IN THE UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF IOWA

CHARMAINE BROCKWAY, Plaintiff, vs. ANGIODYNAMICS, INC., & NAVILYST MEDICAL, INC., Defendants.	Case No.: **COMPLAINT FOR DAMAGES** **(1) NEGLIGENCE** **(2) DESIGN DEFECT** **(3) FAILURE TO WARN** **(4) BREACH OF IMPLIED WARRANTY** **(5) BREACH OF EXPRESS WARRANTY** **(6) FRAUDULENT CONCEALMENT** **(7) IOWA'S PRIVATE RIGHT OF ACTION FOR CONSUMER FRAUDS ACT** **DEMAND FOR JURY TRIAL**

COMPLAINT

COMES NOW Plaintiff, Charmaine Brockway, (hereinafter "Plaintiff"), by and through her undersigned counsel, and brings this Complaint against AngioDynamics, Inc., and Navilyst Medical, Inc., (collectively, the "Defendants"), and alleges as follows:

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

PARTIES

2. Plaintiff, Charmaine Brockway, is an adult resident and citizen of Marshall County, Iowa, and claims damages as set forth below.

3. Defendant AngioDynamics, Inc. ("AngioDynamics") is a Delaware corporation with its principal place of business located in Latham, New York. AngioDynamics is engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, supplying, selling, marketing, and introducing into interstate commerce, either directly or indirectly through third parties or related entities, its medical devices, including the Vortex.

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 Missouri, 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 Vortex.

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

7. Defendants have and continue to conduct substantial business in the State of Iowa

and in this District, distribute vascular access products in this District, receive substantial compensation and profits from sales of vascular access products in this District, and made material omissions and misrepresentations and breaches of warranties in this District, so as to subject them to *in personam* jurisdiction in this District.

8. Consistent with the Due Process Clause of the Fifth and Fourteenth Amendments, this Court has *in personam* jurisdiction over Defendants because Defendants are present in the State of Iowa, such that requiring an appearance does not offend traditional notices of fair and substantial justice.

PRODUCT BACKGROUND

9. In or about 2003, a company called Horizon Medical Products ("Horizon") obtained clearance for the Triumph VTX Port with LiveValve Catheter under the 510(k) number K032557.

10. Shortly after the clearance of the Triumph port, Horizon merged with Rita Medical Systems, which was in the process of being acquired by Angiodynamics.

11. The Vortex port system bears a design and specifications that differ significantly from the Triumph port (including but not limited to the catheter design and connection hub), but Defendants represented to regulatory authorities that the Vortex port was cleared under the K032557 submission.

12. Neither Horizon Medical Products nor Angiodynamics received clearance from the FDA to market the Vortex TR catheter, making such device per se misbranded pursuant to the Food, Drug and Cosmetic Act.

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

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

15. According to Defendants, the Vortex 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.

16. The intended purpose of the Vortex 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.

17. The Vortex is a system consisting of two primary components: an injection port and a polyurethane catheter which includes additives intended to make it radiopaque.

18. 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.

19. The Vortex 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.

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

21. 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.

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

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

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

25. This defect in the manufacturing process led to a heterogeneous modified polymer which led to an irregular catheter surface replete with fissure, pits and cracks.

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

27. Although the surface degradation and resultant mechanical failure can be reduced or avoided with design modifications (e.g., using a higher grade radiopacity compound and/or encapsulating the admixed polymer within polyurethane), Defendants elected not to incorporate those design elements into the Vortex.

28. At all times relevant, Defendants misrepresented the safety of the Vortex system,

[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

and negligently designed, manufactured, prepared, compounded, assembled, processed, labeled, marketed, distributed, and sold the Vortex system as safe and effective device to be surgically implanted to provide repeated access to the vascular system for the delivery of medications, intravenous fluids, parenteral nutrition solutions, and blood products.

29. At all times relevant to this action, Defendants knew and had reason to know, that the Vortex was not safe for the patients for whom they were prescribed and implanted, because once implanted the device was prone to fracturing, perforating internal vasculature, and otherwise malfunctioning.

30. At all times relevant to this action, Defendants knew and had reason to know that patients implanted with a Vortex port had an increased risk of suffering life threatening injuries, including but not limited to: death; infection; hemorrhage; cardiac/pericardial tamponade (pressure caused by a collection of blood in the area around the heart); cardiac arrhythmia and other symptoms similar to myocardial infarction; severe and persistent pain; and perforations of tissue, vessels and organs, or the need for additional surgeries to remove the defective device.

31. Soon after the Vortex was introduced to market, which was years before Plaintiff was implanted with her device, Defendants began receiving large numbers of adverse event reports ("AERs") from health care providers reporting that the Vortex 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 Vortex was found to have perforated internal vasculature. These failures were often associated with reports of severe patient injuries such as:

a. hemorrhage.

b. infection/sepsis;

c. cardia/pericardial tamponade;

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

e. severe and persistent pain;

f. perforations of tissue, vessels and organs; and

g. upon information and belief, even death.

32. In addition to the large number of AERs which were known to Defendants and reflected in publicly accessible databases, there are many recorded device failures and/or injuries related to the Defendants' implantable port products which were concealed from medical professionals and patients through submission to the FDA's controversial Alternative Summary Reporting ("ASR") program.

33. The FDA halted the ASR program after its existence was exposed by a multi-part investigative piece, prompting a widespread outcry from medical professionals and patient advocacy groups.[2]

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

35. Defendants were aware or should have been aware that the Vortex had a substantially higher failure rate than other similar products on the market, yet Defendants failed to warn consumers of this fact.

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

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

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

38. Moreover, Defendants concealed—and continue to conceal—their knowledge of the Vortex's dangerous propensity to precipitate infection. Defendants further concealed their knowledge that the catheter design caused these failures and that these failures cause serious injuries.

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

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

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

c. Recall the Vortex System from the market.

SPECIFIC FACTUAL ALLEGATIONS AS TO PLAINTIFF

40. On or about June 14, 2019, Plaintiff underwent placement of an AngioDynamics Vortex product at University of Iowa. The device was implanted for the purpose of ongoing red

cell exchanges and vein access.

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

42. Defendant manufactured, sold, and/or distributed the Vortex to Plaintiff, through her doctors, to be used for ongoing red cell exchanges and vein access.

43. On or about April 12, 2022, Plaintiff presented herself to the emergency department at UnityPoint Health-Marshalltown with complaints of pleuritic chest wall pain. Plaintiff was also found to be febrile and therefore was transferred to Mary Greeley Medical Center in Ames, Iowa. Upon being admitted at Mary Greeley Medical Center, Plaintiff's blood cultures were drawn and were persistently positive. Plaintiff's medical team determined that the Vortex was the source of the infection and that the defective port had to be removed.

44. On or about April 14, 2022, Plaintiff's defective port was removed by Dr. Gregory Sachs at Mary Greeley Medical Center in Ames, Iowa.

45. On or about August 22, 2022, Plaintiff underwent placement of an additional AngioDynamics Vortex product, reference number LVTX5213, lot number 5730316. The device was implanted by Adeola T Odugbesi, M.D., at University of Iowa Hospitals & Clinics in Coralville, Iowa, for ongoing red cell exchanges and vein access.

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

47. Defendant manufactured, sold, and/or distributed the Vortex to Plaintiff, through her doctors, to be used for ongoing red cell exchanges and vein access.

48. On or about February 13, 2023, Plaintiff's blood cultures were drawn and were positive for staph aureus. Plaintiff's medical team determined that the Vortex was the source of Plaintiff's infection and that the defective device had to be removed.

49. On or about March 9, 2023, Plaintiff presented herself to University of Iowa Hospitals & Clinics for port removal. After multiple defective devices, Plaintiff made the decision to not have another port implanted.

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

51. The Vortex implanted in Plaintiff was in the same or substantially similar condition as when it left the possession of Defendants and in the condition directed by and expected by Defendants.

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

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

54. Defendants had sole access to material facts concerning the defective nature of the Vortex product and its propensity to cause serious and dangerous side effects.

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

56. As a result of having the Vortex implanted, Plaintiff has experienced significant mental and physical pain and suffering, has undergone additional surgeries, and has suffered financial or economic loss, including, but to limited to, obligations for medical services and expenses.

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

58. The Defendants have marketed and sold the Defendants' Vortex to the medical community at large and patients through carefully planned, multifaceted marketing campaigns and strategies. These campaigns and strategies include, but are not limited to, direct to consumer advertising, aggressive marketing to health care providers at medical conferences, hospitals, private offices, and/or group purchasing organizations, and include a provision of valuable consideration and benefits to the aforementioned.

59. The injuries, conditions, and complications suffered due to Defendants' Vortex include, but are not limited to, fracture and leakage; necrosis; infection; blood clots; cardiac/pericardial tamponade; cardiac arrhythmia and other symptoms similar to myocardial infarction; severe and persistent pain; perforations of tissue, vessels and organs; and even death.

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

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

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

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

62. The Vortex implanted into Plaintiff was in the same or substantially similar condition as when it left the possession of the Defendants and in the condition directed by the Defendants.

63. At the time of her operation, Plaintiff was not informed of, and had no knowledge of the complaints, known complications and risks associated with Vortex, including, but not limited to, the extent of seriousness of the danger of infection.

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

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

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

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

COUNT I: NEGLIGENCE
(Against Defendants AngioDynamics and Navilyst)

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

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

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

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

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

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 Vortex;

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

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

71. As a direct, actual, and proximate cause of the Defendants' actions, omissions, and misrepresentations, Plaintiff has suffered, and will continue to suffer, severe injuries and complications which are permanent and lasting in nature, emotional distress, loss of the capacity for the enjoyment of life, medical expenses, and economic loss as alleged herein. These damages have occurred in the past and will continue into the future.

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

COUNT II: STRICT PRODUCTS LIABILITY – DESIGN DEFECT

(Against Defendants AngioDynamics and Navilyst)

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

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

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

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

77. The Vortex was unreasonably dangerous to the user or consumer, taking into consideration the utility of said product and the risks involved in its use. The foreseeable risks associated with the design of the product were more dangerous than a reasonably prudent

consumer such as Plaintiff and/or her physicians would expect when the product was used for its normal and intended purpose.

78. The Vortex was expected to and did reach the consumer without substantial change in the condition in which it was supplied, distributed, sold and/or otherwise placed into the stream of commerce.

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

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

81. The Vortex was used and implanted in the manner in which it was intended to be used and implanted by Defendants pursuant to the instructions for use and the product specifications provided by Defendants.

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

83. As a direct and proximate result of the Vortex's aforementioned defects, the Plaintiff was caused and/or in the future will be caused to suffer severe personal injuries, pain and suffering, severe emotional distress, financial or economic loss, including, but not limited to, obligations for medical services and expenses, and other damages.

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

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

85. At the time Defendants designed, manufactured, prepared, compounded,

assembled, processed, marketed, labeled, distributed, and sold the device into the stream of commerce, the device was defective and presented a substantial danger to users of the product when put to its intended and reasonably anticipated use, namely as an implanted port/catheter system to administer intravenous fluids and/or medications. Defendants failed to adequately warn of the device's known or reasonably scientifically knowable dangerous propensities, and further failed to adequately provide instructions on the safe and proper use of the device.

86. Defendants failed to timely and reasonably warn of material facts regarding the safety and efficacy of the Vortex; no reasonable health care provider, including Plaintiff's, or patient would have used the device in the manner directed, had those facts been made known to the prescribing healthcare providers or the consumers of the device.

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

88. The warnings, labels, and instructions provided by the Defendants at all times relevant to this action, are and were inaccurate, intentionally misleading, and misinformed and misrepresented the risks and benefits and lack of safety and efficacy associated with the device.

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

90. The Vortex, which was designed, manufactured, prepared, compounded, assembled, processed, marketed, labeled, distributed, and sold into the stream of commerce by Defendants, was defective at the time of release into the stream of commerce due to inadequate

warnings, labeling and/or instructions accompanying the product.

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

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

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

94. Plaintiff and her health care providers used the Vortex in a normal, customary, intended, and foreseeable manner, namely as a surgically placed device used to make it easier to deliver medications directly into the patient's bloodstream.

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

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

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

COUNT IV: BREACH OF IMPLIED WARRANTY

(Against Defendants AngioDynamics and Navilyst)

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

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

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

101. The Plaintiff, individually and/or by and through her physician, relied upon Defendants' implied warranties of merchantability in consenting to have the Vortex implanted in her.

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

103. Defendants breached these implied warranties of merchantability because the Vortex implanted in Plaintiff was neither merchantable nor suited for its intended uses as warranted in that the device varied from its intended specifications, which included, but are not limited to, variances in the following respects:

a. Defendants' manufacturing process in constructing the catheter of the Vortex implanted in Plaintiff involved too high of a concentration of barium sulfate particles for the polymer formulation, which led to improperly high viscosity of the admixed polyurethane before polymerization and causing improper mixing of barium sulfate

particles within the polymer matrix;

b. Defendants' knew or should have known barium sulfate is known to contribute to a reduction in the mechanical integrity of the polyurethane in its product, the Vortex, as the barium sulfate particles dissociate from the surface of the catheter over time; and

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

104. Defendants' breaches of their implied warranties resulted in the implantation of an unreasonably dangerous and defective product, the Vortex, into Plaintiff's body, placing said Plaintiff's health and safety in jeopardy.

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

106. As a direct and proximate result of Defendants' breaches of the aforementioned implied warranties, the Plaintiff was caused and/or in the future will be caused to suffer severe personal injuries, pain and suffering, severe emotional distress, financial or economic loss, including, but not limited to, obligations for medical services and expenses, and other damages.

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

COUNT V: BREACH OF EXPRESS WARRANTY

(Against Defendants AngioDynamics and Navilyst)

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

109. Defendants through their officers, directors, agents, representatives, and written literature and packaging, and written and media advertisement, expressly warranted that the Vortex was safe and fit for use by consumers, was of merchantable quality, did not produce dangerous side effects, and was adequately tested and fit for its intended use.

110. The Vortex does not conform to the Defendants' express representations because it is not reasonably safe, has numerous serious side effects, and causes severe and permanent injury.

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

a. Defendant represented to Plaintiff and her physicians and healthcare providers through labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions among other ways that the Defendants' Vortex was safe, meanwhile Defendant fraudulently withheld and concealed information about the substantial risks of serious injury associated with using Vortex;

b. Defendant represented to Plaintiff and her physicians and healthcare providers that the Defendants' Vortex was as safe and/or safer than other alternative procedures and devices then on the market, meanwhile Defendant

fraudulently concealed information that demonstrated that Vortex was not safer than alternative therapies and products available on the market; and

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

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

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

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

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

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

116. As a direct and proximate result of the breach of Defendants' express warranties, Plaintiff has suffered, and will continue to suffer, severe physical pain and injuries which are permanent and lasting in nature, emotional distress, loss of the capacity for the enjoyment of life, medical and nursing expenses, surgical expenses, and economic loss as alleged herein. These damages have occurred in the past and will continue into the future.

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

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

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

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

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

120. Defendants engaged in and fraudulently concealed information with respect to the Vortex in the following respects:

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

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

c. Defendants concealed that it knew of the Vortex's dangerous propensity to precipitate infection and was causing complications from causes other than the manner in which the implanting physician implanted the device; and

d. That frequency of these failures and the severity of injuries were substantially worse than had been reported.

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

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

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

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

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

126. As a direct and proximate result of the Defendants' actions, omissions and misrepresentations, Plaintiff has suffered, and will continue to suffer, severe physical pain and injuries which are permanent and lasting in nature, emotional distress, loss of the capacity for the enjoyment of life, medical and nursing expenses, surgical expenses, and economic loss as alleged herein. These damages have occurred in the past and will continue into the future.

127. The Defendants acted with oppression, fraud, and malice towards Plaintiff, who accordingly requests that the trier of fact, in the exercise of its sound discretion, award additional damages for the sake of example and for the purpose of punishing Defendants for their conduct,

in an amount sufficiently large to be an example to others, and to deter this Defendants and others from engaging in similar conduct in the future.

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

COUNT VII: VIOLATION OF THE IOWA PRIVATE RIGHT OF ACTION FOR CONSUMER FRAUDS ACT – ALL DEFENDANTS

(Against Defendants AngioDynamics and Navilyst)

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

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

131. The acts and practices engaged in by Defendants as outlined above constitute unfair practices, deception, fraud, false pretense and false promises, and the misrepresentation, concealment, suppression, and omission of material facts, all in violation of the Iowa Private Right of Action for Consumer Frauds Act, Iowa Code 714H.1, *et seq*.

132. Defendants engaged in unlawful practices including deception, false promises, misrepresentation, and/or the concealment, suppression, or omission of material facts in connection with the sale, distribution, and/or advertisement of the Vortex in violation of Iowa Code 714H.3.

133. Plaintiff purchased the Vortex, a product that was falsely represented, as set out above, in violation of the Iowa Private Right of Action for Consumer Frauds Act, and as a result Plaintiffs suffered economic damages in that the product purchased was misrepresented to be reasonably safe for use and was worth less than the product Plaintiffs thought they had purchased had Defendants' representations been true.

134. The prohibited practices and acts engaged by Defendants in violation of the Iowa Private Right of Action for Consumer Frauds Act constitutes willful and wanton disregard for the rights and safety of others, including Plaintiff, the very consumers to whom Defendants marketed their product.

PUNITIVE DAMAGES

135. Plaintiff is entitled to an award of punitive and exemplary damages based upon Defendants' intentional, willful, knowing, fraudulent, malicious acts, omissions, and conduct, and their complete and total reckless disregard for the public safety and welfare. Defendants intentionally and fraudulently misrepresented facts and information to both the healthcare community and the general public, including Plaintiff and her health care providers, by making intentionally false and fraudulent misrepresentations about the safety and efficacy of the Vortex. Defendants intentionally concealed the true facts and information regarding the serious risks of harm associated with the implantation of said product, and intentionally downplayed the type, nature, and extent of the adverse side effects of being implanted with the device, despite Defendants' knowledge and awareness of the serious and permanent side effects and risks associated with use of same. Defendants further intentionally sought to mislead health care providers and patients, including Plaintiff and her health care providers, regarding the cause of failures of the device.

136. Defendants had knowledge of, and were in possession of evidence demonstrating that, the Vortex caused serious physical side effects. Defendants continued to market said product by providing false and misleading information with regard to the product's safety and efficacy to the regulatory agencies, the medical community, and consumers of the device, notwithstanding

Defendants' knowledge of the true serious side effects of the Vortex, Defendants failed to provide accurate information and warnings to the healthcare community that would have dissuaded physicians from surgically implanting the Vortex and consumers from agreeing to being implanted with the Vortex, thus depriving physicians and consumers from weighing the true risks against the benefits of prescribing and implanting the Vortex.

137. As a direct, proximate, and legal result of Defendants' acts and omissions a described herein, and Plaintiff's implantation with Defendants' defective product, Plaintiff suffered, and will continue to suffer, the injuries and damages described in this Complaint.

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

PRAYER

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

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

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

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

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

e. Plaintiff be awarded costs, attorney's fees, and statutory damages up to three times the amount of actual damages pursuant Plaintiff's Iowa Private Right of Action for Consumer Frauds Act claim, Iowa Code 714H.1, et seq., and Iowa Code 714H.5;

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

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

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

DEMAND FOR JURY TRIAL

Plaintiff hereby demands trial by jury on all issues.

Dated: April 11, 2024 Respectfully submitted,

By: ***/s/ Dominic F. Pechota***

Dominic F. Pechota AT0006175
Jon Specht AT0012576

ATTORNEYS FOR PLAINTIFF