IN THE UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF CALIFORNIA

'25CV0412 JO VET

IN RE: ANGIODYNAMICS, INC., AND NAVILYST MEDICAL, INC., PORT CATHETER PRODUCTS LIABILITY LITIGATION	Case No. 3:24-MD-03125-JO-VET MDL No. 3125 JUDGE JINSOOK OHTA
JESSICA MALAGON, Plaintiff, vs. ANGIODYNAMICS, INC., & NAVILYST MEDICAL, INC., Defendants.	**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) FLORIDA DECEPTIVE AND UNFAIR TRADE PRACTICES ACT (FDUTPA)** **DEMAND FOR JURY TRIAL**

COMPLAINT

Plaintiff files this Complaint pursuant to CMO No. 1, and is bound by the rights, protections, privileges, and obligations of that CMO. In accordance with CMO No. 1, Plaintiff hereby designates the United States District Court for the Middle District of Florida as the place of remand as this case may have originally been filed there pursuant to 28 U.S.C. §1391.

COMES NOW Plaintiff, Jessica Malagon, (hereinafter "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 failures 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, Jessica Malagon is an adult resident and citizen of Broward County, Florida, 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 Florida, 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 the United States District Court for the Middle District of Florida

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 the District, and (b) Defendants' products are produced, sold to, and consumed by individuals in the State of Florida, thereby subjecting Defendants to personal jurisdiction in this action and making them all "residents" of the judicial District.

7. Defendants have and continue to conduct substantial business in the State of Florida and in the Middle District of Florida, distribute vascular access products in that District, receive substantial compensation and profits from sales of vascular access products in that District, and made material omissions and misrepresentations and breaches of warranties in the District, so as to subject them to *in personam* jurisdiction in the Middle District of Florida.

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 Florida, 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. 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.

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

21. The design of the product at issue in this case includes a catheter with a stripe containing a stripe with a higher concentration of barium sulfate than the rest of the catheter.

22. According to relevant medical literature, such design is proven to have a higher rate of fracture than catheters without the barium-loaded stripe.

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

24. 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.

25. 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 as well as sections of the catheter lumen which contain more than 30% barium sulfate by weight, reducing the catheter strength at those loci.

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

[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

27. 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 polyurethane), Defendants elected not to incorporate those design elements into the SmartPort.

28. 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.

29. 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.

30. 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; infection; 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.

31. 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. cardia/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.

32. 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.

33. 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]

34. Prior to the discontinuation of the ASR program, Defendants reported numerous

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

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.

35. 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.

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

37. 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.

38. 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.

39. The conduct of Defendants, as alleged in this Complaint, constitutes willful, wanton, gross, and outrageous corporate conduct that demonstrates a conscious disregard for the safety of Plaintiff. Defendants had actual knowledge of the dangers presented by the SmartPort System, yet consciously failed to act reasonably to:

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

41. Establish and maintain an adequate quality and post-market surveillance

system; or

42. Recall the SmartPort System from the market.

SPECIFIC FACTUAL ALLEGATIONS AS TO PLAINTIFF

43. On or about June 10, 2020, Plaintiff underwent placement of an AngioDynamics SmartPort product, reference number H787CT66LTPDVI1, lot number 5585461. The device was implanted by Dr. Glenn William Stambo, M.D., at AdventHealth Carrollwood in Tampa, Florida, for the purpose of providing chemotherapy.

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

45. Defendants manufactured, sold, and/or distributed the SmartPort to Plaintiff, through her doctors, to be used for administration of medications and fluids.

46. On or about April 4, 2021, Plaintiff presented herself to the emergency department at John's Hopkins All Children's Hospital, in St. Petersburg, FL, with complaints of fever and bilaterial hip pain. Blood cultures were drawn and were positive for Escherichia coli. Plaintiff's medical team determined that the SmartPort was the source of the infection and that she should be admitted to John's Hopkins and prescribed antibiotics. Her hip pain was determined to be unrelated to the infection. The infection improved over the next five days and Plaintiff was discharged on April 9, 2021, with instructions to return to the hospital should her symptoms reappear.

47. On or about March 17, 2023, Plaintiff presented herself to Tampa GuideWell Emergency Doctors with complaints of a fever and a suspected infection due to her SmartPort. Her medical team prescribed antibiotics to treat a bacterial infection.

48. In the evening of March 17, 2023, when her symptoms continued, she presented herself to the emergency department at St. Joseph's Hospital in Tampa, Florida. Plaintiff's medical team diagnosed her with sepsis due to an infection arising from the SmartPort. Plaintiff was admitted to the hospital to treat the infection and was later discharged on March 21, 2023.

49. On or about December 19, 2023, Plaintiff's defective port was removed by Dr. Ahmed Osman at Broward Health in Fort Lauderdale, Florida. Plaintiff's port was removed due to Plaintiff's history of port related infections, and Plaintiff was experiencing fevers following her port catheter infusions.

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

51. The SmartPort implanted in 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 Defendants.

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

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

54. 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.

55. In reliance on Defendants' representations, Plaintiff's doctors were induced to, and did use the SmartPort.

56. 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 to limited to, obligations for medical services and expenses.

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

58. 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.

59. The injuries, conditions, and complications suffered due to Defendants' SmartPort include, but are not limited to, fracture and leakage; necrosis; infection; blood clots; 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.

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

a. Defendants 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.

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

62. 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.

63. 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.

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

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

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

67. 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)

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

69. 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.

70. 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.

71. 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.

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

COUNT II: STRICT PRODUCTS LIABILITY – DESIGN DEFECT

(Against Defendants AngioDynamics and Navilyst)

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

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

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

76. 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 Defendants.

77. 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 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.

78. 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.

79. A reasonably prudent medical device manufacturer would not have placed the SmartPort with its defective design into the stream of commerce.

80. 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.

81. 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.

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

83. 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)

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

fully set forth herein.

85. 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.

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

87. 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.

88. 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.

89. 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.

90. 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.

91. 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.

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

93. 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.

94. 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 medications directly into the patient's bloodstream.

95. 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.

96. 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.

97. 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)

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

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

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

101. 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 her.

102. 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.

103. 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.

104. 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.

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

106. 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.

107. 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)

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

109. 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.

110. 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.

114. 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. Defendants 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 Defendants fraudulently withheld and concealed information about the substantial risks of serious injury associated with using SmartPort;

b. Defendants 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 Defendants fraudulently concealed information that demonstrated that SmartPort was not safer than alternative therapies and products available on the market; and

c. Defendants 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 Defendants fraudulently concealed information, regarding the true efficacy of SmartPort.

111. 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.

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

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

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

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

116. 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.

117. 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)

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

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

120. Defendants engaged in and 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.

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

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

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

124. 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.

125. 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.

126. 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.

127. The Defendants acted with oppression, fraud, and malice towards Plaintiff, who

accordingly requests that the trier of fact, in the exercise of its sound discretion, award additional damages for the sake of example and for the purpose of punishing Defendants for their conduct, in an amount sufficiently large to be an example to others, and to deter this Defendants and others from engaging in similar conduct in the future.

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

COUNT VII: FLORIDA DECEPTIVE AND UNFAIR TRADE PRACTICES ACT

(Against Defendants AngioDynamics and Navilyst)

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

130. Plaintiff purchased the SmartPort, and the product was intended for personal use.

131. The acts and practices engaged in by Defendants as outlined above constitute unlawful, unfair, and/or fraudulent business practices in violation of the Florida Deceptive and Unfair Trade Practices Act, (FDUTPA), Florida Statute § 501.201, *et seq*.

132. 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, and/or advertisement of the SmartPort in violation of the FDUTPA.

133. Plaintiff purchased the SmartPort, a product that was falsely represented, as set out above, in violation of the FDUTPA, and as a result Plaintiff suffered economic damages in that the product purchased was misrepresented to be reasonably safe for use and was worth less than the product Plaintiff thought they 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 Defendants 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 costs and attorney's fees in connection with Plaintiff's Florida Deceptive and Unfair Trade Practices Act (FDUTPA) claim under Florida Statute §501.201, *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,

HOLMAN SCHIAVONE, LLC

By: */s/ Anne Schiavone*
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