IN THE UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

BEVERLY BIGSBEE, Plaintiff, vs. BECTON, DICKINSON AND COMPANY, C.R. BARD, INC., BARD ACCESS SYSTEMS, INC., Defendants.	Case No

COMPLAINT

COMES NOW, Plaintiff Beverly Bigsbee, by and through her undersigned counsel, for her Complaint against Becton, Dickinson & Company, C.R. Bard, Inc., and Bard Access Systems, Inc. (collectively, "Defendants") states, as follows:

1. This is an action for damages relating to Defendants' design, development, testing, assembling, manufacturing, packaging, promoting, marketing, distribution, supplying, and/or selling the defective device sold under the trade name of Bard PowerPort™ ClearVUE ISP Implantable Port (hereinafter "PowerPort", "Defective Device", "Device', "port", or "Port-A-Cath").

2. Plaintiff Beverly Bigsbee ("Plaintiff") is an adult resident and citizen of Springfield, Tennessee, and claims damages as set forth below.

3. Defendant Becton, Dickinson and Company ("BD") is a New Jersey corporation with a principal place of business at 1 Becton Drive in Franklin Lakes, New Jersey. Defendant BD is one of the largest global medical technology companies in the world with diverse business units offering products in various healthcare subfields. Defendant BD 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. Defendant BD is the parent company of Defendants C.R. Bard, Inc. and Bard Access Systems, Inc.

4. Defendant C.R. Bard, Inc. ("Bard") is a New Jersey corporation with its principal place of business located at 1 Becton Drive in Franklin Lakes, New Jersey. Defendant Bard is a citizen of New Jersey. Defendant Bard conducts business throughout the United States, including the State of New Jersey, and is a wholly owned subsidiary of Defendant BD. Defendant 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. Defendant Bard, along with its subsidiaries and business units, was acquired by Defendant BD in 2017, in a transaction, which integrated and

subsumed Defendant Bard's business units into Defendant BD's business units. In said transaction, Defendant Bard's product offerings, including the PowerPort, were taken over by and integrated into Defendant BD's Interventional segment, one of three of BD's principal business segments. Following the acquisition, Defendant Bard's Board of Directors dissolved, with some former Bard directors joining Defendant BD's Board of Directors.

5. Defendant Bard Access Systems, Inc. ("BAS") is a Utah corporation with its principal place of business located in Salt Lake City, Utah. Defendant BAS is a citizen of Utah. Defendant BAS conducts business throughout the United States, including the State of New Jersey, and is a wholly owned subsidiary of Defendant BD. Defendant BAS 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.

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

7. Defendant BD's control over Defendants Bard and BAS has been purposefully used to perpetrate the violation of various legal duties in contravention of Plaintiff's legal rights.

8. The breaches by Defendant BD of various legal duties as described herein are the proximate cause of the injuries described herein.

9. In addition to Defendant BD's liability for Plaintiff's damages, as a result of its abuse of the corporate form, it is directly liable, as a result of its own wrongful conduct, as set forth herein.

JURISDICTION AND VENUE

10. This Court has subject matter jurisdiction over the parties pursuant to 28 U.S.C. §1332(a)(1) because the parties are citizens of different States and the amount in controversy exceeds the sum of $75,000.00, exclusive of interest and cost.

11. Venue is proper in this Court pursuant to 28 U.S.C. §1391(b)(2) by virtue of the facts that:

(a) a substantial part of the events or omissions giving rise to the claims occurred in this District and

(b) Defendants' products are produced, sold to, and consumed by individuals in the State of New Jersey, thereby subjecting Defendants to personal jurisdiction in this action and making them all "residents" of this judicial District.

12. Defendants have and continue to conduct substantial business in the State of New Jersey and in this District, distribute vascular access products in this District, receive substantial compensation and profits from sales of vascular access products in this District, and made material omissions and misrepresentations and breaches of warranties in this District, to subject them to *in personam* jurisdiction in this District.

13. 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 notices of fair and substantial justice.

14. This is a potential tag-along action and in accordance with 28 U.S.C. §1407, it should be transferred to the United States District Court for the District of Arizona for inclusion in *In re: Bard Implanted Port Catheter Products Liability Litigation,* MDL 3081, Case No. 2:23-md-03081-DGC (Hon. David G. Campbell).

PRODUCT BACKGROUND

15. The Bard PowerPort ClearVUE ISP Implantable Port is one of several varieties of port/catheter systems designed, manufactured, marketed, and sold by Defendants.

16. According to Defendants, the PowerPort is a totally implantable vascular access device designed to provide repeated access to the vascular system

for the delivery of medications, intravenous fluids, parenteral nutrition solutions, and blood products.

17. 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.

18. The PowerPort is a system consisting of two primary components: an injection port and a polyurethane catheter.

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

20. 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." *See PowerPort Implantable Port's Instructions For Use's Indications For Use*, at 1.

21. The injection port reservoir is constructed principally of Polyoxymethylene plastic, which is also known as Delrin.

22. When a metal needle is inserted into the port reservoir, it often makes contact with the plastic on the posterior surface of the inside of the reservoir, creating small holes, scratches and other damage to the plastic material.

23. The resulting defects in the surface of the reservoir plastic are especially hospitable to fibrinous blood products, the accumulation of which can result in the development of the PowerPort-related serious blood clots and the internal jugular vein thrombosis.

24. According to Defendants' marketing materials, the silicone catheter "has less propensity for surface biodegradation, making it more resistant to environmental stress cracking."

25. The silicone comprising the catheter in the PowerPort is a formulation called Chronoflex AL, which, upon information and belief, Defendants obtain from a biomaterials supplier called AdvanSource Biomaterials Corporation ("AdvanSource"), which is a division of Mitsubishi Chemical America, Inc.

26. Chronoflex AL is one of a large number of biomaterials manufactured by AdvanSource, many of which have mechanical properties superior to Chronoflex AL.

27. The Chronoflex catheter included in Defendants' PowerPort is comprised of a polymeric mixture of silicone and barium sulfate, a compound which is visible in certain radiologic studies.

28. Barium sulfate is known to contribute to reduction of the mechanical integrity of silicone *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/eroding the mechanical properties of the catheter.

29. The mechanical integrity of a barium sulfate-impregnated polyurethane is affected by the concentration of barium sulfate as well as the homogeneity of the modified polymer.

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

31. This improper mixing led to pockets of barium sulfate and entrapped air being distributed through the catheter body and on the inner and outer surfaces of same.

32. This defect in the manufacturing process led to a heterogeneous modified polymer, which led to an irregular catheter surface replete with fissures, pits, erosions, and cracks.

33. The roughened catheter surface leads to the collection of fibrinous blood products, the accumulation of which can result in the development of the

PowerPort-related serious blood clots and the internal jugular vein thrombosis in intended PowerPort's users.

34. Although the surface degradation/erosion and resulting substantial risk of the development of the PowerPort-related serious blood clots and the internal jugular vein thrombosis and other serious side effects can be reduced or avoided with design modifications to encapsulate the radiopaque compound or by using a different polymer formulation, Defendants elected not to incorporate those design elements into the PowerPort.

35. At all times relevant to this action, Defendants misrepresented the safety of the PowerPort system, and negligently designed, manufactured, prepared, compounded, assembled, processed, labeled, marketed, distributed, and sold the PowerPort system as 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.

36. At all times relevant to this action, Defendants knew or should have known, that the PowerPort devices were not safe for the patients for whom they were prescribed and implanted, because once implanted, the Device was prone to surface degradation/erosion and resulting development of serious blood clots and the internal jugular vein thrombosis in intended users, mechanical failure, and a variety of other complications.

37. At all times relevant to this action, Defendants knew or should have known that patients implanted with PowerPort systems had an increased risk of suffering serious and life-threatening injuries, including but not limited to:

a. death;

b. hemorrhage;

c. the internal jugular vein thrombosis;

d. thromboembolism;

e. serious infections which may lead to the development of sepsis in intended users;

f. cardiac arrhythmia;

g. severe and persistent pain;

h. perforations of tissue, vessels and organs, and/or the need for additional surgeries to remove the defective device.

38. Soon after the PowerPort was introduced to market, which was years before Plaintiff was implanted with her Device, Defendants began receiving large numbers of Adverse Event Reports ("AERs") from healthcare providers reporting that the PowerPort was precipitating the development of serious blood clots and the internal jugular vein thrombosis in intended users, post- implantation. These failures were often associated with reports of severe patient injuries such as:

a. cardiac/pericardial tamponade;

b. cardiac arrhythmia and other symptoms similar to myocardial infarction;

c. serious infections which may lead to the development of sepsis in intended users;

d. severe and persistent pain;

e. perforations of tissue, vessels and organs; and

f. death.

39. Defendants knew or should have known that the PowerPort had a substantially higher failure rate than other similar products on the market, yet Defendants failed to adequately warn healthcare providers and consumers of this fact.

40. Upon information and belief, Defendants also intentionally concealed the severity of complications caused by the PowerPort and the likelihood of these events occurring, including, but not limited to, the development of the PowertPort-related serious blood clots and the internal jugular vein thrombosis.

41. 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 concerning the PowerPort-related

development of blood clots and thrombosis, and other serious and life-threatening injuries.

42. Multiple feasible safer alternative designs for the PowerPort have been available to Defendants at all times relevant to this matter.

43. Those safer alternative design elements include but are not limited to:

a. Coating or encapsulation of the surfaces of the catheter with a polymer free of barium sulfate;

b. Utilizing a combination of radiopacity agents to reduce the overall volume of barium sulfate per unit of surface area; and

c. Constructing the port reservoir with a titanium backing.

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

a. Adequately warn prescribing physicians, including Plaintiff's healthcare providers, and the public, including Plaintiff, of these dangers;

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

c. Recall the PowerPort System from the market.

SPECIFIC FACTUAL ALLEGATIONS AS TO PLAINTIFF

45. Upon information and belief, on or about September 26, 2018, Plaintiff was implanted with a single lumen PowerPort, Model (Lot) # RECS0857, Ref. no. 5608062, via the right internal jugular vein, to have central IV access available for administration of chemotherapy for her colon carcinoma. This procedure took place by her surgeon at VUMC Northcrest in Springfield, Tennessee.

46. On or about March 4, 2019, Plaintiff presented to Surgical Alliance of Middle Tennessee in Springfield, Tennessee, due to pain and tenderness in her neck. During the visit, it was determined that Plaintiff's neck pain was due to blood clot and the thrombosis of the right internal jugular vein. After confirmation that the blood clot and the thrombosis of the right internal jugular vein were related to the previously implanted catheter, the catheter was removed by using a surgical procedure.

47. Due to the defective device, Plaintiff suffered damages and continues to suffer damages including, but not limited to, multiple hospital admissions, increased risk of future severe and permanent injuries, severe emotional distress, ongoing fear and anxiety from future injuries, including but not limited to, serious and life-threatening blood clots and the resulting internal jugular vein thrombosis, etc.

48. Defendants concealed—and continue to conceal—their knowledge of the PowerPort's unreasonably dangerous risks from Plaintiff, her physicians, and the public at large.

49. Numerous reports of the PowerPort catheter-related serious blood clots and the resulting thrombosis, including, but not limited to, the internal jugular vein thrombosis, which is a potentially life-threatening condition with a high mortality rate, especially so in the individuals with comorbidities similar to Plaintiff's comorbidities, were recorded and reported to Defendants prior to the implantation of the PowerPort into Plaintiff.

50. Defendants continued to actively and aggressively market the PowerPort as safe, despite knowledge of numerous reports of such injuries. Defendants utilized marketing communications, including the *Instruction For Use* ("IFU"), and direct communications from sales representatives to Plaintiff's healthcare providers to intentionally mislead her healthcare providers into believing these failures were caused by factors other than catheter design and composition.

51. Defendants did not adequately warn healthcare providers, including Plaintiff's physicians and general public, including Plaintiff, of the true quantitative or qualitative risk of serious blood clots and the internal jugular vein thrombosis, associated with the PowerPort.

52. Defendants did not adequately warn healthcare providers, including Plaintiff's physicians, and general public, including Plaintiff, that the risk of catheter-related serious blood clots and the internal jugular vein thrombosis increases with extended dwell time.

53. Defendants did not adequately warn healthcare providers, including Plaintiff's physicians, and general public, including Plaintiff, that the function and integrity of the PowerPort should be closely monitored when the Device is in place for a period of greater than one year.

54. Defendants did not adequately warn healthcare providers, including Plaintiff's physicians, and general public, including Plaintiff, that the patients implanted with the PowerPort should be monitored for serious and life-threatening blood clots and the internal jugular vein thrombosis when the Device is in place for longer than a year.

55. Defendants did not adequately communicate the extent or seriousness of the danger of the development of the PowerPort-related serious blood clots and the internal jugular vein thrombosis to healthcare providers, including Plaintiff's physicians, and general public, including Plaintiff.

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

57. Plaintiff's physicians relied upon the representations, including the IFU, distributed with the product implanted into Plaintiff, and advertisements, to Plaintiff's detriment.

58. The Defendants knowingly, intentionally, and maliciously concealed the dangerous propensity of this Device to precipitate the development of serious blood clots and the internal jugular vein thrombosis. Defendants further concealed their knowledge that these failures were caused by the catheter design and composition, and that the failures were known to be causing serious injuries, including the PowerPort-related serious blood clots and the internal jugular vein thrombosis.

59. As a result of the failure of the Defendants' PowerPort and Defendants' wrongful conduct in designing, manufacturing, and marketing this defective product, Plaintiff and Plaintiff's physicians were unaware, and could not have reasonably known or have learned through reasonable diligence, that Plaintiff was exposed to the unreasonable risks identified in this Complaint, and those risks were the direct and proximate result of the Defendants' acts, omissions, and misrepresentations.

60. Upon information and belief, Defendants failed to conduct adequate and sufficient post- marketing surveillance after they began marketing, advertising, distributing, and selling the PowerPort.

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

COUNT I – NEGLIGENCE ALL DEFENDANTS

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

63. Plaintiff brings this Count against Defendants BD, Bard, and BAS.

64. Defendants owed Plaintiff a duty to exercise reasonable care when designing, manufacturing, marketing, advertising, distributing, selling, and conducting post-market surveillance of the PowerPort.

65. 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, which would help to minimize or to avoid the risk of the PowerPort-related serious blood clots and the internal jugular vein thrombosis;

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 adequate warnings 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;

f. Negligently continuing to manufacture, market, advertise, and distribute the PowerPort after Defendants knew or should have known of its serious and life-threatening adverse effects, including, but not limited to, the PowerPort-related serious blood clots and the internal jugular vein thrombosis.

66. As a direct and proximate result of the Defendants' actions, omissions and misrepresentations, Plaintiff has suffered, and will continue to suffer, severe physical pain and injuries which are permanent and lasting in nature, emotional distress, loss of the capacity for the enjoyment of life, medical expenses, and

economic loss as alleged herein. These damages have occurred in the past and will continue into the future.

67. In performing the foregoing acts, omissions, and misrepresentations, Defendants acted grossly negligent, fraudulently, and with malice so as to justify an award of punitive damages which under the New Jersey Punitive Damages Act, are defined as "exemplary damages."

COUNT II – STRICT PRODUCTS LIABILITY FAILURE TO WARN ALL DEFENDANTS

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

69. Plaintiff brings this Count against Defendants BD, Bard, and BAS.

70. Defendants designed, set specifications, manufactured, prepared, compounded, assembled, processed, marketed, labeled, distributed, and sold the PowerPort, including the one implanted into Plaintiff, into the stream of commerce and in the course of same, directly advertised and marketed the Device to consumers and persons responsible for consumers, i.e., physicians, and therefore had a duty to warn of the risk of harm associated with the use of the Device and to provide adequate warnings on the safe and proper use of the Device.

71. At the time Defendants designed, manufactured, prepared, compounded, assembled, processed, marketed, labeled, distributed, and sold the Device into the stream of commerce, the Device was defective and presented a substantial danger 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, etc. Defendants failed to adequately warn of the Device's known or reasonably scientifically knowable dangerous propensities, and further failed to adequately provide warnings on the safe and proper use of the Device.

72. 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 serious and life-threatening injuries, including, the development of the PowerPort-related serious blood clots and the internal jugular vein thrombosis.

73. Defendants further knew that these devices raised the risk of the development of the PowerPort-related serious blood clots and the internal jugular vein thrombosis by virtue of the catheter design and composition.

74. As a result, the devices were unreasonably dangerous when put to a reasonably anticipated use in that the devices were dangerous to an extent beyond that which would be contemplated by the ordinary consumer who purchased the Device or otherwise acquired the said Device from the healthcare providers like Plaintiff did in this case.

75. Defendants failed to timely and adequately warn healthcare providers, including Plaintiff's, and the general public, including Plaintiff, of material facts regarding the safety and efficacy of the PowerPort; no reasonable healthcare

provider, including Plaintiff's, or patient, including Plaintiff, would have used the Device in the manner directed, had those facts been made known to the prescribing healthcare providers, including Plaintiff's, or the consumers of the Device, including Plaintiff.

76. No reasonable healthcare provider, including Plaintiff's, would have used the Device in the manner directed, had those facts been made known to the prescribing healthcare providers.

77. Had the Defendants provided adequate warnings of the risks attendant to the PowerPort enumerated herein, Plaintiff would not have consented to be implanted with the product.

78. The warnings, precautions, labels, and instructions provided by Defendants at all times relevant to this action, are and were inaccurate, intentionally misleading, and misinformed, and misrepresented the risks and benefits, and lack of safety and efficacy associated with the Device.

79. The health risks associated with the Device, as described herein, are of such a nature that ordinary consumers, including Plaintiff, would not have readily recognized the potential harm and its real magnitude.

80. The Device, which was designed, manufactured, prepared, compounded, assembled, processed, marketed, labeled, distributed, and sold into the stream of commerce by Defendants, was defective at the time of release into the

stream of commerce due to inadequate warnings, precautions, labeling and/or instructions accompanying the product.

81. When Plaintiff was implanted with the Device, Defendants failed to provide adequate warnings, precautions, instructions, or labels regarding the severity and extent of health risks posed by the Device, as discussed herein.

82. Defendants intentionally underreported the number and nature of adverse events to Plaintiff's healthcare providers, as well as the FDA, including, but not limited to the number of cases of the PowerPort-related serious blood clots and internal jugular vein thrombosis.

83. Neither Plaintiff nor her healthcare providers knew of the substantial danger and serious and life-threatening risks associated with the intended and foreseeable use of the Device as described herein.

84. Plaintiff and her healthcare providers used PowerPort in a normal, customary, intended, and foreseeable manner, namely as a surgically placed device used to make it easier to deliver medications, etc. directly into the patient's bloodstream. Moreover, Plaintiff's healthcare providers did not place or maintain the Device incorrectly such that it increased the risk of malfunction and/or the substantial risk of the development of the PowerPort-related serious blood clots and the internal jugular vein thrombosis.

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

86. Defendants' lack of adequate warnings was the direct and proximate cause of Plaintiff's serious physical injuries, and economic damages in an amount to be determined at trial. In other words, had Defendants provided adequate warnings, Plaintiff and her physicians would not have used the Device.

COUNT III – STRICT PRODUCTS LIABILITY MANUFACTURING DEFECT ALL DEFENDANTS

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

88. Plaintiff brings this Count against Defendants BD, Bard, and BAS.

89. Defendants designed, set specifications, manufactured, prepared, compounded, assembled, processed, marketed, labeled, distributed, and sold the PowerPort that was implanted into Plaintiff.

90. The PowerPort implanted into Plaintiff contained a manufacturing defect when it left Defendants' possession. The Device differed from Defendants' intended result and/or from other ostensibly identical units of the same product line.

91. Upon information and belief, the PowerPort implanted into Plaintiff varied from its intended specifications.

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

93. The Device's manufacturing defect was the direct and proximate cause of Plaintiff's serious physical injuries and economic damages in an amount to be determined at trial.

COUNT IV – STRICT PRODUCTS LIABILITY – DESIGN DEFECT ALL DEFENDANTS

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

95. Plaintiff brings this Count against Defendants BD, Bard, and BAS.

96. The PowerPort implanted into the Plaintiff was not reasonably safe for its intended use and was defective with respect to its design.

97. The PowerPort was in a defective condition at the time that it left the possession or control of Defendants.

98. The PowerPort was unreasonably dangerous to the user or consumer.

99. The PowerPort was expected to and did reach the consumer, i.e., Plaintiff, without substantial change in its condition.

100. Defendants are strictly liable to Plaintiff for designing, manufacturing, marketing, labeling, packaging, and selling a defective product.

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

COUNT V – BREACH OF IMPLIED WARRANTY
ALL DEFENDANTS

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

103. Plaintiff brings this Count against Defendants BD, Bard, and BAS.

104. Defendants impliedly warranted that the PowerPort was merchantable and fit for the ordinary purposes for which it was intended.

105. When the PowerPort was implanted into Plaintiff, it was being used for the ordinary purposes for which it was intended.

106. Plaintiff, individually and/or by and through her physicians, relied upon Defendants' implied warranties of merchantability in consenting to have the PowerPort implanted in her.

107. Defendants breached these implied warranties of merchantability because the PowerPort implanted into Plaintiff was neither merchantable nor suited

for its intended uses as warranted in that the Device varied from its intended specifications in, but not limited to, the following ways:

a. Defendants' manufacturing process in constructing the Chronoflex Catheter implanted into Plaintiff involved too high a concentration of barium sulfate particles, leading to improperly high viscosity of the raw polyurethane before polymerization and causing improper mixing of barium sulfate particles within the polymer matrix;

b. This improper mixing led to pockets of barium sulfate and entrapped air being distributed through the catheter body and on the surface.

c. This defect in the manufacturing process led to a heterogeneous modified polymer which included weakened areas at the loci of higher barium sulfate concentration and led to surface degradation/erosion which, in this case, created an environment that caused the development of the PowertPort-related serious blood clots and the internal jugular vein thrombosis.

108. Defendants' breaches of their implied warranties resulted in the implantation of unreasonably dangerous and defective PowerPort into the Plaintiff's body, placing Plaintiff's health and safety in jeopardy.

109. At all relevant times, Plaintiff and Defendants were in a direct buyer-seller relationship, and Plaintiff was in privity of contract with Defendants: Plaintiff's healthcare providers/physicians acted as Plaintiff's purchasing agents to assist Plaintiff in the transaction in question, to purchase or to otherwise obtain the Device for Plaintiff's personal use.

110. As a direct and proximate result of Defendants' breaches of the aforementioned implied warranties, Plaintiff was caused and/or in the future will be caused to suffer severe personal injuries, pain and suffering, severe emotional distress, financial or economic loss, including, but not limited to, obligations for medical services and expenses, and other damages.

111. Upon information and belief, Plaintiff's healthcare providers sent notice to Defendants of the adverse event and thus, the nonconformity of the Device at issue, within a reasonable time following discovery of the breach of warranty, and before suit was filed.

COUNT VI – BREACH OF EXPRESS WARRANTY ALL DEFENDANTS

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

113. Plaintiff brings this Count against Defendants BD, Bard, and BAS

114. Defendants through their officers, directors, agents, representatives, and written literature and packaging, and written and media advertisement, expressly warranted to Plaintiff's healthcare providers and/or to the general public, including

Plaintiff, that the PowerPort was safe and fit for use by consumers, was of merchantable quality, did not produce dangerous side effects, and was adequately tested and fit for its intended use.

115. The PowerPort does not conform to the Defendants' express representations because it is not reasonably safe, has numerous serious and life-threatening side effects, and causes severe and permanent injuries.

116. At all times relevant to this action, the PowerPort did not perform as safely as an ordinary consumer would expect, when used as intended or in a reasonably foreseeable manner.

117. Plaintiff, her physicians, and the medical community reasonably relied upon the Defendants' express warranties for the PowerPort.

118. At all times relevant to this action, the PowerPort was used on Plaintiff by Plaintiff's physicians for the purpose and in the manner intended by Defendants.

119. Plaintiff and Plaintiff's physicians, by the use of reasonable care, could not have discovered the breached warranty and realized its danger.

120. As a direct and proximate result of the breach of Defendants' express warranties, Plaintiff has suffered, and will continue to suffer, severe physical pain and injuries which are permanent and lasting in nature, emotional distress, loss of the capacity for the enjoyment of life, medical and nursing expenses, surgical

expenses, and economic loss as alleged herein. These damages have occurred in the past and will continue into the future.

121. Upon information and belief, Plaintiff's healthcare providers sent notice to Defendants of the adverse event and thus, the nonconformity of the Device at issue, within a reasonable time following discovery of the breach of warranty, and before suit was filed.

COUNT VII – FRAUDULENT CONCEALMENT ALL DEFENDANTS

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

123. Plaintiff brings this Count against Defendants BD, Bard, and BAS.

124. Beginning from the time Defendants introduced the devices to the marketplace and continuing to present, Defendants fraudulently concealed information with respect to the PowerPort in the following particulars:

a. Defendants represented through the labeling, advertising, marketing materials, seminar presentations, publications, notice letters, and regulatory submissions that the PowerPort was safe and fraudulently withheld and concealed information about the substantial risks of using the PowerPort;

b. Defendants represented that the PowerPort was safer than other alternative systems and fraudulently concealed

information which demonstrated that the PowerPort was not safer and/or less safe than alternatives available on the market;

c. Defendants concealed that they knew these devices were known to substantially increase the risk of the development of the PowerPort-related serious blood clots and the internal jugular vein thrombosis, and

d. That frequency of these failures and the severity of the catheter-related injuries were substantially worse than had been reported.

125. Defendants had sole access to material facts concerning the dangers and unreasonable risks of the PowerPort.

126. The concealment of information by Defendants about the risks of and serious and life-threatening adverse events associated with the PowerPort was intentional, and the representations made by Defendants were known by Defendants to be false.

127. The concealment of information and the misrepresentations about the PowerPort was made by Defendants with the intent that Plaintiff's healthcare providers and Plaintiff rely upon them.

128. Plaintiff and her physicians relied upon the representations and were unaware of the substantial risks of and serious and life-threatening adverse events

associated with the PowerPort which Defendants concealed from healthcare providers, including Plaintiff's, and from the public, including Plaintiff.

129. As a direct and proximate result of the Defendants' actions, omissions and misrepresentations, Plaintiff has suffered, and will continue to suffer, severe physical pain and injuries which are permanent and lasting in nature, emotional distress, loss of the capacity for the enjoyment of life, medical and nursing expenses, surgical expenses, and economic loss as alleged herein. These damages have occurred in the past and will continue into the future.

130. Defendants acted with oppression, fraud, and malice towards Plaintiff, who accordingly requests that the trier of fact, in the exercise of its sound discretion, awards additional damages for the sake of example and for the purpose of punishing Defendants for their conduct,

in an amount sufficiently large to be an example to others, and to deter these Defendants and others from engaging in similar conduct in the future.

131. Had Defendants not concealed this information, neither Plaintiff's nor her health care providers would have consented to implant the Device into Plaintiff.

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

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

133. Plaintiff brings this Count against Defendants BD, Bard, and BAS.

134. The New Jersey Consumer Fraud Act, N.J.S.A 56:8-1 *et seq*. protects consumers from unfair and/or fraudulent business practices, which are unlawful, for example, under N.J.S.A. 56:8-2.

135. 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. *See generally*, N.J.S.A. § 56:8 1, *et seq*.

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

137. Plaintiff, who was in privity of contract with Defendants, purchased the PowerPort, a product that was falsely represented, as clarified above, in violation of the New Jersey Consumer Fraud Act, from Defendants, for her personal use, using her healthcare providers/physicians as purchasing agents, and as a result, Plaintiff suffered economic damages in that the product she purchased was worth less than the product she thought she had purchased had Defendants' representations been true.

PUNITIVE DAMAGES

138. Plaintiff is entitled to an award of punitive damages which under the New Jersey Punitive Damages Act are defined as "exemplary damages" based upon

Defendants' intentional, willful, knowing, fraudulent, malicious acts, omissions, and conduct, and their complete and total reckless disregard for the public safety and welfare, including that of Plaintiff. 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, including the substantial risk of the development of the PowerPort-related serious blood clots and the internal jugular vein thrombosis, and intentionally downplayed the type, nature, and extent of the said serious adverse effects, and other serious and life-threatening adverse effects in individuals being implanted with the Device, despite Defendants' knowledge and awareness of the serious and permanent side effects and risks associated with use of same. Defendants further intentionally sought to mislead healthcare providers and patients, including Plaintiff and her health care providers, regarding the causes of the PowerPort-related serious blood clots and the internal jugular vein thrombosis.

139. Defendants had knowledge of, and were in possession of evidence demonstrating that, the PowerPort caused serious and life-threatening side effects. Defendants continued to market the PowerPort 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 adequate warnings to the healthcare community and to the general public which would have dissuaded physicians from prescribing and 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.

140. As a direct, proximate, and legal result 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.

WHEREFORE, Plaintiffs demands judgment against Defendants for compensatory, special, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems just and proper.

PRAYER

WHEREFORE, Plaintiff prays for judgment against each of the Defendants, individually, jointly, and severally, on all causes of action of this Complaint and requests as follows:

a. Judgement be entered against all Defendants on all causes of action of this Complaint;

b. Plaintiff be awarded her full, fair, and complete recovery for all claims and causes of action relevant to this action;

c. Plaintiff be awarded general damages according to proof at the time of trial;

d. Plaintiff be awarded compensatory damages, including, but not limited to, past, present, and future medical expenses, pain and suffering, mental anguish, impairment, lost wages, lost earning capacity, loss of household services together with interest and costs provided by law, according to proof at the time of trial;

e. Plaintiff be awarded punitive damages according to proof at the time of trial;

f. Plaintiff be awarded costs and attorney's fees in connection with the New Jersey Consumer Fraud Act;

g. Awarding pre-judgment and post-judgment interest to Plaintiff;

h. Awarding the costs and the expenses of this litigation to Plaintiff; and

i. For such other and further relief as the Court may deem just and proper.

DEMAND FOR JURY TRIAL

Plaintiff hereby demands trial by jury on all issues.

Dated: August 28, 2023

Respectfully submitted,

/s/ Dena R. Young

Dena R. Young
NJ Bar No. 033022010
BERGER MONTAGUE PC
1818 Market Street, Suite 3600
Philadelphia, PA 19103
Telephone: (215) 875-3000
Facsimile: (215) 875-4620
dyoung@bm.net

Max Yefimenko CO Bar # 34796
(To be admitted Pro Hac Vice)
Roman Balaban CO Bar # 39148
(To be admitted Pro Hac Vice)
BALABAN LAW LLC
8055 East Tufts Avenue, Suite 325
Denver, CO 80237
Yefimenko@denverfirm.com
Balaban@denverfirm.com

ATTORNEYS FOR PLAINTIFF

CERTIFICATE OF SERVICE

I hereby certify that on this 28th day of August, 2023, I electronically transmitted the foregoing document to the Clerk's office using the CM/ECF System for filing and transmittal of a Notice of Electronic Filing on all counsel of record.

/s/ Dena R. Young
Dena R. Young