UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: DAVOL, INC./C.R. BARD, INC., POLYPROPYLENE HERNIA MESH PRODUCTS LIABILITY LITIGATION

Case No. 2:18-md-2846

CHIEF JUDGE EDMUND A. SARGUS, JR.
Magistrate Judge Kimberly A. Jolson

This document relates to:
JACOB BRYAN

Civil Action No. 2:18-cv-1440

ORIGINAL COMPLAINT

Plaintiff files this Complaint pursuant to Case Management Order 2 and is to be bound by the rights, protections, and privileges and obligations of that Order. Plaintiff further states the following:

1. This is a device tort action brought on behalf of the Plaintiff, Jacob Bryan, arising out of the failure of Defendants' hernia mesh product, the Bard 3DMax. As a result, Plaintiff Jacob Bryan has suffered permanent injuries and significant pain and suffering, emotional distress, lost wages and earning capacity, and diminished quality of life. Plaintiff respectfully seeks all damages to which she may be legally entitled.

STATEMENT OF PARTIES

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

3. Davol, Inc. ("Davol") is incorporated in Delaware, with 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 a hernia mesh known as the 3DMax, which is a concave polypropylene mesh.

4. C.R. Bard, Inc. ("Bard") is Davol's corporate parent/stockholder. Bard is incorporated and based in New Jersey. It is a multinational marketer, promoter, seller, producer, manufacturer, and developer of medical devices, and controls the largest share of the hernia mesh market. Bard participates in the manufacture and distribution of the 3DMax. Bard also manufactures and supplies Davol with material that forms part of the product.

5. Bard was at all relevant times responsible for the actions of Davol, and exercised control over Davol's functions specific to the oversight of and compliance with applicable safety standards relating to and including 3DMax sold in the United States. In such capacity, Bard 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. Bard's misfeasance and malfeasance caused Plaintiff to suffer injury and damages.

6. Defendants are individually, jointly and severally liable to Plaintiff for damages suffered by Plaintiff arising from their design, manufacture, marketing, labeling, distribution, sale and placement of the defective 3DMax at issue in this suit. All acts were effectuated directly and indirectly through Defendant's respective agents, servants, employees and/or owners, acting within the course and scope of their representative agencies, services, employments and/or ownership.

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

VENUE AND JURISDICTION

8. This Court has subject-matter jurisdiction over this action pursuant to 28 U.S.C. § 1332(a) based on complete diversity of citizenship between Plaintiff and all Defendants. The amount in controversy exceeds $75,000.

9. Venue is proper in the Northern District of Florida, pursuant to 28 U.S.C. § 1391 because the events or omissions giving rise to Plaintiff's claims occurred in that district.

10. Defendants continue to conduct substantial business in the above-referenced district, distribute Bard Hernia Mesh in that district, and made material omissions and misrepresentations and breaches of warranties in that district, so as to subject them to *in personam* jurisdiction in that district.

FACTS COMMON TO ALL COUNTS

11. On or about November 20, 2012, Plaintiff Jacob Bryan underwent inguinal hernia repair by Dr. Angel Caban at Shands in Gainesville, Florida. A 3DMax, Ref No. 0115311 Lot No. HUWI0662 was implanted in Plaintiff during this repair.

12. Defendants, manufactured, sold, and/or distributed the 3DMax to Plaintiff, through Plaintiff's doctors, to be used for treatment of hernia repair.

13. On or about October 20, 2017, Plaintiff Jacob Bryan underwent removal of the failed 3DMax by Dr. Jeffrey L. Rose at North Florida Regional Medical Center in Gainesville, Florida.

14. Defendants' 3DMax is a three-dimensional anatomically shaped pre-formed polypropylene hernia mesh, and it is marketed by Defendants as a mesh to be used in repairing hernias.

15. Defendants' 3DMax product contains polypropylene mesh. Despite claims that this material is inert, a substantial body of scientific evidence shows that this mesh material is biologically incompatible with human tissue and promotes an immune response in a large subset of the population receiving these products. This immune response promotes degradation and contracture of the polypropylene mesh, as well as the surrounding tissue, and can contribute to the formation of severe adverse reactions to the mesh.

16. Upon information and belief, Defendants' numerous suppliers, of various forms of polypropylene, cautioned all users in their United States Material Safety Data Sheet that the polypropylene was not to be used for medical applications involving permanent implantation in the human body or permanent contact with internal body fluids or tissues.

17. Defendants failed to warn or notify doctors, regulatory agencies, and consumers of the severe and life-threatening risks associated with polypropylene.

18. 3DMax is constructed of polypropylene.

19. Defendants' 3DMax can contract up to 70% post implantation.

20. Defendants were responsible for the research, design, development, testing, manufacture, production, marketing, promotion, distribution and sale of 3DMax, including providing the warnings and instructions concerning the product.

21. Among the intended purposes for which Defendants designed, manufactured and sold 3DMax was use by surgeons for hernia repair surgeries, the purpose for which the 3DMax was implanted in Plaintiff.

22. Defendants represented to Plaintiff and Plaintiff's physicians that 3DMax was a safe and effective product for hernia repair.

ESTOPPEL AND TOLLING OF STATUTE OF LIMITATIONS

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

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

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

26. Despite diligent investigation by Plaintiff into the cause of Plaintiff's injuries, including consultations with Plaintiff's medical providers, the nature of Plaintiff's injuries and damages, and their relationship to the 3DMax was not discovered, and through reasonable care and diligence could not have been discovered until a date within the applicable statute of limitations for filing Plaintiff's claims. Therefore, under appropriate application of the discovery rule, Plaintiffs' suits were filed well within the applicable statutory limitations period.

27. The running of the statute of limitations in this cause of action is tolled due to equitable tolling. Defendants are estopped from asserting a statute of limitations defense due to Defendants' fraudulent concealment, through misrepresentations and omissions, from Plaintiff and Plaintiff's physicians of the true risks associated with the 3DMax. As a result of Defendants' fraudulent concealment, Plaintiff and Plaintiff's physicians were unaware, and could not have known or have learned through reasonable diligence that Plaintiff had been exposed to the risks

alleged herein and that those risks were the direct and proximate result of the wrongful acts and omissions of the Defendants.

COUNT I: STRICT LIABILITY – MANUFACTURING DEFECT

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

29. Defendants expected and intended the 3DMax to reach users such as Plaintiff in the condition in which the product was sold.

30. The implantation of 3DMax 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.

31. At the time the 3DMax that was implanted in Plaintiff's body, the product was defectively manufactured.

32. Defendants' poor quality control and general non-compliance resulted in the non-conformance of the 3DMax implanted in Plaintiff. The 3DMax implanted in Plaintiff did not conform to the Defendants' intended manufacturing and design specifications.

33. Upon information and belief, Defendants utilized substandard and adulterated polypropylene in the 3DMax, which deviated from Defendants' material and supply specifications.

34. As a direct and proximate result of the defective manufacture of the 3DMax, Plaintiff suffered injuries and damages as summarized herein.

COUNT II: STRICT LIABILITY – DESIGN DEFECT

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

36. Defendants' 3DMax 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 3DMax, 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; tissue damage and/or death; and other complications.

37. The 3DMax includes a cupped or curved design, which causes the mesh to curl, wrinkle, and/or fold onto itself as the mesh contracts.

38. Mesh porosity impacts tissue ingrowth and the inflammatory response. Mesh pore size should be at least 3mm. Pore sizes smaller than 3mm decreases tissue incorporation, increases inflammation, and results in a fibrotic reaction. The 3DMax has a mesh pore size of 0.8mm.

39. The polypropylene weave of the 3DMax produces very small interstices which allow bacteria to enter and hide from the host defenses designed to eliminate them. The bacteria can secrete an encasing slime (biofilm) which further serves to protect them from destruction by white blood cells and macrophages.

40. Observation of mesh under the scanning electron microscope reveals that very small interstices exists between the 3DMax mesh fibrils, which are too small for a macrophage to enter to destroy incubating bacteria. Some Bacteria are capable of degrading polypropylene.

41. The 3DMax utilizes heavyweight polypropylene, which further increases inflammation and foreign body response.

42. The anatomical shape of the 3DMax results in dense adhesions forming around internal structures, such as veins, ligaments, nerves, and more. When the 3DMax fails and complications arise, the mesh can not be easily or safely removed due to the entrapment of numerous delicate internal structures.

43. These manufacturing and design defects associated with the 3DMax were directly and proximately related to the injuries suffered by Plaintiff.

44. Neither Plaintiff nor Plaintiff's implanting physician were adequately warned or informed by Defendants of the defective and dangerous nature of 3DMax. Moreover, neither Plaintiff nor Plaintiff's implanting physician were adequately warned or informed by Defendants of the risks associated with the 3DMax.

45. The 3DMax implanted in Plaintiff failed to reasonably perform as intended. The 3DMax caused serious injury and had to be surgically removed via invasive surgery, and necessitated additional invasive surgery to repair the hernia that the 3DMax was initially implanted to treat.

46. At the time the 3DMax that was implanted in Plaintiff's body, the product was defectively designed. As described above, there was an unreasonable risk that the 3DMax 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.

47. Defendants expected and intended the 3DMax to reach users such as Plaintiff in the condition in which the 3DMax was sold.

48. The implantation of 3DMax 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 3DMax.

49. The risks of the 3DMax significantly outweigh any benefits that Defendants contend could be associated with the 3DMax. The curved design, which is not used in any other hernia mesh product sold in the United States, promotes mesh deformation and migration, and incites an intense inflammatory response, leading to encapsulation, deformation, scarification and contraction, erosion, rejection and further migration.

50. The polypropylene mesh utilized to manufacture the 3DMax was in itself dangerous and defective, particularly when used in the manner intended by Defendants in the 3DMax. The particular polypropylene material used in the 3DMax was substandard, adulterated and non-medical grade, and was unreasonably subject to oxidative degradation within the body. When implanted adjacent internal organs, structures, nerves, arteries, and vessels, as Defendants intended for 3DMax, polypropylene mesh is unreasonably susceptible to adhesion formation, nerve entrapment, spermatic cord obliteration, organ perforation or erosion, fistula formation and bowel strangulation or hernia incarceration, and other injuries.

51. The appropriate treatment for complications associated with 3DMax 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.

52. At the time the 3DMax 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, porous mesh, or a fully resorbable mesh.

53. The 3DMax product cost significantly more than competitive products because of its unique curved shape, even though the curved shape provided no benefit to consumers, and increased the risks to patients implanted with these devices.

54. The 3DMax 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.

55. 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

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

57. At the time the 3DMax that was implanted in Plaintiff's body, the warnings and instructions provided by Defendant for the 3DMax 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.

58. Defendants expected and intended the 3DMax product to reach users such as Plaintiff in the condition in which the product was sold.

59. Plaintiff and Plaintiff's physicians were unaware of the defects and dangers of 3DMax, and were unaware of the frequency, severity and duration of the risks associated with the 3DMax.

60. The Defendants' Instructions for Use provided with the 3DMax is silent on the fact that the 3DMax has a propensity to shrink, wrinkle, fold, and/or contort after implantation. Defendants provided no warning to physicians about the risks or increased risks specifically associated with the unique curved design of the 3DMax.

61. The Defendants' Instructions for Use for the 3DMax failed to adequately warn Plaintiff's physicians of numerous risks which Defendants knew or should have known were associated with the 3DMax, including the risks of the product's immunologic response, pain, encapsulation, rejection, migration, scarification, contraction, adhesion to internal structures or organs, erosion and migration through adjacent tissue and viscera, bowel obstruction, infection, or hernia incarceration or strangulation.

62. Defendants failed to adequately train or warn Plaintiff or Plaintiff's physicians about the necessity for invasive surgical intervention in the event of complications with the 3DMax, or how to properly treat such complications when they occurred.

63. Defendants failed to adequately warn Plaintiff or Plaintiff's physicians that the surgical removal of the 3DMax 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 3DMax was intended to treat.

64. Defendants represented to physicians, including Plaintiff's physician, that the curved design would prevent or reduce recurrences and pain, and expressly intended for the 3DMax to be implanted near numerous large nerves and organs, and marketed and promoted the 3DMax for said purpose. Defendants failed to warn physicians that the 3DMax would contract over time, increases the rates of recurrence and the ability of the 3DMax to migrate.

65. 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 3DMax were more frequent, more severe and lasted longer than those with safer feasible alternative hernia repair treatments.

66. If Plaintiff and/or Plaintiff's physicians had been properly warned of the defects and dangers of 3DMax, and of the frequency, severity and duration of the risks associated with the 3DMax, Plaintiff would not have consented to allow the 3DMax to be implanted, and Plaintiff's physicians would not have implanted the 3DMax in Plaintiff.

67. 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

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

69. Defendants had a duty to use reasonable care in designing, testing, inspecting, manufacturing, packaging, labeling, marketing, distributing, and preparing written instructions and warnings for 3DMax, but failed to do so.

70. Defendants knew, or in the exercise of reasonable care should have known, that 3DMax was defectively and unreasonably designed and/or manufactured, and was unreasonably dangerous and likely to injure patients in whom 3DMax was implanted. Defendants knew or should have known that Plaintiff and Plaintiff's physicians were unaware of the dangers and defects inherent in the 3DMax.

71. Defendants knew or should have known that the Material Data Safety Sheet for the polypropylene used to manufacturer its 3DMax prohibited permanently implanting the polypropylene into the human body.

72. Defendants utilized non-medical grade polypropylene.

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

74. 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.

75. 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.

76. Defendants knew or should have known that the curved design of the 3DMax would promote mesh deformation and migration.

77. Defendants knew or should have known of the significant risk of complications if the 3DMax is implanted to repair a hernia. Nonetheless, Defendants marketed the 3DMax as being safe and effective for hernia repair.

78. Defendants knew or should have known that small pore size and the heavyweight polypropylene of the 3DMax would increase mesh surface area and foreign body load, which would increase the inflammatory and foreign body response.

79. 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 3DMax, Plaintiff suffered injuries and damages as summarized herein.

COUNT V: BREACH OF IMPLIED WARRANTY

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

81. At all material times, Defendants manufactured, marketed, sold, distributed and otherwise placed in to the stream of commerce the 3DMax.

82. 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 is component parts was of merchantable quality, safe and fit for such use, and adequately tested.

83. 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' 3DMax.

84. Defendants' 3DMax 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.

85. Defendants breached various implied warranties with respect to 3DMax, 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 save. 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 3DMax.

86. In reliance upon Defendants' implied warranties, Plaintiff, individually, and/or by and through his physician, used the 3DMax as prescribed, and in the foreseeable manner normally intended, recommended, promoted, and marketed by Defendants.

87. 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.

88. 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

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

90. Defendants carelessly and negligently manufactured, designed, developed, tested, labeled, marketed and sold the Defendants' 3DMax to Plaintiff.

91. Defendants carelessly and negligently concealed the harmful effects of the Defendants' 3DMax from Plaintiff individually and/or Plaintiff's physician on multiple occasions and continue to do so to this day.

92. Defendants carelessly and negligently misrepresented the quality, safety and efficacy of the 3DMax to Plaintiff individually and/or Plaintiff's physician on multiple occasions and continue to do so to this day.

93. 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 3DMax sold and distributed by Defendants.

94. Defendants continued to carelessly and negligently misrepresent the quality, safety, efficacy, dangers and contraindications of the 3DMax to Plaintiff individually and/or Plaintiff's physician after Plaintiff sustained emotional distress, severe physical injuries, and economic loss.

95. Defendants continued to carelessly and negligently misrepresent the quality, safety, efficacy, dangers and contraindications of the 3DMax 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.

96. 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

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

98. 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 3DMax 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 3DMax was not safe and effective. Defendants continued to represent that its 3DMax was safe and effective.

99. Despite what was known or knowable to Defendants about the lack of safety and efficacy of its 3DMax, Defendants failed to disclose this information to the Plaintiff, to Plaintiff's physicians, and to the public at large.

100. At all times relevant hereto, Defendants had the duty and obligation to disclose to Plaintiff and Plaintiff's physicians the true facts concerning the 3DMax, that is, that said 3DMax was 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' 3DMax.

101. Defendants were under a duty to Plaintiffs to disclose and warn of the defective nature of the 3DMax because:

A) Defendants were in a superior position to know the true quality, safety, and efficacy of its 3DMax;

B) Defendants knowingly made false claims about the safety and quality of its 3DMax in documents and marketing materials;

C) Defendants fraudulently and affirmatively concealed the defective nature of the 3DMax from the Plaintiff.

102. 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' 3DMax.

103. 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.

104. Defendants intentionally concealed and/or failed to disclose the true defective nature of the 3DMax so that Plaintiff would request and purchase the Defendants' 3DMax, and their healthcare providers would dispense, prescribe, and recommend the Defendants' 3DMax, and Plaintiff justifiably acted or relied upon the concealed and/or non-disclosed facts to their detriment.

105. At all times relevant hereto, neither Plaintiff nor Plaintiff's 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' 3DMax in their treatment. Defendants' failure to disclose this information was a substantial factor in Plaintiff's physicians selecting Defendants' 3DMax. The failure to disclose also resulted in the provision of incorrect and incomplete information to Plaintiff, as a patient.

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

COUNT VIII: NEGLIGENT MISREPRESENTATION

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

108. Defendants had a duty to accurately and truthfully represent to the medical and healthcare community, Plaintiff, and the public, that its 3DMax had not been adequately tested

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

109. Defendants failed to exercise ordinary care in the representations concerning the 3DMax while they were involved in their manufacture, sale, testing, quality assurance, quality control, and distribution in interstate commerce, because Defendants negligently misrepresented the 3DMax's high risk of unreasonable and dangerous adverse side effects.

110. Defendants breached their duty in representing that the Defendants' 3DMax had no serious side effects different from older generations of similar products and/or procedures to Plaintiff, Plaintiff's physicians, and the medical community.

111. 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 3DMax 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.

112. 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, economic damages.

PUNITIVE DAMAGES

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

114. Defendants failed to adequately test and study the 3DMax 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 3DMax after obtaining knowledge and information that the product was defective and unreasonably unsafe.

115. Even though Defendants have other hernia repair mesh devices that do not present the same risks as the 3DMax, Defendants developed, designed and sold the 3DMax, and continue to do so, because the 3DMax 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 3DMax, including the risk of failure and serious injury, such as suffered by Plaintiff.

116. At all times relevant hereto, Defendants knew or should have known that the 3DMax was inherently more dangerous with respect to the risk of migration, foreign body response, allergic reactions, rejection, infection, failure, erosion, pain and suffering, organ perforation, dense adhesions, 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.

117. Defendant's misrepresentation included knowingly withholding material information form the medical community and the public, including Plaintiff, concerning the safety and efficacy of the 3DMax, which deprived Plaintiff and Plaintiff's implanting physicians of vitally necessary information with which to make a fully informed decision about whether to use the 3DMax.

118. At all times material hereto, Defendants knew and recklessly and/or intentionally disregarded the fact that the Defendants' 3DMax can cause debilitating and potentially life-threatening side effects with greater frequency than safer alternative methods, products, procedures, and/or treatment.

119. At all times material hereto, Defendants knew and recklessly and/or intentionally disregarded the fact that 3DMax can cause debilitating and potentially life-threatening side effects with greater frequency than safer alternative products and/or methods of treatment and recklessly failed to advise the medical community and the general public, including Plaintiff, of the same.

120. 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 3DMax.

121. Notwithstanding the foregoing and the growing body of knowledge and information regarding the true and defective nature of 3DMax with its increased risk of side effects and serious complications, Defendants continue to aggressively market the 3DMax to the medical community and to consumers without disclosing the true risk of such complications.

122. At the time of the Plaintiff was implanted with the 3DMax and since that time, Defendants knew that the 3DMax was defective and unreasonably dangerous but continued to manufacture, produce, assemble, market, distribute, and sell 3DMax 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 the 3DMax to members of the public including Plaintiff.

123. At all times material, Defendants have concealed and/or failed to disclose to the public the serious risks and the potential complications associated with 3DMax in order to ensure continued and increased sales and profits and to the detriment of the public, including Plaintiff.

124. 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 or enhanced compensatory damages;

iv. Reasonable attorneys' fees as provided by law;

v. The costs of these proceedings, including past and future cost of the suit incurred herein;

vi. All ascertainable economic damages;

vii. Prejudgment interest on all damages as allowed by law; and

viii. Such other and further relief as this Court deems just and proper.

DEMAND FOR JURY TRIAL

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

Date: November 12, 2018

Respectfully submitted,

/s/ *C. Brett Vaughn*
C. Brett Vaughn (KS # 26688)
Hollis Law Firm
5100 W. 95th St.
Prairie Village, KS 66207
Telephone (913) 385-5400
Fax (913) 385-5402
brett@hollislawfirm.com

Attorneys for Plaintiff

JS 44 (Rev. 08/16)

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

Jacob Bryan

(b) County of Residence of First Listed Plaintiff Alachua County, FL
(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

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

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

(For Diversity Cases Only)

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

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

Click here for: Nature of Suit Code Descriptions.

CONTRACT
- ❒ 110 Insurance
- ❒ 120 Marine
- ❒ 130 Miller Act
- ❒ 140 Negotiable Instrument
- ❒ 150 Recovery of Overpayment & Enforcement of Judgment
- ❒ 151 Medicare Act
- ❒ 152 Recovery of Defaulted Student Loans (Excludes Veterans)
- ❒ 153 Recovery of Overpayment of Veteran's Benefits
- ❒ 160 Stockholders' Suits
- ❒ 190 Other Contract
- ❒ 195 Contract Product Liability
- ❒ 196 Franchise

REAL PROPERTY
- ❒ 210 Land Condemnation
- ❒ 220 Foreclosure
- ❒ 230 Rent Lease & Ejectment
- ❒ 240 Torts to Land
- ❒ 245 Tort Product Liability
- ❒ 290 All Other Real Property

TORTS

PERSONAL INJURY
- ❒ 310 Airplane
- ❒ 315 Airplane Product Liability
- ❒ 320 Assault, Libel & Slander
- ❒ 330 Federal Employers' Liability
- ❒ 340 Marine
- ❒ 345 Marine Product Liability
- ❒ 350 Motor Vehicle
- ❒ 355 Motor Vehicle Product Liability
- ❒ 360 Other Personal Injury
- ❒ 362 Personal Injury - Medical Malpractice

PERSONAL INJURY
- ❒ 365 Personal Injury - Product Liability
- ☒ 367 Health Care/ Pharmaceutical Personal Injury Product Liability
- ❒ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ❒ 370 Other Fraud
- ❒ 371 Truth in Lending
- ❒ 380 Other Personal Property Damage
- ❒ 385 Property Damage Product Liability

CIVIL RIGHTS
- ❒ 440 Other Civil Rights
- ❒ 441 Voting
- ❒ 442 Employment
- ❒ 443 Housing/ Accommodations
- ❒ 445 Amer. w/Disabilities - Employment
- ❒ 446 Amer. w/Disabilities - Other
- ❒ 448 Education

PRISONER PETITIONS

Habeas Corpus:
- ❒ 463 Alien Detainee
- ❒ 510 Motions to Vacate Sentence
- ❒ 530 General
- ❒ 535 Death Penalty

Other:
- ❒ 540 Mandamus & Other
- ❒ 550 Civil Rights
- ❒ 555 Prison Condition
- ❒ 560 Civil Detainee - Conditions of Confinement

FORFEITURE/PENALTY
- ❒ 625 Drug Related Seizure of Property 21 USC 881
- ❒ 690 Other

LABOR
- ❒ 710 Fair Labor Standards Act
- ❒ 720 Labor/Management Relations
- ❒ 740 Railway Labor Act
- ❒ 751 Family and Medical Leave Act
- ❒ 790 Other Labor Litigation
- ❒ 791 Employee Retirement Income Security Act

IMMIGRATION
- ❒ 462 Naturalization Application
- ❒ 465 Other Immigration Actions

BANKRUPTCY
- ❒ 422 Appeal 28 USC 158
- ❒ 423 Withdrawal 28 USC 157

PROPERTY RIGHTS
- ❒ 820 Copyrights
- ❒ 830 Patent
- ❒ 840 Trademark

SOCIAL SECURITY
- ❒ 861 HIA (1395ff)
- ❒ 862 Black Lung (923)
- ❒ 863 DIWC/DIWW (405(g))
- ❒ 864 SSID Title XVI
- ❒ 865 RSI (405(g))

FEDERAL TAX SUITS
- ❒ 870 Taxes (U.S. Plaintiff or Defendant)
- ❒ 871 IRS—Third Party 26 USC 7609

OTHER STATUTES
- ❒ 375 False Claims Act
- ❒ 376 Qui Tam (31 USC 3729(a))
- ❒ 400 State Reapportionment
- ❒ 410 Antitrust
- ❒ 430 Banks and Banking
- ❒ 450 Commerce
- ❒ 460 Deportation
- ❒ 470 Racketeer Influenced and Corrupt Organizations
- ❒ 480 Consumer Credit
- ❒ 490 Cable/Sat TV
- ❒ 850 Securities/Commodities/ Exchange
- ❒ 890 Other Statutory Actions
- ❒ 891 Agricultural Acts
- ❒ 893 Environmental Matters
- ❒ 895 Freedom of Information Act
- ❒ 896 Arbitration
- ❒ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ❒ 950 Constitutionality of State Statutes

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 $ 76,000.00

CHECK YES only if demanded in complaint:
JURY DEMAND: ☒ Yes ❒ No

VIII. RELATED CASE(S) IF ANY

(See instructions): JUDGE Edmund A. Sargus Jr. DOCKET NUMBER 2846

DATE 11/12/2018

SIGNATURE OF ATTORNEY OF RECORD C. Brett Vaughn

FOR OFFICE USE ONLY

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