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ATTORNEYS FOR PLAINTIFF

UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

IN RE: ANGIODYNAMICS, INC., AND NAVILYST MEDICAL, INC., PORT CATHETER PRODUCTS LIABILITY LITIGATION

LORRIE SMITH,

Plaintiff,

v.

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

Defendants.

Case No.: 3:24-md-03125-JO-VET
MDL No. 3125
'26CV0470 JO VET
COMPLAINT

JUDGE JINSOOK OHTA

COMPLAINT

Plaintiff files this Complaint pursuant to CMO No. 1, and is bound by the rights, protections, privileges, and obligations of that CMO. In accordance with CMO No. 1, Plaintiff hereby designates the United States District Court for the Northern District of New York as the place of remand as the case may have originally been filed there pursuant to 28 U.S.C. §1391. Plaintiff, Lorrie Smith, (hereinafter "Plaintiff"), by and through her 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 SmartPort (hereinafter "SmartPort" or "Defective Device").

PARTIES

2. Plaintiff Lorrie Smith is an adult resident and citizen of Granville, New York, 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 SmartPort.

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 New York, 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 SmartPort.

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 this District, and (b) Defendants' products are produced, sold to, and consumed by individuals in the State of New York, thereby subjecting Defendants to personal jurisdiction in this action and making them both "residents" of this judicial District.

7. Defendants have and continue to conduct substantial business in the State of New York 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.

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 New York, such that requiring an appearance does not offend traditional notions of fair play 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 SmartPort CT.

11. Defendants' vascular access devices were designed, patented, manufactured, labeled, marketed, sold, and distributed by the Defendants at all relevant times herein.

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

13. According to Defendants, the SmartPort 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 SmartPort 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 SmartPort is a system consisting of two primary components: an injection port and a catheter, made of polyurethane or silicone, 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 SmartPort is indicated for patient therapies requiring repeated access to the vascular system. The port system can be used for infusion of medications, I.V. fluids, parenteral nutrition solutions, blood products, and for the withdrawal of blood samples.

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

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

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

21. The design of the product at issue in this case includes a catheter 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 than catheters without the barium-loaded stripe.

23. 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.

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

25. This defect in the manufacturing process led to a heterogeneous modified polymer which led to an irregular catheter surface replete with fissure, pits and cracks as well 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 also leads to the collection and proliferation of fibrinous blood products, thereby drastically increasing the risk of biofilm, infection, sepsis, fracture, and thrombus.

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 the silicone), Defendants elected not to incorporate those design elements into the SmartPort.

[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

28. Among the most common and concerning complications associated with implanted port catheters, such as the Defective Device system, are IPC-related infections.

29. There are several types of IPC-related infections. The most common and severe are catheter-related bloodstream infections (CRBSIs), which occur when microorganisms, typically bacteria or fungi, colonize the surface of the catheter and enter the bloodstream.[2]

30. IPC pocket infections refer to an infection localized in the subcutaneous pocket where the port is implanted. These types of infections most often occur within a few days of implantation.[3] If clinical signs appear in the IPC pocket after that time-frame, then it is most commonly related to a CRBSI.[4]

31. The least common IPC-related infections are tunnel infections which occur when an infection occurs along the subcutaneous tunnel created for the placement of the central venous catheter.[5]

32. IPC-related infections occur through a multi-step process that begins with device conditioning followed by microbial contamination, microbial adherence and biofilm formation, and ultimately progresses to localized infection and/or bloodstream infection. Biofilm formation on IPCs is particularly problematic because of the frequent

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[2] Teichgräber, UKM., Gebauer, B., Saleh, A. Outcome analysis in 3,160 implantations of radiologically guided placements of totally implantable central venous port systems. European Radiology. 2011;21(6):1224–1232.

[3] Machat, S., et al. Complications of central venous port systems: a pictorial review. Insights into imaging. 2019; 10(1):86; Gominet, M., et al. Central Venous Catheters & Biofilms: Where Do We Stand in 2017? APMS 125:365-375 (2017).

[4] Baang JH, Inagaki K, Nagel J, et al. Inpatient Diagnosis and Treatment of Catheter-Related Bloodstream Infection [Internet]. Ann Arbor (MI): Michigan Medicine University of Michigan; 2023 Jan.

[5] Machat, S., et al. Complications of central venous port systems: a pictorial review. Insights into imaging. 2019; 10(1):86; Gominet, M., et al. Central Venous Catheters & Biofilms: Where Do We Stand in 2017? APMS 125:365-375 (2017).

use and long-term placement of these devices. Microbial contamination, colonization, and biofilm formation on catheter surfaces can begin as early as 24 hrs. after insertion.[6]

33. Vascular access device (VAD), like Defendants' IPC, infections are closely linked to the development of biofilms on the surface of the foreign body.[7] Approximately 60% of hospital acquired infections (HAIs) worldwide are believed to be caused by micro-organisms forming biofilms on medical devices.[8]

34. Once the biofilm is established, it serves as a reservoir for persistent infection. Biofilms are notoriously difficult to eradicate due to their resistance to both the host's immune system and antimicrobial therapy.[9] In most instances, antimicrobial therapy is not sufficient to treat these infections, as antimicrobials will not remove/eliminate the biofilms and their embedded micro-organisms and thus device removal is required.[10]

35. Although not an absolute requirement for microbial adhesion, the initial adhesion of proteins to the surface of a foreign body (also called conditioning) and thrombosis promotes biofilm formation. Immediately after insertion, a conditioning film composed of organic macromolecules from body fluids, such as fibrinogen, fibronectin, vitronectin, thrombospondin, glucose, and pyruvate, coats the catheter surface.[11] This is a

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[6] Donlan, R. M. Biofilms and device-associated infections. Emerging infectious diseases. Centers for Disease Control and Prevention, 2002:7(2), p. 277; Gominet, M., et al. Central Venous Catheters & Biofilms: Where Do We Stand in 2017? APMS 125:365-375 (2017).

[7] Bustos, M. D., et al. Long-term Catheterization: current approaches in the diagnosis and treatment of port-related infections. Infection and Drug Resistance 2014:7 25-35.

[8] Treter, J., Macedo, a J. Catheters: a suitable surface for biofilm formation. Science against microbial pathogens: communicating current research and technological advances; Formatex 2011:835–842.

[9] Gominet et al. (2017); Bustos et al. (2014)

[10] Kojic, EM and Darouiche, RO. Candida Infections of Medical Devices. Clin. Microbiol. Rev. 2004; 17 (2):255-267.; Mack, D., et al. Biofilm formation in medical device-related infection. Int. J. Artif. Organs. 2006; 29 (4):343-59.

[11] Fletcher, S. Catheter-related bloodstream infection, Continuing Education in Anaesthesia Critical Care & Pain, 2005;5(2), pp. 49–51; Gominet, M., et al. Central Venous Catheters & Biofilms: Where Do We Stand in 2017? APMS 125:365-375 (2017).

natural response to a foreign body; however, this film unfortunately provides an ideal environment for microbial attachment.[12]

36. This protein adhesion facilitates microbial adhesion in multiple ways. Protein adhesion creates more surface area for bacteria adhesion.[13] Protein adhesion allows bacteria to adhere to more diverse surfaces.[14] Proteins within the thrombus can attract microbial species.[15] Protein adhesion increases the risk of both biofilm formation and thrombosis, which are closely interconnected and create a reinforcing cycle.[16]

37. Preventing microbial adhesion and biofilm formation leads to a significant drop in infection rates.

38. IPC materials permit rather than inhibit microbial adhesion and biofilm formation.

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[12] Gominet, M., et al. Central Venous Catheters & Biofilms: Where Do We Stand in 2017? APMS 125:365-375 (2017); Nycz, A., et al. Surface Analysis of Long-Term Hemodialysis Catheters Made of Carbothane (Poly(carbonate)urethane) Before and After Implantation in Patients' Bodies. Act of Bioengineering & BioMechanics. 2018; 20(2).

[13] Palmer, J, Flint, S and Brooks, J. Bacterial cell attachment, the beginning of a biofilm. Journal of Industrial Microbiology and Biotechnology. 2007; 34(9):577–588.

[14] Li, Q., et al. Zwitterionic Biomaterials. Chemical Reviews. 2022; 122(23):17073–17154.

[15] Mohammad, SF. Enhanced risk of infection with device-associated thrombi. ASAIO journal. 2000; 46(6):S63–S68; Mehall, JR., et al. Fibrin sheath enhances central venous catheter infection. Critical care medicine. 2002; 30(4):908–912; Neoh, KG., et al. Surface modification strategies for combating catheter-related complications: recent advances and challenges. Journal of Materials Chemistry B. 2017; 5(11):2045–2067.

[16] Galloway, S. et al., Long-term central venous access, 92 British Journal of Anaesthesia 722 (2004); Fletcher, S. Catheter-related bloodstream infection, Continuing Education in Anaesthesia Critical Care & Pain, 2005;5(2), pp. 49–51; van Rooden, CJ., Schippers, EF., et al. Infectious complications of central venous catheters increase the risk of catheter-related thrombosis in hematology patients: a prospective study. Journal of Clinical Oncology. American Society of Clinical Oncology; 2005;23(12):2655–2660; Smith, RS., Zhang, Z., Bouchard, M., et al. Vascular catheters with a nonleaching poly-sulfobetaine surface modification reduce thrombus formation and microbial attachment. Science Translational Medicine. 2012;4(153); Busch JD, Vens M, Mahler C, Herrmann J, Adam G, Ittrich H. Complication Rates Observed in Silicone and Polyurethane Catheters of Totally Implanted Central Venous Access Devices Implanted in the Upper Arm. J Vasc Interv Radiol. 2017 Aug;28(8):1177-1183; Neoh, KG., et al. Surface modification strategies for combating catheter-related complications: recent advances and challenges. Journal of Materials Chemistry B. 2017; 5(11):2045–2067.

a. Polymers used for catheters are hydrophobic surfaces that promote microbial and protein attachment.

b. Catheter surface roughness promotes biofilm formation and increases the risk of infection.

c. Barium Sulfate ($BaSO_4$) diffusion increases surface roughness which promotes biofilm formation and increases the risk of infection.

d. Biodegradation increases surface roughness which promotes biofilm formation and increases the risk of infection.

e. Port Body material and structure can influence microbial adhesion and biofilm formation.

39. Technologies exist that prevent biofilm formation and/or reduce thrombus accumulation which also reduces the risk of biofilm formation.

a. Antimicrobial catheters prevent and/or reduce the risk of CRBSI by preventing or reducing bacterial colonization and biofilm formation on catheter surfaces through traditional bactericidal (lethal) or bacteriostatic (inhibitory) mechanisms.[17]

b. Catheters with non-fouling coatings and substrates reduce risk of CRBSI by inhibiting its triggers—protein adsorption, bacterial adhesion, and biofilm formation on catheter surfaces.[18]

c. Catheters that incorporate both non-fouling coatings or additives

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[17] Zander, Becker. Antimicrobial and Antifouling Strategies for Polymeric Medical Devices. ACS Macro Letters. 2018;7(1):16-25; Neoh, KG., et al. Surface modification strategies for combating catheter-related complications: recent advances and challenges. Journal of Materials Chemistry B. 2017; 5(11):2045–2067; Monzillo, V., et al. Chlorhexidine-silver sulfadiazine–impregnated central venous catheters: In vitro antibacterial activity and impact on bacterial adhesion. New Microbiologica. 2012; 35(2):175–182; Xu, LC., Siedlecki, CA. Antibacterial Polyurethanes. Advances in Polyurethane Biomaterials, 2016.

[18] Li, Q., et al. Zwitterionic Biomaterials. Chemical Reviews. 2022; 122(23):17073–17154; Zhang, Z., et al. Blood compatibility of surfaces with superlow protein adsorption. Biomaterials. 2008;29(32):4285–4291.

(preventing protein adsorption and bacterial adhesion) *and* antimicrobial agents (killing bacteria) reduce the risk of CRBSI.[19]

40. Defendants' IPCs design, such as the Defective Device, increase the risk of infection.

a. Defendants' IPCs have rough and variable surfaces.

b. Defendants' uncoated IPCs permit rather than inhibit microbial adhesion, thus increasing the risk of infection.

c. Defendants' uncoated IPCs permit rather than inhibit thrombus accumulation which increases risk of infection.

d. Defendants' IPCs are impregnated with barium sulfate which increases the risk of CRBSI.

e. Defendants' IPCs are prone to degradation which increases the risk of biofilm formation.

f. Defendants' uncoated IPCs port bodies permit rather than inhibit biofilm formation and thrombus accumulation which increases risk of infection.

g. Defendants failed to incorporate technologies that reduce the risk of infection even though numerous commercially available technologies exist.

41. If Defendants had incorporated safer alternative designs, then the incidence of IPC-related infections would have been reduced.

a. If Defendants had incorporated antimicrobial/antiseptic technology, then the incidence of IPC-related infections would have been reduced.

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[19] Zander, Becker. Antimicrobial and Antifouling Strategies for Polymeric Medical Devices. ACS Macro Letters. 2018;7(1):16-25; Li, Q., et al. Zwitterionic Biomaterials. Chemical Reviews. 2022; 122(23):17073–17154; Neoh, KG., et al. Surface modification strategies for combating catheter-related complications: recent advances and challenges. Journal of Materials Chemistry B. 2017; 5(11):2045–2067; Singha, P., Locklin, J., Handa, H. Multipronged Approach to Combat Catheter-Associated Infections and Thrombosis by Combining Nitric Oxide and a Polyzwitterion: A 7-Day In Vivo Study In a Rabbit Model. ACS Appl. Mater. Interfaces 2020;12:907-9079.

b. If Defendants had incorporated antifouling technology, then the incidence of IPC-related infections would have been reduced.

c. If the Defendants had incorporated technologies that reduce surface roughness, then the incidence of IPC-related infections would have been reduced.

d. If the Defendants had incorporated other technologies, such as combined non-fouling and antimicrobial surface modifications, enzyme treatment or heparin then the incidence of IPC-related infections would have been reduced.

42. At all times relevant, Defendants misrepresented the safety of the SmartPort system, and negligently designed, manufactured, prepared, compounded, assembled, processed, labeled, marketed, distributed, and sold the SmartPort 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.

43. At all times relevant to this action, Defendants knew and had reason to know, that the SmartPort 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.

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

45. Soon after the SmartPort 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 SmartPort 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 SmartPort 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. thrombus;
d. cardia/pericardial tamponade;
e. cardiac arrhythmia and other symptoms similar to myocardial infarction;
f. severe and persistent pain;
g. perforations of tissue, vessels and organs; and
h. upon information and belief, even death.

46. 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.

47. 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.[20]

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

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

physicians and patients.

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

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

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

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

53. 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 SmartPort 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 SmartPort System from the market.

SPECIFIC FACTUAL ALLEGATIONS AS TO LORRIE SMITH

54. On or about October 7, 2022, Plaintiff underwent placement of an AngioDynamics 8F SmartPort product, reference number H787CT80STPD0, lot number 5743901. The device was implanted by Dr. Joseph A. Dagostino Jr., MD at Glens Falls

Hospital in Glens Falls, New York, for the purpose of providing chemotherapy.

55. On or about January 26, 2023, Plaintiff was admitted to Glens Falls Hospital for shortness of breath and chest wall pain. During her extended hospital stay, Plaintiff's SmartPort was found to have a port infection that required port removal and replacement.

56. Following Plaintiff's diagnosis, Plaintiff's defective port was removed at Glens Falls Hospital.

57. On or about February 20, 2023, Plaintiff underwent placement of an AngioDynamics 8F SmartPort product, reference number H787CT80STPD0, lot number 5740777. The device was implanted by Dr. Joseph A. Dagostino Jr., MD at Glens Falls Hospital in Glens Falls, New York, for the purpose of providing chemotherapy.

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

59. Defendants manufactured, sold, and/or distributed the SmartPort to Plaintiff, through her doctors, to be used for vascular access.

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

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

62. Plaintiff and her physicians foreseeably used and implanted the SmartPort and did not misuse or alter the SmartPort in an unforeseeable manner.

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

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

65. In reliance on Defendants' representations, Plaintiff's doctors were induced to, and did use the SmartPort.

66. As a result of having the SmartPort implanted, Plaintiff has experienced significant mental and physical pain and suffering, has undergone additional surgeries, and has suffered financial or economic loss, including, but not to limited to, obligations for medical services and expenses.

67. Defendants' SmartPort 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.

68. The Defendants have marketed and sold the Defendants' SmartPort 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.

69. The injuries, conditions, and complications suffered due to Defendants' SmartPort include, but are not limited to, fracture and leakage; necrosis; infection; blood clots/thrombus; 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.

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

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

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

71. The SmartPort was utilized and implanted in a manner foreseeable to Defendants.

72. The SmartPort 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.

73. At the time of the operation, Plaintiff was not informed of, and had no knowledge of the complaints, known complications and risks associated with SmartPort, including, but not limited to, the extent of seriousness of the danger of fracture and thrombus.

74. Plaintiff was never informed by Defendants of the defective and dangerous nature of SmartPort.

75. At the time of the implant, neither Plaintiff nor Plaintiff's physicians were aware of the defective and dangerous condition of the SmartPort.

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

77. 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.

COUNT I: NEGLIGENCE

(Against Defendants AngioDynamics and Navilyst)

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

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

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

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

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

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 SmartPort;

e. Designing, manufacturing, marketing, advertising, distributing, and selling the SmartPort to consumers, including Plaintiff, without an adequate warning of the significant and dangerous risks of the SmartPort 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 SmartPort; and

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

81. As a direct, actual, and proximate result of the Defendants' actions, omissions, and misrepresentations, Plaintiff has suffered, and will continue to suffer, severe injuries and complications 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.

82. 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)

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

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

85. Defendants' design decision of how it chose to utilize barium sulfate and its specific process for mixing it with polyurethane/silicone leads to a structurally compromised catheter, thereby creating a defective condition and heightened risk to the user or consumer.

86. The SmartPort was in a defective condition and was defective in its design in that when it left the possession 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 SmartPort 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 her physicians would expect when the product was used for its normal and intended purpose.

88. The SmartPort 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 not have placed the

SmartPort with its defective design into the stream of commerce due to the likelihood that the SmartPort's design would cause injuries similar to those sustained by Plaintiff and that the gravity of the injuries outweighed the Defendants' burden of adopting a safer and more reasonable alternative design.

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

91. The SmartPort 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 Plaintiff for designing, manufacturing, marketing, labeling, packaging and selling a defective product.

93. As a direct and proximate result of the SmartPort'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.

COUNT III: STRICT PRODUCTS LIABILITY – MANUFACTURING DEFECT

(Against Defendants AngioDynamics and Navilyst)

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

95. The SmartPort implanted in the Plaintiff was not reasonably safe for its intended use as it was manufactured defectively.

96. Defendants operated under design and manufacturing specifications for the SmartPort, which included appropriate material content, strength, size, durability appearance, resistance levels, and that the devices did not deviate from its intended design. The manufacturing process was intended to identify any end-product products that did not meet Defendants' specifications.

97. Defendants owed Plaintiff a duty to exercise reasonable care when manufacturing, setting design and manufacturing specifications, exercising quality control over, distributing, and selling the SmartPort.

98. Defendants breached this duty and failed to exercise reasonable care when manufacturing, setting design and manufacturing specifications, exercising quality control over, distributing, and selling an unreasonably dangerous SmartPort that was ultimately implanted into Plaintiff. This caused the SmartPort that was implanted into Plaintiff to deviate from its intended design and/or vary from its intended specifications in that the device did not have the specified material content, size, durability, and strength, resulting in a SmartPort that contained 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.

99. The defective and dangerous condition of the SmartPort implanted into Plaintiff existed at the time it left Defendants' possession and at the time it was sold. The device differed from Defendants' intended result and/or from other ostensibly identical units of the same product line.

100. SmartPort ports were expected to and did reach consumers, including the Plaintiff, without substantial change in the condition in which it was supplied, distributed, sold and/or otherwise placed into the stream of commerce.

101. A reasonably prudent medical device manufacturer would have recognized the manufacturing defects of the SmartPort and would not have placed the SmartPort into the stream of commerce.

102. The manufacturing defects in the SmartPort were not known, knowable and/or reasonably apparent to Plaintiff and/or her physician or discoverable upon any reasonable examination.

103. Plaintiff's SmartPort 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.

104. As a direct and proximate result of Defendants' negligent manufacturing, Plaintiff has suffered severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and consortium, economic loss and damages including, but not limited to medical expenses, lost income, and other damages. These damages have occurred in the past and will continue into the future.

105. 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.

COUNT IV: STRICT PRODUCTS LIABILITY – FAILURE TO WARN

(Against Defendants AngioDynamics and Navilyst)

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

107. 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 intravenous fluids and/or 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.

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

109. Defendants knew or should have known at the time they manufactured, labeled, distributed, and sold the SmartPort that was implanted into Plaintiff that the

SmartPort posed a significant and higher risk than other similar devices of device failure and resulting serious injuries.

110. 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.

111. 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.

112. The SmartPort, 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.

113. 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.

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

115. 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.

116. Plaintiff and her health care providers used the SmartPort 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.

117. Upon information and belief, the defective and dangerous condition of the SmartPort, 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.

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

119. 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 SmartPort.

COUNT V: BREACH OF IMPLIED WARRANTY

(Against Defendants AngioDynamics and Navilyst)

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

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

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

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

124. Privity exists between Plaintiff and 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.

125. Defendants breached these implied warranties of merchantability because the SmartPort implanted in Plaintiff was neither merchantable nor suited for its intended uses as warranted in that the device varied from its intended specifications, which included, but are not limited to, variances in the following respects:

a. Defendants' manufacturing process in constructing the catheter of the SmartPort 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 silicone 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 silicone in its product, the SmartPort, 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 catheter fracture and the collection and proliferation of blood products, thereby drastically increasing the risk of thrombus.

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

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

128. 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.

129. 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 SmartPort, within a reasonable period of time following discovery of the breach of warranty and before suit was filed.

COUNT VI: BREACH OF EXPRESS WARRANTY

(Against Defendants AngioDynamics and Navilyst)

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

131. Defendants through their officers, directors, agents, representatives, and written literature and packaging, and written and media advertisements, expressly warranted that the SmartPort 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.

132. The SmartPort 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.

133. Defendants further breached express representations and warranties made to Plaintiff, her physicians and healthcare providers with respect to the SmartPort implanted in Plaintiff in the following respects:

a. Defendants represented to Plaintiff and her physicians and healthcare providers through product labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions among other ways that the Defendants' SmartPort was safe, meanwhile Defendants fraudulently withheld and concealed information about the substantial risks of serious injury associated with using SmartPort;

b. Defendants represented to Plaintiff and her physicians and healthcare providers that the Defendants' SmartPort was as safe and/or safer than other alternative procedures and devices then on the market, meanwhile Defendants fraudulently concealed information that demonstrated that SmartPort was not safer than alternative therapies and products available on the market; and

c. Defendants represented to Plaintiff and her physicians and healthcare providers that the Defendants' SmartPort was more efficacious than other

alternative procedures, therapies and/or devices. Meanwhile Defendants fraudulently concealed information, regarding the true efficacy of SmartPort.

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

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

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

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

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

139. 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.

140. 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 SmartPort, within a reasonable period of time following discovery of the breach of warranty and before suit was filed.

COUNT VII: FRAUDULENT CONCEALMENT

(Against Defendants AngioDynamics and Navilyst)

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

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

143. Defendants engaged in and fraudulently concealed information with respect to the SmartPort in the following respects:

a. Defendants represented through the product labeling, advertising, marketing materials, seminar presentations, publications, notice letters, and regulatory submissions that the SmartPort was safe and fraudulently withheld and concealed information about the substantial risks of using the SmartPort, including, but not limited to, its heightened propensity to increase the risk of fracture and thrombus, and cause complications;

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

c. Defendants concealed that it knew of the SmartPort's dangerous propensity to increase the risk of fracture and thrombus and was causing complications 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.

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

145. Defendants had sole access to material facts concerning the dangers and unreasonable risks of the SmartPort.

146. The concealment of information by the Defendants about the risks of the SmartPort was intentional.

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

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

149. 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.

150. 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 these Defendants and others from engaging in similar conduct in the future.

151. Had Defendants not concealed this information, neither Plaintiff nor her health care providers would have consented to using the SmartPort placed in Plaintiff.

PRAYER

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

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

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

g. 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.

/s/*Cameron Cano*
Cameron Cano (*pro hac vice* forthcoming, TX Bar No. 24101314)
Alex Barlow (admitted *pro hac vice*, TX Bar No. 24006798)
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ATTORNEYS FOR PLAINTIFF

JS 44 (Rev. 03/24)

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

Lorrie Smith

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

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

Scott + Scott Attorneys at Law, LLP , 7718 Wood Hollow Drive, Suite 105, Austin, TX 78731

DEFENDANTS

Angiodynamics, Inc., Navilyst Medical, Inc.

County of Residence of First Listed Defendant Albany
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys *(If Known)*

'26CV0470 JO VET

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

- ☐ 1 U.S. Government Plaintiff
- ☐ 3 Federal Question *(U.S. Government Not a Party)*
- ☐ 2 U.S. Government Defendant
- ☒ 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)*

(For Diversity Cases Only)

	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
- ☐ 110 Insurance
- ☐ 120 Marine
- ☐ 130 Miller Act
- ☐ 140 Negotiable Instrument
- ☐ 150 Recovery of Overpayment & Enforcement of Judgment
- ☐ 151 Medicare Act
- ☐ 152 Recovery of Defaulted Student Loans (Excludes Veterans)
- ☐ 153 Recovery of Overpayment of Veteran's Benefits
- ☐ 160 Stockholders' Suits
- ☐ 190 Other Contract
- ☐ 195 Contract Product Liability
- ☐ 196 Franchise

REAL PROPERTY
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

TORTS

PERSONAL INJURY
- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers' Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury
- ☐ 362 Personal Injury - Medical Malpractice

PERSONAL INJURY
- ☒ 365 Personal Injury - Product Liability
- ☐ 367 Health Care/ Pharmaceutical Personal Injury Product Liability
- ☐ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

CIVIL RIGHTS
- ☐ 440 Other Civil Rights
- ☐ 441 Voting
- ☐ 442 Employment
- ☐ 443 Housing/ Accommodations
- ☐ 445 Amer. w/Disabilities - Employment
- ☐ 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

FORFEITURE/PENALTY
- ☐ 625 Drug Related Seizure of Property 21 USC 881
- ☐ 690 Other

LABOR
- ☐ 710 Fair Labor Standards Act
- ☐ 720 Labor/Management Relations
- ☐ 740 Railway Labor Act
- ☐ 751 Family and Medical Leave Act
- ☐ 790 Other Labor Litigation
- ☐ 791 Employee Retirement Income Security Act

IMMIGRATION
- ☐ 462 Naturalization Application
- ☐ 465 Other Immigration Actions

BANKRUPTCY
- ☐ 422 Appeal 28 USC 158
- ☐ 423 Withdrawal 28 USC 157

INTELLECTUAL PROPERTY RIGHTS
- ☐ 820 Copyrights
- ☐ 830 Patent
- ☐ 835 Patent - Abbreviated New Drug Application
- ☐ 840 Trademark
- ☐ 880 Defend Trade Secrets Act of 2016

SOCIAL SECURITY
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

FEDERAL TAX SUITS
- ☐ 870 Taxes (U.S. Plaintiff or Defendant)
- ☐ 871 IRS—Third Party 26 USC 7609

OTHER STATUTES
- ☐ 375 False Claims Act
- ☐ 376 Qui Tam (31 USC 3729(a))
- ☐ 400 State Reapportionment
- ☐ 410 Antitrust
- ☐ 430 Banks and Banking
- ☐ 450 Commerce
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced and Corrupt Organizations
- ☐ 480 Consumer Credit (15 USC 1681 or 1692)
- ☐ 485 Telephone Consumer Protection Act
- ☐ 490 Cable/Sat TV
- ☐ 850 Securities/Commodities/ Exchange
- ☐ 890 Other Statutory Actions
- ☐ 891 Agricultural Acts
- ☐ 893 Environmental Matters
- ☐ 895 Freedom of Information Act
- ☐ 896 Arbitration
- ☐ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ☐ 950 Constitutionality of State Statutes

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 U.S.C. §1332(a)

Brief description of cause:
Implanted Port Catheter personal injury/products liability

VII. REQUESTED IN COMPLAINT:

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

DEMAND $

CHECK YES only if demanded in complaint:

JURY DEMAND: ☒ Yes ☐ No

VIII. RELATED CASE(S) IF ANY

(See instructions):

JUDGE Jinsook Ohta DOCKET NUMBER 3:24-MD-03125-JO-VET

DATE 1/26/2026

SIGNATURE OF ATTORNEY OF RECORD Cameron Cano

FOR OFFICE USE ONLY

RECEIPT # AMOUNT APPLYING IFP JUDGE MAG. JUDGE

INSTRUCTIONS FOR ATTORNEYS COMPLETING CIVIL COVER SHEET FORM JS 44

Authority For Civil Cover Sheet

The JS 44 civil cover sheet and the information contained herein neither replaces nor supplements the filings and service of pleading 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. Consequently, a civil cover sheet is submitted to the Clerk of Court for each civil complaint filed. The attorney filing a case should complete the form as follows:

I.(a) Plaintiffs-Defendants. Enter names (last, first, middle initial) of plaintiff and defendant. If the plaintiff or defendant is a government agency, use only the full name or standard abbreviations. If the plaintiff or defendant is an official within a government agency, identify first the agency and then the official, giving both name and title.

(b) County of Residence. For each civil case filed, except U.S. plaintiff cases, enter the name of the county where the first listed plaintiff resides at the time of filing. In U.S. plaintiff cases, enter the name of the county in which the first listed defendant resides at the time of filing. (NOTE: In land condemnation cases, the county of residence of the "defendant" is the location of the tract of land involved.)

(c) Attorneys. Enter the firm name, address, telephone number, and attorney of record. If there are several attorneys, list them on an attachment, noting in this section "(see attachment)".

II. Jurisdiction. The basis of jurisdiction is set forth under Rule 8(a), F.R.Cv.P., which requires that jurisdictions be shown in pleadings. Place an "X" in one of the boxes. If there is more than one basis of jurisdiction, precedence is given in the order shown below.
United States plaintiff. (1) Jurisdiction based on 28 U.S.C. 1345 and 1348. Suits by agencies and officers of the United States are included here.
United States defendant. (2) When the plaintiff is suing the United States, its officers or agencies, place an "X" in this box.
Federal question. (3) This refers to suits under 28 U.S.C. 1331, where jurisdiction arises under the Constitution of the United States, an amendment to the Constitution, an act of Congress or a treaty of the United States. In cases where the U.S. is a party, the U.S. plaintiff or defendant code takes precedence, and box 1 or 2 should be marked.
Diversity of citizenship. (4) This refers to suits under 28 U.S.C. 1332, where parties are citizens of different states. When Box 4 is checked, the citizenship of the different parties must be checked. (See Section III below**; NOTE: federal question actions take precedence over diversity cases.**)

III. Residence (citizenship) of Principal Parties. This section of the JS 44 is to be completed if diversity of citizenship was indicated above. Mark this section for each principal party.

IV. Nature of Suit. Place an "X" in the appropriate box. If there are multiple nature of suit codes associated with the case, pick the nature of suit code that is most applicable. Click here for: Nature of Suit Code Descriptions.

V. Origin. Place an "X" in one of the seven boxes.
Original Proceedings. (1) Cases which originate in the United States district courts.
Removed from State Court. (2) Proceedings initiated in state courts may be removed to the district courts under Title 28 U.S.C., Section 1441.
Remanded from Appellate Court. (3) Check this box for cases remanded to the district court for further action. Use the date of remand as the filing date.
Reinstated or Reopened. (4) Check this box for cases reinstated or reopened in the district court. Use the reopening date as the filing date.
Transferred from Another District. (5) For cases transferred under Title 28 U.S.C. Section 1404(a). Do not use this for within district transfers or multidistrict litigation transfers.
Multidistrict Litigation – Transfer. (6) Check this box when a multidistrict case is transferred into the district under authority of Title 28 U.S.C. Section 1407.
Multidistrict Litigation – Direct File. (8) Check this box when a multidistrict case is filed in the same district as the Master MDL docket.
PLEASE NOTE THAT THERE IS NOT AN ORIGIN CODE 7. Origin Code 7 was used for historical records and is no longer relevant due to changes in statute.

VI. Cause of Action. Report the civil statute directly related to the cause of action and give a brief description of the cause. **Do not cite jurisdictional statutes unless diversity.** Example: U.S. Civil Statute: 47 USC 553 Brief Description: Unauthorized reception of cable service.

VII. Requested in Complaint. Class Action. Place an "X" in this box if you are filing a class action under Rule 23, F.R.Cv.P.
Demand. In this space enter the actual dollar amount being demanded or indicate other demand, such as a preliminary injunction.
Jury Demand. Check the appropriate box to indicate whether or not a jury is being demanded.

VIII. Related Cases. This section of the JS 44 is used to reference related cases, if any. If there are related cases, insert the docket numbers and the corresponding judge names for such cases.

Date and Attorney Signature. Date and sign the civil cover sheet.