IN THE UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA

JEREMY MATCHETT Plaintiff, vs. ANGIODYNAMICS INC. & NAVILYST MEDICAL INC. Defendants.	))))))))))	Case No. **JURY TRIAL DEMANDED**

COMPLAINT

COMES NOW Plaintiff Jeremy Matchett, (hereinafter "Plaintiff"), and by and through his undersigned counsel, brings this Complaint against AngioDynamics, Inc. and Navilyst Medical Inc. (collectively "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 Vortex Port (hereinafter "Vortex" or "Defective Device"),

PARTIES

2. Plaintiff is an adult male who resides in New Jersey and was injured in Philadelphia, Pennsylvania.

3. Defendant AngioDynamics Inc. ("AngioDynamics") is a Delaware corporation with its principal place of business 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 in Marlborough, Massachusetts. Navilyst conducts business throughout the United States, including in the State of Pennsylvania, 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, exclusive of interest and cost.

6. Specific personal jurisdiction exists, and venue is proper in this Court pursuant to 28 U.S.C. §1391 as a substantial portion of the events or omissions giving rise to the claims occurred in this District.

PRODUCT BACKGROUND

7. 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.

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

9. 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 K032557.

10. 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.

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

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

13. 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.

14. 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.

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

16. The injection port has a raised center, or "septum", where the needle is inserted for delivery of medication. The medication is carried from the port into the bloodstream through a small, flexible tube, called a catheter, that is inserted into the blood vessel.

17. 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.

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

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

20. Researchers have shown that catheter surface degradation in products featuring a radiopaque barium sulfate stripe concentrated at the locus of the stripe.

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

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

23. This defect in the manufacturing process led to a heterogeneous modified polymer which included weakened areas at the loci of higher barium sulfate concentration and led to fracture of the catheter.

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

25. At all times relevant, Defendants misrepresented the safety of the Vortex system, and negligently designed, manufactured, prepared, compounded, assembled, processed, labeled, marketed, distributed, and sold the Vortex system as a safe and effective device to be surgically

implanted to provide repeated access to the vascular system for the delivery of medications, intravenous fluids, parenteral nutrition solutions, and blood products.

26. At all times relevant, 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, migrating, perforating internal vascular, dislodging/disconnection of catheter from the port reservoir; and otherwise malfunctioning.

27. At all times relevant, 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, fracture, hemorrhage, cardiac/pericardial tamponade (pressure caused by a collection of blood around the heart), cardiac arrhythmia and other symptoms similar to myocardial infarction, severe and persistent pain, perforations of tissue, vessels, and organs, infiltration of subcutaneous tissue, and/or the need for additional surgeries to remove the defective device.

28. Soon after the Vortex was introduced to market, which was years before the Plaintiff was implanted with his 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 the Vortex was found to have perforated internal vasculature. Defendants received reports of the catheter dislodging/disconnecting from the port reservoir. These failures were often associated with reports of severe patient injuries, such as:

a. hemorrhage;

b. fracture and migration;

c. cardiac/pericardial tamponade;

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

e. severe and persistent pain;

f. perforations of tissue, vessels and organs;

g. infiltration of the subcutaneous tissue; and

h. upon information and belief, even death.

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

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

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

32. 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.

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

34. Rather than alter the design of the Vortex to make it safer or adequately warn 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 catheter fracture, dislodging/disconnection of the catheter from the port reservoir, and associated injuries.

35. Moreover, Defendants' warnings suggested that fracture and/or dislodgment of the device could only occur if the physician incorrectly placed the device such that under catheter compression or "pinch off" was allowed to occur. In reality, Defendants knew internally these devices were fracturing and dislodging, and causing serious injuries due to defects in the design, manufacturing, and lack of adequate warnings.

36. The conduct of Defendants, as alleged in the Complaint, constitutes willful, wanton, gross and outrageous corporate conduct that demonstrates conscious disregard for the safety of Plaintiff and evidences malice, fraud, gross negligence, and oppressiveness. 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,

b. Adequately inform or warn his prescribing physicians or the public at large of these dangers;

c. Establish and maintain an adequate quality and post market surveillance system or

d. Recall the Vortex System from the market.

SPECIFIC ALLEGATIONS AS TO JEREMY MATCHETT

37. In August of 2014, Plaintiff was diagnosed with chronic myeloid leukemia.

38. Plaintiff underwent various treatments for his chronic myeloid leukemia including chemotherapy and a stem cell transplant.

39. On August 18, 2018, Plaintiff underwent a surgical procedure to remove his existing port catheter and implant a new port catheter.

40. On August 18, 2018, a Vortex port catheter, Lot #5131154 was implanted in Plaintiff's left side chest. The procedure was performed by Dr. Sarah Abdulla at Temple University Fox Chase Cancer Center.

41. Plaintiff's port catheter was removed on or about May 16, 2023, by Dr. Jeffrey Mondschein, at Hospital of the University of Pennsylvania, as it was no longer needed.

42. At the time of the surgical removal on May 16, 2023, Dr. Mondschein had difficulty removing the Vortex port.

43. During the removal, a portion of the Vortex catheter broke and remained in Plaintiff's body, unbeknownst to Dr. Mondschein or Plaintiff.

44. For several weeks/months thereafter, Plaintiff experienced left side chest pain, pleuritic, and palpations which would worsen when Plaintiff laid on his left side.

45. Plaintiff was treated for chest pain, palpitations and shortness of breath on August 2, 2023 at the Hospital of the University of Pennsylvania.

46. In the course of his treatment in August of 2023, a CT was performed which showed "calcified right atrial mass seen on echo showing up on CT as retained fragment in left brachiocephalic vein".

47. Due to the location of the retained fragment and the risk to Plaintiff for an attempted removal of the fragment, the decision was made to leave the retained Vortex fragment in Plaintiff's body. To date, the retained fragment of the Vortex remains in Plaintiff's left brachiocephalic vein.

48. 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.

49. 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.

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

51. 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.

52. 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.

53. In reliance on Defendants' representations, Plaintiff's doctor was induced to and did use the Vortex.

54. As a result of having the Vortex implanted, Plaintiff has experienced significant mental and physical pain and suffering, and has suffered economic loss, including obligations for medical services and expenses.

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

56. 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.

57. The injuries, conditions and complications suffered due to Defendants' Vortex include but are not limited to, hemorrhage; fracture and migration; cardiac/pericardial tamponade; cardiac arrhythmia and other symptoms similar to myocardial infarction; severe and persistent pain; perforations of tissue, vessels, and organs; dislodging/disconnection of the catheter from the port reservoir; infiltration of subcutaneous tissue; and even death.

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

a. Defendants failed to design and establish a safe and effective connection in the Vortex System, between the catheter and port reservoir, which would prevent the catheter from dislodging/disconnecting.

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

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

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

61. At the time of his operation, Plaintiff was not informed of, and had no knowledge of the complaints, known complications and risks associated with the Vortex, including but not limited to its propensity for the catheter to fracture.

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

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

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

65. Plaintiff has also incurred substantial medical bills due to the defective product that was implanted in his body.

COUNT I – NEGLIGENCE
(Against AngioDynamics and Navilyst)

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

67. 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.

68. The Defendants failed to exercise due care under the circumstances and therefore breached its 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 premarket testing of the Vortex.

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

d. 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, including but not limited to, its propensity to fracture and migrate, and its propensity for the catheter to dislodge/disconnect from the port reservoir, and without proper instructions to avoid the harm which could foreseeably occur as a result of using the device.

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

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

70. As a direct, actual, and proximate cause of the Defendants' actions, omissions, and misrepresentations, Plaintiff has suffered and will continue to suffer severe physical pain and injuries, emotional distress, medical expenses, and other damages.

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

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

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

73. Defendants designed, set specifications, manufactured, assembled, processed, marketed, labeled, distributed, and sold the Vortex, including the one implanted into 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.

74. At the time Defendants designed, manufactured, 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 medications. Defendants failed to adequately warn of the device's known or reasonably scientific knowable dangerous propensities and further failed to adequately provide instructions on the safe and proper use of the device.

75. 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 resulting in serious injuries.

76. Defendants further knew that these devices were fracturing and migrating for reasons other than "pinch off" caused by the physician's placement of the device and knew that these devices were experiencing disconnecting/dislodging of the catheter from the port reservoir.

77. 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, and no reasonable 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.

78. The warnings, labels, and instructions provided by 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.

79. 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.

80. The Vortex, which was designed, manufactured, prepared, 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.

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

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

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

84. Plaintiff and his 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. Moreover, Plaintiff's health care providers did not place or maintain the device incorrectly such that it caused the device to malfunction.

85. Upon information and belief, the defective and dangerous condition of the device, including the one implanted in Plaintiff, existed at the time they were manufactured, prepared, assembled, processed, marketed, labeled, distributed, and sold by Defendants to distributors and/or health care providers and organizations. Upon information and belief, the device implanted in Plaintiff was in the same condition as when it was manufactured, inspected, marketed, labeled, promoted, distributed, and sold by Defendants.

86. Defendants' lack of sufficient warning and/or instructions was the direct and proximate cause of Plaintiff's serious physical injuries. Had Defendants provided adequate warnings, Plaintiff and his physicians would not have used the device.

COUNT III – STRICT LIABILITY – DESIGN DEFECT
(Against Defendants AngioDynamics and Navilyst)

87. Plaintiff incorporates the preceding paragraph as if set out fully herein.

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

89. The Vortex was in a defective condition at the time it left the possession and control of Defendants.

90. The Vortex was unreasonably dangerous to the user or consumer.

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

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

93. 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, and financial loss, including obligations for medical services and expenses, and other damages.

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

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

95. Defendants implied warranty that the Vortex was merchantable and for the ordinary purposes for which it was intended.

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

97. The Plaintiff, individual and/or by and through his physician, relied upon Defendants' implied warranties of merchantability in consenting to have the Vortex implanted in him.

98. Privity existed between Plaintiff and Plaintiff's physicians acted as Plaintiff's purchasing agents in the subject transaction and/or because Plaintiff was a third part beneficiary of the subject contract.

99. 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 devices varied from its intended specifications, which included, but were not limited to, variances in the following respects:

a. Defendants manufacturing process in constructing the catheter and port reservoir, which is the Vortex System, contained a design flaw as it relates to the way in which the catheter connects to the port reservoir.

b. Defendants knew or should have known that the design of the connector contributes to a reduction in the mechanical integrity of the Vortex System.

c. The defect led to detachment or dislodging of the catheter from the port reservoir of the Vortex System.

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

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

102. 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, economic loss, including obligations for medical services and expenses, and other damages.

103. Upon information and belief, Plaintiff's health care 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)

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

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

106. 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.

107. 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.

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

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

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

111. 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, emotional distress, medical expenses, surgical expenses, and other expenses as alleged herein.

112. Upon information and belief, Plaintiff's health care 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 AngioDynamics and Navilyst)

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

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

115. Defendants engaged in and fraudulently concealed information with respect to the Vortex in the following particulars:

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 no limited to, its heightened propensity of the catheter to disconnect/dislodge from the port reservoir.

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 these devices had a design flaw at the port connector causing the catheter to disconnect/dislodge from the port reservoir.

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

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

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

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

119. 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 on them.

120. Plaintiff and his 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 his physicians.

121. 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, emotional distress, medical expenses, surgical expenses, and other damages.

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

123. Had Defendants not concealed this information, neither Plaintiff nor his health care providers would have consented to using the device in Plaintiff.

124. 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 VII – PENNSYLVANIA UNFAIR TRADE PRACTICES AND CONSUMER PROTECTION LAW
(Against Defendants AngioDynamics and Navilyst)

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

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

127. The acts and practices engaged in by Defendants as outlined above constitute unlawful, unfair, and/or fraudulent business practices in violation of the Pennsylvania Unfair Trade Practices and Consumer Protection Law, 73 PS §201-1 *et seq.*

128. Defendants engaged in unlawful practices including deception, false promises, misrepresentation, and/or the concealment, suppression or omission of material facts in connection with he sale, distribution, and/or advertisement of the Vortex in violation of 73 PS §201-1 *et seq.*

129. Plaintiff purchase the Vortex, a product that was falsely represented, as set forth above, in violation of the Pennsylvania Unfair Trade Practices and Consumer Protection Law and as a result Plaintiff suffered economic damages in that the product purchased was misrepresented to be reasonably safe for use and was worth less than the product Plaintiff thought they had purchased had Defendants' representations been true.

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

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

b. Plaintiff be awarded his 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 and attorneys' fees in connection with Plaintiff's Pennsylvania Unfair Trade Practices and Consumer Protection Law, 73 PS §201-1 *et seq*;

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

g. Awarding the costs and 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: September 24, 2024

Respectfully submitted by,

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