UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF SOUTH CAROLINA
COLUMBIA DIVISION

KENNETH E. BRUGGER, Jr. and NANCY K. BRUGGER; Plaintiffs, v. C.R. BARD, INC., and DAVOL, INC., Defendants.	Case No.: 3:17-cv-00228-CMC **COMPLAINT** **JURY TRIAL REQUESTED**

COMPLAINT

COMES NOW Plaintiffs Kenneth E. Brugger, Jr., and Nancy K. Brugger by and through the undersigned attorneys, and for their Complaint against Defendants, state and allege the following:

1. This is an action for damages suffered by Kenneth E. Brugger, Jr., and Nancy K. Brugger, "Plaintiff", as a direct and proximate result of Defendants' wrongful conduct in connection with the development, design, manufacture, marketing, distribution and sale of medical device Composix L/P Mesh with Echo Positioning System 6x8, Product Code 0144680 (hereinafter referred to as "Mesh").
2. Plaintiffs maintain that the Mesh is defective, dangerous to human health, unfit and unsuitable to be marketed and sold in commerce, and lacked proper warnings and directions as to the dangers associated with its use.

PARTIES

3. Plaintiff Kenneth E. Brugger, Jr., hereinafter referred to as "Plaintiff", aged 65, is a resident of Lexington, Lexington County, South Carolina.
4. Plaintiff Nancy K. Brugger, hereinafter referred to as "Plaintiff Spouse", aged 65, is a resident of Lexington, Lexington County, South Carolina.
5. Defendant C.R. Bard, Inc. is a New Jersey based corporation with its principal place of business at 730 Central Avenue, Murray Hill, New Jersey, 07974.
6. Defendant Davol, Inc. is a Rhode Island based corporation with its principal place of business at 100 Crossings Boulevard, Warwick, Rhode Island, 02886. Upon information and belief that Davol, Inc. is a wholly-owned subsidiary of C.R. Bard, Inc.
7. In this Complaint, "Defendants" refers to all named Defendants as well as every parent, subsidiary, predecessor, successor and related entities of which each named Defendant to which these allegations pertain.
8. Defendants are companies which were the researchers and/or designers and/or manufacturers and/or assemblers and/or testers and/or labelers and/or packagers and/or promoters and/or sellers and/or distributors and/or otherwise engaged in placing into the stream of commerce a device that is known as Composix L/P Mesh with Echo Positioning System 6x8, Product Code 0144680, a low-profile, large pore polypropylene/ePTFE prosthesis for laparoscopic ventral hernia repair and placed said product into the stream of commerce throughout the country including South Carolina.

9. This Court has jurisdiction pursuant to 28 U.S.C. § 1332 (a) as Plaintiff and Defendants are citizens of different States and the amount in controversy exceeds $75,000.00 exclusive of interest and costs.
10. This Court also has supplemental jurisdiction pursuant to 28 U.S.C. § 1367.
11. Venue is proper in this Court pursuant to 28 U.S.C. § 1391 as Defendants conduct business here and are subject to personal jurisdiction in this District. Furthermore, Defendants sell, market, and/or distribute Mesh within the District of South Carolina.

BACKGROUND FACTS AND ALLEGATIONS

12. Defendants design, manufacture, market, package, label and sell a medical device known as Mesh, a low-profile, large pore polypropylene/ePTFE prosthesis for laparoscopic ventral hernia repair, where it is intended or reasonably foreseeable that it would be implanted to treat certain persons like Plaintiff.
13. On or around December 13, 2011, Plaintiff had Composix L/P Mesh (hereinafter referred to as "The Product" or "Mesh") implanted during a hernia surgery.
14. In 2012, Plaintiff suffered from complications.
15. On or around August 2, 2013 it was determined that the Plaintiff had developed recurrent hernia, cellulitis, and abscess of the hernia from the previous mesh implantation.
16. Plaintiff underwent laparoscopic surgery on or around August 29, 2013.
17. On or around November 11, 2013 Plaintiff began experiencing acute symptoms and was hospitalized.

18. In January 2014 and continuing through January 30, 2014 Plaintiff was hospitalized and had to have the abscess draining and abdomen resection.
19. Plaintiff has and will continue to suffer from serious adverse health consequences due to the complications of the initial mesh implantation.
20. The first mesh used in contemporary hernia surgery was a heavyweight polypropylene mesh that was invented in the 1960's and has remained virtually unchanged since then.
21. Defendants' mesh product came on the market and was advertised as a safe, efficient and effective solution for hernia repair having over twelve years of clinical success in minimizing tissue attachment.
22. Defendants' marketed the mesh as being 60% lighter than other brands and the soft, compliant nature made it easy to handle and insert laparoscopic.
23. Defendants' marketed the mesh as an proven effective method that eliminated the need for permanent transfixed sutures.
24. Defendants' mesh product was marketed as producing reproducible results with bragging rights of award-winning innovative design that streamlines laparoscopic procedures that save time and reduce procedure variability up to 84% and reduced patient trauma.
25. On or around June 2, 2014 the FDA posted a Class 2 Device Recall for Composix" LP with Echo PS" 6x8 Reorder Number: 0144680, a product indicated for use in the reconstruction of soft tissue deficiencies, such as the repair of hernias.
26. The recall, Recall Number Z-1684-2014 was posted on June 2, 2014.
27. The manufacturer reason for recall was due to the pouch holding the "sterile" inflation assembly had an inflation adapter with a weak seal that may have been open and contaminated the product compromising the sterility.

28. Without compromised sterility, when implanted, this heavyweight mesh is truly a foreign body and causes an inflammatory response which increases due to the high resistance.
29. Its rupture-threshold is, at a minimum, seven times the strength necessary to protect against the normal occurring injury and its pores are much smaller than would be deemed appropriate. These characteristics exacerbate the development of inflammatory responses that form with the introduction of a foreign body. When the foreign body is introduced and the inflammation becomes increasingly worse, the polypropylene mesh shrinks and becomes rigid and sharp.
30. The characteristics of this type of mesh are in contrast of anything physiological.
31. There is no part of the human body that is comparable to this heavyweight mesh.
32. The inflammation caused by the mesh never goes away.
33. The characteristics of the mesh were and continue to be known to the Defendants and they create an increased risk of unreasonable and dangerous injuries and side effects that have severe and lasting adverse health consequences.
34. The products have numerous defects that create a high risk of unreasonable and dangerous injuries and side effects with severe permanent adverse health consequences. These defects include, but are not limited to:
    a. The material is not inert and therefore reacts to human tissues and/or other naturally occurring human bodily contents adversely affecting patient health.
    b. The mesh material harbors infections that adversely affect human tissues and patient health.
    c. The Products and the mesh migrate from the location of their implantation, adversely affecting tissues and patient health.

d. The mesh material abrades tissues adversely affecting patient health.

e. The products regularly fail to perform the purpose of their implantation such that the patient requires removal of the device and repeated treatment and surgery.

f. Due to their various defects, the Products and the mesh regularly cause significant injury to patients such that the Products must be removed, resulting in additional surgery.

g. The Products and the mesh become embedded in human tissue over time such that if it needs to be removed due to its various defects, the removal causes damage to the organs and tissues, adversely affecting patient health.

h. The Products are defective in shape, composition, weight, physical, chemical and mechanical properties and is inappropriately engineered for use in the human body.

i. The Products contained a pouch holding the "sterile" inflation assembly which had an inflation adapter with a weak seal that may have been open and contaminated the product, compromising sterility.

35. Because of its numerous defects, the Product creates an unreasonable risk of injury and other adverse health consequences for patients.

36. Prior to the time that the Products were implanted into Plaintiff, Defendants were aware of numerous defects in the Products, including, but not limited to, the defects and unreasonable risks identified in their Products, Defendants developed, designed, manufactured, labeled, packaged, distributed, marketed, supplied, advertised, sold and otherwise engaged in all activities that are part and parcel of the sale and distribution of the Products with the intent that they would be implanted in patients. Defendants were

aware that implanting the Products in patients was likely to cause injury and harm to the patients, like Plaintiff, into whom the Products were implanted. Alternatively, Defendants failed to exercise reasonable care in determining the risks and potential adverse consequences of implanting the Products into patients.

37. Upon information and belief, Defendants were in control of designing, assembling, manufacturing, marketing, testing, distributing, packaging, labeling, processing, supplying, marketing, advertising, promoting, selling and issuing of Products warnings and related information with respect to its Products.

38. Defendants' Product was utilized and implanted into Plaintiff in a manner that was intended or reasonably foreseeable to Defendants.

39. The Product implanted into Plaintiff was in the same or substantially similar condition as when they left the possession of Defendants, and in the condition directed by Defendants.

40. The Product implanted in Plaintiff subject to recall number Z-1684-2014.

41. Even though Defendants have known or should have known that the Products created a foreseeable, unreasonable risks of harm to patients who they were implanted, Defendants continued to market and sell the Products in the United States, including South Carolina.

42. Defendants failed to provide adequate warning or information about the risks that the Products cause an unreasonably high rate of harm to physicians implant the Products, or patients implanted with the Products.

43. Despite the knowledge of the defects of the use of polypropylene mesh, Defendants manufactured, marketed and distributed the mesh with the intent that it would be implanted in patients. Defendants knew that implanting the mesh into patients such as Plaintiff was likely to cause injury and harm to the patients into whom the mesh was

implanted. Alternatively, Defendants failed to exercise reasonable care in determining the risk and potential adverse consequences of implanting the mesh into patients such as Plaintiff.

44. Defendants made public statements in the form of written product descriptions, product labels, promotional materials and other communications that asserted that implanting the mesh was safe. These statements were made intending that both medical professionals and the general public would rely on them and that the public would pay for the mesh and that medical professionals would insert the mesh into their patients. At the time that the Defendants made these statements they knew or should have known them to be inaccurate.

45. Prior to Plaintiff suffering the injuries described herein, Defendants were or should have been aware of numerous bodily injuries caused by the mesh implantation. These injuries include, but are not limited to, an unreasonably high rate of erosion, infection, extrusion, perforation and chronic pain.

46. The Defendants are global healthcare leaders dedicated to advancing the delivery of Healthcare by creating innovative products and services focusing on products in the three areas of Hernia repair, Vascular, Urology, and Oncology.

47. Regardless that the Defendants knew or should have known that the mesh creates a foreseeable and unreasonable risk of harm to those into whom it is implanted, the Defendants continues to market the Mesh.

48. Defendants have never provided adequate warnings or information concerning the risks that the mesh causes an unreasonably high rate of erosion, infection, extrusion,

perforation, chronic pain and/or abscess to the doctors who implant the product or to the patients into whom the product is implanted.

49. Defendants placed mesh subject to recall number Z-1684-2014 into the stream of commerce.

50. Plaintiff was injured by the recalled mesh.

51. The mesh was implanted into Plaintiff in the same or in a substantially similar condition as it was when it left possession of Defendants and in the condition and manner which was directed by and expected by the Defendants.

CAUSES OF ACTION

COUNT I

STRICT LIABILITY

52. Plaintiffs reallege each and every allegation of this Complaint as if set forth fully herein.

53. At all times relevant to this action, Defendants were responsible for the design, development, processing, manufacturing, testing, packaging, advertising, promoting, marketing, distributing, labeling and/or selling of the Mesh and placing the Mesh into the stream of commerce.

54. At all times material to this action, Mesh was expected to reach, and did reach, consumers in the State of South Carolina and throughout the United States, including Plaintiff and Plaintiff's physicians, without any substantial change in the condition in which the product was sold.

55. At all relevant times, the Defendants intended for Mesh to be implanted into members of the general public, including Plaintiff, and knew or should have known that the Mesh would be surgically implanted into members of the general public including Plaintiff.

56. The implantation of Defendant's Mesh into Plaintiff was done in a manner reasonably foreseeable or intended by the Defendants.

57. At all relevant times to this action, Defendants had a duty to the Plaintiff and the Plaintiff's physicians to design, development, process, manufacture, test, package, advertise, promote, market, distribute, label and/or sell the Mesh that is reasonably safe, suitable, and fit for its intended or reasonably foreseeable uses.

58. At all times material to this action Mesh was designed, developed, processed, manufactured, tested, packaged, advertised, promoted, marketed, distributed, labeled and/or sold in a defective and unreasonably dangerous condition at the time it was placed in the stream of commerce in ways which include, but are not limited to, one or more of the following circumstances:

    a. When placed in the stream of commerce, Defendants' Mesh contained manufacturing and design defects, which rendered the product unreasonably dangerous for its intended use;

    b. The Mesh's manufacturing defects occurred while the product was in the possession and control of Defendants;

    c. The Mesh's manufacturing defects existed before it left the control of the Defendants;

    d. The Products were insufficiently tested;

    e. The Products caused harmful side effects that outweighed any potential utility;

f. The Products were not accompanied by adequate instruction, and/or warnings to fully appraise consumers, including Plaintiff, of the full nature and extent of the risks and side effects associated with its use; and

g. The Product contained a pouch holding the "sterile" inflation assembly which had an inflation adapter with a weak seal that may have been open and contaminated the product, compromising sterility.

59. At the time the Mesh left the control of the Defendants, there were practical, feasible and safer alternative designs that would have prevented and/or significantly reduced the risk of Plaintiff's injuries without impairing the reasonably anticipated or intended function of the Mesh. These safer alternative designs were economically and technologically feasible and would have prevented or significantly reduced the risk of Plaintiff's injuries without substantially impairing the Product's utility.

60. The Defendants' Mesh is inherently dangerous and defective, unfit and unsafe for its intended and reasonably foreseeable uses, and does not meet or perform to the expectations of patients and their healthcare providers.

61. The Mesh creates risks to the health and safety of the patients that are far more significant and devastating than the risks posed by other products and procedures available to treat the corresponding medical conditions, and that outweigh the utility of the Mesh.

62. Defendants have intentionally and recklessly designed, manufactured, marketed, labeled, sold and distributed the Mesh with wanton and willful and/or conscious disregard for the rights and health of Plaintiff and others, and with malice, placing their economic interests above the safety of the Plaintiff others.

63. As a direct and proximate result of the Defendants' wrongful conduct including design, manufacture, labeling, marketing, sale, and distribution of the Mesh, Plaintiff has sustained and will continue to sustain severe and permanent injuries including but not limited to pain, suffering, disability, impairment, loss of enjoyment of life, as well as economic losses.

WHEREFORE, Plaintiffs demand judgment against Defendants in a sum in excess of $75,000, for costs incurred, for attorney's fees, and for such other and further relief as the Court deems equitable, just and proper.

COUNT II

PRODUCTS LIABILITY FAILURE TO WARN

64. Plaintiffs reallege each and every allegation of this Complaint as if fully set forth herein.

65. At all times relevant to this action, Defendants were responsible for the design, development, processing, manufacturing, testing, packaging, advertising, promoting, marketing, distributing, labeling and/or selling of the Mesh and placing the Mesh into the stream of commerce.

66. Defendants have engaged in the business of selling, distributing, supplying, manufacturing, marketing, and/or promoting Mesh and through that conduct have knowingly and intentionally placed Mesh into the stream commerce with full knowledge that it would be surgically implanted in consumers such as Plaintiff.

67. Defendants did in fact sell, distribute, supply, manufacture, and/or promote Mesh to Plaintiff and to his surgeons. Additionally, Defendants expected the Mesh that they were selling, distributing, supplying manufacturing, and/or promoting to reach – and Mesh did

in fact reach – surgeons and consumers, including Plaintiff and his surgeons, without any substantial change in the condition of the product from when it was initially distributed by Defendants.

68. At all times herein mentioned the aforesaid product was defective and unsafe in manufacture such that it was unreasonably dangerous to the user, and was so at the time it was distributed by Defendants and implanted into Plaintiff. The defective condition of the Mesh was due in part to the fact that it was not accompanied by proper warnings regarding the possible side effect of developing long-term and potentially irreversible peripheral neuropathy as a result of its use.

69. This defect caused serious injury to Plaintiff and his surgeons, who used Mesh in its intended and foreseeable manner.

70. At all times herein mentioned, Defendants had a duty to properly design, manufacture, test, inspect, package, label, distribute, market, examine, maintain supply, provide proper warnings, and take such steps to assure that the product did not cause users to suffer from unreasonable and dangerous side effects.

71. Defendants so negligently and recklessly labeled, distributed, and promoted the aforesaid product and failed to warn that it was dangerous and unsafe for the use and purpose for which it was intended.

72. Defendants negligently and recklessly failed to warn of the nature and scope of the side effects associated with Mesh, namely irreversible migration and perforation of vital organs as well as the following:

    a. The warnings and/or instructions that were given by Defendants failed to properly warn and instruct users, including Plaintiff and Plaintiff's physicians, of the risks

associated with Mesh including, but not limited to pain, hardening, migration, perforation, infection, chronic and severe pain, over-engineered mesh and resulting complications or additional surgery;

b. The Mesh was further defective due to inadequate post-marketing warning, labeling, or instruction because, after Defendants knew or should have known of the high risk of serious bodily harm, Defendants knew or should have known of the high risk of serious bodily harm, Defendants failed to provide an adequate warning to persons such as Plaintiff and Plaintiff's physicians of the risks associated with its use and the potential to cause serious injury; and

c. The Products contained a pouch holding the "sterile" inflation assembly which had an inflation adapter with a weak seal that may have been open and contaminated the product, compromising sterility.

73. Defendants were aware of the probable consequences of the aforesaid conduct. Despite the fact that Defendants knew or should have known that Mesh caused serious injuries, they failed to exercise reasonable care to warn of the dangerous side effect of migration and organ perforation from Mesh, even though this side effect was known or reasonably scientifically knowable at the time of distribution. Defendants willfully and deliberately failed to avoid the consequences associated with their failure to warn, and in doing so, Defendants acted with a conscious disregard for the safety of Plaintiff.

74. Plaintiff could not have discovered any defect in the subject product through the exercise of reasonable care.

75. Plaintiff reasonably relied upon the skill, superior knowledge, and judgment of Defendants.

76. Had Defendants properly disclosed the risks associated with Mesh, Plaintiff would have avoided the risk of irreversible peripheral neuropathy by not using Mesh.

77. As a direct and proximate result of the Defendants' wrongful conduct including design, manufacture, labeling, marketing, sale, and distribution of the Mesh, Plaintiff has sustained and will continue to sustain severe and permanent injuries including but not limited to pain, suffering, disability, impairment, loss of enjoyment of life, as well as economic losses.

78. Defendants, as manufacturer and/or distributor of Composix L/P Mesh are held to the level of knowledge of an expert in the field.

WHEREFORE, Plaintiffs demand judgment against Defendants in a sum in excess of $75,000, for costs incurred, for attorney's fees, and for such other and further relief as the Court deems equitable, just and proper.

COUNT III

NEGLIGENCE

79. Plaintiffs reallege each and every allegation of the Complaint as if fully set forth herein.

80. At all relevant times Defendants had a duty to exercise reasonable care in the design, manufacture, marketing, labeling, advertising, supply, promotion, packaging, sale and/or distribution of the Mesh, including a duty to assure that the Mesh did not cause unreasonable, dangerous harm and personal injuries to users.

81. Defendants failed to exercise ordinary care in the design, manufacture, marketing, labeling, advertising, supply, promotion, packaging sale and/or distribution, quality

assurance, quality control, and distribution of the Mesh in that Defendants knew or should have known that the Mesh created a high and unreasonable risk of harm and personal injuries.

82. Defendants' negligence included, but was not limited to, the following acts and omissions:

a. Manufacturing, producing, promoting, formulating, creating, developing, designing, selling and distributing the Mesh without thoroughly and adequately testing it;

b. Not conducting sufficient studies and sufficient studies and tests to determine whether or not the Mesh was safe for its intended use;

c. Failing to warn Plaintiff and healthcare providers, including Plaintiff's physician, the general public or the FDA, of the risks associated with its use;

d. Promoting and recommending the use of the Mesh while suppressing and concealing the known dangers inherent in the use of the Mesh;

e. Suppressing, concealing, omitting, and/or misrepresenting information to Plaintiff, the medical community and/or the FDA concerning the severity of risks and the dangers inherent in the intended use of the Mesh;

f. Failing to conduct adequate testing to determine the safety of the Mesh;

g. Failing to provide a safely manufactured product, healthcare providers and patients, including Plaintiff of the defective nature of the Mesh; and

h. Distributing the Product's sterile inflation assembly in a pouch with a weak seal that may have been open and contaminated the Product and compromising its sterility.

83. Defendants breached their duty of reasonable care to Plaintiff by defectively designing, manufacturing, and/or negligently failing to warn of these defects with the device, thereby causing Plaintiff's injuries and damages.

84. Defendants failed to exercise ordinary and reasonable care in designing, manufacturing, testing, marketing, labeling, packaging, selling and/or distributing Mesh and Defendants negligently failed to provide adequate warnings and instructions to Plaintiff and his surgeons.

85. As a direct and proximate result of the Defendants' wrongful conduct including design, manufacture, labeling, marketing, sale, and distribution of the Mesh, Plaintiff has sustained and will continue to sustain severe and permanent injuries including but not limited to pain, suffering, disability, impairment, loss of enjoyment of life, as well as economic losses.

WHEREFORE, Plaintiffs demand judgment against Defendants in a sum in excess of $75,000, for costs incurred, for attorney's fees, and for such other and further relief as the Court deems equitable, just and proper.

COUNT IV

BREACH OF EXPRESS WARRANTY

86. Plaintiffs reallege each and every allegation of the Complaint as if fully set forth herein.

87. At all times relevant to this action, Defendants were responsible for the design, development, processing, manufacturing, testing, packaging, advertising, promoting,

marketing, distributing, labeling and/or selling of the Mesh and placing the Mesh into the stream of commerce.

88. At all relevant and material times, Defendants manufactured, distributed, marketed, advertised, promoted and sold the Mesh product.

89. At all relevant times Defendants intended that their Mesh be used in the manner that Plaintiff's physician(s) and Plaintiff in fact used the product and Defendants expressly warranted to Plaintiff and Plaintiff's physicians that the mesh was safe, effective, fit, was adequately tested and proper for intended or foreseeable use by physicians and ultimate consumers.

90. Before Plaintiff was implanted and during the period in which he was implanted with Mesh, Defendants expressly warranted Mesh was safe.

91. In allowing the implantation of the Mesh, Plaintiff and his physician(s) relied on the skill, judgment, representations, and express warranties of Defendants. These warranties and representations were false in that the Mesh was not safe and was unfit for the uses for which it was intended or other reasonably foreseeable use.

92. Neither Plaintiff nor his physician had knowledge of the falsity or incompleteness of Defendants' representations concerning mesh when Plaintiff's physician used mesh as it was researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold and otherwise released into the stream of commerce by Defendants. Plaintiff and his physicians justifiably and detrimentally relied on the warranties and representations of Defendants in the use of Mesh.

93. Defendants were under a duty to disclose the defective and unsafe nature of Mesh to physicians and consumers, such as Plaintiff. Defendants had sole access to material facts concerning the defects, and Defendants knew that physicians and users, such as Plaintiff, could not have reasonably discovered such defects.

94. By the conduct alleged, Defendants, their agents and employees expressly warranted to Plaintiff and Plaintiff's physician that the products were merchantable and fit for the purpose intended.

95. This warranty was breached because Mesh is not safe, as Defendants had represented, and Plaintiff was injured as a result of this breach.

96. The Mesh implanted in Plaintiff failed to function as intended and as represented by Defendants because it did not relieve the symptoms or otherwise alleviate the medical problems that it was intended to cure. Instead, the mesh caused Plaintiff to suffer infection or inflammation, tissue abrasion, migration, organ perforation, cellulitis, reoccurring abscesses, reoccurring hernias, and other severe adverse health consequences. Accordingly, the mesh was not fit for the ordinary purpose for which such goods are used and failed to conform to the affirmations or representations of Defendants. Further, Defendants knew that the mesh was to be used for the particular purpose for which it was used on Plaintiff and knew that the expertise of Defendants was relied on to furnish suitable goods.

97. As a direct and proximate result of the Defendants' wrongful conduct including design, manufacture, labeling, marketing, sale, and distribution of the Mesh, Plaintiff has sustained and will continue to sustain severe and permanent injuries

including but not limited to pain, suffering, disability, impairment, loss of enjoyment of life, as well as economic losses.

WHEREFORE, Plaintiffs demand judgment against Defendants in a sum in excess of $75,000, for costs incurred, for attorney's fees, and for such other and further relief as the Court deems equitable, just and proper.

COUNT V

BREACH OF IMPLIED WARRANTY

98. Plaintiffs reallege each and every paragraph of this Complaint as if fully set forth herein.

99. At all times relevant to this action, Defendants were responsible for the design, development, processing, manufacturing, testing, packaging, advertising, promoting, marketing, distributing, labeling and/or selling of the Mesh and placing the Mesh into the stream of commerce.

100. At all relevant and material times, Defendants manufactured, distributed, marketed, advertised, promoted and sold the Mesh product.

101. Prior to the time that the aforementioned product was used by Plaintiff, Defendants impliedly warranted to Plaintiff and/or Plaintiffs' physicians that said products were of merchantable quality, were properly manufactured and/or packaged and/or labeled and were safe, effective and fit for the use for which they were intended or for other known or foreseeable uses.

102. Plaintiff was and is unskilled in the research, design, and manufacture, labeling and sale of the aforementioned products and reasonably relied entirely on the skill, judgment and implied warranties of the Defendants, and each of them, in

being prescribed, purchasing, consuming and otherwise utilizing the aforementioned products.

103. The aforementioned product was not properly manufactured and/or packaged and/or labeled, did not conform to or perform in accordance with design and manufacturing specifications and was not safe or effective for its intended, known or foreseeable uses nor of merchantable quality, as warranted by Defendants, and each of them.

104. As a result of the aforementioned breach of their implied warranties by the Defendants, Plaintiff, after being prescribed and/or after purchasing and/or consuming and/or otherwise utilizing Defendants' non-conforming, defective products, suffered injuries and sustained damages compensable under the laws of this State as alleged herein.

105. Plaintiff individually, and through his physicians reasonably relied upon the skill, superior knowledge, and judgment of the Defendants.

106. As a direct and proximate result of the Defendants' wrongful conduct including design, manufacture, labeling, marketing, sale, and distribution of the Mesh, Plaintiff has sustained and will continue to sustain severe and permanent injuries including but not limited to pain, suffering, disability, impairment, loss of enjoyment of life, as well as economic losses.

WHEREFORE, Plaintiffs demand judgment against Defendants in a sum in excess of $75,000, for costs incurred, for attorney's fees, and for such other and further relief as the Court deems equitable, just and proper.

COUNT VI

FRAUD

107. Plaintiffs reallege all prior paragraphs of the Complaint as if set out here in full.

108. At all times relevant to this action, Defendants were responsible for the design, development, processing, manufacturing, testing, packaging, advertising, promoting, marketing, distributing, labeling and/or selling of the Mesh and placing the Mesh into the stream of commerce.

109. Defendants misrepresented to Plaintiff, his prescribing physicians, and the healthcare industry the safety and effectiveness of Mesh and/or fraudulently, intentionally, and/or negligently concealed material information, including adverse information, regarding the safety and effectiveness of Mesh.

110. These misrepresentations and/or active concealment alleged were perpetuated directly and/or indirectly by Defendants.

111. Defendants knew or should have known that these representations were false, and they made the representations with the intent or purpose of deceiving Plaintiff, his prescribing physicians, and the healthcare industry.

112. Defendants made these false representations with the intent or purpose that Plaintiff, his prescribing physicians, and the healthcare industry would rely on them, leading to the use of Mesh by Plaintiff as well as the general public.

113. At all times herein mentioned, neither Plaintiff nor his physicians were aware of the falsity or incompleteness of the statements of the statements being made by Defendants and believed them to be true. Had they been aware of said facts, his

physicians would not have prescribed and Plaintiff would not have utilized the subject product.

114. Plaintiff, his prescribing physicians, and the healthcare industry justifiably relied on and/or were induced by Defendants' misrepresentations and/or active concealment and relied on the absence of information regarding the dangers of Mesh that Defendants did suppress, conceal, or fail to disclose to Plaintiff's detriment. Plaintiff justifiably relied, directly or indirectly, on Defendants' misrepresentation and/or active concealment regarding the true dangers of Mesh. Based on the nature of the physician-patient relationship, Defendants had reason to expect that Plaintiff would indirectly rely on Defendants' misrepresentations and/or active concealment.

115. Defendants had a post-sale duty to warn Plaintiff, his prescribing physicians, and the general public about the potential risks and complications associated with Mesh in a timely manner.

116. Defendants made the representations and actively concealed information about the defects and dangers of Mesh with the intent and specific desire that Plaintiff's prescribing physicians and the consuming public would rely on such information, or the absence of information, in selecting Mesh as treatment.

117. As a result of the concealment and/or suppression of the material facts set forth above, Plaintiff ingested the Mesh and suffered injuries as set forth herein.

118. As a direct and proximate result of the Defendants' wrongful conduct including design, manufacture, labeling, marketing, sale, and distribution of the Mesh, Plaintiff has sustained and will continue to sustain severe and permanent injuries

including but not limited to pain, suffering, disability, impairment, loss of enjoyment of life, as well as economic losses.

WHEREFORE, Plaintiffs demand judgment against Defendants in a sum in excess of $75,000, for costs incurred, for attorney's fees, and for such other and further relief as the Court deems equitable, just and proper.

COUNT VII

CONSTRUCTIVE FRAUD

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

120. Defendants committed constructive fraud by knowingly making false and material representations with reckless disregard for the truth or falsity of such material representations and with the intent Plaintiff and Plaintiff's health care professionals and consumers would rely on those material representations.

121. Plaintiff and Plaintiff's health care professionals were unaware of the falsity of Defendant's material representations. Plaintiff was injured as a direct and proximate result of the reliance on Defendants' material representations.

122. Additionally, Defendants knowingly omitted material information and remained silent despite the fact that they had a duty to inform Plaintiff, Plaintiff's health care professionals and the general public of the inaccuracy of these misrepresentations. This omission constitutes a positive misrepresentation of material fact with the intent that Plaintiff and Plaintiff's health care professionals would rely on Defendant's misrepresentations. In fact, Plaintiff and Plaintiff's health care professionals would rely on Defendants' misrepresentations. In fact, Plaintiff and Plaintiff's health care

professionals acted with actual and justifiable reliance on Defendants' representations and Plaintiffs were injured as a result.

123. At all times herein mentioned, Defendants had a duty to Plaintiff, Plaintiffs prescribing health care and the general public to accurately inform them of the risks associated with Mesh and the risk of developing infection, migration, organ perforation and other life threatening injuries because Defendants as the manufacturer of Mesh were in a position of super knowledge and judgment regarding any potential risks associated with the Mesh.

124. Defendants committed constructive fraud by breaching one or more legal or equitable duties owed to Plaintiff related to the use of Mesh because of their propensity to deceive others or constitute an injury to public policy.

125. In breaching their duties to Plaintiff, Defendants used their position of trust as the manufacturer of the Mesh to increase sales of the medical device at the expense of informing Plaintiff that, by being implanted with the Mesh, he was placing himself at a significantly increased risk of developing life threatening infections, migration, organ perforation, organ failure and other serious injuries.

126. As a direct and proximate result of Defendants' carelessness, negligence and fraud, Plaintiff suffered infection or inflammation, tissue abrasion, migration, organ perforation, cellulitis, reoccurring abscesses, reoccurring hernias, and other severe adverse health consequences. Plaintiff has endured pain and suffering, has suffered economic loss (including incurring significant expenses for medical care and treatment) and will continue to incur such expenses in the future. Plaintiff seeks actual and punitive damages from Defendants as alleged herein.

WHEREFORE, Plaintiffs demand judgment against Defendants in a sum in excess of $75,000, for costs incurred, for attorney's fees, and for such other and further relief as the Court deems equitable, just and proper.

COUNT VIII

NEGLIGENT MISREPRESENTATION

127. Plaintiffs reallege all prior paragraphs of the Complaint as if set out here in full.

128. At all times relevant to this action, Defendants were responsible for the design, development, processing, manufacturing, testing, packaging, advertising, promoting, marketing, distributing, labeling and/or selling of the Mesh and placing the Mesh into the stream of commerce.

129. Defendants negligently and/or recklessly misrepresented to Plaintiff, his prescribing physicians, and the healthcare industry the safety and effectiveness of Mesh and/or recklessly and/or negligently concealed material information, including adverse information, regarding the safety, effectiveness, and dangers posed by Mesh.

130. Defendants made reckless or negligent misrepresentations and negligently or recklessly concealed information when Defendants knew, or should have known, that Mesh had defects, dangers, and characteristics that were other than what Defendants had represented to Plaintiff, Plaintiff's physician(s) and the healthcare industry generally. Specifically, Defendants negligently or recklessly concealed from Plaintiff, his prescribing physicians, the health care industry, and the consuming public.

131. These negligent or reckless misrepresentations and/or negligent or reckless to disclose were perpetuated directly and/or indirectly by Defendants.

132. Defendants should have known through the exercise of due care leading to the deception of Plaintiff, his prescribing physicians, and the healthcare industry.

133. Defendants made these false representations without the exercise of due care knowing that it was reasonable and foreseeable that Plaintiff, his prescribing physicians, and the healthcare industry would rely on them, leading to the use of Mesh by Plaintiff as well as the general public.

134. At all times herein mentioned neither Plaintiff nor his physicians were aware of the falsity or incompleteness of the statements being made by Defendants and believed them to be true. Had they been aware of said facts, his physicians would not have implanted the Plaintiff with the Mesh.

135. Plaintiff justifiably relied on and/or was induced by Defendants' negligent or reckless misrepresentations and/or negligent or reckless failure to disclose the dangers of Mesh and relied on the absence of information regarding the dangers of Mesh which Defendants negligently or recklessly suppressed, concealed, or failed to disclose to Plaintiff's detriment.

136. Defendants had a post-sale duty to warn Plaintiff, his prescribing physicians, and the general public about the potential risks and complications associated with Mesh in a timely manner.

137. Defendants made the representations and actively concealed information about the defects and dangers of Mesh with the absence of due care such that Plaintiff's prescribing and the consuming public would rely on such information, or the absence of information, in selecting Mesh as a treatment.

138. As a result of Defendant's negligent misrepresentation, Plaintiff was implanted with the Mesh and suffered injuries as set forth herein.

139. As a direct and proximate result of the Defendants' wrongful conduct including design, manufacture, labeling, marketing, sale, and distribution of the Mesh, Plaintiff has sustained and will continue to sustain severe and permanent injuries including but not limited to pain, suffering, disability, impairment, loss of enjoyment of life, as well as economic losses.

WHEREFORE, Plaintiffs demand judgment against Defendants in a sum in excess of $75,000, for costs incurred, for attorney's fees, and for such other and further relief as the Court deems equitable, just and proper.

COUNT IX

UNJUST ENRICHMENT

140. Plaintiff incorporates by this reference the allegations set forth in the paragraphs above as if fully set forth herein.

141. At all times relevant to this action, Defendants were responsible for the design, development, processing, manufacturing, testing, packaging, advertising, promoting, marketing, distributing, labeling and/or selling of the Mesh and placing the Mesh into the stream of commerce.

142. Plaintiff conferred a benefit on Defendants by purchasing Mesh.

143. Plaintiff, however, did not receive a safe and effective medical device for which Plaintiff paid. It would be inequitable for Defendants to retain this money because Plaintiff did not, in fact, receive a safe and efficacious medical device.

144. By virtue of the conscious wrongdoing alleged herein, Defendants have been unjustly enriched at the expense of Plaintiff who hereby seeks the disgorgement and restitution of Defendants' wrongful profits, revenue and benefits to the extent and in the amount deemed appropriate by the Court and for such other relief as the Court deems just and proper to remedy Defendants' unjust enrichment.

145. As a direct and proximate result of Defendants' carelessness and negligence, Plaintiff suffered severe and permanent physical and emotional injuries including but not limited to infection, migration, organ perforation and organ damage. Plaintiff has endured pain and suffering, has suffered economic loss (including incurring significant expenses for medical care and treatment) and will continue to incur such expenses in the future. Plaintiff seeks actual and punitive damages from Defendants as alleged herein.

WHEREFORE, Plaintiffs demand judgment against Defendants in a sum in excess of $75,000, for costs incurred, for attorney's fees, and for such other and further relief as the Court deems equitable, just and proper.

COUNT X

S.C. UNFAIR TRADE PRACTICES ACT

146. Plaintiffs reallege each and every allegation of this Complaint as if set forth fully herein.

147. At all times relevant to this action, Defendants were responsible for the design, development, processing, manufacturing, testing, packaging advertising, promoting,

marketing, distributing, labeling and/or selling of the Mesh and placing the Mesh into the stream of commerce.

148. As a result of the Defendants' actions and inactions, misrepresentations, representations and concealment related to Mesh, Plaintiff suffered an ascertainable loss of money.

149. Defendants' actions and inactions, misrepresentations, representations and concealment related to Mesh were unfair deceptive methods and acts under S.C.Ann. §39-5-20.

150. Defendants' actions and inactions, misrepresentations, representations and concealment related to Mesh were willful and Defendants should have known this conduct was a violation of S.C.Ann.§39-5-20.

151. Defendants' actions and inactions, misrepresentations, representations and concealment related to Mesh were offensive to public policy, immoral, unethical and oppressive.

152. Defendants' actions and inactions, misrepresentations, representations and concealment related to Mesh had the capacity, effect and tendency to deceive.

153. As a direct and proximate cause of Defendants deceptive methods, Plaintiff suffered an ascertainable loss of money.

154. Defendants utilize these same unfair deceptive methods in marketing, distributing and selling Mesh throughout the country and South Carolina and upon information and belief, their actions, inactions, misrepresentations, representations and concealments related to the Mesh have caused Plaintiff as well as other citizens of South Carolina ascertainable losses of money and thus have the potential for repetition.

WHEREFORE, Plaintiffs demand judgment against Defendants in a sum in excess of $75,000, for costs incurred, for attorney's fees, and for such other and further relief as the Court deems equitable, just and proper.

COUNT XI

LOSS OF CONSORTIUM

155. Plaintiffs reallege each and every allegation of this Complaint as if set forth fully herein.

156. At all times relevant to this action, Defendants were responsible for the design, development, processing, manufacturing, testing, packaging advertising, promoting, marketing, distributing, labeling and/or selling of the Mesh and placing the Mesh into the stream of commerce.

157. As a result of the aforementioned injuries sustained by Plaintiff, Plaintiff's Spouse lost the care, comfort, society, aid and suffered damages to the marital relationship.

158. The loss of consortium sustained by Plaintiff's Spouse was the direct and proximate result of the Defendants actions and omissions of Defendants as fully described herein.

159. Defendants utilize these same unfair deceptive methods in marketing, distributing and selling Mesh throughout the country and South Carolina and upon information and belief, their actions, inactions, misrepresentations, representations and concealments related to the Mesh have caused Plaintiff as well as other citizens of South Carolina ascertainable losses of money and thus have the potential for repetition.

WHEREFORE, Plaintiffs demand judgment against Defendants in a sum in excess of $75,000, for costs incurred, for attorney's fees, and for such other and further relief as the Court deems equitable, just and proper.

COUNT XII

PUNITIVE DAMAGES

160. Plaintiffs incorporate by reference the allegations set forth in the paragraphs above as if fully set forth herein.

161. At all times material hereto, Defendants knew or should have known that Mesh was inherently dangerous with respect to the risk of infection, migration, organ perforation, organ damage and other serious life threatening injuries.

162. At all times material hereto, Defendants attempted to misrepresent and did misrepresent the facts concerning the safety and efficacy of Mesh.

163. Defendants' misrepresentations included knowingly withholding material information from the medical community and the public, including Plaintiff, concerning the safety of Mesh.

164. At all times material hereto, Defendants knew and recklessly disregarded the fact that the Mesh causes infection, migration, organ perforation, organ damage and other serious life threatening injuries.

165. Notwithstanding the foregoing, Defendants continued to aggressively market Mesh to consumers, including Plaintiff, without disclosing the aforesaid side effects.

166. Defendants knew of the lack of warnings regarding the risk of infection, migration, organ perforation, organ damage and other serious life threatening injuries, but Defendants intentionally concealed and/or recklessly failed to disclose that risk and

continued to manufacture, package, label, promote, market, distribute and sell Mesh without said warnings so as to maximize sales and profits at the expense of the health and safety of the public, including Plaintiff, in conscious and/or negligent disregard of the foreseeable harm caused by Mesh.

167. Defendants' intentional and/or reckless failure to disclose information deprived Plaintiff of necessary information to enable him to weigh the true risks of using Mesh against its benefits.

168. Had Defendants fulfilled their obligations to health care professionals and consumers, including Plaintiff, by accurately providing the risks and efficacy of Mesh, Defendants would have lost revenue and market share.

169. As a direct and proximate result of Defendants' carelessness and negligence, Plaintiffs suffered severe and permanent physical and emotional injuries including but not limited to infection or inflammation, tissue abrasion, migration, organ perforation, cellulitis, reoccurring abscesses, reoccurring hernias, and other severe adverse health consequences. Plaintiff endured pain and suffering, has suffered economic loss (including incurring significant expenses for medical care and treatment) and will continue to incur such expenses in the future. Plaintiffs seek actual and punitive damages from Defendants as alleged herein.

170. Defendants' aforesaid conduct was committed with knowing, conscious, careless, reckless, willful, wanton and deliberate disregard for the rights and safety of consumers, including Plaintiff, thereby entitling Plaintiff to punitive damages in an amount appropriate to punish Defendants and deter them from similar conduct in the future.

WHEREFOREPlaintiffs demand judgment against Defendants in a sum in excess of $75,000, for costs incurred, for attorney's fees, and for such other and further relief as the Court deems equitable, just and proper.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs demand judgment against Defendants individually, jointly, severally and requests compensatory damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems just and proper as well as:

1. For general (non-economic) and special (economic) damages in a sum in excess of the jurisdictional minimum of this Court;
2. For medical, incidental, and hospital expenses according to proof;
3. For pre-judgment and post-judgment interest as provided by law;
4. For full refund of all purchase costs Plaintiff paid for Mesh;
5. For compensatory damages in excess of the jurisdictional minimum of this Court;
6. For consequential damages in excess of the jurisdictional minimum of this Court;
7. For punitive damages in an amount in excess of any jurisdictional minimum of this Court and in an amount sufficient to impress upon Defendants the seriousness of their conduct and to deter similar conduct in the future;
8. For attorneys' fees, expenses, and costs of this action; and
9. For such further relief as this Court deems necessary, just, and proper.

DEMAND FOR JURY TRIAL

Plaintiffs demand a trial by jury as to all issues.

BY: s/Lynn Seithel

Lynn Seithel
S.C. District Bar 8017
SEITHEL LAW, LLC
Post Office Box 1929
Charleston, South Carolina 29457
(843) 557-1699 direct dial
(800) 818-0433 (fax)
Lynn@SeithelLaw.com
Attorney for Plaintiff

Charleston, South Carolina

Dated: January 24, 2017