Roman Balaban (CO Bar # 39148)*
Max Yefimenko (CO Bar # 34796)*
Rollin Wood (CO Bar # 44920)*
Roman Balaban and Associates, LLC
7350 East Progress Place, STE 106
Greenwood Village, CO 80111
(720) 817-4040
(303) 500-1713 Fax
Email: balaban@rbatort.com
Email: yefimenko@rbatort.com
**Admitted Pro Hac Vice*

Attorneys for Plaintiff

UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

IN RE: ANGIODYNAMICS, INC., AND NAVILYST MEDICAL, INC., PORT CATHETER PRODUCT LIABILITY LITIGATION BRANDI NICOLE DAVISON Plaintiff, vs. ANGIODYNAMICS, INC., & NAVILYST MEDICAL, INC. Defendants. Ther Document Relates to: Civil Action No.	Case No.: 3:24-md-03125-JO-VET **'25CV1818 JO VET** MDL No. 3125 JUDGE JINSOOK OHTA

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 District of Oregon as the place of remand as this case may have originally been filed there pursuant to 28 U.S.C. § 1391.

COMES NOW Plaintiff BRANDI NICOLE DAVISON, by and through the undersigned counsel, and for her Complaint against AngioDynamics, Inc., and Navilyst Medical, Inc., (collectively,

the "Defendants"), alleges as follows:

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

PARTIES

2. Plaintiff BRANDI NICOLE DAVISON ("PLAINTIFF" or "BRANDI DAVISON") is an adult citizen and resident of Jackson County, Oregon. Plaintiff was implanted with the Defendants' SmartPort CT device for the treatment of her medical condition; Plaintiff sustained serious injuries due to the defective SmartPort CT and due to the 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 SmartPort CT.

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 Oregon, 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 CT.

JURISDICTION AND VENUE

5. This Court has subject matter jurisdiction over the parties pursuant to 28 U.S.C. § 1332(a) because the parties are citizens of different states and the amount in controversy exceeds $75,000.00, exclusive of interest and cost.

6. Venue is proper in this Court pursuant to 28 U.S.C. § 1391 by virtue of the facts that (a) a substantial part of the events or omissions giving rise to the claims occurred in this District, and (b) Defendants' products are produced, sold to, and consumed by individuals in the State of Oregon, thereby subjecting the Defendants to personal jurisdiction in this action and making them all "residents" of this judicial District.

7. The Defendants have and continue to conduct substantial business in the State of Oregon 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 the Defendants are present in the State of Oregon, such that requiring an appearance does not offend traditional notions of fair play and substantial justice.

PRODUCT BACKGROUND

9. Upon information and belief, in or about 2007, a company called Rita Medical Systems, Inc. ("Rita") 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. When later, AngioDynamics completed the acquisition of the assets and liabilities of Rita, it rebranded the subject product as SmartPort CT.

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

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

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

14. The intended purpose of SmartPort CT 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 CT in this case, upon information and belief, is a system consisting of two primary components: an injection port and a polyurethane catheter which includes additives intended to make it radiopaque.

16. The injection port has a raised center, or "septum," where the needle is inserted for delivery of the medications. 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 CT 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. Upon information and belief, the product's catheter is comprised of a polymeric mixture of polyurethane and a barium sulfate radiopacity agent.

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

20. Researchers have shown that catheter surface degradation in products featuring a

radiopaque barium sulfate stripe is concentrated at the locus of the stripe.[1]

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

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

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

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

25. This defect in the manufacturing process led to a heterogeneous modified polymer which led to an irregular catheter surface replete with fissure, pits, and cracks as well as sections of the catheter lumen which contain more than 30% barium sulfate by weight, reducing the catheter strength at those loci.

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

27. The fissures, pits and cracks on the catheter's surface thus can harbor bacteria which can cause thrombosis.

28. Although the surface degradation, the development of fissures, pits, and cracks, the development of biofilm, and the subsequent development of thrombosis can be reduced or avoided with design modifications (e.g., using a higher grade radiopacity compound and/or encapsulating the admixed polymer within polyurethane), the Defendants elected not to incorporate those design elements into the SmartPort CT.

[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

29. At all times relevant to this action, the Defendants misrepresented the safety of the SmartPort CT devices, and negligently designed, manufactured, prepared, compounded, assembled, processed, labeled, marketed, distributed, and sold the SmartPort CT devices as safe and effective devices 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.

30. At all times relevant to this action, the Defendants knew or should have known, that the SmartPort CT devices were not safe for the patients for whom they were prescribed and implanted, because once implanted the device facilitated and promoted the catheter-related thrombosis, and otherwise malfunctioning.

31. At all times relevant to this action, the Defendants knew or should have known that patients implanted with a SmartPort CT device had an increased risk of suffering life threatening injuries, including, but not limited to: death; infection; hemorrhage; cardiac/pericardial tamponade; 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.

32. Soon after the SmartPort CT was introduced to market, which upon information and belief, was years before Plaintiff was implanted with her device, the Defendants began receiving large numbers of Adverse Event Reports ("AERs") from health care providers reporting that the SmartPort CT, once implanted, was found to facilitate and to promote the development of the catheter-related thrombosis. These failures were often associated with reports of severe patient injuries such as:

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

33. In addition to the large number of AERs which were known to the Defendants and

reflected in publicly accessible databases, there were 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.

34. 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]

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

36. The Defendants knew of should have known that the SmartPort CT had a substantially higher thrombosis rates than other similar products on the market, yet they failed to warn physicians and consumers of this fact.

37. The Defendants also intentionally concealed the severity of complications caused by the SmartPort CT and the likelihood of these events occurring, e.g., catheter thrombosis.

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

39. Moreover, the Defendants concealed—and continue to conceal—their knowledge of the SmartPort CT's dangerous propensity to cause thrombosis. The Defendants further concealed their knowledge that the Smart Port CT's catheter design caused these failures and that these failures cause serious injuries.

40. The Defendants' conduct, as alleged in this Complaint, constitutes willful, wanton,

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

gross, and outrageous corporate conduct that demonstrates a conscious disregard for the safety of BRANDI DAVISON. The Defendants had actual knowledge of the dangers presented by the SmartPort CT devices, yet consciously failed to act reasonably to:

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

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

c. Recall the SmartPort CT devices from the market.

SPECIFIC FACTUAL ALLEGATIONS AS TO BRANDI DAVISON

41. On March 25, 2020, BRANDI DAVISON underwent placement of an AngioDynamics' SmartPort CT device, Catalog # H787CT80STPD0, Lot # 5525612. Upon information and belief, the device's description is as follows: Smart Port CT Single Titanium Port System with Attachable 8.0F x 66cm Polyurethane Catheter and 8 F Introducer Kit.

42. The device at issue was implanted by Dr. Joseph Thompson, M.D., at Asante Rogue Regional Medical Center, in Medford, Oregon, for the chemotherapy treatment of Plaintiff's rectal cancer.

43. The Defendants, directly or through their agents, apparent agents, servants, or employees designed, manufactured, marketed, advertised, distributed, and sold the SmartPort CT that was implanted in BRANDI DAVISON.

44. Defendant manufactured, sold, and/or distributed the SmartPort CT to BRANDI DAVISON, through her doctors, to be used as outlined in this Complaint.

45. On or around October 13, 2020, Plaintiff presented to Asante Rogue Regional Medical Center in Medford, Oregon with chest pain and upper abdominal pain. Plaintiff's medical team determined that a CT was needed where it was confirmed that Plaintiff had pulmonary emboli in the distal branches of the left lower lobe both anteriorly and posteriorly which would require

anticoagulants to treat before safely removing the SmartPort CT.

46. On or around December 11, 2020, BRANDI DAVISON's defective port was removed by Dr. Seth Urban, MD, at Asante Rogue Regional Medical Center, in Medford, Oregon.

47. After removal of the defective SmartPort CT port-a-cath, Plaintiff did not have an opportunity to consult with Dr. Seth Urban, M.D., about the causes of her catheter thrombosis.

48. Plaintiff knew she had a thrombosis, but she did not know her thrombosis was caused by the SmartPort CT's defects and/or by the Defendants' conduct.

49. Plaintiff did not discover the heightened risk of thrombosis related to the SmartPort CT's defects until around July 2023, when Plaintiff saw a social media ad which detailed potential defects in port catheter products, and when she subsequently filled out a questionnaire, and then got in contact with Balaban Law, LLC law firm.

50. Prior to seeing the aforementioned social media ad and getting in contact with said law firm, Plaintiff was unaware that her SmartPort CT was defective, and that her catheter thrombosis was caused by the defective SmartPort CT and/or by the Defendants' tortious conduct. It was at that point when Plaintiff first learned that her injuries described in this Complaint may have been caused by the Defendants' SmartPort CT's defects and/or by the Defendants' tortious conduct.

51. At all times relevant to this action, the SmartPort CT was utilized and implanted in a manner foreseeable to the Defendants, as the Defendants generated the *Instructions For Use* and created procedures for implanting the product.

52. The SmartPort CT implanted in BRANDI DAVISON was in the same or substantially similar condition as when it left the possession and control of the Defendants and in the condition directed by and expected by the Defendants.

53. BRANDI DAVISON and her physicians foreseeably used and implanted the SmartPort CT and did not misuse or alter the SmartPort CT in an unforeseeable manner.

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

not limited to, catheter thrombosis and the related complications.

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

56. In reliance on Defendants' representations, BRANDI DAVISON's doctors were induced to, and did use the SmartPort CT.

57. As a result of having the SmartPort CT implanted, BRANDI DAVISON 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.

58. Defendants' SmartPort CT devices were 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.

59. The Defendants have marketed and sold the Defendants' SmartPort CT 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.

60. The injuries, conditions, and complications suffered due to Defendants' SmartPort CT include, but are not limited to, infections; 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 death.

61. The Defendants were negligent toward BRANDI DAVISON in the following respects:

a. The Defendants failed to design and establish a safe, effective procedure for removal of SmartPort CT; therefore, in the event of a failure, injury, or

complications it is difficult to safely remove SmartPort CT; and

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

62. The SmartPort CT was utilized and implanted in a manner foreseeable to the Defendants.

63. The SmartPort CT implanted into BRANDI DAVISON was in the same or substantially similar condition as when it left the possession and control of the Defendants and in the condition directed by the Defendants.

64. At the time of her operation, BRANDI DAVISON was not informed of, and had no knowledge of the complaints, known complications and risks associated with SmartPort CT, including, but not limited to, the extent of seriousness of the danger of the catheter thrombosis.

65. BRANDI DAVISON was never informed by the Defendants of the defective and dangerous nature of the SmartPort CT.

66. At the time of her implant, upon information and belief, neither BRANDI DAVISON nor her physicians were aware of the defective and dangerous condition of the SmartPort CT.

67. As a result of the Defendants' actions and inactions, BRANDI DAVISON has been injured and has sustained economic and non-economic damages, including for pain and suffering and medical expenses.

TOLLING OF THE STATUTE OF LIMITATIONS

68. 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.

69. 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 the Plaintiff's injuries, the cause of the Plaintiff's injuries, and the tortious nature of the wrongdoing that caused said injuries. *See* O.R.S. § 30.905(1).

70. The causal relationship between Plaintiff's injuries described in this Complaint and the Defendants' defective SmartPort CT and/or the Defendants' tortious conduct was not discovered, and through reasonable care and due diligence could not have been discovered until around July 2023, as outlined above in this Complaint.

71. The running of the limitations period is also equitably tolled. Defendants are estopped from relying on Oregon's statutes of limitation or repose by virtue of their fraudulent concealment, through affirmative misrepresentations and omissions to Plaintiff and/or regarding the safety of the SmartPort CT.

72. Based on information and belief, the Defendants affirmatively withheld and/or misrepresented facts concerning the SmartPort CT'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 the Defendants' misrepresentations or omissions, that Plaintiff has 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.

73. Given the Defendants' intentional, knowing, willful, reckless and/or careless misrepresentations and/or omissions regarding SmartPort CT's substantial safety risks and dangerous propensities—information over which the Defendants had exclusive control—and because Plaintiff and/or Plaintiff's doctors could not reasonably have known of SmartPort CT's substantial safety risks and dangerous propensities, the 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)

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

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

76. 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 CT 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 CT;

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

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

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

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

g. Negligently continuing to manufacture, market, advertise, and distribute the

SmartPort CT after the Defendants knew or should have known of its adverse effects.

77. 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, including for pain and suffering and medical expenses.

78. In performing the foregoing acts, omissions, and misrepresentations, the Defendants acted grossly negligent, fraudulently, and with malice.

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

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

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

81. The SmartPort CT implanted into Plaintiff was not reasonably safe for its intended use and was defective with respect to its design.

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

83. The SmartPort CT 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.

84. The SmartPort CT 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.

85. A reasonably prudent medical device manufacturer would have recognized the defective design of the SmartPort CT and would thus have avoided placing it into the stream of commerce.

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

87. The SmartPort CT was used and implanted in the manner in which it was intended to be used and implanted by the Defendants pursuant to the *Instructions For Use* and the product specifications provided by Defendants.

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

89. 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, including for pain and suffering and medical expenses.

90. In performing the foregoing acts, omissions, and misrepresentations, the Defendants acted grossly negligent, fraudulently, and with malice.

COUNT III: STRICT PRODUCTS LIABILITY – MANUFACTURING DEFECT

(Against Defendants AngioDynamics and Navilyst)

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

92. The Defendants designed, set specifications for, manufactured, marketed, distributed, and sold the SmartPort CT devices, including the one implanted into Plaintiff, into the stream of commerce, and in the course of the same, directly advertised and marketed the SmartPort CT devices to consumers or persons responsible for consumers, and therefore are strictly liable for manufacturing a defective product.

93. Upon information and belief, the defective and dangerous condition of the device implanted into Plaintiff existed at the time it was manufactured by the Defendants.

94. Upon information and belief, the Defendants operated under design and manufacturing specifications for the SmartPort CT devices, which included appropriate material content, strength, size, durability, appearance, resistance levels, and the SmartPort CT devices were not to be distributed if they exhibited excessive surface damage. The manufacturing process was intended to identify any end-product devices that did not meet design and/or manufacturing specifications, so that those devices would not be placed into the stream of commerce.

95. Upon information and belief, the SmartPort CT device implanted into Plaintiff contained manufacturing defects when it left the Defendants' possession and control. The SmartPort CT device at issue differed from the Defendants' intended result and/or from other ostensibly identical units of the same product line.

96. Upon information and belief, the SmartPort CT device implanted into Plaintiff varied from its intended specifications in that the device at issue did not have the specified material content, strength, size, durability, and contained surface damage, pitting, or cracking on the exterior of the device, which increased the risk of the development of the device-related thrombosis, and other serious related complications.

97. The SmartPort CT device implanted into Plaintiff was in the same condition as when it was manufactured, distributed, and sold by the Defendants.

98. The SmartPort CT device implanted into Plaintiff, which the Defendants manufactured, marketed, distributed, and sold into the stream of commerce, was defective at the time of its release into the stream of commerce.

99. Plaintiff and Plaintiff's healthcare providers used the device at issue in a way that was reasonably foreseeable to the Defendants.

100. The aforementioned device's manufacturing defect created an unreasonably dangerous risk of injury and was the direct and proximate cause of Plaintiff's serious physical injuries and economic and non-economic damages sustained by Plaintiff.

101. 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.

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

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

103. The Defendants designed, set specifications, manufactured, assembled, processed, marketed, labeled, distributed, and sold the SmartPort CT devices, 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.

104. At the time the 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. The 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.

105. The Defendants knew or should have known at the time they manufactured, labeled, distributed, and sold the SmartPort CT that was implanted into Plaintiff that the SmartPort CT posed a significant and higher risk than other similar devices of catheter thrombosis and resulting serious injuries.

106. The Defendants failed to timely and reasonably warn of material facts regarding the safety and efficacy of the SmartPort CT; no reasonable health care provider, including Plaintiff's, or patient, including Plaintiff, 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.

107. 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 SmartPort CT device.

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

109. The SmartPort CT, which was designed, manufactured, prepared, compounded, assembled, processed, marketed, labeled, distributed, and sold into the stream of commerce by the Defendants, was defective at the time of release into the stream of commerce due to inadequate warnings, labeling and/or instructions accompanying the product.

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

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

112. 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 SmartPort CT device as described herein.

113. Plaintiff and her health care providers used the SmartPort CT 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.

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

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

116. The 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 the Defendants provided adequate warnings, Plaintiff and her physicians would not have used the SmartPort CT.

117. 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, including for pain and suffering and medical expenses.

118. In performing the foregoing acts, omissions, and misrepresentations, the Defendants acted grossly negligent, fraudulently, and with malice.

COUNT V: BREACH OF IMPLIED WARRANTY

(Against Defendants AngioDynamics and Navilyst)

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

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

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

122. Plaintiff, individually and/or by and through her physicians, relied upon the Defendants' implied warranties of merchantability in consenting to have the SmartPort CT at issue implanted in her body.

123. 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.

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

125. The Defendants breached these implied warranties of merchantability because the SmartPort CT 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. The Defendants' manufacturing process in constructing the catheter of the SmartPort CT implanted in Plaintiff involved too high of a concentration of barium sulfate particles for the polymer formulation, which led to improperly high viscosity of the admixed polyurethane before polymerization and caused improper mixing of barium sulfate particles within the polymer matrix;

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

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

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

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

128. 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, including for pain and suffering and medical expenses.

129. Upon information and belief, Plaintiff's healthcare providers sent notice to the

Defendants of the adverse event that occurred to Plaintiff and thus, the nonconformity of the SmartPort CT, within a reasonable period of time following discovery of the breach of warranty and before suit was filed.

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

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

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

132. The SmartPort CT at issue did not conform to the Defendants' express representations because it was not reasonably safe, had numerous serious side effects, and caused severe and permanent injury.

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

a. The 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 SmartPort CT was safe, meanwhile the Defendants fraudulently withheld and concealed information about the substantial risks of serious injury associated with using the SmartPort CT;

b. Defendants represented to Plaintiff and her physicians and healthcare providers that the SmartPort CT was as safe and/or safer than other alternative procedures and devices then on the market, but fraudulently concealed

information that demonstrated that the SmartPort CT was not safer than alternative therapies and products available on the market; and

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

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

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

136. Privity exists between Plaintiff and the Defendants because Plaintiff's physicians acted as Plaintiffs' purchasing agents in the subject transaction and/or because Plaintiff was a third-party beneficiary of the subject contract.

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

138. At all times relevant to this action, the SmartPort CT was used on Plaintiff by her physicians for the purpose and in the manner intended by the Defendants.

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

140. 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, including for pain and suffering and medical expenses.

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

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

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

143. The Defendants made false statements and representations to Plaintiff and her healthcare providers concerning the SmartPort CT device implanted in Plaintiff.

144. The Defendants fraudulently concealed information with respect to the SmartPort CT in the following respects:

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

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

c. The Defendants concealed that they knew of the SmartPort CT's dangerous propensity to cause catheter thrombosis and other 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 by the Defendants.

145. The Defendants knew or should have known that the representations they made concerning the SmartPort CT, as stated above, were false.

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

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

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

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

150. 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, including for pain and suffering and medical expenses.

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

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

153. Plaintiff should be awarded punitive damages due to the fact that the Defendants exhibited intentional conduct and/or acted with malice or reckless disregard for Plaintiff's safety and her rights, and with the intent to defraud Plaintiff, i.e., the consumer, or the individuals responsible for Plaintiff, while supplying Plaintiff or her physicians with the defective SmartPort CT device, which was defectively designed, and which contained the manufacturing defect(s), and while failing to adequately warn the Plaintiff's physicians and Plaintiff, as outlined in this Complaint.

154. Moreover, both Defendants, the corporations, knew or should have known that they labeled, advertised, marketed, sold, or otherwise distributed the defective products, i.e., the defective SmartPort CT devices, including the one that was implanted into the Plaintiff's body, because the SmartPort CT devices posed a substantial risks to consumers of said devices, including, but not limited to, the substantial risks of the development of the catheter-related thrombosis and the related injuries and complications.

155. Furthermore, both Defendants, the corporations, fraudulently concealed the serious

safety concerns with the SmartPort CT devices, which they knew or should have known about, including, but not limited to, the heightened propensity of the SmartPort CT devices to facilitate and to promote the catheter-related thrombosis from Plaintiff's physicians and from Plaintiff, acting with malice or reckless disregard for Plaintiff's safety and her rights, with the intent to defraud Plaintiff or the individuals responsible for Plaintiff, i.e., Plaintiff's prescribing and implanting physicians.

COUNT VIII: THE UNLAWFUL TRADE PRACTICES ACT (UTPA)
(Against Defendants AngioDynamics and Navilyst)

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

157. The Plaintiff, a consumer, purchased the SmartPort CT, and said device was intended for Plaintiff's personal use.

158. The acts and practices engaged in by the Defendants as outlined above constitute false, misleading, or deceptive acts or practices in violation of Oregon's Unlawful Trade Practices Act, ("UTPA"). O.R.S. §§ 646.607 *et seq*.

159. The Defendants engaged in unlawful practices including deception, false promises, misrepresentation, false and misleading advertisement, and/or the concealment, suppression, or omission of material facts in connection with the sale, distribution, and/or advertisement of the SmartPort CT in violation of Oregon's UTPA.

160. Plaintiff purchased the SmartPort CT, a product that was falsely represented, as further set forth herein, 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 UTPA.

161. The 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 UTPA, which created a likelihood of confusion or misunderstanding on Plaintiff's part with respect to the SmartPort CT she purchased, including, but not limited to, misrepresenting that the SmartPort CT was reasonably safe for use and failing to adequately disclose the substantial risk of

catheter thrombosis, and harm the product entailed given the large number of adverse events the Defendants knew or should have known of but did not adequately disclose to Plaintiff and her doctors.

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

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

164. As a result of the Defendants' conduct, Plaintiff suffered economic damages in that the product purchased was misrepresented to be reasonably safe for use and was worth far less than the product Plaintiff thought she had purchased had the Defendants' representations been true.

PRAYER

WHEREFORE, Plaintiff prays for judgment against the Defendants, and each of them, individually, jointly, and severally, as follows:

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

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

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

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

e. Plaintiff be awarded punitive damages according to proof;

f. Plaintiff be awarded costs and attorney's fees in connection with Plaintiff's Oregon Unlawful Trade Practices Act (UTPA) claim under O.R.S. §§ 646.607 *et seq.*;

g. Plaintiff be awarded any and all statutory damages allowed by applicable law;

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

i. Awarding the costs and the expenses of this litigation to the 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.

Respectfully submitted,

/s/ Rollin Wood
Roman Balaban (CO # 39148/*Admitted Pro Hac Vice*)
Max Yefimenko (CO # 34796/*Admitted Pro Hac Vice*)
Rollin Wood (CO # 44920/*Admitted Pro Hac Vice*)
Roman Balaban and Associates, LLC
7350 East Progress Place, Suite 106
Greenwood Village, CO 80111
Phone: 720-817-4040
Fax: 303-500-1713
Email: balaban@rbatort.com
Email: yefimenko@rbatort.com
Email: wood@rbatort.com

ATTORNEYS FOR PLAINTIFF

CERTIFICATE OF FILING AND SERVICE

I hereby certify that on July 17, 2025, a true and correct copy of the foregoing was electronically filed with the Clerk of the Court using the CM/ECF system which will send notification of such filing to all counsel of record.

By: */s/ Rollin Wood*

Rollin Wood, Esq.