UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MINNESOTA

MACKENZIE JACOBSEN, Plaintiff, vs. ANGIODYNAMICS, INC., & NAVILYST MEDICAL, INC., Defendants.	Case No.: **COMPLAINT FOR DAMAGES** **1) NEGLIGENCE** **2) DESIGN DEFECT** **3) FAILURE TO WARN** **4) BREACH OF IMPLIED WARRANTY** **5) BREACH OF EXPRESS WARRANTY** **6) FRAUDULENT CONCEALMENT** **7) MINNESOTA'S DECEPTIVE TRADE PRACTICES ACT (MDTPA)** **DEMAND FOR JURY TRIAL**

COMPLAINT

COMES NOW the Plaintiff, MACKENZIE JACOBSEN, (who hereinafter shall be referred to as the "Plaintiff"), by and through her undersigned counsel, and brings this Complaint against AngioDynamics, Inc. and Navilyst Medical, Inc. (collectively, the "Defendants"), and alleges as follows:

1. This is an action for damages arising out of the failure relating to Defendants' design, development, testing, assembling, manufacturing, packaging, promoting, marketing, distribution, supplying, and/or selling the defective implantable vascular access device sold under the trade name of SmartPort (hereinafter "SmartPort", or "Defective Device").

PARTIES

2. Plaintiff, MACKENZIE JACOBSEN, is an adult resident of Dakota County, Minnesota and claims damages as set forth below.

3. Defendant AngioDynamics, Inc. ("AngioDynamics") is a Delaware corporation with its principal place of business located in Latham, New York. AngioDynamics 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 SmartPort.

4. Defendant Navilyst Medical, Inc. ("Navilyst") is a Delaware corporation with its principal place of business located in Marlborough, Massachusetts. Navilyst conducts business throughout the United States, including the State of Minnesota, and is a wholly owned subsidiary of AngioDynamics. Navilyst 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 SmartPort.

JURISDICTION AND VENUE

5. 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.

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

7. Defendants have and continue to conduct substantial business in the State of Minnesota 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.

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

PRODUCT BACKGROUND

9. In or about 2007, a company called Rita Medical Systems, Inc. received clearance via the 510(k) Premarket Notification Program from the Food and Drug Administration (FDA) to market and sell a product called Vortex® CT Port Access System.

10. Around the same time, AngioDynamics completed the acquisition of the assets and liabilities of Rita Medical Systems, Inc. and rebranded the subject product as SmartPort CT.

11. Defendants' Vascular Access Devices were designed, patented, manufactured, labeled, marketed, sold, and distributed by the Defendants at all relevant times herein.

12. The SmartPort is one of several varieties of port/catheter systems that has been designed, manufactured, marketed, and sold by Defendants.

13. According to Defendants, the SmartPort is a totally implantable vascular access device designed to provide repeated access to the vascular system for the delivery of medication, intravenous fluids, parenteral nutrition solutions, and blood products.

14. The intended purpose of the SmartPort is to make it easier to deliver medications directly into the patient's bloodstream. The device is surgically placed completely under the skin and left implanted.

15. The SmartPort is a system consisting of two primary components: an injection port and a polyurethane catheter which includes additives intended to make it radiopaque.

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

17. The SmartPort is indicated for patient therapies requiring repeated access to the vascular system. The port system can be used for infusion of medications, I.V. fluids, parenteral nutrition solutions, blood products, and for the withdrawal of blood samples.

18. The product's catheter is comprised of a polymeric mixture of polyurethane and a barium sulfate radiopacity agent.

19. Thermoplastic polyurethanes are comprised of three compounds, an isocyanate, a diol, and a molecular chain extender.

20. Manufacturers such as Defendants must acquire and qualify these components from suppliers to ensure that the polyurethane which is to be produced from them has the properties which meet the specifications disclosed to the FDA in the process of obtaining clearance to market the device.

21. The physical properties (*e.g.* tensile strength, elongation, etc.) of the finished polymer are largely dependent upon the molecular weight of the diol, which is often determined in relation to its hydroxyl number, an indication of the concentration of hydroxyl groups within a molecule.

22. Because there can be significant variation in hydroxyl numbers among diols, Manufacturers such as Defendants must closely monitor the hydroxyl numbers of units of diol which they procure from suppliers, lest the resulting polyurethane lose the desired physical properties and fail to meet the approved specifications.

23. Upon procuring a diol with a hydroxyl number which falls outside of the specifications, Defendants have a duty to assure that the process of polymerization of the components is carried out by a compounding vendor in such a way that the relative proportions of the reactants (also known as stoichiometry) is modified to achieve a finished polymer which meets specifications.

24. Such failure to meet such specifications renders the subject product "adulterated" pursuant to 501(c) of the Food, Drug & Cosmetic Act.

25. Defendants consistently failed to appropriately monitor the properties of their raw materials and to tailor the stoichiometry of the polymerization process to ensure that the physical properties of the polyurethane in its catheters were adequate.

26. As a result, the polyurethane catheters in Defendants' port products, including that which was implanted in Plaintiff, are distributed with inadequate burst strength, tensile strength, degradation resistance, and many other crucial metrics for a safe and effective medical device.

27. Barium sulfate is known to contribute to reduction of the mechanical integrity of polyurethane *in vivo* as the particles of barium sulfate dissociate from the surface of the catheter over time, leaving microfractures and other alterations of the polymeric structure and degrading the mechanical properties of the polyurethane.

28. Researchers have shown that catheter surface degradation in products featuring a radiopaque barium sulfate stripe is concentrated at the locus of the stripe.[1]

29. The mechanical integrity of barium sulfate-impregnated polyurethane is affected by the concentration of barium sulfate as well as the heterogeneity of the modified polymer.

[1] See Hecker JF, Scandrett LA. Roughness and thrombogenicity of the outer surfaces of intravascular catheters. *J Biomed Mater Res*. 1985;19(4):381-395. doi:10.1002/jbm.820190404

30. Upon information and belief, Defendants' manufacturing process in designing and constructing the catheter implanted in Plaintiff involved too high a concentration of barium sulfate particles for the polymer formulation, leading to improperly high viscosity of the admixed polyurethane before polymerization and causing improper mixing of barium sulfate particles within the polymer matrix.

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

32. The roughened catheter surface leads to the collection and proliferation of fibrinous blood products, thereby drastically increasing the risk of biofilm, infection, and sepsis.

33. Although the surface degradation and resultant mechanical failure can be reduced or avoided with design modifications (e.g. using a higher grade radiopacity compound and/or encapsulating the admixed polymer within an outer layer of pristine polymer), Defendants elected not to incorporate those design elements into the SmartPort.

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

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

36. At all times relevant to this action, Defendants knew and had reason to know that

patients implanted with a SmartPort port had an increased risk of suffering life threatening injuries, including but not limited to: death; hemorrhage; cardiac/pericardial tamponade (pressure caused by a collection of blood in the area around the heart); cardiac arrhythmia and other symptoms similar to myocardial infarction; severe and persistent pain; and perforations of tissue, vessels and organs, or the need for additional surgeries to remove the defective device.

37. Soon after the SmartPort was introduced to market, which was years before Plaintiff was implanted with her device, Defendants began receiving large numbers of adverse event reports ("AERs") from health care providers reporting that the SmartPort was fracturing post-implantation and that fractured pieces were migrating throughout the human body, including to the heart and lungs. Defendants also received large numbers of AERs reporting that SmartPort was found to have perforated internal vasculature. These failures were often associated with reports of severe patient injuries such as:

a. hemorrhage.

b. infection/sepsis;

c. cardiac/pericardial tamponade;

d. cardiac arrhythmia and other symptoms similar to myocardial infarction;

e. severe and persistent pain;

f. perforations of tissue, vessels and organs; and

g. upon information and belief, even death.

38. In addition to the large number of AERs which were known to Defendants and reflected in publicly accessible databases, there are many recorded device failures and/or injuries related to the Defendants' implantable port products which were concealed from medical professionals and patients through submission to the FDA's controversial Alternative Summary

Reporting ("ASR") program.

39. The FDA halted the ASR program after its existence was exposed by a multi-part investigative piece, prompting a widespread outcry from medical professionals and patient advocacy groups.[2]

40. Prior to the discontinuation of the ASR program, Defendants reported numerous episodes of failures of their implanted port/catheter products – including numerous episodes of infection – under the ASR exemption, thereby concealing them from physicians and patients.

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

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

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

44. Moreover, Defendants concealed—and continue to conceal—their knowledge of the SmartPort'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.

45. The conduct of Defendants, as alleged in this Complaint, constitutes willful,

[2] Christina Jewett, *Hidden Harm: Hidden FDA Reports Detail Harm Caused by Scores of Medical Devices*, Kaiser Health News (Mar. 2019)

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 SmartPort System, yet consciously failed to act reasonably to:

a. Adequately inform or warn Plaintiff, her prescribing physicians, or the public at large of these dangers;

b. Establish and maintain an adequate quality and post-market surveillance system; or

c. Recall the SmartPort System from the market.

SPECIFIC FACTUAL ALLEGATIONS AS TO PLAINTIFF

46. On or about May 3, 2022, Plaintiff underwent placement of the AngioDynamics SmartPort, model number: H7887CT80STPD0 and lot number: 5715892. The device was implanted by Dr. Kevin Nguyen M.D., at Regions Hospital in St. Paul, Minnesota for chemotherapy treatment.

47. Defendant, directly or through their agents, apparent agents, servants or employees designed, manufactured, marketed, advertised, distributed and sold the SmartPort that was implanted in Plaintiff.

48. Defendant manufactured, sold, and/or distributed the SmartPort to Plaintiff, through her doctors, to be used for vein access.

49. On or about December 6, 2022, Plaintiff experienced pain and swelling at the port site and underwent a thrombosis workup at Regions Hospital. A Doppler study indicated that Plaintiff was not experiencing a deep venous thrombosis; however, fluid was observed along the medial margin of the port.

50. On or about December 9, 2022, Plaintiff underwent a port study at Regionals Hospital

after being diagnosed with cellulitis. The study revealed significant subcutaneous edema.

51. On or about December 23, 2022, Plaintiff presented to Regions Hospital for port removal due to a port site infection. Plaintiff's medical team determined that the SmartPort was the source of the infection and required removal. Cultures from the catheter tip tested positive for Staphylococcus epidermidis. The defective device was removed by Dr. Cory R. Nordman, M.D.

52. At all times, the SmartPort was utilized and implanted in a manner foreseeable to Defendant, as Defendant generated the instructions for use and created procedures for implanting the product.

53. The SmartPort implanted into the Plaintiff was in the same or substantially similar condition as when it left the possession of Defendants, and in the condition directed by and expected by Defendant.

54. Plaintiff and her physicians foreseeably used and implanted the SmartPort, and did not misuse, or alter the SmartPort in an unforeseeable manner.

55. Defendants advertised, promoted, marketed, sold, and distributed the SmartPort as a safe medical device when Defendant knew or should have known the SmartPort was not safe for its intended purposes and that the product could cause serious medical problems.

56. Defendants had sole access to material facts concerning the defective nature of the SmartPort product and its propensity to cause serious and dangerous side effects.

57. In reliance on Defendants' representations, Plaintiff's doctor was induced to, and did use the SmartPort.

58. As a result of having the SmartPort implanted, Plaintiff has experienced significant mental and physical pain and suffering, has undergone additional surgeries, and has suffered

financial or economic loss, including, but not limited to, obligations for medical services and expenses.

59. Defendants' SmartPort was marketed to the medical community and to patients as safe, effective, reliable, medical devices; implanted by safe and effective, minimally invasive surgical techniques for the treatment of medical conditions, and as a safer and more effective as compared to the traditional products and procedures for treatment, and other competing Vascular Access Devices.

60. The Defendants have marketed and sold the Defendants' SmartPort to the medical community at large and patients through carefully planned, multifaceted marketing campaigns and strategies. These campaigns and strategies include, but are not limited to, direct to consumer advertising, aggressive marketing to health care providers at medical conferences, hospitals, private offices, and/or group purchasing organizations, and include a provision of valuable consideration and benefits to the aforementioned.

61. The injuries, conditions, and complications suffered due to Defendants' SmartPort include but are not limited to hemorrhage; infection and sepsis; fracture and migration; cardiac/pericardial tamponade; cardiac arrhythmia and other symptoms similar to myocardial infarction; severe and persistent pain; perforations of tissue, vessels and organs; and even death.

62. Defendants were negligent toward Plaintiff in the following respects:

a. Defendant failed to design and establish a safe, effective procedure for removal of SmartPort; therefore, in the event of a failure, injury, or complications it is difficult to safely remove SmartPort.

b. Defendants provided incomplete, insufficient, and misleading information to physicians in order to increase the number of physicians using SmartPort for

the purpose of increasing their sales. By so doing, Defendants caused the dissemination of inadequate and misleading information to patients, including the Plaintiff.

63. The SmartPort was utilized and implanted in a manner foreseeable to Defendants.

64. The SmartPort implanted into Plaintiff was in the same or substantially similar condition as when it left the possession of the Defendants, and in the condition directed by the Defendants.

65. At the time of her operation, Plaintiff was not informed of, and had no knowledge of the complaints, known complications and risks associated with SmartPort, including, but not limited to, the extent of seriousness of the danger of infection.

66. Plaintiff was never informed by Defendants of the defective and dangerous nature of SmartPort.

67. At the time of her implant, neither Plaintiff nor Plaintiff's physicians were aware of the defective and dangerous condition of SmartPort.

68. Plaintiff has suffered and will continue to suffer physical pain and mental anguish.

69. Plaintiff has also incurred substantial medical bills and has suffered loss of other monies due to the defective product that was implanted in her body.

COUNT I: NEGLIGENCE
(Against Defendants AngioDynamics and Navilyst)

70. Plaintiff incorporates by reference the preceding paragraphs of this First Amended Complaint as if fully set forth herein.

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

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

a. Failing to properly and thoroughly test the SmartPort before releasing the device to market, and/or failing to implement feasible safety improvements;

b. Failing to properly and thoroughly analyze the data resulting from any pre-market testing of the SmartPort;

c. Failing to conduct sufficient post-market testing and surveillance of the SmartPort;

d. Failing to comply with state and federal regulations concerning the study, testing, design, development, manufacture, inspection, production, advertisement, marketing, promotion, distribution, and/or sale of the SmartPort;

e. Designing, manufacturing, marketing, advertising, distributing, and selling the SmartPort to consumers, including Plaintiff, without an adequate warning of the significant and dangerous risks of the SmartPort and without proper instructions to avoid the harm which could foreseeably occur as a result of using the device;

f. Failing to exercise due care when advertising and promoting the SmartPort; and

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

73. As a direct, actual, and proximate cause of the Defendants' actions, omissions, and misrepresentations, Plaintiff has suffered, and will continue to suffer, severe injuries and complications which are permanent and lasting in nature, emotional distress, loss of the capacity for the enjoyment of life, medical expenses, and economic loss as alleged herein. These damages

have occurred in the past and will continue into the future.

COUNT II: STRICT PRODUCTS LIABILITY – DESIGN DEFECT

(Against Defendants AngioDynamics and Navilyst)

74. Plaintiff incorporates by reference the preceding paragraphs of this Complaint as if fully set forth herein.

75. Defendant supplied, manufactured, sold, distributed and/or otherwise placed into the stream of commerce the SmartPort implanted into Plaintiff.

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

77. The SmartPort was in a defective condition and was defective in its design in that when it left the possession of Defendants, it was not safe for its anticipated use and safer, more reasonable alternative designs existed that could have been utilized by Defendant.

78. The SmartPort was unreasonably dangerous to the user or consumer, taking into consideration the utility of said product and the risks involved in its use. The foreseeable risks associated with the design of the product exceeded any benefits associated with the design and were more dangerous than a reasonably prudent consumer such as Plaintiff and/or her physicians would expect when the product was used for its normal and intended purpose.

79. The SmartPort was expected to and did reach the consumer without substantial change in the condition in which it was supplied, distributed, sold and/or otherwise placed into the stream of commerce.

80. A reasonably prudent medical device manufacturer would have recognized the defective design of the SmartPort and would not have placed the SmartPort into the stream of commerce.

81. The design defects in the SmartPort were not known, knowable and/or reasonably

apparent to Plaintiff and/or her physician or discoverable upon any reasonable examination.

82. The SmartPort was used and implanted in the manner in which it was intended to be used and implanted by Defendants pursuant to the instructions for use and the product specifications provided by Defendants.

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

84. Additionally, at the time the SmartPort left Defendants' control, a practical and technically feasible alternative design was available that would have prevented the harm suffered by Plaintiff.

85. As a direct and proximate result of the SmartPort's aforementioned defects, the Plaintiff was caused and/or in the future will be caused to suffer severe personal injuries, pain and suffering, severe emotional distress, financial or economic loss, including, but not limited to, obligations for medical services and expenses, and other damages.

COUNT III: STRICT PRODUCTS LIABILITY – FAILURE TO WARN

(Against Defendants AngioDynamics and Navilyst)

86. Plaintiff incorporates by reference the preceding paragraphs of this Complaint as if fully set forth herein.

87. Defendants designed, set specifications, manufactured, prepared, compounded, assembled, processed, marketed, labeled, distributed, and sold the SmartPort, including the one implanted into Plaintiff, into the stream of commerce and in the course of same, directly advertised and marketed the device to consumers or persons responsible for consumers, and therefore had a duty to warn of the risk of harm associated with the use of the device and to provide adequate instructions on the safe and proper use of the device.

88. At the time Defendants designed, manufactured, prepared, compounded,

assembled, processed, marketed, labeled, distributed, and sold the device into the stream of commerce, the device was defective and presented a substantial danger to users of the product when put to its intended and reasonably anticipated use, namely as an implanted port/catheter system to administer intravenous fluids and/or medications. Defendants failed to adequately warn of the device's known or reasonably scientifically knowable dangerous propensities, and further failed to adequately provide instructions on the safe and proper use of the device.

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

90. Defendants failed to timely and reasonably warn of material facts regarding the safety and efficacy of the SmartPort and its propensity to cause the injuries suffered by Plaintiff; no reasonable health care provider, including Plaintiff's, or patient would have used the device in the manner directed, had those facts been made known to the prescribing healthcare providers or the consumers of the device.

91. The warnings, labels, and instructions provided by the Defendants at all times relevant to this action, are and were inaccurate, intentionally misleading, and misinformed and misrepresented the risks and benefits and lack of safety and efficacy associated with the device.

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

93. The SmartPort, which was designed, manufactured, prepared, compounded, assembled, processed, marketed, labeled, distributed, and sold into the stream of commerce by Defendants, was defective at the time of release into the stream of commerce due to inadequate

warnings, labeling and/or instructions accompanying the product.

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

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

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

97. Plaintiff and her health care providers used the SmartPort in a normal, customary, intended, and foreseeable manner, namely as a surgically placed device used to make it easier to deliver intravenous fluids and/or medications directly into the patient's bloodstream.

98. Upon information and belief, the defective and dangerous condition of the SmartPort, including the one implanted into Plaintiff, existed at the time they were manufactured, prepared, compounded, assembled, processed, marketed, labeled, distributed, and sold by Defendants to distributors and/or healthcare professionals or organizations.

99. Upon information and belief, the SmartPort implanted in Plaintiff was in the same condition as when it was manufactured, inspected, marketed, labeled, promoted, distributed and sold by Defendants.

100. Defendants' lack of sufficient warning and/or instructions was the direct and proximate cause of Plaintiff's serious physical injuries, and economic damages in an amount to be determined at trial. In other words, had Defendants provided adequate warnings, Plaintiff and her physicians would not have used the SmartPort.

COUNT IV: BREACH OF IMPLIED WARRANTY

(Against Defendants AngioDynamics and Navilyst)

101. Plaintiff incorporates by reference the preceding paragraphs of this First Amended Complaint as if fully set forth herein.

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

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

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

105. Privity exists between Plaintiff 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.

106. Plaintiff was the intended consumer of the device when Defendant made the warranties set forth herein, and such warranties were made to benefit Plaintiff as a patient and consumer.

107. Defendants breached these implied warranties of merchantability because the SmartPort implanted in Plaintiff was neither merchantable nor suited for its intended uses as warranted in that the device varied from its intended specifications, which included, but are not limited to, variances in the following respects:

a. Defendants' manufacturing process in constructing the catheter of the SmartPort implanted in Plaintiff involved too high of a concentration of barium sulfate particles for the polymer formulation, which led to improperly high viscosity of the

admixed polyurethane before polymerization and causing improper mixing of barium sulfate particles within the polymer matrix;

b. Defendants' knew or should have known barium sulfate is known to contribute to a reduction in the mechanical integrity of the polyurethane in its product, the SmartPort, as the barium sulfate particles dissociate from the surface of the catheter over time; and

c. These defects led to a heterogenous modified polymer that included microfractures and weakened areas at the location of the higher barium sulfate concentration that ultimately led to the collection and proliferation of blood products, thereby drastically increasing the risk of biofilm, infection, and sepsis.

108. Defendants' breaches of their implied warranties resulted in the implantation of an unreasonably dangerous and defective product, the SmartPort, into Plaintiff's body, placing said Plaintiff's health and safety in jeopardy.

109. The SmartPort was sold to Plaintiff's health care providers for implantation in patients, such as Plaintiff.

110. As a direct and proximate result of Defendants' breaches of the aforementioned implied warranties, the Plaintiff was caused and/or in the future will be caused to suffer severe personal injuries, pain and suffering, severe emotional distress, financial or economic loss, including, but not limited to, obligations for medical services and expenses, and other damages.

111. Upon information and belief, Plaintiff's healthcare providers sent notice to Defendants of the adverse event that occurred to Plaintiff and thus, the nonconformity of the SmartPort, within a reasonable period of time following discovery of the breach of warranty and before suit was filed.

COUNT V: BREACH OF EXPRESS WARRANTY
(Against Defendants AngioDynamics and Navilyst)

112. Plaintiff incorporates by reference the preceding paragraphs of this Complaint as if fully set forth herein.

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

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

115. Defendants further breached express representations and warranties made to Plaintiff, her physicians and healthcare providers with respect to the SmartPort implanted in Plaintiff in the following respects:

a. Defendant represented to Plaintiff and her physicians and healthcare providers through labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions among other ways that the Defendants' SmartPort was safe, meanwhile Defendant fraudulently withheld and concealed information about the substantial risks of serious injury associated with using the SmartPort;

b. Defendant represented to Plaintiff and her physicians and healthcare providers that the Defendants' SmartPort was as safe and/or safer than other alternative procedures and devices then on the market, meanwhile Defendant fraudulently concealed information that demonstrated that SmartPort was not safer than alternative therapies and products available on the market; and

c. Defendant represented to Plaintiff and her physicians and healthcare providers that the Defendants' SmartPort was more efficacious than other alternative procedures, therapies and/or devices. Meanwhile Defendant fraudulently concealed information, regarding the true efficacy of SmartPort.

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

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

118. Privity exists between Plaintiff 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.

119. Plaintiff was the intended consumer of the SmartPort when Defendant made the warranties set forth herein, and such warranties were made to benefit Plaintiff as a patient and consumer.

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

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

122. 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.

123. Upon information and belief, Plaintiff's healthcare providers sent notice to Defendants of the adverse event that occurred to Plaintiff and thus, the nonconformity of the SmartPort, within a reasonable period of time following discovery of the breach of warranty and before suit was filed.

COUNT VI: FRAUDULENT CONCEALMENT
(Against Defendants AngioDynamics and Navilyst)

124. Plaintiff incorporates by reference the preceding paragraphs of this Complaint as if fully set forth herein.

125. Defendants made false statements and representations to Plaintiff and her healthcare providers concerning the SmartPort product implanted in Plaintiff.

126. Defendants fraudulently concealed information with respect to the SmartPort in the following respects:

a. Defendants represented through the labeling, advertising, marketing materials, seminar presentations, publications, notice letters, and regulatory submissions that the SmartPort was safe and fraudulently withheld and concealed information about the substantial risks of using the SmartPort, including, but not limited to, its heightened propensity to precipitate infection, and cause complications;

b. Defendants represented that the SmartPort was safer than other alternative systems and fraudulently concealed information which demonstrated that the SmartPort was not safer than alternatives available on the market;

c. Defendants concealed that it knew of the SmartPort's dangerous propensity to precipitate infection and was causing complications from causes other than the manner in which the implanting physician implanted the device; and

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

127. Defendants had knowledge that the representations they made concerning the SmartPort, as stated above, were false.

128. The concealment of information by the Defendants about the risks of the SmartPort was intentional.

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

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

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

132. As a direct and proximate result of the Defendants' actions, omissions and misrepresentations, Plaintiff has suffered, and will continue to suffer, severe physical pain and injuries which are permanent and lasting in nature, emotional distress, loss of the capacity for the enjoyment of life, medical and nursing expenses, surgical expenses, and economic loss as alleged herein. These damages have occurred in the past and will continue into the future.

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

COUNT V: MINNESOTA'S DECEPTIVE TRADE PRACTICES ACT
(Against Defendants AngioDynamics and Navilyst)

134. Plaintiff incorporates by reference the preceding paragraphs of this Complaint as if

fully set forth herein.

135. The acts and practices engaged in by Defendants constitute unlawful, unfair, deceptive, and/or fraudulent business or trade practices in violation of the Minnesota's Deceptive Trade Practices Act (the "MDTPA"). Minn. Stat. Ann. § 325D.43, *et seq.*

136. This included, but was not limited to, representing that the SmartPort had characteristics or benefits it did not have and/or misrepresenting that the SmartPort was of a particular standard, namely, that it was reasonably safe for use when it was not.

137. Defendants engaged in in unlawful practices, including deception, false promises, misrepresentation, and/or concealment, suppression, or omission of material facts in connection with the sale, distribution, and/or advertisement of the SmartPort in violation of the MDTPA.

138. Plaintiff purchased the SmartPort, a product that Defendants falsely represented as having certain characteristics and benefits it did not have, *inter alia*, that it was reasonably safe for use, as further set forth above, in violation of the MDTPA.

139. Defendants further knowingly or recklessly engaged in unfair, unconscionable, deceptive, deliberately misleading, false, and/or fraudulent and deceptive acts and practices, all in violation of the MDTPA, and as further described herein, which created a likelihood of confusion or misunderstanding on Plaintiff's part with respect to the SmartPort she purchased, including, but not limited to, misrepresenting that the SmartPort was reasonably safe for use and failing to adequately disclose the substantial risk of infection and harm the product entailed given the large number of adverse events Defendants knew or should have been aware of but did not adequately disclose to Plaintiff.

140. Defendants' practices were likely to mislead consumers who acted reasonably to their detriment in purchasing the product based on Defendants' representations that it was

reasonably safe for use when it in fact was not and had a higher risk of infection due to its defective design.

141. Defendants intended for Plaintiff, Plaintiff's physicians, and other consumers to rely on their deceptive practices and representations in order to continue selling and manufacturing the SmartPort.

142. As a result of Defendants' conduct, Plaintiff suffered actual damages in that the product she purchased was misrepresented and worth far less than the product she thought she had purchased, had Defendants' representations been true.

PRAYER

WHEREFORE, Plaintiff prays for judgment against each of the Defendants as follows:

a. Judgment be entered against all Defendant on all causes of action of this Complaint;

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

c. Plaintiff be awarded general damages according to proof at the time of trial;

d. Plaintiff be awarded damages, including past, present, and future, medical expenses according to proof at the time of trial;

e. Plaintiff be awarded actual damages, attorney's fees, and costs in connection with Plaintiff's claims under the MDTPA Minn. Stat. Ann. § 325D.45 and Minn. Stat. Ann. § 325D.43, *et seq.*;

f. Awarding pre-judgment and post-judgment interest to the Plaintiff;

g. Awarding the costs and the expenses of this litigation to the Plaintiff.

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

DEMAND FOR JURY TRIAL

Plaintiff hereby demands trial by jury on all issues.

Respectfully submitted,

/s/ Noah C. Lauricella

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