UNITED STATES DISTRICT COURT
THE 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
Magistrate Judge Kimberly A. Jolson

This document relates to:
DAVID D. ANDERSON AND FRANCES ANDERSON

Civil Action No._____

ORIGINAL COMPLAINT

Plaintiffs file this Complaint pursuant to Case Management Order 2 and are to be bound by the rights, protections, and privileges and obligations of that Order. Plaintiffs further state the following:

1. This is a device tort action brought on behalf of the Plaintiffs, David D. Anderson and his spouse Frances Anderson, arising out of the failure of Defendants' hernia mesh product, the Bard Composix L/P. As a result, Plaintiff David D. Anderson has suffered permanent injuries and significant pain and suffering, emotional distress, lost wages and earning capacity, and diminished quality of life. Plaintiffs respectfully seek all damages to which they may be legally entitled.

STATEMENT OF PARTIES

2. Plaintiff is, and was, at all relevant times, a citizen and resident of Pennsylvania 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 Composix L/P, which is composed of one layer of polypropylene, and one layer of expanded polytetrafluroethylene (ePTFE), stitched together with PTFE monofilament.

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 Composix L/P. 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 Composix L/P 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 Composix L/P 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 Eastern District of Pennsylvania pursuant to 28 U.S.C. § 1391 because the events or omissions giving rise to Plaintiffs' 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 August 1, 2013, Plaintiff David D. Anderson underwent repair of an incisional hernia by Dr. Michael F. Martinez at St. Luke's Hospital in Allentown, Pennsylvania. A Composix L/P hernia mesh 10.8cm x 15.9cm, Ref No. 0134460, Lot No. HUVK1995 was implanted in Plaintiff during this repair.

12. Defendants manufactured, sold, and/or distributed the Composix L/P to Plaintiff, through his physician, to be used for treatment of hernia repair.

13. On or about October 22, 2016, Plaintiff David D. Anderson underwent surgery by Dr. Andrew Smith for an exploratory laparotomy, duodenorrhaphy, lysis of adhesions, and removal of the Composix L/P. During the surgery, "the mesh from the upper midline portion of

his previous laparotomy was removed as this was bathed in pus. The patient also had an incisional hernia below this." The operative report also states that the "opening into the abdominal cavity revealed purulent peritoneal fluid without odor…There were adhesions in the midline of the small bowel, and the small bowel to the underside of the previous PTFE mesh."

14. Plaintiff experienced excruciating abdominal pain, chronic inflammation, and required a removal surgery related to the Composix L/P. He will likely require additional treatment to repair the damage from Defendants' product.

15. Defendants were responsible for the research, design, development, testing, manufacture, production, marketing, promotion, distribution and sale of the Composix L/P, including providing the warnings and instructions concerning their product.

16. Among the intended purposes for which Defendants designed, manufactured and sold the product was its use by surgeons for hernia repair surgeries. That was the purpose for which the Composix L/P was implanted in David D. Anderson.

17. Defendants represented to Plaintiff and his physician that the Composix L/P was a safe and effective product for hernia repair.

FDA 510(k) CLEARANCE PROCESS

18. The "510(k) clearance process" of the U.S. Food & Drug Administration (FDA) refers to Section 510(k) of the 1976 Medical Device Amendments to the Federal Food, Drug and Cosmetic Act (MDA). Under this process, medical device manufacturers are only required to notify the FDA at least 90 days before they market a device claimed to be "substantially equivalent" to a device the FDA had approved for sale before 1976 (when the MDA was enacted).

19. No clinical testing or clinical study is required to gain FDA approval under this process. Instead, a given device was supposed to demonstrate substantial equivalence to a predicate medical device.

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

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

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

23. At the request of the FDA in 2012, the National Institute of Health (NIH) conducted a thorough review of the 510(k) process, reaching the following major conclusion:

> **The 510(k) clearance process is not intended to evaluate the safety and effectiveness of medical devices with some exceptions. The 510(k) process cannot be transformed into a pre-market evaluation of safety and effectiveness so long as the standard for clearance is substantial equivalence to any previously cleared device.**

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

25. Defendants cleared their Composix L/P, and its related components, under the 510(k) Premarket Notification.

26. Neither Plaintiff nor his physicians were aware of the defective and dangerous condition of the Composix L/P or that this unreasonably defective condition was the cause of Plaintiff's injuries until after the product was removed.

27. Defendants failed to comply with the FDA application and reporting requirements.

ESTOPPEL AND TOLLING OF STATUTE OF LIMITATIONS

28. Due to Defendants' acts of fraudulent concealment, they are estopped from relying on any statutes of limitations or repose. Such acts include Defendants' intentional concealment from David D. Anderson and the general public that the Composix L/P is defective, while continuing to market the product with the adverse effects described in this Complaint.

29. Given Defendants' affirmative actions of concealment by failing to disclose information about the defects known to them but not the public—information over which Defendants had exclusive control—and because Plaintiffs could not reasonably have known the Composix L/P was defective, Defendants are estopped from relying on any statutes of limitations that might overwise be applicable to the claims asserted in this Complaint.

COUNT I: STRICT LIABILITY – MANUFACTURING DEFECT

30. Plaintiffs incorporate by reference the allegations in all prior paragraphs.

31. Defendants expected and intended their Composix L/P to reach users such as Plaintiff in the condition in which the product was sold.

32. The implantation in David D. Anderson's body of the Composix L/P was medically reasonable, and was a type of use that Defendants intended and foresaw when they designed, manufactured and sold the product.

33. When the Composix L/P was implanted in Plaintiff's body, the product was defectively manufactured.

34. Defendants' poor quality control and general non-compliance with industry standards resulted in the non-conformance of the Composix L/P implanted in Plaintiff. The implanted product did not conform to Defendants' intended manufacturing and design specifications.

35. Upon information and belief, Defendants utilized substandard, adulterated, and/or non-medical grade polypropylene and raw materials used to make the Composix L/P product, which deviated from their material and supply specifications. Non-medical grade polypropylene contains less anti-oxidants, resulting in early mesh degradation and failure.

36. As a direct and proximate result of Defendants' defective manufacture of the Composix L/P, Plaintiffs suffered injuries and damages as summarized in this Complaint.

COUNT II: STRICT LIABILITY – DESIGN DEFECT

37. Plaintiffs incorporate by reference the allegations in all prior paragraphs.

38. Defendants' Composix L/P 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 product, there was an unreasonable risk of severe adverse reactions to the mesh or mesh components, including: chronic pain; recurrence of hernia; foreign body response; rejection; infection; scarification; improper wound healing; excessive and chronic inflammation;

allergic reaction; adhesions to internal organs; erosion; abscess; fistula formation; granulomatous response; seroma formation; nerve damage; tumor formation, cancer, tissue damage and/or death; and other complications.

39. Defendants expected and intended the Composix L/P to reach users such as Plaintiff in the condition in which the product was sold.

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

41. The Composix L/P implanted in Plaintiff failed to reasonably perform as intended. The product caused serious injury and had to be surgically removed, necessitating additional invasive surgery to repair the hernia that the product had initially been implanted to treat.

42. The risks of Defendants' Composix L/P significantly outweigh any benefits that Defendants contend could be associated with the product. The multi-layer ePTFE and polypropylene design has a propensity to contort, or deform the intended design of the product, because the ePTFE portion of the Composix L/P shrinks at a faster rate than the polypropylene portion, resulting in dense adhesion formation, injuries to organs, chronic pain, and hernia recurrence.

43. The Composix L/P is designed as a multi-layered patch, which increases the foreign body load and subsequent foreign body reaction, resulting in increased oxidation and subsequent mesh breakdown and failure.

44. Defendants utilize Ethylene Oxide ("ETO") in an attempt to sterilize the Composix L/P. Although ETO is an effective disinfectant, dry spores are highly resistant to

ETO. Moisture must be present to eliminate spores if ETO is used. Presoaking the product to be sterilized is most desirable, but high levels of humidity during the ETO process can also be effective in eliminating spores.

45. The Composix L/P, containing spores, will eventually cause an infection after implantation. The spores can remain dormant for extended periods of time, resulting in infections months or years after the Composix L/P was implanted. The following literature discusses the necessity of moisture during ETO sterilization:

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

Dempsey, D.J. and Thirucote, R.R., *Sterilization of medical devices: A Review*. Journal of Biomaterials Applications, 3(3), pp. 454-523 (1988). DOI: 10.1177/088532828800300303

46. The Composix L/P is cytotoxic, immunogenic, and non-biocompatible, causing or contributing to complications such as delayed wound healing, inflammation, foreign body response, rejection, infection, and other complications.

47. When affixed to the body's tissue, the ePTFE layer of the Composix L/P prevents fluid escape, which leads to seroma formation, and which in turn can cause infection or abscess formation and other complications.

48. The ePTFE layer provides an ideal bacteria breeding ground, in which bacteria cannot be eliminated by the body's immune response, thus allowing infection to proliferate.

49. The solid, flat, relatively smooth and continuous surface of Defendants' Composix L/P inhibits the body's ability to clear toxins.

50. Defendants' Composix L/P has a solid, flat, relatively smooth and continuous surface. Medical devices utilizing this design greatly increase the risk of tumor and cancer formation via the "Oppenheimer Effect":

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

Oppenheimer, B.S. et al, *The Latent Period in Carcinogenesis by Plastics in Rats and its Relations to the Presearcomatous Stage*. Journal of Cancer 1(11). 204 – 213 (1958).

B. In 1999, the World Health Organization's International Agency for Research on Cancer published *Surgical implants and Other Foreign Bodies*, which evaluated the carcinogenic risks of various surgical implants in humans. **Polymeric implants prepared as thin smooth films are possibly carcinogenic to humans.**

Surgical Implants and Other Foreign Bodies. IARC Monogr Eval Carcinog Risks Hum 74:1-409 (1999).

51. The polypropylene mesh of the Composix L/P was in itself dangerous and defective, particularly when used in the product in the manner intended by Defendants. The particular polypropylene material used in their product was substandard, adulterated and non-medical grade, and was unreasonably subject to oxidative degradation within the body. When implanted adjacent to the bowel and other internal organs, as Defendants intended for the Composix L/P, it is unreasonably susceptible to adhesion, bowel erosion, fistula formation and bowel strangulation or hernia incarceration, and other injuries.

52. The polypropylene portion of the Composix L/P has a tendency to unravel, creating a sharp "fishing line" effect, which can slice through the patient's tissue.

53. These manufacturing and design defects associated with the Composix L/P were directly and proximately related to the injuries David D. Anderson suffered.

54. Neither Plaintiff nor his implanting physician was adequately warned or informed by Defendants of the defective and dangerous nature of Composix L/P. Moreover, neither Plaintiff nor his implanting physician was adequately warned or informed by Defendants of the risks associated with the product.

55. The appropriate treatment for complications associated with the Composix L/P involves additional invasive surgery to remove the mesh from the body, thus eliminating any purported benefit that the product was intended to provide to the patient.

56. Defendants' product was designed and intended for intraperitoneal implantation, which required it to be placed in contact with internal organs, thus unnecessarily increasing the risks of adhesion, erosion, fistula formation, and other injuries.

57. When the Composix L/P was implanted in David D. Anderson, there were safer feasible alternative designs for hernia mesh products, including a flat, porous, non-coated, single-layer mesh placed away from the bowel, or a fully resorbable mesh.

58. The Composix L/P product costs significantly more than competitive products due to its design incorporating polypropylene, ePTFE, and PTFE, even though the design provided no benefit to consumers, and increased the risks to patients implanted with these devices.

59. The Composix L/P implanted in David D. Anderson failed to reasonably perform as intended. The product therefore had to be surgically removed, necessitating further invasive surgery to repair the very issue that the Composix L/P was intended to repair. The product thus provided no benefit to Plaintiff.

60. As a direct and proximate result of the product's defective and unreasonably dangerous condition, Plaintiff suffered injuries and damages as summarized in this Complaint.

COUNT III: STRICT LIABILITY – FAILURE TO WARN

61. Plaintiffs incorporate by reference the allegations in all prior paragraphs.

62. When the Composix L/P was implanted in Plaintiff's body, the warnings and instructions provided by Defendants for the product were inadequate and defective. As described above, there was an unreasonable risk the product would not perform safely and effectively for the purposes for which it was intended. Defendants failed to design and/or manufacture against such dangers, and failed to provide adequate warnings and instructions concerning these risks.

63. Defendants expected and intended the Composix L/P to reach users such as Plaintiff in the condition in which the product was sold.

64. David D. Anderson and his physicians were unaware of the defects and dangers of Composix L/P, and were unaware of the frequency, severity and duration of the risks associated with the product.

65. The multi-layered, ePTFE – polypropylene design of the Composix L/P greatly increases the risk bacterial adherence, chronic infection, sepsis, mesh degradation, mesh contracture, mesh deformation, and a significant increase in surgical complexity when complications arise when compared to other feasibly available alternative hernia meshes. Defendants provided no warning to physicians about the risks or increased risks specifically associated with the unique design of the Composix L/P.

66. Defendants failed to warn of the propensity of the Composix L/P to contract and/or shrink once implanted.

67. Defendants failed to warn of the Composix L/P's propensity to degrade, fragment, and disintegrate.

68. Defendants' failed to warn of the rate and manner of mesh erosion and/or extrusion.

69. Defendants' Instructions for Use provided with the Composix L/P expressly understate and misstate the risks known to be associated specifically with the product, representing the associated complications such as inflammation merely as "possible complications." But the Composix L/P will always incite severe inflammation once implanted. The inflammation caused by the Composix L/P is chronic in nature and systemic, not acute localized inflammation.

70. Defendants' Instructions for Use for the Composix L/P also failed to adequately warn Plaintiff's physician of numerous risks that Defendants knew or should have known were

associated with the Composix L/P, including the risks of immunologic response, pain, dehiscence, encapsulation, rejection, migration, scarification, contraction, erosion through adjacent tissue and viscera, infections, bowel obstruction, or hernia incarceration or strangulation.

71. Defendants' Instructions for Use for the Composix L/P notes under "Contraindications" that "literature reports there is a possibility for adhesion formation when the polypropylene is placed in direct contact with the bowel or viscera." However, Defendants' Instructions for Use are silent about the risk and literature reports of adhesion formation when ePTFE is placed in direct contact with the bowel or viscera."

72. Defendants represented to physicians, including Plaintiff's physician, that the ePTFE of the Composix L/P would prevent or reduce adhesions; expressly intended for the Composix L/P to be implanted in contact with the bowel and internal organs; and marketed and promoted the Composix L/P for that purpose. Defendants failed to warn physicians that the Composix L/P would warp as the ePTFE shrinks, which can expose the polypropylene side of the Composix L/P to the bowel and puts the patient at high risk for dense adhesions formation years after implantation.

73. Defendants failed to warn that the ePTFE of the Composix L/P provides the ideal breeding ground for bacteria, and prevents the body from properly clearly the infection.

74. Defendants failed to warn that ePTFE would degrade in the presence of an infection, creating an even more habitable structure for the infection to thrive.

75. Defendants failed to adequately warn Plaintiff or his physician about the necessity for invasive surgical intervention in the event of complications and failed to train the physician how to properly treat such complications when they occurred.

76. Defendants failed to adequately warn Plaintiff or his physician that the surgical removal of the Composix L/P in the event of complications would leave the hernia unrepaired and much larger than the original; and would necessitate further, more complicated medical treatment to attempt to repair the same hernia that the failed product was intended to treat.

77. With respect to the complications listed in the Defendants' warnings, they provided no information or warning regarding the frequency, severity and duration of those complications, even though the complications associated with the Composix L/P were more frequent, more severe and longer lasting than those with safer feasible alternative hernia repair treatments.

78. If Plaintiff and/or his physician had been properly warned of the defects and dangers of the Composix L/P, and of the frequency, severity and duration of the risks associated with the product, Plaintiff would not have consented to allow it to be implanted, and Plaintiff's physician would not have implanted the product in Plaintiff.

79. As a direct and proximate result of the inadequate and defective warnings and instructions, Plaintiffs suffered injuries and damages as summarized in this Complaint.

COUNT IV: NEGLIGENCE

80. Plaintiffs incorporate by reference the allegations in all prior paragraphs.

81. Although Defendants had a duty to use reasonable care in designing, testing, reporting, inspecting, manufacturing, packaging, labeling, marketing, distributing, and preparing written instructions and warnings for the Composix L/P, they failed to do so.

82. Defendants knew, or in the exercise of reasonable care should have known, that their product was defectively and unreasonably designed and/or manufactured, and was unreasonably dangerous and likely to injure patients in whom it was implanted. Defendants

knew or should have known that Plaintiff and his physician were unaware of the dangers and defects inherent in the Composix L/P.

83. Defendants knew or should have known that the Material Safety Data Sheet (MSDS) regarding the polypropylene used to manufacture their product prohibited permanently implanting polypropylene into the human body.

84. Defendants utilized non-medical grade polypropylene.

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

86. Defendants knew or should have known that polypropylene induces a severe inflammatory response once implanted, and continues to induce a severe inflammatory response indefinitely or until removed.

87. 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.

88. Defendants knew or should have known that the Composix L/P caused unreasonable harm and dangerous side effects that many users would be unable to remedy by any means. Nonetheless, Defendants continued to promote and market the Composix L/P's use by consumers, including the Plaintiff.

89. It was foreseeable to Defendants that consumers, including Plaintiff David D. Anderson, would suffer injury as a result of Defendants' failure to exercise ordinary care.

90. As a direct and proximate result of Defendants' negligence in designing, testing, reporting, inspecting, manufacturing, packaging, labeling, marketing, distributing, and preparing

written instructions and warnings for the Composix L/P, Plaintiff suffered injuries and damages as summarized in this Complaint.

COUNT V: BREACH OF IMPLIED WARRANTY

91. Plaintiffs incorporate by reference the allegations in all prior paragraphs.

92. At all material times, Defendants manufactured, marketed, sold, distributed and otherwise placed in to the stream of commerce the Composix L/P.

93. At all material times, Defendants intended for their product to be implanted for the purposes and in the manner that Plaintiff and his 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.

94. Defendants were aware that consumers, including Plaintiff and his physician, would implant their product as directed by the Instructions for Use. Therefore, Plaintiff was a foreseeable user of Defendants' Composix L/P.

95. Defendants' Composix L/P was expected to reach, and did in fact reach consumers, including Plaintiff and his physician, without substantial change in the condition in which it was manufactured and sold by Defendants.

96. Defendants breached various implied warranties with respect to Composix L/P, including the following:

A. Defendants represented to Plaintiff and his 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 his 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 his 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 Composix L/P.

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

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

99. As a direct and proximate result of Defendants' breaches of the aforementioned implied warranties, Plaintiffs suffered 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

100. Plaintiffs incorporate by reference the allegations in all prior paragraphs.

101. Defendants negligently manufactured, designed, developed, tested, labeled, marketed and sold the Composix L/P to Plaintiffs.

102. On multiple occasions Defendants negligently concealed the harmful effects of the product from Plaintiff individually, and/or his physician. They continue to do so to this day.

103. On multiple occasions Defendants carelessly and negligently misrepresented the quality, safety and efficacy of the Composix L/P to Plaintiff individually, and/or his physician. They continue to do so to this day.

104. Plaintiff was directly impacted by Defendants' negligence, in that he 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 product manufactured, sold and distributed by Defendants.

105. After Plaintiff sustained emotional distress, severe physical injuries, and economic loss, Defendants continued to negligently misrepresent the quality, safety, efficacy, dangers and contraindications of their product to Plaintiff and/or his physician.

106. Defendants continued to negligently misrepresent the quality, safety, efficacy, dangers and contraindications of their product to Plaintiff individually, and/or his physician, knowing that doing so would cause Plaintiff to suffer additional and continued emotional distress, severe physical injuries, and economic loss.

107. As a proximate result of Defendants' conduct, Plaintiffs have 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

108. Plaintiffs incorporate by reference the allegations in all prior paragraphs.

109. At all material times it was known or knowable to Defendants that their product caused large numbers of complications. It also 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 the Composix L/P. It was known or knowable to Defendants that the safety and

efficacy of their product had not been proven with respect to, among other things, the product, its components, its performance, and its method of insertion. And it was known or knowable to Defendants that the product was not safe and effective. Defendants continued nonetheless to represent that their product was safe and effective.

110. Despite what was known or knowable to Defendants about the lack of safety and efficacy of their product, Defendants failed to disclose this information to Plaintiff, his physician, and/or public at large.

111. At all material times, Defendants had the duty and obligation to disclose to Plaintiff and his physician the true facts concerning their product, *i.e.*, that the Composix L/P was dangerous and defective, lacking efficacy for its purported use and lacking safety in normal use, and was likely to cause serious consequences to users, including permanent and debilitating injuries. Defendants concealed these material facts before David D. Anderson was implanted with Defendants' product.

112. Defendants were under a duty to Plaintiffs to disclose and warn of the defective nature of the product because:

A. Defendants were in a superior position to know the true quality, safety, and efficacy of the Composix L/P;

B. Defendants knowingly made false claims about the safety and quality of the product in documents and marketing materials; and

C. Defendants fraudulently and affirmatively concealed the defective nature of their product from Plaintiff.

113. The facts Defendants concealed and/or did not disclose to Plaintiffs were material facts that a reasonable person would have considered important in deciding whether to purchase and/or use Defendants' product.

114. At all material times, Defendants willfully, intentionally, and maliciously concealed facts from Plaintiff and his physician, with the intent to defraud them.

115. Defendants intentionally concealed or failed to disclose the true defective nature of the Composix L/P, so that Plaintiff would request and purchase it, and healthcare providers would dispense, prescribe, and recommend it. And Plaintiff justifiably acted or relied upon the concealed or non-disclosed facts to his detriment.

116. At all material times, neither Plaintiff nor his physician was aware of the facts above. Had they been aware of those facts, they would not have acted as they did, *i.e.*, by reasonably relying upon Defendants' representations of safety and efficacy, and by utilizing Defendants' product. Defendants' failure to disclose this information was a substantial factor in the selection by Plaintiff's physician of Defendants' product. Defendants' failure to disclose also resulted in the provision of incorrect and incomplete information to Plaintiff as a patient.

117. As a direct and proximate result of Defendants' conduct, Plaintiffs were injured.

COUNT VIII: NEGLIGENT MISREPRESENTATION

118. Plaintiffs incorporate by reference the allegations in all prior paragraphs.

119. Defendants had a duty to accurately and truthfully represent to the medical and healthcare community, Plaintiffs, and the public, that the Composix L/P had not been adequately tested and found to be a safe and effective treatment. Defendants breached that duty as their representations were false.

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

121. Defendants also breached their duty in representing to Plaintiff, his physician, and the medical community that their product had no serious side effects different from older generations of similar products and/or procedures.

122. As a foreseeable, direct, and proximate result of Defendants' negligent misrepresentations, they knew or had reason to know, that the Composix L/P had been insufficiently tested, or had not been tested at all; and that it lacked adequate and accurate warnings, and created a high risk, or a higher than acceptable reported and represented risk of adverse side effects. Those side effects include pain, graft rejection, graft migration, organ damage, complex seroma, fistula, sinus tract formation, delayed wound closure, infection, sepsis, and death.

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

COUNT IX: LOSS OF CONSORTIUM

124. Plaintiffs incorporate by reference the allegations in all prior paragraphs.

125. As a direct and proximate result of the Defendants' negligence and conduct as detailed above, Plaintiff Frances Anderson was caused to lose the consortium and society of the Plaintiff's spouse, David D. Anderson.

126. WHEREFORE, Plaintiffs respectfully request judgment in their favor and against Defendants for such amount that is determined to be fair and reasonable, for such other relief as may be fair and reasonable under the circumstances, and for their costs.

COUNT X: PUNITIVE DAMAGES

127. Plaintiffs incorporate by reference the allegations in all prior paragraphs.

128. Defendants failed to adequately test and study the Composix L/P to determine and ensure that the product was safe and effective prior to releasing it for sale for permanent human implantation. Further, Defendants continued to manufacture and sell the product after obtaining knowledge and information that it was defective and unreasonably unsafe.

129. Even though Defendants have other hernia repair mesh devices that do not present the same risks as the Composix L/P, they developed, designed and sold the Composix L/P, and continue to do so, because the product 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 product, including the risk of failure and serious injury, such as suffered by Plaintiff.

130. At all material times, Defendants knew or should have known that the Composix L/P was inherently more dangerous with respect to the following: the risk of foreign body response, allergic reaction, rejection, infection, failure, erosion, organ damage, pain and suffering, dense adhesions, tumor or cancer formation, loss of life's enjoyment, remedial surgeries and treatments to cure the conditions proximately related to the use of the product, as well as the other permanent and lasting severe personal injuries.

131. Defendants' misrepresentations included knowingly withholding material information from the medical community and the public, including Plaintiff, concerning the

safety and efficacy of the Composix L/P, which deprived Plaintiff and his implanting physician of vitally necessary information with which to make a fully informed decision about whether to use the product.

132. At all material times, Defendants also knew and recklessly and/or intentionally disregarded the fact that their product can cause debilitating and potentially life-threatening side effects with greater frequency than safer alternative methods, products, procedures, and/or treatments. However, Defendants recklessly failed to advise the medical community and the general public, including Plaintiffs, of that fact.

133. At all material times, Defendants intentionally misstated and misrepresented data; and they continue to misrepresent data so as to minimize the perceived risk of injuries and the rate of complications caused by or associated with the Composix L/P.

134. Notwithstanding the foregoing and the growing body of knowledge and information regarding the true and defective nature of the Composix L/P, with its increased risk of side effects and serious complications, Defendants continue to aggressively market the product to the medical community and to consumers without disclosing the true risk of the complications and side effects.

135. At all material times, Defendants have concealed and/or failed to disclose to the public all of the serious risks and all of the potential complications associated with the product, so as to ensure continued and increased sales and profits and to the detriment of the public, including Plaintiffs.

136. Defendants' acts and omissions are of such character and nature so as to entitle Plaintiffs 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, raising the presumption of conscious indifference to consequences, thereby justifying an award of punitive damages.

WHEREFORE, Plaintiffs David D. Anderson and Frances Anderson demand judgment against Defendants individually and jointly and severally. Plaintiffs also 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

Plaintiffs David D. Anderson and Frances Anderson demand judgment against Defendants, individually and 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 pain and suffering for severe and permanent personal injuries sustained by Plaintiffs; 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 Defendants' profits;

iii. Punitive or enhanced compensatory damages;

iv. Reasonable attorneys' fees as provided by law;

v. Past and future costs of all proceedings;

vi. All ascertainable economic damages;

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

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

DEMAND FOR JURY TRIAL

Plaintiffs David D. Anderson and Frances Anderson hereby demand a trial by jury on all issues so triable.

Dated: October 19, 2018

Respectfully submitted,

/s/ Justin A. Browne
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Attorneys for Plaintiffs

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

David D. Anderson and Frances Anderson

(b) County of Residence of First Listed Plaintiff Carbon County, PA
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
Ketterer, Browne & Anderson, LLC
336 S. Main Street, Bel Air, Maryland 21014
Phone: (410) 420-0184

DEFENDANTS

Davol, Inc. and C.R. Bard, Inc.

County of Residence of First Listed Defendant Kent County, RI
(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. § 1332 - Product Liability

Brief description of cause:
Plaintiff suffered injuries as a result of the implantation of Defendants' hernia mesh product.

VII. REQUESTED IN COMPLAINT:

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

DEMAND $ 75,001.00

CHECK YES only if demanded in complaint:
JURY DEMAND: ◉ Yes ○ No

VIII. RELATED CASE(S) IF ANY

(See instructions): JUDGE Chief Judge Edmund A. Sargus DOCKET NUMBER 2:18-md-2846

DATE 10/19/2018

SIGNATURE OF ATTORNEY OF RECORD /s/ Justin A. Browne

FOR OFFICE USE ONLY

RECEIPT # AMOUNT APPLYING IFP JUDGE MAG. JUDGE

INSTRUCTIONS FOR ATTORNEYS COMPLETING CIVIL COVER SHEET FORM JS 44

Authority For Civil Cover Sheet

The JS 44 civil cover sheet and the information contained herein neither replaces nor supplements the filings and service of pleading 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. Consequently, a civil cover sheet is submitted to the Clerk of Court for each civil complaint filed. The attorney filing a case should complete the form as follows:

I.(a) **Plaintiffs-Defendants.** Enter names (last, first, middle initial) of plaintiff and defendant. If the plaintiff or defendant is a government agency, use only the full name or standard abbreviations. If the plaintiff or defendant is an official within a government agency, identify first the agency and then the official, giving both name and title.

(b) **County of Residence.** For each civil case filed, except U.S. plaintiff cases, enter the name of the county where the first listed plaintiff resides at the time of filing. In U.S. plaintiff cases, enter the name of the county in which the first listed defendant resides at the time of filing. (NOTE: In land condemnation cases, the county of residence of the "defendant" is the location of the tract of land involved.)

(c) **Attorneys.** Enter the firm name, address, telephone number, and attorney of record. If there are several attorneys, list them on an attachment, noting in this section "(see attachment)".

II. **Jurisdiction.** The basis of jurisdiction is set forth under Rule 8(a), F.R.Cv.P., which requires that jurisdictions be shown in pleadings. Place an "X" in one of the boxes. If there is more than one basis of jurisdiction, precedence is given in the order shown below.
United States plaintiff. (1) Jurisdiction based on 28 U.S.C. 1345 and 1348. Suits by agencies and officers of the United States are included here.
United States defendant. (2) When the plaintiff is suing the United States, its officers or agencies, place an "X" in this box.
Federal question. (3) This refers to suits under 28 U.S.C. 1331, where jurisdiction arises under the Constitution of the United States, an amendment to the Constitution, an act of Congress or a treaty of the United States. In cases where the U.S. is a party, the U.S. plaintiff or defendant code takes precedence, and box 1 or 2 should be marked.
Diversity of citizenship. (4) This refers to suits under 28 U.S.C. 1332, where parties are citizens of different states. When Box 4 is checked, the citizenship of the different parties must be checked. (See Section III below; **NOTE: federal question actions take precedence over diversity cases.**)

III. **Residence (citizenship) of Principal Parties.** This section of the JS 44 is to be completed if diversity of citizenship was indicated above. Mark this section for each principal party.

IV. Nature of Suit. Place an "X" in the appropriate box. If there are multiple nature of suit codes associated with the case, pick the nature of suit code that is most applicable. Click here for: Nature of Suit Code Descriptions.

V. **Origin.** Place an "X" in one of the seven boxes.
Original Proceedings. (1) Cases which originate in the United States district courts.
Removed from State Court. (2) Proceedings initiated in state courts may be removed to the district courts under Title 28 U.S.C., Section 1441. When the petition for removal is granted, check this box.
Remanded from Appellate Court. (3) Check this box for cases remanded to the district court for further action. Use the date of remand as the filing date.
Reinstated or Reopened. (4) Check this box for cases reinstated or reopened in the district court. Use the reopening date as the filing date.
Transferred from Another District. (5) For cases transferred under Title 28 U.S.C. Section 1404(a). Do not use this for within district transfers or multidistrict litigation transfers.
Multidistrict Litigation – Transfer. (6) Check this box when a multidistrict case is transferred into the district under authority of Title 28 U.S.C. Section 1407.
Multidistrict Litigation – Direct File. (8) Check this box when a multidistrict case is filed in the same district as the Master MDL docket.
PLEASE NOTE THAT THERE IS NOT AN ORIGIN CODE 7. Origin Code 7 was used for historical records and is no longer relevant due to changes in statue.

VI. **Cause of Action.** Report the civil statute directly related to the cause of action and give a brief description of the cause. **Do not cite jurisdictional statutes unless diversity.** Example: U.S. Civil Statute: 47 USC 553 Brief Description: Unauthorized reception of cable service

VII. **Requested in Complaint.** Class Action. Place an "X" in this box if you are filing a class action under Rule 23, F.R.Cv.P.
Demand. In this space enter the actual dollar amount being demanded or indicate other demand, such as a preliminary injunction.
Jury Demand. Check the appropriate box to indicate whether or not a jury is being demanded.

VIII. **Related Cases.** This section of the JS 44 is used to reference related pending cases, if any. If there are related pending cases, insert the docket numbers and the corresponding judge names for such cases.

Date and Attorney Signature. Date and sign the civil cover sheet.