

**UNITED STATES DISTRICT COURT
DISTRICT OF RHODE ISLAND**

| | | |
|------------------------|---|----------------------------|
| VICTORIA ALFO |) | Civil Action No.: |
| |) | |
| |) | |
| Plaintiff, |) | |
| |) | JURY TRIAL DEMANDED |
| v. |) | |
| |) | |
| DAVOL INC., and |) | |
| C.R. BARD, |) | |
| |) | |
| Defendants. |) | |
| |) | |

Plaintiff, by and through her undersigned counsel, bring this Complaint for damages against Defendants and in support thereof state 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 Victoria Alfo suffered permanent injuries and significant pain and suffering, emotional distress, lost wages and earning capacity, and diminished quality of life. The Plaintiff respectfully seeks all damages to which she may be legally entitled.

STATEMENT OF PARTIES

2. Plaintiffs is, and was, at all relevant times, a citizen and resident of Rhode Island 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. 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”).

5. 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.

6. 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

7. This Court has diversity subject-matter jurisdiction over this action pursuant to 28 U.S.C. § 1332.

8. Venue is proper in this Court pursuant to 28 U.S.C. § 1391 because the events or omissions giving rise to Plaintiff's claims occurred in this district.

9. Defendants have and continue to conduct substantial business in the State of Rhode Island and in this District, distribute ST Bard Mesh in this District, receive substantial compensation and profits from sales of ST 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.

10. Davol is registered to transact business in Rhode Island.

FACTS COMMON TO ALL COUNTS

11. On or about August 5, 2015, Plaintiff Victoria Alfo underwent umbilical hernia repair by Dr. Collin Brathwaite at Winthrop University Hospital in Mineola, New York. A 6" x 8" Ventralight ST Bard Mesh, Ref No. 5955680 Lot No. HUZC1994 was implanted in Plaintiff during this repair.

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

13. On or about September 30, 2015, Plaintiff Victoria Alfo underwent removal of the failed Ventralight ST by Dr. Collin Brathwaite at Winthrop University Hospital in Mineola, New York. During the procedure, Dr. Brathwaite noted "exposed mesh under the skin and purulent material."

14. 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.

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

16. 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.

17. Defendants represented to Plaintiff and Plaintiff's physicians that ST Bard Mesh was a safe and effective product for hernia repair.

THE FDA'S 510(k) CLEARANCE PROCESS

18. 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.

19. No clinical testing is required under this process.

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

21. 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.

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

23. 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.

24. 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.”

25. Defendants cleared the ST 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.

26. 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

27. Defendants are estopped from relying on any statutes 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 is defective, while continually marketing the ST Bard Mesh with the effects described herein.

28. 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 was defective, Defendants are estopped from relying on any statutes of limitations that might otherwise be applicable to the claims asserted herein.

COUNT I: STRICT LIABILITY – MANUFACTURING DEFECT

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

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

31. The implantation of ST 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.

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

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

34. 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.

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

COUNT II: STRICT LIABILITY – DESIGN DEFECT

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

37. 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.

38. 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.

39. 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.

40. 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

41. 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.

42. 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.

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

44. 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.

45. The ST Bard Mesh has a solid, flat, relatively smooth and continuous surface, which promotes tumor and cancer formation via the "Oppenheimer Effect." A phenomenon identified in the 1950s.

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

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

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

49. The ST Bard Mesh implanted in Plaintiff 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.

50. At the time the ST Bard Mesh that was implanted in Plaintiff'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.

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

52. The implantation of ST 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.

53. 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.

54. 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.

55. 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.

56. 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.

57. 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.

58. At the time the ST 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, single-layer mesh placed away from the bowel.

59. 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.

60. 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:

- 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).

61. The ST 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.

62. 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

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

64. At the time the ST Bard Mesh that was implanted in Plaintiff'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.

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

66. 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.

67. 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.

68. 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.

69. 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.

70. 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.

71. 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.

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

73. 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.

74. 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.

75. 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.

76. 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

77. Plaintiffs incorporate herein by reference the allegations in all prior Paragraphs as if fully set forth herein.

78. 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.

79. 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.

80. Defendants knew or should have known that the MSDS for the polypropylene used to manufacture its ST Mesh prohibited permanently implanting the polypropylene into the human body.

81. Defendants utilized non-medical grade polypropylene.

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

83. 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.

84. 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.

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

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

87. 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.

88. 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 V: BREACH OF IMPLIED WARRANTY

89. Plaintiff incorporates by reference the allegations in all prior paragraphs.

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

91. At all material times, Defendants intended for their product to be implanted for the purposes and in the manner that Plaintiff and her implanting physician in fact used it; and

Defendants impliedly warranted that the product and its component parts were of merchantable quality, safe and fit for such use, and adequately tested.

92. Defendants were aware that consumers, including Plaintiff and her physician, would implant their product as directed by the Instructions for Use. Therefore, Plaintiff was a foreseeable user of Defendants' ST Bard Mesh.

93. Defendants' ST Bard Mesh was expected to reach, and did in fact reach consumers, including Plaintiff and her physician, without substantial change in the condition in which it was manufactured and sold by Defendants.

94. Defendants breached various implied warranties with respect to ST Bard Mesh, including the following:

- A. Defendants represented to Plaintiff and her physician and healthcare providers through labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that their product was safe. But at the same time they fraudulently withheld and concealed information about the substantial risks of serious injury associated with using the product;
- B. Defendants represented to Plaintiff and her physician and healthcare providers that their product was safe and/or safer than other alternative procedures and devices. But at the same time they fraudulently concealed information demonstrating that the product was not safer than alternatives available on the market; and
- C. Defendants represented to Plaintiff and her physician and healthcare providers that their product was more efficacious than alternative procedures and/or devices. But at the same

time they fraudulently concealed information regarding the true efficacy of the ST Bard Mesh.

95. 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.

96. Defendants breached their implied warranties to Plaintiff in that their product was not of merchantable quality, nor was it safe and fit for its intended use or adequately tested.

97. As a direct and proximate result of Defendants' breaches of the aforementioned implied warranties, Plaintiff was caused to 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 VI: NEGLIGENT INFLICTION OF EMOTIONAL DISTRESS

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

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

100. 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.

101. 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.

102. 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.

103. 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.

104. 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.

105. 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 VII: FRAUDULENT CONCEALMENT

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

107. 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.

108. 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.

109. 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 Plaintiffs were implanted with Defendants' Products.

110. Defendants were under a duty to Plaintiffs 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 Products;
- B. Defendants knowingly made false claims about the safety and quality of its ST Bard Mesh in documents and marketing materials;
- C. Defendants fraudulently and affirmatively concealed the defective nature of the ST Bard Mesh from the Plaintiff.

111. 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.

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

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

114. At all times relevant hereto, neither Plaintiffs nor their 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.

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

COUNT VIII: NEGLIGENT MISREPRESENTATION

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

117. 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.

118. 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 ST Bard Mesh's high risk of unreasonable and dangerous adverse side effects.

119. 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.

120. 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.

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

PUNITIVE DAMAGES

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

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

124. Even though Defendants have other hernia repair mesh devices that do not present the same risks as the ST Bard Mesh, Defendants developed, designed and sold ST Bard Mesh, and continue to do so, because the ST Bard Mesh has a 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, including the risk of failure and serious injury, such as suffered by Plaintiff.

125. At all times relevant hereto, Defendants knew or should have known that ST Bard Mesh was 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.

126. Defendant's 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, 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.

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

128. At all times material hereto, Defendants knew and recklessly and/or intentionally disregarded the fact that ST 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 Plaintiffs, of the same.

129. 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.

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

131. At the time of the Plaintiff was implanted with the ST Bard Mesh and since that time, Defendants knew that ST Bard Mesh was defective and unreasonably dangerous but

continued to manufacture, produce, assemble, market, distribute, and sell ST 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 to members of the public including Plaintiff.

132. 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 in order to ensure continued and increased sales and profits and to the detriment of the public, including Plaintiff.

133. 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

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and request compensatory damages, punitive damages or enhanced compensatory damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

PRAYER FOR RELIEF

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

- i. Compensatory damages to Plaintiffs 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 damages;
- iv. Reasonable attorneys' fees as provided by law;
- v. Past and future cost of all proceedings;
- 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,

Dated: August 14, 2018

BRIAN CUNHA & ASSOCIATES

By: /s/ Brian Cunha
Brian Cunha (#4074)
904 Broadway
East Providence, RI 02914
(401) 434-5300
BrainCunha@briancunha.com

ATTORNEY FOR PLAINTIFF

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

Victoria Alfó

(b) County of Residence of First Listed Plaintiff Suffolk County, New York (EXCEPT IN U.S. PLAINTIFF CASES)

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

Hollis Law Firm 5100 w. 95th St. Prairie Village, KS 66207 913-385-5400

Brian Cunha & Associates 904 Broadway East Providence, RI 02914 (401) 434-5300

DEFENDANTS

C.R. Bard & Davol

County of Residence of First Listed Defendant Union County, NJ (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
2 U.S. Government Defendant
3 Federal Question (U.S. Government Not a Party)
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)

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

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

Click here for: Nature of Suit Code Descriptions.

Table with 5 columns: CONTRACT, REAL PROPERTY, TORTS, CIVIL RIGHTS, PRISONER PETITIONS, FORFEITURE/PENALTY, LABOR, IMMIGRATION, BANKRUPTCY, SOCIAL SECURITY, FEDERAL TAX SUITS, OTHER STATUTES. Includes various legal categories and codes.

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. Sec 1332

Brief description of cause: Products Liability-Personal Injury Based on Failure of Surgical 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: X Yes [] No

VIII. RELATED CASE(S) IF ANY

(See instructions): JUDGE Sargus DOCKET NUMBER MDL-2846

DATE 08/14/2018 SIGNATURE OF ATTORNEY OF RECORD Brian Cunha

FOR OFFICE USE ONLY

RECEIPT # AMOUNT APPLYING IFP JUDGE MAG. JUDGE