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Attorney for Plaintiff

**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

MDL No. 3125 – JUDGE JINSOOK OHTA

RACHEL DINAN,

Plaintiff,

vs.

ANGIODYNAMICS, INC., AND NAVILYST
MEDICAL, INC.,

Defendants.

**COMPLAINT AND
JURY DEMAND**

Plaintiff, Rachel Dinan, files this Complaint pursuant to Case Management Order (CMO) No. 1 (“Direct Filing Order”), and is bound by the rights, protects, privileges and obligations of that CMO. In accordance with CMO No. 1, Plaintiff hereby designates the United States District Court for the District of Delaware as Plaintiffs’ Designated venue (“Original Venue”) as this case may have originally been filed in this District pursuant to 28 U.S.C. § 1391.

Plaintiff, Rachel Dinan, (“Plaintiff”), by and through undersigned counsel, brings this Complaint against AngioDynamics, Inc. and Navilyst Medical, Inc., (“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 (“Defective Device”).

PARTIES

2. Plaintiff, Rachel Dinan, is a citizen of Wilmington, Delaware 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 Defective Device.

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 Defective Device.

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 California, thereby subjecting Defendants to personal jurisdiction in this action and making them all "residents" of the Original Venue.

7. Defendants have and continue to conduct substantial business in the State of California 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 California, such that requiring an appearance does not offend traditional notions of fair and substantial justice.

PRODUCT BACKGROUND

9. In or about 2007, a company called Rita Medical Systems, Inc. received clearance via the 510(k) Premarket Notification Program from the Food and Drug Administration (FDA) to market and sell a product called Vortex® CT Port Access System.

10. Around the same time, AngioDynamics completed the acquisition of the assets and liabilities of Rita Medical Systems, Inc. and rebranded the subject product as Xcela.

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

12. 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 port 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 port 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 port 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 port 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 design of the product at issue in this case includes a catheter with a stripe containing a stripe with a higher concentration of barium sulfate than the rest of the catheter.

22. According to relevant medical literature, such design is proven to have a higher rate of fracture and infection than catheters without the barium-loaded stripe.

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

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

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

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

as sections of the catheter lumen which contain more than 30% barium sulfate by weight, reducing the catheter strength at those loci.

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

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

28. At all times relevant, Defendants misrepresented the safety of the Xcela port system, and negligently designed, manufactured, prepared, compounded, assembled, processed, labeled, marketed, distributed, and sold the Xcela port system as safe and effective device to be surgically implanted to provide repeated access to the vascular system for the delivery of medications, intravenous fluids, parenteral nutrition solutions, and blood products.

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

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

and perforations of tissue, vessels and organs, or the need for additional surgeries to remove the defective device.

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

- a. hemorrhage.
- b. infection/sepsis;
- c. cardia/pericardial tamponade;
- d. cardiac arrhythmia and other symptoms similar to myocardial infarction;
- e. perforations of tissue, vessels and organs; and
- f. upon information and belief, even death.

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

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

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

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

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

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

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

39. The conduct of Defendants, as alleged in the 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 port system, yet consciously failed to act reasonably to:

- a. Adequately inform or warn Plaintiff, their 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 port system from the market.

SPECIFIC FACTUAL ALLEGATIONS AS TO RACHEL DINAN

40. On or about July 5th, 2016, Plaintiff Rachel Dinan underwent placement of the AngioDynamics Xcela port, Lot# 136785000. The device was implanted at Main Line Health Hospital in Media, Pennsylvania.

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

42. Defendant manufactured, sold, and/or distributed the Xcela port to Plaintiff, through their doctors, to be used for treatment.

43. On September 19th, 2016, Plaintiff was diagnosed with chest wall cellulitis at Main Line Health Hospital. On the same date, it was also ascertained that the port had been displaced, causing swelling around the soft tissues. The port was subsequently removed due to its migration.

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

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

46. Plaintiff and their physicians foreseeably used and implanted the Xcela port and did not misuse or alter the Xcela port in an unforeseeable manner.

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

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

49. In reliance on Defendants' representations, Plaintiff's doctor was induced to and did use the Xcela port.

50. As a result of having the Xcela port implanted, Plaintiff has experienced significant pain and suffering. After just two months of having the port implanted, it got infected causing cellulitis and it migrated. As a result of this, Plaintiff has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses.

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

52. The Defendants have marketed and sold the Defendants' Xcela port 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.

53. The injuries, conditions, and complications suffered due to Defendants' Xcela port include but are not limited to infection; necrosis; fracture and leakage; 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.

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

- a. Defendant failed to design and establish a safe, effective procedure for removal of the Xcela port; therefore, in the event of failure, injury or complications it is difficult to safely remove the Xcela port.
- b. Defendants provided incomplete, insufficient, and misleading information to physicians in order to increase the number of physicians using Xcela port for the purpose of increasing their sales. By so doing, Defendants caused the dissemination of inadequate and misleading information to patients, including the Plaintiff.

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

56. The Xcela port 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.

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

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

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

60. As a result of the Defendants' actions and inactions, Plaintiff has been injured and has sustained economic and non-economic damages, both in the past and future, including for pain and suffering and medical expenses.

FIRST CAUSE OF ACTION
NEGLIGENCE

61. Plaintiff incorporates paragraphs 1 through 60 as if set out fully herein.

62. 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 port.

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

- . Failing to properly and thoroughly test the Xcela port before releasing the device to market, and/or failing to implement feasible safety improvements;
- . Failing to properly and thoroughly analyze the data resulting from any pre-market testing of the Xcela port;
- . Failing to conduct sufficient post-market testing and surveillance of the Xcela port;
- . 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 Xcela port.
- . Designing, manufacturing, marketing, advertising, distributing, and selling the Xcela port to consumers, including Plaintiff, without an adequate warning of the significant and dangerous risks of the Xcela port and without proper instruction to avoid the harm which could foreseeably occur as a result of using the device;
- . Failing to exercise due care when advertising and promoting the Xcela port; and

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

64. As a direct, actual, and proximate cause of the Defendants' actions, omissions, and misrepresentations, Plaintiff has been injured and has sustained economic and non-economic damages, both in the past and future, including for pain and suffering and medical expenses.

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

SECOND CAUSE OF ACTION
STRICT PRODUCTS LIABILITY
FAILURE TO WARN

66. Plaintiff incorporates paragraphs 1 through 65 as if set out fully herein.

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

68. 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.

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

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

71. 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.

72. 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.

73. The Xcela port, 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.

74. 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.

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

76. Upon information and belief, neither Plaintiff nor their health care providers knew of the substantial danger associated with the intended and foreseeable use of the device as described herein.

77. Plaintiff and their health care providers used the Xcela port 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.

78. 78. 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.

79. 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.

80. 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. Had Defendants provided adequate warnings, Plaintiff and their physicians would not have used the device.

81. As a direct, actual, and proximate cause of the Defendants' actions, omissions, and misrepresentations, Plaintiff has been injured and has sustained economic and non-

economic damages, both in the past and future, including for pain and suffering and medical expenses.

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

THIRD CASE OF ACTION
STRICT PRODUCTS LIABILITY
DESIGN DEFECT

83. Plaintiff incorporates paragraphs 1 through 82 as if set out fully herein.

84. Defendants supplied, manufactured, sold, distributed and/or otherwise placed into the stream of commerce the Xcela port implanted into Plaintiff.

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

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

87. The Xcela port was unreasonably dangerous to the user or consumer, taking into consideration the utility of said product and the risks involved in its use. The foreseeable risks associated with the design of the product were more dangerous than a reasonably prudent consumer such as Plaintiff and/or their physicians would expect when the product was used for its normal and intended purpose.

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

89. A reasonably prudent medical device manufacturer would have recognized the defective design of the Xcela port and not placed it into the stream of commerce.

90. The design defects in the Xcela port were not known, knowable and/or reasonably apparent to Plaintiff and/or their physician or discoverable upon any reasonable examination.

91. The Xcela port 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. As a direct, actual, and proximate cause of the Defendants' actions, omissions, and misrepresentations, Plaintiff has been injured and has sustained economic and non-economic damages, both in the past and future, including for pain and suffering and medical expenses.

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

FOURTH CAUSE OF ACTION BREACH OF IMPLIED WARRANTY

94. Plaintiff incorporates paragraphs 1 through 93 as if set out fully herein.

95. Defendants implicitly warranted that the Xcela port was merchantable and fit for the ordinary purposes for which it was intended.

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

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

98. Privity exists between Plaintiff and the Defendants 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.

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

100. Defendants breached these implied warranties of merchantability because the Xcela port 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 were not limited to, variances in the following respects:

- . Defendants' manufacturing process in constructing the catheter of the Xcela port 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;
- . 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 Xcela port, as the barium sulfate particles dissociate from the surface of the catheter over time; and
- . 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.

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

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

103. As a direct, actual, and proximate cause of the Defendants' actions, omissions, and misrepresentations, Plaintiff has been injured and has sustained economic and non-economic damages, both in the past and future, including for pain and suffering and medical expenses.

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

FIFTH CAUSE OF ACTION BREACH OF EXPRESS WARRANTY

105. Plaintiff incorporates paragraphs 1 through 104 as if set out fully herein.

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

107. The Xcela port 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.

108. Defendants further breached express representations and warranties made to Plaintiff, their physicians and healthcare providers with respect to the Xcela port implanted in Plaintiff in the following respects:

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

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

110. Plaintiff, their physicians, and the medical community reasonably relied upon the Defendants' express warranties for the Xcela port.

111. Privity exists between Plaintiff and the Defendants 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.

112. 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.

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

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

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

116. As a direct, actual, and proximate cause of the Defendants' actions, omissions, and misrepresentations, Plaintiff has been injured and has sustained economic and non-economic damages, both in the past and future, including for pain and suffering and medical expenses.

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

SIXTH CAUSE OF ACTION FRAUDULENT CONCEALMENT

118. Plaintiff incorporates paragraphs 1 through 117 as if set out fully herein.

119. Defendants made false statements and representations to Plaintiff and their healthcare providers concerning the Xcela port product implanted in Plaintiff.

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

- . Defendants represented through the labeling, advertising, marketing materials, seminar presentations, publications, notice letters, and regulatory submissions that the Xcela port was safe and fraudulently withheld and concealed information about the substantial risks of using the Xcela port, including but not limited to, its heightened propensity to precipitate infection, and cause complications;
- . Defendants represented that the Xcela port was safer than other alternative systems and fraudulently concealed information which demonstrated that the Xcela port was not safer than alternatives available on the market;
- . Defendants concealed that they knew these devices were fracturing and migrating from causes other than the manner in which the implanting physician implanted the device; and
- . The frequency of these failures and the severity of injuries were substantially worse than had been reported.

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

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

123. The concealment of information by the Defendants about the risks of

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

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

126. As a direct and proximate result of the Defendants' actions, omissions and misrepresentations, Plaintiff has been injured and has sustained economic and non-economic damages, both in the past and future, including for pain and suffering and medical expenses.

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

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

PRAYER

Wherefore, Plaintiffs prays for Judgement against each of the Defendants as follows:

- . Judgment be entered against all Defendant on all causes of action of this Complaint;
- . Plaintiff be awarded their full, fair, and complete recovery for all claims and causes of action relevant to this action;
- . Plaintiff be awarded general damages according to proof at the time of trial;
- . Plaintiff be awarded damages, including past, present, and future, medical expenses according to proof at the time of trial;
- . Awarding pre-judgment and post-judgment interest to the Plaintiff;
- . Awarding the costs and the expenses of this litigation to the

Plaintiff; and

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

DEMAND FOR JURY TRIAL

Plaintiff hereby demands trial by jury on all issues.

Dated: August 11, 2026

/s/Ashleigh Raso

Ashleigh Raso (MN 0399353)

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CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)

I. (a) PLAINTIFFS

Rachel Dinan

(b) County of Residence of First Listed Plaintiff New Castle
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys (Firm Name, Address, and Telephone Number)

Ashleigh Raso, NGRV, 60th S. 6th St. Suite 2900,
Minneapolis, MN 55402 (202) 792-7927

DEFENDANTS

ANGIODYNAMICS, INC., AND NAVILYST
MEDICAL, INC..County of Residence of First Listed Defendant _____
(IN U.S. PLAINTIFF CASES ONLY)NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF
THE TRACT OF LAND INVOLVED.

Attorneys (If Known)

'26CV4577 JO VET

II. BASIS OF JURISDICTION (Place an "X" in One Box Only)

- ☐ 1 U.S. Government Plaintiff
- ☐ 2 U.S. Government Defendant
- ☐ 3 Federal Question
(U.S. Government Not a Party)
- ☒ 4 Diversity
(Indicate Citizenship of Parties in Item III)

III. CITIZENSHIP OF PRINCIPAL PARTIES (Place an "X" in One Box for Plaintiff and One Box for Defendant)

- | | PTF | DEF | | PTF | DEF |
|---|---------------------------------------|----------------------------|---|----------------------------|---------------------------------------|
| Citizen of This State | ☐ 1 | ☐ 1 | Incorporated or Principal Place of Business In This State | ☐ 4 | ☐ 4 |
| Citizen of Another State | ☒ 2 | ☐ 2 | Incorporated and Principal Place of Business In Another State | ☐ 5 | ☒ 5 |
| Citizen or Subject of a Foreign Country | ☐ 3 | ☐ 3 | Foreign Nation | ☐ 6 | ☐ 6 |

IV. NATURE OF SUIT (Place an "X" in One Box Only)

Click here for: [Nature of Suit Code Descriptions.](#)

CONTRACT	TORTS	FORFEITURE/PENALTY	BANKRUPTCY	OTHER STATUTES
☐ 110 Insurance	PERSONAL INJURY	☐ 625 Drug Related Seizure of Property 21 USC 881	☐ 422 Appeal 28 USC 158	☐ 375 False Claims Act
☐ 120 Marine	☐ 310 Airplane	☐ 690 Other	☐ 423 Withdrawal 28 USC 157	☐ 376 Qui Tam (31 USC 3729(a))
☐ 130 Miller Act	☐ 315 Airplane Product Liability		INTELLECTUAL PROPERTY RIGHTS	☐ 400 State Reapportionment
☐ 140 Negotiable Instrument	☐ 320 Assault, Libel & Slander		☐ 820 Copyrights	☐ 410 Antitrust
☐ 150 Recovery of Overpayment & Enforcement of Judgment	☐ 330 Federal Employers' Liability		☐ 830 Patent	☐ 430 Banks and Banking
☐ 151 Medicare Act	☐ 340 Marine		☐ 835 Patent - Abbreviated New Drug Application	☐ 450 Commerce
☐ 152 Recovery of Defaulted Student Loans (Excludes Veterans)	☐ 345 Marine Product Liability		☐ 840 Trademark	☐ 460 Deportation
☐ 153 Recovery of Overpayment of Veteran's Benefits	☐ 350 Motor Vehicle	LABOR	☐ 880 Defend Trade Secrets Act of 2016	☐ 470 Racketeer Influenced and Corrupt Organizations
☐ 160 Stockholders' Suits	☐ 355 Motor Vehicle Product Liability	☐ 710 Fair Labor Standards Act	SOCIAL SECURITY	☐ 480 Consumer Credit (15 USC 1681 or 1692)
☐ 190 Other Contract	☐ 360 Other Personal Injury	☐ 720 Labor/Management Relations	☐ 861 HIA (1395ff)	☐ 485 Telephone Consumer Protection Act
☐ 195 Contract Product Liability	☐ 362 Personal Injury - Medical Malpractice	☐ 740 Railway Labor Act	☐ 862 Black Lung (923)	☐ 490 Cable/Sat TV
☐ 196 Franchise		☐ 751 Family and Medical Leave Act	☐ 863 DIWC/DIWW (405(g))	☐ 850 Securities/Commodities/Exchange
		☐ 790 Other Labor Litigation	☐ 864 SSID Title XVI	☐ 890 Other Statutory Actions
REAL PROPERTY	CIVIL RIGHTS	☐ 791 Employee Retirement Income Security Act	☐ 865 RSI (405(g))	☐ 891 Agricultural Acts
☐ 210 Land Condemnation	☐ 440 Other Civil Rights		FEDERAL TAX SUITS	☐ 893 Environmental Matters
☐ 220 Foreclosure	☐ 441 Voting	IMMIGRATION	☐ 870 Taxes (U.S. Plaintiff or Defendant)	☐ 895 Freedom of Information Act
☐ 230 Rent Lease & Ejectment	☐ 442 Employment	☐ 462 Naturalization Application	☐ 871 IRS—Third Party 26 USC 7609	☐ 896 Arbitration
☐ 240 Torts to Land	☐ 443 Housing/ Accommodations	☐ 465 Other Immigration Actions		☐ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
☐ 245 Tort Product Liability	☐ 445 Amer. w/Disabilities - Employment			☐ 950 Constitutionality of State Statutes
☐ 290 All Other Real Property	☐ 446 Amer. w/Disabilities - Other			
	☐ 448 Education			
	PRISONER PETITIONS			
	Habeas Corpus:			
	☐ 463 Alien Detainee			
	☐ 510 Motions to Vacate Sentence			
	☐ 530 General			
	☐ 535 Death Penalty			
	Other:			
	☐ 540 Mandamus & Other			
	☐ 550 Civil Rights			
	☐ 555 Prison Condition			
	☐ 560 Civil Detainee - Conditions of Confinement			

V. ORIGIN (Place an "X" in One Box Only)

- ☐ 1 Original Proceeding
- ☐ 2 Removed from State Court
- ☐ 3 Remanded from Appellate Court
- ☐ 4 Reinstated or Reopened
- ☐ 5 Transferred from Another District (specify)
- ☒ 6 Multidistrict Litigation - Transfer
- ☐ 8 Multidistrict Litigation - Direct File

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing (Do not cite jurisdictional statutes unless diversity):

28 USC 1332

Brief description of cause:

Product Liability resulting in injury

VII. REQUESTED IN COMPLAINT:

☐ CHECK IF THIS IS A CLASS ACTION UNDER RULE 23, F.R.Cv.P.

DEMAND \$

75,000

CHECK YES only if demanded in complaint:

JURY DEMAND:

☒ Yes ☐ No

VIII. RELATED CASE(S) IF ANY

(See instructions):

JUDGE Judge Ohta

DOCKET NUMBER MDL 3125

DATE

SIGNATURE OF ATTORNEY OF RECORD

8/11/2026

/s/Ashleigh Raso

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____