IN THE UNITED STATES DISTRICT COURT OF THE SOUTHERN DISTRICT OF ILLINOIS

CRYSTAL SUSSEN,

Plaintiff,

VS.

Case No. 23-3546

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

Defendants.

COMPLAINT

Plaintiff, Crystal Sussen, through 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 PowerPort MRI Implantable Port (hereinafter "PowerPort" or "Defective Device").

I. <u>PARTIES</u>

A. Plaintiff

2. Plaintiff, Crystal Sussen, is an adult resident of Marion County, Illinois, and claims damages as set forth below. Plaintiff Crystal Sussen is a resident of and domiciled in the city of Centralia, Marion County, Illinois. Plaintiff Crystal Sussen therefore is a citizen of the State of Illinois.

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. BD is engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, supplying, selling, marketing and introducing into interstate commerce, either directly or indirectly through third parties or related entities, its medical devices, including the PowerPort. BD is the parent company of Defendants C.R. Bard, Inc. and Bard Access Systems, Inc.
- 4. Defendant C.R. Bard, In. ("Bard") is a New Jersey corporation with its principal place of business located in Murray Hill, New Jersey. Bard is engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, supplying, selling, marketing and introducing into interstate commerce, either directly or indirectly through third parties or related entities, its medical devices, including the PowerPort. Bard, along with its subsidiaries and business units, was acquired by BD in 2017 in a transaction which integrated and subsumed Bard's business units into BD's business units. In said transaction, Bard's product offerings, including the PowerPort were taken over by and integrated into BD's Interventional segment, one of three of BD's principal business segments.
- 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 Illinois, and is a wholly owned subsidiary of BD. BAS is engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, supplying, selling, marketing and introducing into interstate commerce, either directly or indirectly through third parties or related entities, its medical devices, including the PowerPort.

- 6. BD is the nominal corporate parent of Bard and BAS, but the latter two are alter egos of BD in that BD exercises complete domination and control over Bard and BAS, having completely integrated the latter's assets, liabilities, and operations into its own such that Bard and BAS have ceased to function as separate corporate entities.
- 7. BD's control over Bard and BAS has been purposefully used to perpetrate the violation of various legal duties in contravention of Plaintiff's legal rights.
- 8. The breaches by BD of various legal duties as described herein are the proximate cause of the injuries described herein.
- 9. In addition to BD's liability for Plaintiff's damages as a result of its abuse of the corporate form, BD is directly liable as a result of its own wrongful conduct as set forth herein.
- 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.

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

III. PRODUCT BACKGROUND

- 15. The PowerPort MRI Implantable Port ("PowerPort") is one of several port-catheter devices that Defendants designed, manufactured, marketed, and sold.
- 16. According to Defendants, the PowerPort is a totally implantable vascular access device designed and intended to provide repeated access to the vascular system for the delivery of medication, intravenous fluids, parenteral nutrition solutions, blood products, and for the withdrawal of blood samples.
- 17. The PowerPort is surgically placed under the skin, intended to be left implanted, and consists of two primary components: an injection port and a polyurethane catheter.
- 18. The injection port has a raised center, or "septum," where the needle is inserted for medication delivery. The medication is carried from the port into the bloodstream through the polyurethane catheter, which is a small flexible tube that is inserted into a blood vessel.
- 19. According to Defendants' marketing materials, this polyurethane catheter "has less propensity for surface biodegradation, making it more resistant to environmental stress cracking."

- 20. The PowerPort's catheter is constructed from a polymeric formulation of polyurethane called ChronoFlex. In order to manufacture the catheters in the PowerPort, Defendants obtain an exclusive, proprietary formulation of ChronoFlex from AdvanSource Biomaterials Corporation (AdvanSource), a division of Mitsubishi Chemical America, Inc.
- 21. AdvanSource manufactures numerous biomaterials that have superior mechanical properties to ChronoFlex.
- 22. ChronoFlex is a polymeric mixture of polyurethane and barium sulfate, a compound which is visible in certain radiologic studies.
- 23. It is scientifically knowable—and Defendants were aware or reasonably should have been aware—that Barium sulfate affects the mechanical integrity of polymers like the ChronoFlex polyurethane used in the PowerPort's catheter.
- 24. First, barium sulfate reduces the mechanical integrity of the PowerPort's catheter *in vivo* as the particles of barium sulfate dissociate from the polyurethane's surface over time. This dissociation leaves microfractures and other alterations to the catheter's polymeric structure that degrade its mechanical properties.
- 25. 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—like the PowerPort's catheter—at the locus of the stripe.
- 26. Last, the homogeneity of the modified polymer affects the mechanical integrity of Defendants' catheter. Defendants' manufacturing process in constructing the PowerPort's catheter

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.

- 27. This improper mixing led to pockets of barium sulfate and entrapped air being distributed through the catheter body and on the surface.
- 28. This defect in the manufacturing process led to a heterogeneous modified polymer which included weakened areas at the loci of higher barium sulfate concentration and led to fracture of the catheter.
- 29. The roughened catheter surface leads to the collection and proliferation of microbes and/or fungi, thereby drastically increasing the risk of infection and sepsis.
- 30. Although the surface degradation and resulting risk of infection can be reduced or avoided with design modifications to encapsulate the radiopaque compound or by using a different polymer formulation, Defendants elected not to incorporate those design elements into the PowerPort.
- 31. At all times relevant, Defendants misrepresented the safety of the PowerPort system, and negligently designed, manufactured, prepared, compounded, assembled, processed, labeled, marketed, distributed, and sold the PowerPort system as safe and effective device to be surgically implanted to provide repeated access to the vascular system for the delivery of medications, intravenous fluids, parenteral nutrition solutions, and blood products.
- 32. At all times relevant to this action, Defendants knew and had reason to know, that the PowerPort was not safe for the patients for whom they were prescribed and implanted, because once implanted the device was prone to surface degradation and resulting thromboembolism, infection, mechanical failure, and a variety of other complications.

- 33. At all times relevant to this action, Defendants knew and had reason to know that patients implanted with PowerPort had an increased risk of suffering life threatening injuries, including but not limited to: death; hemorrhage; thromboembolism; infection; cardiac arrhythmia; severe and persistent pain; and perforations of tissue, vessels and organs, or the need for additional surgeries to remove the defective device.
- 34. Indeed, soon after the PowerPort was introduced to market Defendants began receiving large numbers of adverse event reports ("AERs") from healthcare providers reporting that the PowerPort was precipitating infection post-implantation. Defendants also received large numbers of AERs reporting that PowerPort was found to have perforated internal vasculature. These failures were often associated with reports of severe patient injuries such as:
 - a. hemorrhage;
 - b. cardiac/pericardial tamponade;
 - c. cardiac arrhythmia and other symptoms similar to myocardial infarction;
 - d. severe and persistent pain;
 - e. and perforations of tissue, vessels and organs; and
 - f. upon information and belief, even death.
- 35. In addition to the large number of AERs which were known to Defendants and reflected in publicly accessible databases, there are thousands of recorded device failures and/or injuries related to the Defendants' implantable port products—including the device implanted in Plaintiff—that Defendants intentionally concealed.
- 36. Defendants also intentionally concealed the severity of complications caused by the PowerPort and the likelihood of these events occurring.
 - 37. Defendants were aware or should have been aware that the PowerPort had a

substantially higher failure rate than other similar products on the market, yet Defendants failed to warn consumers of this fact.

- 38. Defendants represented through the labeling, advertising, marketing materials, seminar presentations, publications, notice letters, and regulatory submissions that the PowerPort was safe, yet fraudulently withheld and concealed information about the substantial risks of using the PowerPort.
- 39. Rather than alter the design of the PowerPort to make it safer or adequately warn patients and physicians of the dangers associated with the PowerPort, Defendants continued to actively and aggressively market the PowerPort as safe, despite their knowledge of numerous reports of infection and other serious injuries.
- 40. The conduct of Defendants, as alleged in this Complaint, constitutes willful, wanton, gross, and outrageous corporate conduct that demonstrates a conscious disregard for the safety of Plaintiff. Defendants had actual knowledge of the dangers presented by the PowerPort System, yet consciously failed to act reasonably to:
 - a. Adequately Inform or warn Plaintiff, Plaintiff's prescribing physicians, or the public at large of these dangers;
 - b. Establish and maintain an adequate quality control procedure in the PowerPort'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 PowerPort System from the market.

IV. SPECIFIC FACTUAL ALLEGATIONS AS TO PLAINTIFF

41. On or about June 24, 2011, Plaintiff underwent placement of the PowerPort, reference number 1808000, lot number REVE0353.

- 42. The device was implanted by Dr. Ravindra George for the purpose of ongoing cancer treatment due Plaintiff's malignant melanoma.
- 43. On or about November 2, 2011, Plaintiff presented to St. Mary's Good Samaritan Hospital with complaints of severe pain. Plaintiff suffered from fracture of her catheter due to the defect of the PowerPort. This resulted in a malfunctioning port that caused pain, occlusion, extravasation of fluids, thrombus, pulmonary emboli, and other potential cardiovascular injury.
- 44. On or about November 4, 2011, Plaintiff underwent excision of defective PowerPort and underwent placement of a new PowerPort, reference number 1808000, lot number REV10647.
- 45. The device was implanted by Dr. Ravindra George for the purpose of ongoing cancer treatment due to Plaintiff's malignant melanoma and was necessary due to removal of the previously fractured, defective catheter.
- 46. On or about October 28, 2015, Plaintiff presented to The Surgery Center of Centralia with a nonfunctional, defective PowerPort and it was removed at that time.
- 47. Defendants, directly or through their agents, apparent agents, servants or employees designed, manufactured, marketed, advertised, distributed and sold the PowerPorts that were implanted in Plaintiff.
- 48. The PowerPorts were correctly and properly installed by Dr. Ravindra George, in accordance with the manufacturer's instructions.
- 49. At all times, the PowerPorts were used for their intended purpose of ongoing cancer treatment and Plaintiff's healthcare providers did not place, maintain, or use the devices incorrectly such that it caused the device to malfunction.
- 50. Due to the defective devices, Plaintiff suffered damages and continues to suffer damages including, but not limited to, undergoing an unnecessary major surgery, increased risk of

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future severe and permanent injuries, severe emotional distress, ongoing fear and anxiety from future injuries, including but not limited to, bloodstream infections, pulmonary embolisms, arrhythmia, necrosis, perforations or lacerations, and other cardiac issues.

- 51. The Defendants concealed—and continue to conceal—their knowledge of the PowerPort's unreasonably dangerous risks from Plaintiff and Plaintiff's physicians.
- 52. Numerous reports of PowerPort catheter-related infection, with no medical-provider error, were recorded and reported to Defendants before the PowerPort was implanted into Plaintiff.
- 53. Despite knowledge of such injuries, Defendants continued to actively and aggressively market the PowerPort as safe. Defendants utilized marketing communications—including the Device's Instruction for Use and direct communications to Plaintiff's healthcare providers—to intentionally mislead Plaintiff's healthcare providers into believing these failures were caused by factors other than catheter design and composition.
- 54. Defendants did not adequately warn Plaintiff or Plaintiff's physicians of the true quantitative or qualitative risk of infection associated with the PowerPort.
- 55. Defendants did not adequately warn Plaintiff or Plaintiff's physicians that the risk of infection associated with the PowerPort increases the longer the product is placed in a patient.
- 56. Defendants did not adequately warn Plaintiff or Plaintiff's physicians that the function and integrity of the PowerPort should be closely monitored when the device is in place for over a year.
- 57. Defendants did not adequately communicate the extent or seriousness of the danger of infection to Plaintiff's prescribing physicians.
- 58. Rather than alter the design of their product to make it safer or warn physicians of the dangers associated with the PowerPort, Defendants chose to continue their efforts to promote the

defective product.

- 59. Plaintiff's physicians relied upon Defendants' representations—including the Instructions for Use distributed with the product implanted in Plaintiff—and advertisements to Plaintiff's detriment.
- 60. Moreover, Defendants concealed—and continue to conceal—their knowledge of the PowerPort's dangerous propensity to precipitate infection. Defendants further concealed their knowledge that the catheter design caused these failures and that these failures cause serious injuries.
- 61. Further, Defendants failed to conduct adequate and sufficient post-marketing surveillance after they began marketing, advertising, distributing, and selling the PowerPort.
- 62. As a result of Defendants' intentional actions and Defendants' wrongful conduct in designing, manufacturing, and marketing this defective product, Plaintiff and Plaintiff's physician were unaware, and could not have reasonably known or have learned through reasonable diligence, that Plaintiff had been exposed to the risks identified in this Complaint, and that those risks were the direct and proximate result of the Defendants' acts, omissions, and misrepresentations.
- 63. As a result of the 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

- 64. Defendants' failure to document or follow up on the known defects in its product, and concealment of known defects, constitutes fraudulent concealment that equitably tolls applicable statutes of limitation.
 - 65. 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 represent their PowerPort as safe for their intended use.

- 66. 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 their PowerPort, Defendants are estopped from relying on any statute of limitations defense.
- 67. Defendants furthered this fraudulent concealment through a continued and systematic failure to disclose information to Plaintiff, Plaintiff's healthcare Providers, and the public.
- 68. Defendants' acts before, during and/or after the act causing Plaintiff's injury prevented Plaintiff from discovering the injury or the cause of the injury.
- 69. Defendants' conduct, as described in this Complaint, amounts to conduct purposely committed, which Defendants must have realized was dangerous, heedless, reckless, and without regard to the consequences or Plaintiff's rights and safety.
- 70. Defendants' conduct, as described in this Complaint, also amounts to a continuing tort, and continues up through and including the date of the filing of Plaintiff's Complaint.

VI. <u>DISCOVERY RULE AND TOLLING</u>

- 71. Plaintiff incorporates the preceding paragraphs as if set out fully herein.
- 72. Plaintiff did not know or have any way of knowing about the risk of serious injury associated with Defendant's PowerPort until approximately May 2023.
- 73. Within the time period of any applicable statutes of limitations, Plaintiff could not have discovered, through the exercise of reasonable diligence, that Defendant's PowerPort is injurious to human health.
 - 74. Plaintiff could not have discovered and did not know the facts that would cause a

reasonable person to suspect the risks associated with Defendant's PowerPort; nor would a reasonable and diligent investigation by Plaintiff have disclosed that Defendant's PowerPort would cause or had caused Plaintiff's injuries.

- 75. For these reasons, all applicable statutes of limitations have been tolled by operation of the discovery rule with respect to Plaintiff's claims.
- 76. Defendants were under a continuous duty to disclose to consumers, users, and other persons coming into contact with its products, including Plaintiff, accurate safety information concerning its products and the risks associated with the use of and/or exposure to Defendant's PowerPort.
- 77. Instead, Defendants knowingly, affirmatively, and actively concealed safety information concerning PowerPort and the serious risks associated with the use of and/or exposure to its products.
- 78. Based on the foregoing, Defendants are estopped from relying on any statutes of limitations in defense of this action.

VII. <u>CAUSES OF ACTION</u> <u>COUNT I: NEGLIGENCE</u>

- 79. Plaintiff incorporates the preceding paragraphs as if set out fully herein.
- 80. Plaintiff brings this count against Defendants BD, Bard, BAS, and Does 1 through 10, inclusive.
- 81. 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.
- 82. Defendants breached their duty of care and were negligent in the design, manufacture, labeling, warning, instruction, training, selling, marketing, and distribution of the PowerPort 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 so as to avoid an unreasonable risk of harm to people in whom the PowerPort was implanted, including Plaintiff;
- c. Failing to manufacture the PowerPort so as 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 so as 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 so as 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 so as to avoid unreasonable risk of harm to people in whom the PowerPort was implanted, including Plaintiff;
- g. Failing to use reasonable care in instructing and/or warning healthcare providers, regulatory agencies, and the public of risks associated with the PowerPort, so as to avoid unreasonable risk of harm to people in whom the PowerPort was implanted, including Plaintiff;
- h. Failing to use reasonable care in the marketing and promoting of the PowerPort so as to avoid an unreasonable risk of harm to people in whom the PowerPort was implanted, including Plaintiff;
- i. Failing to use reasonable care in the labeling of the PowerPort so as to avoid an unreasonable risk of harm to people in whom the PowerPort was implanted, including Plaintiff;
- j. Failing to properly and thoroughly test the PowerPort before releasing the device to market, and/or failing to implement feasible safety improvements, so as to avoid unreasonable risk of harm to people in whom the PowerPort was implanted, including Plaintiff;
- k. Failing to properly and thoroughly analyze the data resulting from any pre-market testing of the PowerPort, so as to avoid unreasonable risk of harm to people in whom the PowerPort was implanted, including Plaintiff;
- 1. 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;
- m. Intentionally underreporting the number and nature of adverse events related to the

- PowerPort to Plaintiff, Plaintiff's prescribing physicians, or the public at large
- n. Designing, manufacturing, marketing, advertising, distributing, and selling the PowerPort to consumers, including Plaintiff and Plaintiff's healthcare providers, without an adequate warning of the significant and dangerous risks of the PowerPort and without proper instructions to avoid the harm which could foreseeably occur as a result of using the device;
- o. Negligently continuing to manufacture, market, advertise, and distribute the PowerPort after Defendants knew or reasonably should have known of its adverse effects; and
- p. Failing to act as a reasonable manufacturer, distributor, seller under the same or similar circumstances would have acted.
- 83. As a direct and proximate result of Defendants' negligence, Plaintiff has suffered severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and consortium, economic loss and damages including, but not limited to medical expenses, lost income, and other damages. These damages have occurred in the past and will continue into the future.

<u>COUNT II: NEGLIGENCE – FAILURE TO WARN</u>

- 84. Plaintiff incorporates the preceding paragraphs as if set out fully herein.
- 85. Plaintiff brings this count against Defendants BD, Bard, BAS, and Does 1 through 10, inclusive.
- 86. Defendants owed Plaintiff and Plaintiff's healthcare providers a duty to disclose whether the PowerPort had been adequately tested and of the substantial danger and/or potential risks associated with the PowerPort when used or misused in a reasonably foreseeable manner.
- 87. Defendants knew or reasonably 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.
 - 88. Defendants knew or reasonably 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.

- 89. Defendants failed to adequately warn Plaintiff and Plaintiff's prescribing physician 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.
- 90. A reasonable manufacturer, distributor, seller under the same or similar circumstances would have warned that the PowerPort was not adequately tested and/or of the substantial danger and/or potential risks associated with the PowerPort.
- 91. Plaintiff would not have consented to be implanted with the PowerPort if Defendants had provided an adequate warning that the PowerPort was not adequately tested or of the substantial danger and/or potential risks associated with the PowerPort.
- 92. Upon information and belief, Plaintiff's prescribing physician would not have implanted the PowerPort into Plaintiff if Defendants had provided an adequate warning that the PowerPort was not adequately tested or of the substantial danger and/or potential risks associated with the PowerPort.
- 93. As a direct and proximate result of Defendants' failure to warn, Plaintiff has suffered severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and consortium, economic loss and damages including, but not limited to medical expenses, lost income, and other damages. These damages have occurred in the past and will continue into the future.

COUNT III: NEGLIGENCE – DESIGN DEFECT

- 94. Plaintiff incorporates the preceding paragraphs as if set out fully herein.
- 95. Plaintiff brings this count against Defendants BD, Bard, BAS, and Does 1 through 10,

inclusive.

- 96. 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.
- 97. Defendants breached their duty of care and were negligent in the designing, manufacturing, and/or supplying of the PowerPort.
- 98. 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 PowerPort—were commercially, technologically, and scientifically attainable and feasible.
- 99. As a direct and proximate result of Defendants' negligent design, Plaintiff has suffered severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and consortium, economic loss and damages including, but not limited to medical expenses, lost income, and other damages. These damages have occurred in the past and will continue into the future.

COUNT IV: NEGLIGENCE - MANUFACTURING DEFECT

- 100. Plaintiff incorporates the preceding paragraphs as if set out fully herein.
- 101. Plaintiff brings this count against Defendants BD, Bard, BAS, and Does 1 through 10, inclusive.
- 102. Defendants operated under design and manufacturing specifications for the PowerPort, which included appropriate material content, strength, size, durability appearance, resistance levels, and that the devices did not deviate from its intended design. The manufacturing process was intended to identify any end-product products that did not meet Defendants' specifications.
 - 103. 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.

- 104. 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 specifications in that the device did not have the specified material content, size, durability, and strength.
- 105. The defective and dangerous condition of the PowerPort implanted into Plaintiff existed at the time it left Defendants' possession. The device differed from Defendants' intended result and/or from other ostensibly identical units of the same product line.
- 106. As a direct and proximate result of Defendants' negligent manufacturing, Plaintiff has suffered severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and consortium, economic loss and damages including, but not limited to medical expenses, lost income, and other damages. These damages have occurred in the past and will continue into the future.

COUNT V: STRICT LIABILITY - FAILURE TO WARN

- 107. Plaintiff incorporates the preceding paragraphs as if set out fully herein.
- 108. Plaintiff brings this count against Defendants BD, Bard, BAS, and Does 1 through 10, inclusive.
- 109. Defendants designed, set specifications, manufactured, prepared, compounded, assembled, processed, marketed, labeled, distributed, and sold the PowerPort into the stream of commerce (including commerce in the State of Illinois. Moreover, Defendants directly advertised and marketed the device to patients and the healthcare providers responsible for those patients.

Therefore, Defendants had a duty to warn of the risk of harm associated with the use of the PowerPort and to provide adequate instructions on the safe and proper use of the device.

- 110. Defendants have a continuing duty to warn of the risk of harm associated with the use of the PowerPort and to provide adequate instructions on the safe and proper use of the device as long as the PowerPort is still in use.
- 111. At the time Defendants designed, manufactured, prepared, compounded, assembled, processed, marketed, labeled, distributed, and sold the subject PowerPort into the stream of commerce, the PowerPort had potential risks or side effects that were known or knowable in light of the scientific and medical knowledge that was generally accepted in the scientific community.
- 112. The PowerPort's potential risks or side effects present a substantial danger when the PowerPort is used or misused in an intended or reasonably foreseeable manner.
- 113. No reasonable ordinary prescribing physician would have recognized the substantial danger and/or potential risks associated with the intended and foreseeable use of the PowerPort.
- 114. No reasonable ordinary consumer would have recognized the substantial danger and/or potential risks associated with the intended and foreseeable use of the PowerPort.
- 115. Defendants failed to adequately warn Plaintiff and Plaintiff's prescribing physician of the substantial danger and/or potential risks associated with the PowerPort when used or misused in a reasonably foreseeable manner.
- 116. In addition, Defendants failed to adequately warn Plaintiff and Plaintiff's prescribing physician of necessary and appropriate warnings regarding, 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 PowerPort had an increased risk of suffering life threatening injuries, including but not limited to: death; hemorrhage; thromboembolism; infection; cardiac arrhythmia; severe and persistent pain; and perforations of tissue, vessels and organs, or the need for additional surgeries to remove the defective device;
- c. The PowerPort posed a significant and higher risk than other similar devices of device failure and resulting serious injuries;
- d. The inadequate research and testing of the PowerPort;
- e. the true quantitative or qualitative risk and the true extent of infection associated with the PowerPort
- f. The risk of thromboembolism 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 infection by virtue of the catheter design and composition; and
- i. The number and nature of adverse events related to the PowerPort.
- 117. Defendants intentionally underreported the number and nature of adverse events related to the PowerPort to Plaintiff, Plaintiff's prescribing physicians, or the public at large.
- 118. Plaintiff would not have consented to be implanted with the PowerPort if Defendants had provided an adequate warning of the substantial danger and/or potential risks associated with the PowerPort
- 119. Upon information and belief, Plaintiff's prescribing physician would not have implanted the PowerPort into Plaintiff if Defendants had provided an adequate warning of the substantial danger and/or potential risks associated with the PowerPort.
 - 120. At all times relevant to this action, Defendants intentionally, recklessly, and

maliciously misrepresented the safety, risks, and benefits of the Defendants' the PowerPort, understating the risks and exaggerating the benefits in order to advance their own financial interests, with wanton and willful disregard for the rights and health of Plaintiff.

- 121. As a direct and proximate result of Defendants' lack of sufficient warning and/or instructions, Plaintiff has suffered severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and consortium, economic loss and damages including, but not limited to medical expenses, lost income, and other damages. These damages have occurred in the past and will continue into the future.
 - 122. Defendants are strictly liable in tort to Plaintiff for their wrongful conduct.

COUNT VI: STRICT LIABILITY – DESIGN DEFECT

- 123. Plaintiff incorporates the preceding paragraphs as if set out fully herein.
- 124. Plaintiff brings this count against Defendants BD, Bard, BAS, and Does 1 through 10, inclusive.
- 125. Defendants designed, manufactured, prepared, compounded, assembled, processed, labeled, marketed, distributed, and sold the PowerPort—including the device implanted into Plaintiff—as safe and effective surgically-implanted device to provide repeated access to the vascular system for the delivery of medications, intravenous fluids, parenteral nutrition solutions, and blood products.
- 126. At all times relevant, Plaintiff and Plaintiff's healthcare providers used the PowerPort for its intended use or in a way that was reasonably foreseeable to Defendants.
- 127. 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.
 - 128. At all times relevant, safer alternative designs—that would have prevented or

reduced the substantial danger and/or potential risks associated with the PowerPort—were commercially, technologically, and scientifically attainable and feasible.

- 129. At the time the PowerPort left Defendants' control, the PowerPort implanted in Plaintiff was in substantially the same condition, defective in its design, and unreasonably dangerous.
- 130. Defendants have intentionally and recklessly designed the PowerPort with wanton and willful disregard for the rights and health of the Plaintiff and, with malice, placed their economic interests above the health and safety of Plaintiff.
- 131. As a direct and proximate result of the PowerPort's design defects, Plaintiff has suffered severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and consortium, economic loss and damages including, but not limited to medical expenses, lost income, and other damages. These damages have occurred in the past and will continue into the future.
 - 132. Defendants are strictly liable in tort to Plaintiff for their wrongful conduct.

COUNT VII: STRICT LIABILITY - MANUFACTURING DEFECT

- 133. Plaintiff incorporates the preceding paragraphs as if set out fully herein.
- 134. Plaintiff brings this count against Defendants BD, Bard, BAS, and Does 1 through 10, inclusive.
- 135. Defendants designed, manufactured, prepared, compounded, assembled, processed, labeled, marketed, distributed, and sold the PowerPort—including the device implanted into Plaintiff—as safe and effective surgically-implanted device to provide repeated access to the vascular system for the delivery of medications, intravenous fluids, parenteral nutrition solutions, and blood products.
 - 136. The PowerPort that was implanted into Plaintiff deviated from its intended design

and/or varied from its intended specifications in that the device did not have the specified material content, size, durability, and strength.

- 137. Due to the manufacturing 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.
- 138. 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.
- 139. The manufacturing defects of the PowerPort implanted into Plaintiff existed at the time it left Defendants' possession and was in the substantially same condition when the device was surgically implanted into Plaintiff.
- 140. At all times relevant, Plaintiff and Plaintiff's healthcare providers used the PowerPort for its intended use or in a way that was reasonably foreseeable to Defendants.
- 141. Defendants have intentionally and recklessly manufactured the PowerPort with wanton and willful disregard for the rights and health of the Plaintiff and, with malice, placed their economic interests above the health and safety of Plaintiff.
- 142. As a direct and proximate result of the PowerPort's manufacturing defects, Plaintiff has suffered severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and consortium, economic loss and damages including, but not limited to medical expenses, lost income, and other damages. These damages have occurred in the past and will continue into the future.
 - 143. Defendants are strictly liable in tort to Plaintiff for their wrongful conduct.

COUNT VIII: COMMON LAW FRAUD

- 144. Plaintiff incorporates the preceding paragraphs as if set out fully herein.
- 145. Plaintiff brings this count against Defendants BD, Bard, BAS, and Does 1 through 10, inclusive.
- 146. Defendants owed Plaintiff and Plaintiff's healthcare providers a duty to disclose the substantial danger and/or potential risks associated with the PowerPort when used or misused in a reasonably foreseeable manner.
- 147. Defendants represented and continue to represent to the medical and healthcare community, Plaintiff, and the public 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.
- 148. Defendants' representations were, in fact, false. When Defendants made their representations, Defendants knew or reasonably should have known that the PowerPort was not adequately tested and/or dangerous or was likely to be dangerous when used or misused in a reasonably foreseeable manner.
- 149. Moreover, Defendants knew and/or had reason to know that those representations were false, and Defendants willfully, wantonly, and recklessly disregarded the inaccuracies in their representations and the dangers and health risks to users of the PowerPort.
- 150. 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 PowerPort had an increased risk of suffering life threatening injuries, including but not limited to: death; hemorrhage; thromboembolism; infection; cardiac arrhythmia; severe and persistent pain; and perforations of tissue, vessels and organs, or the need for additional surgeries to

remove the defective device;

- c. The PowerPort posed a significant and higher risk than other similar devices of device failure and resulting serious injuries;
- d. The inadequate research and testing of the PowerPort;
- e. The true quantitative or qualitative risk and the true extent of infection associated with the PowerPort
- f. The risk of infection 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 infection by virtue of the catheter design and composition; and
- i. The number and nature of adverse events related to the PowerPort.
- 151. Further, Defendants intentionally underreported the number and nature of adverse events related to the PowerPort to Plaintiff, Plaintiff's prescribing physicians, or the public at large.
- 152. Defendants' misrepresentations, concealment, and omissions of material fact regarding the PowerPort's safety and efficacy were made through but not limited to: device inserts, Instructions for Use, training materials, websites, information presented at medical and professional meetings, information disseminated by sales representatives to physicians and other medical care providers, regulatory submissions, adverse event reports, other reports, press releases, advertising campaigns, television commercials, print advertisements, billboards and other commercial media.
- 153. Defendants' misrepresentations, concealment, and omissions of material fact regarding the PowerPort's safety and efficacy were made to purposefully, willfully, wantonly, and/or recklessly mislead Plaintiff, Plaintiff's healthcare provider, and the public into recommending, prescribing, dispensing, and purchasing the PowerPort.

- 154. At the time Defendants made these false representations, Plaintiff was unaware these representations were false, reasonably believed the representations were true, and relied on these representations to his detriment.
- 155. At the time Defendants made these false representations, Plaintiff's healthcare providers were unaware these representations were false, reasonably believed the representations were true, and relied on these representations to their detriment.
- 156. Plaintiff would not have consented to be implanted with the PowerPort if Defendants had made true representations regarding the PowerPort's safety and efficacy.
- 157. Upon information and belief, Plaintiff's prescribing physician would not have implanted the PowerPort into Plaintiff if Defendants had made true representations regarding the PowerPort's safety and efficacy.
- 158. In reliance upon these false representations, Plaintiff was induced to, and did use, the PowerPort which caused severe and permanent personal injuries and damages. Defendants knew or had reason to know that Plaintiff and Plaintiff's healthcare providers had no way to determine the truth behind Defendants' concealment and omissions.
- 159. At all times relevant to this action, Defendants intentionally, recklessly, and maliciously misrepresented the safety, risks, and benefits of the Defendants' the PowerPort, understating the risks and exaggerating the benefits in order to advance their own financial interests, with wanton and willful disregard for the rights and health of Plaintiff.
- 160. Defendants' wrongful conduct constitutes fraud and deceit, and was committed and perpetrated willfully, wantonly, and/or purposefully on Plaintiff.
- 161. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff has suffered severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life,

loss of care, comfort, and consortium, economic loss and damages including, but not limited to medical expenses, lost income, and other damages. These damages have occurred in the past and will continue into the future.

COUNT IX: FRAUDULENT CONCEALMENT

- 162. Plaintiff incorporates the preceding paragraphs as if set out fully herein.
- 163. Plaintiff brings this count against Defendants BD, Bard, BAS, and Does 1 through 10, inclusive.
- 164. Throughout the relevant time period, Defendants knew that the PowerPort was defective and unreasonably unsafe for its intended purpose.
- 165. Defendants fraudulently concealed from and/or failed to disclose to or warn Plaintiff, Plaintiff's healthcare providers, and the public that the PowerPort was defective, unsafe, and unfit for its intended purposes intended and that it was not of merchantable quality.
- 166. Defendants were under a duty to Plaintiff to disclose and warn of the PowerPort's defective 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, regulatory agencies, and the general public; and
 - c. Defendants fraudulently and affirmatively concealed the PowerPort's defective nature from Plaintiff.
- 167. The facts concealed and/or not disclosed by Defendants 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.
 - 168. Defendants' misrepresentations, concealment, and omissions of material fact

regarding the PowerPort's safety and efficacy were made to mislead Plaintiff, Plaintiff's healthcare provider, and the public into recommending, prescribing, dispensing, and purchasing the PowerPort.

- 169. Plaintiff justifiably acted or relied upon the concealed and/or non-disclosed material facts to her detriment, as evidenced by her purchase and use of the PowerPort.
- 170. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff has suffered severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and consortium, economic loss and damages including, but not limited to medical expenses, lost income, and other damages. These damages have occurred in the past and will continue into the future.

COUNT X: NEGLIGENT MISREPRESENTATION

- 171. Plaintiff incorporates the preceding paragraphs as if set out fully herein.
- 172. Plaintiff brings this count against Defendants BD, Bard, BAS, and Does 1 through 10, inclusive.
- 173. Defendants owed Plaintiff and Plaintiff's healthcare providers a duty to disclose material facts including, but not limited to whether the PowerPort had been adequately tested and the substantial danger and/or potential risks associated with the PowerPort when used or misused in a reasonably foreseeable manner.
- 174. Defendants breached their duty in representing and continue to represent to the medical and healthcare community, Plaintiff, and the public that the PowerPort was tested and found to be safe and effective.
- 175. Defendants knew or reasonably should have known that the PowerPort was not adequately tested and/or dangerous or was likely to be dangerous when used or misused in a

reasonably foreseeable manner.

- 176. Defendants' misrepresentations of material facts regarding the PowerPort's safety and efficacy were made to induce Plaintiff, Plaintiff's healthcare provider, and the public into recommending, prescribing, dispensing, and purchasing the PowerPort.
- 177. A reasonable ordinary consumer would have acted or relied upon Defendants' misrepresentations of material facts regarding the PowerPort's safety and efficacy.
- 178. Plaintiff justifiably acted or relied upon Defendants' misrepresentations of material facts to her detriment and was induced to, and did use, the PowerPort which caused severe and permanent personal injuries and damages.
- 179. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff has suffered severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and consortium, economic loss and damages including, but not limited to medical expenses, lost income, and other damages. These damages have occurred in the past and will continue into the future.

COUNT XI: BREACH OF EXPRESS WARRANTY

- 180. Plaintiff incorporates the preceding paragraphs as if set out fully herein.
- 181. Plaintiff brings this count against Defendants BD, Bard, BAS, and Does 1 through 10, inclusive.
- 182. At all relevant and material times, Defendants manufactured, distributed, advertised, promoted, and sold the PowerPort.
- 183. Defendants through their officers, directors, agents, representatives, and written literature and packaging, and written and media advertisement, expressly 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 side effects, and was adequately tested and fit for its intended use.

- 184. At all relevant and material times, 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 side effects; and/or was not adequately tested and fit for its intended use.
- 185. Defendants were aware that consumers, including Plaintiff, would use the PowerPort; which is to say that Plaintiff was a foreseeable user of the PowerPort.
- 186. Plaintiff and/or 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.
- 187. At all relevant times, Plaintiff's healthcare providers used the PowerPort on Plaintiff for the purpose and in the manner that Defendants intended.
- 188. The PowerPort implanted into Plaintiff was in the substantially same condition as the time it left Defendants' possession.
- 189. At all relevant times, the PowerPort did not perform as an ordinary consumer would expect, when used as intended or in a reasonably foreseeable manner.
- 190. Plaintiff and/or Plaintiff's implanting physician reasonably relied upon Defendants' express warranties for the PowerPort and could not have reasonably discovered the breached warranty.
- 191. Defendants breached their express warranties. At the time of making such express warranties, 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 side effects; and/or was not adequately tested and fit for its intended use.

- 192. 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.
- 193. Upon information and belief, Plaintiff's healthcare providers sent notice to Defendants of the adverse event and thus, the nonconformity of the device at issue, within a reasonable time following discovery of the breach of warranty and before suit was filed.

COUNT XII: BREACH OF IMPLIED WARRANTY

- 194. Plaintiff incorporates the preceding paragraphs as if set out fully herein.
- 195. Plaintiff brings this count against Defendants BD, Bard, BAS, and Does 1 through 10, inclusive.
- 196. At all relevant and material times, Defendants manufactured, distributed, advertised, promoted, and sold the PowerPort.
- 197. At all relevant times, Defendants intended the PowerPort to be surgically implanted and used a totally implantable vascular access device to provide repeated access to the vascular system for the delivery of medication, intravenous fluids, parenteral nutrition solutions, blood products, and for the withdrawal of blood samples.
- 198. 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 side effects, and was adequately tested and fit for its intended use.

- 199. At all relevant and material times, the PowerPort did not conform to the Defendants' implied warranties because the PowerPort was not safe and fit for use by consumers; was not of merchantable quality; did produce dangerous side effects; and/or was not adequately tested and fit for its intended use.
- 200. Defendants were aware that consumers, including Plaintiff, would use the PowerPort; which is to say that Plaintiff was a foreseeable user of the PowerPort.
- 201. At all relevant times, Plaintiff and/or Plaintiff's implanting physician were in privity with Defendants.
- 202. In reliance upon Defendants' implied warranty, Plaintiff's healthcare providers implanted and used the PowerPort on Plaintiff for the purpose and in the manner that Defendants intended.
- 203. The PowerPort implanted into Plaintiff was in the substantially same condition as the time it left Defendants' possession.
- 204. Defendants breached their implied warranties to Plaintiff because the PowerPort was not safe and fit for use by consumers; was not of merchantable quality; did produce dangerous side effects; and/or was not adequately tested and fit for its intended use.
- 205. As a direct and proximate result of the breach of Defendants' implied 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.

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

COUNT XIII: ILLINOIS CONSUMER FRAUD AND DECEPTIVE BUSINESS PRACTICES ACT – ALL DEFENDANTS

- 207. Plaintiff incorporates the preceding paragraphs as if set out fully herein.
- 208. Plaintiff brings this count against Defendants BD, Bard, BAS, and Does 1 through 10, inclusive, 815 Ill. Comp. Stat. Ann Sec. 505/1, et seq.
 - 209. Plaintiff is a "consumer" pursuant to 815 Ill. Comp. Stat. Ann Sec. 505/1, et seq.
- 210. At all times relevant to this Complaint, the conduct of Defendants constitutes the "sale" of "merchandise" pursuant to 815 Ill. Comp. Stat. Ann Sec. 505/1, et seq.
- 211. As described throughout this Complaint, Defendants engaged in deceptive acts or practices and/or false advertising in the conduct of business, trade, and/or commerce related to the PowerPort.
 - 212. Defendants' deceptive acts and practices were consumer-oriented.
- 213. Defendants represented and continue to represent to the medical and healthcare community, Plaintiff, and the public 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.
- 214. Defendants' representations were, in fact, false. When Defendants made their representations, Defendants knew or reasonably should have known that the PowerPort was not adequately tested and/or dangerous or was likely to be dangerous when used or misused in a reasonably foreseeable manner.
 - 215. Moreover, Defendants knew and/or had reason to know that those representations

were false, and Defendants willfully, wantonly, and recklessly disregarded the inaccuracies in their representations and the dangers and health risks to users of the PowerPort.

- 216. In representations to Plaintiff and/or to Plaintiff's healthcare providers, Defendants fraudulently concealed and intentionally or recklessly omitted material information, 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 PowerPort had an increased risk of suffering life threatening injuries, including but not limited to: death; hemorrhage; thromboembolism; infection; cardiac arrhythmia; severe and persistent pain; and perforations of tissue, vessels and organs, or the need for additional surgeries to remove the defective device;
 - c. The PowerPort posed a significant and higher risk than other similar devices of device failure and resulting serious injuries;
 - d. The inadequate research and testing of the PowerPort;
 - e. The true quantitative or qualitative risk and the true extent of infection associated with the PowerPort;
 - f. The risk of infection 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 infection by virtue of the catheter design and

composition; and

- i. The number and nature of adverse events related to the PowerPort.
- 217. The aforesaid acts and practices constitute unfair deceptive acts or practices and/or unlawful false advertising as prohibited by 815 Ill. Comp. Stat. Ann. 505/1, et seq., including, without limitation:
 - a. Representing that goods or services have sponsorships, approval, characteristics, ingredients, uses, benefits, or quantities that they do not have; and
 - b. Representing that goods or services are of a particular standard, quality, or grade, or that good are of a particular style or model if they are of another.
- 218. As the sellers and advertisers of the PowerPort, Defendants had a statutory duty to refrain from deceptive or unfair trade practices or acts in their sale and advertisement of the PowerPort.
- 219. As a result of Defendants conduct prohibited by 815 Ill. Comp. Stat. Ann. 505/1, et seq., Plaintiff suffered the injuries described in this Complaint.

COUNT XIV: GROSS NEGLIGENCE

- 220. Plaintiff incorporates the preceding paragraphs as if set out fully herein.
- 221. Plaintiff brings this count against Defendants BD, Bard, BAS, and Does 1 through 10, inclusive.
- 222. 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 Plaintiff's healthcare providers, by making intentionally false and fraudulent misrepresentations about the safety and efficacy of the

PowerPort. Defendants intentionally concealed the material 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 healthcare providers and patients, including Plaintiff and Plaintiff's healthcare providers, regarding the cause of catheter-related infection.

- 223. Defendants had knowledge of, and were in possession of, evidence demonstrating that the PowerPort caused serious side effects. Defendants continued to market said product by providing false and misleading information with regard to the product's safety and efficacy to the regulatory agencies, the medical community, and consumers of the device, notwithstanding Defendants' knowledge of the true serious side effects of the PowerPort, Defendants failed to provide accurate information and warnings to the healthcare community that would have dissuaded physicians from surgically implanting the PowerPort and consumers from agreeing to being implanted with the PowerPort, thus depriving physicians and consumers from weighing the true risks against the benefits of prescribing and implanting the PowerPort.
- 224. Plaintiff therefore will seek to assert claims for exemplary damages at the appropriate time under governing law in an amount within the jurisdictional limits of the Court.
- 225. Plaintiff also alleges that the acts and omissions of named Defendants, whether taken singularly or in combination with others, constitute gross negligence that proximately caused the injuries to Plaintiff. In that regard, Plaintiff will seek exemplary damages in an amount that would punish Defendants for their conduct and which would deter other manufacturers from engaging in such misconduct in the future.

VIII. DEMAND FOR JURY TRIAL

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

IX. 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 consumer fraud and deceptive business practices act under 815 Ill. Comp. Stat. Ann. 505/1, et seq.
- d. Plaintiff be awarded punitive damages according to proof at the time of trial;
- e. Awarding pre-judgment and post-judgment interest to Plaintiff;
- f. Awarding the costs and the expenses of this litigation to Plaintiff; and
- g. For such other and further relief as the court may deem just and proper.

Dated: October 31, 2023

Respectfully submitted,

/s/ BRETT A. EMISON
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ATTORNEYS FOR PLAINTIFF CRYSTAL SUSSEN **CERTIFICATE OF SERVICE**

I hereby certify that on October 31st, 2023, a copy of the foregoing was served

electronically and notice of the service of this document will be sent to all parties by operation of

the Court's electronic filing system to CM/ECF participants registered to receive service in this

matter. Parties may access this filing through the Court's system.

/s/Brett A. Emison

Brett A. Emison

Attorney for Plaintiff