

Edward J. Fanning
Christopher A. Rojao
McCARTER & ENGLISH, LLP
Four Gateway Center
100 Mulberry Street
Newark, New Jersey 07102
(973) 622-4444
(973) 624-7070 FAX
dkott@mccarter.com
efanning@mccarter.com
crojao@mccarter.com
*Attorneys for Defendant,
C.R. Bard, Inc.*

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

ALFRED HANKINS,

Plaintiff,

v.

C.R. BARD, INC.,

Defendant.

Case No. 2:25-cv-01887

**NOTICE OF REMOVAL
AND COPIES OF ALL PROCESS AND
PLEADINGS IN STATE COURT**

TO: The United States District Court for the District of New Jersey, Newark Division

PLEASE TAKE NOTICE that Defendant, C.R. Bard, Inc., (“Defendant”) is hereby removing the above-styled action from the Superior Court of New Jersey, Law Division, Bergen County, to the United States District Court for the District of New Jersey pursuant to 28 U.S.C. §§ 1332, 1441 and 1446. In support of this Notice, Defendant states:

1. Plaintiff James Bagley (“Plaintiff”), filed the above-entitled action in the Superior Court of New Jersey, Law Division, Bergen County, Docket No. BER-L-001803-25 on March 14, 2025, at 10:20:16 a.m.. Pursuant to 28 U.S.C. § 1446(a), a copy of the original Complaint filed in State Court is attached hereto as Exhibit A.

2. This Court has original jurisdiction over this matter pursuant to 28 U.S.C. § 1332(a). By virtue of the provisions of 28 U.S.C. §§ 1441 and 1446, this entire case is one that may be removed to this Court.

3. As required by 28 U.S.C. § 1446(b), Defendant files this Notice of Removal within thirty (30) days of receipt of the Complaint. Accordingly, removal of this action is timely.

4. Plaintiff is an adult citizen of Mississippi (Complaint, ¶ 1).

5. C.R. Bard, Inc. (“Bard”) is a New Jersey corporation with its principal place of business located in Murray Hill, New Jersey. (Complaint, ¶ 2).

6. For diversity purposes, a corporation is a citizen of the state in which it is incorporated and of the state where it has its principal place of business. 28 U.S.C. § 1332(c)(1). Therefore, complete diversity of citizenship existed between the parties at the time of filing.

7. The amount in controversy in this case exceeds \$75,000, exclusive of interest and cost, under the “reasonable probability” standard recognized by this Court. Section 1446(c)(2)(B) instructs that “removal . . . is proper on the basis of an amount of controversy asserted” by defendant “if the district courts find, by the preponderance of the evidence, that the amount in controversy exceeds” the jurisdictional threshold. The preponderance of the evidence standard is satisfied by “proof to a reasonable probability.” *Roundtree v. Primeflight Aviation Service, Inc.*, 2017 WL 3207439, at *2 (D.N.J. 2017).

8. It is apparent from the face of the Complaint that Plaintiff seeks recovery of an amount beyond \$75,000.00 exclusive of costs and interest. Specifically, Plaintiff alleges that she “experienced significant physical and mental pain and suffering, sustained permanent injury, undergone medical treatment and will likely undergo further medical treatment, and suffered financial or economic loss, including obligations for medical services and expenses, lost income,

and other damages.” (Compl., ¶ 46). Plaintiff further alleges she suffered and continues to suffer “past, present, and future physical and mental pain and suffering, physical disabilities; and past, present and future medical, hospital, rehabilitative, and pharmaceutical expenses, as well as other related damages.” *Id.* ¶ 51. Plaintiff also seeks punitive damages. *Id.* ¶ 53.

9. Given the severity and type of injuries alleged in Plaintiff’s Complaint, the amount-in-controversy requirement is met here because it is facially apparent from the complaint that the amount in controversy exceeds the jurisdictional requirement. *See In re Rezulin Prods. Liab. Litig.*, 133 F. Supp. 2d 272, 296 (S.D.N.Y. 2001) (holding that the amount in controversy is satisfied where plaintiffs alleged economic loss, medical and health expenses, and claimed serious medical conditions).

10. At the time of the filing of this Removal, upon information and belief, Defendant has not been served with a Summons and Complaint in the State Court Action. Attached as Exhibit A and incorporated by reference are true and correct copies of all pleadings and papers filed in this action in the Superior Court of New Jersey, Law Division, Bergen County. Defendant knows of no other pleadings or papers that have been served or filed with the Superior Court of New Jersey, Law Division, Bergen County in this matter.

11. This Court has jurisdiction over this matter because no Defendant has been served in this action and complete diversity exists. *See* 28 U.S.C. §§ 1332, 1441. As such, this case may be properly removed. *See Encompass Ins. Co. v. Stone Mansion Restaurant, Inc.*, 902 F.3d 147, 152-54 (3d Cir. 2018); *Avenatti v. Fox News Network LLC*, 41 F.4th 125, 128, n.1 (3d Cir. 2022).

12. Copies of this Removal Petition are simultaneously being served upon counsel for all parties of records and the State Court from which this action was removed.

13. Pursuant to 28 U.S.C. § 1446(d), Defendant is filing a written Notice of the Filing of the Removal with the Clerk of the Superior Court of New Jersey, Law Division, Bergen County, along with a copy of this Notice of Removal. These papers are being served upon Plaintiff's counsel as required by 28 U.S.C. § 1446(d).

WHEREFORE, Defendant prays that this cause proceed in this Court as an action properly removed hereto.

Respectfully submitted,

McCARTER & ENGLISH, LLP

Attorneys for Defendant

C.R. Bard, Inc.,

By: s/ Edward J. Fanning, Jr.
Edward J. Fanning, Jr.

Dated: March 14, 2025

EXHIBIT A

NAPOLI SHKOLNIK PLLC
BY: SHAYNA E. SACKS
N.J. BAR NO: 043172002
400 BROADHOLLOW ROAD, SUITE 305
MELVILLE, NEW YORK 11747
Phone: (212) 397-1000
Fax: (646) 843-7619
Ssacks@napolilaw.com
Attorneys for Plaintiff Alfred Hankins

ALFRED HANKINS,

Plaintiff,

v.

C.R. BARD, INC.,

Defendant.

SUPERIOR COURT OF NEW JERSEY
LAW DIVISION: BERGEN COUNTY

CIVIL ACTION

COMPLAINT

JURY TRIAL DEMANDED

COMPLAINT

Plaintiff, by and through his counsel, brings this suit against Defendant, and alleges as follows:

I. PARTIES

1. Plaintiff, Alfred Hankins, (hereinafter “Plaintiff”), is a resident of the Mississippi, currently residing in Charleston, Mississippi. Plaintiff was a resident of Mississippi when Defendant’s product was implanted, and when the mesh was removed via surgery.

2. Defendant, C.R. Bard, Inc. (hereinafter “Bard” or “Defendant”) is a New Jersey corporation with its principal place of business located at 1 Becton Dr Franklin Lakes, NJ, 07417-1815, and is the corporate parent/stockholder of Davol, Inc. (hereinafter “Davol”). It is a multinational developer, manufacturer, producer, seller, marketer, and promoter of medical

devices. Defendant controls the largest U.S. market share of hernia mesh devices and participates in the manufacture and distribution of the Hernia Mesh Devices throughout all states and territories of the United States. It also manufactures and supplies Davol with material forming part of the Hernia Mesh Devices. Defendant has derived substantial revenue related to Hernia Mesh Devices from its business throughout the states and territories of the United States.

3. Defendant was at all material times responsible for the actions of Davol. It exercised control over Davol's functions specific to the oversight and compliance with applicable safety standards regarding Hernia Mesh Devices sold throughout the states and territories of the United States. In such capacity, Defendant committed or allowed to be committed tortious and wrongful acts, including the violation of numerous safety standards relating to manufacturing, quality assurance/control, and conformance with design and manufacturing specifications.

II. JURISDICTION AND VENUE

4. This is an action for damages against corporations formed in New Jersey, registered to do business in New Jersey and/or conducting substantial business in New Jersey, individually or in concert with other entities.

5. Plaintiff underwent hernia repair surgery on August 6, 2020 at Baptist Memorial Hospital in Oxford, Mississippi. Plaintiff also underwent an additional hernia repair surgery on March 21, 2022, also at Baptist Memorial Hospital in Oxford, Mississippi. At that time, the Ventralex that Defendant designed, marketed, manufactured, promoted, distributed, and sold, and warranted as safe and effective for use, were implanted into Plaintiff. Plaintiff's implanting surgeons conformed to the accepted standard of care for hernia repair surgery.

6. Defendant, individually and as the parent company of Davol, is liable to Plaintiff for damages he suffered arising from the design, manufacture, marketing, labeling,

improper/inadequate warnings, distribution, sale, and placement of Defendant's Hernia Mesh Devices, effectuated directly and indirectly through Defendant's agents servants, employees and/or owners, all acting within the course and scope of their representative agencies, services, employments and/or ownership.

7. Defendant has expected or should have expected their acts to have consequences within each of the states and territories of the United States, and has derived substantial revenue related to the Hernia Mesh Devices from interstate commerce in each of the states and territories of the United States, including the state of New Jersey.

8. Defendant is also vicariously liable for the acts and omissions of its employees and/or agents who were at all material times acting on Defendant's behalf and within the scope of their employment or agency.

9. Either directly, or through their agents, apparent agents, servants or employees, Defendant at all material times sold, distributed and marketed the defective hernia repair devices in the State of New Jersey. Defendant derives substantial revenue from those products used or implanted in the State of New Jersey. Therefore, Defendant expected, or should have expected, that their business activities could or would subject them to legal action in the State of New Jersey.

10. Defendant was also involved in the business of monitoring and reporting adverse events concerning their Ventralex, and having a role in the decision process and response related to any adverse events.

11. Defendant is subject to jurisdiction within the State of New Jersey and this Court because:

- a. Defendant is engaged in substantial business activity within the State of New Jersey, Bergen County.

- b. Defendant designed, manufactured, and placed into the stream of commerce their polypropylene Hernia Mesh devices, including the Ventralex.
- c. Defendant maintains offices within the State of New Jersey.
- d. Upon information and belief, at all material times Defendant committed tortious acts within the State of New Jersey, out of which Plaintiff's causes of action arise.

12. Defendant designed, manufactured, fabricated, marketed, promoted, distributed, advertised, and sold polypropylene Hernia Mesh devices throughout the United States and worldwide, including in Bergen County, State of New Jersey.

13. At all material times, Defendant developed, manufactured, advertised, promoted, marketed, and distributed their defective Ventralex throughout the United States, including within the State of New Jersey; and specifically, to Plaintiff and his implanting surgeons or practice groups, or to hospitals where Defendant's product was implanted.

14. Since Defendant is a New Jersey corporation maintaining its principal place of business in New Jersey, Plaintiff's claims and causes of action are solely state-law claims. Any reference to a federal agency, regulation or rule is stated as background information only and does not raise a federal question. Accordingly, this Court may rightfully exercise jurisdiction, and venue is proper.

15. Defendant knowingly markets to, and derives income from, patients across the United States, including the State of New Jersey, from the sale of polypropylene Hernia Mesh Devices, including the Ventralex.

16. This is an action for damages in excess of Fifteen Thousand Dollars (\$15,000.00), exclusive of interest and cost.

17. Venue in this action properly lies in New Jersey in that Defendant is a domestic corporation with their principal place of business in New Jersey.

INTRODUCTION

18. Defendant's Hernia Mesh Devices are defined as hernia mesh devices that were designed, manufactured, marketed, labeled, distributed, sold, or otherwise placed on the market by Defendant and are comprised in whole or in part of polypropylene, including the related product listed and described below:

- a. **Ventralex Hernia Patch**: Two layers of small pore, heavyweight polypropylene adhered to a sheet of ePTFE. Through 2013, contained a permanent PET memory recoil ring. After 2013, moved to a resorbable memory ring composed of extruded polydioxanone (PDO) within a knitted polypropylene mesh tube. Includes polypropylene straps to aid in mesh placement and positioning.

19. Defendant sought and obtained FDA clearance to market their Hernia Mesh Devices under Section 510(k) of the Medical Device Amendment to the Food, Drug and Cosmetics Act. Section 510(k) provides for marketing of a medical device if the device is deemed "substantially equivalent" to other predicate devices marketed prior to May 28, 1976. The 510(k) process is not a formal review for safety or efficacy. No clinical testing or clinical study is required to gain FDA clearance under this process. Upon information and belief, no formal review for safety or efficacy was ever conducted for the Hernia Mesh Devices.

FACTUAL ALLEGATIONS

I. Defects and Risks of Defendant's Hernia Mesh Devices

20. Defendant's Hernia Mesh Devices share one common denominator: they all contain polypropylene. Despite Defendant's claims that polypropylene is inert, scientific evidence shows it is biologically incompatible with human tissue, and promotes an immune response in much of the population receiving it. The immune response to polypropylene promotes degradation and contracture of the mesh, as well as the surrounding tissue, and can contribute to the formation of severe adverse reactions to the Hernia Mesh Devices.

21. The numerous suppliers to Defendant of various forms of polypropylene cautioned all users in their U.S. Material Safety Data Sheets (MSDS) that polypropylene was not to be used for medical applications involving permanent implantation in the human body or permanent contact with internal body fluids or tissues.

22. The Hernia Mesh Devices are defective due to their high rates of failure, injury, and complications, their failure to perform as intended, their requirement of frequent and often debilitating re-operations, and their cause of severe and irreversible injuries, conditions, and damage to numerous patients, including Plaintiff.

23. The specific nature of the Hernia Mesh Devices' defects includes, but is not limited to, the following:

- a. The use of polypropylene in the Devices and the immune reactions resulting from such material, cause adverse reactions and injuries.
- b. Adverse reactions to the polypropylene in the Devices consist of adhesions, injuries to nearby organs, nerves, or blood vessels, and other complications, including infection, chronic pain, and hernia recurrence.
- c. The Devices have a propensity to degrade or fragment over time, causing a chronic inflammatory and fibrotic reaction, and resulting in continuing injury over time as the polypropylene acts as a chronic trigger for inflammation.
- d. Upon information and belief, Defendant utilized various substandard and/or adulterated polypropylene resins in the Devices.

- e. The weave of the polypropylene mesh produces very small interstices allowing bacteria to enter and hide from white blood cells and macrophages—the host defenses designed to eliminate bacteria. The bacteria also secrete an encasing biofilm, serving to further protect them from destruction by white blood cells and macrophages. In addition, some bacteria are capable of degrading polypropylene.
- f. Polypropylene is always impure; there is no pure polypropylene. Polypropylene contains about 15 additional compounds that leach from the product and are toxic to tissue, enhancing the inflammatory reaction and the intensity of fibrosis.
- g. Scanning electron microscopy has shown mesh to not be inert, with degradation leading to flaking, fissuring, and release of toxic compounds. This enhances the inflammatory and fibrotic reactions.
- h. By 1998 at the latest, polypropylene mesh was known to shrink 30-50%.
- i. Polypropylene is subject to oxidation by acids produced during the inflammatory reaction, causing degradation and loss of compliance.
- j. Mesh porosity is important for tissue ingrowth, with low porosity decreasing tissue incorporation. Porosity also affects the inflammatory and fibrotic reaction. With mechanical stress, the effective porosity is decreased.
- k. After implantation in the human body, polypropylene is known to depolymerize, cross-link, undergo oxidative degradation by free radicals, and stress crack.
- l. The large surface area of polypropylene promotes wicking of fluids and bacteria, and is a “bacterial super highway” providing a safe haven for bacteria.
- m. Common complications associated with polypropylene include restriction of abdominal wall mobility and local wound disturbances. Failures of polypropylene often include persistent and active inflammatory processes, irregular or low formation of scar tissue and unsatisfying integration of the mesh in the regenerative tissue area.

24. Shrinkage and stiffness of flexible meshes is affected by scar tissue. The majority of the Hernia Mesh Devices have smaller inter-filament distances and pores that increase the risk of bridging by scar tissue.

25. In most Devices, Defendant use heavyweight, small pore polypropylene, which increases inflammation, foreign body response, and subsequent complications.

26. Although Hernia Mesh Devices mostly utilize the heavyweight, small pore polypropylene, Defendant implemented a design modification in some Devices—lighter weight polypropylene with larger pores. But Defendant knew or should have known that the benefit of larger pores becomes irrelevant in folded or multilayered mesh (e.g., Composix L/P and Ventralight ST), and in the designs that allow significant pore collapse (e.g., Perfix Light Plug and 3D Max Light Mesh).

27. Defendant knew or should have known that the Hernia Mesh Devices implanted in the groin will be subject to movement and bending. Polypropylene in the groin has a higher likelihood of folding and bunching, and the scar fills the spaces between the folds. The phenomenon was termed a “meshoma” because the mesh forms a tumor-like mass. Therefore, the implementation of the lightweight polypropylene in inguinal (groin) devices (e.g., PerFix Light Plug and 3D Max Light Mesh) did not cure any defects inherent in the Hernia Mesh Devices as described in this Master Complaint. Further, in 2018 the HerniaSurge Group published *International Guidelines for Groin Hernia Management*, which advised: “The incidence of erosion seems higher with plug versus flat mesh. It is suggested not to use plug repair techniques.” These guidelines have been endorsed worldwide by hernia mesh societies.

II. Defendant’s Acts & Omissions Regarding Their Defective Devices

28. At all material times, Defendant was responsible for designing, manufacturing, producing, testing, studying, inspecting, labeling, marketing, advertising, selling, promoting, and distributing their Hernia Mesh Devices, and providing warnings/information about the Devices.

29. Defendant's Devices were defectively designed and manufactured; and were also defective as marketed due to inadequate warnings, instructions, labeling and/or inadequate testing, despite Defendant's knowledge of the Devices' lack of safety.

30. Defendant had obligations to know and timely and adequately disclose scientific and medical information about their Hernia Mesh Devices; and to warn of their risks and side effects as soon as Defendant was aware of them, but they did not do so.

31. Defendant also knew or should have known that their Hernia Mesh Devices unreasonably exposed Plaintiff to the risk of serious harm, while conferring no benefit over available feasible and safer alternatives that did not present the same risks and adverse effects.

32. Defendant made claims regarding the benefits of implanting the Devices but minimized or omitted their risks and adverse effects. Although Defendant knew or should have known that their claims were false and misleading, they failed to adequately disclose the true health consequences and the true risks and adverse effects of the Hernia Mesh Devices.

33. At all material times, Defendant failed to provide sufficient warnings and instructions that would have put Plaintiff, his health care providers, and the general public on notice of the dangers and adverse effects caused by implantation of the Hernia Mesh Devices.

34. Defendant has marketed and continues to market their Hernia Mesh Devices to Plaintiff and health care providers as safe, effective and reliable, and implantable by safe and effective, minimally invasive surgical techniques. Further, Defendant continues to market their Devices as safer and more effective than available feasible alternative treatments for hernias, and

other competing products. Those alternatives have existed at all material times, and have always presented less frequent and less severe risks and adverse effects than the Hernia Mesh Devices.

35. The risks of the Hernia Mesh Devices' design outweigh any potential benefits associated with the design. As a result of their defective design and/or manufacture, an unreasonable risk of severe adverse reactions can occur, including but not limited to: foreign body response; granulomatous response; allergic reaction; rejection; erosion; excessive and chronic inflammation; adhesions to internal organs; scarification; improper wound healing; infection; seroma; abscess; fistula; tissue damage and/or death; nerve damage; chronic pain; recurrence of hernia; and other complications.

36. Defendant omitted mention of the Devices' risks, dangers, defects, and disadvantages when they advertised, promoted, marketed, sold and distributed them as safe to regulatory agencies, health care providers, Plaintiff and other consumers. But Defendant knew or should have known that the Hernia Mesh Devices were not safe for their intended purposes, and that they would and did cause serious medical problems, including severe and permanent injuries and damages—and in some cases, catastrophic injuries and death.

37. Defendant has underreported information about the propensity of the Hernia Mesh Devices to fail and cause injury and complications; and have made unfounded representations regarding the efficacy and safety of the Devices through various means and media.

38. Defendant knew or should have known that at all material times their communications about the benefits, risks and adverse effects of the Hernia Mesh Devices, including communications in labels, advertisements and promotional materials, were materially false and misleading.

39. Defendant's nondisclosures, misleading disclosures, and misrepresentations were material and were substantial factors contributing directly to the serious injuries and damages Plaintiff has suffered.

40. Plaintiff would not have agreed to allow the implantation of the Hernia Mesh Devices had Defendant disclosed the true health consequences, risks and adverse effects caused by their Hernia Mesh Devices.

41. Upon information and belief, Defendant failed to conduct adequate pre-market clinical testing and research, and failed to conduct adequate post-marketing surveillance to determine the safety of the Hernia Mesh Devices.

42. Upon information and belief, Defendant failed to disclose on their warning labels or elsewhere that adequate pre-market clinical testing and research, and adequate post-marketing surveillance had not been done on the Hernia Mesh Devices, thereby giving the false impression that the Devices had been sufficiently tested.

43. The Hernia Mesh Devices are defective due to Defendant's failure to adequately warn or instruct Plaintiff and his health care providers concerning at least the following subjects:

- a. The Hernia Mesh Devices' propensities for degradation and fragmentation.
- b. The rate and manner of mesh erosion or extrusion in the Devices.
- c. The risk of chronic inflammation resulting from the Devices.
- d. The risk of chronic infections resulting from the Devices.
- e. The Devices would be "tension free" only at the time of implantation; and would drastically contract once implanted.
- f. The risk of recurrent hernias, intractable hernia pain, and other pain resulting from the Devices.
- g. The need for corrective or revision surgery to revise or remove the Devices.
- h. The severity of complications that could arise as a result of implantation of the Devices.

- i. The hazards associated with the Devices.
- j. The Devices' defects described in this Complaint.
- k. Treatment of hernias with the Devices is no more effective than with feasible available alternatives; and exposes patients to greater risk than with feasible available alternatives.
- l. Treatment of hernias with the Devices makes future surgical repairs more difficult than with feasible available alternatives.
- m. Use of the Devices puts patients at greater risk of requiring additional surgery than use of feasible available alternatives.
- n. Complete removal of the Devices may not be possible and may not result in complete resolution of the complications, including pain.
- o. The Hernia Mesh Devices are cytotoxic, immunogenic, and/or non-biocompatible, causing or contributing to complications such as delayed wound healing, chronic inflammation, adhesion formation, foreign body response, rejection, infection, seroma formation, and others.
- p. The Devices significantly contract and harden post-implantation.

44. The Hernia Mesh Devices were at all times utilized and implanted in a manner foreseeable to Defendant: Defendant generated Instructions for Use for the Devices, created implantation procedures, and allegedly trained the implanting physicians. But Defendant provided incomplete and insufficient training and information to physicians regarding the use of the Devices, subsequent anatomical changes, and aftercare of patients, including Plaintiff.

45. The Hernia Mesh Devices implanted in Plaintiff were in the same or substantially similar condition as when they left Defendant's possession, and in the condition directed by and expected by Defendant.

46. As a result of having the Hernia Mesh Devices implanted, Plaintiff has experienced significant physical and mental pain and suffering, sustained permanent injury, undergone medical

treatment and will likely undergo further medical treatment, and suffered financial or economic loss, including obligations for medical services and expenses, lost income, and other damages.

III. Plaintiff-Specific Allegations

47. The Ventralex, which was defectively designed and manufactured like other polypropylene Hernia Mesh Devices, left Defendant's hands in its defective condition and was delivered into the stream of commerce. Richard W. Byars, MD implanted a Ventralex as part of Plaintiff's umbilical hernia repair surgery on August 6, 2020 in Oxford, Mississippi. Plaintiff was implanted with a Ventralex (Lot Number: HUDW2067 / Model Number: 5950008)

48. On March 21, 2022 Plaintiff underwent additional surgical intervention at at Baptist Memorial Hospital in Oxford, Mississippi by Richard W. Byars, MD as a result of a recurrent incarcerated umbilical hernia. The procedure performed was a robotic repair of recurrent incarcerated umbilical hernia with mesh. Dr. Byars indicates that there was a small bowel incarcerated in the hernia. An extensive lysis of adhesions was performed, freeing the small bowel and omentum from the hernia sac. Afterwards, the old mesh was excised. Plaintiff was implanted with a Ventralex (Lot Number: HUFU1404 / Model Number: 5991015)

49. As a result of being implanted with the Ventralex, Plaintiff experienced and/or currently experiences additional surgical intervention, recurrence, and chronic pain, which have impaired daily activities.

50. The mechanism of failure in Plaintiff's device was a mechanism of failure that Defendant had marketed and/or warranted would not occur because of Defendant's Hernia Mesh design and composition. The implanted device that Defendant marketed and warranted (*i.e.*, the Ventralex) would not have failed but for the defective design and composition of Defendant's Hernia Mesh.

51. As a direct and proximate result of Defendant's defective design, manufacturing, marketing, distribution, sale and warnings concerning the Ventralex, Plaintiff suffered, and continues to suffer, injuries and damages, including: past, present and future physical and mental pain and suffering; physical disabilities; and past, present, and future medical, hospital, rehabilitative, and pharmaceutical expenses; as well as other related damages.

IV. Exemplary / Punitive Damages Allegations

52. Plaintiff incorporates the allegations in all prior paragraphs, and further alleges as follows:

53. Plaintiff is entitled to punitive damages because Defendant's wrongful acts and/or omissions were wanton or in conscious disregard of the rights of others. Defendant misled both the medical community and the public at large, including Plaintiff, by making false representations about the safety and efficacy of their Ventralex and other types of Defendant's Hernia Mesh; and by failing to provide adequate instructions and training concerning the use of their products. Defendant downplayed, understated, and/or disregarded their knowledge of the serious and permanent side effects and associated risks, despite available information demonstrating the following: the Ventralex lacked adequate testing, would significantly contract upon implantation, would cause an increased and prolonged inflammatory and foreign body response, high rates of chronic and debilitating pain, foreign body sensation, organ complications, seroma and fistula formation, infections, pain, and other harm to patients. Such risks and adverse effects could have been avoided had Defendant not concealed their knowledge of the serious and permanent side effects and risks associated with the use of their Hernia Mesh, or provided proper training and instruction to health care professionals regarding their use. Defendant's misrepresentations

included knowingly withholding material information from the FDA, the medical community and the public, including Plaintiff, concerning the safety of their products.

54. Defendant was, or should have been, in possession of evidence demonstrating that their Hernia Mesh caused serious side effects. Nevertheless, they continued to market the products by providing false and misleading information with regard to their safety and efficacy.

55. Defendant failed to provide warnings that would have dissuaded health care professionals from using their Hernia Mesh devices, including the Ventralex, thus preventing health care professionals and consumers, including Plaintiff, from weighing the true risks against the benefits of using the products.

56. Defendant failed to provide adequate training, testing and instructions to health care professionals, which could have prevented the failure of hernia repair devices made with Defendant's Hernia Mesh, thus preventing serious harm and suffering to patients, including Plaintiff.

57. Accordingly, Plaintiff requests punitive damages against Defendant for the harms caused to Plaintiff.

TOLLING OF STATUTE OF LIMITATIONS AND ESTOPPEL

58. Within the time period of any applicable statute of limitations, the nature of Plaintiff's injuries, damages, or his resulting relationship to Defendant's conduct was not discovered, and through reasonable care and due diligence could not have been discovered.

59. As a result of Defendant's misrepresentations and concealment, Plaintiff and his health care providers were unaware, and could not have known or have learned through reasonable diligence, that Plaintiff had been exposed to the risks alleged in this Complaint; and that those risks were the direct and proximate result of Defendant' wrongful acts and or omissions.

60. Limitations are tolled due to equitable or statutory tolling. Defendant is therefore estopped from asserting a statute of limitations defense due to their fraudulent concealment, through affirmative misrepresentations and omissions, from Plaintiff and his health care providers of the risks and defects associated with Defendant's Hernia Mesh Devices, including the severity, duration and frequency of risks and complications.

61. Defendant affirmatively withheld and/or intentionally misrepresented facts concerning the safety of their Devices, including adverse data and information from studies and testing conducted with respect to the Devices, showing that the risks and dangers associated with the Hernia Mesh Devices were unreasonable.

62. Defendant is estopped from asserting any limitations defense based on their intentional acts of withholding material information about the safety of the Hernia Mesh Devices from Plaintiff and his health care providers.

CAUSES OF ACTION- THEORIES OF RECOVERY

**COUNT I: STRICT LIABILITY – FAILURE TO WARN
(N.J. Products Liability Act-N.J.S.A. 2A:58C-1 et seq.)**

63. Plaintiff incorporates the allegations in all prior paragraphs, and further alleges as follows:

64. Defendant was the manufacturer, distributor, and/or retailer of Hernia Mesh Devices.

65. Their Devices are inherently dangerous.

66. The use of any of Defendant's Hernia Mesh Devices in a reasonably foreseeable manner involves a substantial danger that a user would not readily recognize.

67. Defendant knew or should have known of these dangers, given the generally recognized and prevailing scientific knowledge available at the time of the manufacture and distribution of their Hernia Mesh Devices.

68. Defendant failed to provide adequate warning of the dangers created by the reasonably foreseeable use of their Devices.

69. When the Ventralex was implanted in Plaintiff, Defendant's warnings and instructions were inadequate and defective. As described above, there was an unreasonable risk that the device would not perform safely and effectively for the purposes for which it was intended. Defendant failed to design and/or manufacture against such dangers and failed to provide adequate warnings and instructions concerning the risks of the Ventralex.

70. Defendant expected and intended their products to reach users such as Plaintiff in the condition in which they were sold.

71. Plaintiff and the implanting surgeons were unaware of the Ventralex's defects and dangers, and were unaware of the frequency, severity, and duration of the defects and risks associated with it.

72. Defendant's Instructions for Use for the Devices expressly understated, misstated, or concealed the risks Defendant knew or should have known were associated specifically with them, as described in this Complaint.

73. Defendant's Instructions for Use for the Hernia Mesh Devices failed to adequately warn Plaintiff or his health care providers of numerous risks Defendant knew or should have known were associated with the Devices.

74. Defendant failed to adequately train or warn Plaintiff or his health care providers about the necessity for surgical intervention in the event of complications, or how to properly treat such complications associated with the Hernia Mesh Devices when they occurred.

75. Defendant failed to adequately warn Plaintiff, his health care providers, and the general public, that the necessary surgical removal of a Hernia Mesh Device in the event of complications would leave the hernia unrepaired, and would necessitate a further attempt to repair the same hernia that the failed Device was intended to treat.

76. Defendant failed to adequately warn health care professionals and the public, including Plaintiff and the implanting surgeons, of the true risks of the product. They did not warn that the Ventralex would contract significantly upon implantation, resulting in chronic and debilitating pain, foreign body sensation, organ complications, hernia recurrence, reoperation, infections, fistula, seroma and hematoma formation, erosion, extrusion, subsequent operations, and more.

77. Defendant failed to timely and reasonably provide adequate instructions and training concerning the safe and effective use of their Ventralex.

78. Defendant failed to perform or otherwise facilitate adequate testing of the product; failed to reveal and/or concealed their testing and research data; and selectively and misleadingly revealed and/or analyzed such testing and research data.

79. Defendant's Hernia Mesh, which Defendant researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and released into the stream of commerce, was defective due to inadequate post-marketing warnings and/or instruction. Defendant knew or should have known that there was reasonable evidence of an association between their devices and dense adhesion formation, mesh contracture, and hernia

recurrence, causing serious injury and pain. Nonetheless, Defendant failed to provide adequate warnings to health care professionals and the consuming public, including Plaintiff, and continued to aggressively promote their hernia repair devices and the mesh they contained, including the Ventralex.

80. With respect to the complications listed in their warnings, Defendant provided inadequate information or warning regarding the complications, frequency, severity and duration of those complications, although the associated complications were more frequent and severe, and lasted longer than those with safer feasible alternative hernia repair treatments.

81. If Plaintiff or the implanting surgeons had been properly warned of the defects and dangers of the Ventralex, and of the frequency, severity and duration of the associated risks, Plaintiff would not have consented to allow it to be implanted, and the implanting surgeons would not have implanted the product.

82. Defendant is strictly liable in tort to Plaintiff for their wrongful conduct, including their failure to warn or provide adequate instructions regarding Hernia Mesh Devices. Defendant's actions give rise to a claim for damages under the product liability statute and common law jurisprudence of New Jersey.

83. As a direct and proximate result of Defendant's inadequate and defective warnings and instructions, Plaintiff has been injured and undergone medical treatment, and will likely undergo future medical treatment. Plaintiff has also sustained severe and permanent physical and mental pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort and consortium, economic loss, and damages, including medical expenses, lost income, and other damages.

84. Plaintiff's injuries were a reasonably foreseeable result of Defendant's failure to provide adequate warnings and instructions.

85. Plaintiff is entitled to recover compensatory, non-compensatory, punitive, and all other damages available under law for injuries sustained as a result of Defendant's failure to provide adequate warnings and instructions on the risks and dangers associated with their Hernia Mesh Devices.

86. As a result of Defendant's failure to warn or to provide adequate warnings, Plaintiff and his health care providers were unaware, and could not have known or learned through reasonable diligence, that Plaintiff had been exposed to the risks alleged in this Complaint; and that those risks were the direct and proximate result of Defendant's wrongful acts and/or omissions.

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

WHEREFORE, Plaintiff respectfully requests this Court to enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees and all such other and further relief as this Court deems just and proper.

DAMAGES

88. Plaintiff respectfully request the following damages be considered separately and individually for the purpose of determining the sum of money that will fairly and reasonably compensate Plaintiff:

- a. Medical Expenses;
- b. Pain and Suffering;
- c. Mental Anguish, Anxiety, and Discomfort of Plaintiff.;

- d. Physical Impairment;
- e. Loss of Enjoyment of Life;
- f. Pre and post judgment interest;
- g. Exemplary and Punitive Damages;
- h. Economic Loss
- i. Loss of Consortium (if applicable);
- j. Treble damages; and
- k. Reasonable and necessary attorneys' fees, costs, pre-judgement interest; and
such other relief to which Plaintiff may be justly entitled.

WHEREFORE, Plaintiff prays for judgment of and from Defendant in an amount for compensatory damages against Defendant for pain and suffering actual damages; consequential damages; exemplary damages; interest on damages (pre and post-judgment) in accordance with the law; Plaintiff's reasonable attorney's fees, as well as costs of court and all other costs incurred; and such other and further relief as the Court may deem just and proper.

DEMAND FOR TRIAL BY JURY

Plaintiff hereby demands a trial by jury to the full extent permitted by law.

DEMAND FOR JURY TRIAL

The Plaintiff hereby demands a trial by jury on all counts and as to all issues.

DESIGNATION OF TRIAL COUNSEL

Pursuant to R. 4:25-4, Shayna E. Sacks, is hereby designated as trial counsel in this matter.

Dated: March 14, 2025

NAPOLI SHKOLNIK PLLC

By: /s/ Shayna E. Sacks
Shayna E. Sacks, Esq.
New Jersey Bar No: 043172002
400 Broadhollow Road, Suite 305
Melville, NY 11747
Phone: (212) 397-1000
Fax: (646) 927-1676
Attorneys for Plaintiff

Civil Case Information Statement

Case Details: BERGEN | Civil Part Docket# L-001805-25

Case Caption: HANKINS ALFRED VS C.R. BARD, INC.

Case Initiation Date: 03/14/2025

Attorney Name: SHAYNA E SACKS

Firm Name: NAPOLI SHKOLNIK PLLC

Address: 360 LEXINGTON AVE 11TH FL
NEW YORK NY 10017

Phone: 2123971000

Name of Party: PLAINTIFF : Hankins, Alfred

Name of Defendant's Primary Insurance Company
(if known): Unknown

Case Type: PRODUCT LIABILITY

Document Type: Complaint with Jury Demand

Jury Demand: YES - 6 JURORS

Is this a professional malpractice case? NO

Related cases pending: NO

If yes, list docket numbers:

Do you anticipate adding any parties (arising out of same transaction or occurrence)? NO

Does this case involve claims related to COVID-19? NO

Are sexual abuse claims alleged by: Alfred Hankins? NO

THE INFORMATION PROVIDED ON THIS FORM CANNOT BE INTRODUCED INTO EVIDENCE

CASE CHARACTERISTICS FOR PURPOSES OF DETERMINING IF CASE IS APPROPRIATE FOR MEDIATION

Do parties have a current, past, or recurrent relationship? NO

If yes, is that relationship:

Does the statute governing this case provide for payment of fees by the losing party? NO

Use this space to alert the court to any special case characteristics that may warrant individual management or accelerated disposition:

Do you or your client need any disability accommodations? NO

If yes, please identify the requested accommodation:

Will an interpreter be needed? NO

If yes, for what language:

Please check off each applicable category: Putative Class Action? NO **Title 59?** NO **Consumer Fraud?** NO
Medical Debt Claim? NO

I certify that confidential personal identifiers have been redacted from documents now submitted to the court, and will be redacted from all documents submitted in the future in accordance with *Rule* 1:38-7(b)

03/14/2025

Dated

/s/ SHAYNA E SACKS

Signed

McCARTER & ENGLISH, LLP

Four Gateway Center
100 Mulberry Street
Newark, New Jersey 07102
(973) 622-4444
(973) 624-7070 FAX
Attorneys for Defendant
C.R. Bard, Inc.,

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

ALFRED HANKINS,

Plaintiff,

v.

C.R. BARD, INC.,

Defendant.

Case No. 2:25-cv-01887

CERTIFICATION OF SERVICE

Edward J. Fanning, Jr. hereby certifies as follows:

1. I am a partner at the Firm of McCarter & English, LLP, attorneys for Defendant C.R. Bard, Inc.

2. I hereby certify that I have caused to be served upon the Clerk of the United States District Court for the District of New Jersey via ECF the following:

- (a) Civil Cover Sheet;
- (b) Notice of Removal and Copies of All Process and Pleadings; and
- (c) Certification of Service.

3. I hereby certify that I have caused to be served the aforementioned documents via regular mail and email upon the following party:

Shayna E. Sacks, Esq.
NAPOLI SHKOLNIK, PLLC
400 Broadhollow Road, Suite 305
Melville, New York, 11747
Attorney for Plaintiff

I hereby certify that the foregoing statements made by me are true. If the foregoing statements made by me are willfully false, I am subject to punishment.

s/ Edward J. Fanning, Jr.

Edward J. Fanning, Jr.

Dated: March 14, 2025

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

DEFENDANTS
County of Residence of First Listed Defendant
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)
PTF DEF
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)
CONTRACT
REAL PROPERTY
TORTS
CIVIL RIGHTS
PRISONER PETITIONS
FORFEITURE/PENALTY
LABOR
IMMIGRATION
BANKRUPTCY
INTELLECTUAL PROPERTY RIGHTS
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