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:
JENNIFER S. TEDDER

Civil Action No._____

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 Plaintiff Tedder arising out of the failure of Defendants' Ventralex Mesh. As a result, Plaintiff Tedder, suffered injuries and significant pain and suffering, emotional distress, lost wages and earning capacity, and diminished quality of life. Defendants C.R. Bard, Inc. ("Bard") and its subsidiary Davol, Inc. ("Davol") were both responsible for the design, manufacture, production, testing, study, inspection, labeling, marketing, advertising, sales, promotion and/or distribution of the Ventralex Mesh that caused Plaintiff Tedder' injuries. Plaintiff Tedder respectfully seeks all damages to which she may be legally entitled.

STATEMENT OF PARTIES

2. Plaintiff Tedder currently resides in Tallahassee, Florida, and is a citizen and resident of Florida and the United States. She underwent hernia repair surgery on July 25, 2014

at Tallahassee Memorial Hospital in Tallahassee, Florida. At that time, the Ventralex Mesh product that Defendants manufactured, designed, distributed, and warranted was implanted into her. Her surgeon, medical staff, and other healthcare providers met or exceeded the standard of care applicable to the hernia surgery.

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

4. Davol, Inc. ("Davol") is incorporated in Delaware and has its principal place of business in Rhode Island. Davol is a medical device company involved in the research, development, testing, manufacture, production, marketing, promotion and/or sale of medical devices, including Ventralex Mesh, composed of a polypropylene base, an expanded polytetrafluroethylene (ePTFE) tissue separating layer, a permanent polyethylene terephthalate (PET) ring, and polypropylene positioning straps.

5. At all material times, Bard was responsible for Davol's actions, and exercised control over its functions, specific to the oversight and compliance with applicable safety standards relating to the Ventralex Mesh 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 Tedder to suffer injury and damages.

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

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

JURISDICTION & VENUE

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

9. Venue is proper in the U.S. District Court for the Northern District of Florida, Tallahassee Division, 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 July 25, 2014, Plaintiff underwent laparoscopic-assisted umbilical hernia repair by Dr. J.W. Crooms at Tallahassee Memorial Hospital in Tallahassee, Florida. A Ventralex device was implanted in Plaintiff during this repair.

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

13. On or about December 5, 2014, Plaintiff Tedder underwent surgery to remove the failed Ventralex Mesh at Tallahassee Memorial Hospital in Tallahassee, Florida by Dr. J.W. Crooms.

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

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

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

17. The polypropylene side of the Ventralex mesh was intended to promote incorporation (scarring into the abdominal wall), while the ePTFE side was intended to prevent adhesion formation from the polypropylene being exposed to underlying organs. However, the utilization of ePTFE results in the product being highly prone to infection, while the utilization of polypropylene results in the product being extremely difficult to remove once the Ventralex Mesh becomes infected. Additionally, both the ePTFE and polypropylene of the Ventralex Mesh are prone to excessive shrinkage.

18. The Ventralex Mesh also contains a permanent memory recoil ring ("PET ring"), which is prone to breaking once under the strain and pressure of the ePTFE and polypropylene contacting.

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

20. Defendants represented to Plaintiff and Plaintiff's physicians that Ventralex Mesh was a safe and effective product for hernia repair.

21. In 2013, Defendants conducted a silent recall by changing the design of the Ventralex Mesh to no longer include the defective PET ring. Defendants never issued a recall on the Ventralex Mesh, nor did they notify the public or health care professional of its defective nature.

THE FDA'S 510(k) CLEARANCE PROCESS

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

23. No clinical testing is required under this process.

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

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

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

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

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

28. The NIH explained, "The assessment of substantial equivalence does not require an independent demonstration that the new device provides a 'reasonable assurance of safety and effectiveness.'" Further, the NIH even pointed out that the classification of predicate devices

approved for sale prior to the 1976 MDA "did not include any evaluation of the safety and effectiveness of individual medical devices . . .Thus it is common for devices to be cleared through the 510(k) program by being found substantially equivalent to devices that were never individually evaluated for safety and effectiveness, either through the original device classification program or through the 510(k) process."

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

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

ESTOPPEL AND TOLLING OF STATUTE OF LIMITATIONS

31. Defendants are estopped from relying on any statues of limitations or repose by virtue of their acts of fraudulent concealment, which include the Defendants' intentional concealment from Plaintiff and the general public that the Ventralex Mesh is defective, while continually marketing the Ventralex Mesh with the effects described in this Complaint.

32. Given the Defendants' affirmative actions of concealment by failing to disclose this known but non-public information about the defects—information over which the Defendants had exclusive control—and because Plaintiff could not reasonably have known the Ventralex Mesh was defective, Defendants are estopped from relying on any statutes of limitations.

COUNT I: STRICT LIABILITY – MANUFACTURING DEFECT

33. Plaintiff incorporates the allegations in all prior paragraphs as of fully set forth herein.

34. Defendants expected and intended the Ventralex Mesh product to reach users such as Plaintiff Tedder in the condition in which the product was sold.

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

36. At the time the Ventralex Mesh that was implanted in Plaintiff's body, the product was defectively manufactured.

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

38. Upon information and belief, Defendants utilized substandard and adulterated polypropylene and raw materials used to make the Ventralex mesh coating on their finished Ventralex Mesh, which deviated from Defendants' material and supply specifications.

39. As a direct and proximate result of the defective manufacture of the Ventralex Mesh, Plaintiff suffered injuries and damages as summarized in herein.

COUNT II: STRICT LIABILITY – DESIGN DEFECT

40. Plaintiff incorporates the allegations in all prior paragraphs as if fully set forth herein.

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

42. When affixed to the body's tissue, the impermeable ePTFE coating of the Ventralex Mesh prevents fluid escape, which in turn can cause infection or abscess formation, adhesions, and/or other complications relating to interference with proper ingrowth processes.

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

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

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

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

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

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

47. The multi-layer design of the Ventralex Mesh results in ineffective sterilization more often than with a single layer mesh.

48. The Defendants' Ventralex Mesh is cytotoxic, immunogenic, and not biocompatible, which causes or contributes to complications such as delayed wound healing, inflammation, foreign body response, rejection, excess adhesion formation, infection, and other complications.

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

50. These manufacturing and design defects associated with the Ventralex Mesh were directly and proximately related to the injuries suffered by Plaintiff.

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

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

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

54. Defendants expected and intended the Ventralex Mesh product to reach users such as Plaintiff in the condition in which the product was sold.

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

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

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

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

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

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

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

62. The Ventralex Mesh contains a defectively designed PET ring. The Ventralex Mesh is vulnerable to buckling, folding, and/or migrating due to weaknesses in the PET ring and the forces produced as the polypropylene and ePTFE of the Ventralex Mesh shrinks post implantation.

63. The risks of Defendants' Ventralex Mesh significantly outweigh any benefits that Defendants contend could be associated with the product. The PET ring—which is no longer utilized in any hernia mesh product sold in the United States—has a propensity to buckle or break, resulting in organ perforation and hernia recurrence.

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

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

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

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

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

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).

67. The numerous layers utilized to create the Ventralex Mesh increases the intensity and duration of inflammation and foreign body response.

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

69. 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

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

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

72. Defendants expected and intended the Ventralex Mesh product to reach users such as Plaintiff in the condition in which the product was sold.

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

74. Defendants' Instructions for Use provided with the Ventralex Mesh expressly understate and misstate the risks known to be associated specifically with the Ventralex Mesh, by representing complications such as inflammation associated with the Ventralex Mesh as "possible complications." The Ventralex Mesh will always incite severe inflammation once implanted. The inflammation caused by the Ventralex Mesh is chronic in nature and systemic, not acute localized inflammation. No other surgical mesh sold in the United States has the dangerous and defective

Ventralex Mesh coating, which itself causes or increases the risks of numerous complications, including increased risk of excess adhesion formation, immunologic response, increased risk for infection, and increased inflammatory reaction and foreign body response. Defendants provided no warning to physicians about the risks or increased risks specifically associated with the unique design of the Ventralex Mesh.

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

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

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

78. The Defendants' Instructions for Use for the Ventralex failed to disclose the risk of ring break or buckling.

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

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

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

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

83. 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 Ventralex Mesh were more frequent, more severe and lasted longer than those with safer feasible alternative hernia repair treatments.

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

85. 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

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

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

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

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

90. Defendants utilized non-medical grade polypropylene.

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

92. 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.

93. 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.

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

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

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

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

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

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

100. Defendants knew or should have known that the PET ring was prone to breaking or buckling, increasing the risk of severe, permanent injuries.

101. 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 Ventralex Mesh, Plaintiff suffered injuries and damages as summarized herein.

COUNT V: BREACH OF IMPLIED WARRANTY

102. Plaintiff Tedder incorporates the allegations in all prior paragraphs.

103. At all material times, Defendants manufactured, marketed, sold distributed, and otherwise placed into the stream of commerce, the Ventralex Mesh.

104. At all material times, Defendants intended for their product to be implanted for the purposes and in the manner than 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.

105. 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' Ventralex Mesh.

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

107. Defendants breached various implied warranties with respect to Ventralex Mesh, including the following:

A. Defendants represented to Plaintiff and her physician and healthcare providers through labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that their product was 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 Ventralex Mesh.

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

109. 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.

110. 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: VIOLATION OF CONSUMER PROTECTION LAWS

111. Plaintiff Tedder incorporates by reference the allegations in all prior paragraphs.

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

113. Had Defendants not engaged in the deceptive conduct described in this Complaint, Plaintiff would not have purchased and/or paid for the product, and would not have incurred related medical costs and injury.

114. Defendants engaged in wrongful conduct while at the same time obtaining, under false pretenses, moneys from Plaintiff for the Ventralex Mesh, which would not have been paid but for Defendants' unfair and deceptive conduct.

115. Unfair methods of competition or deceptive acts or practices proscribed by law include the following:

A) Representing that goods or services have characteristics, ingredients, uses, benefits or qualities that they do not have;

B) advertising goods or services with the intent not to sell them as advertised; and

C) engaging in fraudulent or deceptive conduct that creates a likelihood of confusion or misunderstanding.

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

117. Defendants have a statutory duty to refrain from unfair or deceptive acts or trade practices in the design, labeling, development, manufacture, promotion, and sale of Ventralex Mesh.

118. Had Defendants not engaged in the deceptive conduct described above, Plaintiff would not have purchased and/or paid for the product, and would not have incurred related medical costs.

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

120. Defendants' actions constitute unfair competition or unfair, unconscionable, deceptive or fraudulent acts, or trade practices in violation of state consumer protection statutes.

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

- 15 U.S.C. §§ 2301-2312 (1982).
- N.J. STAT. ANN §§ 56:8-1, *et seq*.
- R.I. GEN. LAWS §§ 6-13.1, *et. seq*.

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

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

124. Defendants' actions and omissions are uncured or incurable deceptive acts under the consumer protection statute.

125. Defendants had actual knowledge of the defective and dangerous conditions of Ventralex Mesh, but failed to take any action to cure those conditions.

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

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

128. By reason of the unlawful acts in which Defendants engaged, and as a direct and proximate result, Plaintiff Tedder has suffered ascertainable losses and damages.

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

COUNT VII: GROSS NEGLIGENCE

130. Plaintiff Tedder incorporates herein by reference the allegations in all prior paragraphs.

131. The wrongs done by Defendants were aggravated by the kind of malice, fraud, and grossly negligent disregard for the rights of others, the public, and Plaintiff Tedder for which the law would allow, and for which Plaintiff Tedder will seek at the appropriate time under governing law, the imposition of exemplary damages. Defendants' conduct, including the failure to comply with applicable federal standards, was specifically intended to cause substantial injury to Plaintiff

Tedder or when viewed objectively from Defendants' standpoint at the time of the conduct, involved an extreme degree of risk, considering the probability and magnitude of the potential harm to others. Defendants were actually, subjectively aware of the risk involved, but nevertheless proceeded with conscious indifference to the rights, safety, or welfare of others; or included a material representation that was false, with Defendants, knowing that it was false or with reckless disregard as to its truth and as a positive assertion, intended that the representation is acted on by Plaintiff and in which Plaintiff indeed relied upon and suffered injury as a proximate result.

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

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

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

COUNT VIII: NEGLIGENT INFLICTION OF EMOTIONAL DISTRESS

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

136. Defendants carelessly and negligently manufactured, designed, developed, tested, labeled, marketed and sold Defendants' Ventralex Mesh to Plaintiff Tedder.

137. Defendants carelessly and negligently concealed the harmful effects of Defendants' Ventralex Mesh from Plaintiff and/or her physician on multiple occasions, and continue to do so to this day.

138. Defendants carelessly and negligently misrepresented the quality, safety and efficacy of the Ventralex Mesh to Plaintiff and/or her physician on multiple occasions, and continue to do so to this day.

139. 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 Ventralex Mesh sold and distributed by Defendants.

140. Defendants continued to carelessly and negligently misrepresent the quality, safety, efficacy, dangers and contraindications of Ventralex Mesh to Plaintiff and/or her physician, after she sustained emotional distress, severe physical injuries, and economic loss.

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

142. As a proximate result of Defendants' conduct, Plaintiff Tedder 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 IX: FRAUDULENT CONCEALMENT

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

144. At all times relevant hereto, it was known and knowable to Defendants that their product caused large numbers of complications. Moreover, it was known and 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 and knowable to Defendants that the safety and efficacy of Ventralex Mesh had not been proven with respect to, among other things, the product, its components, its performance, and its method of insertion. It was known and knowable to Defendants that that the product was not safe and effective. Defendants continued to represent that its product was safe and effective.

145. Despite what was known or knowable to Defendants about the lack of safety and efficacy of its product, Defendants failed to disclose this information to Plaintiff, her physicians, and the public at large.

146. At all times relevant hereto, Defendants had the duty and obligation to disclose to Plaintiff Tedder and her physicians the true facts concerning Ventralex Mesh, that is, that said product was dangerous and defective, lacking efficacy for its purported use and lack of 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 before Plaintiff was implanted with Defendants' Ventralex Mesh.

147. Defendants were under a duty to Plaintiff to disclose and warn of the defective nature of the Ventralex Mesh because:

A. Defendants were in a superior position to know the true quality, safety, and efficacy of the Ventralex Mesh;

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

C. Defendants fraudulently and affirmatively concealed the defective nature of the Ventralex Mesh from Plaintiff.

148. The facts concealed and/or not disclosed by Defendants to Plaintiff Tedder were material facts that a reasonable person would have considered important in deciding whether to purchase and/or use Defendants' Ventralex Mesh.

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

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

151. At all times relevant hereto, neither Plaintiff nor her physician was aware of the facts set forth above, and had they been aware of said facts, they would not have acted as they did, that is, would not have reasonably relied upon the representations of safety and efficacy and utilized Defendants' Ventralex Mesh. Defendants' failure to disclose this information was a substantial factor in Plaintiff's physician's selection of Ventralex Mesh. The failure to disclose

also resulted in the provision of incorrect and incomplete information to Plaintiff Tedder, as a patient.

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

COUNT X: NEGLIGENT MISREPRESENTATION

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

154. Defendants had a duty to accurately and truthfully represent to the medical and healthcare community, Plaintiff Tedder, and the public, that its Ventralex Mesh had not been adequately tested and found to be a safe and effective treatment. Defendants' representations were in fact false.

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

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

157. As a foreseeable, direct, and proximate result of Defendants' negligent misrepresentations, they knew, or had reason to know, that It's Ventralex Mesh had been insufficiently tested, or had not been tested at all; and that the product lacked adequate and accurate warnings, and created a high risk—and/or higher than acceptable or reported and represented

risk—of adverse side effects, including pain, graft rejection, graft migration, organ damage, complex seroma, fistula, sinus tract formation, delayed wound closure, infection, sepsis, and death.

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

PUNITIVE DAMAGES ALLEGATIONS

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

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

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

162. At all times relevant hereto, Defendants knew or should have known that Ventralex Mesh was inherently more dangerous with respect to the risk of foreign body response, allergic reactions, rejection, infection, failure, erosion, pain and suffering, organ perforation, dense adhesions, tumor or cancer formation, loss of life's enjoyment, remedial surgeries and treatments

in an effort to cure the conditions proximately related to the use of the product, as well as the other severe and personal injuries which are permanent and lasting in nature.

163. Defendants' misrepresentations included knowingly withholding material information from the medical community and the public, including Plaintiff, concerning the safety and efficacy of the Ventralex Mesh, which deprived Plaintiff and her implanting physician of vitally necessary information with which to make a fully informed decision about whether to use Ventralex Mesh.

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

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

166. 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 associated with Ventralex Mesh.

167. Notwithstanding the foregoing and the growing body of knowledge and information regarding the true and defective nature of Ventralex Mesh, with its increased risk of side effects and serious complications, Defendants continue to aggressively market the Ventralex

Mesh to the medical community and to consumers without disclosing the true risk of such complications.

168. At the time Plaintiff Tedder was implanted with the Ventralex Mesh, and since that time, Defendants knew that Ventralex Mesh was defective and unreasonably dangerous, but continued to manufacture, produce, assemble, market, distribute, and sell the product 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 Ventralex Mesh to members of the public including Plaintiff.

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

170. 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, gross negligence, or that entire want of care raising the presumption of conscious indifference to consequences, thereby justifying an award of punitive damages

WHEREFORE, Plaintiff Jennifer S. Tedder demands judgment against Defendants individually, and jointly and severally and in the alternative, and requests 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 Jennifer S. Tedder 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 Plaintiff for past, present, and future damages, including but not limited to, pain and suffering for severe and permanent personal injuries she sustained, permanent impairment, mental pain and suffering, loss of enjoyment of life, health and medical care costs, economic damages, together with interest and costs as provided by law;

ii. Restitution and disgorgement of profits;

iii. Punitive damages or enhanced compensatory damages;

iv. Reasonable attorneys' fees as provided by law;

v. Past and future cost of all proceedings;

vi. All ascertainable economic damages;

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

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

DEMAND FOR JURY TRIAL

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

Date: November 27, 2018

Respectfully submitted,

/s/ *Kelsey L. Stokes*
Kelsey L. Stokes
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Attorneys for Plaintiff

JS 44 (Rev. 08/18)

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

JENNIFER S. TEDDER

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

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
KELSEY L. STOKES, FLEMING, NOLEN & JEZ, L.L.P., 2800 POST OAK BLVD., SUITE 4000, HOUSTON, TX 77056-6109; (713) 621-7944

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
- ❒ 835 Patent - Abbreviated New Drug Application
- ❒ 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
- ❒ 485 Telephone Consumer Protection Act
- ❒ 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 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 $ 20,000,000.00

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 11/27/2018

SIGNATURE OF ATTORNEY OF RECORD /s/ Kelsey L. Stokes

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.
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.