IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

SHEILA GOODSON, Heir at Law, and Personal Representative of the Estate of KRYSTAL JOHNSON, 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) NEW JERSEY CONSUMER FRAUD ACT** **(8) PUNITIVE DAMAGES** **DEMAND FOR JURY TRIAL**

COMPLAINT

COMES NOW Plaintiff, SHEILA GOODSON, (hereinafter "Plaintiff"), by and through his 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 Vaxcel Port (hereinafter "Vaxcel" or "Defective Device").

PARTIES

2. Plaintiff, SHEILA GOODSON, is an adult resident and citizen of Atlantic County, New Jersey, and is the surviving mother of Decedent KRYSTAL JOHNSON (hereinafter Decedent).

3. Plaintiff, SHEILA GOODSON, is the Personal Representative and surviving heir at

law of Decedent.

4. Decedent, KRYSTAL JOHNSON, was a resident and citizen of Atlantic County, New Jersey at the time of her death.

5. 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 Vaxcel.

6. 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 New Jersey, 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 Vaxcel.

JURISDICTION AND VENUE

7. 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.

8. 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

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

9. Defendants have and continue to conduct substantial business in the State of New Jersey 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.

10. 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 New Jersey, 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 Boston Scientific Corp. received clearance via the 510(k) Premarket Notification Program from the Food and Drug Administration (FDA) to market and sell a product called the Vaxcel Port.

10. Around the same time, Navilyst completed the acquisition of the Vaxcel Port.

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

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

13. According to Defendants, the Vaxcel 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 Vaxcel 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 Vaxcel is a system consisting of two primary components: an injection port and a polyurethane catheter which includes additives intended to make it radiopaque and anti-thrombogenic.

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

17. The Vaxcel 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 polyurethane, a barium sulfate radiopacity agent, and a low molecular weight fluorinated additive intended to reduce formation of blood clots.

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

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

21. The mechanical integrity of a 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 Decedent 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.

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. The roughened and otherwise compromised catheter surface also leads to the increased risk of the development of Vaxcel- related complications such as fracture.

25. 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 Vaxcel.

26. At all times relevant, Defendants misrepresented the safety of the Vaxcel system, and negligently designed, manufactured, prepared, compounded, assembled, processed, labeled,

[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

marketed, distributed, and sold the Vaxcel 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.

27. Defendants obtained "clearance" to market these products under Section 510(k) of the Medical Device Amendments to the Food, Drug, and Cosmetic Act.

28. Section 510(k) permits the marketing of medical devices if the device is substantially equivalent to other legally marketed predicate devices without formal review for the safety or efficacy of the device. The FDA explained the difference between the 510(k) process and the more rigorous "premarket approval" ("PMA") process in its amicus brief filed with the Third Circuit in *Horn v. Thoratec Corp.*, which the court quoted from:

> A manufacturer can obtain an FDA findings of 'substantial equivalence' by submitting a premarket notification to the agency in accordance with section 510(k) of the [Food Drug and Cosmetic Act.] 21 U.S.C. § 360(k). A device found to be 'substantially equivalent' to a predicate device is said to be 'cleared' by the FDA (as opposed to "approved' by the agency under a PMA.
>
> 376 F.3d 163, 167 (3d. Cir. 2004).

29. A pre-market notification submitted under 510(k) is thus entirely different from a PMA, which must include data sufficient to demonstrate that the product involved is safe and effective.

30. In *Medtronic, Inc.* v. Lohr, the U.S. Supreme Court similarly described the 510(k) process, observing:

> If the FDA concludes on the basis of the [manufacturer's] § 510(k) notification that the device is 'substantially equivalent' to a pre-existing device, it can be marketed without further regulatory analysis…. The § 510(k) notification process is by no means comparable to the PMA process; in contrast to the 1,200 hours necessary to complete a PMA review, the § 510(k) review is completed in average of 20 hours

> …. As one commentator noted: "The attraction of substantial equivalence to manufacturers is clear. Section 510(k) notification requires little information, rarely elicits a negative response form the FDA, and gets processed quickly.
>
> 518 U.S. 470, 478-79 (1996).

31. Pursuant to *Wyeth v. Levine*, 555 U.S. 555 (2009), once a product is cleared "the manufacturer remains under an obligation to investigate and report any adverse associated with the drug…and must periodically submit any new information that may affect the FDA's previous conclusions about the safety, effectiveness, or labeling …." This obligation extends to post-market monitoring of adverse events/complaints.

32. At all times relevant to this action, Defendants misrepresented the safety of the Vaxcel system, and negligently designed, manufactured, prepared, compounded, assembled, processed, labeled, marketed, distributed, and sold the Vaxcel 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.

33. At all times relevant to this action, Defendants knew and had reason to know, that the Vaxcel was not safe for the patients for whom they were prescribed and implanted, because once implanted the device was prone to surface degradation and mechanical failure, increasing the risk of fracture.

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

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

a. hemorrhage;

b. cardiac/pericardial tamponade;

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

d. severe and persistent pain;

e. perforations of tissue, vessels and organs; and

f. upon information and belief, even death.

36. 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.

37. 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]

38. Prior to the discontinuation of the ASR program, Defendants reported numerous episodes of failures of their implanted port/catheter products – including episodes of catheter fracture and leakage, dislodgment, blood clot formation post-implantation, and infection – under the ASR exemption, thereby concealing them from physicians and patients.

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

40. Defendants also intentionally concealed the severity of complications caused by the Vaxcel and the likelihood of these events occurring. This included, but was not limited to, infection, thrombosis, and fracture.

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

42. Multiple feasible alternative designs for the Vaxcel have been available to Defendants at all times relevant to this matter.

43. 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 Decedent and evidences malice, fraud, gross negligence, and oppressiveness. Defendants had actual knowledge of the dangers presented by the Vaxcel System, yet consciously failed to act

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

reasonably to:

a. Adequately inform or warn Decedent, 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 Vaxcel System from the market.

SPECIFIC FACTUAL ALLEGATIONS AS TO DECEDENT

44. On or about January 18, 2011, the Decedent underwent placement of an AngioDynamics Vaxcel product. The device was implanted by Dr. David May, M.D., at Shore Medical Center in Somers Point, New Jersey, for the purpose of administering chemotherapy.

45. Defendants, directly or through their agents, apparent agents, servants, or employees designed, manufactured, marketed, advertised, distributed and sold the Vaxcel that was implanted in the Decedent.

46. Defendant manufactured, sold, and/or distributed the Vaxcel to the Decedent, through her doctors, to be used for delivery of chemotherapy.

47. On or about July 16, 2014, the Decedent underwent a port removal procedure. During the procedure, the medical team discovered that the Decedent's catheter had fractured and migrated to her right ventricle. The Decedent was urgently transferred to Interventional Radiology for retrieval of the fragment. Dr. Thomas Yu attempted to remove the catheter fragment but was unsuccessful. The catheter fragment remained inside the Decedent until her death.

48. At all times, the Vaxcel 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 Vaxcel implanted in Decedent was in the same or substantially similar condition as when it left the possession of Defendants and in the condition directed by and expected by Defendants.

50. Decedent and her physicians foreseeably used and implanted the Vaxcel and did not misuse or alter the Vaxcel in an unforeseeable manner.

51. Defendants advertised, promoted, marketed, sold, and distributed the Vaxcel as a safe medical device when Defendant knew or should have known the Vaxcel was not safe for its intended purposes and that the product could cause serious medical problems, including but not limited to fracture.

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

53. In reliance on Defendants' representations, Decedent's doctors were induced to, and did use the Vaxcel.

54. As a result of having the Vaxcel implanted, Decedent sustained significant mental and physical pain and suffering, and has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses.

55. Defendants' Vaxcel 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.

56. The Defendants have marketed and sold the Defendants' Vaxcel 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' Vaxcel include, but are not limited to, dislodgment, 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.

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

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

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

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

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

61. At the time of her operation, Decedent was not informed of, and had no knowledge of the complaints, known complications, and risks associated with Vaxcel, including, but not limited to fracture.

62. Decedent was never informed by Defendants of the defective and dangerous nature of Vaxcel.

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

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

FRAUDLENT CONCEALMENT

65. Defendants' failure to document or follow up on the known defects in its product, and concealment of known defects, constitutes fraudulent concealment that equitably tolls applicable statutes of limitation.

66. Defendants are estopped from relying on the statute of limitations defense because Defendants actively concealed the defects, suppressing reports, failing to follow through on regulatory requirements, and failing to disclose known defects to physicians. Instead of revealing the defects, Defendants continued to represent their Vaxcel as safe for their intended use.

67. Defendants are and were under a continuing duty to disclose the true character, quality, and nature of risks and dangers associated with their Vaxcel. Due to Defendants'

concealment of the true character, quality, and nature of their Vaxcel, Defendants are estopped from relying on any statute of limitations defense.

68. Defendants furthered this fraudulent concealment through a continued and systematic failure to disclose information to Decedent, Decedent's healthcare Providers, and the public.

69. Defendants' acts before, during and/or after the act causing Decedent's injury prevented Plaintiff and Decedent from discovering the injury or the cause of the injury.

70. Defendants' conduct, as described in this Complaint, amounts to conduct purposely committed, which Defendants must have realized was dangerous, heedless, reckless, and without regard to the consequences or Decedent's rights and safety.

71. Defendants' conduct, as described in this Complaint, also amounts to a continuing tort, and continues up through and including the date of the filing of Plaintiff's Complaint.

DISCOVERY RULE AND TOLLING

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

73. Despite diligent investigation by Plaintiff into the cause of Decedent's injuries, the nature of her injuries and damages, her relationship to the Vaxcel product was not discovered, and through reasonable care and diligence could not have discovered until a date within the applicable statute of limitations for filing her claims. Therefore, under appreciate application of the discovery rule, Plaintiff's suit was filed well within the applicable statutory limitations period.

74. Plaintiff did not learn of Defendants' wrongful conduct until a time within the applicable statute of limitations. Furthermore, in the existence of due diligence, Plaintiff could not have reasonably discovered the Defendant's wrongful conduct, including, but not limited to, the

defective design of the product, until a date within the statute of limitations. Therefore, under appropriate application of the discovery rule, Plaintiff's suit was filed well within the statutory limitations period.

COUNT I: NEGLIGENCE
(Against Defendants AngioDynamics and Navilyst)

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

76. The Defendants owed Decedent a duty to exercise reasonable care when designing, manufacturing, marketing, advertising, distributing, selling, conducting post-market surveillance of the Vaxcel, and recruitment and training of physicians to implant the Vaxcel.

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

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

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

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 Vaxcel;

e. Designing, manufacturing, marketing, advertising, distributing, and selling the Vaxcel to consumers, including Decedent, without an adequate warning of the significant and dangerous risks of the Vaxcel, including, but not limited to, its propensity to fracture, 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 Vaxcel; and

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

78. As a direct and proximate result of the defective Vaxcel and the wrongful acts and omissions of the Defendants as alleged herein, Decedent was injured due to the use of the Vaxcel, which caused Decedent various physical, mental, and emotional injuries and damages. Accordingly, Plaintiff as heir and representative of the Decedent seeks compensatory damages.

79. 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)

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

81. Defendant supplied, manufactured, sold, distributed and/or otherwise placed into the stream of commerce the Vaxcel implanted into Decedent.

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

83. The product was defective in its design in that when it left the hands of Defendant, it was not safe for its anticipated use and safer, more reasonable alternative designs existed that could have been utilized by Defendant.

84. The Vaxcel was in a defective condition at the time that it left the possession or

control of Defendants.

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

86. The Vaxcel was defectively designed when supplied, sold, distributed and/or otherwise placed into the stream of commerce and when it was implanted in Decedent.

87. The Vaxcel was unreasonably dangerous, 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 Decedent and/or her physician would expect when the product was used for its normal and intended purpose.

88. The Vaxcel reached Decedent's implanting surgeon and was implanted in Decedent without any substantial change in the condition in which it was supplied, distributed, sold and/or otherwise placed into the stream of commerce.

89. The Vaxcel failed to perform as safely as an ordinary consumer and/or her physician would expect when used as intended or when used in a manner reasonably foreseeable by the manufacturer, and the risks and dangers of the Vaxcel outweigh its benefits.

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

91. The Vaxcel 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.

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

93. As a direct and proximate result of Defendants' wrongdoing alleged in Count II, Decedent suffered severe pain, suffering, disability, impairment, emotional distress, loss of enjoyment of life, loss of care, comfort, and consortium, and economic losses and damages including, but not limited to medical expenses, lost income, and other special damages. Accordingly, Plaintiff as heir and representative of Decedent seeks compensatory damages.

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

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

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

96. 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.

97. 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.

98. Defendants knew or should have known at the time they manufactured, labeled,

distributed and sold the Vaxcel that was implanted into Decedent that the Vaxcel posed a significant and higher risk than other similar devices of device failure and resulting serious injuries.

99. Defendants failed to timely and reasonably warn of material facts regarding the safety and efficacy of the Vaxcel; no reasonable health care provider, including Decedent'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.

100. 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.

101. 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.

102. The Vaxcel, 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.

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

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

105. Neither Decedent nor her health care providers knew of the substantial danger

associated with the intended and foreseeable use of the device as described herein.

106. Decedent and her health care providers used the Vaxcel 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.

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

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

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

110. As a direct and proximate result of defective Vaxcel and the wrongful acts and omissions of the Defendants as alleged herein, Decedent was injured due to the use of the Vaxcel, which caused Decedent various physical, mental, and emotional injuries and damages. Accordingly, Plaintiff as heir and representative of the Decedent seeks compensatory damages.

COUNT IV: BREACH OF IMPLIED WARRANTY

(Against Defendants AngioDynamics and Navilyst)

111. Plaintiff incorporates preceding paragraphs as if set out fully herein.

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

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

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

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

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

117. Defendants breached these implied warranties of merchantability because the Vaxcel implanted in Decedent 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 Vaxcel implanted in Decedent 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 Vaxcel, 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 fractures and dislodgments of the Vaxcel and associated injuries.

d. Defendants represented to Decedent and her physicians and healthcare providers through its labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that the Defendants' Vaxcel was of merchantable quality and safe when used for its intended purpose meanwhile Defendant fraudulently withheld and concealed information about the substantial risks of serious injury associated with using Vaxcel;

e. Defendant represented to Decedent and her physicians and healthcare providers that the Defendants' Vaxcel was safe, as safe as and/or safer than other alternative procedures and devices, meanwhile Defendant fraudulently concealed information, which demonstrated that the Vaxcel was not safe, as safe as or safer than alternatives and other products available on the market; and

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

118. Defendants' breaches of their implied warranties resulted in the implantation of an

unreasonably dangerous and defective product, the Vaxcel, into Decedent's body, placing said Decedent's health and safety in jeopardy.

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

120. As a direct and proximate result of the defective Vaxcel and the wrongful acts and omissions of the Defendants as alleged herein, Decedent was injured due to the use of the Vaxcel, which caused Decedent various physical, mental, and emotional injuries and damages. Accordingly, Plaintiff as heir and representative of the Decedent seeks compensatory damages.

121. Upon information and belief, Decedent's healthcare providers sent notice to Defendants of the adverse event that occurred to Decedent and thus, the nonconformity of the Vaxcel, 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)

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

123. Defendants through their officers, directors, agents, representatives, and written literature and packaging, and written and media advertisement, expressly warranted that the Vaxcel 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.

124. The Vaxcel 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 Decedent, her physicians and healthcare providers with respect to the Vaxcel implanted in Decedent in the following respects:

1. Defendant represented to Decedent 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' Vaxcel was safe, meanwhile Defendant fraudulently withheld and concealed information about the substantial risks of serious injury associated with using Vaxcel;
2. Defendant represented to Decedent and her physicians and healthcare providers that the Defendants' Vaxcel was as safe and/or safer than other alternative procedures and devices then on the market, meanwhile Defendant fraudulently concealed information that demonstrated that Vaxcel was not safer than alternative therapies and products available on the market; and
3. Defendant represented to Decedent and her physicians and healthcare providers that the Defendants' Vaxcel was more efficacious than other alternative procedures, therapies and/or devices. Meanwhile Defendant fraudulently concealed information, regarding the true efficacy of Vaxcel.

125. The Vaxcel 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.

126. At all relevant times, the Vaxcel did not perform as safely as an ordinary consumer

would expect, when used as intended or in a reasonably foreseeable manner.

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

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

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

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

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

132. As a direct and proximate result of the defective Vaxcel and the wrongful acts and omissions of the Defendants are alleged herein, Decedent was injured due to the use of the Vaxcel, which caused Decedent various physical, mental, and emotional injuries and damages. Accordingly, Plaintiff as heir and representative of the Decedent seeks compensatory damages.

133. Upon information and belief, Decedent's healthcare providers sent notice to Defendants of the adverse event that occurred to Decedent and thus, the nonconformity of the Vaxcel, 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)

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

135. Defendants made false statements and representations to Decedent and her healthcare providers concerning the Vaxcel product implanted in Decedent.

136. Defendants engaged in and fraudulently concealed information with respect to the Vaxcel in the following respects:

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

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

c. Defendants concealed that it knew these devices were dislodging and causing complications from causes other than the manner in which the implanting physician implanted the device;

d. Defendants knew that neither Medicare, Medicaid, nor most private insurance entities offer reimbursement for medical devices which aren't approved or cleared by the FDA; and

e. That frequency of these failures and the severity of injuries were substantially

worse than had been reported.

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

138. Defendants had sole access to material facts concerning the dangers and unreasonable risks of the Vaxcel.

139. The concealment of information by the Defendants about the risks of the Vaxcel was intentional.

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

141. Decedent and her physicians relied upon the representations and were unaware of the substantial risks of the Vaxcel which the Defendants concealed from the public, including Decedent and her physicians.

142. As a direct and proximate result of the defective Vaxcel and the wrongful acts and omissions of the Defendants as alleged herein, Decedent was injured due to the use of the Vaxcel, which caused Decedent various physical, mental, and emotional injuries and damages. Accordingly, Plaintiff as heir and representative of the Decedent seeks compensatory damages.

143. The Defendants acted with oppression, fraud, and malice towards Decedent.

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

COUNT VII: VIOLATION OF THE NEW JERSEY CONSUMER FRAUD ACT

(Against Defendants AngioDynamics and Navilyst)

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

146. Decedent purchased the Vaxcel, and the product was intended for personal use.

147. The acts and practices engaged in by Defendants constitute unlawful, unfair and/or fraudulent business practices in violation of the New Jersey Consumer Fraud Act, N.J.S.A. § 56:8-2, *et. seq*.

148. 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 Vaxcel in violation of the N.J.S.A. § 56:8-2, *et. seq*.

149. Decedent purchased the Vaxcel, a product that was 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 New Jersey Consumer Fraud Act.

150. 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 New Jersey Consumer Fraud Act, and as further described herein, which created a likelihood of confusion or misunderstanding on Decedent's part with respect to the Vaxcel she purchased, including, but not limited to, misrepresenting that the Vaxcel was reasonably safe for use and failing to adequately disclose the substantial risk of fracture, and harm the product entailed given the large number of adverse events Defendants knew or should have been aware of but did not adequately disclose to Decedent.

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

design.

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

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

PUNITIVE DAMAGES

154. 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 Decedent and her health care providers, by making intentionally false and fraudulent misrepresentations about the safety and efficacy of the Vaxcel. 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 Decedent and her health care providers, regarding the cause of failures of the device.

155. Defendants had knowledge of, and were in possession of evidence demonstrating

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

156. As a direct, proximate, and legal result of Defendants' acts and omissions a described herein, and Decedent's implantation with Defendants' defective product, Decedent suffered the injuries and damages described in this Complaint.

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 reasonable attorney's fees and costs incurred as permitted under the New Jersey Consumer Fraud Act, N.J.S.A. § 56:8-2, et. seq.;

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.

Respectfully submitted,
JAVERBAUM WURGAFT HICKS KAHN WIKSTROM & SININS, P.C.

/s/ Michael A. Galpern

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*Motion for admission *pro hac vice* forthcoming