

**IN THE UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI**

JUDY HICKS,

Plaintiff,

vs.

Case No.

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

Defendants.

COMPLAINT

Plaintiff JUDY HICKS, by and through counsel, files this Complaint against Becton, Dickinson & Company, C.R. Bard, Inc.; Bard Access Systems, Inc.; and DOES 1 through 10 (collectively “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® M.R.I. Implantable PowerPort ISP (hereinafter “Device” or “Defective Device”).

I. PARTIES

A. Plaintiff

2. Plaintiff, JUDY HICKS, is an adult resident of Bonne Terre, Missouri, which is located in the Eastern District of Missouri, 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. 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. 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. 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. Bard, along with its subsidiaries and business units, was acquired by BD in 2017 in a transaction that integrated and subsumed Bard’s business units into BD’s business units. In said transaction, Bard’s product offerings, including the Device 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 of Missouri, 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 Device.

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 Missouri, thereby subjecting Defendants to personal jurisdiction in this action and making them all "residents" of this judicial District.

13. Defendants have and continue to conduct substantial business in the State of Missouri and in this District, distribute vascular access products in this District, receive substantial compensation and profits from sales of vascular access products in this District, and made material

omissions and misrepresentations and breaches of warranties in this District, so as to subject them to *in personam* jurisdiction in this District.

14. Consistent with the Due Process Clause of the Fifth and Fourteenth Amendments, this Court has *in personam* jurisdiction over Defendants, because Defendants are present in the State of Missouri, such that requiring an appearance does not offend traditional notions of fair and substantial justice.

III. PRODUCT BACKGROUND

15. The Bard PowerPort® M.R.I. Implantable PowerPort ISP is one of several implantable-port-catheter devices that Defendants designed, manufactured, marketed, and sold.

16. 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 medication, intravenous fluids, parenteral nutrition solutions, blood products, and for the withdrawal of blood samples.

17. 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.

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 catheter, which is a small flexible tube that is inserted into a blood vessel.

19. 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.

20. 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 type used in the Device’s catheter when it is not encapsulated, coated, or otherwise separated from polymer’s

surface.

21. 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 its mechanical properties.

22. 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.

23. Last, the homogeneity of the modified polymer affects the mechanical integrity of Defendants' catheter. 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.

24. 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.

25. This defective manufacturing process drastically increases the risk of fracture and migration and leads to the collection and proliferation of: (a) fibrinous blood products, thereby drastically increasing the risk of thromboembolism; and (b) microbes and/or fungi, thereby drastically increasing the risk of infection and sepsis.

26. This unsafe condition and the resulting risk for severe complications increases over

time as barium sulfate continually dissociates from the catheter surface, yet Defendants failed to adequately warn Plaintiff or Plaintiff's healthcare providers of this fact.

27. Although the surface degradation and resulting risk of fracture and migration, thromboembolism, and 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 Device.

28. At all times relevant, 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.

29. At all times relevant to this action, Defendants knew and had reason to know, that the Device was not adequately tested and was not safe and effective for patients implanted with the Device.

30. At all times relevant to this action, Defendants knew and had reason to know that patients implanted with Device had an unreasonable 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.

31. 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 migrating; (b) precipitating thromboembolism; and/or (c) precipitating infection. 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.

32. 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 in Plaintiff—that Defendants intentionally concealed.

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

34. 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 that these devices were fracturing and causing serious injuries due to defects in the Device's design and/or Defendants' manufacturing process.

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

36. 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 substantial risks of using the Device.

37. Rather than alter the design of the Device to make it safer or adequately warn patients and physicians 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.

38. Defendants' 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 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 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 System from the market.

IV. SPECIFIC FACTUAL ALLEGATIONS AS TO PLAINTIFF

39. A Bard Groshong MRI implantable injection port ("PowerPort") was surgically placed in Plaintiff Judy Hicks on February 17, 2021. The installed port was manufactured by Bard Access Systems. It is identified as Serial Number REDZ3192, with Lot Number 0607540.

40. The device was implanted by Plaintiff's surgeon, Dr. Theresa Cavins MD, for ongoing treatment of breast cancer.

41. The PowerPort was correctly and properly installed by Dr. Cavins, in accordance with the manufacturer's instructions.

42. The PowerPort device installed in Plaintiff was not installed in such a manner that would have caused it to compress or "pinch off."

43. The PowerPort was properly utilized by Plaintiff's treating physicians for treatment, strictly in accordance with the manufacturer's instructions.

44. At all times the PowerPort was used for its intended purpose of injecting medication into (or withdrawing blood from) Plaintiff, all medical personnel who provided treatment to Plaintiff properly followed the instructions for use of the PowerPort, including the requirement for use of certain sized needles.

45. Plaintiff and her health care providers used the PowerPort in a normal, customary, intended and foreseeable manner, namely as a surgically placed device used to make it easier to deliver medications into Plaintiff's bloodstream. Moreover, Plaintiff's health care providers did not place, maintain or use the device incorrectly such that it caused the device to malfunction.

46. Less than a month after the PowerPort implant, Plaintiff began to develop fevers due to what was diagnosed as neutropenia, and Staph aureus bacteremia due to suspected seeding from her port site.

47. On May 27, 2022, Plaintiff presented to Parkland Cancer Center to declot an embolism in relation to the catheter. Plaintiff was required to undergo surgery to remove the PowerPort.

48. On August 3, 2022, Plaintiff had to undergo another procedure to remove the PowerPort.

49. Due to the defective device, Plaintiff suffered damages and continues to suffer damages

including, but not limited to, undergoing an unnecessary major surgery, increased risk of future severe and permanent injuries, severe emotional distress, ongoing fear and anxiety from future injuries, including but not limited to, bloodstream infections.

50. Defendants, directly or through their agents, apparent agents, and employees, designed, manufactured, marketed advertised, distributed and sold the PowerPort that was implanted in Plaintiff.

51. The Defendants intentionally and knowingly concealed their knowledge of the propensity of the PowerPort catheter to erode or fracture from Plaintiff and her physicians.

52. Defendants intentionally and knowingly concealed the dangerous propensity of the PowerPort device to erode, fracture, and migrate, necessitating surgical intervention. Defendants further intentionally concealed their knowledge of the cause of these failures, and that the failures were known to cause serious injuries.

53. The Defendants knowingly and intentionally concealed their knowledge of the PowerPort's faulty design and manufacturing, and the unreasonably dangerous risks associated with the faulty device from Plaintiff, her physicians and the FDA.

54. Numerous reports of PowerPort catheter erosions, fractures, dislodgment, and/or thrombosis in the absence of physician error were recorded and reported to BAS prior to prior to the implantation of the PowerPort in Plaintiff.

55. Despite knowledge of numerous reports of catheter failure. Defendants continued to actively and aggressively market the PowerPort as safe. BAS, with BD's knowledge and consent, utilized marketing communications, including the Instruction for Use, and direct communications from sales representatives to Plaintiff's health care providers to intentionally misled her health care providers into believing the known erosions or fractures were caused only by physician error,

and no eroding or fracturing occurred due to the chemical makeup of the catheter itself, despite knowing this to be exactly the case.

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

57. Rather than correct the faulty design and manufacture of the PowerPort product to make it safer or warn physicians of the known dangers associated with the PowerPort, the Defendants knowingly and intentionally chose to continue with their sales and marketing efforts to sell their knowingly defective product to health care providers and patients such as Plaintiff.

58. Plaintiff's healthcare providers did in fact review the product insert Defendants distributed with the PowerPort prior to prescribing the product to Plaintiff.

59. Plaintiff's physician relied upon the representations, including the instructions for use distributed with the PowerPort product implanted in the Plaintiff and the product advertising to Plaintiff's detriment.

60. The Defendants knowingly concealed the dangerous propensity of the device to erode, fracture, or dislodge and create a life-threatening medical condition, such as happened to Plaintiff.

61. As a result of the intentional actions of the Defendants (including their failures to notify the FDA, the medical profession and consumers), and the Defendants' wrongful conduct in designing, manufacturing, and marketing a known defective product, Plaintiff and Plaintiff's physician were unaware, and could not have reasonably known or have learned through reasonable diligence, that Plaintiff would have been exposed to risks identified in this Complaint, and that those risks were the direct and proximate result of the Defendants' acts, omissions and intentionally and knowingly-made misrepresentations.

62. The Defendants failed to notify the FDA, the medical community and consumers of the

known defects in the PowerPort device, and knowingly and intentionally withheld information about the known defects of the device, which were known to Defendants prior to the manufacture of the device that was implanted in Plaintiff.

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

64. Due directly to the defective PowerPort, Plaintiff suffered damages and continues to suffer damages including, but not limited to, undergoing multiple surgeries, medical and hospital expenses, increased risk of future severe and permanent injuries, severe emotional distress, physical impairment, lost wages, ongoing fear of and anxiety from future injuries, including but not limited to cardiac injuries. Accordingly, Plaintiff seeks compensatory damages.

V. FRAUDULENT CONCEALMENT

65. 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.

66. 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 Device as safe for their intended use.

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

68. Defendants furthered this fraudulent concealment through a continued and systematic

failure to disclose information to Plaintiff, Plaintiff's healthcare Providers, and the public.

69. 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.

70. 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.

71. 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. CAUSES OF ACTION

COUNT I: NEGLIGENCE

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

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

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

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

- a. The Device 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 Device so as to avoid an unreasonable risk of harm to people in whom the Device was implanted, including Plaintiff;
- c. Failing to manufacture the Device so as to avoid an unreasonable risk of harm to people in whom the Device was implanted, including Plaintiff;

- d. Failing to use reasonable care in the testing of the Device so as to avoid an unreasonable risk of harm to people in whom the Device was implanted, including Plaintiff;
- e. Failing to use reasonable care in the inspecting of the Device so as to avoid an unreasonable risk of harm to people in whom the Device was implanted, including Plaintiff;
- f. Failing to use reasonable care in training its employees and healthcare providers related to the use of the Device so as to avoid unreasonable risk of harm to people in whom the Device 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 Device, so as to avoid unreasonable risk of harm to people in whom the Device was implanted, including Plaintiff;
- h. Failing to use reasonable care in instructing and/or warning Plaintiff, healthcare providers, regulatory agencies, and the public of risks that the risk for severe complications increases over time as barium sulfate continually dissociates from the catheter surface;
- i. Failing to use reasonable care in instructing and/or warning Plaintiff, healthcare providers, regulatory agencies, and the public of risks that the Device could cause serious injuries even when the Device is placed correctly;
- j. Failing to use reasonable care in the marketing and promoting of the Device so as to avoid an unreasonable risk of harm to people in whom the Device was implanted, including Plaintiff;
- k. Failing to use reasonable care in the labeling of the Device so as to avoid an unreasonable risk of harm to people in whom the Device was implanted, including Plaintiff;
- l. Failing to properly and thoroughly test the Device 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 Device was implanted, including Plaintiff;
- m. Failing to properly and thoroughly analyze the data resulting from any pre-market testing of the Device, so as to avoid unreasonable risk of harm to people in whom the Device was implanted, including Plaintiff;
- n. Failing to conduct sufficient post-market testing and surveillance of the Device, so as to avoid unreasonable risk of harm to people in whom the Device was implanted, including Plaintiff;
- o. Intentionally underreporting the number and nature of adverse events related to the

Device to Plaintiff, Plaintiff's prescribing physicians, or the public at large

- p. Designing, manufacturing, marketing, advertising, distributing, and selling the Device to consumers, including Plaintiff and Plaintiff's healthcare providers, without an adequate warning of the significant and dangerous risks of the Device and without proper instructions to avoid the harm which could foreseeably occur as a result of using the device;
- q. Negligently continuing to manufacture, market, advertise, and distribute the Device after Defendants knew or reasonably should have known of its adverse effects; and
- r. Failing to act as a reasonable manufacturer, distributor, seller under the same or similar circumstances would have acted.

76. 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.

COUNT II: NEGLIGENCE – FAILURE TO WARN

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

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

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

80. Defendants knew or reasonably should have known that the Device was not adequately tested and was dangerous or was likely to be dangerous when used or misused in a reasonably foreseeable manner.

81. Defendants knew or reasonably should have known that the users of the Device would not realize and reasonably could not realize that the Device was not adequately tested or the

substantial danger or potential risks associated with the Device when used or misused in a reasonably foreseeable manner.

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

83. 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 Device 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 Device 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 Device posed a significant and higher risk than other similar devices of device failure and resulting serious injuries;
- d. The Device could cause serious injuries even when the Device is placed correctly;
- e. The inadequate research and testing of the Device;
- f. The true quantitative or qualitative risk and the true extent of catheter fracture and migration, thromboembolism, and/ or infection associated with the Device
- g. The risk of catheter fracture and migration, thromboembolism, and/ or infection was higher in cases where the Device stays in place for longer than a year;
- h. The Device should be closely monitored in cases where it is left in place for over a year;
- i. The Device raised the risk of catheter fracture and migration, thromboembolism, and/ or infection by virtue of the catheter design and composition; and
- j. The number and nature of adverse events related to the Device.

84. A reasonable manufacturer, distributor, seller under the same or similar circumstances

would have warned that the Device was not adequately tested and/or of the substantial danger and/or potential risks associated with the Device.

85. Plaintiff would not have consented to be implanted with the Device if Defendants had provided an adequate warning that the Device was not adequately tested or of the substantial danger and/or potential risks associated with the Device.

86. Upon information and belief, Plaintiff's prescribing physician would not have implanted the Device into Plaintiff if Defendants had provided an adequate warning that the Device was not adequately tested or of the substantial danger and/or potential risks associated with the Device.

87. 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

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

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

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

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

92. At the time the Device 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.

93. 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

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 operated under design and manufacturing specifications for the Device, 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.

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

98. 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 Device that was implanted into Plaintiff. This caused the Device 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.

99. The defective and dangerous condition of the Device 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.

100. 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

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

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

103. Defendants designed, set specifications, manufactured, prepared, compounded, assembled, processed, marketed, labeled, distributed, and sold the Device into the stream of commerce. 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 Device and to provide adequate instructions on the safe and proper use of the device.

104. Defendants have a continuing duty to warn of the risk of harm associated with the use of the Device and to provide adequate instructions on the safe and proper use of the device as long as the Device is still in use.

105. At the time Defendants designed, manufactured, prepared, compounded, assembled, processed, marketed, labeled, distributed, and sold the subject Device into the stream of commerce, the Device 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.

106. The Device's potential risks or side effects present a substantial danger when the Device is used or misused in an intended or reasonably foreseeable manner.

107. No reasonable ordinary prescribing physician would have recognized the substantial danger and/or potential risks associated with the intended and foreseeable use of the Device.

108. No reasonable ordinary consumer would have recognized the substantial danger and/or potential risks associated with the intended and foreseeable use of the Device.

109. Defendants failed to adequately warn Plaintiff and Plaintiff's prescribing physician of the substantial danger and/or potential risks associated with the Device when used or misused in a reasonably foreseeable manner.

110. 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 Device 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 Device 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 Device posed a significant and higher risk than other similar devices of device failure and resulting serious injuries;
- d. The Device could cause serious injuries even when the Device is placed correctly;
- e. The inadequate research and testing of the Device;
- f. The true quantitative or qualitative risk and the true extent of catheter fracture and

migration, thromboembolism, and/ or infection associated with the Device

- g. The risk of catheter fracture and migration, thromboembolism, and/ or infection was higher in cases where the Device stays in place for longer than a year;
- h. The Device should be closely monitored in cases where it is left in place for over a year;
- i. The Device raised the risk of catheter fracture and migration, thromboembolism, and/ or infection by virtue of the catheter design and composition; and
- j. The number and nature of adverse events related to the Device.

111. Defendants intentionally underreported the number and nature of adverse events related to the Device to Plaintiff, Plaintiff's prescribing physicians, or the public at large.

112. Plaintiff would not have consented to be implanted with the Device if Defendants had provided an adequate warning of the substantial danger and/or potential risks associated with the Device

113. Upon information and belief, Plaintiff's prescribing physician would not have implanted the Device into Plaintiff if Defendants had provided an adequate warning of the substantial danger and/or potential risks associated with the Device.

114. At all times relevant to this action, Defendants intentionally, recklessly, and maliciously misrepresented the safety, risks, and benefits of the Defendants' the Device, 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.

115. 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.

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

COUNT VI: STRICT LIABILITY – DESIGN DEFECT

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

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

119. Defendants designed, manufactured, prepared, compounded, assembled, processed, labeled, marketed, distributed, and sold the Device—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.

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

121. Due to the design defects, the Device 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. At all times relevant, 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.

123. At the time the Device left Defendants' control, the Device implanted in Plaintiff was in substantially the same condition, defective in its design, and unreasonably dangerous.

124. Defendants have intentionally and recklessly designed the Device 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.

125. As a direct and proximate result of the Device'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.

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

COUNT VII: STRICT LIABILITY – MANUFACTURING DEFECT

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

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

129. Defendants designed, manufactured, prepared, compounded, assembled, processed, labeled, marketed, distributed, and sold the Device—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.

130. The Device 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.

131. Due to the manufacturing defects, the Device 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.

132. The Device'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 Device.

133. The manufacturing defects of the Device 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.

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

135. Defendants have intentionally and recklessly manufactured the Device 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.

136. As a direct and proximate result of the Device'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.

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

COUNT VIII: COMMON LAW FRAUD

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

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

140. Defendants owed Plaintiff and Plaintiff's healthcare providers a duty to disclose the substantial danger and/or potential risks associated with the Device when used or misused in a reasonably foreseeable manner.

141. Defendants represented and continue to represent to the medical and healthcare community, Plaintiff, and the public that the Device 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 Device.

142. Defendants' representations were, in fact, false. When Defendants made their representations, Defendants knew or reasonably should have known that the Device was not adequately tested and/or dangerous or was likely to be dangerous when used or misused in a reasonably foreseeable manner.

143. 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 Device.

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

- a. The Device 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 Device 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 Device 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 Device;
- e. The true quantitative or qualitative risk and the true extent of catheter fracture and migration, thromboembolism, and/ or infection associated with the Device
- f. The risk of catheter fracture and migration, thromboembolism, and/ or infection was higher in cases where the Device stays in place for longer than a year;
- g. The Device should be closely monitored in cases where it is left in place for over a year;

- h. The Device raised the risk of catheter fracture and migration, thromboembolism, and/ or infection by virtue of the catheter design and composition; and
- i. The number and nature of adverse events related to the Device.

145. Further, Defendants intentionally underreported the number and nature of adverse events related to the Device to Plaintiff, Plaintiff's prescribing physicians, or the public at large.

146. Defendants' misrepresentations, concealment, and omissions of material fact regarding the Device'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.

147. Defendants' misrepresentations, concealment, and omissions of material fact regarding the Device'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 Device.

148. 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 Plaintiff's detriment.

149. 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.

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

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

152. In reliance upon these false representations, Plaintiff was induced to, and did use, the Device 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.

153. At all times relevant to this action, Defendants intentionally, recklessly, and maliciously misrepresented the safety, risks, and benefits of the Defendants' the Device, 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.

154. Defendants' wrongful conduct constitutes fraud and deceit, and was committed and perpetrated willfully, wantonly, and/or purposefully on Plaintiff.

155. 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

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

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

158. Throughout the relevant time period, Defendants knew that the Device was

defective and unreasonably unsafe for its intended purpose.

159. Defendants fraudulently concealed from and/or failed to disclose to or warn Plaintiff, Plaintiff's healthcare providers, and the public that the Device was defective, unsafe, and unfit for its intended purposes intended and that it was not of merchantable quality.

160. Defendants were under a duty to Plaintiff to disclose and warn of the Device's defective nature because:

- a. Defendants were in a superior position to know the true quality, safety and efficacy of the Device;
- b. Defendants knowingly made false claims about the safety and quality of the Device 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 Device's defective nature from Plaintiff.

161. The facts concealed and/or not disclosed by Defendants to Plaintiffs were material facts that a reasonable person would have considered to be important in deciding whether or not to purchase and/or use the Device.

162. Defendants' misrepresentations, concealment, and omissions of material fact regarding the Device's safety and efficacy were made to mislead Plaintiff, Plaintiff's healthcare provider, and the public into recommending, prescribing, dispensing, and purchasing the Device.

163. 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 Device.

164. 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

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

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

167. Defendants owed Plaintiff and Plaintiff's healthcare providers a duty to disclose material facts including, but not limited to whether the Device had been adequately tested and the substantial danger and/or potential risks associated with the Device when used or misused in a reasonably foreseeable manner.

168. Defendants breached their duty in representing and continue to represent to the medical and healthcare community, Plaintiff, and the public that the Device was tested and found to be safe and effective.

169. Defendants knew or reasonably should have known that the Device was not adequately tested and/or dangerous or was likely to be dangerous when used or misused in a reasonably foreseeable manner.

170. Defendants' misrepresentations of material facts regarding the Device's safety and efficacy were made to induce Plaintiff, Plaintiff's healthcare provider, and the public into recommending, prescribing, dispensing, and purchasing the Device.

171. A reasonable ordinary consumer would have acted or relied upon Defendants' misrepresentations of material facts regarding the Device's safety and efficacy.

172. Plaintiff justifiably acted or relied upon Defendants' misrepresentations of material facts to her detriment and was induced to, and did use, the Device which caused severe and permanent personal injuries and damages.

173. 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

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

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

176. At all relevant and material times, Defendants manufactured, distributed, advertised, promoted, and sold the Device.

177. 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 Device 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.

178. At all relevant and material times, the Device did not conform to the Defendants' express representations because the Device 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.

179. Defendants were aware that consumers, including Plaintiff, would use the Device; which is to say that Plaintiff was a foreseeable user of the Device.

180. 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.

181. At all relevant times, Plaintiff's healthcare providers used the Device on Plaintiff for the purpose and in the manner that Defendants intended.

182. The Device implanted into Plaintiff was in the substantially same condition as the time it left Defendants' possession.

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

184. Plaintiff and/or Plaintiff's implanting physician reasonably relied upon Defendants' express warranties for the Device and could not have reasonably discovered the breached warranty.

185. Defendants breached their express warranties. At the time of making such express warranties, Defendants knew or should have known that the Device did not conform to the Defendants' express representations because the Device 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.

186. 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.

187. 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

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

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

190. At all relevant and material times, Defendants manufactured, distributed, advertised, promoted, and sold the Device.

191. At all relevant times, Defendants intended the Device 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.

192. 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 Device 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.

193. At all relevant and material times, the Device did not conform to the Defendants' implied warranties because the Device 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.

194. Defendants were aware that consumers, including Plaintiff, would use the Device; which is to say that Plaintiff was a foreseeable user of the Device.

195. At all relevant times, Plaintiff and/or Plaintiff's implanting physician were in privity with Defendants.

196. In reliance upon Defendants' implied warranty, Plaintiff's healthcare providers implanted and used the Device on Plaintiff for the purpose and in the manner that Defendants intended.

197. The Device implanted into Plaintiff was in the substantially same condition as the time it left Defendants' possession.

198. Defendants breached their implied warranties to Plaintiff because the Device 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.

199. 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.

200. 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: VIOLATION OF THE MISSOURI MERCHANDISING PRACTICES ACT--ALL DEFENDANTS

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

202. Plaintiff brings this count against Defendants BD, Bard, BAS.

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

204. Plaintiff purchased and used the PowerPort primarily for personal purposes.

205. Defendants engaged in unlawful practices including deception, false promises, misrepresentation, and/or the concealment, suppression, or omission of material facts in connection with the sale, distribution or advertisement of the PowerPort in violation of RSMo. § 407.020

206. Plaintiff purchased the PowerPort, a product that was falsely represented, as set out above, in violation of the Missouri Merchandising Practices Act and as a result, Plaintiff suffered economic damages in that the product she purchased was worth less than the product she thought she had purchased had Defendants' representations been true.

COUNT XIV: GROSS NEGLIGENCE – 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.

209. 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 Device. 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 fracture and migration, thromboembolism, and/ or infection.

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

211. Plaintiffs 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.

212. Plaintiffs also allege 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 Plaintiffs. In that regard, Plaintiffs 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.

VII. DEMAND FOR JURY TRIAL

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

VIII. 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 Plaintiffs 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 claim under the Missouri Merchandising Practices Act, RSMO § 407.010 *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: 6/30/2023

Respectfully submitted,

BUTLER & KEMPER

/s/ Thomas G. Kemper

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Attorney for Plaintiff

CERTIFICATE OF SERVICE

I hereby certify that on June 30th, 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/Tom Kemper
Tom Kemper
Attorney for Plaintiff