Chelsea O. Dickerson (admitted *pro hac vice*)
MO Bar # 63374
Blair B. Matyszczyk (admitted *pro hac vice*)
MO Bar # 66067
Elsa Linares-Mascote (admitted *pro hac vice*)
MO Bar # 71994
DICKERSON OXTON, LLC
1100 Main St., Suite 2550
Kansas City, MO 64105
T: (816) 268-1960
F: (816) 268-1968
cdickerson@dickersonoxton.com
bmatyszczyk@dickersonoxton.com
elmascote@dickersonoxton.com

Attorneys for Plaintiff

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF CALIFORNIA

IN RE: ANGIODYNAMICS, INC., AND NAVILYST MEDICAL, INC., PORTCATHETER PRODUCTS LIABILITY LITIGATION	Case No.: 3:24-md-03125-JO-VET MDL No. 3125 JUDGE JINSOOK OHTA
ROBERT MCDONALD, HEIR AT LAW AND PETITIONING PERSONAL REPRESENTATIVE OF THE ESTATE OF ANNA MCDONALD, *Plaintiff*, vs. ANGIODYNAMICS, INC., & NAVILYST MEDICAL, INC., *Defendants*.	COMPLAINT AND JURY DEMAND

Civil Action No.: **'25CV1482 JO VET**

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 Plaintiff's designated venue "Original Venue." The

Original Venue is a judicial district in which a substantial part of the events or omissions giving rise to the claim occurred, specifically (28 USC § 1391(b)(2)

COMES NOW the Plaintiff, ROBERT MCDONALD, HEIR AT LAW AND PETITIONING PERSONAL REPRESENTATIVE OF THE ESTATE OF ANNA MCDONALD, (hereinafter referred to as "Plaintiff"), by and through his undersigned counsel, and brings this Survivorship action on behalf of Anna McDonald (hereinafter referred to as "Decedent") against AngioDynamics, Inc, and Navilyst Medical, Inc. (collectively, the "Defendants"), and alleges as follows:

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

PARTIES

2. Plaintiff, ROBERT MCDONALD, HEIR AT LAW AND PETITIONING PERSONAL REPRESENTATIVE OF THE ESTATE OF ANNA MCDONALD, is an adult citizen of Lake County, Florida, and claims damages for personal injuries as set forth below on behalf of Decedent Anna McDonald in this survivorship action.

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. The United States District Court for the Middle District of Florida 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 this 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 that judicial District.

7. Defendants have and continue to conduct substantial business in the State of Florida and in The United States District Court for the Middle District of Florida, distribute vascular access products in this 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 that District, subjecting them to in personam jurisdiction in that District.

8. Consistent with the Due Process Clause of the Fifth and Fourteenth Amendments, The United States District Court for the Middle District of Florida 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 silicone 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 compromised of a polymeric mixture of silicone and a barium sulfate radiopacity agent.

19. 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.

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

22. 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 matrix.

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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

23. 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.

24. 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 SmartPort.

25. 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.

26. 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, migrating, perforating internal vasculature and otherwise malfunctioning.

27. At all times relevant to this action, Defendants knew and had reason to know that patients implanted with a SmartPort device had an increased risk of suffering life threatening injuries, including but not limited to: death; fracture; 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.

28. 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 the 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. thrombosis
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.

29. 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.

30. 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]

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

32. 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.

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

34. 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 fracture and associated injuries.

35. 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, yet consciously failed to act reasonably to:

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

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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).

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 DECEDENT

36. On or about June 10, 2021, Decedent Anna McDonald underwent placement of an AngioDynamics SmartPort product, model number CT96STSD, lot number 5669968. The SmartPort was implanted by Dr. Christopher J. Johnson, D.O., at Orlando Health South Lake Hospital in Clermont, Florida.

37. 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.

38. Defendants manufactured, sold, and/or distributed the SmartPort to Decedent, through her doctors, to be used for vein access.

39. On or about July 6, 2021, Decedent presented to Orlando Lake South Hospital for a port evaluation. The port study demonstrated that the catheter fractured and migrated into the right ventricle.

40. On or about July 7, 2021, Decedent underwent fragment retrieval. This procedure occurred at Orlando Lake South Hospital and was performed by Dr. Paul E. Gibson, M.D.

41. On or about July 8, 2021, Defendants' defective SmartPort device was removed from the Decedent by Dr. Alexander D. Schroder, M.D., at Orlando Health South Lake Hospital.

42. 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.

43. The SmartPort implanted into Decedent 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.

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

45. 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.

46. Defendants had sole access to material facts concerning the defective nature of the products and their propensity to cause serious and dangerous side effects.

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

48. As a result of having the SmartPort implanted, Decedent sustained significant mental and physical pain and suffering, suffered permanent injury, permanent and substantial physical deformity, underwent corrective surgery or surgeries, and suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses.

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

50. The Defendants have marketed and sold the 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.

51. The injuries, conditions, and complications suffered due to Defendants' SmartPort include but are not limited to hemorrhage; 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.

52. Defendants were negligent toward Decedent in the following respects:

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

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

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

54. 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.

55. At the time of her operation, Decedent was not informed of, and had no knowledge of the complaints, known complications, and risks associated with SmartPort.

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

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

58. At the time of the injuries referenced herein, Decedent did not know that the corrective surgery she underwent was due to a defect in the SmartPort.

59. As a direct and proximate result of the defective SmartPort and the wrongful acts and omissions of the Defendants as alleged herein, Decedent was injured due to the use of the SmartPort, which caused Decedent various physical, mental, and emotional injuries and damages.

FIRST CAUSE OF ACTION

NEGLIGENCE

(Against Defendants AngioDynamics and Navilyst)

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

61. 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.

62. 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. 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 SmartPort;

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

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

63. As a direct and proximate result of the Defendants' actions, omissions and misrepresentations, Decedent was injured due to the use of the SmartPort, which caused Decedent's various physical, mental, and emotional injuries and damages.

64. 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.

65. As a direct and proximate result of the aforementioned, Decedent was injured due to the use of the SmartPort, which caused Decedent various physical, mental, and emotional injuries and damages. Accordingly, Plaintiff seeks compensatory damages on behalf of Decedent's Estate.

SECOND CAUSE OF ACTION

STRICT PRODUCTS LIABILITY – FAILURE TO WARN

(Against Defendants AngioDynamics and Navilyst)

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

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

68. 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 the 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.

69. 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.

70. 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'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.

71. 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.

72. 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.

73. The device, 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.

74. When Decedent 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.

75. Defendants intentionally underreported the number and nature of adverse events associated with dislodgement and migration of the devices to Decedent's health care providers, as well as the FDA.

76. 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.

77. 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 Decedent's bloodstream. Moreover, Decedent's health care providers did not place or maintain the device incorrectly such that it caused the device to "pinch off" or otherwise malfunction.

78. Upon information and belief, the defective and dangerous condition of the device, including the one implanted into Decedent, 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. Upon information and belief, the device implanted in Decedent was in the same condition as when it was manufactured, inspected, marketed, labeled, promoted, distributed and sold by Defendants.

79. Defendants' lack of sufficient warning and/or instructions was the direct and proximate cause of Decedent's 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 device.

80. As a direct and proximate result of the aforementioned, Decedent was injured due to the use of the SmartPort, which caused Decedent various physical, mental, and emotional injuries and damages. Accordingly, Plaintiff seeks compensatory damages on behalf of Decedent's Estate.

THIRD CAUSE OF ACTION

STRICT PRODUCTS LIABILITY – DESIGN DEFECT

(Against Defendants AngioDynamics and Navilyst)

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

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

83. The SmartPort was in a defective condition at the time that it left the possession or control of Defendants.

84. The SmartPort was unreasonably dangerous to the user or consumer.

85. The SmartPort was expected to and did reach the consumer without substantial change in its condition.

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

87. As a direct and proximate result of the SmartPort's aforementioned defects, Decedent was injured due to the use of the SmartPort, which caused Decedent various physical, mental, and emotional injuries and damages. Accordingly, Plaintiff seeks compensatory damages on behalf of Decedent's Estate.

FOURTH CAUSE OF ACTION

BREACH OF IMPLIED WARRANTY

(Against Defendants AngioDynamics and Navilyst)

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

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

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

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

92. Defendants breached these implied warranties of merchantability because the SmartPort implanted in Decedent was neither merchantable nor suited for its intended uses as warranted.

93. Defendants' breaches of their implied warranties resulted in the implantation of unreasonably dangerous and defective SmartPort in Decedent's body, placing said Decedent's health and safety in jeopardy.

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

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

96. As a direct and proximate result of the aforementioned, Decedent was injured due to the use of the SmartPort, which caused Decedent various physical, mental, and emotional injuries and damages. Accordingly, Plaintiff seeks compensatory damages on behalf of Decedent's Estate.

FIFTH CAUSE OF ACTION

BREACH OF EXPRESS WARRANTY

(Against Defendants AngioDynamics and Navilyst)

97. Plaintiff incorporates by reference the preceding paragraphs 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. 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.

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

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

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

104. 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.

105. As a direct and proximate result of the aforementioned, Decedent was injured due to the use of the SmartPort, which caused Decedent various physical, mental, and emotional injuries and damages. Accordingly, Plaintiff seeks compensatory damages on behalf of Decedent's Estate.

SIXTH CAUSE OF ACTION

FRAUDULENT CONCEALMENT

(Against Defendants AngioDynamics and Navilyst)

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

107. Defendants fraudulently concealed information with respect to the SmartPort in the following particulars:

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;

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 these devices were fracturing and migrating 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.

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

109. The concealment of information by the Defendants about the risks of the SmartPort was intentional, and the representations made by Defendants were known by Defendants to be false.

110. 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.

111. 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.

112. As a direct and proximate result of the SmartPort's aforementioned defects, Decedent was injured due to the use of the SmartPort, which caused Decedent various physical, mental, and emotional injuries and damages. Accordingly, Plaintiff seeks compensatory damages on behalf of Decedent's Estate.

113. 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 this Defendants and others from engaging in similar conduct in the future.

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

SEVENTH CAUSE OF ACTION

FLORIDA'S DECEPTIVE AND UNFAIR TRADE PRACTICES ACT

(Against Defendants AngioDynamics and Navilyst)

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

116. The acts and practices engaged in by Defendants constitute unlawful, unfair, deceptive, and/or fraudulent business or trade practices in violation of Florida's Deceptive and Unfair Trade Practices Act, § 501.201, Fla. Stat. Ann., *et seq.* (the "FDUPTA").

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

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

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

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

121. Defendants' practices were likely to mislead consumers who acted reasonably to their detriment in purchasing the product based on Defendants' representations that it was reasonably safe for use when it in fact was not and had a higher risk of fracture due to its defective design.

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

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

PRAYER

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

a. Judgement 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 medical expenses according to proof at the time of trial;

e. Plaintiff be awarded punitive damages according to proof at the time of trial;

f. Plaintiff be awarded actual damages, attorney's fees and costs in connection with Plaintiff's claims under Florida's Deceptive and Unfair Trade Practices and Consumer Protection Act, § 501.201, Fla. Stat. Ann., *et seq*. (the "FDUTPA").

g. Plaintiff be awarded punitive damages according to Awarding pre-judgment and post-judgment interest to the Plaintiff;

h. Awarding the costs and the expenses of this litigation to the Plaintiff; and

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

Respectfully submitted,

Dated: June 10, 2025

By: /s/ Elsa Linares-Mascote

Blair B. Matyszczyk (admitted *pro hac vice*)
MO Bar # 66067
Chelsea O. Dickerson (admitted *pro hac vice*)
MO Bar # 63374
Elsa Linares-Mascote (admitted *pro hac vice*)
MO Bar # 71994
DICKERSON OXTON, LLC
1100 Main St., Suite 2550
Kansas City, MO 64105
T: (816) 268-1960
F: (816) 268-1960
bmatyszczyk@dickersonoxton.com
cdickerson@dickersonoxton.com
elmascote@dickersonoxton.com

Attorneys for Plaintiff

CERTIFICATE OF SERVICE

I hereby certify that on June 10, 2025, a copy of the foregoing was served electronically and notice of the service of this document will be sent to all parties by operation of the Court's electronic filing system to CM/ECF participants registered to receive service in this matter.

By: /s/ Elsa Linares-Mascote

Attorney for Plaintiff