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7 **UNITED STATES DISTRICT COURT**
8 **FOR THE SOUTHERN DISTRICT OF CALIFORNIA**

9 **'25CV0623 JO VET**

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

Case No. 3:24-md-03125-JO-VET
MDL No. 3125

JUDGE JINSOOK OHTA

12 Frank Browning,
13 *Plaintiff,*
vs.
14 AngioDynamics, Inc., Navilyst
15 Medical, Inc., and PFM Medical, Inc.
Defendants.

COMPLAINT AND JURY DEMAND

16 This Document Relates to: Civil
17 Action No.:

18 **COMPLAINT**

19
20 Plaintiff files this Complaint pursuant to CMO No. 1, and is bound by the rights,
21 protections, privileges, and obligations of that CMO. In accordance with CMO No. 1, Plaintiff
22 hereby designates the United States District Court for the District of Oregon, as the place of
23 remand as this case may have originally been filed there pursuant to 28 U.S.C. §1391.

24 COMES NOW the Plaintiff, FRANK BROWNING, (who hereinafter shall be referred to
25 as the "Plaintiff"), by and through his undersigned counsel, and brings this Complaint against
26 AngioDynamics, Inc., Navilyst Medical, Inc. and PFM Medical, Inc. (collectively, the
27 "Defendants"), and alleges as follows:
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2 1. This is an action for damages arising out of failures relating to Defendants’
3 design, development, testing, assembling, manufacturing, packaging, promoting, marketing,
4 distribution, supplying, and/or selling the defective implantable vascular access device sold
5 under the trade name of Xcela (hereinafter “Xcela”, “Device”, or “Defective Device”).
6

7 **PARTIES**

8 2. Plaintiff, FRANK BROWNING is an adult resident and citizen of Lane County,
9 Oregon, and claims damages as set forth below.

10 3. Defendant AngioDynamics, Inc. (“AngioDynamics”) is a Delaware corporation
11 with its principal place of business located in Latham, New York. AngioDynamics is engaged in
12 the business of researching, developing, designing, licensing, manufacturing, distributing,
13 supplying, selling, marketing, and introducing into interstate commerce, either directly or
14 indirectly through third parties or related entities, its medical devices, including the Xcela.
15

16 4. Defendant Navilyst Medical, Inc. (“Navilyst”) is a Delaware corporation with its
17 principal place of business located in Marlborough, Massachusetts. Navilyst conducts business
18 throughout the United States, including the State of Oregon, and is a wholly owned subsidiary of
19 AngioDynamics. Navilyst is engaged in the business of researching, developing, designing,
20 licensing, manufacturing, distributing, supplying, selling, marketing, and introducing into
21 interstate commerce, either directly or indirectly through third parties or related entities, its
22 medical devices, including the Xcela.
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24 5. Defendant PFM Medical, Inc., is a Cologne, Germany corporation with its
25 principal place of business located in Carlsbad, California. PFM Medical Inc. is a medical device
26 manufacturer and distributor who conducts business throughout the United States, including the
27 State of Oregon. PFM Medical, Inc., is engaged in the business of developing, manufacturing,
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1 marketing, and distributing throughout the United States its medical devices, either directly or
2 indirectly through third parties or related entities, including the Xcela.

3 **JURISDICTION AND VENUE**

4 6. This Court has subject matter jurisdiction over the parties pursuant to 28 U.S.C. §
5 1332(a) because the parties are citizens of different states and the amount in controversy exceeds
6 \$75,000.00, exclusive of interest and cost.
7

8 7. Venue is proper in this Court pursuant to 28 U.S.C. § 1391 by virtue of the facts
9 that (a) a substantial part of the events or omissions giving rise to the claims occurred in this
10 District, and (b) Defendants’ products are produced, sold to, and consumed by individuals in the
11 State of Oregon, thereby subjecting Defendants to personal jurisdiction in this action and making
12 them all “residents” of this judicial District.
13

14 8. Defendants have and continue to conduct substantial business in the State of
15 Oregon and in this District, distribute vascular access products in this District, receive substantial
16 compensation and profits from sales of vascular access products in this District, and made
17 material omissions and misrepresentations and breaches of warranties in this District, so as to
18 subject them to *in personam* jurisdiction in this District.
19

20 9. Consistent with the Due Process Clause of the Fifth and Fourteenth Amendments,
21 this Court has *in personam* jurisdiction over Defendants because Defendants are present in the
22 State of Oregon, such that requiring an appearance does not offend traditional notions of fair and
23 substantial justice.
24

25 **PRODUCT BACKGROUND**

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

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

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

5 13. According to Defendants, the Xcela is a totally implantable vascular access
6 device designed to provide repeated access to the vascular system for the delivery of medication,
7 intravenous fluids, parenteral nutrition solutions, and blood products.

8 14. The intended purpose of the Xcela is to make it easier to deliver medications
9 directly into the patient's bloodstream. The device is surgically placed completely under the skin
10 and left implanted.

11 15. The Xcela is a system consisting of two primary components: an injection port
12 and a polyurethane catheter which includes additives intended to make it radiopaque.

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

16 17. The Xcela is indicated for patient therapies requiring repeated access to the
17 vascular system. The port system can be used for infusion of medications, I.V. fluids, parenteral
18 nutrition solutions, blood products, and for the withdrawal of blood samples.

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

21 19. Barium sulfate is known to contribute to reduction of the mechanical integrity of
22 polyurethane *in vivo* as the particles of barium sulfate dissociate from the surface of the catheter
23 over time, leaving microfractures and other alterations of the polymeric structure and degrading
24 the mechanical properties of the polyurethane.
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1 20. Researchers have shown that catheter surface degradation in products featuring a
2 radiopaque barium sulfate stripe is concentrated at the locus of the stripe.¹

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

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

11 23. This improper mixing led to pockets of barium sulfate and entrapped air being
12 distributed through the catheter body and on the inner and outer surfaces of same.

13 24. This defect in both the design and the manufacturing process led to a
14 heterogeneous modified polymer which led to an irregular catheter surface replete with fissure,
15 pits and cracks.

16 25. The roughened catheter surface leads to the collection and proliferation of
17 fibrinous blood products, thereby drastically increasing the risk of thromboembolism, catheter
18 fracture, and/or infection.

19 26. Although the surface degradation and resulting risks of thromboembolism,
20 catheter fracture, and/or infection can be reduced or avoided with design modifications to
21 encapsulate the radiopaque compound or by using a different polymer formulation, Defendants
22 elected not to incorporate those design elements into the Xcela.
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28 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

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

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7 28. At all times relevant to this action, Defendants knew and had reason to know, that
8 the Xcela was not safe for the patients for whom they were prescribed and implanted, because
9 once implanted the device was prone to surface degradation and resulting thromboembolism,
10 infection, mechanical failure, and a variety of other complications.

11 29. At all times relevant to this action, Defendants knew and had reason to know that
12 patients implanted with a Xcela port had an increased risk of suffering life threatening injuries,
13 including but not limited to: death; hemorrhage; thromboembolism; infection; cardiac/pericardial
14 tamponade (pressure caused by a collection of blood in the area around the heart); cardiac
15 arrhythmia and other symptoms similar to myocardial infarction; severe and persistent pain; and
16 perforations of tissue, vessels and organs, or the need for additional surgeries to remove the
17 defective device.

18
19 30. Soon after the Xcela was introduced to market, which was years before Plaintiff
20 was implanted with his device, Defendants began receiving large numbers of adverse event
21 reports (“AERs”) from health care providers reporting that the Xcela was fracturing post-
22 implantation and that fractured pieces were migrating throughout the human body, including to
23 the heart and lungs. Defendants also received large numbers of AERs reporting that the Xcela
24 was found to have perforated internal vasculature. These failures were often associated with
25 reports of severe patient injuries such as:

26
27 a. hemorrhage.

- 1 b. infection/sepsis;
- 2 c. cardia/pericardial tamponade;
- 3 d. cardiac arrhythmia and other symptoms similar to myocardial infarction;
- 4 e. severe and persistent pain;
- 5 f. perforations of tissue, vessels and organs; and
- 6 g. upon information and belief, even death.

7
8 31. In addition to the large number of AERs which were known to Defendants and
9 reflected in publicly accessible databases, there are many recorded device failures and/or injuries
10 related to the Defendants’ implantable port products which were concealed from medical
11 professionals and patients through submission to the FDA’s controversial Alternative Summary
12 Reporting (“ASR”) program.

13
14 32. The FDA halted the ASR program after its existence was exposed by a multi-part
15 investigative piece, prompting a widespread outcry from medical professionals and patient
16 advocacy groups.²

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

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

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

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

1 36. Rather than alter the design of the Xcela to make it safer or adequately warn
2 physicians of the dangers associated with the Xcela, Defendants continued to actively and
3 aggressively market the Xcela as safe, despite their knowledge of numerous reports of infections
4 and associated injuries.

5 37. Moreover, Defendants concealed—and continue to conceal—their knowledge of
6 the Xcela’s dangerous propensity to increase the risk of infection. Defendants further concealed
7 their knowledge that the catheter design caused these failures and that these failures cause
8 serious injuries.

9 38. The conduct of Defendants, as alleged in this Complaint, constitutes willful,
10 wanton, gross, and outrageous corporate conduct that demonstrates a conscious disregard for the
11 safety of Plaintiff. Defendants had actual knowledge of the dangers presented by the Xcela
12 System, yet consciously failed to act reasonably to:
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- 14
- 15 a. Adequately inform or warn Plaintiff, his prescribing physicians, or the
16 public at large of these dangers;
 - 17 b. Establish and maintain an adequate quality and post-market surveillance
18 system; or
 - 19 c. Recall the Xcela from the market.
- 20

21 **SPECIFIC FACTUAL ALLEGATIONS AS TO RICHARD MELETICHE**

22 39. On or about March 18, 2022, Plaintiff underwent placement of an
23 AngioDynamics Xcela product, Reference Number H965451090, Lot Number 150475000. The
24 device was implanted at Sacred Heart Medical Center RiverBend, 3333 RiverBend Drive,
25 Springfield, Oregon by Dr. Amit A. Kainth, MD for chemotherapy administration.
26

27 40. Defendants, directly or through their agents, apparent agents, servants, or
28 employees designed, manufactured, marketed, advertised, distributed, and sold the Xcela that

1 was implanted in Plaintiff.

2 41. Defendant manufactured, sold, and/or distributed the Xcela to Plaintiff, through
3 his doctors, to be used for vein access.

4 42. On or about May 19, 2023, Plaintiff presented to Sacred Heart Medical Center
5 RiverBend with pain and was diagnosed with an acute embolism and thrombosis of the right
6 subclavian vein and right internal jugular vein. His physician determined the source of the acute
7 embolism and thrombosis was the Xcela port and required removal.

8 43. On or about June 27, 2023, Plaintiff's port was removed by Dr. Amit Kainth, MD
9 at Sacred Heart Medical Center RiverBend.

10 44. At all times, the Xcela was utilized and implanted in a manner foreseeable to
11 Defendants, as Defendants generated the instructions for use and created procedures for
12 implanting the product.
13

14 45. The Xcela implanted in Plaintiff was in the same or substantially similar
15 condition as when it left the possession of Defendants and in the condition directed by and
16 expected by Defendants.
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18 46. Plaintiff and his physicians foreseeably used and implanted the Xcela and did not
19 misuse or alter the Xcela in an unforeseeable manner.
20

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

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

26 49. In reliance on Defendants' representations, Plaintiff's doctors were induced to,
27 and did use the Xcela.
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1 50. As a result of having the Xcela implanted, Plaintiff has experienced significant
2 pain and suffering, has undergone additional surgeries, and has suffered financial or economic
3 loss, including, but to limited to, obligations for medical services and expenses.

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

9 52. The Defendants have marketed and sold the Defendants' Xcela port to the
10 medical community at large and patients through carefully planned, multifaceted marketing
11 campaigns and strategies. These campaigns and strategies include, but are not limited to, direct
12 to consumer advertising, aggressive marketing to health care providers at medical conferences,
13 hospitals, private offices, and/or group purchasing organizations, and include a provision of
14 valuable consideration and benefits to the aforementioned.

15 53. The injuries, conditions, and complications suffered due to Defendants' Xcela
16 port include, but are not limited to, infection; necrosis; fracture and leakage; blood clots;
17 cardiac/pericardial tamponade; cardiac arrhythmia and other symptoms similar to myocardial
18 infarction; severe and persistent pain; perforations of tissue, vessels and organs; and even death.

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

- 20
- 21
- 22 a. Defendant failed to design and establish a safe, effective procedure for
23 removal of the Xcela; therefore, in the event of a failure, injury, or
24 complications it is difficult to safely remove the Xcela.
- 25 b. Defendants provided incomplete, insufficient, and misleading information
26 to physicians in order to increase the number of physicians using the
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1 Xcela for the purpose of increasing their sales. By so doing, Defendants
2 caused the dissemination of inadequate and misleading information to
3 patients, including the Plaintiff.

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

5 56. The Xcela implanted into Plaintiff was in the same or substantially similar
6 condition as when it left the possession of the Defendants and in the condition directed by the
7 Defendants.

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

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

13 59. At the time of his implant, upon information and belief, neither Plaintiff nor
14 Plaintiff's physicians were aware of the defective and dangerous condition of the Xcela.

15 60. At the time of the injuries referenced herein, Plaintiff did not know that the
16 corrective surgery he underwent was due to a defect in the Xcela.

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

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

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FRAUDULENT CONCEALMENT

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2 63. Defendants’ failure to document or follow up on the known defects in its product,
3 and concealment of known defects, constitutes fraudulent concealment that equitably tolls
4 applicable statutes of limitation.

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

11 65. Defendants are and were under a continuing duty to disclose the true character,
12 quality, and nature of risks and dangers associated with their Xcela. Due to Defendants’
13 concealment of the true character, quality, and nature of their Xcela, Defendants are estopped
14 from relying on any statute of limitations defense.

15
16 66. Defendants furthered this fraudulent concealment through a continued and
17 systematic failure to disclose information to Plaintiff, Plaintiff’s healthcare Providers, and the
18 public.

19 67. Defendants’ acts before, during and/or after the act causing Plaintiff’s injury
20 prevented Plaintiff from discovering the injury or the cause of the injury.

21
22 68. Defendants’ conduct, as described in this Complaint, amounts to conduct
23 purposely committed, which Defendants must have realized was dangerous, heedless, reckless,
24 and without regard to the consequences or Plaintiff’s rights and safety.

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

DISCOVERY RULE AND TOLLING

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

4 71. Despite diligent investigation by Plaintiff into the cause of Plaintiff’s injuries, the
5 nature of his injuries and damages, his relationship to the Xcela product was not discovered, and
6 through reasonable care and diligence could not have discovered until a date within the
7 applicable statute of limitations for filing his claims. Therefore, under appreciate application of
8 the discovery rule, Plaintiff’s suit was filed well within the applicable statutory limitations
9 period.
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11 72. Plaintiff did not learn of Defendants’ wrongful conduct until a time within the
12 applicable statute of limitations. Furthermore, in the existence of due diligence, Plaintiff could
13 not have reasonably discovered the Defendant’s wrongful conduct, including, but not limited to,
14 the defective design of the product, until a date within the statute of limitations. Therefore, under
15 appropriate application of the discovery rule, Plaintiff’s suit was filed well within the statutory
16 limitations period.
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COUNT I: NEGLIGENCE

(Against Defendants AngioDynamics, Navilyst and PFM Medical)

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

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

25 75. The Defendants failed to exercise due care under the circumstances and therefore
26 breached this duty by:
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28 a. Failing to properly and thoroughly test the Xcela before releasing the

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- device to market, and/or failing to implement feasible safety improvements;
- b. Failing to properly and thoroughly analyze the data resulting from any pre-market testing of the Xcela;
- c. Failing to conduct sufficient post-market testing and surveillance of the Xcela;
- d. 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;
- e. Designing, manufacturing, marketing, advertising, distributing, and selling the Xcela to consumers, including Plaintiff, without an adequate warning of the significant and dangerous risks of the Xcela and without proper instructions to avoid the harm which could foreseeably occur as a result of using the device;
- f. Failing to exercise due care when advertising and promoting the Xcela; and
- g. Negligently continuing to manufacture, market, advertise, and distribute the Xcela after Defendants knew or should have known of its adverse effects.

76. 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.

77. In performing the foregoing acts, omissions, and misrepresentations, Defendants

1 acted grossly negligent, fraudulently, and with malice so as to justify an award of punitive and/or
2 exemplary damages.

3 **COUNT II: STRICT PRODUCTS LIABILITY – DESIGN DEFECT**

4 (Against Defendants AngioDynamics, Navilyst and PFM Medical)

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

7
8 79. Defendants supplied, manufactured, sold, distributed and/or otherwise placed into
9 the stream of commerce the Xcela implanted into Plaintiff.

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

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

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

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

23 84. The Xcela was expected to and did reach the consumer without substantial change
24 in the condition in which it was supplied, distributed, sold and/or otherwise placed into the
25 stream of commerce.
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1 85. A reasonably prudent medical device manufacturer would have recognized the
2 defective design of the Xcela and not placed it into the stream of commerce.

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

5 87. The Xcela was used and implanted in the manner in which it was intended to be
6 used and implanted by Defendants pursuant to the instructions for use and the product
7 specifications provided by Defendants.
8

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

11 89. As a direct, actual, and proximate cause of the Xcela's aforementioned defects,
12 the Plaintiff was caused and/ or in the future will be caused to suffer severe personal injuries,
13 pain and suffering, severe emotional distress, financial or economic loss, including, but not
14 limited to, obligations for medical services and expenses, and other damages.
15

16 **COUNT III: STRICT PRODUCTS LIABILITY – MANUFACTURING DEFECT**

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

19 91. The Xcela implanted in the Plaintiff was not reasonably safe for its intended use
20 as it was manufactured defectively.
21

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

26 93. Defendants owed Plaintiff a duty to exercise reasonable care when
27 manufacturing, setting design and manufacturing specifications, exercising quality control over,
28

1 distributing, and selling the Xcela.

2 94. Defendants breached this duty and failed to exercise reasonable care when
3 manufacturing, setting design and manufacturing specifications, exercising quality control over,
4 distributing, and selling an unreasonably dangerous Xcela that was ultimately implanted into
5 Plaintiff. This caused the Xcela that was implanted into Plaintiff to deviate from its intended
6 design and/or vary from its intended specifications in that the device did not have the specified
7 material content, size, durability, and strength, resulting in an Xcela that contained too high a
8 concentration of barium sulfate particles for the polymer formulation, leading to improperly high
9 viscosity of the admixed polyurethane before polymerization and causing improper mixing of
10 barium sulfate particles within the polymer matrix.

11
12 95. The defective and dangerous condition of the Xcela implanted into Plaintiff
13 existed at the time it left Defendants' possession and at the time it was sold. The device differed
14 from Defendants' intended result and/or from other ostensibly identical units of the same product
15 line.

16
17 96. Xcela ports were expected to and did reach consumers, including the Plaintiff,
18 without substantial change in the condition in which it was supplied, distributed, sold and/or
19 otherwise placed into the stream of commerce.

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21 97. A reasonably prudent medical device manufacturer would have recognized the
22 manufacturing design of the Xcela and would not have placed the Xcela into the stream of
23 commerce.

24 98. The manufacturing defects in the Xcela were not known, knowable and/or
25 reasonably apparent to Plaintiff and/or his physician or discoverable upon any reasonable
26 examination.

27 99. The Xcela was used and implanted in the manner in which it was intended to be
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1 used and implanted by Defendants pursuant to the instructions for use and the product
2 specifications provided by Defendants

3 100. As a direct and proximate result of Defendants' negligent manufacturing, Plaintiff
4 has suffered severe and permanent pain, suffering, disability, impairment, loss of enjoyment of
5 life, loss of care, comfort, and consortium, economic loss and damages including, but not limited
6 to medical expenses, lost income, and other damages. These damages have occurred in the past
7 and will continue into the future.
8

9 101. WHEREFORE, Plaintiff demands judgment against Defendants for
10 compensatory, special, and punitive damages, together with interest, costs of suit, attorneys'
11 fees, and all such other relief as the Court deems proper.
12

13 **COUNT IV: STRICT PRODUCTS LIABILITY – FAILURE TO WARN**
14 (Against Defendants AngioDynamics, Navilyst and PFM Medical)

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

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

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

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

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

10 107. The warnings, labels, and instructions provided by Defendants at all times
11 relevant to this action, are and were inaccurate, intentionally misleading, and misinformed and
12 misrepresented the risks and benefits and lack of safety and efficacy associated with the device.
13

14 108. The health risks associated with the device as described herein are of such a
15 nature that ordinary consumers would not have readily recognized the potential harm.
16

17 109. The Xcela, which was designed, manufactured, prepared, compounded,
18 assembled, processed, marketed, labeled, distributed, and sold into the stream of commerce by
19 Defendants, was defective at the time of release into the stream of commerce due to inadequate
20 warnings, labeling and/or instructions accompanying the product.
21

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

25 111. Defendants intentionally underreported the number and nature of adverse events
26 associated with thromboembolism of the devices to Plaintiff’s health care providers, as well as
27 the FDA.
28

1 112. Upon information and belief, neither Plaintiff nor his health care providers knew
2 of the substantial danger associated with the intended and foreseeable use of the device as
3 described herein.

4 113. Plaintiff and his health care providers used the Xcela in a normal, customary,
5 intended, and foreseeable manner, namely as a surgically placed device used to make it easier to
6 deliver medications directly into the patient's bloodstream.

7 114. Upon information and belief, the defective and dangerous condition of the Xcela,
8 including the one implanted into Plaintiff, existed at the time they were manufactured, prepared,
9 compounded, assembled, processed, marketed, labeled, distributed, and sold by Defendants to
10 distributors and/or healthcare professionals or organizations.

11 115. Upon information and belief, the Xcela implanted in Plaintiff was in the same
12 condition as when it was manufactured, inspected, marketed, labeled, promoted, distributed and
13 sold by Defendants.

14 116. Defendants' lack of sufficient warning and/or instructions was the direct and
15 proximate cause of Plaintiff's serious physical injuries and economic damages in an amount to
16 be determined at trial. Had Defendants provided adequate warnings, Plaintiff and his physicians
17 would not have used the Xcela.

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

21 118. In performing the foregoing acts, omissions, and misrepresentations, Defendants
22 acted grossly negligent, fraudulently, and with malice malice so as to justify an award of
23 punitive and/or exemplary damages.

COUNT V: BREACH OF IMPLIED WARRANTY

(Against Defendants AngioDynamics, Navilyst and PFM Medical)

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

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

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

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

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

124. 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.

125. Defendants breached these implied warranties of merchantability because the Xcela 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 Xcela implanted in Plaintiff involved too high of a concentration of barium sulfate particles for the polymer formulation, which led to

1 improperly high viscosity of the admixed polyurethane before
2 polymerization and causing improper mixing of barium sulfate particles
3 within the polymer matrix;

4 b. Defendants knew or should have known barium sulfate is known to
5 contribute to a reduction in the mechanical integrity of the polyurethane in
6 its product, the Xcela, as the barium sulfate particles dissociate from the
7 surface of the catheter over time; and

8 c. These defects led to a heterogenous modified polymer that included
9 microfractures and weakened areas at the location of the higher barium
10 sulfate concentration that ultimately led to an increased risk of infection.

11
12 126. Defendants' breaches of their implied warranties resulted in the implantation of an
13 unreasonably dangerous and defective product, the Xcela, into Plaintiff's body, placing said
14 Plaintiff's health and safety in jeopardy.

15
16 127. The Xcela was sold to Plaintiff's health care providers for implantation in
17 patients, such as Plaintiff.

18
19 128. As a direct, actual, and proximate cause of the Defendants' breaches of the
20 aforementioned implied warranties, the Plaintiff has suffered and/or in the future will be caused
21 to suffer severe personal injuries, pain and suffering, severe emotional distress, financial or
22 economic loss, including but not limited to, obligations for medical services and expenses, and
23 other damages.

24
25 129. Upon information and belief, Plaintiff's healthcare providers sent notice to
26 Defendants of the adverse event that occurred to Plaintiff and thus, the nonconformity of the
27 Xcela, within a reasonable period of time following discovery of the breach of warranty and
28 before suit was filed.

COUNT VI: BREACH OF EXPRESS WARRANTY

(Against Defendants AngioDynamics, Navilyst and PFM Medical)

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 advertisement, expressly warranted that the Xcela was safe and fit for use by consumers, was of merchantable quality, did not produce dangerous side effects, and was adequately tested and fit for its intended use.

132. The Xcela does not conform to the Defendants' express representations because it is not reasonably safe, has numerous serious side effects, and causes severe and permanent injury.

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

- a. Defendant represented to Plaintiff and his 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' Xcela port was safe, meanwhile Defendant fraudulently withheld and concealed information about the substantial risks of serious injury associated with using the Xcela;
- b. Defendants represented to Plaintiff and his 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

1 fraudulently concealed information that demonstrated that Xcela was not
2 safer than alternative therapies and products available on the market; and

3 c. Defendants represented to Plaintiff and his physicians and healthcare
4 providers that the Xcela was more efficacious than other alternative
5 procedures, therapies and/or devices. Meanwhile, Defendants fraudulently
6 concealed information, regarding the true efficacy of the Xcela.
7

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

10 135. Plaintiff, his physicians, and the medical community reasonably relied upon the
11 Defendants' express warranties for the Xcela.

12 136. Privity exists between Plaintiff because Plaintiff's physicians acted as Plaintiff's
13 purchasing agents in the subject transaction and/or because Plaintiff was a third-party beneficiary
14 of the subject contract.
15

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

19 138. Plaintiff was the intended consumer of the Xcela when Defendant made the
20 warranties set forth herein, and such warranties were made to benefit Plaintiff as a patient and
21 consumer.
22

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

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

27 141. As a direct, actual, and proximate cause of the Defendants' express warranties,
28

1 Plaintiff has suffered, and will continue to suffer, severe physical pain and injuries which are
2 permanent and lasting in nature, emotional distress, loss of the capacity for the enjoyment of life,
3 medical and nursing expenses, surgical expenses, and economic loss as alleged herein. These
4 damages have occurred in the past and will continue into the future.

5
6 142. Upon information and belief, Plaintiff's healthcare providers sent notice to
7 Defendants of the adverse event that occurred to Plaintiff and thus, the nonconformity of the
8 Xcela, within a reasonable period of time following discovery of the breach of warranty and
9 before suit was filed.

10 **COUNT VII: FRAUDULENT CONCEALMENT**

11 (Against Defendants AngioDynamics, Navilyst and PFM Medical)

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

14 144. Defendants made false statements and representations to Plaintiff and his
15 healthcare providers concerning the Xcela product implanted in Plaintiff.

16 145. Defendants engaged in and fraudulently concealed information with respect to the
17 Xcela in the following respects:

- 18
- 19 a. Defendants represented through the product labeling, advertising, marketing
20 materials, seminar presentations, publications, notice letters, and regulatory
21 submissions that the Xcela was safe and fraudulently withheld and concealed
22 information about the substantial risks of using the Xcela, including, but not
23 limited to, its heightened propensity to increase the risk of infection and cause
24 complications;
 - 25 b. Defendants represented that the Xcela was safer than other alternative systems
26 and fraudulently concealed information which demonstrated that the Xcela was
27
28

1 not safer than alternatives available on the market;

2 c. Defendants concealed that it knew of the Xcela's dangerous propensity to
3 increase the risk of infection and was causing complications from causes other
4 than the manner in which the implanting physician implanted the device; and

5 d. That frequency of these failures and the severity of injuries were substantially
6 worse than had been reported.
7

8 146. Defendants had knowledge that the representations they made concerning the
9 Xcela, as stated above, were false.

10 147. Defendants had sole access to material facts concerning the dangers and
11 unreasonable risks of the Xcela.

12 148. The concealment of information by the Defendants about the risks of the Xcela
13 was intentional.

14 149. The concealment of information and the misrepresentations about the Xcela was
15 made by the Defendants with the intent that Plaintiff's health care providers and Plaintiff rely
16 upon them.
17

18 150. Plaintiff and his physicians relied upon the representations and were unaware of
19 the substantial risks of the Xcela which the Defendants concealed from the public, including
20 Plaintiff and his physicians.
21

22 151. As a direct and proximate result of the Defendants' actions, omissions and
23 misrepresentations, Plaintiff has suffered, and will continue to suffer, severe physical pain and
24 injuries which are permanent and lasting in nature, emotional distress, loss of the capacity for the
25 enjoyment of life, medical and nursing expenses, surgical expenses, and economic loss as
26 alleged herein. These damages have occurred in the past and will continue into the future.
27

28 152. The Defendants acted with oppression, fraud, and malice towards Plaintiff, who

1 accordingly requests that the trier of fact, in the exercise of its sound discretion, award additional
2 damages for the sake of example and for the purpose of punishing Defendants for their conduct,
3 in an amount sufficiently large to be an example to others, and to deter these Defendants and
4 others from engaging in similar conduct in the future.

5 153. Had Defendants not concealed this information, neither Plaintiff's nor his health
6 care providers would have consented to using the device in Plaintiff.
7

8 **COUNT VIII: OREGON'S UNLAWFUL TRADE PRACTICES ACT**

9 (Against Defendants AngioDynamics, Navilyst and PFM Medical)

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

12 155. Plaintiff, a consumer, purchased the Xcela, and the product was intended for
13 personal use.

14 156. The acts and practices engaged in by Defendants as outlined above constitute
15 unlawful, unfair, and/or fraudulent business practices in violation of the Oregon Unlawful Trade
16 Practices Act, (UTPA), O.R.S. § 646.605 *et seq.*
17

18 157. Defendants engaged in unlawful practices including deception, false promises,
19 misrepresentation, and/or the concealment, suppression, or omission of material facts in
20 connection with the sale, distribution, and/or advertisement of the Xcela in violation of O.R.S. §
21 646.605 *et seq.*
22

23 158. Plaintiff purchased the Xcela, a product that was falsely represented, as further set
24 forth herein, as having certain characteristics and benefits it did not have, *inter alia*, that it was
25 reasonably safe for use, as further set forth above, in violation of the UTPA.

26 159. Defendants further knowingly or recklessly engaged in unfair, unconscionable,
27 deceptive, deliberately misleading, false, and/or fraudulent and deceptive acts and practices, all
28

1 in violation of the UTPA, and as further described herein, which created a likelihood of
2 confusion or misunderstanding on Plaintiff's part with respect to the Xcela he purchased,
3 including, but not limited to, misrepresenting that the Xcela was reasonably safe for use and
4 failing to adequately disclose the substantial risk of infection, and harm the product entailed
5 given the large number of adverse events Defendants knew or should have been aware of but did
6 not adequately disclose to Plaintiff.
7

8 160. Defendants' practices were likely to mislead consumers who acted reasonably to
9 their detriment in purchasing the product based on Defendants' representations that it was
10 reasonably safe for use when it in fact was not and had a greater propensity to increase the risk
11 of infection due to its defective design and manufacturing.
12

13 161. Defendants intended for Plaintiff, Plaintiff's physicians, and other consumers to
14 rely on their deceptive practices and representations in order to continue selling and
15 manufacturing the Xcela.
16

17 162. Plaintiff purchased the Xcela, a product that was falsely represented, as set out
18 above, in violation of the Oregon Unlawful Trade Practices Act and as a result Plaintiff suffered
19 economic damages in that the product he purchased was worth less than the product he thought
20 he had purchased had Defendants' representations been true.
21

PUNITIVE DAMAGES

22 163. Plaintiff is entitled to an award of punitive and exemplary damages based upon
23 Defendants' intentional, willful, knowing, fraudulent, malicious acts, omissions, and conduct,
24 and their complete and total reckless disregard for the public safety and welfare. Defendants
25 intentionally and fraudulently misrepresented facts and information to both the healthcare
26 community and the general public, including Plaintiff and her health care providers, by making
27 intentionally false and fraudulent misrepresentations about the safety and efficacy of the Xcela.
28

1 Defendants intentionally concealed the true facts and information regarding the serious risks of
2 harm associated with the implantation of said product, and intentionally downplayed the type,
3 nature, and extent of the adverse side effects of being implanted with the device, despite
4 Defendants' knowledge and awareness of the serious and permanent side effects and risks
5 associated with use of same. Defendants further intentionally sought to mislead health care
6 providers and patients, including Plaintiff and her health care providers, regarding the cause of
7 failures of the device.
8

9 164. Defendants had knowledge of, and were in possession of evidence demonstrating
10 that, the Xcela caused serious physical side effects. Defendants continued to market said product
11 by providing false and misleading information with regard to the product's safety and efficacy to
12 the regulatory agencies, the medical community, and consumers of the device, notwithstanding
13 Defendants' knowledge of the true serious side effects of the Xcela, Defendants failed to provide
14 accurate information and warnings to the healthcare community that would have dissuaded
15 physicians from surgically implanting the Xcela and consumers from agreeing to being
16 implanted with the Xcela, thus depriving physicians and consumers from weighing the true risks
17 against the benefits of prescribing and implanting the Xcela.
18

19 165. As a direct, proximate, and legal result of Defendants' acts and omissions as
20 described herein, and Plaintiff's implantation with Defendants' defective product, Plaintiff
21 suffered, and will continue to suffer, the injuries and damages described in this Complaint.
22 Moreover, the acts and omissions of the Defendants described herein unmistakably showcase
23 their flagrant disregard for the safety of consumers, including the Plaintiff.
24
25
26
27
28

PRAYER

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

- a. Judgment be entered against all Defendant on all causes of action of this Complaint;
- b. Plaintiff be awarded his full, fair, and complete recovery for all claims and causes of action relevant to this action;
- c. Plaintiff be awarded general damages according to proof at the time of trial;
- d. Plaintiff be awarded damages, including past, present, and future, medical expenses according to proof at the time of trial;
- e. Plaintiff be awarded costs and attorney’s fees in connection with Plaintiff’s Oregon Unlawful Trade Practices Act, (UTPA) claim under O.R.S. § 646.605 *et seq.*;
- f. Awarding pre-judgment and post-judgment interest to the Plaintiff;
- g. Awarding the costs and the expenses of this litigation to the Plaintiff;
- h. For such other and further relief as the court may deem just and proper.

DEMAND FOR JURY TRIAL

Plaintiff hereby demands trial by jury on all issues.

Respectfully submitted,

/s/ Robert D. Cain, Jr.
Robert D. Cain, Jr. (admitted *pro hac vice*)
MS Bar # 104283
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Attorney for Plaintiff

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

Frank Browning

(b) County of Residence of First Listed Plaintiff Lane Co., Oregon (EXCEPT IN U.S. PLAINTIFF CASES)

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

Robert D. Cain, Jr., Davis & Crump, P. C., 2601 14th Street, Gulfport, MS 39501 (228-863-6000)

DEFENDANTS

AngioDynamics, Inc., Navilyst Medical, Inc. and PFM 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)

25CV0623 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)

- Citizen of This State, Citizen of Another State, Citizen or Subject of a Foreign Country, PTF DEF, 1 1, 2 2, 3 3, 4 4, 5 5, 6 6

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

Click here for: Nature of Suit Code Descriptions.

Table with columns: CONTRACT, REAL PROPERTY, TORTS, CIVIL RIGHTS, PRISONER PETITIONS, FORFEITURE/PENALTY, LABOR, IMMIGRATION, BANKRUPTCY, SOCIAL SECURITY, FEDERAL TAX SUITS, OTHER STATUTES. Includes various legal categories like Insurance, Personal Injury, Real Estate, Labor, etc.

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. Section 1332(a)

Brief description of cause: Plaintiff alleges injury from product manufactured/sold by defendants

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: [X] Yes [] No

VIII. RELATED CASE(S) IF ANY

(See instructions): JUDGE Honorable Jinsook Ohta DOCKET NUMBER 3:24-md-03125-JO-VET

DATE 03/17/2025 SIGNATURE OF ATTORNEY OF RECORD /S/ Robert D. Cain, Jr.

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.