

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY

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JULIO NUNEZ,

Plaintiff,

File No.

vs.

JURY DEMAND

C.R. BARD, INC., and BARD DAVOL, INC.,

Defendants.

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**COMPLAINT AND JURY DEMAND**

NOW COMES the Plaintiff, JULIO NUNEZ by and through the undersigned counsel, hereby files this Complaint against the Defendants, C.R. BARD, INC. and BARD DAVOL, INC. in this litigation and states as follows:

**JURISDICTION AND VENUE**

1. At all times material, Plaintiff was a resident of Randolph County, North Carolina.
2. Defendant C.R. BARD, INC., is a New Jersey corporation with its principal place of business in New Jersey.
3. At all times relevant herein, the Defendant, C.R. BARD, INC., (“BARD”) was conducting business in the State of North Carolina and New Jersey. C.R. BARD, INC. is a corporation based out of New Jersey, with its corporate headquarters located at 730 Central Avenue, Murray Hill, New Jersey. Defendant conducts substantial business in Texas and is headquartered in New Jersey, and is subject to the personal jurisdiction served by this Court.
4. Defendant BARD DAVOL, INC. (“BD”) is a foreign for-profit Corporation with its principal place of business in Rhode Island and is a citizen of the state of Rhode Island. All

acts and omissions of BD as described herein were done by its agents, servants, employees, and/or owners, acting in the course and scope of their respective agencies, services, employments, and/or ownership. BD is a manufacturer of surgery products and is a citizen of the State of Rhode Island, with its corporate headquarters located at 100 Crossings Blvd, Warwick, RI 02886.

5. C.R BARD, INC. and BARD DAVOL, INC. are collectively referred to hereinafter as “Defendants.”

6. Jurisdiction is proper in District Court for the District of New Jersey as the amount in controversy exceeds \$75,000 exclusive with interests and costs.

7. Defendant has substantial contacts with Randolph County, North Carolina which are more than sufficient to cause them to be subject to personal jurisdiction in said county.

#### **FACTUAL BACKGROUND**

8. At all times material hereto, the Bard Defendants developed, designed, manufactured, labeled, packaged, distributed, marketed, supplied, advertised, sold and otherwise engaged in all activities that are part and parcel of the sale and distribution of the pelvic mesh products at issue in this matter. By said activities, Bard’s Pelvic Mesh Products were placed into the stream of commerce throughout the United States, including North Carolina.

9. At all times material to this action, the Bard Defendants designed, patented, manufactured, labeled, marketed, sold and distributed a line of pelvic mesh products. The products by the Bard Defendants were designed primarily for the purposes of treating hernias and pelvic organ prolapse. The Bard’s Defendants products at issue in this case were cleared for sale in the U.S. after the Bard Defendants made assertions to the Food and Drug Administration of “Substantial Equivalence” under section 510(k) of the Food, Drug and Cosmetic Act; this clearance process does not require the applicant to prove safety of efficacy.

10. The Plaintiff was operated on to repair a hernia, during which operation a variety of surgical mesh manufactured, sold and marketed by Defendants was implanted.

11. The surgical mesh used in the surgery was known as the “Ventralight ST Hernia Patch” (herein referred to as “Product”) and it was designed, manufactured, packaged, labeled, marketed, sold and distributed by Defendant.

12. The Product was made of materials which are biologically incompatible with human tissue and react negatively and sometimes dangerously with a large number of those on whom it is used.

13. Defendant knew or should have known that their Product was unreasonably harmful.

14. The scientific evidence Defendant knew or should have known of demonstrates that the mesh is incompatible with human tissue and often causes a negative immune response in patients implanted with the Product, including Plaintiff.

15. In April 2016, the FDA published an article on hernia mesh, identifying “pain, infection, hernia recurrence, adhesion and bowel obstruction” as the most common adverse events associated with hernia mesh implants, as well as other possible complications, like mesh migration and mesh shrinkage.

16. The Ventralight ST mesh is marketed to the medical community and to patients as a safe, effective, and reliable medical device, implanted by safe and effective, minimally invasive surgical techniques, and is safer and more effective as compared to other products.

17. Defendant failed to perform proper and adequate testing and research in order to determine and evaluate the risks and benefits of the Product.

18. Feasible and suitable alternatives to the Product have existed at all times relevant that do not present the same frequency or severity of risks as the Product.

19. The Product was at all times utilized and implanted in a manner foreseeable to and in fact intended by the Defendant, its instructions and procedures for use and its training of the health care providers.

20. The Product was implanted in Plaintiff in the same or substantially similar condition as when it left Defendant's possession.

21. Defendant failed to disclose the known risks and failed to warn of known or scientifically knowable dangers and risks associated with the Product.

22. The Product as designed, manufactured, distributed, sold and/or supplied by Defendant was defective as marketed due to inadequate warnings, labeling and/or inadequate testing.

23. As a result of having the Product implanted, the Plaintiff has experienced significant mental and physical pain and suffering and mental anguish, has sustained permanent injury, has undergone medical treatment and will likely undergo further medical treatment and procedures, has suffered financial or economic loss, and/or lost income, and other damages.

#### **PLAINTIFF'S FACTUAL BACKGROUND**

24. Plaintiff Julio Nunez is a sixty-five (65) year old male who was diagnosed with a ventral hernia in August 2014.

25. On August 28, 2014, Plaintiff Julio Nunez underwent ventral hernia repair with a Ventralight ST mesh, utilizing the Bard Echo System for implantation.

26. Defendants manufactured, sold, and/or distributed the Ventralight ST and the related Ventralex Products to Plaintiff Julio Nunez through his doctors, to be used for treatment of hernia repair.

27. Immediately following the August 28, 2014 surgical implantation of the Ventralight ST mesh, Plaintiff Julio Nunez continued to experience abdominal pain, nausea and fatigue.

28. On September 18 2014, the Plaintiff Julio Nunez underwent surgical drainage of an abdominal wall abscess, removal of the Ventralight ST mesh and placement of a wound VAC.

29. Plaintiff continues to experience chronic pain from the implantation of the Ventralight ST mesh.

**CAUSES OF ACTION**  
**COUNT I: NEGLIGENCE**

30. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein and additionally or in the alternative, if same be necessary, allege as follows:

31. Defendant had a duty to individuals, including the Plaintiff, to use reasonable care in designing, manufacturing, marketing, labeling, packaging and selling their Product.

32. Defendant breached its duty to its customers, including Plaintiff, by failing to design, manufacture, market, label, package, and/or sell its Product in such a manner as the exercise of reasonable care would dictate.

33. Defendant negligently failed to warn or instruct the Plaintiff and/or his health care providers of the full extent of the risks and hazards known to exist with use of the mesh in a manner commensurate with the exercise of reasonable care.

34. As a direct and proximate result of the Defendant's negligence, Plaintiff has experienced significant physical injury, mental and physical pain and suffering, permanent injury has undergone medical treatment and will likely undergo further medical treatment and procedures, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, lost income, and other damages.

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

35. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein and additionally or in the alternative, if same be necessary, allege as follows:

36. At the time each implanting surgeon implanted the mesh product in patients, Defendants were engaged in the business of selling said product.

37. The Ventralight ST mesh product was defectively designed when sold.

38. The Ventralight ST mesh product was unreasonably dangerous, taking into consideration the utility of said product and the risks involved in their use.

39. The Ventralight ST mesh product in question was improperly designed in that it was:

- a. not designed to remain in the human body indefinitely;
- b. not designed to remain in place and not migrate
- c. designed in such a way that could cause infection,
- d. designed in such a way that the mesh could grow into the patient's skin, causing scar tissue and becoming unremovable.

40. Safer alternative designs were available at the time of sale.

41. The mesh product reached Plaintiff's implanting surgeon without substantial change in the condition in which it was sold

42. The defective and unreasonably dangerous condition of the mesh product was the proximate cause of the damages and injuries to Plaintiff.

43. As a direct and proximate result of the mesh product's aforementioned defects, Plaintiff was caused and in the future will be caused to suffer severe personal injuries, pain and suffering, severe emotional distress, financial or economic loss, including, but not limited to, obligations for medical services and expenses, and other damages.

**COUNT III: STRICT LIABILITY**  
**MANUFACTURING DEFECT**

44. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein and additionally or in the alternative, if same be necessary, allege as follows:

45. The Product implanted in Plaintiff was not reasonably safe for its intended use and was manufactured defectively due to having deviated materially from Defendant's design specifications.

46. The deviations from design specs resulted in defective manufacturing which posed unreasonable risks of serious bodily harm to customers, including the Plaintiff.

47. As a direct and proximate of the aforementioned defects, Plaintiff has experienced mental and physical pain and suffering has sustained permanent injury, has undergone medical treatment and/or corrective surgery and hospitalization, has suffered financial or economic loss, including, but not limited to, obligation for medical services and expenses, and/or lost income, and other damages.

48. Defendant is strictly liable to the Plaintiff for designing, manufacturing, marketing, labeling, packaging and selling a defective product.

**COUNT IV: STRICT LIABILITY**  
**FAILURE TO WARN**

49. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein and additionally or in the alternative, if same be necessary, allege as follows:

50. The Product was not reasonably safe for its intended uses and was defective due to its lack of appropriate and necessary warnings. Specifically, Defendant's did not provide sufficient or adequate warnings regarding, among other things, the serious risk of bodily harm posed by the incompatibility of the material used to make the mesh and human blood and tissue or the serious risk of infection or serious scarring.

51. As a direct and proximate result of the Product's defects, the Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and will likely undergo further medical treatment and procedures, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, and/or lost income, and other damages.

52. Defendant is strictly liable to the Plaintiff for designing, manufacturing, marketing, labeling or packaging and selling a defective Product.

**COUNT V**  
**BREACH OF EXPRESS WARRANTY**

53. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein and additionally or in the alternative, if same be necessary, allege as follows:

54. Defendant made assurances as described herein to the general public, hospitals and health care professionals that the Product was safe and reasonably fit for its intended purposes.

55. The Plaintiff and/or his health care provider chose the Product based upon Defendant's warranties and representations regarding the safety and fitness of its product.

56. The Plaintiff, individually and/or by and through his health care providers, reasonably relied upon Defendant's express warranties and guarantees that the product was safe, merchantable, and reasonably fit for its intended purposes.

57. Defendant breached these express warranties because the Product was unreasonably dangerous and defective as described herein and not as Defendant had represented.

58. Defendant's breach of its express warranties resulted in the implantation of an unreasonably dangerous and defective product.

59. As a direct and proximate result of Defendant's breach of the aforementioned express warranties, the Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and will likely undergo further medical treatment and procedures, has suffered financial or economic loss, including, but not limited to, obligation for medical services and expenses, and/or lost income, and other damages.

**COUNT VI**  
**BREACH OF IMPLIED WARRANTY**

60. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein and additionally or in the alternative, if same be necessary, allege as follows:

61. Defendant impliedly warranted that the subject mesh was merchantable and was fit for the ordinary purposes for which it was intended.

62. When the mesh was implanted in the Plaintiff to treat a hernia, the product was being used for the ordinary purpose for which it was intended.

63. Plaintiff, individually and/or by and through his providers, relied upon Defendant's implied warranties of merchantability in consenting to have the subject mesh implanted.

64. The Defendant breached these implied warranties of merchantability because the Product implanted in Plaintiff was neither merchantable nor suited for their intended uses as warranted.

65. Defendant's breach of their implied warranties resulted in the implantation of an unreasonably dangerous and defective product which placed Plaintiff's health and safety in jeopardy.

66. As a direct and proximate result of Defendant's breach of the aforementioned implied warranties, Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and will likely undergo further medical treatment and procedures, has suffered financial or economic loss, including, but not limited to, obligation for medical services and expenses, and/or lost income, and other damages.

**COUNT VII**  
**VIOLATION OF CONSUMER PROTECTION LAWS**

67. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein and additionally or in the alternative, if same be necessary, allege as follows:

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

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

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

71. 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.

72. 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' Ventralight ST Mesh. Each aspect of Defendants' conduct combined to artificially create sales of the Defendants' Ventralight ST Mesh.

73. 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' Ventralight ST Mesh.

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

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

76. 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.

77. 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
- North Carolina Consumer Protection Act (N.C. Gen. Stat § 75-1.1)

78. 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.

79. Defendants violated the statutes that were enacted to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising, by knowingly and falsely representing that the Defendants' Ventralight ST

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.

80. 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.

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

82. 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).

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

84. 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.

85. As a direct and proximate result of Defendants' violations of 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.

**WHEREFORE**, Plaintiff JULIO NUNEZ demands judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests restitution and disgorgement of profits, together with interest, and such further relief as the Court deems just and proper.

**REQUEST FOR JURY TRIAL**

The Plaintiffs herein request trial by jury of all issues triable by right.

Dated: September 14, 2017

By: /s/ Nicholas R. Farnolo  
Nicholas R. Farnolo  
**NAPOLI SHKOLNIK, PLLC**  
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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

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

(c) Attorneys (Firm Name, Address, and Telephone Number)

DEFENDANTS

County of Residence of First Listed Defendant (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: 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)

Click here for: Nature of Suit Code Descriptions.

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):

Brief description of cause:

VII. REQUESTED IN COMPLAINT:

CHECK IF THIS IS A CLASS ACTION UNDER RULE 23, F.R.Cv.P. DEMAND \$ CHECK YES only if demanded in complaint: JURY DEMAND: Yes No

VIII. RELATED CASE(S) IF ANY

(See instructions):

JUDGE DOCKET NUMBER

DATE SIGNATURE OF ATTORNEY OF RECORD

FOR OFFICE USE ONLY

RECEIPT # AMOUNT APPLYING IFP JUDGE MAG. JUDGE