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IN THE UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF CALIFORNIA

LAURA SCHULTZ 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** **DEMAND FOR JURY TRIAL**

COMES NOW Plaintiff LAURA SCHULTZ, by and through the undersigned counsel, and for her 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 LifePort (hereinafter "LifePort" or "Defective Device").

PARTIES

2. Plaintiff LAURA SCHULTZ ("Plaintiff" or "LAURA SCHULTZ") is an adult citizen and resident of Oakdale, California, and claims damages as set forth below. Plaintiff was implanted with the Defendants' LifePort Product for chemotherapy for her Breast cancer; Plaintiff sustained serious injuries due to the defective LifePort and Defendants' tortious conduct, as shown below in the main body of this Complaint.

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 LifePort.

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 California, 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 LifePort.

JURISDICTION AND VENUE

5. Ther 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 California, 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 California 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 California, such that requiring an appearance does not offend traditional notices of fair and substantial justice.

PRODUCT BACKGROUND

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

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

11. According to Defendants, the LifePort 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.

12. The intended purpose of LifePort 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.

13. Upon information and belief, the LifePort in this case is a system consisting of two primary components: an injection port and a silicone catheter which includes additives intended to make it radiopaque.

14. 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.

15. The LifePort 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.

16. Upon information and belief, the product's catheter is comprised of a polymeric mixture of silicone and a barium sulfate radiopacity agent.

17. Barium sulfate is known to contribute to reduction of the mechanical integrity of silicone *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 silicone.

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

19. 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.

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

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

22. When the barium sulfate degrades *in vivo*, it can cause cracks, fissures, and/or pitting on the surface of the silicone catheter, which in turn, can cause that catheter fracture. The aforementioned changes to the surface of the silicone catheter caused by *in vivo* degradation of barium sulfate can also cause thrombosis by facilitating the collection/proliferation of fibrinous material circulating in one's bloodstream.

23. 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 silicone before polymerization and causing improper mixing of barium sulfate particles within the polymer

[1] See Shecker 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

matrix.

24. This defect in the manufacturing process led to a heterogeneous modified polymer which led to an irregular catheter surface replete with fissures, 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.

25. The roughened catheter surface leads to the collection and proliferation of fibrinous blood products, thereby drastically increasing the risk of the development of thrombosis.

26. 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 silicone), Defendants elected not to incorporate those design elements into the LifePort.

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

28. At all times relevant to this action, Defendants knew and had reason to know, that the LifePort was not safe for the patients for whom they were prescribed and implanted, because once implanted the device was prone to fracturing with a subsequent migration of the fractured pieces within one's body, perforating internal vasculature, and otherwise malfunctioning, and facilitating the development of thrombosis.

29. At all times relevant to this action, Defendants knew and had reason to know that patients implanted with a LifePort port had an increased risk of suffering life threatening injuries, including but not limited to: death; infection; thrombosis; 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.

30. Soon after the LifePort was introduced to market, which, upon information and belief, was years before Plaintiff was implanted with her device, Defendants began receiving large numbers of adverse event reports ("AERs") from health care providers reporting LifePort-related fracture and migration, and LifePort-related thrombosis. These failures were often associated with reports of severe patient injuries such as:

1. hemorrhage;
2. infection/sepsis;
3. cardia/pericardial tamponade;
4. cardiac arrhythmia and other symptoms similar to myocardial infarction;
5. severe and persistent pain;
6. perforations of tissue, vessels and organs; and
7. upon information and belief, even death.

31. 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.

32. 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]

33. Prior to the discontinuation of the ASR program, Defendants reported numerous episodes of failures of their implanted port/catheter products – including numerous episodes of port-a-cath fracture, fracture and migration, and the port-a-cath-related thrombosis – under the ASR exemption, thereby concealing them from physicians and patients.

34. Defendants were aware or should have been aware that the LifePort had a substantially higher failure rate than other similar products on the market, yet Defendants failed to

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

warn consumers of this fact.

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

36. Rather than alter the design of the LifePort to make it safer or adequately warn physicians of the dangers associated with the LifePort, Defendants continued to actively and aggressively market the LifePort as safe, despite their knowledge of numerous reports of catheter-related fracture, fracture and migration, thrombosis, and associated injuries.

37. Moreover, Defendants concealed—and continue to conceal—their knowledge of the LifePort's dangerous propensity to precipitate fracture, fracture and migration, and thrombosis. Defendants further concealed their knowledge that the catheter design caused these failures and that these failures cause serious injuries.

38. 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 LAURA SCHULTZ. Defendants had actual knowledge of the dangers presented by the LifePort 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 LifePort System from the market.

SPECIFIC FACTUAL ALLEGATIONS AS TO PLAINTIFF

39. On or about February 4, 2009, LAURA SCHULTZ underwent placement of an AngioDynamics LifePort product, Catalog No.: LPS5013, LOT number 941892.

40. Upon information and belief, the device was implanted by Dr. L Ray Cimino, M.D., at Stanislaus Surgical Hospital, in Modesto, California, for chemotherapy treatment for Plaintiff's Breast Cancer.

41. Defendants, directly or through their agents, apparent agents, servants, or employees designed, manufactured, marketed, advertised, distributed, and sold the LifePort that was implanted

in LAURA SCHULTZ.

42. Defendants manufactured, sold, and/or distributed the LifePort to LAURA SCHULTZ, through her doctors, to be used for vein access.

43. Upon information and belief, in November 2009, Plaintiff presented to Stanislaus Surgical Hospital in Modesto, California, to be evaluated for irregular heart rate. LAURA SCHULTZ's medical team determined at that time that she needed to be admitted overnight.

44. On or about January 14, 2010, LAURA SCHULTZ returned to Stanislaus Surgical Hospital. After further review of the imaging, it was determined that defective port was thrombosed and that it fractured, and that the fractured piece migrated into her right atrium. Upon information and belief, the fractured and thrombosed port (namely the LifePort reservoir and the parts of the dislodged catheter) was then removed by Dr. Stephen Liu, M.D., at the same facility.

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

46. The LifePort implanted in LAURA SCHULTZ 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.

47. LAURA SCHULTZ and her physicians foreseeably used and implanted the LifePort and did not misuse or alter the LifePort in an unforeseeable manner.

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

49. Defendants had sole access to material facts concerning the defective nature of the LifePort product and its propensity to cause serious and dangerous side effects, such as catheter fracture, fracture and migration, and the catheter-related thrombosis.

50. In reliance on Defendants' representations, LAURA SCHULTZ's doctors were induced to, and did use the LifePort.

51. As a result of having the LifePort implanted, LAURA SCHULTZ has experienced

significant 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.

52. Defendants' LifePort 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 safer and more effective as compared to the traditional products and procedures for treatment and other competing Vascular Access Devices.

53. The Defendants have marketed and sold the Defendants' LifePort 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.

54. The injuries, conditions, and complications suffered due to Defendants' LifePort include, but are not limited to, infection; thrombosis; necrosis; fracture and leakage; 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.

55. Defendants were negligent toward LAURA SCHULTZ in the following respects:

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

b. Defendants provided incomplete, insufficient, and misleading information to physicians in order to increase the number of physicians using LifePort for the purpose of increasing their sales. By so doing, Defendants caused the dissemination of inadequate and misleading information to patients, including LAURA SCHULTZ.

56. The LifePort was utilized and implanted in a manner foreseeable to Defendants.

57. The LifePort implanted into LAURA SCHULTZ 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.

58. At the time of her operation, LAURA SCHULTZ was not informed of, and had no knowledge of the complaints, known complications and risks associated with LifePort, including, but not limited to the extent and seriousness of the dangers of catheter-related fracture, fracture and migration, and catheter-related thrombosis.

59. LAURA SCHULTZ was never informed by Defendants of the defective and dangerous nature of LifePort.

60. At the time of her implant, upon information and belief, neither LAURA SCHULTZ nor her physicians were aware of the defective and dangerous condition of the LifePort.

61. As a result of the Defendants' actions and inactions, LAURA SCHULTZ has been injured and has sustained economic and non-economic damages, both in the past and future, including for pain and suffering and medical expenses.

TOLLING OF THE STATUTE OF LIMITATIONS

62. Plaintiff asserts all applicable statutory and common law rights and theories related to the tolling or extension of any applicable statutes of limitations, including equitable tolling, delayed discovery, discovery rule and/or fraudulent concealment.

63. The discovery rule applies to toll the running of the statute of limitations until Plaintiff knew, or through the exercise of reasonable care and diligence should have known, of her injuries, the cause of her injuries, and the tortious nature of the wrongdoing that caused her injuries.

64. The nature of Plaintiff's injuries, damages, or their causal relationship to Defendants' conduct was not discovered, and through reasonable care and due diligence could not have been discovered, until a date within the applicable statute of limitations for filing Plaintiff's claims.

65. The running of the limitations period is also equitably tolled. Defendants are estopped from relying on California statutes of limitation or repose by virtue of their fraudulent concealment, through affirmative misrepresentations and omissions to Plaintiff regarding the safety of LifePort. Based on information and belief, Defendants affirmatively withheld and/or

misrepresented facts concerning LifePort's safety. As a result of the Defendants' misrepresentations and concealment, Plaintiff was unaware, and could not have known or have learned through reasonable diligence, of facts related to Defendants' misrepresentations or omissions, that Plaintiff had been exposed to the risks alleged herein, or that those risks were the direct and proximate result of the wrongful acts and/or omissions of the Defendants.

66. Given the Defendants' intentional, knowing, willful, reckless and/or careless misrepresentations and/or omissions regarding LifePort's substantial safety risks and dangerous propensities—information over which the Defendants had exclusive control—and because Plaintiff could not reasonably have known of LifePort's substantial safety risks and dangerous propensities, Defendants are estopped from relying on any statutes of limitations or repose that might otherwise be applicable to the claims asserted herein.

COUNT I: NEGLIGENCE
(Against Defendants AngioDynamics and Navilyst)

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

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

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

a. Failing to properly and thoroughly test the LifePort 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 LifePort;

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

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 LifePort;

e. Designing, manufacturing, marketing, advertising, distributing, and selling the LifePort to consumers, including Plaintiff, without an adequate warning of the significant and dangerous risks of the LifePort 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 LifePort; and

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

70. As a direct, actual, and proximate cause of the Defendants' actions, omissions, and misrepresentations, Plaintiff has been injured and has sustained economic and non-economic damages, both in the past and future, including for pain and suffering and medical expenses.

71. In performing the foregoing acts, omissions, and misrepresentations, Defendants acted with gross negligence, fraudulently, and with malice.

COUNT II: STRICT PRODUCTS LIABILITY – DESIGN DEFECT

(Against Defendants AngioDynamics and Navilyst)

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

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

74. The LifePort implanted into Plaintiff was not reasonably safe for its intended use and was defective with respect to its design.

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

76. The LifePort 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.

77. The LifePort 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.

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

79. The design defects in the LifePort were not known, knowable and/or reasonably apparent to Plaintiff and/or her physicians or discoverable upon any reasonable examination.

80. The LifePort 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.

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

82. As a direct, actual, and proximate cause of the Defendants' actions, omissions, and misrepresentations, Plaintiff has been injured and has sustained economic and non-economic damages, both in the past and future, including for pain and suffering and medical expenses.

83. In performing the foregoing acts, omissions, and misrepresentations, Defendants acted with gross negligence, fraudulently, and with malice.

COUNT III: STRICT PRODUCTS LIABILITY – FAILURE TO WARN
(Against Defendants AngioDynamics and Navilyst)

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

85. Defendants designed, set specifications, manufactured, assembled, processed, marketed, labeled, distributed, and sold the LifePort, including the one implanted in Plaintiff, into the stream of commerce and in the course of the 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.

86. 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.

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

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

89. The warnings, labels, and instructions provided by Defendants at all times relevant to the 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.

90. 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.

91. The LifePort, 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.

92. 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.

93. Defendants intentionally underreported the number and nature of adverse events associated with fracture and migration of the devices and the catheter-related thrombosis to the Plaintiff's health care providers, as well as the FDA.

94. Upon information and belief, 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.

95. Plaintiff and her health care providers used the LifePort 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.

96. Upon information and belief, the defective and dangerous condition of the LifePort 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.

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

98. Defendants' lack of sufficient warnings 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. Had Defendants provided adequate warnings, Plaintiff and her physicians would not have used the LifePort.

99. As a direct, actual, and proximate cause of the Defendants' actions, omissions, and misrepresentations, Plaintiff has been injured and has sustained economic and non-economic damages, both in the past and future, including for pain and suffering and medical expenses.

100. In performing the foregoing acts, omissions, and misrepresentations, Defendants acted with gross negligence, fraudulently, and with malice.

COUNT IV: BREACH OF IMPLIED WARRANTY

(Against Defendants AngioDynamics and Navilyst)

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

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

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

104. Plaintiff, individually and/or by and through her physician, relied upon Defendants'

implied warranties of merchantability in consenting to have the LifePort implanted in her body.

105. Privity exists between Plaintiff and the 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.

106. Plaintiff was the intended consumer of the device when Defendants 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 LifePort 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 LifePort 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 silicone 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 silicone in their product, the LifePort, 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 catheter fracture and the migration of the fractured pieces within Plaintiff's body, and to the collection and proliferation of fibrinous material present in Plaintiff's bloodstream, thereby drastically increasing the risk of development of the catheter-related thrombosis and development of subsequent thrombosis. Defendants' breaches of their implied warranties resulted in the implantation of an unreasonably dangerous and

defective product, the LifePort, into Plaintiff's body, placing Plaintiff's health and safety in jeopardy.

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

109. As a direct, actual, and proximate cause of the Defendants' actions, omissions, and misrepresentations, Plaintiff has been injured and has sustained economic and non-economic damages, both in the past and future, including for pain and suffering and medical expenses.

110. Upon information and belief, Plaintiff's health providers sent notice to Defendants of the adverse event that occurred to Plaintiff and thus, the nonconformity of the LifePort, 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)

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

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

113. The LifePort 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 LifePort 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' LifePort was safe. Meanwhile, Defendants fraudulently withheld and concealed information about the substantial risks of serious injuries associated with using LifePort;

b. Defendants represented to Plaintiff and her physicians and healthcare providers that the Defendants' LifePort was as safe and/or safer than other alternative procedures and devices then on the market, but fraudulently concealed information that demonstrated that LifePort 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 LifePort was more efficacious than other alternative procedures, therapies and/or devices. Meanwhile, Defendants fraudulently concealed information regarding the true efficacy of the LifePort.

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

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

117. Privity exists between Plaintiff and the 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.

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

119. At all relevant times, the LifePort was used on Plaintiff by her physicians for the purpose and in the manner intended by Defendants.

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

121. As a direct, actual, and proximate cause of the Defendants' actions, omissions, and misrepresentations, Plaintiff has been injured and has sustained economic and non-economic damages, both in the past and future, including for pain and suffering and medical expenses.

122. 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

LifePort, 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)

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

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

125. Defendants engaged in and fraudulently concealed information with respect to the LifePort in the following respects:

a. Defendants represented through the labeling, advertising, marketing materials, seminar presentations, publications, notice letters, and regulatory submissions that the LifePort was safe and fraudulently withheld and concealed information about the substantial risks of using the LifePort, including, but not limited to its heightened propensity to precipitate catheter fracture and the subsequent migration of the fractured pieces within one's body, and the development of catheter-related thrombosis, and cause complications;

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

c. Defendants concealed that they knew of the LifePort's dangerous propensity to precipitate catheter fracture and the subsequent migration of the fractured pieces within one's body, and the development of catheter-related thrombosis, 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.

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

127. Defendants had sole access to material facts concerning the dangers and unreasonable risks of the LifePort.

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

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

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

131. As a direct and proximate result of the Defendants' actions, omissions and misrepresentations, Plaintiff has been injured and has sustained economic and non-economic damages, both in the past and future, including for pain and suffering and medical expenses.

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

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

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. Declare, adjudge, and decree Defendants' conduct as alleged herein to be unlawful and that Defendants are liable to Plaintiff;

f. For disgorgement of profits;

g. For punitive or exemplary damages according to proof;

h. Plaintiff be awarded costs and attorney's fees;

i. Awarding pre-judgment and post-judgment interest to Plaintiff; and

j. 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.

Dated: September 9, 2024

Respectfully submitted,

KERSHAW TALLEY BARLOW

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