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, JR.
Magistrate Judge Kimberly A. Jolson

This document relates to:
TARI K. MOTSINGER

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 the Plaintiff, Tari K. Motsinger, arising out of the failure of Defendants' hernia mesh product, Ventrio ST Mesh ("ST Bard Mesh"). As a result, Plaintiff has suffered permanent injuries and significant pain and suffering, emotional distress, lost wages and earning capacity, and diminished quality of life. Plaintiff respectfully seeks all damages to which she may be legally entitled.

STATEMENT OF PARTIES

2. Plaintiff Motsinger currently resides in Tillamook, Oregon, and is a citizen and resident of Oregon 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. Such devices include hernia meshes composed of polypropylene, and polyglycolic acid (PGA) fibers coated with Sepra Technology (ST), a bioresorbable, chemically modified sodium hyalurnate, carboxymethylcellulose, and polyethylene glycol-based hydrogel.

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 Ventrio ST Mesh. It also manufactures and supplies Davol with material that forms part of the product.

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 Ventrio ST 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 Motsinger to suffer injury and damages.

6. Defendants are individually and jointly and severally liable to Plaintiff Motsinger for damages she suffered, arising from their design, manufacture, marketing, labeling, distribution, sale and placement of the defective Ventrio ST Mesh, effectuated directly and indirectly through their agents, servants, employees and/or owners, all acting within the course and scope of their 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.

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 District of Oregon, Portland 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 December 15, 2016, Plaintiff Motsinger underwent repair of a ventral hernia by Dr. Frederick A. Foss at Tillamook Regional Medical Center in Tillamook, Oregon. A Medium Ventrio ST Mesh patch, 4.3 in x 5.5 in, in diameter, Ref No. 5950040, Lot No. HUZG0239 was implanted in Plaintiff during this repair.

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

13. After a CT scan revealed a fistula communicating with the mesh, it was determined that the infected mesh should be removed. Accordingly, on November 3, 2017, Plaintiff Motsinger underwent surgery by Dr. Bruce Ham to explant the Ventrio ST Mesh.

14. Plaintiff continues to experience complications related to the Ventrio ST Mesh. She will likely require additional surgeries 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 Ventrio ST Mesh, 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 Ventrio ST Mesh was implanted in Plaintiff Motsinger.

17. Defendants represented to Plaintiff and her physician that the Ventrio ST Mesh 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 Ventrio ST Mesh, and its related components, under the 510(k) Premarket Notification.

26. On June 18, 2002, the FDA issued a document entitled "Guidance for Resorbable Adhesion Barrier Devices for Use in Abdominal and/or Pelvic Surgery; Guidance for Industry." The 26-page document starts by explaining:

> **FDA has determined that the resorbable adhesion barrier is a significant risk device as defined in 21 CFR 812.3(m)(4). The resorbable adhesion barrier is a Class III device which is subject to premarket approval in accordance with section 515 of the Federal Food, Drug, and Cosmetics (FD&C) Act.**

ESTOPPEL AND TOLLING OF STATUTE OF LIMITATIONS

27. 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 Plaintiff Motsinger and the general public that the Ventrio ST Mesh is defective, while continuing to market the product with the adverse effects described in this Complaint.

28. 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 Plaintiff could not reasonably have known the Ventrio ST Mesh 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

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

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

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

32. When the Ventrio ST Mesh was implanted in Plaintiff's body, the product was defectively manufactured.

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

34. Upon information and belief, Defendants utilized substandard and adulterated polypropylene and raw materials used to make the ST coating on their finished Ventrio ST Mesh product, which deviated from their material and supply specifications.

35. As a direct and proximate result of Defendants' defective manufacture of the Ventrio ST Mesh, Plaintiff suffered injuries and damages as summarized in this Complaint.

COUNT II: STRICT LIABILITY – DESIGN DEFECT

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

37. Defendants' Bard ST 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 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.

38. When affixed to the body's tissue, the impermeable coating of the Bard ST Mesh prevents fluid escape, which leads to seroma formation, and which in turn can cause infection or abscess formation and other complications.

39. The acidic polymer(s) of the Bard ST Mesh inhibit the body's natural defenses.

40. Defendants utilize Ethylene Oxide ("ETO") in an attempt to sterilize the Bard ST Mesh. 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.

41. The Bard ST Mesh, 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 ST Mesh 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

42. Defendants' Bard ST Mesh is acidic, causing bacteriostasis (inhibition of the growth of bacteria without killing the bacteria), increasing the difficultly in properly validating sterilization.

43. The coating of the Bard ST Mesh, which is intended to prevent adhesion formation to the polypropylene portion of the mesh, resorbs within 5 to 7 days. The period in which adhesions can form is longer than 7 days.

44. The risks of Defendants' Bard ST Mesh significantly outweigh any benefits that Defendants contend could be associated with the product. The ST coating and acidic polymer(s)—

which are not used in any other polypropylene hernia mesh product sold in the United States—do not prevent adhesion formation to polypropylene, but instead incite an intense inflammatory response, leading to encapsulation, deformation, scarification and contraction, migration, erosion and rejection. The long resorption period of the acidic polymer(s) lead to seroma formation, increase the chance of infection, and protects bacteria from being eliminated through the body's natural immune response.

45. The ST coating of the Bard ST Mesh, which was marketed, promoted and intended as an adhesion barrier, was only temporary; it was expected and intended to degrade over time inside the body. Thus, the coating potentially prevented tissue ingrowth for the first few days, and degraded within a week, leaving the "naked" polypropylene mesh and acidic polymer(s) exposed to the internal viscera and tissues. Once exposed to the viscera, the inflammatory nature of the polypropylene and the acidic polymer(s) will inevitably stimulate adhesion formation and eventually adhere to the viscera, initiating a cascade of adverse consequences. Any purported beneficial purpose of the coating (to prevent adhesion to the bowel and internal viscera) was non-existent; the product provided no benefit while substantially increasing the risks to the patient.

46. The resorbable polymers of the Bard ST Mesh promote the formation of Collagen type III (weak collagen) instead of Collagen type I (strong collagen), increasing the risk of recurrent hernia.

47. The polypropylene mesh within the defective coating of the Bard ST Mesh was in itself dangerous and defective, particularly when utilized in the manner intended by Defendants. The particular polypropylene material used in the Bard ST Mesh was substandard, adulterated and/or non-medical grade, and was unreasonably subject to oxidative degradation within the body, further exacerbating the adverse reactions to the product once the ST coating degraded. When

implanted adjacent to the bowel and other internal organs, as Defendants intended for the Bard ST Mesh, it is unreasonably susceptible to adhesion formation, bowel perforation or erosion, fistula formation and bowel strangulation or hernia incarceration, and other injuries.

48. The Bard ST Mesh is "heat set" to bond the polypropylene, acidic polymer(s), and ST coating together. The temperature at which the Bard ST Mesh is "heat set" is above the temperature polypropylene begins to degrade and change chemical composition.

49. Defendants' Bard ST Mesh 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.

50. When the Ventrio ST Mesh was implanted in Plaintiff Motsinger, there were safer feasible alternative designs for hernia mesh products, including a flat, non-coated, single-layer mesh, made with medical-grade polymers, placed away from the bowel.

51. The Bard ST Mesh product costs significantly more than competitive products due to its unique ST coating, even though the ST coating provided no benefit to consumers and increased the risks to patients implanted with these devices.

52. Plaintiff Motsinger was implanted with Defendants' Ventrio ST Mesh product, which also includes an inner ring of polydioxanone (PDO ring), to aid in the memory and stability of the device. The inner PDO ring is called SorbaFlex Memory Technology.

53. Once implanted, the PDO ring breaks down via hydrolysis over a period of at least 6 to 8 months. The PDO ring elicits an intense inflammatory response during absorption.

54. The Ventrio ST Mesh is vulnerable to buckling, folding, and/or migrating once the PDO ring has absorbed.

55. Defendants secure the ST coating to the polypropylene base of the mesh by suturing two circular rings of PGA. The two securing circular rings of PGA are not ST coated and are the closest part of the mesh to underlying organs once implanted. This results in significant amounts of bare PGA being exposed to underlying organs at the time of implantation.

56. The two circular rings of PGA securing the ST coating to the polypropylene have a tendency to come unstitched, resulting in segments of PGA protruding toward the underlying organs.

57. The method by which Defendants secure the ST coating to the polypropylene base of the mesh does not provide adequate or uniform coverage to the outer aspects of the base polypropylene from the time of implantation.

58. The securing circular rings of PGA do not extend to the outer aspects of the polypropylene base, which can result in the ST coating folding upon itself and exposing bare polypropylene.

59. The polypropylene portion of the Ventrio ST Mesh has a tendency to unravel, creating a sharp "fishing line" effect, which can slice through the patient's tissue.

60. The additional layers increase the intensity and duration of inflammation and foreign body response.

61. The Ventrio ST Mesh implanted in Plaintiff Motsinger 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 Ventrio ST Mesh was intended to repair. The product thus provided no benefit to Plaintiff.

62. 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

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

64. Defendants failed to warn that the ST coating of the Bard ST Mesh could resorb within as 5 days.

65. When the Ventrio ST Mesh 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.

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

67. Plaintiff Motsinger and Plaintiff's physicians were unaware of the defects and dangers of Ventrio ST Mesh, and were unaware of the frequency, severity and duration of the risks associated with the product.

68. Defendants' Instructions for Use provided with the Ventrio ST Mesh 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 Ventrio ST Mesh will always incite severe inflammation once implanted. The inflammation caused by the Ventrio ST Mesh is chronic in nature and systemic, not acute localized inflammation.

69. No other polypropylene surgical mesh sold in the United States has the dangerous and defective ST coating and acidic polymer(s), which itself causes or increases the risks of numerous complications, including increased risk of seroma formation, immunologic response, increased risk for infection, and increased inflammatory reaction and foreign body response.

Defendants provided no warning to physicians about the risks or increased risks specifically associated with the unique design of the Ventrio ST Mesh.

70. Defendants' Instructions for Use for the product also failed to adequately warn Plaintiff's physician of numerous risks that Defendants knew or should have known were associated with the Ventrio ST 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.

71. Defendants failed to adequately warn Plaintiff or her 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.

72. Defendants failed to adequately warn Plaintiff or her physician that the surgical removal of the Ventrio ST Mesh 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.

73. Defendants represented to physicians, including Plaintiff's physician, that the ST coating would prevent or reduce adhesions; expressly intended for the ST Mesh to be implanted in contact with the bowel and internal organs; and marketed and promoted the Ventrio ST Mesh for that purpose. Defendants failed to warn physicians that the ST coating was temporary, and therefore at best would provide only a temporary adhesion barrier. Further, Defendants did not warn physicians that when the coating inevitably degraded, the exposed polypropylene and PGA would become adhered to the bowel or tissue.

74. Defendants failed to warn Plaintiff and her physician that the FDA considered the Ventrio ST Mesh device a significant risk.

75. Defendants marketed and continue to market the Ventrio ST Mesh in brochures and online without disclosing or making evident that PGA is utilized in the product.

76. 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 Ventrio ST Mesh were more frequent, more severe and longer lasting than those with safer feasible alternative hernia repair treatments.

77. If Plaintiff and/or her physician had been properly warned of the defects and dangers of the Ventrio ST Mesh, 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.

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

COUNT IV: NEGLIGENCE

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

80. Although Defendants had a duty to use reasonable care in designing, testing, inspecting, manufacturing, packaging, labeling, marketing, distributing, and preparing written instructions and warnings for the Ventrio ST Mesh, they failed to do so.

81. 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 her physician were unaware of the dangers and defects inherent in the Ventrio ST Mesh.

82. 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.

83. Defendants utilized non-medical grade polypropylene.

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

85. 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.

86. 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.

87. Defendants knew or should have known that PGA (polyglycolic acid) induces an intense local inflammatory response following implantation.

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

89. Defendants knew or should have known of the cytotoxic and immunogenic properties of the coating on the Ventrio ST Mesh before introducing it into the stream of commerce.

90. 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 the Ventrio ST Mesh, Plaintiff suffered injuries and damages as summarized in this Complaint.

COUNT V: BREACH OF IMPLIED WARRANTY

91. Plaintiff incorporates 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 Ventrio ST Mesh.

93. At all material times, Defendants intended for their product to be implanted for the purposes and in the manner than 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 her physician, would implant their product as directed by the Instructions for Use. Therefore, Plaintiff was a foreseeable user of Defendants' Ventrio ST Mesh.

95. Defendants'' Ventrio ST Mesh 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 Ventrio ST Mesh, 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 Ventrio ST Mesh.

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

98. 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.

99. As a direct and proximate result of Defendants' breaches of the aforementioned implied warranties, Plaintiff was caused to suffer severe personal injuries, pain and suffering, severe emotional distress, financial or economic loss, including obligations for medical services and expenses, impairment of personal relationships, and other damages.

COUNT VI: NEGLIGENT INFLICTION OF EMOTIONAL DISTRESS

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

101. Defendants negligently manufactured, designed, developed, tested, labeled, marketed and sold the Ventrio ST Mesh to Plaintiff.

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

104. Plaintiff was directly impacted by Defendants' negligence, in that she 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 her physician.

106. Defendants continued to negligently misrepresent the quality, safety, efficacy, dangers and contraindications of their product to Plaintiff individually, and/or her 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, Plaintiff has been injured. He has 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. Plaintiff incorporates 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 Ventrio ST Mesh. 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, her physician, and/or public at large.

111. At all material times, Defendants had the duty and obligation to disclose to Plaintiff and her physician the true facts concerning their product, *i.e.*, that the Ventrio ST Mesh 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 Plaintiff Motsinger was implanted with Defendants' product.

112. Defendants were under a duty to Plaintiff 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 Ventrio ST Mesh;

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 Plaintiff 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 her physician, with the intent to defraud them.

115. Defendants intentionally concealed or failed to disclose the true defective nature of the Ventrio ST Mesh, 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 her detriment.

116. At all material times, neither Plaintiff nor her 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, Plaintiff was injured.

COUNT VIII: NEGLIGENT MISREPRESENTATION

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

119. Defendants had a duty to accurately and truthfully represent to the medical and healthcare community, Plaintiff, and the public, that the Ventrio ST Mesh 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 Ventrio ST Mesh's high risk of unreasonable and dangerous adverse side effects.

121. Defendants also breached their duty in representing to Plaintiff, her 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 Ventrio ST Mesh 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, Plaintiff Motsinger 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

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

125. Defendants failed to adequately test and study the Ventrio ST Mesh 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.

126. Even though Defendants have other hernia repair mesh devices that do not present the same risks as the Ventrio ST Mesh, they developed, designed and sold the Ventrio ST Mesh, 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.

127. At all material times, Defendants knew or should have known that Ventrio ST Mesh was inherently more dangerous with respect to the following: the risk of foreign body response, allergic reaction, rejection, infection, failure, erosion, pain and suffering, organ perforation, 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.

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

129. 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. But Defendants recklessly failed to advise the medical community and the general public, including Plaintiffs, of that fact.

130. 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 Ventrio ST Mesh.

131. Notwithstanding the foregoing and the growing body of knowledge and information regarding the true and defective nature of the Ventrio ST Mesh, 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.

132. When Plaintiff Motsinger was implanted with the Ventrio ST Mesh and since then, Defendants have known the product was defective and unreasonably dangerous. But they continued to manufacture, produce, assemble, market, distribute, and sell Ventrio ST Mesh so as to maximize sales and profits at the expense of the health and safety of the public in a conscious, reckless and/or intentional disregard of the likely and foreseeable harm caused by the product to members of the public, including Plaintiff.

133. At all material times, Defendants have concealed and/or failed to disclose to the public the serious risks and 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 Plaintiff.

134. Defendants' acts and omissions are of such character and nature so as to entitle Plaintiff to an award of punitive damages in accordance with applicable statutory and common law. Defendants' conduct shows willful misconduct, malice, fraud, wantonness, oppression, or that entire want of care, raising the presumption of conscious indifference to consequences, thereby justifying an award of punitive damages.

WHEREFORE, Plaintiff Motsinger demands judgment against Defendants individually and jointly and severally. Plaintiff also 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 Motsinger demands 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 Plaintiff for past, present, and future damages, including pain and suffering for severe and permanent personal injuries sustained by Plaintiff; permanent impairment, mental pain and suffering, loss of enjoyment of life, health and medical care costs, economic damages, together with interest and costs as provided by law;

ii. Restitution and disgorgement of 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

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

Date: September 21, 2018

Respectfully submitted,

/s/ *Kelsey L. Stokes*
Kelsey L. Stokes
Texas Bar No. 24083912
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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

TARI K. MOTSINGER

(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	TORTS		FORFEITURE/PENALTY	BANKRUPTCY	OTHER STATUTES
❒ 110 Insurance	PERSONAL INJURY	PERSONAL INJURY	❒ 625 Drug Related Seizure of Property 21 USC 881	❒ 422 Appeal 28 USC 158	❒ 375 False Claims Act
❒ 120 Marine	❒ 310 Airplane	❒ 365 Personal Injury - Product Liability	❒ 690 Other	❒ 423 Withdrawal 28 USC 157	❒ 376 Qui Tam (31 USC 3729(a))
❒ 130 Miller Act	❒ 315 Airplane Product Liability	☒ 367 Health Care/ Pharmaceutical Personal Injury Product Liability		PROPERTY RIGHTS	❒ 400 State Reapportionment
❒ 140 Negotiable Instrument	❒ 320 Assault, Libel & Slander	❒ 368 Asbestos Personal Injury Product Liability		❒ 820 Copyrights	❒ 410 Antitrust
❒ 150 Recovery of Overpayment & Enforcement of Judgment	❒ 330 Federal Employers' Liability	PERSONAL PROPERTY	LABOR	❒ 830 Patent	❒ 430 Banks and Banking
❒ 151 Medicare Act	❒ 340 Marine	❒ 370 Other Fraud	❒ 710 Fair Labor Standards Act	❒ 835 Patent - Abbreviated New Drug Application	❒ 450 Commerce
❒ 152 Recovery of Defaulted Student Loans (Excludes Veterans)	❒ 345 Marine Product Liability	❒ 371 Truth in Lending	❒ 720 Labor/Management Relations	❒ 840 Trademark	❒ 460 Deportation
❒ 153 Recovery of Overpayment of Veteran's Benefits	❒ 350 Motor Vehicle	❒ 380 Other Personal Property Damage	❒ 740 Railway Labor Act	SOCIAL SECURITY	❒ 470 Racketeer Influenced and Corrupt Organizations
❒ 160 Stockholders' Suits	❒ 355 Motor Vehicle Product Liability	❒ 385 Property Damage Product Liability	❒ 751 Family and Medical Leave Act	❒ 861 HIA (1395ff)	❒ 480 Consumer Credit
❒ 190 Other Contract	❒ 360 Other Personal Injury		❒ 790 Other Labor Litigation	❒ 862 Black Lung (923)	❒ 485 Telephone Consumer Protection Act
❒ 195 Contract Product Liability	❒ 362 Personal Injury - Medical Malpractice		❒ 791 Employee Retirement Income Security Act	❒ 863 DIWC/DIWW (405(g))	❒ 490 Cable/Sat TV
❒ 196 Franchise				❒ 864 SSID Title XVI	❒ 850 Securities/Commodities/ Exchange
				❒ 865 RSI (405(g))	❒ 890 Other Statutory Actions
REAL PROPERTY	CIVIL RIGHTS	PRISONER PETITIONS	IMMIGRATION		❒ 891 Agricultural Acts
❒ 210 Land Condemnation	❒ 440 Other Civil Rights	Habeas Corpus:	❒ 462 Naturalization Application	FEDERAL TAX SUITS	❒ 893 Environmental Matters
❒ 220 Foreclosure	❒ 441 Voting	❒ 463 Alien Detainee	❒ 465 Other Immigration Actions	❒ 870 Taxes (U.S. Plaintiff or Defendant)	❒ 895 Freedom of Information Act
❒ 230 Rent Lease & Ejectment	❒ 442 Employment	❒ 510 Motions to Vacate Sentence		❒ 871 IRS—Third Party 26 USC 7609	❒ 896 Arbitration
❒ 240 Torts to Land	❒ 443 Housing/ Accommodations	❒ 530 General			❒ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
❒ 245 Tort Product Liability	❒ 445 Amer. w/Disabilities - Employment	❒ 535 Death Penalty			❒ 950 Constitutionality of State Statutes
❒ 290 All Other Real Property	❒ 446 Amer. w/Disabilities - Other	Other:			
	❒ 448 Education	❒ 540 Mandamus & Other			
		❒ 550 Civil Rights			
		❒ 555 Prison Condition			
		❒ 560 Civil Detainee - Conditions of Confinement			

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 09/21/2018

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.