

**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:  
BILLY EDWARD KEY, JR.**

**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 above-named Plaintiff arising out of the failure of the Defendants' hernia mesh product. As a result, Plaintiff Billy Edward Key, Jr. suffered permanent injuries and significant pain and suffering, emotional distress, lost wages and earning capacity, and diminished quality of life. The Plaintiff respectfully seeks all damages to which he may be legally entitled.

**STATEMENT OF PARTIES**

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

3. 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 a hernia mesh patch composed of an absorbable polydioxanone (PDO) recoil ring concealed between two layers of polypropylene mesh, and an expanded polytetrafluoroethylene (ePTFE) sheet, which attached to one side the polypropylene mesh (hereinafter “ePTFE Bard Mesh” or “product”).

4. 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 market share of the hernia mesh market. Bard is the parent company of Davol. Bard controls the largest market share of the hernia mesh market. Bard is the corporate parent/stockholder of Davol and participates in the manufacture and distribution of ePTFE Bard Mesh. It also manufactures and supplies Davol with material that forms part of the ePTFE Bard Mesh.

5. Bard was, at all times relevant hereto, 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 EPTFE Bard Mesh sold in the United States. In such capacity, they 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 and malfeasance caused Plaintiff to suffer injury and damages.

6. Defendants are individually, jointly and severally liable to Plaintiff for damages suffered by Plaintiff arising from the Defendants’ design, manufacture, marketing, labeling, distribution, sale and placement of its defective ePTFE Bard 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 times relevant hereto acting on behalf of Defendants and within the scope of their employment or agency with Defendants.

### **VENUE AND JURISDICTION**

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

9. Venue is proper in the Southern District of Texas Houston 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 August 4, 2010, Plaintiff Billy Edward Key, Jr. underwent repair of a ventral hernia by Dr. Juan Mario Villafani, MD at Kingwood Medical Center in Kingwood, Texas. A Ventrion Mesh patch 27.4 cm x 34.9 cm, Reference No. 0010217, Lot No. HUUA0814 was implanted in Plaintiff Billy Edward Key, Jr. during this repair (Hereinafter "Ventrion" or "ePTFE Bard Mesh").

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

13. On or about July 19, 2017, Plaintiff Billy Edward Key, Jr. underwent surgery by Dr. Samir Kreit, MD to explant the infected Ventrion mesh. During the surgery, Plaintiff noted that "the mesh appeared to be involved with an infected abscess within the abdomen." The following week, on July 26, 2017, Plaintiff Billy Edward Key, Jr. underwent a repair of an intestinal fistula secondary to the mesh infection. During this surgery, Dr. Kreit noted that Plaintiff would require an additional surgery to implant another mesh device.

14. Plaintiff Billy Edward Key, Jr. continues to experience complications related to the ePTFE Bard Mesh and will likely require additional surgeries to repair the damage from the ePTFE Bard Mesh.

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

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

17. The ePTFE Bard Mesh is composed of the following layers:

- i) ePTFE sheet
- ii) Polypropylene mesh
- iii) PDO absorbable recoil ring
- iv) Polypropylene mesh

18. The polypropylene side of the ePTFE Bard 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 ePTFE Bard Mesh becomes infected.

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.

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

#### **THE FDA'S 510(k) CLEARANCE PROCESS**

21. 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.

22. No clinical testing is required under this process.

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

24. 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.

25. Clearance for sale under the 510(k) process does not equate to FDA approval of the cleared device.

26. In 2012, at the request of the FDA, 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.**

27. 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.”

28. Defendants cleared the ePTFE Bard 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.

**ESTOPPEL AND TOLLING OF STATUTE OF LIMITATIONS**

29. Defendants are estopped from relying on any statutes 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 ePTFE Bard Mesh is defective, while continually marketing the ePTFE Bard Mesh with the effects described herein.

30. 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 ePTFE Bard Mesh was defective, Defendants are estopped from relying on any statutes of limitations that might otherwise be applicable to the claims asserted herein.

**COUNT I: STRICT LIABILITY – MANUFACTURING DEFECT**

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

32. Defendants expected and intended the ePTFE Bard Mesh product to reach users such as Plaintiff in the condition in which the product was sold.

33. The implantation of ePTFE Bard 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.

34. At the time the ePTFE Bard Mesh that was implanted in Plaintiff's body, the product was defectively manufactured.

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

36. Upon information and belief, Defendants utilized substandard and adulterated polypropylene and raw materials used to make the ePTFE Bard Meshes, which deviated from Defendants' material and supply specifications.

37. As a direct and proximate result of the defective manufacture of the ePTFE Bard Mesh, Plaintiff suffered injuries and damages as summarized herein.

**COUNT II: STRICT LIABILITY – DESIGN DEFECT**

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

39. Defendants' ePTFE Bard 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 ePTFE Bard Mesh, there was an unreasonable risk of severe adverse reactions to the mesh or mesh components including: chronic infections; 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.



40. When affixed to the body's tissue, the impermeable ePTFE layer prevents fluid escape, which leads to seroma formation, and which in turn can cause infection or abscess formation and other complications.

41. The smooth surface of the ePTFE Bard Mesh provides an ideal bacteria breeding ground in which the bacteria cannot be eliminated by the body's immune response, which allows bacteria to lie dormant and infection to eventually proliferate.

42. The ePTFE Bard 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 ePTFE Bard Mesh curling after implantation.

43. 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.

44. Defendants utilize Ethylene Oxide ("ETO") in an attempt to sterilize the ePTFE Bard Mesh. ETO is an effective disinfectant; however, 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. ePTFE Bard 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 ePTFE Bard 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

45. The multi-layer design of the ePTFE Bard Mesh results in ineffective sterilization more often.

46. The Defendants' ePTFE Bard Mesh is cytotoxic, immunogenic, and not biocompatible, which causes or contributes to complications such as delayed wound healing, inflammation, foreign body response, rejection, infection, and other complications.

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

48. These manufacturing and design defects associated with the ePTFE Bard Mesh were directly and proximately related to the injuries suffered by Plaintiff.

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

50. The ePTFE Bard Mesh implanted in Plaintiff failed to reasonably perform as intended. The ePTFE Bard Mesh caused serious injury and had to be surgically removed via

invasive surgery, and necessitated additional invasive surgery to repair the hernia that the ePTFE Bard Mesh was initially implanted to treat.

51. At the time the ePTFE Bard Mesh that was implanted in Plaintiff's body, the product was defectively designed. As described above, there was an unreasonable risk that the ePTFE Bard 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.

52. Defendants expected and intended the ePTFE Bard Mesh product to reach users such as Plaintiff in the condition in which the product was sold.

53. The implantation of ePTFE Bard 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.

54. The risks of the ePTFE Bard Mesh significantly outweigh any benefits that Defendants contend could be associated with the product. The ePTFE Bard 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.

55. The polypropylene mesh patch was in itself dangerous and defective, particularly when used in the manner intended by Defendants in the ePTFE Bard Mesh. The particular polypropylene material used in the ePTFE Bard 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 ePTFE Bard Mesh curls, exposing the underlying polypropylene. When implanted adjacent to the bowel and other internal organs, as Defendants intended for ePTFE Bard Mesh, polypropylene mesh is unreasonably susceptible to adhesion, bowel perforation or erosion, fistula formation and bowel strangulation or hernia incarceration, and other injuries.

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

57. 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 ePTFE Bard Mesh.

58. The appropriate treatment for complications associated with ePTFE Bard 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.

59. The ePTFE Bard 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.

60. At the time the ePTFE Bard 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.

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

62. The ePTFE Bard 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 Presarcomatous 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).

63. Plaintiff was implanted with a Ventrilo mesh patch, which also includes an inner ring of PDO, to aid in the short-term memory and stability of the device. The inner PDO ring is called SorbaFlex Memory Technology.

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

65. The Ventrío mesh patch is vulnerable to buckling, folding, and/or migrating once the PDO ring has absorbed.

66. The numerous layers utilized to create the ePTFE Bard Mesh increases the intensity and duration of inflammation and foreign body response.

67. The ePTFE Bard 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 him.

68. 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**

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

70. At the time the ePTFE Bard Mesh that was implanted in Plaintiff's body, the warnings and instructions provided by Defendant for the ePTFE Bard 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.

71. Defendants expected and intended the ePTFE Bard Mesh product to reach users such as Plaintiff in the condition in which the product was sold.

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

73. The Defendants' Instructions for Use provided with the EPTFE Bard Mesh expressly understates and misstates the risks known to be associated specifically with the EPTFE Bard Mesh by representing that the complications such as inflammation associated with the EPTFE Bard Mesh as "possible complications." The EPTFE Bard Mesh will always incite severe inflammation once implanted. The inflammation caused by the EPTFE Bard Mesh is chronic in nature and systemic, not acute localized inflammation. Defendants provided no warning to physicians about the risks or increased risks specifically associated with the unique design of the ePTFE Bard Mesh.

74. The Defendants' Instructions for Use for the ePTFE Bard Mesh failed to adequately warn Plaintiff's physicians of numerous risks which Defendants knew or should have known were associated with the ePTFE Bard Mesh, including the risks of the product's immunologic response, infection, pain, dehiscence, encapsulation, rejection, migration, scarification, contraction, erosion through adjacent tissue and viscera, bowel obstruction, and tumor or cancer formation.

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

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

77. 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.

78. Defendants failed to adequately warn Plaintiff or Plaintiff's physicians that the surgical removal of the ePTFE Bard 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 ePTFE Bard Mesh was intended to treat.

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

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

81. 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 ePTFE Bard Mesh were more frequent, more severe and lasted longer than those with safer feasible alternative hernia repair treatments.

82. If Plaintiff and/or Plaintiff's physicians had been properly warned of the defects and dangers of ePTFE Bard Mesh, and of the frequency, severity and duration of the risks associated with the ePTFE Bard Mesh, Plaintiff would not have consented to allow the ePTFE



Bard Mesh to be implanted, and Plaintiff's physicians would not have implanted the ePTFE Bard Mesh in Plaintiff.

83. 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**

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

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

86. Defendants knew, or in the exercise of reasonable care should have known, that ePTFE Bard Mesh was defectively and unreasonably designed and/or manufactured, and was unreasonably dangerous and likely to injure patients in whom ePTFE Bard 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 ePTFE Bard Mesh.

87. Defendants knew or should have known that the MSDS for the polypropylene used to manufacture its ePTFE Bard Mesh prohibited permanently implanting the polypropylene into the human body.

88. Defendants utilized non-medical grade polypropylene.

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

90. 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.

91. 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.

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

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

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

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

96. 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.

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

98. 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 ePTFE Bard Mesh, Plaintiff suffered injuries and damages as summarized herein.

**COUNT V: BREACH OF EXPRESS WARRANTY**

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

100. At all relevant and material times, Defendants manufactured, marketed, sold, distributed and otherwise placed in to the stream of commerce ePTFE Bard Mesh.

101. In advertising, marketing and otherwise promoting ePTFE Bard Mesh to physicians, hospitals and other healthcare providers, Defendants expressly warranted that their ePTFE Bard Mesh was safe for use and reasonably fit for their intended purposes. In advertising, marketing and otherwise promoting ePTFE Bard Mesh, Defendants' intended that physicians, hospitals and other healthcare providers rely upon their representations regarding safety and fitness in an effort to induce them to implant ePTFE Bard Mesh in their patients.

102. With respect to the Plaintiff, Defendants intended that ePTFE Bard Mesh be implanted by Plaintiff's treating surgeon in a reasonable and foreseeable manner in which it was implanted and in accordance with the instructions for use and product specifications provided by Defendants. The Plaintiff was in privity with Defendants.

103. Defendants expressly warranted to physicians, hospitals, other healthcare providers and the general public including Plaintiffs that ePTFE Bard Mesh was safe and fit for use by consumers, that it was of merchantable quality, that its risks, side effects and potential complications were minimal and comparable to other hernia mesh products, that it was adequately researched and tested, and that it was fit for its intended use. Plaintiff and Plaintiff's physicians

and healthcare providers reasonably relied upon Defendants' express representations and warranties, and consequently, Plaintiff was implanted with Defendants' ePTFE Bard Mesh.

104. The ePTFE Bard Mesh was manufactured from polypropylene, ePTFE, and PDO. The ePTFE was represented by the Defendants to decrease complications, but it did not. Instead, the ePTFE harbors and protects bacteria, resulting in a severe, chronic infection, that can take years to manifest.

105. Defendant breached these express warranties because the ePTFE Bard Mesh implanted in Plaintiff was unreasonably dangerous, defective, and not as Defendants had represented.

106. Defendants breached express representations and warranties made to the Plaintiff, as well as Plaintiff's physicians and healthcare providers, with respect to the ePTFE Bard Mesh, including, but not limited to, the following particulars:

- A. Defendants represented to Plaintiff and Plaintiff's physicians and healthcare providers through labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions among other ways that the Defendants' ePTFE Bard Mesh was safe, meanwhile Defendants fraudulently withheld and concealed information about the substantial risks of serious injury associated with using ePTFE Bard Mesh.
- B. Defendants represented to Plaintiff and their physicians and healthcare providers that the Defendants' ePTFE Bard Mesh was as safe and/or safer than other alternative procedures and devices on the market, meanwhile Defendants fraudulently concealed

information that demonstrated that ePTFE Bard Mesh was not safer than alternative therapies and products available on the market; and

- C. Defendants represented to Plaintiff and Plaintiff's physicians and healthcare providers that the Defendants' ePTFE Bard Mesh was more efficacious than other alternative procedures, therapies and/or devices, meanwhile Defendants fraudulently concealed information, regarding the true efficacy of ePTFE Bard Mesh.

107. Defendants' breach of their express warranties resulted in the implantation of an unreasonably dangerous and defective product into the Plaintiff, placing Plaintiff's health and safety in jeopardy

108. At the time of making such express warranties, Defendants knew or should have known that Defendants' ePTFE Bard Mesh does not conform to the express warranties and Defendants' acts were motivated by financial gain while the adverse consequences of Defendants' conduct was outrageous, fraudulent, oppressive, done with malice or gross negligence and evidenced reckless indifference to Plaintiff's rights, health and safety so as to warrant the imposition of punitive damages.

**COUNT VI: VIOLATION OF CONSUMER PROTECTION LAWS**

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

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

111. Had Defendants not engaged in the deceptive conduct described herein, Plaintiff would not have purchased and/or paid for the Defendants' ePTFE Bard Mesh, and would not have incurred related medical cost and injury.

112. Defendants engaged in wrongful conduct while at the same time obtaining, under false pretenses, moneys from Plaintiff for the ePTFE Bard Mesh that would not have been paid had Defendants not engaged in unfair and deceptive conduct.

113. Unfair methods of competition or deceptive acts or practices that were proscribed by law, including 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.

114. Plaintiff 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 the Defendants' ePTFE Bard Mesh. Each aspect of Defendants' conduct combined to artificially create sales of the Defendants' ePTFE Bard Mesh.

115. 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 the Defendants' ePTFE Bard Meshes.

116. Had Defendants not engaged in the deceptive conduct described above, Plaintiff would not have purchases and/or paid for the ePTFE Bard Mesh, and would not have incurred related medical cost.

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

118. Defendants' actions, as complained of herein, constitute unfair competition or unfair, unconscionable, deceptive or fraudulent acts, or trade practices in violation of state consumer protection statutes, as listed below.

119. 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)
- Tex. Bus. & Com. Code Ann. § 17.46, et seq.
- N.J. Stat. Ann §§ 56:8-1, et seq.
- R.I. Gen. Laws §§ 6-13.1, et. seq.

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

121. Defendants violated the statutes that were enacted in these states to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising, by knowingly and falsely representing that the Defendants' ePTFE Bard

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 herein. These representations were made in marketing and promotional materials.

122. The actions and omissions of Defendants alleged herein are uncured or incurable deceptive acts under the statutes enacted in the states to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising.

123. Defendants had actual knowledge of the defective and dangerous condition of the Defendants' ePTFE Bard Mesh and failed to take any action to cure such defective and dangerous conditions.

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

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

126. By reason of the unlawful acts engaged in by Defendants, and as a direct and proximate result thereof, Plaintiff has suffered ascertainable losses and damages.

127. As a direct and proximate result of Defendants' violations of the states; consumer protection laws, Plaintiff 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**

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



129. 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 for which the law would allow, and which Plaintiff will seek at the appropriate time under governing law for the imposition of exemplary damages, in that Defendants' conduct, including the failure to comply with applicable Federal standards: was specifically intended to cause substantial injury to Plaintiff; 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, and 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, with the intent that the representation is acted on by Plaintiff.

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

131. 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.

132. Plaintiff also alleges that the acts and omissions of named 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**

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

134. Defendants carelessly and negligently manufactured, designed, developed, tested, labeled, marketed and sold the Defendants' ePTFE Bard Mesh to Plaintiff.

135. Defendants carelessly and negligently concealed the harmful effects of the Defendants' ePTFE Bard Mesh from Plaintiff individually and/or Plaintiff's physician on multiple occasions and continue to do so to this day.

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

137. Plaintiff was directly impacted by Defendants' carelessness and negligence, in that Plaintiff has sustained and will continue to sustain emotional distress, severe physical injuries, economic losses, and other damages as a direct result of the decision to purchase the ePTFE Bard Mesh sold and distributed by Defendants.

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

139. Defendants continued to carelessly and negligently misrepresent the quality, safety, efficacy, dangers and contraindications of the ePTFE Bard Mesh to Plaintiff individually and/or

Plaintiff's physician knowing that doing so would cause the Plaintiff to suffer additional and continued emotional distress, severe physical injuries, and economic loss.

140. As a proximate result of the Defendants' conduct, Plaintiff has been injured, sustained severe and permanent pain, suffering, anxiety, depression, disability, impairment, loss of enjoyment of life, loss of care, comfort, and economic damages.

### **COUNT IX: FRAUDULENT CONCEALMENT**

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

142. At all times relevant hereto, it was known or knowable to Defendants that their Products caused large numbers of complications. Moreover, it was known or knowable to Defendants that the surgical technique and training of implanting physicians was not the cause of the adverse events associated with these devices. It was known or knowable to Defendants that the safety and efficacy of its Products had not been proven with respect to, among other things, the product, its components, its performance, and its method of insertion. It was known or knowable to Defendants that the Products were not safe and effective. Defendants continued to represent that its Products were safe and effective.

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

144. At all times relevant hereto, Defendants had the duty and obligation to disclose to Plaintiff and Plaintiff's physicians the true facts concerning the Products, that is, that said Products were dangerous and defective, lacking efficacy for its purported use and lacking safety in normal

use, and how likely it was to cause serious consequences to users, including permanent and debilitating injuries. Defendants concealed these material facts prior to the time that Plaintiff was implanted with Defendants' Products.

145. Defendants were under a duty to Plaintiff to disclose and warn of the defective nature of the ePTFE Bard Mesh because:

- A. Defendants were in a superior position to know the true quality, safety, and efficacy of its Products;
- B. Defendants knowingly made false claims about the safety and quality of its ePTFE Bard Mesh in documents and marketing materials;
- C. Defendants fraudulently and affirmatively concealed the defective nature of the ePTFE Bard Mesh from the Plaintiff.

146. The facts concealed and/or not disclosed by Defendants to Plaintiff were material facts that a reasonable person would have considered to be important in deciding whether or not to purchase and/or use the Defendants' Products.

147. At all times relevant hereto, Defendants and each of them, willfully, intentionally, and maliciously concealed facts as set forth above from Plaintiffs and their physicians with the intent to defraud, as alleged herein.

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

149. At all times relevant hereto, neither Plaintiff nor his physicians were aware of the facts set forth above, and had they been aware of said facts, they would not have acted as they did, that is, would not reasonably relied upon said representations of safety and efficacy and utilized Defendants' Products in his treatment. Defendants' failure to disclose this information was a substantial factor in Plaintiff's physicians selecting Defendants' Products. The failure to disclose also resulted in the provision of incorrect and incomplete information to Plaintiff, as a patient.

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

**COUNT X: NEGLIGENT MISREPRESENTATION**

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

152. Defendants had a duty to accurately and truthfully represent to the medical and healthcare community, Plaintiff, and the public, that its ePTFE Bard Mesh had not been adequately tested and found to be a safe and effective treatment. The representations made by Defendants were, in fact, false.

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

154. Defendants breached their duty in representing that the Defendants' ePTFE Bard 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.

155. As a foreseeable, direct, and proximate result of the negligent misrepresentation of Defendants, as set forth herein, Defendants knew, and had reason to know, that the ePTFE Bard Mesh had been insufficiently tested, or had not been tested at all, and that they lacked adequate and accurate warnings, and that they created a high risk—and/or higher than acceptable risk, and/or higher than reported and represented risk—of adverse side effects, including, but not limited to, pain, graft rejection, graft migration, organ damage, complex seroma, fistula, sinus tract formation, delayed wound closure, infection, sepsis, and death.

156. As a direct and proximate result of the Defendants' conduct, Plaintiff 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**

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

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

159. Even though Defendants have other hernia repair mesh devices that do not present the same risks as the ePTFE Bard Mesh, Defendants developed, designed and sold ePTFE Bard Mesh, and continue to do so, because the ePTFE Bard Mesh has a significantly higher profit margin than safer hernia repair products. Defendants were aware of the probable consequences of

implantation of the dangerous and defective ePTFE Bard Mesh, including the risk of failure and serious injury, such as suffered by Plaintiff.

160. At all times relevant hereto, Defendants knew or should have known that ePTFE Bard 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.

161. Defendants' misrepresentation included knowingly withholding material information from the medical community and the public, including Plaintiff, concerning the safety and efficacy of the ePTFE Bard Mesh, which deprived Plaintiff and Plaintiff's implanting physicians of vitally necessary information with which to make a fully informed decision about whether to use ePTFE Bard Mesh.

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

163. At all times material hereto, Defendants knew and recklessly and/or intentionally disregarded the fact that ePTFE Bard 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.

164. At all times material hereto, Defendants intentionally misstated and misrepresented data and continue to misrepresent data so as to minimize the perceived risk of injuries and the rate of complications caused by the associated with ePTFE Bard Mesh.

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

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

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

168. Defendants' conduct, acts and omissions, as described herein, are of such character and nature so as to entitle Plaintiff to an award of punitive damages in accordance with applicable statutory and common law. Defendants' conduct shows willful misconduct, malice, fraud,



wantonness, oppression, or that entire want of care which raises the presumption of conscious indifference to consequences, thereby justifying an award of punitive damages

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and request compensatory damages, punitive damages or enhanced compensatory damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

**PRAYER FOR RELIEF**

Plaintiff demands judgment against Defendants, and each of them, individually, jointly and severally and prays for the following relief in accordance with applicable law and equity:

- i. Compensatory damages to Plaintiff for past, present, and future damages, including but not limited to, pain and suffering for severe and permanent personal injuries sustained by Plaintiff, permanent impairment, mental pain and suffering, loss of enjoyment of life, health and medical care costs, economic damages, together with interest and costs as provided by law;
- ii. Restitution and disgorgement of profits;
- iii. Punitive or enhanced compensatory damages;
- iv. Reasonable attorneys' fees as provided by law;
- v. The costs of these proceedings, including past and future cost of the suit incurred herein;
- vi. All ascertainable economic damages;
- vii. Prejudgment interest on all damages as allowed by law; and
- viii. Such other and further relief as this Court deems just and proper.

**DEMAND FOR JURY TRIAL**

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

Date: October 17, 2018

Respectfully submitted,

*/s/ Kelsey L. Stokes*

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Kelsey L. Stokes

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*Attorneys for Plaintiff*

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

BILLY EDWARD KEY, JR.

(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
2 U.S. Government Defendant
3 Federal Question (U.S. Government Not a Party)
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)

Table with columns for Plaintiff (PTF) and Defendant (DEF) citizenship and business location (Citizen of This State, Citizen of Another State, Citizen or Subject of a Foreign Country, Incorporated or Principal Place of Business In This State, Incorporated and Principal Place of Business In Another State, Foreign Nation).

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

Large table with categories: CONTRACT, REAL PROPERTY, CIVIL RIGHTS, TORTS, PRISONER PETITIONS, FORFEITURE/PENALTY, LABOR, IMMIGRATION, BANKRUPTCY, SOCIAL SECURITY, FEDERAL TAX SUITS, OTHER 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 10/17/2018 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 statute.
- 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.