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

IN RE: ANGIODYNAMICS, INC., AND NAVILYST MEDICAL, INC., PORT CATHETER PRODUCTS LIABILITY LITIGATION	Case No. 3:24-md-03125-JO-VET MDL No. 3125 HON. JINSOOK OHTA
MATTHEW MASSINGILL, *Plaintiff*, vs. ANGIODYNAMICS, INC., AND NAVILYST MEDICAL, INC., *Defendants*. Civil Action No.:	**'25CV3711 JO VET** **COMPLAINT AND JURY DEMAND**

Plaintiff, MATTHEW MASSINGILL, files this Complaint pursuant to Case Management Order (CMO) No. 1 ("Direct Filing Order"), 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 Massachusetts as Plaintiff's designated venue ("Original Venue"), as this case may have originally been filed in this District pursuant to 28 U.S.C. § 1391.

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

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

PARTIES

2. Plaintiff, Matthew Massingill, is an adult citizen and resident of Gordon County, Georgia 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 conducts business throughout the United States, including the State of Massachusetts. 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 Massachusetts, 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 the Original Venue and (b) Defendants' products are produced, sold to and consumed by individuals in the State of Massachusetts 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 Massachusetts and in the Original Venue, distribute vascular access products in the Original Venue, receive substantial compensation and profits from sales of vascular access products in the Original Venue, and made material omissions and misrepresentations and breaches of warranties in the Original Venue, subjecting them to *in personam* jurisdiction in the Original Venue.

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 Massachusetts, such that requiring an appearance does not offend traditional notices of fair and substantial justice.[1]

PRODUCT BACKGROUND

9. In or about 2003, a company called Horizon Medical Products ("Horizon") obtained clearance from 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. Defendant's Vascular Access Devices were designed, patented, manufactured, labeled, marketed, sold, and distributed by 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 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.

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[1] *See* Mass. Gen. L. Ch. 223a § 3 (2021) (Massachusetts' "Long Arm" Statute).

16. The intended purpose of the Vortex is to make it easier to deliver medications directly into the patient's blood stream. 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 silicone or 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 silicone and a barium sulfate radiopacity agent.

21. 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.

22. Researchers have shown that catheter surface degradation in products featuring a radiopaque barium sulfate stripe is concentrated at the locus of the stripe.[2]

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[2] *See* Hecker JF, Scandrett LA. Roughness and thrombogenicity of the outer surfaces of intravascular catheters. *J Biomed Mater Res*. 1985;19(4):381-395. doi:10.1002/jbm.820190404

23. 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.

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

27. 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 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.

28. 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 infection, thrombosis, fracturing, migrating, perforating internal vasculature and otherwise malfunctioning.

29. 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; hemorrhage; cardiac/pericardial tamponade (pressure caused by a collection of blood in the area around the heart); infection; 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.

30. Soon after the Vortex was introduced to market, which was years before 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. These failures were often associated with reports of severe patient injuries such as:

a. hemorrhage;
b. infection/ sepsis;
c. cardiac/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.

31. 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.

32. 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.[3]

33. 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.

34. 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.

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

36. 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.

37. 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.

38. The conduct of Defendants, as alleged in this Complaint, constitutes willful, wanton, gross, and outrageous corporate conduct that demonstrates a conscious disregard

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

for the safety of Plaintiff. Defendants had actual knowledge of the dangers presented by the Vortex, yet consciously failed to act reasonably to:

a. Adequately inform or warn Plaintiff, his 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

39. On or about August 22, 2013, Plaintiff underwent left subclavian placement of Defendants' Vortex product, with model number PSAX-10-1, and Lot Number 592665.[4] The Vortex port is comprised of a port body and silicone catheter. The device was implanted by Dr. Michael G. Carr, at Children's Hospital at Erlanger in Chattanooga, Tennessee.

40. 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.

41. Defendants manufactured, sold, and/or distributed the Vortex to Plaintiff, through his doctors, to be used for vein access.

42. On or about January 18, 2014, Plaintiff presented to Children's Hospital at Erlanger in Chattanooga, Tennessee. Plaintiff's medical team determined that he had developed an infection, and the Vortex was the source of the infection, resulting in the removal of the Vortex, and the procedure was performed by Dr. Curtis S. Koontz, M.D.

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[4] *See* Access GUDID Product Information for Vortex, available at https://accessgudid.nlm.nih.gov/devices/H787PSAX10I0 (last visited Dec. 22, 2025).

43. 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.

44. 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 and expected by Defendants.

45. Plaintiff and Plaintiff's physicians foreseeably used and implanted the Vortex, and did not misuse, or alter the Vortex in an unforeseeable manner.

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

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

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

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

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

51. Defendants have marketed and sold the 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.

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

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

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

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 so doing, Defendants caused the dissemination of inadequate and misleading information to patients, including the Plaintiff.

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

55. 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.

56. At the time of her implant procedure, Plaintiff was not informed of, and had no knowledge of the complaints, known complications, and risks associated with Vortex.

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

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

59. At the time of the injuries referenced herein, Plaintiff did not know that the corrective surgery Plaintiff underwent was due to a defect in the Vortex.

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

TOLLING OF THE STATUTE OF LIMITATIONS

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

62. Plaintiff's action has been filed within the applicable statute of limitations period allowable pursuant to Massachusetts law.

63. In Massachusetts, actions of tort . . . to recover for personal injuries . . . shall be commenced only within three years after the cause of action accrues."[5]

64. Under Massachusetts law, the statute of limitations is tolled for minors until the age of eighteen.[6]

65. Plaintiff was born February 10, 2005, which indicates Plaintiff has until three years after reaching the age of majority to pursue a cause of action for personal

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[5] Mass. Gen. L. Ch. 260 § 2a (2023).

[6] Mass. Gen. L. Ch. 260 § 7 ("If the person entitled thereto is a minor . . . when a right to bring an action first accrues, the action may be commenced within the time hereinbefore limited after the disability is removed," which for minors, is the date in which the minor turns eighteen years old).

injuries. Plaintiff reached the age of majority – eighteen years old – on February 10, 2023, which means his cause of action must be filed by the time he reaches the age of twenty-one, which is February 10, 2026. Pursuant to Massachusetts law, Plaintiff has timely filed his cause of action.

FIRST CAUSE OF ACTION
NEGLIGENCE

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

69. 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.

70. As a direct and proximate result of the aforementioned, Plaintiff was injured due to the use of the Vortex, which caused Plaintiff various physical, mental, and emotional injuries and damages. Accordingly, Plaintiff seeks compensatory damages.

SECOND CAUSE OF ACTION
STRICT PRODUCTS LIABILITY – FAILURE TO WARN

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

72. Defendants designed, set specifications, manufactured, prepared, compounded, 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 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.

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

74. 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.

75. 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.

76. 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.

77. 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.

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

79. 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.

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

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

82. Plaintiff and her healthcare 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 intravenous fluids and/or medications directly into the patient's bloodstream.

83. 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.

84. 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.

85. 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.

86. 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.

87. As a direct and proximate result of the aforementioned, Plaintiff was injured due to the use of the Vortex, which caused Plaintiff various physical, mental, and emotional injuries and damages. Accordingly, Plaintiff seeks compensatory damages.

THIRD CAUSE OF ACTION
STRICT LIABILITY – DESIGN DEFECT

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

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

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

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

92. 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 exceeded any benefits associated with the design and 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.

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

94. A reasonably prudent medical device manufacturer would have recognized the defective design of the Vortex and would not have placed the Vortex into the stream of commerce.

95. 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.

96. 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.

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

98. Additionally, at the time the Vortex left Defendants' control, a practical and technically feasible alternative design was available that would have prevented the harm suffered by Plaintiff.

99. As a direct and proximate result of the aforementioned, Plaintiff was injured due to the use of the Vortex, which caused Plaintiff various physical, mental, and emotional injuries and damages. Accordingly, Plaintiff seeks compensatory damages.

FOURTH CAUSE OF ACTION
BREACH OF IMPLIED WARRANTY

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

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

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

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

104. 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.

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

106. 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.

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

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

109. As a direct and proximate result of the aforementioned, Plaintiff was injured due to the use of the Vortex, which caused Plaintiff various physical, mental, and emotional injuries and damages. Accordingly, Plaintiff seeks compensatory damages.

FIFTH CAUSE OF ACTION
BREACH OF EXPRESS WARRANTY

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

111. 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.

112. 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. 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 Defendants' Vortex was safe, meanwhile Defendant fraudulently withheld and concealed information about the substantial risks of serious injury associated with using the 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.

113. 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.

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

115. 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.

116. Plaintiff was the 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.

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

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

119. As a direct and proximate result of the aforementioned, Plaintiff was injured due to the use of the Vortex, which caused Plaintiff various physical, mental, and emotional injuries and damages. Accordingly, Plaintiff seeks compensatory damages.

SIXTH CAUSE OF ACTION
FRAUDULENT CONCEALMENT

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

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

122. Defendants 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;

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 were fracturing and migrating from causes other than the manner in which the implanting physician implanted the device; and

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

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

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

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

126. 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.

127. 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 Plaintiff's physicians.

128. 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.

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

130. As a direct and proximate result of the aforementioned, Plaintiff was injured due to the use of the Vortex, which caused Plaintiff various physical, mental, and emotional injuries and damages. Accordingly, Plaintiff seeks compensatory damages.

SEVENTH CAUSE OF ACTION
VIOLATION OF THE MASSACHUSETTS CONSUMER PROTECTION ACT

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

132. The acts and practices engaged in by Defendants constitute unlawful, unfair, deceptive, and/or fraudulent business or trade practices in violation of the Massachusetts Consumer Protection Act, Mass. Gen. Ch. 93a § 1, *et seq*. (the "MCPA").

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

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

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

136. 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 MCPA, and as further described herein, which created a likelihood of confusion or misunderstanding on Plaintiff's part with respect to the Vortex Plaintiff purchased, including, but not limited to, misrepresenting that the Vortex was reasonably safe for use and failing to adequately disclose the substantial risk of infection and other injuries or harm the product entailed given the large number of adverse events Defendants knew or should have been aware of but did not adequately disclose to Plaintiff.

137. Defendants' conduct and practices engaged in offends established public policy, is unethical, and is substantially injurious to consumers such as Plaintiff.

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

139. 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 Vortex.

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

141. As a direct and proximate result of the aforementioned, Plaintiff was injured due to the use of the Vortex, which caused Plaintiff various physical, mental, and emotional injuries and damages. Accordingly, Plaintiff seeks compensatory damages.

PUNITIVE DAMAGES

142. 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 Plaintiff's 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 Plaintiff's health care providers, regarding the cause of infection and failures of the Vortex.

143. 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 Vortex, 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.

144. As a direct, proximate, and legal result of Defendants' acts and omissions as described herein, and Plaintiff's implantation with Defendants' defective product, Plaintiff suffered the injuries and damages described in this complaint.

WHEREFORE, Plaintiff 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 proper.

PRAYER

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

a. Judgement be entered against all Defendants on all causes of action of this Complaint;
b. Plaintiff be awarded her full, fair, and complete recovery for all claims and causes of action relevant to this action;
c. Plaintiff be awarded general damages according to proof at the time of trial;
d. Plaintiff be awarded damages, including past medical expenses according to proof at the time of trial;
e. Plaintiff be awarded actual damages, attorneys' fees and costs in connection with Plaintiff's claims under the Massachusetts Consumer Protection Act;
f. Plaintiff be awarded punitive damages according to proof at the time of trial;
g. Awarding pre-judgment and post-judgment interest to the Plaintiff;

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

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

Dated: December 22, 2025

By: /s/ Blair B. Matyszczyk

Blair B. Matyszczyk (admitted *pro hac vice*) – MO Bar # 66067
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CERTIFICATE OF SERVICE

I hereby certify that on December 22, 2025, a copy of the foregoing was served electronically and notice of the service of this document will be sent to all parties by operation of the Court's electronic filing system to CM/ECF participants registered to receive service in this matter.

By: /s/ Blair B. Matyszczyk
Blair B. Matyszczyk
Attorney for Plaintiff