UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF MISSOURI

REBECCA ELI	)	**Civil Action No.:**
	)	
	)	
Plaintiff,	)	
	)	**JURY TRIAL DEMANDED**
v.	)	
	)	
	)	
DAVOL INC., and C.R. BARD,	)	
	)	
	)	
	)	
Defendants.	)	
	)	

Plaintiff, by and through his undersigned counsel, bring this Complaint for damages against Defendants and in support thereof state 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 Rebecca Eli 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. Plaintiffs is, and was, at all relevant times, a citizen and resident of Missouri 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 hernia meshes composed of polypropylene, and polyglycolic acid (PGA) fibers coated with Sepra Technology, a bioresorbable, chemically modified sodium hyalurnate, carboxymethylcellulose, and polyethylene glycol based hydrogel (hereinafter "ST 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 the ST Bard Mesh. It also manufactures and supplies Davol with material that forms part of the ST 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 ST 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 ST 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 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. This Court has personal jurisdiction over each of the Defendants pursuant to the Missouri Long-Arm Statute, RSMO § 506.500. Defendants transact business within the State of Missouri, contracted to sell and supply their ST Bard Mesh products in the State of Missouri, and committed tortious acts and omissions in Missouri. Defendants' tortious acts and omissions caused injury to Plaintiff in the State of Missouri. Defendants employ sales representatives in the State of Missouri to sell their ST Bard Mesh products throughout the State, including the ST Bard Mesh implanted in Plaintiff. Defendants have purposefully engaged in the business of developing, manufacturing, publishing information, marketing, distributing, promoting and/or selling, either directly or indirectly, through third parties, as successor in interest, or other related entities, medical devices including ST Bard Mesh in Missouri, for which they derived significant and regular income. The Defendants intended and reasonably expected that that their defective mesh products, including ST Bard Mesh, would be sold and implanted in Missouri and could cause injury in Missouri.

10. Davol is registered to transact business in Missouri.

11. Venue is proper in this Court pursuant to 28 U.S.C. § 1391(b)(2).

FACTS COMMON TO ALL COUNTS

12. On or about October 17, 2013, Plaintiff Rebecca Eli underwent repair of an incisional hernia by Dr. M. Brook Redd at Lee's Summit Medical Center in Lee's Summit, Missouri. A Ventralex ST Mesh patch 8 cm in diameter, Cat No. 595009, Lot No. HUWF0766 was implanted in Rebecca Eli during this repair (Hereinafter "Ventralex ST Mesh" or "ST Bard Mesh").

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

14. On or about April 28, 2014, Plaintiff Rebecca Eli underwent surgery by Dr. Mohsin Soliman to explant the failed Ventralex ST Mesh. Dr. Soliman noted "finding of significant intraabdominal adhesion formation which necessitated a greater than 45 minute laparoscopic lysis of adhesions in addition to the necessity of the laparoscopic removal of already indwelling synthetic mesh." Plaintiff Rebecca Eli was implanted with a 6" x 8" Ventralight ST Mesh, Red No. 5955680, Lot No. HUYA1003.

15. Plaintiff Rebecca Eli continues to experience complications related to the ST Bard Mesh and will likely require additional surgeries to repair the damage from the ST Bard Mesh.

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

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

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

THE FDA'S 510(k) CLEARANCE PROCESS

19. 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.

20. No clinical testing is required under this process.

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

22. 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.

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

24. 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.**

25. 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."

26. Defendants cleared the ST 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.

27. On June 18, 2002, the Food and Drug Administration issued a document titled "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

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

29. 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 ST Hernia Mesh was defective, Defendants are estopped from relying on any statutes of limitations that might overwise be applicable to the claims asserted herein.

COUNT I: STRICT LIABILITY – MANUFACTURING DEFECT

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

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

32. The implantation of ST 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.

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

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

35. Upon information and belief, Defendants utilized substandard and adulterated polypropylene and raw materials used to make the ST coating on their finished ST Bard Meshes, which deviated from Defendants' material and supply specifications.

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

COUNT II: STRICT LIABILITY – DESIGN DEFECT

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

38. Defendants' ST 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 ST Bard Mesh, there was an unreasonable risk of severe adverse reactions to the mesh or mesh components including: chronic pain; recurrence of hernia; foreign body response; rejection; infection; scarification; improper wound healing; excessive and chronic inflammation; allergic reaction; adhesions to internal organs; erosion; abscess; fistula formation; granulomatous response; seroma formation; nerve damage; tumor formation, cancer, tissue damage and/or death; and other complications.

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

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

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

42. The ST Bard Mesh is acidic, causing bacteriostasis (inhibition of the growth of bacteria without killing the bacteria), which results in the inability to properly validate sterilization.

43. The coating on the Defendants' ST 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.

44. The ST coating is designed and intended to resorb in less than 30 days.

45. When the ST coating is disrupted, degrades, and/or resorbs, the "naked" polypropylene mesh and PGA is exposed to the adjoining tissue and viscera, and can become adhered to organs, and cause incarceration of organs, and fistula formation.

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

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

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

49. The ST Bard Mesh implanted in Plaintiff failed to reasonably perform as intended. The ST 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 ST Bard Mesh was initially implanted to treat.

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

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

52. The implantation of ST 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.

53. The risks of the ST Bard Mesh significantly outweigh any benefits that Defendants contend could be associated with the product. The ST coating, which is not used in any other hernia mesh product sold in the United States, incites an intense inflammatory response, leading to encapsulation, deformation, scarification and contraction, migration, erosion and rejection. The impermeable ST coating leads to seroma formation, and provides a breeding ground for infection, and protects bacteria from being eliminated by the body's natural immune response. This ST coating also caused immunogenic response, and was known to be cytotoxic.

54. The coating of the ST Bard Mesh, which was marketed, promoted and intended as a barrier against adhesion to the bowel, was only temporary; it was expected and intended to degrade over time inside the body. Thus, this coating prevented tissue ingrowth in the short term, and degraded in the long-term, eventually leaving the "naked" polypropylene mesh and PGA exposed to the internal viscera and tissues. Once exposed to the viscera, the polypropylene and PGA will inevitably 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.

55. The polypropylene mesh within the defective coating of the ST Mesh was in itself dangerous and defective, particularly when used in the manner intended by Defendants in the ST Bard Mesh. The particular polypropylene material used in the ST Bard Mesh was substandard, adulterated and 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 ST 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. The appropriate treatment for complications associated with ST Bard Mesh involves additional invasive surgery to remove the mesh from the body, thus eliminating any purported benefit that the mesh was intended to provide to the patient.

57. The ST 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.

58. At the time the ST 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, single-layer mesh placed away from the bowel.

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

60. The ST 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 Presearcomatous Stage*. Journal of Cancer 1(11). 204 – 213 (1958).

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

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

61. Plaintiff was implanted with a Ventralex ST Mesh, which also includes an inner ring of polydioxanone (hereinafter PDO ring), to aid in the memory and stability of the device. The inner PDO ring is called SorbaFlex Memory Technology.

62. 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.

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

64. 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.

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

66. The method by which the 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.

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

68. The positioning/securing strap of the Ventralex ST Mesh is bare polypropylene without an ST coating.

69. The instructions for use for the Ventralex ST Mesh instruct to secure the ST Mesh with tacks or sutures through the polypropylene positioning straps.

70. The polypropylene positioning straps have a tendency to tear at the base of the ST Mesh after implantation, resulting in mesh migration and other injuries.

71. The polypropylene positioning straps have a tendency to tear where tacked or sutured, resulting in mesh migration and other injuries.

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

73. The additional layers utilized to create the patch of the Ventralex ST Mesh increases the intensity and duration of inflammation and foreign body response.

74. The ST 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.

75. 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

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

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

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

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

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

81. The Defendants' Instructions for Use for the ST Mesh failed to adequately warn Plaintiff's physicians of numerous risks which Defendants knew or should have known were associated with the ST Mesh, including the risks of the product's 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.

82. 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.

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

84. Defendants represented to physicians, including Plaintiff's physician, that the ST coating would prevent or reduce adhesions, and expressly intended for the ST Mesh to be implanted in contact with the bowel and internal organs and marketed and promoted the product for said purpose. Defendants failed to warn physicians that the ST coating was only temporary and therefore at best would provide only a temporary adhesion barrier, and when the coating inevitably degraded, the exposed polypropylene and PGA would become adhered to the bowel or tissue.

85. Defendants failed to warn Plaintiff and Plaintiff's physicians that the ST Bard Mesh was considered a significant risk device by the FDA.

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

87. 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 ST Bard Mesh were more

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

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

89. 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

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

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

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

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

94. Defendants utilized non-medical grade polypropylene.

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

96. 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.

97. 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.

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

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

100. Defendants knew or should have known of the cytotoxic and immunogenic properties of the coating on the ST Mesh prior to introducing it into the stream of commerce.

101. As a direct and proximate result of Defendants' negligence in designing, testing, inspecting, manufacturing, packaging, labeling, marketing, distributing, and preparing written instructions and warnings for ST Bard Mesh, Plaintiff suffered injuries and damages as summarized herein.

COUNT V: BREACH OF EXPRESS WARRANTY

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

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

104. In advertising, marketing and otherwise promoting ST Bard Mesh to physicians, hospitals and other healthcare providers, Defendants expressly warranted that their ST Bard Mesh was safe for use and reasonably fit for their intended purposes. In advertising, marketing and otherwise promoting ST 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 Bard ST Mesh in their patients.

105. With respect to the Plaintiff, Defendants intended that ST 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.

106. Defendants expressly warranted to physicians, hospitals, other healthcare providers and the general public including Plaintiffs that ST 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' ST Bard Mesh.

107. The ST Bard Mesh was manufactured from polypropylene, polyglycolic acid fibers coated with a bioresorbable, chemically modified sodium hyalurnate, carboxymethylcellulose, and polyethylene glycol based hydrogel. The ST coating was

represented by the Defendants to prevent or minimize adhesion and inflammation and to facilitate incorporation of the mesh into the body, but it did not. Instead, the ST coating caused an intense systemic inflammatory and chronic foreign body response, resulting in an adverse tissue reaction including damage to surrounding tissue in the form of sclerotic, granulomatous and/or fibrotic tissue and improper or delayed healing.

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

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

A. Defendants represented to Plaintiff and Plaintiff's physicians and healthcare provides through labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions among other ways that the Defendants' ST Bard Mesh was safe, meanwhile Defendants fraudulently withheld and concealed information about the substantial risks of serious injury associated with using ST Bard Mesh.

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

110. 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

111. At the time of making such express warranties, Defendants knew or should have known that Defendants' ST 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

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

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

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

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

116. 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.

117. 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' ST Bard Meshes. Each aspect of Defendants' conduct combined to artificially create sales of the Defendants' ST Bard Meshes.

118. 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' ST Bard Meshes.

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

120. 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.

121. 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 statues, as listed below.

122. 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)
- Mo Rev. Stat. §§ 407.010, et seq.
- N.J. Stat. Ann §§ 56:8-1, et seq.
- R.I. Gen. Laws §§ 6-13.1, et. seq.

123. 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.

124. 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' ST Bard Meshes were fit to be used for the purpose for which they were intended, when in fact they were defective and dangerous, and by other acts alleged herein. These representations were made in marketing and promotional materials.

125. 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.

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

127. 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).

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

129. 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.

130. 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

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

132. 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.

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

134. 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.

135. 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

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

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

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

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

140. 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 ST Bard Mesh sold and distributed by Defendants.

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

142. Defendants continued to carelessly and negligently misrepresent the quality, safety, efficacy, dangers and contraindications of the ST 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.

143. 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

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

145. 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.

146. 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.

147. 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 Plaintiffs were implanted with Defendants' Products.

148. Defendants were under a duty to Plaintiffs to disclose and warn of the defective nature of the Products 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 ST Bard Mesh in documents and marketing materials;

C. Defendants fraudulently and affirmatively concealed the defective nature of the ST Bard Mesh form the Plaintiff.

149. 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.

150. 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.

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

152. At all times relevant hereto, neither Plaintiffs nor their 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 their 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.

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

COUNT X: NEGLIGENT MISREPRESENTATION

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

155. Defendants had a duty to accurately and truthfully represent to the medical and healthcare community, Plaintiff, and the public, that its ST 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.

156. 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 ST Bard Mesh's high risk of unreasonable and dangerous adverse side effects.

157. Defendants breached their duty in representing that the Defendants' ST Bard Meshes have no serious side effects different from older generations of similar products and/or procedures to Plaintiff, Plaintiff's physicians, and the medical community.

158. 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 ST 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.

159. 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

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

161. Defendants failed to adequately test and study the ST 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 ST Bard Mesh after obtaining knowledge and information that the product was defective and unreasonably unsafe.

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

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

163. At all times relevant hereto, Defendants knew or should have known that ST 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.

164. Defendant's misrepresentation included knowingly withholding material information form the medical community and the public, including Plaintiff, concerning the safety and efficacy of the ST 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 ST Bard Mesh.

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

166. At all times material hereto, Defendants knew and recklessly and/or intentionally disregarded the fact that ST 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 Plaintiffs, of the same.

167. 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 ST Bard Mesh.

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

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

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

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

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

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

PRAYER FOR RELIEF

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

i. Compensatory damages to Plaintiffs for past, present, and future damages, including but not limited to, pain and suffering for severe and permanent personal injuries sustained by Plaintiff, permanent impairment, mental pain and suffering, loss of enjoyment of life, health and medical care costs, economic damages, together with interest and costs as provided by law;

ii. Restitution and disgorgement of profits;

iii. Punitive or enhanced compensatory damages;

iv. Reasonable attorneys' fees as provided by law;

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

vi. All ascertainable economic damages;

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

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

DEMAND FOR JURY TRIAL

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

Date: February 13, 2018

Respectfully submitted,

Krause & Kinsman, LLC

/s/ Robert L. Kinsman
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ATTORNEYS FOR PLAINTIFF

JS 44 (Rev 09/10)

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF MISSOURI

CIVIL COVER SHEET

This automated JS-44 conforms generally to the manual JS-44 approved by the Judicial Conference of the United States in September 1974. The data is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. The information contained herein neither replaces nor supplements the filing and service of pleadings or other papers as required by law. This form is authorized for use only in the Western District of Missouri.

The completed cover sheet must be saved as a pdf document and filed as an attachment to the Complaint or Notice of Removal.

Plaintiff(s):

First Listed Plaintiff:
Rebecca Eli ;
1 Citizen of This State;
County of Residence: Jackson County

Defendant(s):

First Listed Defendant:
Davol, Inc. ;
2 Citizen of Another State; Rhode Island
County of Residence: Outside This District

Additional Defendants(s):
C.R. Bard, Inc. ;
2 Citizen of Another State; New Jersey

County Where Claim For Relief Arose: Jackson County

Plaintiff's Attorney(s):

Robert L. Kinsman (Rebecca Eli)
Krause & Kinsman, LLC
4717 Grand Ave., Suite 250
Kansas City, Missouri 64112
Phone: (816) 760-2700
Fax: (816) 760-2800
Email: robert@krauseandkinsman.com

Defendant's Attorney(s):

Basis of Jurisdiction: 4. Diversity of Citizenship

Citizenship of Principal Parties (Diversity Cases Only)

Plaintiff: 1 Citizen of This State

Defendant: 2 Citizen of Another State

Origin: 1. Original Proceeding

Nature of Suit: 365 Other Personal Injury Product Liability
Cause of Action: 28 U.S.C. § 1332(a); 28 U.S.C. § 1391(b)(2); RSMO § 506.500
Requested in Complaint

Class Action: Not filed as a Class Action

Monetary Demand (in Thousands): $75,000+

Jury Demand: Yes

Related Cases: Is NOT a refiling of a previously dismissed action

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Signature: /s/ Robert L. Kinsman

Date: 02/13/2018

If any of this information is incorrect, please close this window and go back to the Civil Cover Sheet Input form to make the correction and generate the updated JS44. Once corrected, print this form, sign and date it, and submit it with your new civil action.