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

CHAYA CALDWELL,

Plaintiff,

vs.

ANGIODYNAMICS, INC., & NAVILYST MEDICAL, INC., & PFM MEDICAL, INC.,

Defendants.

Case No.: '25CV0142 JO VET

COMPLAINT FOR DAMAGES

(1) NEGLIGENCE.
(2) FAILURE TO WARN
(3) DESIGN DEFECT
(4) BREACH OF IMPLIED WARRANTY
(5) BREACH OF EXPRESS WARRANTY
(6) FRAUDULENT CONCEALMENT

DEMAND FOR JURY TRIAL

COMPLAINT

COMES NOW the Plaintiff, CHAYA CALDWELL, (who hereinafter shall be referred to as the "Plaintiff"), by and through her undersigned counsel, and brings this Complaint against AngioDynamics, Inc, Navilyst Medical, Inc., and PFM Medical, Inc., (collectively, the "Defendants"), and 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 Xcela (hereinafter "Xcela", or "Defective Device").

PARTIES

2. Plaintiff, CHAYA CALDWELL, is an adult citizen of Grant County, Kentucky, and claims damages as set forth below.

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

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 California, 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 Xcela.

5. Defendant PFM Medical, Inc., is a Cologne, Germany corporation with its principal place of business located in Carlsbad, California. PFM Medical Inc. is a medical device manufacturer and distributor who conducts business throughout the United States, including the State of California. PFM Medical, Inc., is engaged in the business of developing, manufacturing, marketing, and

distributing throughout the United States its medical devices, either directly or indirectly through third parties or related entities, including the Xcela.

JURISDICTION AND VENUE

6. 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.

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

8. Defendants have and continue to conduct substantial business in the State of California 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.

9. 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 California, such that requiring an appearance does not offend traditional notices of fair and substantial justice.

PRODUCT BACKGROUND

10. In or about 2008, Defendants received clearance via the 510(k) Premarket Notification Program from the Food and Drug Administration (FDA) to market and sell Xcela.

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

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

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

16. The injection port has a raised center, or "septum," where the needle is inserted for delivery of the 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 Xcela 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 and a barium sulfate radiopacity agent.

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

of the polymeric structure and degrading the mechanical properties of the polyurethane.

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

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

22. Upon information and belief, Defendants' manufacturing process in designing and constructing the catheter implanted in Plaintiff involved too high a concentration of barium sulfate particles for the polymer 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 led to an irregular catheter surface replete with fissure, pits and cracks.

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

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 an outer layer of pristine polymer), Defendants elected not to incorporate those design elements into the Xcela.

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[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

26. At all times relevant, Defendants misrepresented the safety of the Xcela system, and negligently designed, manufactured, prepared, compounded, assembled, processed, labeled, marketed, distributed, and sold the Xcela 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. At all times relevant to this action, Defendants knew and had reason to know, that the Xcela 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.

28. At all times relevant to this action, Defendants knew and had reason to know that patients implanted with a Xcela 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); 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.

29. Soon after the Xcela was introduced to market, which was years before Plaintiff was implanted with her device, Defendants began receiving large numbers of adverse event reports ("AERs") from health care providers reporting that the Xcela 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 Xcela 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. thrombosis;

d. cardiac/pericardial tamponade;

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

f. severe and persistent pain;

g. and perforations of tissue, vessels, and organs; and

h. upon information and belief, even death.

30. 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.

31. 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]

32. 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 and thrombosis– under the ASR exemption, thereby concealing them from physicians and patients.

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

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

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

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

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

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

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

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

c. Recall the Xcela from the market.

SPECIFIC FACTUAL ALLEGATIONS AS TO CHAYA CALDWELL

38. On or about May 14, 2020, Plaintiff underwent placement of an AngioDynamics Xcela implantable port catheter product, model number H965451030. The device was implanted by Dr. Alexander H. Hou, M.D., at St. Elizabeth Edgewood Hospital in Edgewood, Kentucky. The device was implanted for the purpose of ongoing venous access.

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

40. Defendants manufactured, sold, and/or distributed the Xcela to Plaintiff, through her doctors, to be used for administrating ongoing venous access.

41. On or about October 20, 2021, Plaintiff presented to St. Elizabeth Edgewood Hospital in Edgewood, Kentucky, with complaints of a fever. Plaintiff's medical team determined that she had developed an infection, which was identified as originating from her Xcela Port.

42. On or about October 23, 2021, Plaintiff's defective port was removed by Dr. Darren Hurst, M.D., at St. Elizabeth Edgewood Hospital.

43. At all times, the Xcela 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 Xcela implanted into the 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 her physicians foreseeably used and implanted the Xcela, and did not misuse, or alter the Xcela in an unforeseeable manner.

46. Defendants advertised, promoted, marketed, sold, and distributed the Xcela as a safe medical device when Defendants knew or should have known the Xcela 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 Xcela.

49. As a result of having the Xcela implanted, Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury, permanent and substantial physical deformity, has undergone and will undergo

corrective surgery or surgeries, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, and present and future lost wages.

50. Defendants' Xcela 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 a safer and more effective as compared to the traditional products and procedures for treatment, and other competing Vascular Access Devices.

51. The Defendants have marketed and sold the Defendants' Xcela 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' Xcela 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. Despite diligent investigation by Plaintiff into the cause of her injuries, including consultations with her medical providers, the nature of her injuries and damages, and their relationship to the Product was not discovered, and through reasonable care and diligence could not have been discovered until a date within the applicable statute of limitations for filing Plaintiff's claims. Therefore, under appropriate application of the discovery rule, Plaintiff's suit was filed well within the applicable statutory limitations period.

54. 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 Defendants' wrongful conduct, including, but not limited to, the defective design and/or manufacturing 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.

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

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

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

56. The Xcela was utilized and implanted in a manner foreseeable to Defendants.

57. The Xcela 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.

58. At the time of her operation, Plaintiff was not informed of, and had no knowledge of the complaints, known complications and risks associated with Xcela.

59. Plaintiff was never informed by Defendants of the defective and dangerous nature of the Xcela.

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

61. At the time of the injuries referenced herein, Plaintiff did not know that the surgery he underwent was due to a defect in these products.

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

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

FIRST CAUSE OF ACTION

NEGLIGENCE

(Against Defendants AngioDynamics, Navilyst and PFM Medical)

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

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

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

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

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

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

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

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

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

68. 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.

SECOND CAUSE OF ACTION

STRICT PRODUCTS LIABILITY – FAILURE TO WARN

(Against Defendants AngioDynamics, Navilyst and PFM Medical)

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

70. Defendants designed, set specifications, manufactured, prepared, compounded, assembled, processed, marketed, labeled, distributed, and sold the Xcela, 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.

71. 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.

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

73. Defendants further knew that these devices were fracturing and migrating for reasons other than "pinch-off" caused by the physician's initial placement of the device.

74. Defendants failed to timely and reasonably warn of material facts regarding the safety and efficacy of the Xcela; 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.

75. 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.

76. 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.

77. 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.

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

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

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

81. Plaintiff and her health care providers used Xcela 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 Plaintiff's bloodstream. Moreover, Plaintiff's health care providers did not place or maintain the device incorrectly such that it caused the device to "pinch off" or otherwise malfunction.

82. Upon information and belief, the defective and dangerous condition of the device, 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. Upon information and belief, the device implanted in Plaintiff was in the same condition as when it was manufactured, inspected, marketed, labeled, promoted, distributed and sold by Defendants.

83. 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 device.

THIRD CAUSE OF ACTION

STRICT PRODUCTS LIABILITY – DESIGN DEFECT

(Against Defendants AngioDynamics, Navilyst and PFM Medical)

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

85. The Xcela implanted in the Plaintiff was not reasonably safe for its intended use and was defective with respect to its design.

86. The Xcela was in a defective condition at the time that it left the possession or control of Defendants.

87. The Xcela was unreasonably dangerous to the user or consumer.

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

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

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

FOURTH CAUSE OF ACTION

BREACH OF IMPLIED WARRANTY

(Against Defendants AngioDynamics, Navilyst and PFM Medical)

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

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

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

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

95. Defendants breached these implied warranties of merchantability because the Xcela implanted in the Plaintiff was neither merchantable nor suited for its intended uses as warranted.

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

97. The Xcela was sold to the Plaintiff's health care providers for implantation in patients, such as the Plaintiff.

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

FIFTH CAUSE OF ACTION

BREACH OF EXPRESS WARRANTY

(Against Defendants AngioDynamics, Navilyst and PFM Medical)

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

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

101. The Xcela 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.

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

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

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

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

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

SIXTH CAUSE OF ACTION

FRAUDULENT CONCEALMENT

(Against Defendants AngioDynamics, Navilyst and PFM Medical)

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

108. Defendants fraudulently concealed information with respect to the Xcela in the following particulars:

a. Defendants represented through the labeling, advertising, marketing materials, seminar presentations, publications, notice letters, and regulatory submissions that the Xcela was safe and fraudulently

withheld and concealed information about the substantial risks of using the Xcela;

b. Defendants represented that the Xcela was safer than other alternative systems and fraudulently concealed information which demonstrated that the Xcela 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.

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

110. The concealment of information by the Defendants about the risks of the Xcela was intentional, and the representations made by Defendants were known by Defendants to be false.

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

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

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

114. The Defendants acted with oppression, fraud, and malice towards Plaintiff, who accordingly requests that the trier of fact, in the exercise of its sound discretion, award additional damages for the sake of example and for the purpose of punishing Defendants for their conduct, in an amount sufficiently large to be an example to others, and to deter this Defendants and others from engaging in similar conduct in the future.

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

PUNITIVE DAMAGES

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

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

118. 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, and will continue to suffer, 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, present, and future, medical expenses according to proof at the time of trial;

e. Plaintiff be awarded punitive damages according to proof at the time of trial;

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.

Respectfully submitted,

Dated: January 22, 2025

By: */s/ Ruth Rizkalla*

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Attorneys for Plaintiff

*Motion for admission *pro hac vice* forthcoming

CERTIFICATE OF SERVICE

I hereby certify that on January 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/ Ruth Rizkalla
Ruth Rizkalla
Attorney for Plaintiff