IN THE UNITED STATES DISTRICT COURT DISTRICT OF NEW JERSEY

MARY NELK,

VS.

Plaintiff,

Case No. 23-cv-1173

BECTON, DICKINSON AND COMPANY; C.R. BARD, INC.; BARD ACCESS SYSTEMS, INC., and DOES 1 through 10,

Defendants.

COMPLAINT

COMES NOW, Plaintiff, Mary Nelk, by and through Balaban Law LLC and for her Complaint against Becton, Dickinson & Company, C.R. Bard, Inc.; Bard Access Systems, Inc.; and DOES 1 through 10 (collectively, the "Defendants") states:

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 Implantable Port (hereinafter "PowerPort" or "Defective Device").

2. Plaintiff, Mary Nelk, is an adult citizen of Blue Springs, Missouri, 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. BD is one of the largest global medical technology companies in the world with diverse business units offering products in various healthcare subfields. 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. 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. Bard is a citizen of New Jersey. Bard conducts business throughout the United States, including the State of Missouri, and is a wholly owned subsidiary of BD. Bard, as an agent of 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. 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. Following the acquisition, Bard's Board of Directors dissolved, with some former Bard directors joining 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. BAS is a citizen of Utah. BAS conducts business throughout the United States, including the State of New Jersey, and is a wholly owned subsidiary of BD. 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. 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.

7. BD's control over 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 BD of various legal duties as described herein are the proximate cause of the injuries described herein.

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

Plaintiff is ignorant of the true names and capacities of defendants sued herein as
 DOES 1 through 10, inclusive, and therefore sues these defendants by such fictitious names.
 Plaintiff will amend this complaint to allege their true names and capacities when ascertained.

JURISDICTION AND VENUE

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

12. Venue is proper in this Court pursuant to 28 U.S.C. §1391 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 Missouri, thereby subjecting Defendants to personal jurisdiction in this action and making them all "residents" of this judicial District.

13. Defendants have and continue to conduct substantial business in the State of Missouri 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, so as to subject them to *in personam* jurisdiction in this District.

14. 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.

PRODUCT BACKGROUND

15. The Bard PowerPort ClearVue Implantable Port ("PowerPort") 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 medication, 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 the medication. 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."

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

22. The polyurethane comprising the catheter in the PowerPort is a formulation called Chronoflex AL, which Defendants obtain from a biomaterials supplier called AdvanSource Biomaterials Corporation (AdvanSource), which is a division of Mitsubishi Chemical America, Inc.

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

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

25. Barium sulfate is known to contribute to reduction of the mechanical integrity of polyurethane *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 the catheter.

26. 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.

27. Upon information and belief, Defendants' manufacturing process in constructing the Chronoflex Catheter implanted in 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.

28. 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.

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

30. The roughened catheter surface leads to the collection and proliferation of fibrinous blood products, thereby drastically increasing the risk of thromboembolism.

31. Although the surface degradation and resulting risk of thromboembolism 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.

32. At all times relevant, 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.

33. At all times relevant to this action, 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 surface degradation and resulting thromboembolism, infection, mechanical failure, and a variety of other complications.

34. At all times relevant to this action, Defendants knew and had reason to know that patients implanted with PowerPort systems had an increased 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.

35. 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 health care providers reporting that the PowerPort was precipitating thromboembolism post-implantation. Defendants also received large numbers of AERs reporting that PowerPort was found to have perforated internal vasculature. These failures were often associated with reports of severe 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;

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

f. upon information and belief, even death.

36. 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 of this fact.

37. Upon information and belief, Defendants also intentionally concealed the severity of complications caused by the PowerPort and the likelihood of these events occurring.

38. 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 thromboembolism and other serious injuries.

39. 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 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.

SPECIFIC FACTUAL ALLEGATIONS AS TO PLAINTIFF

40. On or about February 17, 2021, Plaintiff was implanted with a single lumen Bard PowerPort via right internal jugular vein, for administration of nutrients for treatment of her Crohn's Disease. This procedure took place at OSF Sacred Heart Medical Center in Danville, Illinois, and was performed by Dr. William J. Bowen, M.D.

41. On or about February 28, 2021, Plaintiff presented to OSF Sacred Heart Medical Center with complaints of issues with her port leading to a hematoma, arm pain, and a high fever. An X-Ray was performed and labs were ordered, with findings concerning a potential bloodstream infection. Lab tests were performed, confirming a bloodstream infection, and she was admitted to the hospital on March 3, 2021.

42. On or about March 4, 2021, IV fluid therapy was performed, noting that the port was accessed that day before and did not function.

43. Due to the defective device, Plaintiff suffered damages and continues to suffer damages including, but not limited to, multiple hospital admissions related to infections, increased risk of future severe and permanent injuries, severe emotional distress, ongoing fear and anxiety from future injuries, including but not limited to, bloodstream infections.

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

45. Numerous reports of PowerPort catheter-related thromboembolism in the absence

of medical provider error were recorded and reported to Defendants prior to the implantation of the PowerPort in Plaintiff.

46. 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 health care providers to intentionally mislead her health care providers into believing these failures were caused by factors other than catheter design and composition.

47. Defendants did not adequately warn Plaintiff or Plaintiff's physicians of the true quantitative or qualitative risk of thromboembolism associated with the PowerPort.

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

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

50. The Defendants knowingly concealed the dangerous propensity of this device to precipitate thromboembolism. Defendants further concealed their knowledge that these failures were caused by the catheter design, and that the failures were known to be causing serious injuries.

51. 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 physician were unaware, and could not have reasonably known or have learned through reasonable diligence, Plaintiff was exposed to the risks identified in this Complaint, and those risks were the direct and proximate result of the Defendants' acts, omissions and misrepresentations.

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

53. 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.

<u>COUNT I – NEGLIGENCE</u> <u>ALL DEFENDANTS</u>

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

55. Plaintiff brings this count against Defendants BD, Bard, BAS, and Does 1 through10, inclusive.

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

57. 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 premarket 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

f. Negligently continuing to manufacture, market, advertise, and distribute the PowerPort after Defendants knew or should have known of its adverse effects.

58. 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.

59. 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.

<u>COUNT II – STRICT PRODUCTS LIABILITY FAILURE TO WARN</u> <u>ALL DEFENDANTS</u>

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

61. Plaintiff brings this count against Defendants BD, Bard, BAS, and Does 1 through10, inclusive.

62. 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 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.

63. 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. Defendants 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.

64. 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 injuries.

65. Defendants further knew that these devices raised the risk of thromboembolism by virtue of the catheter design and composition.

66. Defendants failed to timely and reasonably warn of material facts regarding the safety and efficacy of the PowerPort; no reasonable health care 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.

67. The warnings, labels, and instructions provided by the Defendants at all time 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.

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

69. 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, labeling and/or instructions accompanying the product.

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

71. Defendants intentionally underreported the number and nature of adverse events to Plaintiff's health care providers, as well as the FDA.

72. Neither Plaintiff nor her health care providers knew of the substantial danger associated with the intended and foreseeable use of the device as described herein.

73. Plaintiff and her health care 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 directly into the patient's bloodstream. Moreover, Plaintiff's health care providers did not place or maintain the device incorrectly such that it increased the risk of malfunction.

74. 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, 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 in Plaintiff was in the same condition as when it was manufactured, inspected, marketed, labeled, promoted, distributed and sold by Defendants.

75. 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. In other words, had Defendants provided adequate warnings, Plaintiff and her physicians would not have used the device.

<u>COUNT III – STRICT PRODUCTS LIABILITY</u> <u>MANUFACTURING DEFECT – ALL DEFEDNANTS</u>

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

Plaintiff brings this count against Defendants BD, Bard, BAS, and Does 1 through10, inclusive.

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

79. The PowerPort implanted in Plaintiff contained a manufacturing defect when it left Defendants' possession. The device differed from said Defendants' intended result and/or from other ostensibly identical unites of the same product line.

80. Upon information and belief, the PowerPort implanted in Plaintiff varied from its intended specifications.

81. Plaintiff and her health care providers used the PowerPort in a way that was reasonably foreseeable to Defendants.

82. 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.

<u>COUNT IV – STRICT PRODUCTS LIABILITY – DESIGN DEFECT</u> <u>ALL DEFENDANTS</u>

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

84. Plaintiff brings this count against Defendants BD, Bard, BAS, and Does 1 through10, inclusive.

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

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

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

88. The PowerPort was expected to and did reach the consumer without substantial change in its condition.

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

90. As a direct and proximate result of the PowerPort's aforementioned defects, the 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.

<u>COUNT V – BREACH OF IMPLIED WARRANTY</u> <u>ALL DEFENDANTS</u>

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

92. Plaintiff brings this count against Defendants BD, Bard, BAS, and Does 1 through10, inclusive.

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

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

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

in her.

96. Defendants breached these implied warranties of merchantability because the PowerPort implanted in the Plaintiff was neither merchantable nor suited for its intended uses as warranted.

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

98. The PowerPort was sold to the Plaintiff's health care providers for implantation in patients, such as the Plaintiff.

99. As a direct and proximate result of Defendants' breaches of the aforementioned implied warranties, the 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.

<u>COUNT VI – BREACH OF EXPRESS WARRANTY</u> <u>ALL DEFENDANTS</u>

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

101. Plaintiff brings this count against Defendants BD, Bard, BAS, and Does 1 through10, inclusive.

102. Defendants through their officers, directors, agents, representatives, and written literature and packaging, and written and media advertisement, expressly warranted 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.

103. The PowerPort does not conform to the Defendants' express representations because it is not reasonably safe, has numerous serious side effects, and causes severe and

permanent injury.

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

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

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

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

108. 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.

<u>COUNT VII – FRAUDULENT CONCEALMENT</u> <u>ALL DEFENDANTS</u>

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

110. Plaintiff brings this count against Defendants BD, Bard, BAS, and Does 1 through10, inclusive.

112. 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 than alternatives available on the market;

c. Defendants concealed that it knew these devices were fracturing and migrating from causes other than the manner in which the implanting physician implanted the device; and

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

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

114. The concealment of information by Defendants about the risks of the PowerPort was intentional, and the representations made by Defendants were known by Defendants to be false.

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

116. Plaintiff and her physicians relied upon the representations and were unaware of the substantial risks of the PowerPort which the Defendants concealed from the public, including Plaintiff and her physicians.

117. 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.

118. The Defendants acted with oppression, fraud, and malice towards Plaintiff, who accordingly requests that the trier of fact, in the exercise of its sound discretion, award 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 this Defendants and others from engaging in similar conduct in the future.

119. Had Defendants not concealed this information, neither Plaintiff's nor her health care providers would have consented to using the device in Plaintiff.

<u>COUNT VIII – VIOLATION OF THE MISSOURI MERCHANDISING</u> <u>PRACTICES ACT – ALL DEFENDANTS</u>

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

121. Plaintiff brings this count against Defendants BD, Bard, BAS, and Does 1 through10, inclusive.

122. The acts and practices engaged in by Defendants constitute unlawful, unfair and/or fraudulent business practices in violation of the Missouri Merchandising Practices Act, R.S.Mo. § 407.010 *et seq.*

123. 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 R.S.Mo. § 407.020.

124. Plaintiff purchased the PowerPort, a product that was falsely represented, as set out above, in violation of the Missouri Merchandising Practices Act 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.

<u>COUNT VIII – VIOLATION OF THE NEW JEREY CONSUMER FRAUD ACT</u> <u>ALL DEFENDANTS</u>

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

126. Plaintiff brings this count against Defendants BD, Bard, BAS, and Does 1 through10, inclusive.

127. 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.*

128. 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 N.J.S.A. § 56:8-2 *et. seq.*

129. 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 she purchased was worth less than the product she thought she had purchased had Defendants' representations been true.

PUNITIVE DAMAGES

130. Plaintiffs are entitled to an award of punitive and 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. Defendants intentionally and fraudulently misrepresented facts and information to both the healthcare community and the general public, including Plaintiff and her health care 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. Defendants further intentionally sought to mislead health care providers and patients, including Plaintiff and her health care providers, regarding the cause of dislodgement and migration failures of the device.

131. 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.

132. As a direct, proximate, and legal result of Defendants' acts and omissions a 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 as follows:

- Judgement be entered against all Defendant 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 damages, including past, present, and future, medical expenses according to proof at the time of trial;
- e. Plaintiff be awarded punitive damages according to proof at the time of trial;
- f. Awarding pre-judgment and post-judgment interest to the Plaintiff;
- g. Awarding the costs and the expenses of this litigation to the Plaintiff.
- h. 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.

DICKERSON OXTON, LLC

By: /s/ Adam M. Evans Adam M. Evans 1200 Main St., Ste. 2120 Kansas City, MO 64105 Phone: 816-268-1960 Fax: 816-268-1965 aevans@dickersonoxton.com

BALABAN LAW LLC

/s/ <u>Roman Balaban Roman</u> Balaban (CO 39148) <u>/s/ Olga Steinreich</u> Olga Steinreich (CO 48200)

/s/ Sarah A. Wolter

Sarah A. Wolter (CO 47599) 8055 E Tufts Avenue, Suite 325 Denver, CO 80237 T: (303) 377-3474 F: (303) 377-3576 balaban@denverfirm.com steinreich@denverfirm.com wolter@denverfirm.com

JS 44 (Rev. 04/2) ase 2:23-cv-01173-SDW-MAC Decret Still 92/28/23 Page 1 of 2 PageID: 24

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. *(SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)*

purpose of initiating the civil do		CHONS ON NEXT PAGE O	F THIS FOL	/	TO					
I. (a) PLAINTIFFS Mary Nelk				DEFENDANTS Becton Dickinson and Company C.R. Bard Bard Access Systems, and Does 1 through 10.						
(b) County of Residence of First Listed Plaintiff Vermilion County, Illinois				County of Residence of First Listed Defen				Bergen County, New Jersey		
(EXCEPT IN U.S. PLAINTIFF CASES)				(IN U.S. PLAINTIFF CASES ONLY)						versey
x		,		NOTE: IN LANI	D COND	EMNATIO	ON CASES, USE TH	E LOCATION	OF	
				THE TRA	ACT OF	LAND IN	VOLVED.			
(c) Attorneys (Firm Name, Address, and Telephone Number)				Attorneys (If Kno	wn)					
Dickerson Oxton	120									
1200 Main St., Suite 2 Kanaga City, MO 6410										
Kansas City, MO 6410 816-268-1960	03									
II. BASIS OF JURISD	ICTION (Place an "X" in	One Box Only)	III. CIT	IZENSHIP OF	F PRI	NCIPA	L PARTIES	Place an "X" in	One Box fi	or Plaintiff
				For Diversity Cases Or				nd One Box for		
1 U.S. Government					PTF	DEF			PTF	DEF
Plaintiff	(U.S. Government Not a Party)			n of This State	1	X 1	Incorporated or Pri of Business In T		4	X 4
							of Busiliess III 1	ins State		
2 U.S. Government	X 4 Diversity			n of Another State	X 2	2	Incorporated and P		5	5 🗹
Defendant	(Indicate Citizenship of Parties in Item III)						of Business In A	nother State		
			Citizen	n or Subject of a	3	3	Foreign Nation		6	6
			Fore	eign Country						
IV. NATURE OF SUIT		Click here for: <u>Nature of Suit Code Descriptions</u> .								
CONTRACT TORTS			FORFEITURE/PENALTY			BAN	KRUPTCY	OTHER STATUTES		
110 Insurance	PERSONAL INJURY			Drug Related Seizure		422 Appeal 28 USC 158 423 Withdrawal		375 False Claims Act		
120 Marine 130 Miller Act	310 Airplane 315 Airplane Product	X 365 Personal Injury - Product Liability	690	of Property 21 USC 8 Other		-	idrawal JSC 157	376 Qui Ta 3729(am (31 US(С
140 Negotiable Instrument	Liability	367 Health Care/					LLECTUAL	`	a)) Reapportion	nment
150 Recovery of Overpayment	320 Assault, Libel &	Pharmaceutical				PROPERTY RIGHTS		410 Antitrust		
& Enforcement of Judgment		Personal Injury				820 Copyrights		430 Banks and Banking		
151 Medicare Act 152 Recovery of Defaulted	330 Federal Employers' Liability	Product Liability 368 Asbestos Personal				830 Patent 835 Patent - Abbreviated		450 Commerce 460 Deportation		
Student Loans	340 Marine	Injury Product				New Drug Application		470 Racketeer Influenced and		
(Excludes Veterans)	345 Marine Product	Liability				840 Trademark		Corrupt Organizations		
153 Recovery of Overpayment of Veteran's Benefits	Liability 350 Motor Vehicle	PERSONAL PROPERT	Y LABOR 710 Fair Labor Standards			880 Defend Trade Secrets		480 Consumer Credit (15 USC 1681 or 1692)		
160 Stockholders' Suits	355 Motor Vehicle	371 Truth in Lending		Act		Act of 2016		485 Telephone Consumer		
190 Other Contract	Product Liability	380 Other Personal	720	720 Labor/Management		SOCIAL SECURITY Protection				
195 Contract Product Liability	360 Other Personal	Property Damage		Relations		861 HIA (1395ff)		490 Cable/Sat TV		
196 Franchise	Injury 362 Personal Injury -	385 Property Damage Product Liability		740 Railway Labor Act 751 Family and Medical		862 Black Lung (923) 863 DIWC/DIWW (405(g))		850 Securities/Commodities/ Exchange		iodities/
	Medical Malpractice	I foduct Elability		Leave Act			D Title XVI		Statutory A	Actions
REAL PROPERTY	CIVIL RIGHTS	PRISONER PETITION		Other Labor Litigation		865 RSI	(405(g))	- v	ultural Acts	
210 Land Condemnation	440 Other Civil Rights	Habeas Corpus:	791	Employee Retirement					onmental M	
220 Foreclosure 230 Rent Lease & Ejectment	441 Voting 442 Employment	463 Alien Detainee 510 Motions to Vacate		Income Security Act	_		AL TAX SUITS es (U.S. Plaintiff	895 Freedo	om of Infor	mation
240 Torts to Land	442 Employment 443 Housing/	Sentence					Defendant)	896 Arbitr	ation	
245 Tort Product Liability	Accommodations	530 General				1	—Third Party	899 Admin	nistrative P	rocedure
290 All Other Real Property	445 Amer. w/Disabilities -			IMMIGRATION		26	USC 7609		eview or Aj	
	Employment 446 Amer. w/Disabilities -	Employment Other: 446 Amer. w/Disabilities - 540 Mandamus & Oth		462 Naturalization Application 465 Other Immigration				Agency Decision 950 Constitutionality of		
	Other	550 Civil Rights	- P	Actions					Statutes	
	448 Education	555 Prison Condition								
		560 Civil Detainee - Conditions of								
		Confinement								
V. ORIGIN (Place an "X" in	n One Box Only)									
		Remanded from	4 Reinst		nsferred		6 Multidistri		Multidis	
Proceeding Sta	te Court	Appellate Court	Reope		other D	istrict	Litigation - Transfer	-	Litigatio	
	Cite the U.S. Civil St.	atute under which you are	e filine (D	1	ecify)				Direct F	ile
	28 U.S.C.§133	32(a)	e ming (De	o not cite jurisaictional	<i>i statute</i> :	s uniess ai	versity):			
VI. CAUSE OF ACTIO	DN Brief description of ca									
	Product Liability									
VII. REQUESTED IN COMPLAINT:	CHECK IF THIS UNDER RULE 2	S IS A CLASS ACTION	DE	MAND \$ 1,000,00	00.00		HECK YES only i	if demanded i XYes	n complai	
		- , •••• •				J	URY DEMAND:	1 5		
VIII. RELATED CASI										
IF ANY (See instructions): JUDGE				DOCKET NUMBER						
DATE		SIGNATURE OF ATT	ORNEY O	F RECORD						
02/28/2023		/s/ Adam M								
FOR OFFICE USE ONLY										
	MOUNT	APPLYING IFP		JUDG	Е		MAG. JUD)GE		
					Ľ					

INSTRUCTIONS FOR ATTORNEYS COMPLETING CIVIL COVER SHEET FORM JS 44

Authority For Civil Cover Sheet

The JS 44 civil cover sheet and the information contained herein neither replaces nor supplements the filings and service of pleading or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. Consequently, a civil cover sheet is submitted to the Clerk of Court for each civil complaint filed. The attorney filing a case should complete the form as follows:

- **I.(a) Plaintiffs-Defendants.** Enter names (last, first, middle initial) of plaintiff and defendant. If the plaintiff or defendant is a government agency, use only the full name or standard abbreviations. If the plaintiff or defendant is an official within a government agency, identify first the agency and then the official, giving both name and title.
- (b) County of Residence. For each civil case filed, except U.S. plaintiff cases, enter the name of the county where the first listed plaintiff resides at the time of filing. In U.S. plaintiff cases, enter the name of the county in which the first listed defendant resides at the time of filing. (NOTE: In land condemnation cases, the county of residence of the "defendant" is the location of the tract of land involved.)
- (c) Attorneys. Enter the firm name, address, telephone number, and attorney of record. If there are several attorneys, list them on an attachment, noting in this section "(see attachment)".

II. Jurisdiction. The basis of jurisdiction is set forth under Rule 8(a), F.R.Cv.P., which requires that jurisdictions be shown in pleadings. Place an "X" in one of the boxes. If there is more than one basis of jurisdiction, precedence is given in the order shown below. United States plaintiff. (1) Jurisdiction based on 28 U.S.C. 1345 and 1348. Suits by agencies and officers of the United States are included here. United States defendant. (2) When the plaintiff is suing the United States, its officers or agencies, place an "X" in this box. Federal question. (3) This refers to suits under 28 U.S.C. 1331, where jurisdiction arises under the Constitution of the United States, an amendment

to the Constitution, an act of Congress or a treaty of the United States. In cases where the U.S. is a party, the U.S. plaintiff or defendant code takes precedence, and box 1 or 2 should be marked.

Diversity of citizenship. (4) This refers to suits under 28 U.S.C. 1332, where parties are citizens of different states. When Box 4 is checked, the citizenship of the different parties must be checked. (See Section III below; NOTE: federal question actions take precedence over diversity cases.)

- **III.** Residence (citizenship) of Principal Parties. This section of the JS 44 is to be completed if diversity of citizenship was indicated above. Mark this section for each principal party.
- IV. Nature of Suit. Place an "X" in the appropriate box. If there are multiple nature of suit codes associated with the case, pick the nature of suit code that is most applicable. Click here for: <u>Nature of Suit Code Descriptions</u>.
- V. Origin. Place an "X" in one of the seven boxes.

Original Proceedings. (1) Cases which originate in the United States district courts.

Removed from State Court. (2) Proceedings initiated in state courts may be removed to the district courts under Title 28 U.S.C., Section 1441. Remanded from Appellate Court. (3) Check this box for cases remanded to the district court for further action. Use the date of remand as the filing date.

Reinstated or Reopened. (4) Check this box for cases reinstated or reopened in the district court. Use the reopening date as the filing date. Transferred from Another District. (5) For cases transferred under Title 28 U.S.C. Section 1404(a). Do not use this for within district transfers or multidistrict litigation transfers.

Multidistrict Litigation – Transfer. (6) Check this box when a multidistrict case is transferred into the district under authority of Title 28 U.S.C. Section 1407.

Multidistrict Litigation – Direct File. (8) Check this box when a multidistrict case is filed in the same district as the Master MDL docket. **PLEASE NOTE THAT THERE IS NOT AN ORIGIN CODE 7.** Origin Code 7 was used for historical records and is no longer relevant due to changes in statute.

- VI. Cause of Action. Report the civil statute directly related to the cause of action and give a brief description of the cause. Do not cite jurisdictional statutes unless diversity. Example: U.S. Civil Statute: 47 USC 553 Brief Description: Unauthorized reception of cable service.
- VII. Requested in Complaint. Class Action. Place an "X" in this box if you are filing a class action under Rule 23, F.R.Cv.P. Demand. In this space enter the actual dollar amount being demanded or indicate other demand, such as a preliminary injunction. Jury Demand. Check the appropriate box to indicate whether or not a jury is being demanded.
- VIII. Related Cases. This section of the JS 44 is used to reference related pending cases, if any. If there are related pending cases, insert the docket numbers and the corresponding judge names for such cases.

Date and Attorney Signature. Date and sign the civil cover sheet.