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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

EMMALI RICHMOND, Plaintiff, v. C.R. BARD, INC.; BARD ACCESS SYSTEMS, INC., and BECTON DICKINSON AND COMPANY, Defendants.	Case No. _____ **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 C.R. Bard, Inc., Bard Access Systems, Inc. and Becton, Dickinson and Company (collectively, "Defendants") are 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, Defendants state:

1. Plaintiff Emmali Richmond ("Plaintiff"), filed the above-entitled action in the Superior Court of New Jersey, Law Division, Bergen County, Docket No. BER-L-006208-23 on

November 16, 2023 at 1:20 p.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), Defendants file this Notice of Removal within thirty (30) days of receipt of the Complaint. Accordingly, removal of this action is timely.

4. Plaintiff is a resident of Illinois. (Complaint, ¶ 3).

5. Becton Dickinson and Company ("BD") is a New Jersey corporation with its principal place of business located in Franklin Lakes, New Jersey. (Complaint, ¶ 4).

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

7. Bard Access Systems, Inc. ("BAS") is a Utah corporation with its principal place of business located in Salt Lake City, Utah. (Complaint, ¶ 6).

8. 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.

9. 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).

10. 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 "suffered damages and continues to suffer damages including, but not limited to, undergoing an unnecessary major surgery, increased risk of future severe and permanent injuries, severe emotional distress, ongoing fear and anxiety from future injuries, including but not limited to, cardiac tamponade." (Complaint, ¶ 64).

11. Plaintiff seeks both compensatory and punitive damages.

12. At the time of the filing of this Removal, upon information and belief, Defendants have 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. Defendants know 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.

13. This Court has jurisdiction over this matter because none of the Defendants have been served in this action and complete diversity exists. *See* 28 U.S.C. §§ 1332, 1441. As such, this case may be properly removed. *Encompass Ins. Co. v. Stone Mansion Restaurant, Inc.*, 902 F.3d 147 (3d Cir. 2018).

14. 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.

15. Pursuant to 28 U.S.C. § 1446(d), Defendants are 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, Defendants prays that this cause proceed in this Court as an action properly removed hereto.

Respectfully submitted,

McCARTER & ENGLISH, LLP
Attorneys for Defendants
C.R. Bard, Inc., Bard Access Systems, Inc.
and Becton Dickinson and Company

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

Dated: November 16, 2023

EXHIBIT A

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EMMALI RICHMOND, Plaintiff, v. C.R. BARD, INC.; BARD ACCESS SYSTEMS, INC., and BECTON DICKINSON AND COMPANY; JOHN DOES 1 -10; JOHN ROES 1-10 Defendants.	SUPERIOR COURT OF NEW JERSEY LAW DIVISION: BERGEN COUNTY DOCKET NO.: MASTER CASE NO. Civil Action

COMPLAINT FOR STRICT PRODUCTS LIABILITY, NEGLIGENT MISREPRESENTATION, FRAUD, FRAUDULENT CONCEALMENT, AND PUNITIVE DAMAGES

The Plaintiff, Emmali Richmond, by and through the undersigned counsel, for her Complaint against Defendants for Strict Products Liability, Negligent Misrepresentation, Fraud, Fraudulent Concealment and for Punitive Damages, states as follows:

JURISDICTION AND VENUE

1. This Court is the appropriate Court for jurisdiction and venue. Most Defendants are headquartered in New Jersey, with their principal place of business in New Jersey. Many of the acts complained of below occurred in New Jersey. The defendants regularly conduct business in Bergen County, and Bergen County will prove to be the most convenient forum for this case.

2. This is an action for damages relating to Defendants' design, development, testing, assembling, manufacturing, packaging, promoting, marketing, distribution, supplying, and/or selling of a surgically implanted defective medical device sold under the trade name of PowerPort isp M.R.I. Implantable Port (hereinafter "PowerPort," or "Device").

3. Plaintiff Emmali Richmond is an adult resident of Illinois.

4. Defendant Becton Dickinson and Company ("BD") is a New Jersey Corporation with its principal place of business located in Franklin Lakes, New Jersey. BD is engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, supplying, selling, marketing, and introducing into interstate commerce its medical devices, including the PowerPort.

5. C.R. Bard, Inc. ("Bard") is a New Jersey corporation with its principal place of business located in Murray Hill, New Jersey. Bard is engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, supplying, selling, marketing, and introducing into interstate commerce, either directly or indirectly through third parties or related entities, its medical devices, including the PowerPort. Bard, along with its subsidiaries and business units, was acquired by BD in 2017 in a transaction which integrated and subsumed Bard's business units into BD's business units. In said transaction, Bard's product offerings, including the

PowerPort, were taken over by and integrated into BD's Interventional segment, one of three of BD's principal business segments.

6. Defendant Bard Access Systems, Inc. ("BAS") is a Utah corporation, with its principal place of business located in Salt Lake City, Utah. BAS conducts its business throughout the United States, including the states of New Jersey and Illinois. BAS is engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, supplying, selling, marketing, and introducing into interstate commerce its medical devices, including the PowerPort. BAS is a wholly owned subsidiary of Defendant BD.

7. BD is the nominal corporate parent of Bard and BAS, but the latter two are alter egos of BD in that BD exercises complete domination and control over Bard and BAS, having completely integrated the latter's assets, liabilities, and operations into its own such that Bard and BAS have ceased to function as separate corporate entities.

8. The New Jersey Superior Court has jurisdiction over this action pursuant to Constitution Article VI 3, 2 which grants the Superior Court "original jurisdiction throughout the State in all cases." The statutes under which this action is brought do not contravene this choice of venue.

9. The New Jersey Superior Court has jurisdiction over the Defendants because, based upon information and belief, BD and Bard are New Jersey residents, corporations and/or entities organized under the laws of the State of New Jersey, authorized to do business in New Jersey and registered with the New Jersey Secretary of State or have sufficient minimum contact in New Jersey, or otherwise intentionally avail themselves of the New Jersey market so as to render the exercise of jurisdiction over it by the New Jersey courts consistent with traditional notions of fair play and substantial justice.

10. Venue is proper in this Court under New Jersey Rule of Court 4:3-2(b) because all Defendants regularly do business in New Jersey and Bergen County. Defendants have and continue to conduct substantial business in the State of New Jersey, distribute vascular products, receive substantial compensation and profits from sales of vascular products in the state of New Jersey, and made omissions and misrepresentations and breaches of warranties, so as to subject them to *in personam* jurisdiction in this State.

11. Consistent with the Due Process Clause of the Fifth and Fourteenth Amendments, this Court has *in personam* jurisdiction over Defendants, because Defendants are present in the State of New Jersey, such that requiring an appearance does not offend traditional notions of fair and substantial justice.

FACTS

I. PRODUCT BACKGROUND

12. PowerPort is one of several varieties of port/catheter systems that has been designed, manufactured, marketed, and sold by Defendants.

13. According to the BAS, the PowerPort is a totally implantable vascular access device designed to provide repeated access to the vascular system for the delivery of medication, intravenous fluids, parenteral nutrition solutions, and blood products.

14. The intended purpose of the PowerPort is to make it easier to deliver medications directly into the patient's bloodstream. The device is surgically placed completely under the skin and left implanted.

15. The PowerPort consists of two primary components: an injection port and a silicone catheter.

16. The injection port has a raised center, or "septum," where the needle is inserted for delivery of the medication. The medication is carried from the port into the bloodstream through a small, flexible tube, called a catheter, which is inserted into a blood vessel.

17. The PowerPort is "indicated for patient therapies requiring repeated access to the vascular system. The port system can be used for infusion of medications, I.V. fluids, parenteral nutrition solutions, blood products, and for the withdrawal of blood samples."[1]

18. According to BAS marketing materials, its Groshong© Central Venous Catheter "open ended central venous catheters continue to set the standard for performance and reliability," and is described as a "medical-grade radiopaque silicone construction [that] ensures biocompatibility.

19. The catheter is comprised of a polymeric mixture of silicone and barium sulfate, a compound which is visible in certain radiologic studies.

20. Barium sulfate is known to contribute to reduction of the mechanical integrity of polymers *in vivo* as the particles of barium sulfate dissociate from the surface of the catheter over time, leaving microfractures and other alterations of the polymeric structure and degrading the mechanical properties of silicone.

21. Researchers have shown that catheter surface degradation in products featuring a radiopaque barium sulfate stripe is concentrated at the locus of the stripe.[2]

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[1] "Safety Information." *Bard - Port Ready*, 12 Aug. 2019, portready.com/infusion-therapy/safety-information/.

[2] *See* Hecker JF, Scandrett LA. *Roughness and thrombogenicity of the outer surfaces of intravascular catheter*s. *J Biomed Mater Res*. 1985;19(4):381-395. doi:10.1002/jbm.820190404.

22. The surface integrity of barium sulfate-impregnated silicone catheter is affected by the concentration of barium sulfate as well as the homogeneity of the modified polymer.

23. As the barium sulfate content increases, medical polymer products that use barium sulfate begin to show losses of the base polymer's tensile strength and other mechanical properties.[3]

24. Upon information and belief, Defendants' manufacturing process in constructing the catheter implanted in Plaintiff involved too high a concentration of barium sulfate particles, leading to improperly high viscosity of the raw silicone before polymerization and causing improper mixing of barium sulfate particles within the silicone matrix.

25. This defect in the manufacturing process led to a heterogeneous modified polymer which included weakened areas of higher barium sulfate concentration and led to surface degradation of the catheter which, in turn, created multiple locations for the development of microbes and/or fungi.

26. Although the surface degradation can be reduced or avoided with design modifications to encapsulate the radiopaque compound, Defendants elected not to incorporate those design elements into the PowerPort.

27. Defendants obtained "clearance" to market the PowerPort product implanted in Plaintiff under Section 510(k) of the Medical Device Amendments to the Food, Drug, and Cosmetic Act. Unlike the rigorous pre-market approval requirements under the FDA, §510(k) permits the marketing of medical devices if the device is substantially equivalent to other legally marketed predicate devices without formal review for the safety or efficacy of the device. Section 510(k) reviews are completed in an average of 20 hours as compared to the 1200 hours necessary

[3] *See* Tilak M. Shah, *Radiopaque Polymer Formulations for Medical Device*, March 1, 2000, Medical Device and Diagnostic Industry, https://www.mddionline.com/print/60.

to complete a PMA review, and rarely elicit negative responses from the FDA. *See McDonald v Zimmer, Inc.,* 2020- NMCA-020, ¶ 11, 461 P.3d 930, citing to *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 479 (1996) ("Whereas the premarket review process ((which requires 1,200 hours to complete)) is a federal safety review, the on-average 20-hour review process for devices marketed under 510k "requires little information, rarely elicits a negative response from the FDA, and gets processed very quickly.")

28. Although implantable medical devices such as the PowerPort are ordinarily required to undergo a rigorous premarket approval process, the Medical Device Amendments Act of 1976, Pub. L. No. 94-295, 90 Stat. 539 (the Act), permitted devices that are "substantially equivalent" to devices already on the market to avoid the premarket approval process. *See* 21 U.S.C. § 360e(b)(1)(B) (2018). Courts have observed that this truncated route (known as the "510k process," under a prior version of the Act) is "focused on equivalence, not safety." *Medtronic, Id,* 518 U.S. at 493.

29. Once a product is cleared by the FDA under the §510(k), the manufacturer remains under an obligation to investigate and report any adverse events associated with the device and must periodically submit any new information to the FDA that may affect the agency's previous conclusions regarding safety and efficacy. This obligation extends to post-market monitoring of adverse events/complaints.

30. Pursuant to *Wyeth v. Levine*, 555 U.S. 555 (2009), once a product is cleared "the manufacturer remains under an obligation to investigate and report any adverse associated with the drug…and must periodically submit any new information that may affect the FDA's previous conclusions about the safety, effectiveness, or labeling …." This obligation extends to post-market monitoring of adverse events/complaints.

31. At all times relevant hereto, Defendants misrepresented the safety of the PowerPort system, and marketed, distributed, and sold the PowerPort system as a safe and effective device to be surgically implanted to provide repeated access to the vascular system for the delivery of medications, intravenous fluids, parenteral nutrition solutions and blood products.

32. At all times relevant hereto, Defendants knew, and had reason to know, that the PowerPort was not safe for the patients for whom they were prescribed and implanted, because once implanted, the device was prone to precipitating serious infections.

33. At all times relevant hereto, Defendants knew and had reason to know that patients implanted with a PowerPort had an increased risk of suffering life threatening injuries, including but not limited to: death, hemorrhage, cardiac/pericardial tamponade (pressure caused by a collection of blood in the area around the heart), cardiac arrhythmia and other symptoms similar to myocardial infarction, severe and persistent pain, bacterial bloodstream infections, and perforations of tissue, vessels and organs, or the need for additional surgeries to remove the defective device.

34. Soon after the PowerPort was introduced to the market, which was years before Plaintiff's PowerPort device was implanted, Defendants received large numbers of Adverse Event Reports (AERs) from healthcare providers, reporting that the PowerPort was precipitating serious infections which may lead to the development of sepsis in intended users, post-implantation.

35. Defendants also received large numbers of AERs reporting that the PowerPort was associated with reports of patient injuries such as:

a. Hemorrhage;

b. Cardiac/pericardial tamponade;

c. Cardiac arrhythmia and other symptoms similar to myocardial infarction;

d. Severe and persistent pain; and

e. perforations of tissue, vessels, and organs; and,

f. upon information and belief, even death.

36. In addition to the large number of AERs which were known to Defendants and reflected in publicly accessible databases, there are thousands of recorded device failures and/or injuries related to the Defendants' implantable port products – including the product implanted in Plaintiff which were concealed from medical professionals and patients through submission to the FDA's controversial Alternative Summary Reporting ("ASR") program.

37. The FDA halted the ASR program after its existence was exposed by a multi-part investigative piece, prompting a widespread outcry from medical professionals and patient advocacy groups.[4]

38. Prior to the discontinuation of the ASR program, Defendants reported thousands of episodes under the ASR exemption, thereby concealing them from physicians and patients.

39. Defendants were aware or should have been aware that the PowerPort had a substantially higher failure rate than other similar products on the market, yet Defendants failed to warn consumers - or medical providers - of this fact.

40. After becoming aware of the adverse outcomes in patients associated directly to the PowerPort device, Defendants did not warn patients, treating physicians or other healthcare providers about the risk of serious infections related to the PowerPort device.

41. Defendants also intentionally concealed the severity of complications caused by the PowerPort and the likelihood of these events occurring.

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[4] Christina Jewett, *Hidden Harm: Hidden FDA Reports Detail Harm Caused by Scores of Medical Devices*, Kaiser Health News (Mar. 2019)

42. Rather than alter the design of the PowerPort to make it safer or adequately warn physicians of the dangers associated with the PowerPort, Defendants continued to actively and aggressively market the PowerPort as safe, despite their knowledge of numerous reports of catheter infection and associated injuries.

43. The conduct of Defendants, as alleged in this Complaint, constitutes willful, wanton, gross and outrageous corporate conduct that demonstrates a conscious disregard for the safety of Plaintiff.

44. Defendants had actual knowledge of the dangers presented by the PowerPort System, yet consciously failed to act reasonably to:

a. Adequately inform or warn Plaintiff, her prescribing physicians, or the public at large of these dangers;

b. Establish and maintain an adequate quality and post-market surveillance system; or

c. Recall the PowerPort system from the market.

45. Despite knowing of a design and manufacturing defect in the PowerPort device, which created excessive risk in patients, Defendants did not change the design or manufacture of the device. Despite being aware of the significant failures of the PowerPort device through the AER reports, Defendants took no action to warn medical providers or consumers of the known flaws in the PowerPort device.

46. There are thousands of recorded device failures and/or injuries related to the Defendants' implantable port products, including the product type implanted in Plaintiff, which were concealed from medical professionals and patients through submission to the controversial Alternative Summary Reporting ("ASR") program.

47. The Defendants improperly hid the device failures in the ASR program when the reports should have been made through the publicly searchable MAUDE database.

48. Defendants were aware or should have been aware that the PowerPort had a substantially higher failure rate than other similar products on the market, yet the Defendants failed to warn consumers of this fact.

49. Defendants were aware of a design defect of the PowerPort device and took intentional action to conceal the design defect from the FDA and consumers.

50. Defendants were also aware of a manufacturing defect of the PowerPort device and took intentional action to conceal the design defect from the FDA and consumers.

51. Despite being aware of defects in the PowerPort devices manufactured by Defendants, Defendants intentionally concealed the severity of complications caused by PowerPort and the likelihood of these events occurring from both the FDA and consumers.

52. Rather than correct the design and manufacturing process of the PowerPort to make it safer, or adequately warn physicians of the dangers associated with the PowerPort, Defendants continued to actively and aggressively market the PowerPort as safe, despite their knowledge of design and manufacturing defects, and despite numerous reports of catheter infection, and related injuries to numerous patients in which the PowerPort had been installed.

53. The conduct of the Defendants, as alleged in this Complaint, constitutes willful, wanton, gross, and outrageous corporate conduct that demonstrates a conscious disregard for the safety of Plaintiff. Defendants had actual knowledge of the dangers presented by the PowerPort System, yet consciously failed to act reasonably to:

a. Adequately inform or warn Plaintiff, her prescribing physicians, the Food and Drug Administration, or the public at large of these dangers; and,

b. Establish and maintain an adequate quality control procedure in the PowerPort manufacturing process; and,

c. Establish and maintain an adequate quality and post-market quality control system to ensure the design, manufacturing and labeling deficiencies associated with the device were timely identified and corrected; and,

d. Recall the known-defective PowerPort System from the market.

II. SPECIFIC FACTUAL ALLEGATIONS AS TO PLAINTIFF

54. On or about February 24, 2022, Plaintiff was implanted with a PowerPort isp M.R.I. Implantable Port, Model Number: 1808060, Lot Number: REFR4191, Device Identifier: 00801741027031, for administration of chemotherapy in treatment of breast cancer. The procedure took place at Advocate South Suburban Hospital, Hazel Crest, Illinois, and was performed by Dr. David B. Pierce, M.D.

55. Defendants, directly or through their agents, apparent agents, servants or employees designed, manufactured, marketed, advertised, distributed and sold the Device that was implanted in Plaintiff.

56. The Device was correctly and properly installed by Dr. David B. Pierce, M.D. in accordance with the manufacturer's instructions.

57. The Device was not implanted in such a manner that would have caused it to compress, erode or "pinch off."

58. At all times relevant, the Device was used for its intended purpose of repeated access to the vascular system for the delivery of medication, intravenous fluids, parenteral nutrition solutions, blood products, and for the withdrawal of blood samples.

59. At all times relevant, Plaintiff's healthcare providers did not place, maintain, or

use the Device incorrectly or use the Device for an unforeseeable purpose.

60. On or about May 4, 2022, Plaintiff presented to Advocate South Suburban Hospital where it was confirmed that her Device was infected. Plaintiff was diagnosed with pseudomonas bacteremia and given antibiotics for treatment purposes.

61. On or about May 9, 2022, Dr. Michael S. Romberg, M.D. performed surgery to remove the infected Device.

62. On or about May 10, 2022, while still admitted to Advocate South Suburban Hospital, Plaintiff went into septic shock and was transferred to the intensive care unit for further treatment of septic shock and acute liver failure. Plaintiff's hospital course was subsequently complicated by pulmonary edema and acute hypoxic respiratory failure, disseminated intravascular coagulation and profound thrombocytopenia, and progressively worsening acute liver failure.

63. On or about May 15, 2022, Plaintiff was transferred from Advocate South Suburban Hospital to the intensive care unit of Loyola University Medical Center, Maywood, Illinois, for higher level care. She was admitted for approximately five days of treatment related to their determination that Plaintiff had a serious or life-threatening alteration in organ system function or was at high risk for deterioration of vital organ system function.

64. Due to the defective Device, Plaintiff suffered damages and continues to suffer damages including, but not limited to, undergoing an unnecessary major surgery, increased risk of future severe and permanent injuries, severe emotional distress, ongoing fear and anxiety from future injuries, including but not limited to, cardiac tamponade.

65. The Defendants concealed, and continue to conceal, their knowledge of the Device's unreasonably dangerous risks from Plaintiff and Plaintiff's physicians.

66. Numerous reports of catheter fractures and migration, thromboembolism, and infection, in the absence of medical provider error were recorded and reported to Defendants before the Device was implanted into Plaintiff.

67. Despite knowledge of such injuries, Defendants continued to actively and aggressively market the Device as safe. Defendants utilized marketing communications—including the Device's Instruction for Use and direct communications to Plaintiff's healthcare providers—to intentionally mislead Plaintiff's healthcare providers into believing these failures were caused by factors other than catheter design and composition.

68. Defendants did not adequately warn Plaintiff or Plaintiff's physicians of the true quantitative or qualitative risk of fracture and migration, thromboembolism, and infection associated with the Device.

69. Defendants did not adequately warn Plaintiff or Plaintiff's physicians that the risk of fracture and migration, thromboembolism, and infection associated with the Device increases the longer the product is placed in a patient.

70. Defendants did not adequately warn Plaintiff or Plaintiff's physicians that the function and integrity of the Device should be closely monitored when the device is in place for over a year to reduce the risk of injury.

71. Defendants did not adequately communicate the extent or seriousness of the danger of fracture and migration, thromboembolism, and infection to Plaintiff or Plaintiff's prescribing physicians.

72. Rather than alter the design of their product to make it safer or warn physicians of the dangers associated with the Device, Defendants chose to continue their efforts to promote the defective Device.

73. Plaintiff's physicians relied upon Defendants' representations—including the Instructions for Use distributed with the product implanted in Plaintiff—and advertisements to Plaintiff's detriment.

74. Defendants concealed—and continue to conceal—their knowledge of the Device's dangerous propensity to (a) fracture and/or dislodge and cause foreign materials to be introduced into the Plaintiff's bloodstream; and (b) precipitate thromboembolism and/or infection. Moreover, Defendants concealed that the Device's design caused these failures and that these failures cause serious and life-threatening injuries.

75. Further, Defendants failed to conduct adequate and sufficient post-marketing surveillance after they began marketing, advertising, distributing, and selling the Device.

76. As a result of Defendants' intentional actions and Defendants' wrongful conduct in designing, manufacturing, and marketing this defective product, Plaintiff and Plaintiff's physician were unaware, and could not have reasonably known or have learned through reasonable diligence, that Plaintiff had been exposed to the risks identified in this Complaint, and that those risks were the direct and proximate result of the Defendants' acts, omissions, and misrepresentations.

77. As a result of the Defendants' actions and inactions, Plaintiff was injured due to the use of the Device, which has caused and will continue to cause Plaintiff's various physical, mental, and emotional injuries and damages. Accordingly, Plaintiff seeks compensatory damages.

COUNT I – NEGLIGENCE
ALL DEFENDANTS

78. Plaintiff incorporates the preceding paragraphs as if set forth herein.

79. The Defendants owed Plaintiff a duty to exercise reasonable care when designing, manufacturing, marketing, advertising, distributing, selling, and conducting post-market

surveillance of the PowerPort.

80. The Defendants failed to exercise due care under the circumstances and therefore breached this duty by:

a. Failing to properly and thoroughly test the PowerPort before releasing the device to market, and/or failing to implement feasible safety improvements;

b. Failing to properly and thoroughly analyze the data resulting from any pre-market testing of the PowerPort;

c. Failing to conduct sufficient post-market testing and surveillance of the PowerPort;

d. Designing, manufacturing, marketing, advertising, distributing, and selling the PowerPort to consumers, including Plaintiff, without an adequate warning of the significant and dangerous risks of the PowerPort and without proper instructions to avoid the harm which could foreseeably occur as a result of using the device;

e. Failing to exercise due care when advertising and promoting the PowerPort; and negligently continuing to manufacture, market, advertise, and distribute the PowerPort after Defendants knew or should have known of its adverse effects.

81. As a direct and proximate result of the Defendants' actions, omissions and misrepresentations, Plaintiff suffered severe physical pain and injuries, emotional distress, loss of the capacity for the enjoyment of life, medical expenses, and economic loss as alleged herein. Accordingly, Plaintiff seeks compensatory damages.

82. In performing the foregoing acts, omissions, and misrepresentations, Defendants

acted grossly negligent, fraudulently, and with malice so as to justify an award of punitive and/or exemplary damages.

COUNT II – STRICT LIABILITY- FAILURE TO WARN
ALL DEFENDANTS

83. Plaintiff incorporates the preceding paragraphs as if set forth herein.

84. Defendants designed, set specifications for, manufactured, marketed, distributed, and sold the PowerPort, including the one implanted into Plaintiff into the stream of commerce (including commerce in the State of Illinois and New Jersey) and in the course of same, directly advertised and marketed the PowerPort to consumers or persons responsible for consumers, and therefore had a duty to warn of the risk of harm associated with the use of the device and to provide adequate instructions on the safe and proper use of the device.

85. At the time Defendants manufactured, marketed, distributed, and sold the PowerPort device implanted into Plaintiff, Defendants were aware the device was defective and presented an unreasonably dangerous risk of injury to users of the product when put to its intended and reasonably anticipated use, namely as an implanted port/catheter system to administer the medications.

86. Defendants knew or should have known at the time they manufactured, labeled, distributed, and sold the PowerPort that was implanted into Plaintiff that the PowerPort posed a significant and higher risk than other similar devices of device failure and resulting in serious injuries.

87. Had Plaintiff's physician been informed through the Defendant's warnings, labels, and instructions of the PowerPort device failures resulting in serious injuries Plaintiff's physician would have had the opportunity to evaluate the implantation of the device with full knowledge of all risks and serious potential complications.

88. Prior to manufacturing the PowerPort device implanted into Plaintiff, Defendants knew the PowerPort devices were causing patient injuries at much higher reported failure rates than had ever been revealed to or expected by consumers.

89. Defendants knew or should have known at the time they manufactured marketed, distributed, and sold the PowerPort device implanted into Plaintiff, that the PowerPort posed a significant and higher risk than other similar devices of device failure and resulting serious injuries.

90. Defendants failed to timely and reasonably warn of material facts regarding the safety and efficacy of the PowerPort; no reasonable healthcare provider, including Plaintiff's, or patient would have used the device in the manner directed, had those facts been made known to the prescribing healthcare providers or the consumers of the device.

91. The warnings, labels and instructions provided by Defendants at all time relevant to this action, are and were inaccurate, intentionally misleading, misinformed and misrepresented the risks and benefits and lack of safety and efficacy associated with the device, and failed to adequately indicate the known scope of the danger of using the device.

92. Defendants knowingly and intentionally failed to adequately warn of the device's known or reasonably scientifically knowable dangerous propensities, and further failed to adequately provide instructions on the safe and proper use of the device.

93. The health risks associated with the PowerPort device as described herein are of such a nature that ordinary consumers would not have readily recognized the potential harm.

94. At the time Defendants manufactured, marketed, distributed, and sold the PowerPort device implanted into Plaintiff, Defendants were aware that a substantial number of PowerPort devices sold by Defendants were defective and presented a substantial danger to users of the product when put to its intended and reasonably anticipated use. Despite this knowledge,

Defendants failed to provide a warning (much less an adequate warning) of the device's known or reasonably scientifically knowable dangerous propensities, and further failed to adequately provide instructions on the safe and proper use of the device.

95. Defendants failed to timely and reasonably warn of material facts regarding the safety and efficacy of the PowerPort to medical providers and the FDA, despite having full knowledge of the failures of the PowerPort, which resulted in the device presenting an unreasonably dangerous risk of injury to patients.

96. When the PowerPort device was implanted in Plaintiff, Defendants failed to provide adequate warnings, instructions, or labels regarding the severity and extent of health risks posed by the device, which were known to Defendants.

97. The device, which was designed, manufactured, assembled, and sold in the stream of commerce by Defendants, was defective at the time of release into the stream of commerce due to inadequate warnings, labeling and/or instructions accompanying the product.

98. When the PowerPort device was surgically implanted into Plaintiff, Defendants failed to provide adequate warnings, instructions, or labels regarding the severity and extent of health risks posed by the device, as described herein.

99. Defendants intentionally underreported the number and nature of adverse events associated with the PowerPort device to Plaintiff's healthcare providers, as well as the FDA.

100. Due directly to Defendants' failure to report the known failures and medical risks associated with the PowerPort devices, neither Plaintiff nor her healthcare providers had any reason to know of the substantial danger associated with the defective device.

101. Had Defendants provided adequate warnings, Plaintiff and her physicians would not have used the PowerPort device.

102. Upon information and belief, the defective and dangerous condition of the device including the one implanted into Plaintiff, existed at the time they were manufactured, marketed, labeled, distributed, and sold by Defendants to distributors and/or healthcare professionals or organizations. Upon information and belief, the device implanted in Plaintiff was in the same condition as when it was manufactured, inspected, marketed, labeled, promoted, distributed, and sold by Defendants.

103. Defendants' lack of sufficient warnings and instructions created an unreasonably dangerous risk of injury and was the direct and proximate cause of Plaintiff's serious physical injuries; if Defendants had provided adequate warnings, Plaintiff and her physicians would not have used the device, as similar competitive devices existed at the time.

104. Defendants' lack of sufficient warning and/or instructions was the direct and proximate cause of Plaintiff's serious physical injuries, and economic damages in an amount to be determined at trial. Plaintiff has suffered damages due directly to Defendants' failure to warn.

COUNT III - STRICT LIABILITY - DESIGN DEFECT
ALL DEFENDANTS

105. Plaintiff incorporates the preceding paragraphs as if set forth herein.

106. Defendants designed, set specifications for, manufactured, marketed, distributed, and sold the PowerPort, including the one implanted into Plaintiff into the stream of commerce (including commerce in the States of Illinois & New Jersey) and in the course of same, directly advertised and marketed the device to consumers or persons responsible for consumers, and therefore are strictly liable for distributing a defectively designed product.

107. The PowerPort implanted in Plaintiff was defective in its design and unreasonably dangerous at the time it left the control of Defendants and entered the stream of commerce; it failed to perform as safely as an ordinary consumer would expect when used as intended or in a manner

reasonably foreseeable, and because the foreseeable risks of the devices exceeded any benefits associated with its use.

108. At the time PowerPort implanted in Plaintiff was manufactured, safer alternative designs were commercially, technologically, and scientifically attainable and feasible.

109. At the time Defendants manufactured, marketed, distributed, and sold the PowerPort device implanted into Plaintiff, Defendants were aware the design of the device was defective and presented a substantial danger to users of the product when put to its intended and reasonably anticipated use.

110. Plaintiff and her healthcare providers used the PowerPort in a manner that was reasonably foreseeable to Defendants and in the manner it was intended to be used.

111. Neither Plaintiff nor her healthcare providers could have by the exercise of reasonable care discovered the defective condition or perceived the unreasonable dangers with the PowerPort prior to the device being implanted into Plaintiff.

112. Defendants are strictly liable to the Plaintiff for designing, manufacturing, marketing, and selling the defectively designed PowerPort implanted in Plaintiff.

113. The design defect of the PowerPort implanted into Plaintiff created an unreasonably dangerous risk of injury and was a direct and proximate cause of Plaintiff's serious physical injuries, and Plaintiff has suffered damages due directly to the design defect.

COUNT IV - STRICT LIABILITY – MANUFACTURING DEFECT
ALL DEFENDANTS

114. Plaintiff incorporates the preceding paragraphs as if set forth herein.

115. Defendants designed, set specifications for, manufactured, marketed, distributed, and sold the PowerPort, including the one implanted into Plaintiff into the stream of commerce (including commerce in the States of Illinois & New Jersey) and in the course of same, directly

advertised and marketed the device to consumers or persons responsible for consumers, and therefore are strictly liable for manufacturing a defective product.

116. Upon information and belief, the defective and dangerous condition of the device implanted into Plaintiff existed at the time it was manufactured by Defendants.

117. Based on information and belief, Defendants operated under design and manufacturing specifications for the PowerPort, which included appropriate material content, strength, size, durability appearance, resistance levels, and the devices were not to be distributed if they exhibited excessive surface damage. The manufacturing process was intended to identify any end-product products that did not meet design specifications, so that those devices would not be placed into the stream of commerce.

118. Based upon information and belief, the PowerPort implanted in Plaintiff contained manufacturing defects when it left Defendants' possession. The device differed from said Defendants' intended result and/or from other ostensibly identical units of the same product line.

119. The device implanted in Plaintiff was in the same condition as when it was manufactured, distributed, and sold by Defendants.

120. The PowerPort device implanted into Plaintiff, which Defendants manufactured, marketed, distributed, and sold into the stream of commerce was defective at the time of its release into the stream of commerce.

121. Plaintiff and her healthcare providers used the PowerPort in a way that was reasonably foreseeable to Defendants.

122. The device's manufacturing defect created an unreasonably dangerous risk of injury and was the direct and proximate cause of Plaintiff's serious physical injuries and economic damages.

COUNT V - NEGLIGENT MISREPRESENTATION
ALL DEFENDANTS

123. Plaintiff incorporates the preceding paragraphs as if set forth herein.

124. Defendants distributed, marketed, and provided the labeling and warning materials distributed with the PowerPort device that was implanted in Plaintiff.

125. Prior to, on, and after the dates during which Defendants distributed the PowerPort to Plaintiff via her healthcare providers, Defendants negligently and carelessly represented to Plaintiff, their healthcare providers, and the general public that certain material facts were true.

126. The information distributed by Defendants to Plaintiff and her healthcare providers was in the form of reports, press releases, advertising campaigns, labeling materials, print advertisements commercial media containing material representations, and instructions for use.

127. Upon information and belief, Plaintiff's prescribing physicians reviewed these materials including specifically the labeling materials provided with these devices, prior to deciding to use the specific PowerPort device in Plaintiff.

128. Prior to, on, and after the dates during which Plaintiff and her physicians purchased and used the PowerPort, said representations were not true, and there was no reasonable ground for believing said representations to be true at the times said representations were made.

129. Prior to, on, and after the dates during which Plaintiff and her physicians purchased and used the device, Defendants intended that Plaintiff, her physicians, and the general public would rely on said representations and prescribe the PowerPort, which did in fact occur. Defendants' fraudulent misrepresentations to Plaintiff's healthcare providers were a substantial factor in their decision to use this device in Plaintiff.

130. Defendants' misrepresentations were a substantial factor in causing Plaintiff's

injuries and damages, as described herein.

COUNT VI - FRAUD – MISREPRESENTATION
ALL DEFENDANTS

131. Plaintiff incorporates the preceding paragraphs as if set forth herein.

132. At all times relevant to this cause, and as described herein, Defendants intentionally provided Plaintiff, her physicians, the medical community, and the FDA with false or inaccurate information, and/or omitted material information concerning the PowerPort including, but not limited to, misrepresentations regarding the following topics:

a. The safety of the devices;

b. The efficacy of the devices;

c. The rate of failure of the devices; and

d. The pre-market testing of the devices.

133. The information distributed by Defendants to the public, the medical community, Plaintiff and her physicians, was in the form of reports, press releases, advertising campaigns, labeling materials, print advertisements, commercial media containing material representations, and instructions for use, as well as through their officers, directors, agents, and representatives. These materials contained false and misleading material representations, which included:

a. That the devices were safe, fit, and effective when used for its intended purpose or in a reasonably foreseeable manner; That the devices did not pose dangerous health risks in excess of those associated with the use of other similar devices;

b. That the device was safer and more effective than other available port devices.

134. Defendants made the foregoing misrepresentations knowing that they were false. These materials included instructions for use and a warning document that was included in the

package of the device implanted in Plaintiff.

135. Defendants' purpose in making these misrepresentations was to deceive and defraud Plaintiff and her healthcare providers; to gain the confidence of Plaintiff and her healthcare providers; to falsely assure them of the quality of the device and its fitness for use; and to induce Plaintiff's healthcare providers to request, recommend, prescribe, implant, purchase, and continue to use the PowerPort, all in reliance on Defendants' misrepresentations.

136. The representations and omissions by Defendants were in fact false, and Defendants were at all times aware of the false nature of the representations.

137. Defendants acted to serve their own interests, and having reasons to know the misrepresentations were false, consciously disregarded the substantial risk that the device could significantly harm patients.

138. Plaintiff's healthcare providers did in fact review and rely on these written materials distributed by Defendants, including specifically the product inserts provided in the packaging of the PowerPort device, in respect to performing a risk/benefit analysis in determining whether or not to prescribe the PowerPort to Plaintiff. Plaintiff's healthcare providers also relied on these materials in determining what risk information to pass on to Plaintiff as part of the informed consent process.

139. In reliance upon the concealed information as well as the false representations made by Defendants, Plaintiff and her healthcare providers were induced to, and did use the PowerPort, thereby causing Plaintiff to sustain the injuries described herein.

140. Defendants knew that Plaintiff and her healthcare providers did not have the ability to determine the true facts intentionally concealed and misrepresented by Defendants and would not have prescribed and implanted this device in Plaintiff if the true facts regarding the device had

not been concealed and misrepresented by Defendants.

141. Defendants had sole access to material facts concerning the defective nature of the PowerPort and its propensity to cause serious side effects in the form of dangerous injuries and damages to persons who are implanted with the device.

142. At the time Defendants failed to disclose and intentionally misrepresented the foregoing facts, and at the time Plaintiff's healthcare providers purchased and used this device, Plaintiff's healthcare providers were unaware of these misrepresentations by Defendants.

143. Plaintiff's healthcare providers reasonably relied upon misrepresentations made by Defendants where the concealed and misrepresented facts were critical to understanding the true dangers inherent in the use of the device.

144. Defendants' fraudulent misrepresentations to Plaintiff's healthcare providers were a substantial factor in their decision to use this device in Plaintiff.

145. Defendants' misrepresentations were a substantial factor in causing Plaintiff's injuries and damages, as described herein.

COUNT VII- FRAUDULENT CONCEALMENT
ALL DEFENDANTS

146. Plaintiff incorporates the preceding paragraphs as if set forth herein.

147. In marketing and selling the PowerPort device, Defendants concealed material facts from Plaintiff and her healthcare providers.

148. Defendants concealed material facts regarding the PowerPort including, but not limited to, the following:

a. That the devices were unsafe and not fit when used for their intended purpose or in a reasonably foreseeable manner;

b. That the devices posed dangerous health risks in excess of those associated with the use of other similar devices;

c. That there were additional side effects related to implantation and use of these devices that were not accurately and completely reflected in the warnings associated with the devices; and,

d. That the devices were not adequately tested to withstand normal placement within the human body.

149. Plaintiff and her healthcare providers were not aware of these and other facts concealed by Defendants.

150. Defendants are and were under a continuing duty to disclose the true character, quality and nature of the device that was implanted in Plaintiff, but instead they concealed them. Defendants' conduct as described herein, amounts to conduct purposely committed, which Defendants must have realized was dangerous, heedless and reckless, without regard to the consequences or the rights and safety of Plaintiff.

151. In concealing these and other facts, Defendants intended to deceive Plaintiff and her healthcare providers as to the true facts regarding the safety and efficacy of the PowerPort.

152. Plaintiff's healthcare providers reviewed and relied on these product inserts for the purpose of making a risk benefit assessment as to whether or not to prescribe the PowerPort. Plaintiff's healthcare providers also relied on these materials in determining what risk information to pass on to Plaintiff as part of the informed consent process.

153. Plaintiff and her healthcare providers reasonably and justifiably relied on the above-described concealments by Defendants.

154. This concealment by Defendants of material facts from Plaintiff and her healthcare

providers was a substantial factor in Plaintiff's healthcare providers deciding to use the devices and in Plaintiff's agreement to be implanted with the devices.

155. Plaintiff's physician would not have prescribed the PowerPort to Plaintiff had Defendants not concealed the above-described information.

156. Defendants' fraudulent concealment was a substantial factor in causing Plaintiff's injuries and damages, as described herein.

COUNT VIII – VIOLATION OF THE NEW JERSEY CONSUMER FRAUD ACT
ALL DEFENDANTS

157. Plaintiff incorporates the preceding paragraphs as if set out fully herein.

158. Plaintiff brings this count against Defendants BD, Bard, BAS, and Does 1 through 10, inclusive.

159. The acts and practices engaged in by Defendants constitute unlawful, unfair and/or fraudulent business practices in violation of the New Jersey Consumer Fraud Act, N.J.S.A. § 56:8-2 et. seq.

160. Defendants engaged in unlawful practices including deception, false promises, misrepresentation, and/or the concealment, suppression, or omission of material facts in connection with the sale, distribution, or advertisement of the PowerPort in violation of the N.J.S.A. § 56:8-2 et. seq.

161. Plaintiff purchased the PowerPort, a product that was falsely represented, as set out above, in violation of the New Jersey Consumer Fraud Act and as a result Plaintiff suffered economic damages in that the product purchased was worth less than the product she thought she had purchased had Defendants' representations been true.

COUNT IX - VIOLATION OF THE NEW JERSEY PRODUCT LIABILITY ACT
ALL DEFENDANTS

162. Plaintiff incorporates the preceding paragraphs as if set out fully herein.

163. Pursuant to N.J.S.A. 2A:58-C, *et. seq.* (New Jersey Products Liability Act) Plaintiff asserts all claims and causes of action against Defendants, including but not limited to, negligence, breach of implied warranty of merchantability, breach of implied warranty of fitness, strict liability, failure to warn and/or inadequate warning on theories of both negligence and strict liability, all claims and causes of action pertaining to the design, manufacture, sale and distribution of the defective product which was not reasonably fit, suitable, or safe for their intended purpose as it was defectively designed, manufactured and/or failed to contain adequate warnings.

164. At all relevant times, Defendants were engaged in the business of manufacturing and designing the PowerPort.

165. The PowerPort included barium sulfate, a well-known risk in the industry of causing a reduction of mechanical integrity of polyurethane as the particles of barium sulfate dissociate from the surface of the catheter over time.

166. Defendants failed to warn Plaintiffs that the use of barium sulfate presented a risk of suffering life threatening injuries, including but not limited to death; hemorrhage; thromboembolism; infection; cardiac arrhythmia; severe and persistent pain; and perforations of tissue, vessels and organs, or the need for additional surgeries to remove the defective device.

167. The PowerPort was expected to and did reach Plaintiff without substantial change to the condition in which it was designed, manufactured, and sold by Defendants.

168. The PowerPoint that did reach Plaintiff was defective and unfit for its intended use.

169. The use of the PowerPort by Plaintiff caused injuries including but not limited to death; hemorrhage; thromboembolism; infection; cardiac arrhythmia; severe and persistent pain; and perforations of tissue, vessels and organs, or the need for additional surgeries to remove the

defective device.

170. The PowerPort was so defective in design, formulation, or manufacture that when it left the hands of Defendants, the foreseeable risks exceeded the benefits associated with the design, formulation, or manufacture of the PowerPort.

171. At all times mentioned herein, the PowerPoint was in a defective condition and unsafe; and Defendants knew or should have known, that the PowerPort was defective and unsafe, especially when used in the form and manner as provided by Defendants and as intended by Plaintiff.

172. Plaintiff utilized the PowerPort for the purposes and manner as designed and sold by the Defendants and as normally intended.

173. Defendants had a duty to create a product that was not unreasonably dangerous for its normal, intended use and would not result in personal injury to Plaintiff.

174. Plaintiff acting reasonably prudent, could not have discovered Defendants' PowerPort was defective as herein mentioned, or perceived its danger.

175. By reason of the foregoing, Defendants are strictly liable to Plaintiff for designing, manufacturing, and selling the PowerPort.

176. As a direct and proximate result of the Defendants' defective design and failure to war, Plaintiff suffered losses as alleged herein, in an amount to be determined at trial.

COUNT X- PUNITIVE DAMAGES
ALL DEFENDANTS

177. Plaintiff incorporates the preceding paragraphs as if set forth herein.

178. Not only did Defendants intentionally fail to issue any warning regarding the known hazardous condition of the PowerPort device to the FDA, to the medical community and

to patients, Defendants knowingly, intentionally and with conscious disregard for the health and safety of patients, including Plaintiff, concealed defects of the device that were known to Defendants from the FDA, from the medical community and from patients such as Plaintiff.

179. Defendants intentionally and fraudulently misrepresented facts and information to both the healthcare community and the general public, including Plaintiff and her healthcare providers, by making intentionally false and fraudulent misrepresentations about the safety and efficacy of the PowerPort. Defendants intentionally concealed the true facts and information regarding the serious risks of harm associated with the implantation of said product, and intentionally downplayed the type, nature, and extent of the adverse side effects of being implanted with the device, despite Defendants' knowledge and awareness of the serious and permanent side effects and risks associated with use of same.

180. Defendants further intentionally sought to mislead healthcare providers and patients, including Plaintiff and her healthcare providers, regarding the serious risk of harm associated with the implantation of the PowerPort, including the risk of serious infections which may lead to the development of sepsis in intended users.

181. Defendants had knowledge of, and were in possession of evidence demonstrating that, the PowerPort caused serious physical side effects. Defendants continued to market said product by providing false and misleading information with regard to the product's safety and efficacy to the regulatory agencies, the medical community, and consumers of the device, notwithstanding Defendants' knowledge of the true serious side effects of the PowerPort, Defendants failed to provide accurate information and warnings to the healthcare community that would have dissuaded physicians from surgically implanting the PowerPort and consumers from agreeing to being implanted with the PowerPort, thus depriving physicians and consumers from

weighing the true risks against the benefits of prescribing and implanting the PowerPort.

182. As a direct and proximate cause of Defendants' acts and omissions as described herein, and Plaintiff's implantation with Defendants' defective product, Plaintiff suffered, and will continue to suffer, the injuries and damages described in this complaint.

183. The conduct of the Defendants was malicious, reckless, wanton and/or in bad faith.

184. Punitive damages should be awarded against Defendants.

PRAYER

WHEREFORE, Plaintiff Emmali Richmond respectfully requests that the Court:

A. Enter Judgment against Defendants on all causes of action set forth in this Complaint; and,

B. Award Plaintiff compensatory damages, including for pain & suffering, emotional damages, and all other allowable damages, for each of her claims against Defendants, in an amount to be proven at trial; and,

C. Award Plaintiff damages for past, medical expenses, in an amount to be proven at trial; and,

D. Award appropriate punitive damages against Defendants; and,

E. Award Plaintiff pre-judgment and post-judgment interest; and,

F. Award Plaintiff her reasonable attorneys' fees and costs incurred as permitted under New Jersey law; and,

G. Enter such further relief as the Court deems just and appropriate.

JURY DEMAND

Plaintiff demands trial by jury on all counts.

DESIGNATION OF TRIAL COUNSEL

Pursuant to R. 4:25-4, Michael A. Galpern is hereby designated as trial counsel.

DEMAND FOR ANSWERS TO INTERROGATORIES

Please take notice that Plaintiff demands that Defendants answer Form Product Interrogatories C and C4 in accordance with Rule 4:17(b)(2).

NOTICE PURSUANT TO RULES 1:5-l(a) AND 4:17-4(c)

Please take notice that the undersigned attorneys, counsel for Plaintiff, do hereby demand, pursuant to Rules 1:5-l(a) and 4:17-4(c), that each party herein serving pleadings and interrogatories and receiving answers thereto, serve copies of all such pleadings and answered interrogatories received from any party, including any documents, papers and other material referred to therein, upon the undersigned attorneys. Please take notice that this is a continuing demand.

ANTI- SPOLIATION/PRESERVATION WARNING

The term "you," "your" or "yours" as used herein shall refer to you (the recipient of this letter), as well any and all affiliates, subsidiaries, agents, employees, representatives, officers, and/or officials thereof, and any and all named defendants in this matter, its affiliates and/or subsidiaries, its employees, representatives and/or agents and officials, as well as any and all individuals responsible for the custody and control of the below information, including but not limited to those individual's administrative assistants, secretaries, agents, employees, information technology personnel and third-party vendors.

You are directed from this point forward to prevent any spoliation", defined as alteration, change, updating, periodic destruction of, editing or deletion of, any of the information which is set forth hereafter.

If you cause any such alteration, destruction or change, directed or allow it to occur, you will be potentially charged with discovery rule violations for which sanctions may be imposed. Further, the Complaint may be amended to add purposeful and/or reckless or negligent destruction or spoliation of evidence. Finally, we may ask for specific instructions to the jury to find certain facts to your disadvantage by virtue of the destroyed or inaccessible evidence.

Please be advised that you are hereby directed to prevent any spoliation of all records and/or recordings related to and/or regarding this patient for the past ten (10) years, including but not limited to any and all, medical records, time logs, videos, quality control reports, morbidity and mortality reports, morbidity and mortality statements, and any and all reports made to local, state, and/or federal agencies.

ELECTRONICALLY STORED INFORMATION

In terms of electronically stored information, you are directed to prevent any destructive, alterative or other change to any web pages, virtual profiles or identities (including *but not limited to* Myspace, Facebook, Instagram, Pinterest, Twitter, Tumblr, Linkedln, Snapchat, Google Plus+, Flickr, Vine, About.me, etc. or any other social media-based web profile or networking site account.), emails, voice messages, text messages, instant messages or messaging systems, pertaining in any way to this controversy or to the parties or witnesses, recordings, digital recordings, media images and videos, temporary memory, memory sticks, portable memory devices, laptops or computers, CDs, DVDs, USB devices, databases, computer activity logs, internet browsing history (including cookies), network access and server activity logs, word processing files and file fragments, back-up and archival files, imaging and facsimile files, electronic calendar and scheduling program files and file fragments as well as any other contact and relationship management data (e.g., Outlook, ACT!), electronic spreadsheet files and file

fragments, related to this matter. This includes a request that such information not be modified, altered or deleted as a result of data compression or disk fragmentation (or other optimizations procedures), which processes you are hereby directed to suspend until such time as that data can be preserved, copied and produced.

You are directed to not modify, alter or delete-or allow modifications, alterations or deletions to be made to-any such electronically stored information unless an exact replica or "mirror image" has been made and will be preserved and made accessible for purposes of discovery in this litigation and unless, in addition, an activity log of all document modifications already made to any electronically stored information is maintained.

Electronic documents and the storage media on which they reside contain relevant, discoverable information beyond that which may be found in printed documents. Therefore, even where a paper copy exists, we will seek all documents in their electronic form along with information about those documents contained on the media. We also will seek paper printouts of only those documents that contain unique information after they were printed out (such as paper documents containing hand writing, signatures, marginalia, drawings, annotations, highlighting and redactions) along with any paper documents for which no corresponding electronic files exist.

You are further directed to preserve and not destroy all passwords, decryption procedures (including, if necessary, the software to decrypt the files); network access codes, manuals, tutorials, written instructions, decompression or reconstruction software, and any and all other information and things necessary to access, view and (if necessary) reconstruct the electronic data we will request through discovery.

PAPER INFORMATION

In terms of paper information, you are directed to preserve any and all contracts and contract drafts, emails, memos and drafts of memos, handbooks (past and present), policies (past and present) and drafts, employment files, pay stubs or duplicates, spreadsheets, lists, reports, documents, notes, correspondence, photographs, investigative information or other documents which pertain in any way to the controversy, parties or witnesses in this matter.

Dated: 11/16/2023

/s/ Michael A. Galpern

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RULE 4:5-1 CERTIFICATION

I hereby certify that to the best of my knowledge the matter in controversy is the subject of numerous other actions filed in other courts and that no other parties are necessary to join at this time.

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

Dated: 11/16/2023

/s/ Michael A. Galpern

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Attorneys for Plaintiff

Civil Case Information Statement

Case Details: BERGEN | Civil Part Docket# L-006208-23

Case Caption: RICHMOND EMMALI VS C.R. BARD, INC.
Case Initiation Date: 11/16/2023
Attorney Name: MICHAEL ANDREW GALPERN
Firm Name: JAVERBAUM WURGAFT HICKS KAHN WIKSTROM & SININS
Address: 1000 HADDONFIELD-BERLIN RD STE 203 VOORHEES NJ 08043
Phone: 8565964100
Name of Party: PLAINTIFF : Richmond, Emmali
Name of Defendant's Primary Insurance Company (if known): None

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: Emmali Richmond? 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

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)

11/16/2023
Dated

/s/ MICHAEL ANDREW GALPERN
Signed