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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF CALIFORNIA

IN RE: ANGIODYNAMICS, INC., AND NAVILYST MEDICAL, INC., PORT CATHETER PRODUCTS LIABILITY LITIGATION	Case No.: 3:24-md-030125-JO-VET MDL No. 3125 JUDGE JINSOOK OHTA '26CV1440 JO VET
FRANK WHITTEMORE, as successor-in-interest to NANCY WHITTEMORE, deceased, Plaintiff v. ANGIODYNAMICS, INC., & NAVILYST MEDICAL, INC., Defendants.	**COMPLAINT AND JURY DEMAND**

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, Southern District of California as Plaintiff's venue as this case may have originally been filed there pursuant to 28 U.S.C. § 1391.

COME NOW Plaintiff, Frank Whittemore, individually and as Successor in-Interest to Nancy Whittemore, as well Lisa Piancone and Nicholas Whittemore individually, by and through undersigned counsel, and bring this Complaint against AngioDynamics, Inc., and Navilyst Medical, Inc., (collectively, the "Defendants"), and allege 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, Frank Whittemore, is Decedent's husband, and successor-in-interest to Nancy Whittemore, ("Decedent") who died intestate. As such, Plaintiff is lawfully entitled to, and does, maintain this action, and claims damages as set forth below.

3. Nancy Whittemore at the time of her death, was an adult resident and citizen of San Diego County, California.

4. Lisa Piancone is the surviving daughter of Nancy Whittemore.

5. Nicholas Whittemore is the surviving daughter of Nancy Whittemore.

6. Plaintiffs Frank Whittemore, Nancy Whittemore, Nicholas Whittemore are asserting claims for wrongful death of Nancy Whittemore. Additionally, Frank Whittemore is pursuing a survival claim on behalf of Nancy Whittemore as the successor in-interest.

7. References to "Plaintiffs" hereinafter shall refer to Frank Whittemore, Lisa Piancone, and Nicholas Whittemore collectively.

8. Defendant AngioDynamics, Inc. ("AngioDynamics") is a Delaware corporation with its principal place of business located in Latham, New York. AngioDynamics conducts business throughout the United States, including the State of California. 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.

9. 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 SmartPort.

JURISDICTION AND VENUE

10. 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 costs.

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

12. 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.

PRODUCT BACKGROUND

13. 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.

14. 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.

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

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

17. 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.

18. 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.

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

20. 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.

21. 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.

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

23. 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.

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

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

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

27. 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.

28. Upon information and belief, Defendants' manufacturing process in designing and constructing the specific catheter implanted in Decedent 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 matrix.

29. 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.

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

31. Although the surface degradation and resultant mechanical failure can be reduced or avoided with design modifications (e.g., using a higher grade radiopacity

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[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

compound and/or encapsulating the admixed polymer within the silicone), Defendants elected not to incorporate those design elements into the SmartPort.

32. 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.

33. 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.

34. 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; thrombus; 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.

35. Soon after the SmartPort was introduced to market, which was years before Decedent 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. thrombus;

d. cardiac/pericardial tamponade;

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

f. severe and persistent pain;

g. perforations of tissue, vessels and organs; and

h. upon information and belief, even death.

36. 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.

37. 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]

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

39. 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.

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

41. Rather than alter the design of the SmartPort to make it safer or adequately

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

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.

42. Moreover, Defendants concealed—and continue to conceal—their knowledge of the SmartPort's dangerous propensity to precipitate injuries, including, but not limited to, infection, thrombus, and catheter fracture. Defendants further concealed their knowledge that the catheter design caused these failures and that these failures cause serious injuries.

43. 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 Decedent. Defendants had actual knowledge of the dangers presented by the SmartPort System, yet consciously failed to act reasonably to:

a. Adequately inform or warn Decedent, 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 NANCY WHITTEMORE

44. On or about January 17, 2024, Decedent, underwent placement of an AngioDynamics SmartPort product, reference number H787CT96STSDVI1, and lot number A2823026. The device was implanted as Jacobs Medical Center in San Diego, California.

45. Decedent's port system subsequently became infected and the catheter portion of the device fractured and embolized. Due to these complications Decedent suffered substantial harm and required extensive medical care but ultimately died on April 20, 2024. Decedent's pre-death injuries included but were not limited to: infection, shock, multiple surgical procedures, Bacteremia, weakness, malaise, and cardiac arrest. She was admitted

at Jacobs Medical Center in San Diego from February 19, 2024 through March 18, 2024, and April 2, 2024 through April 16, 2024. She was pronounced dead at Scripps Memorial Hospital – La Jolla.

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

47. Defendants manufactured, sold, and/or distributed the SmartPort to Decedent, through her doctors, to be used for chemotherapy.

48. 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.

49. The SmartPort implanted in Decedent was in the same or substantially similar condition as when the SmartPort left the possession of Defendants and in the condition directed by and expected by Defendants.

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

51. 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.

52. 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.

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

54. As a result of having the SmartPort implanted, Decedent experienced significant mental and physical pain and suffering, underwent additional surgeries, and suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses.

55. 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.

56. 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.

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

58. Defendants were negligent toward Decedent 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 Decedent.

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

60. The SmartPort implanted into Decedent 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.

61. At the time of her implant operation, Decedent 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.

62. Decedent was never informed by Defendants of the defective and dangerous nature of SmartPort.

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

64. As a result of the Defendants' actions and inactions, Decedent was injured due to the use of the SmartPort, which has caused Decedent various physical, mental, and emotional injuries and damages, which lasted until her death on April 20, 2024.

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

COUNT I:
NEGLIGENCE
(Against Defendants AngioDynamics and Navilyst)

66. Plaintiffs incorporate by reference paragraphs one (1) through sixty-eight (65) of this Complaint as if fully set forth herein.

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

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

a. Failing to institute safety mechanisms in the design of the device that would have lowered its risk level;

b. Defendants' design decision of how it chose to utilize barium sulfate and

its specific process for mixing it with polyurethane/silicone leads to a structurally compromised catheter, thereby creating a defective condition and heightened risk to the user or consumer;

c. Defendants' decision not to employ safer alternative designs that would reduce risk of bacteria adhering to the implanted port system and therefore increasing risk of infection and inibility to treat the infection;

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

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

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

g. 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;

h. Designing, manufacturing, marketing, advertising, distributing, and selling the SmartPort to consumers, including Decedent, 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;

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

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

69. As a direct, actual, and proximate cause of the Defendants' actions, omissions,

and misrepresentations, Decedent suffered death, severe injuries and complications which were permanent and lasting in nature, emotional distress, loss of the capacity for the enjoyment of life, medical expenses, and economic loss, as alleged herein.

70. 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.

WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory, special, and punitive damages, together with interest, costs of suit, and all such other relief as the Court deems proper.

COUNT II:
STRICT PRODUCTS LIABILITY – MANUFACTURING DEFECT
(Against Defendants AngioDynamics and Navilyst)

71. Plaintiffs incorporates by reference paragraphs one (1) through sixty-eight (70) of this Complaint as if fully set forth herein.

72. The SmartPort implanted in the Decedent was not reasonably safe for its intended use as it was manufactured defectively.

73. Defendants operated under design and manufacturing specifications for the SmartPort, which included appropriate material content, strength, size, durability appearance, resistance levels, and that the devices did not deviate from its intended design. The manufacturing process was intended to identify any end-product products that did not meet Defendants' specifications.

74. Defendants owed Decedent a duty to exercise reasonable care when manufacturing, setting design and manufacturing specifications, exercising quality control over, distributing, and selling the SmartPort.

75. Defendants breached this duty and failed to exercise reasonable care when manufacturing, setting design and manufacturing specifications, exercising quality control over, distributing, and selling an unreasonably dangerous SmartPort that was ultimately implanted into Decedent. This caused the SmartPort that was implanted into Decedent to

deviate from its intended design and/or vary from its intended specifications in that the device did not have the specified material content, size, durability, and strength, resulting in a SmartPort that contained 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.

76. The defective and dangerous condition of the SmartPort implanted into Decedent existed at the time it left Defendants' possession and at the time it was sold. The device differed from Defendants' intended result and/or from other ostensibly identical units of the same product line.

77. SmartPort ports were expected to and did reach consumers, including the Decedent, 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 manufacturing and design defects of the SmartPort and would not have placed the SmartPort into the stream of commerce.

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

80. Decedent's 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.

81. As a direct and proximate result of Defendants' negligent manufacturing, Decedent suffered death, severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and consortium, economic loss and damages including, but not limited to medical expenses, lost income, and other damages.

82. WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory, special, and punitive damages, together with interest, costs of suit, and all

such other relief as the Court deems proper.

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

83. Plaintiffs incorporate by reference paragraphs one (1) through sixty-eight (82) of this Complaint as if fully set forth herein.

84. 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.

85. Defendants failed to timely and reasonably warn of material facts regarding the safety and efficacy of the SmartPort; no reasonable health care provider, including Decedent, 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.

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

87. 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.

88. 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.

89. 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.

90. When Decedent was implanted with her 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.

91. Defendants intentionally underreported the number and nature of adverse events associated with infection due to SmartPorts to Decedent's health care providers, as well as the FDA.

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

93. Decedent 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.

94. Upon information and belief, the defective and dangerous condition of SmartPorts 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.

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

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

WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory,

special, and punitive damages, together with interest, costs of suit, and all such other relief as the Court deems proper.

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

97. Plaintiffs incorporate by reference paragraphs one (1) through sixty-eight (96) of this Complaint as if fully set forth herein.

98. 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.

99. 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.

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

a. Defendants represented to Decedent and her physicians and healthcare providers through product 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 Decedent 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 Decedent 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.

101. 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.

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

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

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

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

106. As a direct and proximate result of the breach of Defendants' express warranties, Decedent suffered death, severe physical pain and injuries which were 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.

107. Upon information and belief, Decedent's healthcare providers sent notice to Defendants of the adverse event that occurred to Decedent 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.

WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory,

special, and punitive damages, together with interest, costs of suit, and all such other relief as the Court deems proper.

COUNT V
FRAUDULENT CONCEALMENT
(Against Defendants AngioDynamics and Navilyst)

108. Plaintiffs incorporate by reference paragraphs one (1) through sixty-eight (107) of this Complaint as if fully set forth herein.

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

110. Defendants engaged in and fraudulently concealed information with respect to the SmartPort in the following respects:

a. Defendants represented through the product 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 increase the risk of 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 increase the risk of 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.

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

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

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

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

115. Decedent 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 Decedent and her physicians.

116. As a direct and proximate result of the Defendants' actions, omissions and misrepresentations, Decedent suffered death, severe physical pain and injuries which were 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.

117. The Defendants acted with oppression, fraud, and malice towards Decedent, 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 these Defendants and others from engaging in similar conduct in the future.

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

WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory, special, and punitive damages, together with interest, costs of suit, and all such other relief as the Court deems proper.

COUNT VI
WRONGFUL DEATH

119. Plaintiffs incorporates by reference paragraphs one (1) through sixty-eight (118) of this Complaint as if fully set forth herein.

120. Decedent's death was precipitated by the Defendants' defective SmartPort and by the Defendants' tortious conduct.

121. Decedent is no longer available to bring her own action to court.

122. Plaintiffs are the surviving spouse and children of Decedent.

123. Plaintiffs suffered loss because of Decedent's death.

124. Plaintiffs have the right to recover the damages as follows, under California Code of Civil Procedure § 377.60 *et seq*: for mental anguish; loss of love, affection, and companionship; loss of marital care, attention, advice, and counsel; the reasonable expenses of Decedent's last illness and burial; and all other applicable economic and non-economic damages recoverable to Plaintiff.

COUNT VII
SURVIVAL ACTION

125. Plaintiff Frank Whittemore incorporates by reference paragraphs one (1) through sixty-eight (124) of this Complaint as if fully set forth herein.

126. Under California Code of Civil Procedure § 377.20 *et seq*, the causes of action for the injuries to Decedent and, but for Decedent's death, survived; the actions may be brought notwithstanding Decedent's death.

127. The causes of action for personal injury outlined in this Complaint survived to Plaintiff Frank Whittemore is Decedent's Successor In-interest.

128. Plaintiff seeks damages on behalf of Decedent, as her Successor In Interest, which Decedent could have claimed, and to which Decedent was entitled to, if she had survived, including, but not limited to, medical expenses; lost wages and future earnings; pain and suffering from the time of Decedent's injuries until her death; and all other applicable economic and non-economic damages recoverable to Decedent. Plaintiff also seeks punitive damages.

PRAYER

WHEREFORE, Plaintiffs pray 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 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 special damages, including past, present, and future, medical expenses according to proof at the time of trial;

e. Awarding pre-judgment and post-judgment interest to the Plaintiffs;

f. Awarding the costs and the expenses of this litigation to the Plaintiffs;

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

DEMAND FOR JURY TRIAL

Plaintiffs hereby demands trial by jury on all issues.

Dated: March 6, 2026

Respectfully submitted,

/s/ Troy Brenes

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