UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

SA'DA CHESTER, Plaintiff, vs. BECTON, DICKINSON AND COMPANY, C.R. BARD, INC., BARD ACCESS SYSTEMS, INC., Defendants.	**Case No.** **JURY TRIAL DEMANDED**

COMPLAINT

Plaintiff SA'DA CHESTER, by and through her undersigned counsel, files this Complaint against Becton, Dickinson & Company, C.R. Bard, Inc., and Bard Access Systems, Inc. ("Defendants"):

1. This is an action for damages relating to Defendants' design, development, testing, assembling, manufacturing, packaging, promoting, marketing, distribution, supplying, and/or selling an implantable port-catheter device sold under the trade name of Bard PowerPort® isp M.R.I.™ Implantable Port (hereinafter "PowerPort" or "Defective Device", or "Device", or "Port-A-Cath", or "Port", or "port", or "left-sided chest port").

I. PARTIES

A. Plaintiff

2. Plaintiff Sa'da Chester ("Plaintiff) is an adult citizen of Chicago, Illinois, which is in the Northern District of Illinois, and claims damages as set forth below.

B. Defendants

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. 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 Device. 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 in Murray Hill, New Jersey. 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 Device. Defendant Bard, along with its subsidiaries and business units, was acquired by Defendant BD in 2017, in a transaction which integrated and subsumed Bard's business units into BD's business units. In said transaction, Defendant Bard's product offerings, including the Device, were taken over by and integrated into Defendant BD's Interventional segment, one of three of BD's principal business segments.

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 Illinois, 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 Device.

6. Defendant BD is the nominal corporate parent of Defendants Bard and BAS, but the latter two are alter egos of BD as it 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 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 injuries and damages because of its abuse of the corporate form, BD is directly liable as a result of its own wrongful conduct as set forth herein.

II. 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 matter in controversy exceeds the sum of $75,000.00, exclusive of interest and costs.

11. Venue is proper in this Court pursuant to 28 U.S.C. §1391(b)(2) because:

(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 Illinois, 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 Illinois 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 Illinois, such that requiring an appearance does not offend traditional notices of fair and substantial justice.

III. PRODUCT BACKGROUND

14. The Bard PowerPort™ isp M.R.I.™ Implantable Port is one of many implantable port-catheter devices that Defendants designed, manufactured, marketed, and sold.

15. According to Defendants, the Device is a totally implantable vascular access device designed and intended to provide repeated access to the vascular system for the delivery of medications, intravenous fluids, parenteral nutrition solutions, blood products, and for the withdrawal of blood samples.

16. The Device is surgically placed under the skin, intended to be left implanted, and consists of two primary components: an injection port and a catheter.

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

18. The Device's catheter is a polymeric mixture of silicone or polyurethane and barium sulfate, a radiopaque compound that is visible in certain radiologic studies.

19. Defendants knew or should have known that barium sulfate affects the mechanical integrity of polymers like the type used in the Device's catheter when it is not encapsulated, coated, or otherwise separated from polymer's surface.

20. First, barium sulfate reduces the mechanical integrity of the Device's catheter *in vivo* as the particles of barium sulfate dissociate from the polymer's surface over time. This dissociation leaves microfractures and other alterations to the catheter's polymeric structure that degrade and erode its mechanical properties.

21. Second, the concentration of barium sulfate reduces the mechanical integrity of Defendants' catheter. As the barium sulfate content increases, medical-polymer products that use barium sulfate begin to show losses of the base polymer's tensile strength and other mechanical properties. Indeed, researchers have shown that catheter surface degradation in products featuring a radiopaque barium sulfate stripe is concentrated at the locus of the stripe.1. *See* Hecker JF, Scandrett LA., *Roughness and thrombogenicity of the outer surfaces of intravascular catheters,* J Biomed Mater Res. 1985 Apr; 19(4): 381-395. doi: 10.1002/jbm.820190404.

22. Third, the homogeneity of the modified polymer affects the

mechanical integrity of the Device's catheter. Upon information and belief, Defendants' manufacturing process in constructing the Device's catheter involved too high a concentration of barium sulfate particles, leading to improperly high viscosity of the raw silicone or polyurethane before polymerization and causing improper mixing of barium sulfate particles within the polymer matrix.

23. This improper mixing forms pockets of barium sulfate and entrapped air throughout the catheter body and surface, which weakens the catheter's mechanical integrity and creates a rough catheter surface.

24. This defective manufacturing process drastically increases the risk of surface degradation and erosion, catheter fracture and cardiac migration, and leads to the collection and proliferation of fibrinous blood products, thereby drastically increasing the risk of the development of PowerPort-related or PowerPort's catheter fragment-related emboli.

25. This unsafe condition and the resulting risk for severe complications increase over the time as barium sulfate continually dissociates from the catheter surface, yet Defendants failed to adequately warn healthcare providers, including Plaintiff's healthcare providers, and the public, including Plaintiff, of this fact, and of the real magnitude of such life-threatening complications.

26. Although the surface degradation and erosion, catheter fracture and cardiac migration, and the development of PowerPort-related or PowerPort's catheter fragment-related emboli, 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 Device.

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

28. At all times relevant to this action, Defendants knew or should have known that the Device was not adequately tested and was not safe and effective for patients implanted with the Device.

29. At all times relevant to this action, Defendants knew or should have known that patients implanted with the Device had an unreasonable risk of suffering life-threatening injuries, including but not limited to, catheter fracture and cardiac migration, and the development of PowerPort-related or PowerPort's catheter fragment-related emboli, and/or the need for additional surgeries to remove the Defective Device and the PowerPort's catheter fragment(s).

30. Indeed, soon after these implanted port devices were introduced to market, Defendants began receiving large numbers of Adverse Event Reports ("AERs") from healthcare providers stating that post-implantation the implanted port devices were: (a) fracturing and were a subject to cardiac migration, and/or (b) precipitating the development of emboli. Defendants also received large numbers of AERs reporting that PowerPort devices were 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. Perforations of tissue, vessels, and organs; and

f. Death.

31. In addition to the large number of AERs that were known to Defendants and reflected in publicly accessible databases, there are thousands of recorded device failures and/or injuries related to the Defendants' implantable port-catheter devices—including the Device implanted into Plaintiff—that Defendants intentionally concealed.

32. Moreover, Defendants intentionally concealed known device failures and injuries— including the severity of complications caused by the devices, including Plaintiff's Device, and the likelihood of these events occurring—from medical professionals and patients.

33. Further, Defendants misrepresented that fracture of the Device could only occur if the physician incorrectly placed the Device in such a way that "compression or pinch-off" could occur. In reality, Defendants knew or should have known that these devices were fracturing and causing serious injuries due to defects in the devices' design and/or Defendants' manufacturing process.

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

35. Defendants represented through the labeling, advertising, marketing materials, seminar presentations, publications, notice letters, and regulatory submissions that the Device was safe, yet fraudulently withheld and concealed information about the PowerPort-related life-threatening adverse events and substantial risks of using the PowerPort, and the real magnitude of such risks, including, but not limited to, catheter fracture and cardiac migration, and the development of PowerPort-related or PowerPort's catheter fragment-related emboli.

36. Rather than alter the design of the Device to make it safer or adequately warn healthcare providers and patients of the Device's dangers, Defendants continued to aggressively market the Device as safe and effective, despite their knowledge of numerous reports of serious complications and injuries.

37. Defendants' tortious conduct, 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 Device, yet consciously failed to act reasonably to:

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

b. Establish and maintain an adequate quality control procedure in the Device's manufacturing process;

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

d. Recall the Device from the market.

IV. SPECIFIC FACTUAL ALLEGATIONS AS TO PLAINTIFF

38. On or about March 11, 2020, the PowerPort was surgically inserted into Plaintiff's left internal jugular vein for Plaintiff's breast cancer-related chemotherapy. Upon information and belief, the installed PowerPort at issue, i.e., a Groshong type catheter, was manufactured by Defendant BAS. It is identified as Ref. Number 4808550, or Ref. Number 4808560, or Ref. Number 4808580, with Lot Number REDX1710.

39. The PowerPort was implanted into Plaintiff by Dr. Scott Reishus, DO, a surgeon, at West Suburban Medical Center in Oak Park, Illinois.

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

41. The PowerPort was correctly and properly installed by Plaintiff's surgeon Dr. Scott Reishus, DO, in accordance with the manufacturer's instructions.

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

43. At all times relevant to this action, the PowerPort was used for its intended purpose of repeated access to Plaintiff's vascular system for the delivery of medications, intravenous fluids, parenteral nutrition solutions, blood products, and for the withdrawal of blood samples.

44. At all times relevant to this action, Plaintiff's healthcare providers did not place, maintain, or use the PowerPort incorrectly or use the Device for an

unforeseeable purpose.

45. On or about November 16, 2021, the Radiology Report that followed the Xray Chest 2 Views Exam administered at West Suburban Medical Center in Oak Park, Illinois, revealed the presence of Plaintiff's Port-A-Cath fragment mostly in the Plaintiff's right atrium [i.e., right atrium is one of the four chambers of the heart]. It was then observed that the proximal portion of Plaintiff's Port-A-Cath was likely lodged within the azygos vein [azygos vein is located on the right side at the back of the thorax (i.e., the chest)]. Dr. Gregg Weinberg, M.D. noted that Plaintiff's catheter fragment extended from her azygos vein into her right atrium.

46. On or about November 16, 2021, the surgical procedure took place at West Suburban Medical Center in an attempt to remove Plaintiff's left-sided chest port. Upon information and belief, Dr. Rabia Z. Bhatti MD performed the surgical procedure in question. The catheter component of Plaintiff's port was unable to be removed although the surgeon attempted to capture the catheter from two different locations within Plaintiff's body. Upon information and belief, the catheter's component at issue became embedded with a fibrin sheath. Plaintiff suffered multiple episodes of ventricular tachycardia during the surgical procedure described in this paragraph. Upon information and belief, said multiple episodes of ventricular tachycardia prevented the surgeon from further attempts to remove Plaintiff's port.

47. Upon information and belief, on November 17, 2021, the surgical procedure took place at the Interventional Radiology Department of West Suburban Medical Center, to remove the fragment of Plaintiff's catheter, which was discovered in her right atrium on November 16, 2021. The procedure was unsuccessful.

48. On November 17, 2021, Dr. Rabia Bhatti, MD provided Plaintiff with Interventional Cardiology Referral based on complication of catheter, to retrieve the catheter. The Interventional Cardiology Referral was Urgent.

49. On November 19, 2021, Rush University Interventional Services' Radiology Results showed mechanical complication of device.

50. On November 23, 2021, Plaintiff presented at Rush Oak Park Hospital's Emergency Department with chest pain. In addition to chest pain, Plaintiff was then diagnosed with embolus from catheter fragment. Upon information and belief, on November 23, 2021, her chest pain became worse after a partial removal of the port that took place on November 16, 2021. The retained fragment of Plaintiff's Port-A-Cath in her heart was noted.

51. On November 23, 2021, while at the Emergency Department, CT Angiography Chest imaging test was ordered and administered. CT Angiography Chest imaging test showed the abandoned catheter with its proximal tip in Plaintiff's azygos vein and the distal tip in her right ventricle. Dr. Anupam Basu, MD reviewed and interpreted the results of said CT Angiography Chest imaging test. Dr. Joshua Faucher, MD confirmed the diagnosis of the embolized catheter fragment to right heart.

52. On November 23, 2021, Plaintiff was transported to Rush University Medical Center in Chicago, IL, to remove the retained catheter. The catheter was successfully removed, via the sheath procedure, the next day, on November 24, 2021.

53. Upon information and belief, on November 24, 2021, Dr. Rehan M. Riaz, MD of the Department of Interventional Radiology at Rush University Medical Center in Chicago, assisted by Dr. Michael T. Dombrowski, MD, successfully retrieved

Plaintiff's retained catheter, via femoral access, using the procedure called Sheath Insertion.

54. Due to the Defective Device, Plaintiff suffered injuries and damages and continues to suffer damages including, but not limited to, undergoing unnecessary major surgeries, increased risk of future severe and permanent injuries, severe emotional distress, ongoing fear and anxiety from future injuries, including but not limited to, the Port-A-Cath-related injuries such as catheter fracture and cardiac migration.

55. Defendants concealed, and continue to conceal, their knowledge of the Device's unreasonably dangerous risks from healthcare providers, including Plaintiff's, and from the consumers, including Plaintiff.

56. Numerous reports of severe complications and injuries from the Device, including the reports of catheter fracture and cardiac migration—with no evidence of the medical provider's error—were recorded and reported to Defendants before the Device was implanted into Plaintiff.

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

58. Defendants did not adequately warn healthcare providers, including Plaintiff's, and the consumers, including Plaintiff, of the true quantitative or qualitative risk of erosion, catheter fracture, cardiac migration, and the development of PowerPort-

related emboli.

59. Defendants did not adequately warn healthcare providers, including Plaintiff's, and the consumers, including Plaintiff, that the risk of erosion, catheter fracture, and cardiac migration, and the development of emboli associated with the Device or with catheter fragments increases the longer the Device is placed in a patient.

60. Defendants did not adequately warn healthcare providers, including Plaintiff's, and the consumers, including Plaintiff, that the function and integrity of the Device should be closely monitored when the Device is in place for over a year to reduce the risk of injury, including, but not limited to catheter fracture and cardiac migration.

61. Defendants did not adequately communicate the extent or seriousness of the danger of erosion, catheter fracture, and cardiac migration, and the development of PowerPort-related emboli to healthcare providers, including Plaintiff's, and to the consumers, including Plaintiff.

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

63. Plaintiff's physicians reasonably relied upon Defendants' representations—including the *Instructions For Use* distributed with the PowerPort implanted into Plaintiff—and advertisements, to Plaintiff's detriment.

64. Defendants concealed and continue to conceal their knowledge of the Device's dangerous propensities to fracture and/or dislodge and to cause cardiac migration, and to precipitate the development of the PowerPort-related or PowerPort's catheter fragment-related emboli. Moreover, Defendants concealed that the PowerPort's

design and/or manufacturing defects caused these failures and that these failures cause serious and life-threatening injuries.

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

66. As a result of Defendants' intentional actions and Defendants' tortious conduct in designing, manufacturing, and marketing the PowerPort at issue, Plaintiff's healthcare providers and Plaintiff were unaware, and could not have reasonably known or have learned through reasonable due diligence, (a) that Plaintiff had been exposed to the risks identified in this Complaint, (b) the identities of the tortfeasors, i.e., the named Defendants in this case, who owned Plaintiff a duty of care, and that Defendants breached their duty of care, and (c) the causal link between Defendants' tortious conduct and/or their defective PowerPort and Plaintiff's injuries and damages.

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

V. FRAUDULENT CONCEALMENT

68. The fact that Defendants knowingly concealed the known defects and risks associated with the PowerPort at issue, and other material facts concerning the PowerPort's safety, constitutes fraudulent concealment, as Defendants acted with an intent to deceive Plaintiff's healthcare providers and Plaintiff, and to induce them to use the PowerPort at issue, which they did, and Plaintiff sustained damages as the result of

her justifiable reliance. Under the circumstances of this case, fraudulent concealment equitably tolls applicable statutes of limitation.

69. Defendants are estopped from relying on the statute of limitations defense because Defendants actively concealed the defects, suppressing reports, failing to follow through on regulatory requirements, and failing to disclose known defects to physicians. Instead of revealing the defects, Defendants continued to present the PowerPort at issue as safe for its intended use.

70. Defendants are and were under a continuing duty to disclose the true character, quality, and nature of risks and dangers associated with their PowerPort. Due to Defendants' concealment of the true character, quality, and nature of the PowerPort, Defendants are estopped from relying on any statute of limitations defense.

71. Defendants furthered this fraudulent concealment through a continued and systematic failure to disclose information to Plaintiff's healthcare providers and to Plaintiff.

72. Defendants' acts before, during and/or after the acts causing Plaintiff's injuries prevented Plaintiff from immediately ascertaining that she was injured, the identities of Defendants, and the causal link between her injuries and Defendants' tortious conduct and/or the defective PowerPort at issue.

73. Defendants' tortious conduct, as described in this Complaint, amounts to conduct purposely committed, which Defendants knew or should have known was dangerous, heedless, reckless, and without regard to the consequences or Plaintiff's rights and safety.

74. Defendants' tortious conduct, as described in this Complaint, also

amounts to a continuing tort, and continues up through and including the date of the filing of this Complaint.

VI. COUNT I: NEGLIGENCE

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

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

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

78. Defendants breached their duty of care and were negligent in the design, manufacture, labeling, warning, instruction, training, selling, marketing, and distribution of the PowerPort at issue in one or more of the following respects:

a. The PowerPort was inherently dangerous and defective, unfit and unsafe for its intended and reasonably foreseeable use and did not meet or perform to the user's intended expectations;

b. Failing to design the PowerPort to avoid an unreasonable risk of harm to people in whom the PowerPort was implanted, including Plaintiff;

c. Failing to manufacture the PowerPort to avoid an unreasonable risk of harm to people in whom the PowerPort was implanted, including Plaintiff;

d. Failing to use reasonable care in the testing of the PowerPort to avoid an unreasonable risk of harm to people in whom the

PowerPort was implanted, including Plaintiff;

e. Failing to use reasonable care in the inspecting of the PowerPort to avoid an unreasonable risk of harm to people in whom the PowerPort was implanted, including Plaintiff;

f. Failing to use reasonable care in training its employees and healthcare providers related to the use of the PowerPort to avoid unreasonable risk of harm to people in whom the PowerPort was implanted, including Plaintiff;

g. Failing to use reasonable care in warning healthcare providers, regulatory agencies, and the public of risks associated with the PowerPort, to avoid unreasonable risk of harm to people in whom the PowerPort was implanted, including Plaintiff;

h. Failing to use reasonable care in warning healthcare providers, regulatory agencies, and the public of the fact that the risk for severe complications, including, but not limited to, PowerPort's catheter fracture and cardiac migration, increases over time as barium sulfate continually dissociates from the catheter surface;

i. Failing to use reasonable care in warning healthcare providers, regulatory agencies, and the public of risks that the PowerPort could cause serious injuries even when it is placed correctly;

j. Failing to use reasonable care in the marketing and promoting of the PowerPort to avoid an unreasonable risk of harm to people in whom the PowerPort was implanted, including Plaintiff;

k. Failing to use reasonable care in the labeling of the PowerPort to avoid an unreasonable risk of harm to people in whom the PowerPort was implanted, including Plaintiff;

l. Failing to properly and thoroughly test the PowerPort before releasing it to market, and/or failing to implement feasible safety improvements, to avoid unreasonable risk of harm to people in whom the PowerPort was implanted, including Plaintiff;

m. Failing to properly and thoroughly analyze the data resulting from any pre-market testing of the PowerPort, to avoid unreasonable risk of harm to people in whom the PowerPort was implanted, including Plaintiff;

n. Failing to conduct sufficient post-market testing and surveillance of the PowerPort, so as to avoid unreasonable risk of harm to people in whom the PowerPort was implanted, including Plaintiff;

o. Initially underreporting the number and nature of adverse events related to the PowerPort to Plaintiff's prescribing physicians;

p. Designing, manufacturing, marketing, advertising, distributing, and selling the PowerPort to consumers, including Plaintiff and to Plaintiff's healthcare providers, without adequate warnings of the significant and dangerous risks of the PowerPort-related injuries, including, but not limited to, the risks of catheter fracture and cardiac migration, and the risk of development of the catheter fragment-related emboli, and without proper instructions to avoid

the harm which could foreseeably occur as a result of using the PowerPort;

q. Negligently continuing to manufacture, market, advertise, and distribute the PowerPort after Defendants knew or should have known of the serious and life-threatening adverse events associated with the PowerPort; and

r. Failing to act as a reasonable manufacturer, distributor, seller would have acted under the same or similar circumstances.

79. As a direct and proximate result of Defendants' negligence, Plaintiff was injured and has suffered severe and permanent pain and injuries which are permanent and lasting in nature, emotional distress, loss of 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.

COUNT II: NEGLIGENCE – FAILURE TO WARN

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

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

82. Defendants owed Plaintiff and Plaintiff's healthcare providers a duty to disclose whether the PowerPort had been adequately tested and of the substantial dangers and/or potential risks associated with the Device when used or misused in a reasonably foreseeable manner.

83. Defendants knew or should have known that the PowerPort was not

adequately tested and was dangerous or was likely to be dangerous when used or misused in a reasonably foreseeable manner.

84. Defendants knew or should have known that the users of the PowerPort would not realize and reasonably could not realize that the PowerPort was not adequately tested, or the substantial danger or potential risks associated with the PowerPort when used or misused in a reasonably foreseeable manner.

85. Defendants failed to adequately warn Plaintiff's prescribing physicians and Plaintiff that the PowerPort was not adequately tested or of the substantial danger and/or potential risks associated with the PowerPort when used or misused in a reasonably foreseeable manner.

86. In addition, Defendants failed to adequately warn Plaintiff's prescribing physicians and Plaintiff as to the points, including, but not limited to the following:

a. The PowerPort was inherently dangerous and defective, unfit and unsafe for its intended and reasonably foreseeable use and did not meet or perform to the user's intended expectations;

b. Patients implanted with the PowerPort had an increased risk of suffering dangerous PowerPort-related complications, including, but not limited to: death, hemorrhage, catheter fracture and cardiac migration, thromboembolism, serious infections, cardiac arrhythmia, severe and persistent pain, and perforations of tissue, vessels and organs, and/or the need for additional surgeries to remove the defective PowerPort, or its catheter, or its fragments.

c. The PowerPort posed a significant and higher risk than other similar devices of device failure, catheter fracture and cardiac migration, and resulting serious injuries;

d. The PowerPort could cause serious and life-threatening injuries even when the PowerPort is placed correctly;

e. The inadequate research and testing of the PowerPort;

f. The true quantitative or qualitative risks and the true extent of catheter erosion, catheter fracture cardiac migration, and other serious and life-threatening injuries associated with the PowerPort;

g. The risk of catheter erosion, catheter fracture and cardiac migration, and the development of the PowerPort-related or PowerPort's catheter fragment-related emboli was significantly higher in cases where the PowerPort stays in place for longer than a year;

h. The PowerPort should be closely monitored in cases where it is left in place for over a year;

i. The PowerPort raised the risk of catheter erosion, catheter fracture and cardiac migration, and other serious and life-threatening adverse events by virtue of the catheter design and composition; and

j. The number and nature of serious and life-threatening adverse events related to the PowerPort.

87. A reasonable manufacturer, distributor, and/or seller, under the same or similar circumstances, would have adequately warned Plaintiff's healthcare providers

and Plaintiff that the PowerPort was not adequately tested and/or of the substantial danger and/or of the potential risks associated with the PowerPort.

88. Plaintiff would not have consented to be implanted with the PowerPort if Defendants had provided adequate warnings that the PowerPort was not adequately tested or of the substantial danger, and/or of potential serious and life-threatening risks associated with the PowerPort, including, but not limited to, the increased risk of catheter fracture and cardiac migration, and the development of the PowerPort catheter fragment-related emboli.

89. Upon information and belief, Plaintiff's healthcare providers would not have prescribed and implanted the PowerPort into Plaintiff if Defendants had provided adequate warnings that the PowerPort was not adequately tested or of the substantial danger and/or of potential risks associated with the PowerPort, including, but not limited to, the increased risk of catheter fracture and cardiac migration, and the development of the PowerPort catheter fragment-related emboli.

90. As a direct and proximate result of Defendants' failure to warn, Plaintiff was injured and has suffered, and will continue to suffer, severe physical pain and injuries which are permanent and lasting in nature, emotional distress, loss of 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.

COUNT III: NEGLIGENCE – DESIGN DEFECT

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

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

inclusive.

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

94. Defendants breached their duty of care and were negligent in the designing, manufacturing, and/or supplying of the PowerPort.

95. At the time the PowerPort left Defendants' control, safer alternative designs—that would have prevented or reduced the substantial danger and/or potential risks associated with the Device—were commercially, technologically, and scientifically attainable and feasible.

96. As a direct and proximate result of Defendants' design defect as it concerns the PowerPort at issue, Plaintiff was injured and 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.

COUNT IV: NEGLIGENCE – MANUFACTURING DEFECT

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

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

99. Defendants operated under design and manufacturing specifications for the PowerPort, which included appropriate material content, strength, size, durability

appearance, resistance levels, etc., to ensure that the devices did not deviate from their intended design and their established manufacturing specifications. The manufacturing process was intended to identify any end-product products that did not meet Defendants' specifications.

100. Defendants owed Plaintiff a duty to exercise reasonable care when manufacturing, setting design and manufacturing specifications, exercising quality control over, distributing, and selling the PowerPort.

101. Defendants breached this duty and failed to exercise reasonable care when manufacturing, setting design and manufacturing specifications, exercising quality control over, distributing, and selling the PowerPort that was implanted into Plaintiff. This caused the PowerPort that was implanted into Plaintiff to deviate from its intended design and/or vary from its intended manufacturing specifications in that the PowerPort at issue did not have the specified material content, size, durability, and strength.

102. The defective and dangerous condition of the PowerPort implanted into Plaintiff existed at the time it left Defendants' possession. The PowerPort at issue differed from Defendants' intended result and/or from other ostensibly identical units of the same product line.

103. As a direct and proximate result of Defendants' negligent manufacturing and the resulting manufacturing defect, Plaintiff was injured and has suffered and will continue to suffer, severe physical pain and injuries which are permanent and lasting in nature, emotional distress, loss of 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.

COUNT V: STRICT LIABILITY – FAILURE TO WARN

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

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

106. Defendants designed, set specifications, manufactured, prepared, compounded, assembled, processed, marketed, labeled, distributed, and sold the PowerPort into the stream of commerce. Moreover, Defendants directly advertised and marketed the PowerPort to patients and the healthcare providers responsible for those patients.

107. The PowerPort at issue that caused harm to Plaintiff was unsafe or dangerous when Defendants designed, manufactured, or distributed it.

108. Defendants, the sellers of the PowerPort at issue, expected or intended for the PowerPort to reach Plaintiff, i.e., the consumer, without any changes made to the PowerPort by any third parties. No changes were made to the PowerPort and it reached Plaintiff without any changes being made to it by any third party.

109. Plaintiff sustained injuries and damages due to the defective PowerPort, as described in this Complaint.

110. Defendants failed to adequately warn Plaintiff's prescribing physicians and Plaintiff of the substantial dangers and/or potential risks associated with the PowerPort at issue which was unsafe and dangerous as described above.

111. In addition, Defendants failed to adequately warn Plaintiff's prescribing physicians and Plaintiff as to the points, including, but not limited to the following:

a. The PowerPort at issue was inherently dangerous and defective, unfit and unsafe for its intended and reasonably foreseeable use and did not meet or perform to the user's intended expectations;

b. Patients implanted with the PowerPort had an increased risk of suffering serious complications, including but not limited to: death, hemorrhage, catheter fracture and cardiac migration, thromboembolism, serious infections, cardiac arrhythmia, severe and persistent pain and perforations of tissue, vessels and organs, and/or the need for additional surgeries to remove the defective or fractured PowerPort;

c. The PowerPort posed a significant and higher risk than other similar devices of device failure, catheter fracture and cardiac migration, and resulting serious injuries;

d. The PowerPort could cause serious injuries even when the PowerPort is placed correctly; and

e. The PowerPort at issue raised the risk of catheter erosion, catheter fracture and cardiac migration, and the development of the PowerPort-related or the PowerPort's catheter fragment-related emboli, by virtue of the catheter design and composition.

112. As a direct and proximate result of Defendants' failure to adequately warn Plaintiff's healthcare providers and Plaintiff, Plaintiff was injured due to the defective PowerPort, and 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.

113. Defendants are strictly liable in tort to Plaintiff for their wrongful conduct.

COUNT VI: STRICT LIABILITY – DESIGN DEFECT

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

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

116. The PowerPort's condition was defective as a result of the PowerPort's design defect(s).

117. The PowerPort's defective condition made the PowerPort unreasonably dangerous to be implanted into Plaintiff for her chemotherapy.

118. The PowerPort's defective and unreasonably dangerous condition existed at the time the PowerPort at issue left Defendants' control.

119. Plaintiff sustained injuries and damages, as described in this Complaint, which were proximately caused by the PowerPort's defective and unreasonably dangerous conditions.

120. At all times relevant to this action, Plaintiff and Plaintiff's healthcare providers used the PowerPort for its intended use or in a way that was reasonably foreseeable to Defendants.

121. Due to the design defects, the PowerPort was inherently dangerous and defective, unfit and unsafe for its intended and reasonably foreseeable use and did not meet or perform to the expectations of Plaintiff and Plaintiff's healthcare providers.

122. The PowerPort implanted into Plaintiff was in substantially the same condition, defective in its design, and unreasonably dangerous, as when it left Defendants' control.

123. The PowerPort's defective and unreasonably dangerous condition caused by the PowerPort's design defects, made the PowerPort dangerous to an extent beyond that which would be understood by Plaintiff, an ordinary consumer.

124. As a direct and proximate result of the PowerPort's design defects, Plaintiff was injured and 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.

125. Defendants are strictly liable in tort to Plaintiff for their wrongful conduct.

COUNT VII: STRICT LIABILITY – MANUFACTURING DEFECT

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

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

128. The PowerPort's condition was defective and unreasonably dangerous as a result of manufacturing defect.

129. The PowerPort's defective and unreasonably dangerous condition existed at the time the PowerPort left Defendants' control.

130. The defective and unreasonably dangerous PowerPort was the

proximate cause of Plaintiff's injuries and damages described in this Complaint.

131. Due to the manufacturing defects, the PowerPort was inherently dangerous and defective, unfit and unsafe when put to use in an intended or reasonably foreseeable manner, and did not meet or perform to the expectations of Plaintiff and Plaintiff's healthcare providers.

132. The PowerPort's risks to Plaintiff's health and safety were (1) far more significant and devastating than the risks posed by other products and procedures available to treat Plaintiff's corresponding medical conditions; and (2) far outweigh the utility of the PowerPort at issue.

133. The manufacturing defects of the PowerPort implanted into Plaintiff existed at the time it left Defendants' control and the PowerPort was in the substantially same condition when it was surgically implanted into Plaintiff.

134. At all times relevant to this action, Plaintiff and Plaintiff's healthcare providers used the PowerPort for its intended use or in a reasonably foreseeable manner.

135. As a direct and proximate result of the Device's manufacturing defects, Plaintiff was injured and has suffered, and will continue to suffer, severe physical pain and injuries which are permanent and lasting in nature, emotional distress, loss of 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.

136. Defendants are strictly liable in tort to Plaintiff for their wrongful conduct.

COUNT VIII: COMMON LAW FRAUD

137. Plaintiff incorporates the preceding paragraphs as if set out fully

herein.

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

139. Defendants represented and continue to represent to Plaintiff's healthcare providers and to Plaintiff that the PowerPort was tested and found to be safe and effective. Defendants had sole access to material facts concerning the substantial danger and/or potential risks associated with the PowerPort at issue, including, but not limited to, the catheter fracture and cardiac migration, and other serious and life-threatening adverse events associated with the PowerPort.

140. Defendants' representations were, in fact, false. When Defendants made their representations to Plaintiff's healthcare providers and to Plaintiff, Defendants knew or should have known that the PowerPort was not adequately tested and/or dangerous or was likely to be dangerous when put to use in a reasonably foreseeable manner.

141. Moreover, Defendants knew or should have known that those representations were false, and Defendants willfully, wantonly, and recklessly disregarded the inaccuracies and falsehood in their representations and the dangers and health risks to Plaintiff.

142. In representations to Plaintiff and/or to Plaintiff's healthcare providers, Defendants fraudulently concealed and intentionally or recklessly omitted the following material information:

a. The PowerPort was inherently dangerous and defective, unfit and unsafe for its intended and reasonably foreseeable use and did not

meet or perform to the user's intended expectations;

b. Patients implanted with the PowerPort had an increased risk of suffering serious complications, including but not limited to: death, hemorrhage, catheter fracture and cardiac migration, thromboembolism, serious infections, cardiac arrhythmia, severe and persistent pain, and perforations of tissue, vessels and organs, and/or the need for additional surgeries to remove the defective and/or fractured PowerPort;

c. The PowerPort posed a significant and higher risk than other similar devices of device failure and resulting serious and life-threatening injuries;

d. The inadequate research and testing of the PowerPort;

e. The true quantitative or qualitative risk and the true extent of catheter erosion, catheter fracture and cardiac migration, and other serious and life-threatening adverse events associated with the PowerPort;

f. The risk of catheter erosion, catheter fracture and cardiac migration, and other serious and life-threatening adverse events associated with the PowerPort was higher in cases where the PowerPort stays in place for longer than a year;

g. The PowerPort should be closely monitored in cases where it is left in place for over a year;

h. The PowerPort raised the risk of catheter erosion catheter fracture

and cardiac migration, etc. by virtue of the catheter defective design and composition; and

i. The number and nature of serious and life-threatening adverse events related to the PowerPort.

143. Defendants' misrepresentations, concealment, and omissions of material facts regarding the PowerPort's safety and efficacy were made through: product inserts, the *Instructions For Use*, training materials, websites, information presented at medical and professional meetings, information disseminated by sales representatives to Plaintiff's physicians and other Plaintiff's healthcare providers, regulatory submissions, Adverse Event Reports, other reports, press releases, advertising campaigns, television commercials, print advertisements, billboards, and other commercial media.

144. Defendants' misrepresentations, concealment, and omissions of material facts regarding the PowerPort's safety and efficacy were made to purposefully, willfully, wantonly, and/or recklessly with an intent to mislead Plaintiff and Plaintiff's healthcare providers, into recommending, prescribing, dispensing and purchasing, and implanting the PowerPort at issue.

145. At the time Defendants made these false representations, Plaintiff 's healthcare providers and Plaintiff were unaware these representations were false, reasonably believed the representations were true, and reasonably relied on these representations to Plaintiff's detriment.

146. Plaintiff would not have consented to be implanted with the PowerPort if Defendants had made true representations regarding the PowerPort's safety and efficacy.

147. Upon information and belief, Plaintiff's prescribing physicians would not have implanted the PowerPort into Plaintiff if Defendants had made true representations regarding the PowerPort's safety and efficacy.

148. In reasonable reliance upon Defendants' false representations, Plaintiff was induced to use/be implanted with the PowerPort and did in fact use/was implanted with the PowerPort which caused Plaintiff's severe and permanent personal injuries and damages, including, but not limited to, catheter fracture and cardiac migration, and the development of the PowerPort's catheter fragment-related emboli, and other related injuries and damages.

149. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff was injured and 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.

COUNT IX: FRAUDULENT CONCEALMENT

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

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

152. At all times relevant to this action, Defendants knew or should have known that the PowerPort was defective and unreasonably unsafe for its intended purpose.

153. Defendants fraudulently concealed from and/or failed to disclose to,

and/or failed to adequately warn Plaintiff's healthcare providers and Plaintiff that the PowerPort was defective, unsafe, and unfit for its intended purposes and that it was not of merchantable quality.

154. Defendants were under a duty to the Plaintiff's healthcare providers and to Plaintiff to disclose and to adequately warn of the PowerPort's defective and inherently dangerous nature because:

a. Defendants were in a superior position to know the true quality, safety and efficacy of the PowerPort;

b. Defendants knowingly made false claims about the safety and quality of the PowerPort in the documents and marketing materials Defendants provided to the Plaintiff, Plaintiff's healthcare providers, and to regulatory agencies,; and

c. Defendants fraudulently and affirmatively concealed the PowerPort's defective and inherently dangerous nature from Plaintiff's healthcare providers and from Plaintiff.

155. The facts concealed and/or not disclosed by Defendants to Plaintiff's healthcare providers and to Plaintiff were material facts that a reasonable person would have considered to be important in deciding whether or not to purchase and/or use the PowerPort.

156. Defendants' misrepresentations, concealment, and omissions of material facts regarding the PowerPort's safety and efficacy were made to mislead Plaintiff's healthcare providers into recommending, prescribing, dispensing, and purchasing the PowerPort at issue and to induce Plaintiff to agree to be implanted with

the PowerPort at issue.

157. Plaintiff reasonably believed Defendants' statements and justifiably acted or relied upon Defendants' misrepresentations, concealed and/or non-disclosed material facts to her detriment, as evidenced by her purchase and use of the PowerPort.

158. As a direct and proximate result of Defendants' fraudulent concealment, Plaintiff was injured and 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.

COUNT X: NEGLIGENT MISREPRESENTATION

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

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

161. Defendants owed Plaintiff's healthcare providers and Plaintiff a duty to disclose material facts including, but not limited to, whether the PowerPort had been adequately tested and the facts concerning the substantial dangers and/or potential risks associated with the PowerPort when put to use in a reasonably foreseeable manner, including, but not limited to, catheter fracture and cardiac migration, and the development of the PowerPort's catheter fragment-related emboli.

162. Defendants breached their duty in representing and continuing to represent to Plaintiff's healthcare providers and to Plaintiff, that the PowerPort was tested and found to be safe and effective.

163. Defendants knew or should have known that the PowerPort was not adequately tested and that it was dangerous or was likely to be dangerous when put to use in a reasonably foreseeable manner. Defendants were careless or negligent in ascertaining the truth of their statements concerning safety and efficacy of the PowerPort.

164. Defendants' misrepresentations of material facts regarding the PowerPort's safety and efficacy were made with an intent to induce Plaintiff's healthcare providers into recommending, prescribing, dispensing, and purchasing the PowerPort, and with an intent to induce Plaintiff to agree to be implanted with the PowerPort.

165. An ordinary consumer would have acted or reasonably relied upon Defendants' misrepresentations of material facts regarding the PowerPort's safety and efficacy.

166. Plaintiff justifiably acted or justifiably relied upon Defendants' misrepresentations of material facts to her detriment, and was induced to, and did use/was implanted with the PowerPort at issue, which caused Plaintiff's severe and permanent injuries and damages. Plaintiff's injuries and damages resulted from her reliance when Defendants were under a duty to communicate accurate information concerning the PowerPort's safety and efficacy to Plaintiff's healthcare providers and to Plaintiff.

167. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff was injured and 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.

COUNT XI: BREACH OF EXPRESS WARRANTY

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

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

170. At all times relevant to this action, Defendants manufactured, distributed, advertised, promoted, and sold the PowerPort.

171. Defendants, the sellers of the PowerPort, through their officers, directors, agents, representatives, and written literature and packaging, and written and media advertisement, created express warranty as to the PowerPort, and expressly warranted Plaintiff and/or Plaintiff's healthcare providers that the PowerPort was safe and fit for use by consumers, was of merchantable quality, did not produce dangerous and life-threatening side effects, and was adequately tested and fit for its intended use.

172. At all times relevant to this action, the PowerPort did not comply with the express warranty created by Defendants as it failed to conform to Defendants' express representations because the PowerPort was not safe and fit for use by consumers, was not of merchantable quality, did produce dangerous and life-threatening adverse events, and/or was not adequately tested and fit for its intended use.

173. Defendants were aware that consumers, including Plaintiff, would use the PowerPort, which is to say that Plaintiff, a cancer patient, used the PowerPort for her chemotherapy, and thus, Plaintiff was a foreseeable user of the PowerPort.

174. Plaintiff and/or Plaintiff's healthcare providers, including Plaintiff's implanting physician, were in privity with Defendants because Plaintiff's physicians acted as Plaintiff's purchasing agents in the subject transaction and/or because Plaintiff

was a third-party beneficiary of the subject contract concerning the PowerPort.

175. At all times relevant to this action, Plaintiff's healthcare providers used the PowerPort on Plaintiff for the purpose and in the manner that Defendants intended.

176. At all times relevant to this action, the PowerPort did not comply with express warranty at issue as the PowerPort did not perform as an ordinary consumer would expect, when used as intended or in a reasonably foreseeable manner.

177. Plaintiff and/or Plaintiff's healthcare providers, including Plaintiff's implanting physician, reasonably relied upon Defendants' express warranty for the PowerPort and could not have reasonably discovered the breached warranty.

178. Defendants breached their express warranty. At the time of creating such express warranty, Defendants knew or should have known that the PowerPort did not conform to the Defendants' express representations because the PowerPort was not safe and fit for use by consumers, was not of merchantable quality, did produce dangerous and life-threatening adverse events, and/or was not adequately tested and fit for its intended use.

179. As a direct and proximate result of the PowerPort's failure to comply with Defendants' express warranty, Plaintiff was injured, and 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.

180. Upon information and belief, Plaintiff's healthcare providers sent a

pre-suit notice to Defendants of the adverse events in question within a reasonable time following discovery of the breach of warranty.

COUNT XII: BREACH OF IMPLIED WARRANTY

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

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

183. At all times relevant to this action, Defendants, the sellers of the PowerPort, manufactured, distributed, advertised, promoted, and sold the PowerPort. The implied warranty that the PowerPort is merchantable is implied in a contract for sale of the PowerPort due to the fact that Defendants, i.e., the sellers, are also the merchants of the PowerPort devices, including the PowerPort at issue, and such implied warranty existed at all times relevant to this action.

184. Defendants through their officers, directors, agents, representatives, and written literature and packaging, and written and media advertisement, impliedly warranted to Plaintiff and/or to Plaintiff's healthcare providers that the PowerPort was safe and fit for use by consumers, was of merchantable quality, did not produce dangerous and life-threatening side effects, and was adequately tested and fit for its intended use.

185. At all times relevant to this action, the PowerPort did not comply with said implied warranty because the PowerPort was not safe and fit for use by consumers, including Plaintiff; was not of merchantable quality; did produce dangerous and life-threatening adverse events; and/or was not adequately tested and fit for its intended use.

186. Defendants were aware that consumers, including Plaintiff, a cancer

patient, would use the PowerPort, which is to say that Plaintiff was a foreseeable user of the PowerPort at issue.

187. At all relevant times, Plaintiff and/or Plaintiff's healthcare providers, including her implanting physician were in privity with Defendants..

188. Defendants breached their implied warranty to Plaintiff because the PowerPort was not safe and fit for use by consumers, including Plaintiff, was not of merchantable quality, did produce dangerous and life-threatening adverse events, and/or was not adequately tested and fit for its intended use.

189. The PowerPort's failure to comply with Defendants' implied warranty, as it concerned the PowerPort, caused Plaintiff's injuries and damages.

190. As a direct and proximate result of the PowerPort's failure to comply with the implied warranty, Plaintiff was injured and has suffered, and will continue to suffer, severe physical pain and injuries which are permanent and lasting in nature, emotional distress, loss of 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.

191. Upon information and belief, Plaintiff's healthcare providers sent a pre-suit notice to Defendants of the adverse events in question within a reasonable time following discovery of the breach of warranty.

COUNT XIII: VIOLATION OF THE ILLINOIS CONSUMER FRAUD AND DECEPTIVE BUSINESS PRACTICES ACT

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

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

inclusive.

194. At all times relevant to this action, Defendants' unfair or deceptive acts or practices, as they related to their fraudulent misrepresentations or the concealment, suppression or omission of the materials facts concerning the PowerPort-associated danger and the increased risks of catheter erosion, catheter fracture and cardiac migration, and the development of the PowerPort catheter fragment-related emboli, and other serious and life-threatening adverse events, have constituted and continue to constitute consumer fraud and deceptive business practices under Illinois statutory law as provided in 815 ILCS 505/2. Defendants' acts and practices described in this Complaint are unlawful. *See id*.

195. At all times relevant to this action, Defendants performed unfair or deceptive acts and practices within the meaning of 815 ILCS 505/2 by engaging in false advertising, misrepresentation of the PowerPort or services, and concealment of material facts, regarding the safety and efficacy of their PowerPort.

196. Defendants intended Plaintiff to rely on their conduct to agree to be implanted with the PowerPort at issue.

197. Defendants' unfair or deceptive acts or practices, described in this Complaint, occurred in the course of conduct involving commerce as Defendants, the manufacturers, distributors, and/or sellers of the PowerPort at issue conducted the following activities outlined under 815 ILCS 505/1(f), as such activities related to the PowerPort: "advertising, offering for sale, sale, or distribution of any services…or thing of value…directly or indirectly affecting the people [in the State of Illinois]."

198. Plaintiff's damages described in this Complaint are proximately

resulting from the deception.

199. As a proximate result of the Defendants' unfair or deceptive acts or practices, Plaintiff was injured and 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.

COUNT XIV: GROSS NEGLIGENCE

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

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

202. Defendants intentionally, willfully, wantonly, and recklessly misrepresented facts and information to Plaintiff's healthcare providers and to Plaintiff, by making intentionally false and fraudulent misrepresentations about the safety and efficacy of the PowerPort. At all times relevant to this action, Defendants' conduct represented an extreme departure from the ordinary standard of care.

203. Defendants intentionally, willfully, wantonly, and recklessly concealed the material facts and information regarding the serious risks of harm associated with the implantation of the PowerPort, including, but not limited to, the risks of catheter erosion, catheter fracture and cardiac migration, and the development of the PowerPort catheter fragment-related emboli, etc., and intentionally, willfully, wantonly, and recklessly downplayed the type, nature, and extent of the serious and life-threatening adverse events of being implanted with the PowerPort, despite Defendants' full

knowledge and awareness of the serious and life-threatening adverse events and risks associated with use of the PowerPort. Defendants further intentionally, willfully, wantonly, and recklessly sought to mislead Plaintiff's healthcare providers and Plaintiff regarding the cause of catheter erosion, catheter fracture and cardiac migration, the development of the PowerPort catheter fragment-related emboli, and other serious and life-threatening adverse events.

204. Defendants had knowledge of, and were in possession of, evidence demonstrating that the PowerPort caused serious and life-threatening adverse events. Defendants continued to market the PowerPort by providing false and misleading information with regard to the PowerPort's safety and efficacy to the regulatory agencies, the medical community, and the Plaintiff's healthcare providers, and to Plaintiff, notwithstanding Defendants' knowledge of the true serious adverse events associated with the PowerPort, Defendants failed to provide accurate information and warnings to the Plaintiff's healthcare providers that would have dissuaded Plaintiff's prescribing physician from surgically implanting the PowerPort and Plaintiff from agreeing to being implanted with the PowerPort, thus depriving Plaintiff's healthcare providers, including, but not limited to Plaintiff's prescribing physician and Plaintiff from weighing the true risks against the benefits of prescribing and implanting the PowerPort at issue..

205. At all times relevant to this action, Defendants' willful, wanton, and reckless conduct affected Plaintiff's life and safety, and Plaintiff's rights as Defendants acted in reckless disregard of Plaintiff's safety and rights.

206. Plaintiff therefore will seek to assert claims for punitive damages at the appropriate time under governing law in an amount within the jurisdictional limits of the Court.

207. Defendants' willful, wanton, and reckless acts and omissions constitute gross negligence that proximately caused Plaintiff's injuries and damages.

PRAYER

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

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

b. Compensatory damages to Plaintiff for past, present, and future damages, including, but not limited to, pain and suffering, mental anguish, disfigurement, impairment, medical expenses, lost wages, lost earning capacity, and loss of household services together with interest and costs as provided by law;

c. Plaintiff be awarded costs and attorney's fees in connection with Plaintiff's cause of action grounded in Illinois Consumer Fraud and Deceptive Business Practices Act under 815 ILCS 505/2.

d. Awarding pre-judgement and post-judgement interest to Plaintiff;

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

f. For such other and further relief as the court may deem just and proper.

DEMAND FOR JURY TRIAL

Plaintiff hereby demands trial by jury as to all Counts of Plaintiff's Complaint.

Dated: October 4, 2023

Submitted Respectfully,

/s/ Shanon J. Carson

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**Pro Hac Vice* Application forthcoming

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