulted Student Loans (Excludes Veterans)	❒ 345 Marine Product Liability	❒ 371 Truth in Lending	❒ 720 Labor/Management Relations	❒ 840 Trademark	❒ 460 Deportation
❒ 153 Recovery of Overpayment of Veteran's Benefits	❒ 350 Motor Vehicle	❒ 380 Other Personal Property Damage	❒ 740 Railway Labor Act	SOCIAL SECURITY	❒ 470 Racketeer Influenced and Corrupt Organizations
❒ 160 Stockholders' Suits	❒ 355 Motor Vehicle Product Liability	❒ 385 Property Damage Product Liability	❒ 751 Family and Medical Leave Act	❒ 861 HIA (1395ff)	❒ 480 Consumer Credit
❒ 190 Other Contract	❒ 360 Other Personal Injury		❒ 790 Other Labor Litigation	❒ 862 Black Lung (923)	❒ 490 Cable/Sat TV
❒ 195 Contract Product Liability	❒ 362 Personal Injury - Medical Malpractice		❒ 791 Employee Retirement Income Security Act	❒ 863 DIWC/DIWW (405(g))	❒ 850 Securities/Commodities/ Exchange
❒ 196 Franchise				❒ 864 SSID Title XVI	❒ 890 Other Statutory Actions
				❒ 865 RSI (405(g))	❒ 891 Agricultural Acts
					❒ 893 Environmental Matters
					❒ 895 Freedom of Information Act
REAL PROPERTY	CIVIL RIGHTS	PRISONER PETITIONS	IMMIGRATION	FEDERAL TAX SUITS	❒ 896 Arbitration
❒ 210 Land Condemnation	❒ 440 Other Civil Rights	**Habeas Corpus:**	❒ 462 Naturalization Application	❒ 870 Taxes (U.S. Plaintiff or Defendant)	❒ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
❒ 220 Foreclosure	❒ 441 Voting	❒ 463 Alien Detainee	❒ 465 Other Immigration Actions	❒ 871 IRS—Third Party 26 USC 7609	❒ 950 Constitutionality of State Statutes
❒ 230 Rent Lease & Ejectment	❒ 442 Employment	❒ 510 Motions to Vacate Sentence			
❒ 240 Torts to Land	❒ 443 Housing/ Accommodations	❒ 530 General			
❒ 245 Tort Product Liability	❒ 445 Amer. w/Disabilities - Employment	❒ 535 Death Penalty			
❒ 290 All Other Real Property	❒ 446 Amer. w/Disabilities - Other	**Other:**			
	❒ 448 Education	❒ 540 Mandamus & Other			
		❒ 550 Civil Rights			
		❒ 555 Prison Condition			
		❒ 560 Civil Detainee - Conditions of Confinement			

V. ORIGIN *(Place an "X" in One Box Only)*

☒ 1 Original Proceeding ❒ 2 Removed from State Court ❒ 3 Remanded from Appellate Court ❒ 4 Reinstated or Reopened ❒ 5 Transferred from Another District *(specify)* ❒ 6 Multidistrict Litigation - Transfer ❒ 8 Multidistrict Litigation - Direct File

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing ***(Do not cite jurisdictional statutes unless diversity)***:
28 U.S.C. 1332

Brief description of cause:
PRODUCT LIABILITY MATTER AS A RESULT OF A DEFECTIVE HERNIA MESH

VII. REQUESTED IN COMPLAINT:

❒ CHECK IF THIS IS A **CLASS ACTION** UNDER RULE 23, F.R.Cv.P.

DEMAND $ 75,001.00

CHECK YES only if demanded in complaint:

JURY DEMAND: ☒ Yes ❒ No

VIII. RELATED CASE(S) IF ANY

(See instructions): JUDGE _____ DOCKET NUMBER _____

DATE 08/24/2018

SIGNATURE OF ATTORNEY OF RECORD /s JOSHUA S. KINCANNON, ESQ.

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____