

**IN THE UNITED STATES DISTRICT COURT
DISTRICT OF ARIZONA**

LORI PRENTICE,

Plaintiff,

vs.

Case No.

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

Defendants.

COMPLAINT

COMES NOW, Plaintiff, Lori Prentice, by and through the undersigned counsel 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 BardPort M.R.I Implantable Port (hereinafter “BardPort” or “Defective Device”).

2. Plaintiff, Lori Prentice, is an adult citizen of Arizona, 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 BardPort. 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 in 1 Becton Drive in Franklin Lakes, New Jersey. Bard conducts business throughout the United States, including the State of Arizona, 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 BardPort. 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 BardPort 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 conducts business throughout the United States, including the State of Arizona, 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 BardPort.

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.

10. 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

11. 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 Arizona, 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 Arizona 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 Arizona, such that requiring an appearance does not offend traditional notions of fair and substantial justice.

PRODUCT BACKGROUND

15. The BardPort M.R.I Implantable Port (“BardPort”) is one of several varieties of port/catheter systems that has been designed, manufactured, marketed, and sold by Defendants.

16. According to Defendants, the BardPort 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 BardPort 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 BardPort 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 BardPort 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 BardPort 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' BardPort 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. 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. Although the surface degradation and mechanical failure 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 BardPort.

22. At all times relevant, Defendants misrepresented the safety of the BardPort system, and negligently designed, manufactured, prepared, compounded, assembled, processed, labeled, marketed, distributed, and sold the BardPort 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.

23. At all times relevant to this action, Defendants knew and had reason to know, that the BardPort was not safe for the patients for whom they were prescribed and implanted, because once implanted the device was prone to fracturing, migrating, perforating internal vasculature and otherwise malfunctioning.

24. At all times relevant to this action, Defendants knew and had reason to know that patients implanted with BardPorts had an increased risk of suffering life threatening injuries, including but not limited to: death; hemorrhage; cardiac/pericardial tamponade (pressure caused by a collection of blood in the area around the heart); 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.

25. Soon after the BardPort 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 BardPort was fracturing post-implantation. Defendants also received large numbers of AERs reporting that BardPort 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.

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

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

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

29. Moreover, Defendants' warnings suggested that fracture of the device could only occur if the physician incorrectly placed the device such that "compression or pinch-off" was allowed to occur. In reality, however, Defendants knew internally these devices were fracturing and causing serious injuries due to defects in the design, manufacturing and lack of adequate warnings.

30. 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 BardPort 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 BardPort System from the market.

SPECIFIC FACTUAL ALLEGATIONS AS TO PLAINTIFF

33. On or about January 10, 2022, Plaintiff was implanted with the BardPort via right subclavian vein, for administration of chemotherapy in treatment of breast cancer. This procedure took place at St. Joseph's Outpatient Surgery Center in Phoenix, Arizona, and was performed by Dr. Charles Castillo, M.D.

34. On or about December 9, 2022, Plaintiff's BardPort became inaccessible, and prevented her chemotherapy from being administered. A CT scan was performed which revealed that Plaintiff's BardPort had fractured and a piece of the catheter had moved into the right atrium and the right ventricle. As a result of the breakage, emergency surgery was performed to remove the BardPort and catheter and to implant a second port.

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

36. The Defendants concealed—and continue to conceal—their knowledge of the BardPort's unreasonably dangerous risks from Plaintiff and her physicians.

37. Numerous reports of BardPort catheter fractures and migration in the absence of medical provider error were recorded and reported to Defendants prior to the implantation of the BardPort in Plaintiff.

38. However, Defendants continued to actively and aggressively market the BardPort as safe, despite knowledge of numerous reports of such injuries. Defendants utilized marketing communications, including the Instruction for Use, 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.

39. Defendants did not adequately warn Plaintiff or Plaintiff's physicians of the true quantitative or qualitative risk of catheter fracture and migration associated with the BardPort.

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

41. Plaintiff's physicians relied upon the representations, including the instructions for use distributed with the product implanted in Plaintiff, and advertisements to Plaintiff's detriment.

42. The Defendants knowingly concealed the dangerous propensity of this device to fracture and/or dislodge and cause foreign materials to be introduced into the Plaintiff's bloodstream. 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.

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

44. The Defendants failed to conduct adequate and sufficient post-marketing surveillance after they began marketing, advertising, distributing and selling the BardPort.

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

COUNT I
NEGLIGENCE
(ALL DEFENDANTS)

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

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

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

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

- a. Failing to properly and thoroughly test the BardPort before releasing the device to market, and/or failing to implement feasible safety improvements;
- b. Failing to properly and thoroughly analyze the data resulting from any pre-market testing of the BardPort;
- c. Failing to conduct sufficient post-market testing and surveillance of the BardPort;
- d. Designing, manufacturing, marketing, advertising, distributing, and selling the BardPort to consumers, including Plaintiff, without an adequate warning of the significant and dangerous risks of the BardPort 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 BardPort; and

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

50. 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.

51. In performing the foregoing acts, omissions, and misrepresentations, Defendants acted grossly negligent, fraudulently, and with malice so as to justify an award of punitive and/or exemplary damages.

COUNT II
STRICT PRODUCTS LIABILITY – FAILURE TO WARN
(ALL DEFENDANTS)

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

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

54. Defendants designed, set specifications, manufactured, prepared, compounded, assembled, processed, marketed, labeled, distributed, and sold the BardPort, 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.

55. 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.

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

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

58. Defendants failed to timely and reasonably warn of material facts regarding the safety and efficacy of the BardPort; 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.

59. 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.

60. 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.

61. 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.

62. 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.

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

64. 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.

65. Plaintiff and her health care providers used BardPort 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.

66. 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.

67. 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.

COUNT III – STRICT PRODUCTS LIABILITY
MANUFACTURING DEFECT
(ALL DEFENDANTS)

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

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

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

71. The BardPort 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.

72. Upon information and belief, the BardPort implanted in Plaintiff varied from its intended specifications.

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

74. 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)

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

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

77. The BardPort implanted in the Plaintiff was not reasonably safe for its intended use and

was defective with respect to its design.

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

79. The BardPort was unreasonably dangerous to the user or consumer.

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

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

82. As a direct and proximate result of the BardPort'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.

COUNT V
BREACH OF IMPLIED WARRANTY
(ALL DEFENDANTS)

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 through 10, inclusive.

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

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

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

in her.

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

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

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

91. 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.

COUNT VI
BREACH OF EXPRESS WARRANTY
(ALL DEFENDANTS)

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

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

94. Defendants through their officers, directors, agents, representatives, and written literature and packaging, and written and media advertisement, expressly warranted that the BardPort 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.

95. The BardPort 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.

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

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

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

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

100. 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.

COUNT VII
FRAUDULENT CONCEALMENT
(ALL DEFENDANTS)

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

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

103. Defendants fraudulently concealed information with respect to the BardPort in the following particulars:

- a. Defendants represented through the labeling, advertising, marketing materials, seminar presentations, publications, notice letters, and regulatory submissions that the BardPort

was safe and fraudulently withheld and concealed information about the substantial risks of using the BardPort;

- b. Defendants represented that the BardPort was safer than other alternative systems and fraudulently concealed information which demonstrated that the BardPort 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.

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

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

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

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

108. 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.

109. 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 these Defendants and others from engaging in similar conduct in the future.

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

COUNT VIII
VIOLATION OF THE ARIZONA CONSUMER FRAUD ACT
(ALL DEFENDANTS)

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

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

113. The acts and practices engaged in by Defendants constituted acts of deception, deceptive or unfair acts or practices, false pretenses, false promises, misrepresentations, concealments, and suppressions or omissions of material fact in violation of the Arizona Consumer Fraud Act, § 44-1522 *et seq.*

114. Defendants intended for others, including Plaintiff and Plaintiff's healthcare providers, to rely on their concealments and suppressions or omissions in connection with the sale and advertisement of the Defendants' product at issue here.

115. Plaintiff purchased the BardPort, a product that was falsely represented, as set out above, in violation of the Arizona Consumer Fraud Act and as a result Plaintiff suffered damages.

PUNITIVE DAMAGES

116. Plaintiff is 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 BardPort. 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.

117. Defendants had knowledge of, and were in possession of evidence demonstrating that, the BardPort 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 BardPort, Defendants failed to provide accurate information and warnings to the healthcare community that would have dissuaded physicians from surgically implanting the BardPort and consumers from agreeing to being implanted with the BardPort, thus depriving physicians and consumers from weighing the true risks against the benefits of prescribing and implanting the BardPort.

118. 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 as follows:

- a. Judgment 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.

Respectfully submitted,

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