BEFORE THE UNITED STATES JUDICIAL PANEL ON MULTIDISTRICT LITIGATION

IN RE: ANGIODYNAMICS AND NAVILYST PORT CATHETER PRODUCTS LIABILITY LITIGATION	))))	**MDL DOCKET NO. _____**

MEMORANDUM IN SUPPORT OF PLAINTIFFS' MOTION TO TRANSFER ACTIONS PURSUANT TO 28 U.S.C. § 1407 FOR COORDINATED OR CONSOLIDATED PRETRIAL PROCEEDINGS

I. INTRODUCTION

Pursuant to 28 U.S.C § 1407 and Rule 6.2 of the Rules of Procedure of the Judicial Panel on Multidistrict Litigation ("the Panel"), Movants Kimberly Boyer, Danny Brierly, Charmaine Brockway, Serena Coleman, Ramsey Ghabra, Noelia Hernandez-Ayala, Maxwell Jones, Patricia Kitchen, Brandon Mcmillian, Claude Preston, Rosa Timmons, Stephen Zuppo, Gage Colyer and William Colyer on his behalf, Lindsay Baldwin, JaiTonia Cain Harvey, L.L., a minor by and through her Next Friend and father John Larson, Robert Barnes, Jessica Garst, and Kimberly Howard ("Movants") respectfully submit this Memorandum in Support of their Motion to Transfer Actions pursuant to 28 U.S.C. § 1407 for Coordinated or Consolidated Pretrial Proceedings. Movants seek transfer of all cases identified in the Schedule of Actions, attached hereto as Exhibit "A", to a single District Court selected by this Panel, as well as the transfer of any later filed cases against the same Defendants, AngioDynamics, Inc. and/or Navilyst Medical, Inc. ("Defendants") that involve similar facts or claims.

Consolidation and coordination of these actions is appropriate under 28 U.S.C. § 1407. The Actions involve common issues of fact and law. Transfer will further benefit and serve the convenience of the parties, attorneys, and witnesses involved. Transfer will also promote the just and efficient conduct of the Actions. The objectives of transfer iterated by the Manual for Complex

Litigation § 20.131 all support consolidation in this instance. The United States District Court for the Western District of Missouri is the most appropriate jurisdiction for the consolidated proceedings of the Actions because of its central location and ability to efficiently and effectively run a multi-district litigation proceeding.

II. BACKGROUND

The cases on the Exhibit A Schedule of Actions all allege product liability claims for personal injuries caused by failures of implanted port catheter medical device products manufactured by Defendants (hereinafter collectively, the "Actions"). Movants comprise 21 Plaintiffs with pending cases against Defendants involving their port catheter products. Their cases are currently pending in 14 different United States District Courts across the country.

Defendants design and manufacture a variety of port catheter products at issue in the Actions (hereinafter collectively, "Angio Port Catheter Products"). The Angio Port Catheter Products are implantable vascular access medical devices that are implanted under a patient's skin in the chest area and are designed to administer intravenous therapies, including medication, fluids, parenteral nutrition, and blood products. The Angio Port Catheter Products consist of an injection port reservoir, which is connected to a catheter tube. The tube then acts as a conduit for the intravenous therapies injected into the port reservoir component of the product. Implanted ports are commonly used in chemotherapy treatment for patients with cancer or for those with autoimmune disorders. The Angio Port Catheter Products are meant for long-term use; Defendants have not given any warnings or indications that they should be removed after a certain period of time after implantation.

All of the Actions on the Exhibit A Schedule of Actions carry claims for personal injuries caused by the Angio Port Catheter Products due to alleged tortious conduct engaged in by

Defendants concerning these products. The injuries that are the subjects of the Actions involve infections, fractures, or blood clots the Movants claim were caused by defects inherent in the Angio Port Catheter Products. The legal claims pursued sound in product liability and include, but are not limited to, claims for negligence in the design, manufacture, testing, sale, and marketing of the Angio Port Catheter Products; design defect; failure to warn; breach of implied warranty; breach of express warranty; the violation of state consumer protection laws; fraudulent concealment; and punitive damages.

III. LEGAL STANDARD

The creation of a multidistrict litigation ("MDL") is appropriate when "civil actions involving one or more common questions of fact are pending in different districts," and transfer will serve "the convenience of parties and witnesses" and "promote the just and efficient conduct of such actions." 28 U.S.C. § 1407(a); *see also*, *In re Nifedipine Antitrust Litigation*, 266 F. Supp. 2d 1382, 1382-83 (J.P.M.L. 2003) (finding transfer and consolidation appropriate for seven actions pending in two different district courts that involved allegations with shared factual questions).

IV. ARGUMENT

Transfer and consolidation of the Actions involving Angio Port Catheter Products is appropriate under Section 1407. They all involve common issues of fact and law; the Actions are pending in multiple different district courts across the country; and transfer will benefit the parties, witnesses, and the courts and will ensure the Actions are justly and efficiently conducted going forward. Transfer is further appropriate to the Western District of Missouri due to its geographically central location and its ability to effectively run a multi-district litigation proceeding.

A. The Actions Involve Common Issues of Fact & Law.

All of the Actions involve common questions of fact and law. At the heart of and at issue in all of these matters are the Angio Port Catheter Products and claims for injuries stemming from the same. The injuries alleged are the same or substantially similar and involve either claims for infections, fracture, or blood clot injuries caused by the devices. The underlying complaints discuss and allege problems relating to the materials used in and the design of the Angio Port Catheter Products that led to such injuries. All of the Actions involve common questions of fact relating to the design, development, testing, manufacture, marketing, sale, and adequacy of warnings concerning the Angio Port Catheter Products. More specifically, the Actions allege that the Defendants deceptively marketed and sold a dangerous medical device that caused serious injuries to patients who have had the devices implanted. These common facts alone warrant consolidation.

The legal claims asserted by Movants are also the same or substantially similar. Movants have alleged claims for negligence in Defendants' design, manufacture, and sale of the Angio Port Catheter Products; design defect; failure to warn; breach of implied and express warranties; fraudulent concealment; state consumer protection and deceptive trade practices act claims; and punitive damages. This will require the courts' determination of whether Defendants violated the same or similar laws, namely those involving product liability, warranty, and tort, all of which concern the shared core issues surrounding the design, manufacture, and sale of the Angio Port Catheter Products.

B. Transfer will Serve the Convenience of the Parties and Witnesses and will Promote the Just and Efficient Conduct of the Actions.

Transfer and centralization of the Actions will serve the convenience of the parties and ensure the Actions move forward efficiently. The Manual for Complex Litigation describes the objectives of transfer, and accordingly, how transfer is appropriate when these elements can be

accomplished: 1) preventing duplicative discovery; 2) avoiding inconsistent rulings and conflicting schedules; 3) reducing litigation cost; and 4) saving time and effort of the parties, attorneys, witnesses, and the courts involved. Manual for Complex Litigation (Fourth), § 20.131, at 220 (2004) (citing *In re Plumbing Fixture Cases*, 298 F. Supp. 484, 491-92 (J.P.M.L. 1968)); see also, *In re Ethicon Physiomesh Flexible Composite Hernia Mesh Products Liability Litigation*, 254 F. Supp. 3d 1381, 1382 (J.P.M.L. 2017) (noting centralization is meant to "eliminate duplicative discovery; prevent inconsistent pretrial rulings; and conserve the resources of the parties, their counsel, and the judiciary" in finding for consolidation of 18 actions pending across 10 districts); *In re Bristol Bay, Salmon Fishery Antitrust Litig.*, 424 F. Supp. 504, 506-07 (J.P.M.L. 1976) (finding for consolidation of four cases pending in two districts "to prevent duplicative discovery, eliminate the possibility of conflicting pretrial rulings and streamline the remainder of the pretrial proceedings"). All of the above objectives would be met by consolidating the Actions here.

1. Transfer will eliminate duplicative discovery and avoid placing undue burden and expense on the parties.

Undoubtedly, given the similar claims made by plaintiffs in the Actions, the parties will engage in the same or similar discovery. This will involve not only similar and overlapping written discovery requests but also depositions of the same witnesses in multiple actions, particularly as it pertains to Defendants. The Movants and plaintiffs involved in the Actions will inevitably want to conduct depositions of Defendants' current and former employees and corporate representatives with knowledge of the design, manufacture, sale, and approval of the Angio Port Catheter Products at issue. These general discovery matters are shared amongst all the Actions. Without centralization, many of these witnesses would likely be subjected to having their deposition taken multiple times. Having these actions go forward at an individual, unconsolidated level in multiple districts would inevitably result in wasted time, resources, work, and expense for

not only the parties and their counsel, but also the court system as a whole. Transfer and centralization are necessary to avoid such a result.

2. Transfer and centralization will avoid inconsistent rulings and pretrial schedules.

As it stands now, there are 23 different cases total involving Angio Port Catheter Products pending in 16 different districts across the country that involve product liability, personal injury claims against Defendants. The cases are in various stages, but most are relatively early on. Pertaining to Movants' cases in particular, the parties have not completed substantial discovery, except for serving Rule 26(a)(1) initial disclosures in some of those matters. Defendants have filed motions to dismiss in many, if not all, of the Actions. Many of those motions await rulings. There are also a multitude of different scheduling orders, pending protective orders and ESI protocols the parties either have submitted or plan on submitting, and a variety of other pretrial matters at issue going forward, including establishing deposition protocols, given the early stage the majority of these cases are in.

This situation is ripe for creating inconsistent rulings and scheduling orders that will unnecessarily burden the courts and all parties involved. Given the scenario with so many actions pending and so many different district courts involved, the Actions are best suited to go in front of one judge for resolution and determination of these pretrial matters. *See* *Bristol Bay*, 424 F. Supp. at 506 (noting the Panel prefers to place actions under the control of a single judge to ensure the objectives of Section 1407 are met if the actions are otherwise appropriate for transfer).

These Actions have only recently been filed, and prompt centralization minimizes the risk of inconsistent rulings. As the Panel recognized in *Camp Lejeune*, delaying centralization "only invites inconsistent rulings," which Section 1407 is designed to avoid. *In re Camp Lejeune, North Carolina Water Contamination Litigation*, 763 F. Supp. 2d 1381, 1382 (J.P.M.L. 2011).

Moreover, early centralization of these Actions avoids potential prejudice to the parties. Only one substantive ruling on a motion to dismiss has been made in the Actions to date, and the majority of the cases have yet to conduct any discovery beyond exchanging initial disclosures. The timing of the filing of these Actions and this Motion places these cases in the best position to reap the full benefits of Section 1407.

Early centralization will maximize the benefits of the transfer and coordination under Section 1407. As discussed above, Movants will seek substantially the same discovery from Defendants; review the same documents produced in discovery; take depositions of the same corporate officers and other witness, as well as of the same or substantially similar expert witnesses; and will involve the same questions of law surrounding expert qualifications under *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993) and issues raised under motions for summary judgment. *See infra.*, at Sec. III.(B)(1). Coordination of these Actions will avoid unnecessarily duplicative discovery across multiple Actions and eliminate potentially conflicting or inconsistent rulings. *See In re Zimmer Nexgen Knee Implant Prods. Liab. Litig.*, 802 F. Supp. 2d 1374, 1376 (J.P.M.L. 2011) ("Centralization under Section 1407 will eliminate duplicative discovery, [and] prevent inconsistent pretrial rulings on *Daubert* and other pretrial issues."); *In re Transocean Tender Offer Sec. Litig.*, 415 F. Supp. 382, 384 (J.P.M.L. 1976) ("[T]he likelihood of motions for partial dismissal and summary judgment in all three actions grounded at least in part on [a common issue] makes Section 1407 treatment additionally necessary to prevent conflicting pretrial rulings and conserve judicial effort.").

There are—and will continue to be—numerous actions with common questions of fact filed in multiple districts involving Angio Port Catheter Products. Given the common nature of these cases, the number of current actions, and the likely number of additional actions to be filed across the country, transfer and coordination are necessary to avoid "multiplied delay, confusion, conflict,

inordinate expenses and inefficiency." *In re Plumbing Fixture Cases*, 298 F. Supp. 484, 495 (J.P.M.L. 1968). The high likelihood of inconsistent judicial rulings affecting the 20 currently existing actions in multiple districts, and the possible scores more to be filed, is precisely why Section 1407 was enacted.

Transfer is warranted in this instance to avoid multiple courts reaching contrary conclusions and inconsistent scheduling of pretrial matters involved in the Actions and to avoid subjecting litigants to conflicting responsibilities and obligations.

3. Transfer will promote efficiency and judicial economy, reduce litigation costs, and save the time and effort of the parties, attorneys, witnesses, and the courts involved.

Movants' claims are based on materially identical conduct of Defendants concerning the Angio Port Catheter Products. Without centralization under Section 1407, the actions would inevitably proceed in a manner that would be highly inconvenient for the courts and parties. The attorneys would be briefing the same issues numerous times in different courts; the same witnesses would be called for depositions in numerous cases; and third parties would be asked to produce the same or similar documents in discovery across multiple actions. This would inevitably entail substantially more expense and time for the attorneys and parties involved and would ultimately be an inefficient use of judicial resources.

Section 1407 is designed to conserve the resources of the parties, attorneys, witnesses, and courts, and transfer here would indeed accomplish such a result in placing the matters in front of one judge to ensure they are justly and efficiently conducted going forward. *See In re Brimonidine Patent Litigation*, 507 F. Supp.2d 1381, 1382 (J.P.M.L. 2007) (finding in favor of transfer so actions may be assigned "to a single judge who can formulate a pretrial program that ensures that pretrial proceedings will be conducted in a manner leading to the just and expeditious resolution

of all actions to the overall benefit of the parties and expeditious resolution of all actions to the overall benefit of the parties and the courts"). Transfer is warranted in this instance to avoid subjecting litigants to conflicting responsibilities and obligations and to over-burden the parties with having to do the same or substantially similar work across multiple cases.

4. Informal coordination pursuant 28 U.S.C. § 1404 is inappropriate and has previously been rejected by Defendants.

On April 12, 2024, counsel for Movants contacted counsel for Defendants to request informal coordination of several of the Actions that were existing at the time via transfer pursuant to 28 U.S.C. § 1404 to promote efficiency in discovery and the convenience of the parties. Counsel for Defendants responded that Defendants were not agreeable to such transfer and coordination.

In light of this, informal coordination is not a practical possibility. Regardless of this previous attempt and Defendants' rejection, informal coordination is inappropriate here given the continued number of actions being filed involving Angio Port Catheter Products that involve a growing number of judicial district courts. Coordination pursuant to 28 U.S.C. § 1407 is necessary to conserve judicial resources and serve the convenience of the parties.

C. These Actions Should Be Transferred to the Western District of Missouri.

Plaintiffs urge the Panel to transfer the Actions to the Western District of Missouri, where a court with Multidistrict Litigation experience can efficiently, justly, and capably manage them. The Western District of Missouri is the optimal court to manage a complex product liability litigation like this one.

In determining an appropriate transferee forum, the Panel balances several factors, including the experience, skill, and caseloads of the available judges; the number of cases pending in the jurisdiction; convenience of the parties; location of the witnesses and evidence; and the minimization of cost and inconvenience to the parties. *See, e.g.*, *In re Wheat Farmers Antitrust*

Class Action Litig., 366 F.Supp. 1087, 1088 (J.P.M.L. 1973); *In re Preferential Drugs Prods. Pricing Antitrust Litig.*, 429 F.Supp. 1027, 1029 (J.P.M.L. 1977); *In re Tri-State Crematory Litig.*, 206 F.Supp. 1376, 1378 (J.P.M.L. 2002); Manual of Complex Litigation (Fourth) (2004), § 20.131, at 221. Factors including experience, number of pending cases, available resources, and convenience to the parties and witnesses all weigh heavily in favor of transferring all related cases to the Western District of Missouri.

The Western District of Missouri judges are well-versed in handling multidistrict litigations and have guided numerous MDLs to successful partial or complete resolutions. Examples include: *Dollar General Corp. Motor Oil Marketing and Sales Practices Litigation,* MDL Number 16-md-2709; *Smitty's/Cam2 303 Tractor Hydraulic Fluid Marketing, Sales Practices and Products Liability Litigation,* MDL Number 20-md-2936; and *T-Mobile Customer Data Security Breach Litigation,* MDL Number 21-md-3019. These are but a few of the examples showing that the Western District of Missouri is an efficient, well-run District with impressive case-processing statistics. The Western District of Missouri has had a proven track record with a short median time from case filing to disposition for civil cases.[1]

The Panel has also held that the pendency of a related action in a particular forum is an important factor in selecting the forum. See *In re: Sugar Industry Antitrust Litig.*, 395 F.Supp. 1271, 1274 (J.P.M.L. 1975) (citations omitted). Of the 20 Actions currently on file, three are on file in the Western District of Missouri. Exh. A, Schedule of Actions (*Larsen v. Angiodynamics, Inc., et al.*, Case No. 2:24-cv-04114; *Colyer, et al. v. Angiodynamics, Inc., et al.*, Case No. 2:24-cv-04121; *Baldwin v. Angiodynamics, Inc., et al.*, Case No. 3:24-cv-05055). The remaining cases not pending

[1] See Federal Judicial Caseload Statistics; U.S. District Courts—Median Time From Filing to Disposition of Civil Cases, by Action Taken—During the 12-Month Period Ending March 31, 2022 (https://www.uscourts.gov/statistics/table/c-5/federal-judicial-caseload-statistics/2022/03/31).

before the Western District of Missouri have been filed across 15 District Courts, with no other district presiding over more than two related Actions. *See* David F. Hen, Multidistrict Litigation Manual § 6:8 (2010) ("[T]he Panel will not normally transfer actions to a district in which no action is then pending and the panel clearly considers the number of actions pending in various districts to determine the selection.").

In addition to other factors, consolidation in the Western District of Missouri offers a convenient and affordable location for both the Plaintiffs and Defendants in these Actions. Kansas City has a new $1.5 billion airport opened in February 2023 that has substantially improved air travel into and out of the Kansas City metropolitan area. Kansas City's central location provides direct flights from more than 50 U.S. cities daily. Kansas City's centralized geographic location will make it an easily accessible destination for the parties, witnesses, experts, and others involved in this litigation. Indeed, the Panel has previously acknowledged the Western District of Missouri as "centrally located and easily accessible, making it a convenient forum for … nationwide litigation." *In re Smittys*, 466 F. Supp. 3d at 1382.

Each judge serving in the Western District of Missouri is eminently qualified to oversee these Actions, and several of the judges in the District have already demonstrated the ability to steer an MDL on a prudent course. The Honorable Brian C. Wimes is well-suited to oversee this litigation. Judge Wimes is vastly experienced, as he has been on the federal bench for approximately 13 years. Judge Wimes has overseen complex litigations including at least two MDL cases. *See In re T-Mobile Customer Data Security Breach Litigation*, 576 F.Supp.3d 1373, 1375 (J.P.M.L. 2021) (data breach case involving more than 54 million potential claimants); *In re National Ski Pass Insurance Litigation*, 492 F.Supp.3d 1352, 1355 (J.P.M.L. 2020). In *T-Mobile*, Judge Wimes shepherded the case to resolution just seven months after he received the assignment, demonstrating his ability to efficiently resolve cases and decide complex issues, while conserving

judicial resources and the time and expense required of litigants.

The Actions would also be prudently and efficiently managed if assigned to the Honorable Stephen R. Bough. Judge Bough is an experienced jurist with a professional background involving substantial complex litigation. Judge Bough's comprehensive and unique experience, including presiding over other MDL cases, makes him an excellent choice to oversee this litigation. Judge Bough has shown particular skill in efficiently shepherding cases through discovery and trial to reach final adjudication of issues. His guidance would be instrumental in these cases, which are expected to involve voluminous discovery and complex questions of law. The Panel previously expressed confidence in Judge Bough's ability to steer a complex MDL on a prudent course given his experience as a jurist and ability and willingness to manage complex litigation efficiently. *In re Smitty's*, 466 F. Supp. 3d at 1382.

Additionally, Judge Bough's knowledge and expertise regarding complex MDL litigation is demonstrated in the article he co-authored with Elizabeth Chamblee Burch, "Collected Wisdom on Selecting Leaders and Managing MDLs," where he discusses, among other things, the importance of cultivating diversity when choosing MDL leadership. Even more, Judge Bough has actively participated in continuing legal education programs addressing the uniqueness of MDL litigation. One recent example, "Hot Topics in MDLs," presented on March 29, 2023, allowed Judge Bough and other presenters to directly address some current topics related to MDL litigation including early vetting and the process of determining appropriate MDL leadership.

V. CONCLUSION

Consolidation and coordination of these actions is appropriate under 28 U.S.C. § 1407. The Actions involve common issues of fact and law arising from product liability, personal injury claims against Defendants concerning their port catheter products. Transfer will avoid inconsistent

rulings and serve the convenience of the parties, attorneys, witnesses, and the court system overall. Transfer will also promote the just and efficient conduct of the Actions. The objectives of transfer iterated by the Manual for Complex Litigation § 20.131 all support consolidation in this instance. Movants respectfully request transfer of all pending and future related actions to the Western District of Missouri before either the Honorable Brian C. Wimes or the Honorable Stephen R. Bough. Such district is the most appropriate location for the consolidated proceedings of the Actions because of its central location and ability to effectively run a multi-district litigation proceeding.

Dated: July 25, 2024

Respectfully submitted,

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Exhibit A

U.S. District Court
Nort ern District of West Virginia (Clarksburg)
CIVIL DOCKET FOR CASE #: 1:22-cv-00097-TSK

Pettit v. Angiodynamics, Inc. et al
Assigned to: Chief District Judge Thomas S Kleeh **h**
Cause: 28:1332 Diversity-Product Liability **h**

Date Filed: 09/22/2022
Jury Demand: Plaintiff
Nature of Suit: 365 Personal Inj. Prod. Liability
Jurisdiction: Diversity

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Date Filed d	#	**Docket Text**
09/ / 0	_	CO LAINT against All Defen ants, file by Nicole Pettit. Receipt #AWVNDC- d 3 777 . (Attachments: # _ Civil Cover Sheet)(wrr) (Entere : 09/ / 0)

09/22/2022	2	VER ON O ORNEY DM ISS ON as to roy . Brenes. wrr Entered: 09/22/2022
09/30/2022	4	MO ON for Leave to ppear Pro Hac Vice *of Troy A. Brenes* by Nicole Pettit. (ttachments: # 1 ttachment Verified Statement of pplication for Pro Hac Vice dmission of roy . Brenes, # 2 ttachment he State Bar of alifornia ertificate of Good Standing, # 3 ttachment Supreme ourt of alifornia ertificate of Good Standing, # 4 ttachment Receipt from he West Virginia State Bar, # 5 Proposed Order Proposed Order, # 6 ttachment ertificate of Service (oster, Jason (Entered: 09/30/2022
09/30/2022	5	MO ON for Leave to ppear Pro Hac Vice *of Andrew Mathews* by Nicole Pettit. (ttachments: # 1 ttachment Verified Statement of pplication for Pro Hac Vice dmission of ndrew Mathews, # 2 ttachment he alifornia State Bar ertificate of Good Standing, # 3 ttachment Supreme ourt of laifornia ertificate of Good Standing, # 4 ttachment West Virginia State Bar receipt # 5 Proposed Order Proposed Order, # 6 ttachment ertificate of Service (oster, Jason (Entered: 09/30/2022
10/06/2022	6	SUMMONS Returned Executed as to Navilyst Medical, nc. served on 9/29/2022. (jb (Entered: 10/06/2022
10/06/2022	7	SUMMONS Returned Executed as to ngiodynamics, nc. served on 9/29/2022. (jb (Entered: 10/06/2022
10/19/2022	8	Pro Hac Vice iling fee as to . Brenes and . Mathews) P D: $ 400.00, receipt number WVN 003524. (wrr (Entered: 10/19/2022
11/02/2022	9	**ORDER granting 4 Motion for Leave to Appear Pro Hac Vice for Attorney Troy A. Brenes. Signed by Chief District Judge Thomas S Kleeh on 11/2/2022. (Copy counsel of record)(jmm)** (Entered: 11/02/2022
11/02/2022	10	**ORDER granting 5 Motion for Leave to Appear Pro Hac Vice for Andrew Mathews. Signed by Chief District Judge Thomas S Kleeh on 11/2/2022. (jmm)** (Entered: 11/02/2022
11/03/2022	12	Mail sent to Navilyst Medical, nc. 6 Summons Returned Executed Returned as Undeliverable "Return to Sender. Not Deliverable as ddressed. Unable to forward." (jb (Entered: 11/15/2022)
11/15/2022	13	SUMMONS Returned Executed as to Navilyst Medical, nc. served on 11/10/2022. (oster, Jason (Entered: 11/15/2022
07/14/2023	14	**NOTICE OF INTENT TO DISMISS. The Court gives NOTICE that, barring objections, it intends to dismiss this case without prejudice in its entirety on August 15, 2023. Signed by Chief District Judge Thomas S Kleeh on 7/14/2023. (snc)** (Entered: 07/14/2023)
07/27/2023	15	First MO ON for Default Judgment as to by Nicole Pettit. Responses due by 8/10/2023 (ttachments: # 1 ttachment Declaration (oster, Jason (Entered: 07/27/2023
07/28/2023	16	V ED based on 27 Order entered 09/28/2023. lerk's EN RY O DE UL as to ngiodynamics, nc., Navilyst Medical, nc. (entered per chambers (opy to defendants by cm/rrr (snc (dditional attachment(s added on 7/28/2023: # 1 ertified Mail Return Receipt (snc . Modified on 8/8/2023 (snc . Modified on 9/28/2023 to V E order (snc . (Entered: 07/28/2023
08/08/2023	17	RE URN RE E P for ngiodynamics, nc. as to 16 lerk's Entry of Default. Per USPS website, SERV E EP ED on 7/31/2023. (snc (Entered: 08/08/2023

08/11/2023	18	M nt to N v y t M d c , Inc. 16 C rk' ntry of f u t, turn d Und v r b . (nc) (nt r d 08/11/2023)
08/15/2023	19	OBJECTIONS *to Notice of Intent to Dismiss* to 14 Ord r by N co P tt t. (Fo t r, J on) (Ent r d: 08/15/2023)
08/21/2023	20	NOTICE of App r nc by Ky T. Turnbu on b h f of A f nd nt (Turnbu , Ky) (Ent r d: 08/21/2023)
08/21/2023	21	MOTION to V c t *Default Judgment* by Ang odyn m ic , Inc., N v y t M d c , Inc.. (Att chm nt : # 1 Att chm nt Memor ndum of L w, # 2 Exh b t c r t on, # 3 Propo d Ord r Propo d Ord r Gr nt ng Mot on to V c t)(Turnbu , Ky) (Ent r d: 08/21/2023)
08/22/2023	22	VERIFICATION OF ATTORNEY A MISSION to ttorn y Thom a J. Yoo nd Amy D McV gh. (nc) (Ent r d: 08/22/2023)
09/01/2023	23	RESPONSE to Mot on r 21 MOTION to V c t *Default Judgment* f d by N co P tt t. (Att chm nt : # 1 Exh b t c D t on)(Fo t r, J on) (Ent r d: 09/01/2023)
09/08/2023	24	REPLY to R ponD to Mot on r 21 MOTION to V c t *Default Judgment* f d by Ang odyn m ic , Inc., N v y t M d c , Inc.. (Turnbu , Ky) (Ent r d: 09/08/2023)
09/08/2023	25	*Declaration of Brooke Lynn Meyers in Support of Plaintiff's Response to Defendants' Motion to Vacate Entry of Default* Oth r ocum nt r 23 R pon to Mot on f d by N co P tt t. (Fo t r, J on) (Ent r d: 09/08/2023)
09/26/2023	26	NOTICE of App r nc by L nd y M. S d on b h f of Ang odyn m ic , Inc., N v y t M d c , Inc. (S d, L nd y) (Ent r d: 09/26/2023)
09/28/2023	27	**ORDER GRANTING MOTION TO VACATE ENTRY OF DEFAULT (ECF NO. 21). The Court GRANTS the Defendants' motion and DIRECTS the Clerk of Court to vacate its entry of default. Signed by Chief District Judge Thomas S Kleeh on 9/28/2023. (snc)** (Ent r d: 09/28/2023)
10/03/2023	28	**FIRST ORDER AND NOTICE REGARDING DISCOVERY AND SCHEDULING CONFEERNCE** ******NOTICE TO ATTORNEYS*** : Pursuant to Rule 7.1 of the Federal Rules of Civil Procedure, ALL Non-governmental CORPORATE parties must file a DISCLOSURE STATEMENT with the Court. Forms are available on the Court's Web Site at http://www.wvnd.uscourts.gov/forms.htm*** **Rule 26 Meeting to be held by 11/2/2023. Rule 26 Meeting Report due by 11/16/2023. Discovery due by 12/4/2023. Signed by Chief District Judge Thomas S Kleeh on 10/03/2023. (snc)** (Ent r d: 10/03/2023)
10/31/2023	29	Attorn y u d ncorr ct v nt. P ntry 31. (S d, L nd y) Mod f d on 10/31/2023 (nc). (Ent r d: 10/31/2023)
10/31/2023	30	Attorn y u d ncorr ct v nt. P D ntry 32. (S d, L nd y) Mod f d on 10/31/2023 (nc). (Ent r d: 10/31/2023)
10/31/2023	31	MOTION for L v to App r Pro H c V c *Thomas J. Yoo* by Ang odyn m ic , Inc.. (S d, L nd y) (Ent r d: 10/31/2023)
10/31/2023	32	MOTION for L v to App r Pro H c V c *Amy McVeigh* by Ang odyn m ic , Inc.. (S d, L nd y) (Ent r d: 10/31/2023)
11/01/2023	33	Pro H c V c F ng f for Thom a Yoo nd Amy McV gh n th mount of $ 400.

		Receipt n e 00003758. (snc) (Ente ed: /0 /2023)
/06/2023	34	**OR ER rant n 32 M ot on of Amy McVe h for Leave to Appear Pro Hac V ce on behalf of Angiodynamics, Inc. and Navilyst Medical, Inc. Signed by Chief istrict Judge Thom as S K leeh on 11/6/2023. (dk)** (Ente ed: /06/2023)
/06/2023	35	**OR ER granting 31 Motion of Thomas J. Yoo for Leave to Appear Pro Hac Vice on behalf of Angiodynamics, Inc. and Navilyst Medical, Inc. Signed by Chief istrict Judge Thomas S Kleeh on 11/6/2023. (dk)** (Ente ed: /06/2023)
/ 5/2023	36	MOTION TO DISMISS FOR FAILURE TO STATE A CLAIM y Angiodyna cs, Inc., Navilyst Medical, Inc.. (Saad, Lindsey) (Ente ed: / 5/2023)
/ 5/2023	37	MEMORANDUM *OF LAW IN SUPPORT OF THEIR PARTIAL MOTION TO DISMISS PLAINTIFFS COMPLAINT* by Angiodyna cs, Inc., Navilyst Medical, Inc. e 36 MOTION TO DISMISS FOR FAILURE TO STATE A CLAIM . (Saad, Lindsey) (Ente ed: / 5/2023)
/ 6/2023	38	REPORT of R le 26(f) Planning Meeting. (Saad, Lindsey) (Ente ed: / 6/2023)
/ 6/2023	39	P oposed O de e 36 MOTION TO DISMISS FOR FAILURE TO STATE A CLAIM y Angiodyna cs, Inc., Navilyst Medical, Inc.. (Saad, Lindsey) (Ente ed: / 6/2023)
/29/2023	40	Fi st MOTION Plaintiff's M e and of Law in S ppo t of He Opposition to Defendants' Pa tial Motion to Dis ss Plaintiff's Co lpint y Nicole Pettit. (Foste , Jason) M odified on 2/ 2/2023 to c eate elationship to 36 , 37 (ag). (Ente ed: /29/2023)
2/04/2023	4	CERTIFICATE OF SERVICE y Angiodyna cs, Inc. *Defendants Initial Disclosures*. (Saad, Lindsey) (Ente ed: 2/04/2023)
2/06/2023	42	REPLY to Response to Motion e 36 MOTION TO DISMISS FOR FAILURE TO STATE A CLAIM *Reply in Further Support of Defendants' Partial Motion to Dismiss* filed y Angiodyna cs, Inc., Navilyst Medical, Inc.. (Saad, Lindsey) (Ente ed: 2/06/2023)
2/ 4/2023	43	**COMPLEX CASE SCHE ULING OR ER. Plaintiff's Amended Pleadings and Joinder of Parties are due by 12/28/2023. efendant's Amended Pleadings and Joinder of Parties due by 1/11/2024. Case Management Conference is set for 1/18/2024 11:00 AM in Clarksburg istrict Judge Courtroom, 2nd Floor before Chief istrict Judge Thomas S Kleeh. isc very due by 11/29/2024. Case Management Conference is set for 12/16/2024 10:00 AM in Clarksburg istrict Judge Courtroom, 2nd Floor before Chief istrict Judge Thomas S Kleeh. Motions due by 1/24/2025. aubert Hearing set for 3/24/2025 10:00 AM in Clarksburg istrict Judge Courtroom, 2nd Floor before Chief istrict Judge Thomas S Kleeh. Proposed Pretrial Order due by 6/9/2025. Final Pretrial Conference/ Settlement Conference is set for 6/30/2025 10:00 AM in Clarksburg istrict Judge Courtroom, 2nd Floor before Chief istrict Judge Thomas S Kleeh. Jury Selection and Jury Trial are set for 7/25/2025 09:30 AM in Clarksburg istrict Judge Courtroom, 2nd Floor before Chief istrict Judge Thomas S Kleeh. Trial is anticipated to last 10 days. Signed by Chief istrict Judge Thomas S Kleeh on 12/14/2023. (jb)** Modified on 2/28/2023 to co ect location of p et ial confe ence in docket text (j). (Ente ed: 2/ 4/2023)
0 / 6/2024	44	MOTION to Withd aw as Atto ney *and Substitute New Counsel* y Nicole Pettit. (A so, C.) (Ente ed: 0 / 6/2024)
0 / 6/2024	45	P oposed O de *Granting Motion to Withdraw and Substitute Counsel* y Nicole Pettit. (A so, C.) (Ente ed: 0 / 6/2024)
0 7/2024	46	MOTION fo Leave o Appea Pe tely y Nicole Pettit. (Foste , Jason) (Ente ed: 0 / 7/2024)

01/17/2024	47	C CA O S V C by Angiodynamics, nc , Na ilys Medical, nc *De endant Angiodynamics, Inc.'s and Navilyst Medical, Inc.'s First Set o Interrogatories to Plainti* (Saad, Lindsey) (ntered: 01/17/2024)
01/17/2024 v	48	C CA O S V C by Angiodynamics, nc., Na ilyst Medical, nc. *Defendant Angiodynamics, Inc.'s and Navilyst Medical, Inc.'s First Requests for Production to Plaintiff* (Saad, Lindsey) (ntered: 01/17/2024) v
01/18/2024	49	**ORDER GRANTING 46 MOTION TO APPEAR REMOTELY. Signed by Chief District Judge Thomas S Kleeh on 01/18/2024. (snc)** (ntered: 01/18/2024)
01/18/2024 v	50	**ORAL ORDER granting 44 Motion to Withdraw as Attorney. Attorney C. Edward Amos and Scott S. Segal terminated. Signed by Chief District Judge Thomas S Kleeh on 1/28/2024. (dk)** (ntered: 01/18/2024)
01/18/2024 v	51	M NU v N v Y: ******NOTICE*** THE ATTACHED DOCUMENT IS NOT ACCESSIBLE. IT IS FOR STATISTICAL PURPOSES ONLY.*** Proceedings held before Chief District Judge homas S Kleeh. Status Conference held on 1/18/2024. (Court eporter achel Kocher) (dk) (ntered: 01/18/2024)

PACER Service Center

Transaction Receipt

07/16/2024 12:20:50

PACER Login:	dickersonoxton	**Client Code:**	Angiodynamics
Description:	Docket eport	**Search Criteria:**	1:22-c -00097- SK v
Billable Pages:	5	**Cost:**	0.50

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF WEST VIRGINIA

NICOLE PETTIT,	)	**Case No. 1:22-CV-97 (Kleeh)**
Plaintiff	)	
	)	
vs.	)	**PLAINTIFF'S COMPLAINT AND JURY DEMAND**
ANGIODYNAMICS, INC. & NAVILYST MEDICAL, INC.	)	
	)	
Defendants	)	

PLAINTIFF'S COMPLAINT AND JURY DEMAND

Plaintiff, by and through her undersigned counsel, brings this Complaint for Damages against Defendants and in support thereof states the following:

1. This is a device tort action brought on behalf of the above-named Plaintiff arising out of the failure of Defendants' implantable vascular access device ("Smartport" or "product"). As a result, Plaintiff NICOLE PETTIT suffered permanent injuries and significant pain and suffering, emotional distress, lost wages and earning capacity, and diminished quality of life. The Plaintiff respectfully seeks all damages to which she may be legally entitled.

I. STATEMENT OF PARTIES

2. Plaintiff Nicole Pettit ("Plaintiff") is, and was, at all relevant times, a citizen and resident of West Virginia and the United States.

3. Defendant Angiodynamics, Inc. ("Angiodynamics") is a corporation organized and existing under the laws of Delaware, with its headquarters and principal place of business

located at 14 Plaza Drive, Latham, New York, 12110, and doing business within the State of West Virginia and elsewhere in the United States.

4. Defendant Navilyst Medical, Inc. ("Navilyst") is a corporation organized and existing under the laws of Delaware, with its headquarters and principal place of business at 26 Forest Street, Marlborough, Massachusetts, 01752. Angiodynamics completed a purchase of Navilyst in 2012, expanding the former's share of the market for vascular access devices.

5. Defendant Angiodynamics and Defendant Navilyst are referred to in the collective, at times herein, as "Defendants."

II. JURISDICTION

6. The Court has subject matter and personal jurisdiction over the issues and the parties to this cause of action. Defendants have conducted business and derived substantial revenue from within the State of West Virginia and have sufficient minimum contacts and intentionally avails themselves of the West Virginia market so as to render the exercise of jurisdiction over Defendants by the West Virginia courts consistent with traditional notions of fair play and substantial justice.

7. Defendants, with respect to the product at issue in the case at bar, have made or performed contracts or promises substantially connected to the State of West Virginia.

8. This court may exercise jurisdiction over Defendants under the laws of West Virginia, the West Virginia Constitution, and the Constitution of the United States.

9. Venue is proper in this Court as a substantial part of the counts giving rise to this Complaint occurred in West Virginia.

10. Plaintiff brings this complaint solely under state law and not under federal law and specifically not under the United States Constitution, or any of its amendments. Plaintiff believes and alleges that causes of action exist under the hereinafter set out state law claims for the conduct complained of herein.

III. STATEMENT OF FACTS

11. At all relevant times, each of the Defendants designed, developed, manufactured, licensed, marketed, distributed, sold and/or placed Vascular Access Devices in the stream of commerce, including the SmartPort CT product that is at issue in this lawsuit.

12. All acts and omissions of each Defendant as described herein were done by its agents, servants, employees, representatives, and/or owners, acting in the course and scope of their respective agencies, services, employments and/or ownership.

13. At all relevant times, each of the Defendant, was and still is a corporation authorized to do business in the State of West Virginia.

14. At all times hereinafter mentioned, upon information and belief, Defendants were and still are business entities actually doing business in the State of West Virginia.

15. At all times hereinafter mentioned, Defendants were engaged in the business of designing, manufacturing, advertising, marketing, and selling Vascular Access Devices including the SmartPort CT Injectable Port (referred to herein, at times as "SmartPort"), and in pursuit of this business, transacted business within the State of West Virginia and contracted to provide goods and services in the State of West Virginia.

16. At all times hereinafter mentioned, upon information and belief, Defendant committed tortious acts inside the State of West Virginia, which caused injury to Plaintiff.

17. At all times hereinafter mentioned, upon information and belief, Defendants expected or should reasonably expect its acts to have consequences in the State of West Virginia.

A. DEFENDANTS' SMARTPORT VASCULAR ACCESS DEVICE

15. In or about 2010, Defendants received clearance via the 510(k) Premarket Notification Program from the Food and Drug Administration (FDA) to market and sell SmartPort.

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

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

18. 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.

19. 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.

20. The SmartPort is a system consisting of two primary components: an injection port and a silicone catheter.

21. 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.

22. 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."

23. According to Defendants' marketing materials, the Fluoromax^{tm} Catheter is a high-radiopacity catheter made from 100% silicone.

24. The catheter is joined to the body of the injection port by a connection sleeve.

25. The connection sleeve is improperly designed in relation to the step of the port body due to, *inter alia*, a mismatch of the diameter of the connection sleeve to those of the catheter and port stem.

26. This sizing mismatch and lack of a functional locking mechanism creates the risk of catheter separation from the port while implanted in the patient.

27. When a catheter separates from the port, chemotherapy drugs are released in direct contact with subcutaneous and subdermal tissues, a complication known as extravasation.

28. Because chemotherapy drugs are known to be cytotoxic, extravasation causes profound damage to the aforementioned tissues to which it is exposed, prepitating severe pain, tissue necrosis, and subsequent surgical intervention.

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

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

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

376. F.3d 163, 167 (3d. Cir. 2004). A pre-market notification submitted under 510(k) is thus entirely different from a PMA, which must include data sufficient to demonstrate that the produce involved is safe and effective.

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

> If the FDA concludes on the basis of the [manufacturer's] § 510(k) notification that the device is 'substantially equivalent' to a pre-existing device, it can be marketed without further regulatory analysis…. The § 510(k) notification process is by no means comparable to the PMA process; in contrast to the 1,200 hours necessary to complete a PMA review, the § 510(k) review is completed in average of 20 hours …. As on commentator noted: "The attraction of substantial equivalence to manufacturers is clear. Section 510(k) notification required little information, rarely elicits a negative response form the FDA, and gets processed quickly.

518 U.S. 470, 478-79 (1996).

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

35. 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.

36. 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, migrating, perforating internal vasculature and otherwise malfunctioning.

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

38. 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. cardiac/pericardial tamponade;

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

d. severe and persistent pain;

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

f. upon information and belief, even death.

39. 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 – including the product implanted in Plaintiff – which were concealed from medical professionals and patients through submission to the FDA's controversial Alternative Summary Reporting ("ASR") program.

40. 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.[1]

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

42. 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.

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

44. 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 catheter fracture and associated injuries.

45. 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.

B. PLAINTIFF-SPECIFIC FACTUAL BACKGROUND

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

46. On October 19, 2018, Plaintiff underwent placement of an implantable vascular access device at Fairmont Regional Medical Center in Fairmont, West Virginia, where she was implanted with an AngioDynamics Smart Port, Ref # CT80STPD-VI, Lot # 5378436.

47. Defendant manufactured, sold, and/or distributed the SmartPort to Plaintiff, through her doctors, to be used for delivery of chemotherapy.

48. On February 13, 2019, at a routine chemotherapy session at United Hospital Center in Bridgeport, West Virginia, nurses initiated a saline flush prior to the administration of her Doxorubicin chemotherapy; immediately it was noticed that there was infiltration of the saline, which began leaking from her chest. She was sent for a chest X-ray and evaluation of the port with angiogram and superior vena cava venogram, which demonstrated that the left-sided port had become completely disconnected from the catheter tubing. She underwent placement of a PICC line in her left arm by Dr. John Adeniyi, M.D., and recommended to have her port removed.

49. On February 19, 2019, Plaintiff underwent surgery at Fairmont Regional Medical Center to remove the SmartPort and catheter, performed by Dr. Charles Frank, M.D. During said procedure, Dr. Frank observed that the blue hub, as well as the catheter, was completely off the injection port. He then removed the port and passed it off the field to be returned to the manufactures to see if they could ascertain why it had become unattached.

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

51. The SmartPort implanted into the Plaintiff was in the same or substantially similar condition as when it left the possession of Defendants, and in the condition directed by and expected by Defendant.

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

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

54. Defendants had sole access to material facts concerning the defective nature of the products and their propensity to cause serious and dangerous side effects.

55. In reliance on Defendants' representations, Plaintiff's doctor was induced to, and did use the SmartPort.

56. As a result of having the SmartPort implanted, Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury, permanent and substantial physical deformity, has undergone and will undergo corrective surgery or surgeries, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, and present and future lost wages.

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

58. 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.

59. The injuries, conditions, and complications suffered due to Defendants' SmartPort include but are not limited to hemorrhage; cardiac/pericardial tamponade; cardiac arrhythmia and other symptoms similar to myocardial infarction; severe and persistent pain; perforations of tissue, vessels and organs; and even death.

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

61. Plaintiff did not learn of Defendants' wrongful conduct until a time within the applicable statute of limitations. Furthermore, in the existence of due diligence, Plaintiff could not have reasonably discovered the Defendants' wrongful conduct, including, but not limited to, the defective design and/or manufacturing of the product until a date within the statute of limitations. Therefore, under appropriate application of the discovery rule, Plaintiff's suit was filed well within the statutory limitations period.

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

a) Defendant failed to correct a known design defect which exposed patients to unreasonable risk of harm;

b) Defendant failed to adequately test the SmartPort, allowing defective devices to be placed in the stream of commerce;

c) Defendant 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.

d) 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.

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

64. 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.

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

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

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

68. In 2019, Plaintiff did not know that the surgery she underwent was due to a defect in these products.

69. It was not until a time within the applicable statute of limitations, that Plaintiff discovered Defendants' wrongful conduct. Furthermore, Plaintiff could not have reasonably discovered the Defendants' wrongful conduct, including but not limited to, the defective design and/or manufacturing of these devices until a date within the statute of limitations. Therefore,

under appropriate application of the discovery rule, Plaintiff's suit was filed well within the statutory limitations period.

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

71. 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.

IV. STATEMENT OF CLAIM

COUNT I: NEGLIGENCE

72. Plaintiff re-alleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein.

73. At all relevant times, Defendant had a duty to exercise reasonable and ordinary care in the manufacture, design, labeling, instructions, warnings, sale, marketing, and distribution of the Defendants' SmartPort, and recruitment and training of physicians to implant the SmartPort.

74. Defendants breached the duty of care to the Plaintiff, as aforesaid, in the manufacture, design, labeling, warnings, instructions, sale, marketing, distribution, and recruitment and training of physicians to implant the SmartPort.

75. Defendants breached their duty by 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.

76. As a direct and proximate result of the duties breached, the SmartPort failed, resulting in much pain and suffering, mental anguish, doctor visits, subsequent procedures, and substantial medical bills.

77. As a direct and proximate result of Defendant's negligence, Plaintiff suffered severe pain, injuries and damages.

78. As a direct and proximate result of Defendant's conduct, Plaintiff has suffered and will continue to suffer great pain and mental anguish.

79. Defendant's conduct in continuing to market, sell and distribute the SmartPort after obtaining knowledge that the products were failing and not performing as represented and intended, showed complete indifference to or a conscious disregard for the safety of others, justifying an award of additional damages for aggravating circumstances in such a sum which will serve to deter Defendant and others from similar conduct in the future.

80. Defendants knew or should have known that its failure to exercise ordinary care in the manufacture, design, labeling, warnings, instructions, sale, marketing, distribution and recruitment and training of physicians to implant the SmartPort would cause foreseeable harm, injuries and damages to individuals such as Plaintiff who are implanted with SmartPort.

81. As a direct, proximate and foreseeable result of the Defendants' design, manufacture, labeling, marketing, sale, and distribution of the SmartPort, Plaintiff has been injured, sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and consortium, and economic damages.

82. Each act or omission of negligence was a proximate cause of the damages and injuries to Plaintiff.

WHEREFORE, Plaintiff demands judgment against Defendant, and requests compensatory damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT II: STRICT LIABILITY – DESIGN DEFECT

83. Plaintiff re-alleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein and additionally or in the alternative, if same be necessary, allege as follows:

84. Defendant supplied, manufactured, sold, distributed and/or otherwise placed into the stream of commerce the SmartPort implanted into Plaintiff. The product was defective in its design in that when it left the hands of Defendant, it was not safe for its anticipated use and safer, more reasonable alternative designs existed that could have been utilized by Defendant. A reasonably prudent medical device manufacturer would not have placed the SmartPort with its defective design into the stream of commerce.

85. The SmartPort was defectively designed when supplied, sold, distributed and/or otherwise placed into the stream of commerce and when it was implanted in Plaintiff.

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

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

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

89. The defective and unreasonably dangerous condition of the SmartPort was the proximate cause of the damages and injuries complained of by Plaintiff.

90. As a direct and proximate result of the SmartPort's aforementioned design defects, Plaintiff was caused and 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.

91. Defendants are strictly liable to Plaintiff.

WHEREFORE, Plaintiff demands judgment against Defendant and requests compensatory damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT III: STRICT LIABILITY – MANUFACTURING DEFECT

92. Plaintiff re-alleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein and additionally or in the alternative, if same be necessary, allege as follows:

93. Defendants supplied, manufactured, sold, distributed and/or otherwise placed into the stream of commerce the SmartPort implanted in Plaintiff. The SmartPort was defective in its manufacture and construction when it left the hands of Defendant in that its manufacture and construction deviated from good manufacturing practices and/or manufacturing specifications as

would be used and/or maintained by a reasonably prudent and careful medical device manufacturer.

94. The SmartPort as manufactured and constructed by Defendants was unreasonably dangerous to end consumers including Plaintiff and posed an unreasonable degree of risk, danger and harm to Plaintiff.

95. The SmartPort was expected to reach and did reach Plaintiff's implanting surgeon and Plaintiff without substantial change in the condition in which it was manufactured, supplied, distributed sold and/or otherwise placed in the stream of commerce.

96. The manufacturing defect in the SmartPort implanted in Plaintiff was not known, knowable or readily apparent to Plaintiff's physician or to Plaintiff. Nor was it discoverable upon any reasonable examination by Plaintiff's physician or Plaintiff. The SmartPort was used and implanted in the very manner in which it was intended to be used and implanted by Defendant in accordance with the instructions for use and specifications provided by Defendants.

97. The SmartPort implanted in Plaintiff was different from its intended design and failed to perform as safely as a product manufactured in accordance with the intended design would have performed.

98. The defective and unreasonably dangerous condition of the SmartPort product was a proximate cause of damages and injuries suffered by Plaintiff.

99. As a direct and proximate result of the SmartPort's aforementioned manufacturing defect, Plaintiff was caused and 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.

100. Defendant is strictly liable to Plaintiff.

WHEREFORE, Plaintiff demands judgment against Defendant and requests compensatory damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT IV: STRICT LIABILITY – FAILURE TO WARN

101. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein and additionally or in the alternative, if same be necessary, allege as follows:

102. Defendant manufactured, designed, marketed, sold and/or otherwise placed into the stream of commerce their SmartPort vascular access device.

103. The Defendants failed to properly and adequately warn and instruct Plaintiff and her treating physician that SmartPort was designed and/or manufactured in a way that could cause injuries and damages including lasting and permanent injuries. Defendants further failed to inform and further warn Plaintiff and her treating physician with respect to the most effective proper technique and methods of implantation and/or the selection of appropriate candidates to receive SmartPort.

104. The Defendants failed to properly and adequately warn and instruct Plaintiff and her treating physician as to the risks and benefits of the Defendants' SmartPort. To the contrary, Defendants withheld information from Plaintiff and her treating physician regarding the true risks as relates to implantation of their SmartPort.

105. The Defendants failed to properly and adequately warn and instruct Plaintiff and her treating physician that inadequate research and testing of the SmartPort was done prior to

SmartPort being placed on the market and in the stream of commerce and that Defendants lacked a safe, effective procedure for removal of the SmartPort once complications from same arise.

106. The Defendant intentionally, recklessly, and maliciously misrepresented the efficacy, safety, risks, and benefits of SmartPort, understating the risks and exaggerating the benefits in order to advance its own financial interest, with wanton and willful disregard for the rights, safety and health of Plaintiff.

107. The dangerous and defective conditions in the SmartPort existed at the time they were delivered by the manufacturer to the distributor. At the time Plaintiff had her implant surgery, the SmartPort was in the same condition as when manufactured, distributed and sold.

108. Plaintiff did not know at the time of surgery that the SmartPort placed during Plaintiff's surgery or at any time prior thereto, of the existence of the defects or dangerous propensities in the SmartPort.

109. As a direct and proximate result of the Defendants' design, manufacture, marketing, sale, and distribution of the SmartPort, Plaintiff has been injured and sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and economic damages.

110. The Defendants are strictly liable in tort to the Plaintiff for their wrongful conduct in failing to properly warn Plaintiff.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory damages, interest, attorneys' fees, costs of suit, and such further relief as the Court deems equitable and just.

COUNT V: BREACH OF EXPRESS WARRANTY

111. Plaintiff re-alleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein and additionally or in the alternative, if same be necessary, allege as follows:

112. At all relevant and material times, Defendant manufactured, marketed, sold, distributed and otherwise placed into the stream of commerce SmartPort.

113. In advertising, marketing and otherwise promoting SmartPort to physicians, hospitals and other healthcare providers, Defendants' expressly warranted that their SmartPort was safe for use. In advertising, marketing and otherwise promoting SmartPort, Defendant intended that physicians, hospitals and other healthcare providers rely upon their representations in an effort to induce them to use SmartPort for their patients.

114. The Plaintiff was a person whom the defendants could reasonably have expected to use, consume, or be affected by the Defendant' Vascular Access Devices within the meaning of Massachusetts General Laws ch. 106, §2-3l8, as the Defendant specifically designed the SmartPort for implantation in patients requiring repeated vascular access such as Plaintiff.

115. With respect to Plaintiff, Defendant intended that SmartPort be implanted in Plaintiff by her treating surgeon in the reasonable and foreseeable manner in which it was implanted and in accordance with the instructions for use and product specifications provided by Defendants. Plaintiff was in privity with Defendants.

116. Defendants expressly warranted to physicians, hospitals, other healthcare providers and the general public including Plaintiff that SmartPort was safe and fit for use by consumers including Plaintiff, that it was of merchantable quality, that its risks, side effects and potential complications are minimal and are comparable to other Vascular Access Devices, that

it was adequately researched and tested and was fit for its intended use. Plaintiff and her physicians and healthcare providers relied upon these express representations and warranties made by Defendants and consequently, Plaintiff was implanted with Defendants' SmartPort.

117. Defendants breached express representations and warranties made to Plaintiff and her physicians and healthcare providers with respect to the SmartPort implanted in Plaintiff including the following particulars:

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

b) Defendant 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 Defendant fraudulently concealed information that demonstrated that SmartPort was not safer than alternative therapies and products available on the market; and

c) Defendant 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 Defendant fraudulently concealed information, regarding the true efficacy of SmartPort.

119. At the time of making such express warranties, Defendants knew or should have known that Defendants' SmartPort does not conform to the express warranties and Defendants' acts were motivated by financial gain while the adverse consequences of Defendants' conduct was outrageous, fraudulent, oppressive, done with malice or gross negligence and evidenced reckless indifference to Plaintiff's rights, health and safety.

120. As a direct and proximate result of Defendants' breaches of the aforementioned express warranties, Plaintiff was caused and 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, impairment of personal relationships, and other damages.

WHEREFORE, Plaintiff demands judgment against Defendant and requests compensatory damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT VI: BREACH OF IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS OF PURPOSE

121. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein and additionally or in the alternative, if same be necessary, allege as follows:

122. At all relevant and material times, Defendant manufactured, distributed, advertised, promoted, and sold the Defendants' SmartPort.

123. At all relevant times, Defendants intended that its SmartPort be implanted for the purposes and in the manner that Plaintiff's implanting surgeon did in fact implant it in accordance with the instructions for use and product specifications provided by Defendant and Defendant impliedly warranted that their SmartPort was of merchantable quality, safe and fit for its intended use of implantation in Plaintiff and was properly and adequately tested prior to being placed in the stream of commerce.

124. When the SmartPort was distributed into the stream of commerce and sold by Defendant, they were unsafe for their intended use, and not of merchantable quality, as warranted

by Defendant, in that they had very dangerous propensities when used as intended and implanted into a patient's body and, as a result, could cause serious injury of harm or death to the end user.

125. The Plaintiff was a person whom the defendants could reasonably have expected to use, consume, or be affected by the Defendant' Vascular Access Devices within the meaning of Massachusetts General Laws ch. 106, §2-318, as the Defendant specifically designed the SmartPort for implantation in patients requiring repeated vascular access such as Plaintiff.

126. Defendant was aware that consumers such as Plaintiff would be implanted with SmartPort by their treating physicians in accordance with the instructions for use and product specifications provided by Defendant to Plaintiff's physicians. Plaintiff was a foreseeable user of Defendants' SmartPort, and plaintiff was in privity with Defendants.

127. Defendants breached implied warranties with respect to the SmartPort including the following particulars:

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

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

c) Defendants represented to Plaintiff and her physicians and healthcare providers that the Defendants' SmartPort were more efficacious than other alternative procedures and/or devices. Meanwhile Defendant fraudulently concealed information, regarding the true efficacy of SmartPort.

128. In reliance upon Defendants' implied warranty, Plaintiff's implanting surgeon used SmartPort to treat Plaintiff in the foreseeable manner normally intended, recommended, promoted, and marketed by Defendants and in accordance with the instructions for use and product specification provided by Defendants.

129. Defendants breached their implied warranty to Plaintiff in that the Defendants' SmartPort was not of merchantable quality, safe and fit for its intended use nor was it adequately tested prior to being placed in the stream of commerce.

130. Defendants' acts were motivated by financial gain while the adverse consequences of the conduct were actually known by Defendant. Defendants' conduct was outrageous, fraudulent, oppressive, done with malice and with gross negligence, and evidenced reckless disregard and indifference to Plaintiff's rights, health and safety.

131. As a direct and proximate result of Defendants' breach of the aforementioned implied warranties, Plaintiff was caused and 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, impairment of personal relationships, and other damages.

WHEREFORE, Plaintiff demands judgment against Defendant and requests compensatory damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT VII: GROSS NEGLIGENCE AND INTENTIONAL CONDUCT

132. Plaintiff re-alleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein and additionally or in the alternative, if same be necessary, allege as follows:

133. The acts and omissions of Defendant as alleged herein are of a character and nature that is outrageous, fraudulent, oppressive, done with malice and evidenced reckless disregard for Plaintiff's rights, health and safety and constitute gross negligence and/or willful or intentional indifference or conduct.

134. The acts and omissions of Defendant, whether taken singularly or in combination with others, constitute gross negligence or willful and/or intentional conduct that proximately caused injuries to Plaintiff.

WHEREFORE, Plaintiff demands judgment against Defendant and requests compensatory damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT VIII: UNJUST ENRICHMENT

135. Plaintiff re-alleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein and additionally or in the alternative, if same be necessary, allege as follows:

136. Defendant at all times was the manufacturer, seller, and/or supplier of SmartPort.

137. Plaintiff was implanted with Defendants' SmartPort for the purpose of treatment of ovarian cancer, and Defendants were paid for Plaintiffs use of said product.

138. Defendant have accepted payment by Plaintiff and/or by others on Plaintiff's behalf for the purchase of the SmartPort with which Plaintiff was implanted.

139. Plaintiff was not implanted with nor did she receive the medical device that Defendants' represented and warranted to be safe, effective and efficacious and for which Plaintiff paid.

140. Equity demands that Defendant be required to disgorge any and all moneys, profits and/or any other thing of value received by Defendant on account of Plaintiff receiving a product that was substantially different than that which was represented and/or warranted and because of Defendants' conduct, acts and omissions as set out herein.

WHEREFORE, Plaintiff demands judgment against Defendant and requests compensatory damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

VICARIOUS LIABILITY

141. Whenever in this complaint it is alleged that Defendant did or omitted to do any act, it is meant that Defendants' officers, agents, servants, employees, or representatives did or omitted to do such act and that at the time such act or omission was done, it was done with the full authorization or ratification of Defendant or was done in the normal and routine course and scope of employment of Defendants' officers, agents, servants, employees, and representatives.

EQUITABLE TOLLING OF THE APPLICABLE STATUTE OF LIMITATION

142. The running of any statute of limitation has been tolled by reason of the Defendants' fraudulent conduct. Defendant, through its affirmative misrepresentations and omissions, actively concealed from Plaintiff and Plaintiff's treating physicians the true risks associated with SmartPort.

143. As a result of the Defendants' actions, Plaintiff and Plaintiff's treating physicians were unaware, and could not reasonably know or have learned through reasonable diligence that Plaintiff had been exposed to the risks alleged herein and that those risks were the direct and proximate result of Defendants' acts and omissions.

144. Furthermore, Defendants are estopped from relying on any statute of limitations defense because of their fraudulent concealment of the truth regarding the quality and nature of SmartPort. Defendant had a duty to disclose the true character, quality and nature of SmartPort because this was non-public information over which Defendant had and continued to have exclusive control, and because Defendant knew that this information was not available to the Plaintiff, medical providers and/or to health facilities. Defendant is estopped from relying on any statute of limitation because of their intentional concealment of these facts.

145. The Plaintiff had no knowledge that Defendant was engaged in the wrongdoing alleged herein. Because of the fraudulent acts of concealment and wrongdoing by Defendant, Plaintiff could not have reasonably discovered the wrongdoing until less than the applicable limitations period prior to the filing of this action.

PRAYER FOR RELIEF

Plaintiff demands judgment against Defendant and prays for the following relief in accordance with applicable law and equity:

i. Compensatory damages to Plaintiff for past, present, and future damages, including, but not limited to, pain and suffering for severe and permanent personal injuries sustained by Plaintiff, permanent impairment, mental pain and suffering, loss of enjoyment of life, past and future health and medical care costs and economic damages including past and future lost earnings and/or earning capacity together with interest and costs as provided by law;

ii. Reasonable attorneys' fees as provided by law;

iii. The costs of these proceedings, including past a future cost of the suit incurred herein;

iv. Prejudgment interest on all damages as is allowed by law;

v. Such other and further relief as this Court deems just and proper.

JURY TRIAL DEMANDED

Plaintiff hereby demands a trial by jury on all issues so triable.

Respectfully submitted,

NICOLE PETTIT,

Plaintiff,

By counsel:

/s/ Jason P. Foster
Jason P. Foster (WV Bar I.D. #10593)
THE SEGAL LAW FIRM
A Legal Corporation
810 Kanawha Boulevard, East
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Troy A. Brenes (CA Bar No. 249776) (*pro hac vice* admission pending)
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tbrenes@breneslawgroup.com

Counsel for Plaintiff

Exhibit E

MAG o

U.S. District C urt
SOUTHERN DISTRICT OF TEXAS (McAllen)
CIVIL DOCKET FOR CASE #: 7:23-cv-00384

Hernandez-Ayala
Assigned to: Judge Drew B Tipton o
Cause: 28:1332 Diversity-Personal Injury o

Date Filed: 11/02/2023 o
Jury Demand: Plaintiff
Nature of Suit: 245 Tort Product Liability
Jurisdiction: Diversity

Plaintiff

N elia Hernandez-Ayala o

represented by **Adam M Evans**
Dickerson Oxton, LLC
1200 Main St
Suite 2120
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816-268-1960
Email: aevans@dickersonoxton.com
LEAD ATTORNEY
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512-337-8430
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ATTORNEY TO BE NOTICED

V. o

Defendant

Angi Dynamics, Inc. o

represented by **Ge rge G stin R berts n**
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ATTORNEY TO BE NOTICED

Defendant

Navilyst Medical, Inc. @ represented by **George Gostin Robertson**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Thomas J Yoo
(See above for address)
LEAD ATTORNEY
PRO HAC VICE
ATTORNEY TO BE NOTICED

Amy McVeigh
(See above for address)
PRO HAC VICE
ATTORNEY TO BE NOTICED @

Date Filed	#	Docket Text
11/ 2/2 23	1	COMPLAINT against Noe ia Hernandez-Aya a (Fi ing fee $ 4 2 receipt number ATXSD -3 756881) fi ed by Noe ia Hernandez-Aya a.(Bar ow A ex) (Entered: 11/ 2/2 23)
11/ 6/2 23 @	2	MOTION to Appear Pro Hac Vice for Adam M. Evans (Fee Paid: $1 @receipt number@ ATXSD -3 767 13) by Noe ia Hernandez-Aya a fi ed. Motion Docket Date 11/27/2 23. (Evans Adam) (Entered: 11/ 6/2 23)
11/ 7/2 23 @	3	ORDER granting 2 Motion for Adam M. Evans to Appear Pro Hac Vice **Note: Instructions to request Texas Southern CM/ECF registration through PACER are found here**.(Signed by Judge Drew B Tipton) Parties notified.(JenniferNogueira 7) (Entered: 11/ 7/2 23)
11/13/2 23 @	4	ORDER for Initia Pretria and Schedu ing onference and Order to Disc ose Interested Persons. Initia onference set for 1/1 /2 24 at 3:5 PM by video before Judge Drew B Tipton. Zoom Link: https://www.zoomgov.com/j/161 6 763? pwd=Y1ZydDU3TWxIUDN a FrSjVxN1FvUT @Meeting ID: 161 6 763 Passcode: 3 7 5 Dia by your ocation +1 66 254 5252 US (San Jose) +1 646 828 7666 US (New @

		York) +5 5 5 59 (Mexico) Per L.R. .7 Except b le ve o the presidin jud e no a photo- or electro-mech nic l me ans o record tion or tr nsmission o courta proceedin s is permitted. (Signed by Judge Drew B Tipton) P rties notified.(KellieP p io nnou,) (Entered: / / 0)
/ 4/ 0 a	5	WAIVER OF SERVICE Returned Executed s to AngioDyn mics, Inc. served on / / 0 , nswer due / / 0 4; N vilyst Medic l, Inc. served on / / 0 , nswer due / / 0 4, filed. (Att chments: # _ Executed Notice of L wsuit nd Request for W iver of a Service - AngioDyn mics Inc.)(Ev ns, Ad m) (Entered: / 4/ 0)
/ 0/ 0	_	NOTICE of Appe r nce by George G. Robertson on beh lf of AngioDyn mics, Inc., N vilyst Medic l, Inc., filed. (Robertson, George) (Entered: / 0/ 0)
/ 0/ a0	7 a	CERTIFICATE OF INTERESTED PARTIES by Noeli Hern ndez-Ay a , filed.(Ev ns, a Ad m) (Entered: / 0/ 0)
/ / 0	_	CORPORATE DISCLOSURE STATEMENT by AngioDynamics, Inc., filed.(Robertson, George) (Entered: / / 0)
/ / 0	9	CORPORATE DISCLOSURE STATEMENT by N vilyst Medic l, Inc., filed.(Robertson, George) (Entered: / / 0)
/ 7/ 0	0	REPORT of Rule a(f) Pl nning Meeting by Noeli Hern ndez-Ay l , filed. (Att chments: # _ Proposed Order)(Ev ns, Ad m) (Entered: / 7/ 0)
0 a0 a 0 4	__	MOTION to Dismiss by AngioDyn mics, Inc., N vilyst Medic l, Inc., filed. Motion Docket D te / 9/ 0 4. (Att chments: # _ Proposed Order)(Robertson, George) (Entered: 0 /0 / 0 4)
0 /09/ 0 4 a	__	MOTION to Appe r Pro H c Vice for Thom s J. Yoo (Fee P id: $ 00, receipt number ATXSDC- 0) by AngioDynamics, Inc., N vilyst Medic l, Inc., filed. Motion Docket D te / 0/ 0 4. (Robertson, George) (Entered: 0 /09/ 0 4)
0 /09/ 0 4 a	__	MOTION to Appe r Pro H c Vice for Amy McVeigh (Fee P id: $ 00, receipt number ATXSDC- 0) by AngioDynamics, Inc., N vilyst Medic l, Inc., filed. Motion Docket D te / 0/ 0 4. (Robertson, George) (Entered: 0 /09/ 0 4)
0 / 0/ 0 4 a	4	NOTICE of Resetting. P rties notified. Initi l Conference reset for / 7/ 0 4 t 0 :00 PM by video before Judge Drew B Tipton, filed. Zoom Link: https://www.zoomgov.com/j/ a 0 907 ? a pwd=Y ZydDU TWxIUDNl 0FrSjVxN FvUT09 Meeting ID: 0 9 07 P sscode: 07095 Di l by your loc tion + 9 54 5 5 US (S n Jose) + 4 7 US (New York) +5 5 5 59 (Mexico) Per L.R. .7 Except by le ve of the presiding judge, no photo- or electro-mech nic l me ns of record tion or tr nsmission of court proceedings is permitted. (KellieP p io nnou,) (Entered: 0 / 0/ 0 4)
0 / 0/ 0 4 a	5	ORDER gr anting a Motion for Thom s J. Yoo to Appe r Pro H c Vice **Note: Instructions to request Texas Southern CM/ECF registration through PACER are found here**.(Signed by Judge Drew B Tipton) P rties notified.(JenniferNogueir , 7) (Entered: 0 / / 0 4)
0 / 0/ 0 4 a	__	ORDER gr nting __ Motion for Amy McVeigh to Appe r Pro H c Vice **Note: Instructions to request Texas Southern CM/ECF registration through PACER are found here**.(Signed by Judge Drew B Tipton) P rties notified.(JenniferNogueir , 7) (Entered: 0 / / 0 4)
0 / 7/ 0 4 a		Minute Entry for proceedings held before Judge Drew B Tipton. SCHEDULING CONFERENCE held on / 7/ 0 4. St tus of c se nd de dlines discussed. Scheduling Order to be issued. Appe r nces: George Gostin Robertson, Thom s J Yoo, Alex B rlow.

		(Digital - 17)(ERO Nelda Garcia), filed.(elliePa aioa ou,) (E tered 1/17/ 4)
1/17/ 4	17	SCHEDULING ORDER. Amended Pleadings due by 1/ 1/ 4. Joinder of Parties due by 1/ 1/ 4. Pltf Ex ert Re ort due by 11/15/ 4. Deft Ex ert Re ort due by /15/ 4. Discovery due by 5/1 / p 5. Dis ositive Motion Filing due by 8/ 5/ p 5. Non-Dis ositive Motion Filing due by 8/ 5/ p 5. Joint Pretrial Order due by /5/ p 6. Docket Call set for /19/ p 6 at p PM before Judge Drew B Ti ton.(Signed by Judge Drew B Ti ton) Parties notified.(JenniferNogueira, 7) (Entered 1/17/ p 4)
1/18/ 4		***Reset Deadlines Deft Ex ert Re ort due by /15/ p 5. (KelliePa aioannou,) (Entered 1/18/ p 4)
1/18/ p 4	18	CERTIFICATE of service *INITIAL RULE 26 DISCLOSURES* by Noelia Hernandez-Ayala, filed.(Evans, Adam) (Entered 1/18/ p 4)
1/ 9/ 4	19	First AMENDED COMPLAINT with Jury Demand against All Defendants filed by Noelia Hernandez-Ayala.(Evans, Adam) (Entered 1/ 9/ 4)
1/ 9/ 4	__	First AMENDED COMPLAINT with Jury Demand against All Defendants filed by Noelia Hernandez-Ayala.(Evans, Adam) (Entered 1/ 9/ p 4)
/1 / p 4	1	MOTION to Dismiss *Plaintiff's First Amended Complaint* by AngioDynamics, Inc., Navilyst Medical, Inc., filed. Motion Docket Date /4/ p 4. (Robertson, George) (Entered /1 / p 4)
/ 4/ p 4 p	__	Uno osed MOTION for Extension of Time To Res ond to Defendants' Motion to Dismiss Plaintiff's First Amended Com laint by Noelia Hernandez-Ayala, filed. Motion Docket Date / 5/ p 4. (Attachments 1 Pro osed Order)(Evans, Adam) (Entered / 4/ p 4)
/ 4/ p 4 p	__	ORDER granting __ Uno osed MOTION for Extension of Time To Res ond to Defendants' Motion to Dismiss Plaintiff's First Amended Com laint. Res onse due by /11/ p 4.(Signed by Judge Drew B Ti ton) Parties notified.(KelliePa aioannou,) (Entered / 4/ p 4)
/11/ 4	4	RESPONSE in O osition to 1 MOTION to Dismiss *Plaintiff's First Amended Complaint*, filed by Noelia Hernandez-Ayala. (Evans, Adam) (Entered /11/ p 4)
/18/ p 4 p	5	REPLY in Su ort of 1 MOTION to Dismiss *Plaintiff's First Amended Complaint*, filed by AngioDynamics, Inc., Navilyst Medical, Inc.. (Robertson, George) (Entered /18/ p 4)

PACER Service Center p			
Transaction Receipt			
7/16/ 4 11 5 5			
PACER Login:	dickersonoxton	**Client Code:**	Angiodynamics p
Description:	Docket Re ort	**Search Criteria:**	7 -cv- 84
Billable Pages:	4	**Cost:** 0	.4

UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS MCALLEN DIVISION

NOELIA HERNANDEZ-AYALA, Plaintiff, vs. ANGIODYNAMICS, INC., & NAVILYST MEDICAL, INC., Defendants.	Case No.: 7:23-cv-00384 **COMPLAINT FOR DAMAGES** **DEMAND FOR JURY TRIAL**

COMES NOW the Plaintiff, Noelia Hernandez-Ayala, (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 Vortex TR Injectable Port (hereinafter "Vortex" or "Defective Device").

PARTIES

2. Plaintiff, Noelia Hernandez-Ayala is an adult resident and citizen of Hidalgo County, Texas, 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 Vortex.

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 Texas, 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 Vortex.

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. Specific personal jurisdiction exists, and venue is proper in this Court pursuant to 28 U.S.C. §1391 by virtue of the facts that a substantial part of the events or omissions giving rise to the claims occurred in this District.

PRODUCT BACKGROUND

9. In or about 2003, a company called Horizon Medical Products ("Horizon") obtained clearance for the Triumph VTX Port with LiveValve Catheter under the 510(k) number K032557.

10. Shortly after the clearance of the Triumph port, Horizon merged with Rita Medical Systems, which was in the process of being acquired by Angiodynamics.

11. The Vortex port system bears a design and specifications that differ significantly from the Triumph port (including but not limited to the catheter design and connection hub), but

Defendants represented to regulatory authorities that the Vortex port was cleared under the K032557.

12. Neither Horizon Medical Products nor Angiodynamics received clearance from the FDA to market the Vortex TR catheter, making such device *per se* misbranded pursuant to the Food, Drug and Cosmetic Act.

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

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

15. According to Defendants, the Vortex 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.

16. The intended purpose of the Vortex 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.

17. The Vortex is a system consisting of two primary components: an injection port and a silicone catheter which includes additives intended to make it radiopaque.

18. 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.

19. The Vortex 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.

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

21. 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.

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

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 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 included weakened areas at the loci of higher barium sulfate concentration and led to fracture of the catheter.

26. 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

[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

encapsulating the admixed polymer within an outer layer of pristine polymer), Defendants elected not to incorporate those design elements into the Vortex.

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

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

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

30. Soon after the Vortex 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 Vortex was fracturing post-implantation and that fractured pieces were migrating throughout the human body, including to the heart and lungs. Defendants also received large numbers of AERs reporting that the Vortex was found to have perforated internal vasculature. These failures were often associated with reports of severe

patient injuries such as:

a. hemorrhage;

b. fracture and migration;

c. cardiac/pericardial tamponade;

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

e. severe and persistent pain;

f. perforations of tissue, vessels and organs; and

g. upon information and belief, even death.

31. 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.

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

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

34. Defendants were aware or should have been aware that the Vortex had a

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

substantially higher failure rate than other similar products on the market, yet Defendants failed to warn consumers of this fact.

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

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

37. Moreover, Defendants' warnings suggested that fracture of the device could only occur if the physician incorrectly placed the device such that undue catheter compression or "pinch-off" was allowed to occur. In reality, Defendants knew internally these devices were fracturing and causing serious injuries due to defects in the design, manufacturing and lack of adequate warnings.

38. 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 and evidences malice, fraud, gross negligence, and oppressiveness. Defendants had actual knowledge of the dangers presented by the Vortex System, yet consciously failed to act reasonably to:

a. Adequately inform or warn Plaintiff, her

b. prescribing physicians, or the public at large of these dangers;

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

d. Recall the Vortex System from the market.

SPECIFIC FACTUAL ALLEGATIONS AS TO NOELIA HERNANDEZ-AYALA

39. On or about January 2, 2019, Plaintiff underwent placement of the AngioDynamics Vortex product, reference number SSAX-16-1, lot number 5174381. The device was implanted by Dr. Rodolfo Guerrero, M.D., at Knapp Medical Center in Weslaco, Texas, for the purpose of ongoing chemotherapy.

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

41. Defendant manufactured, sold, and/or distributed the Vortex to Plaintiff, through her doctors, to be used for delivery of chemotherapy.

42. On or about November 3, 2021, Plaintiff underwent imaging, which demonstrated a catheter fracture. The fragment was positioned in the base of Plaintiff's right atrium and right ventricle.

43. On or about November 8, 2021, Plaintiff presented herself to Knapp Medical Center in Weslaco, TX for fragment retrieval. After multiple attempts, Plaintiff's medical team were unable to retrieve the catheter fragment.

44. On or about November 22, 2021, Plaintiff underwent a second surgery to remove the catheter fragment from her right atrium and right ventricle. After multiple attempts, Plaintiff's medical team were once again unable to retrieve the fragment. Plaintiff was referred to an interventional cardiologist for further assessment and treatment.

45. On or about December 23, 2021, Plaintiff presented herself to Rio Grande Regional Hospital in McAllen, TX for fragment retrieval. After multiple attempts, Plaintiff's medical team were unable to retrieve the catheter fragment.

46. On or about January 5, 2022, Plaintiff returned to Rio Grande Regional for a follow-up appointment, where her medical team determined that the risks of further attempts to remove the catheter fragment were too high; the catheter fragment remains inside of Plaintiff.

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

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

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

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

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

52. In reliance on Defendants' representations, Plaintiff's doctor was induced to and did use the Vortex.

53. As a result of having the Vortex implanted, Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury, permanent and substantial physical deformity, has undergone corrective surgeries, and has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses.

54. Defendants' Vortex 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.

55. The Defendants have marketed and sold the Defendants' Vortex 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.

56. The injuries, conditions, and complications suffered due to Defendants' Vortex include but are not limited to hemorrhage; fracture and migration; 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.

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

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

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

58. The Vortex was utilized and implanted in a manner foreseeable to Defendants.

59. The Vortex 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.

60. At the time of her operation, Plaintiff was not informed of, and had no knowledge of the complaints, known complications, and risks associated with Vortex, including but not limited to its propensity to fracture or break and cause pieces of the product to migrate to other major organs such as the heart.

61. Plaintiff was never informed by Defendants of the defective and dangerous nature of Vortex.

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

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

64. Plaintiff has also incurred substantial medical bills due to the defective product that was implanted in her body.

FIRST CAUSE OF ACTION

NEGLIGENCE

(Against Defendants AngioDynamics and Navilyst)

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

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

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

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

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

d. Designing, manufacturing, marketing, advertising, distributing, and selling the Vortex to consumers, including Plaintiff, without an adequate warning of the significant and dangerous risks of the Vortex, including but not limited to, its propensity to fracture and migrate, and without proper instructions to avoid the harm which could foreseeably occur as a result of using the device;

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

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

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

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

SECOND CAUSE OF ACTION

STRICT PRODUCTS LIABILITY – FAILURE TO WARN

(Against Defendants AngioDynamics and Navilyst)

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

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

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

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

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

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

76. The warnings, labels, and instructions provided by the Defendants at all time

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.

77. 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.

78. The Vortex, 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.

79. 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.

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

81. 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.

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

83. Upon information and belief, the defective and dangerous condition of the device, including the one implanted into Plaintiff, existed at the time they were manufactured, prepared,

compounded, assembled, processed, marketed, labeled, distributed, and sold by Defendants to distributors and/or healthcare professionals or organizations. Upon information and belief, the device implanted in Plaintiff was in the same condition as when it was manufactured, inspected, marketed, labeled, promoted, distributed and sold by Defendants.

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

THIRD CAUSE OF ACTION

STRICT PRODUCTS LIABILITY – DESIGN DEFECT

(Against Defendants AngioDynamics and Navilyst)

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

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

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

88. The Vortex was unreasonably dangerous to the user or consumer.

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

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

91. As a direct and proximate result of the Vortex's aforementioned defects, the Plaintiff was caused and/or in the future will be caused to suffer severe personal injuries, pain and suffering, severe emotional distress, financial or economic loss, including, but not limited to,

obligations for medical services and expenses, and other damages.

FOURTH CAUSE OF ACTION

BREACH OF IMPLIED WARRANTY

(Against Defendants AngioDynamics and Navilyst)

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

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

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

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

96. 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.

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

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

c. These defects led to a heterogenous modified polymer that included microfractures and weakened areas at the location of the higher barium sulfate concentration that ultimately led to fractures of the Vortex and migration of catheter fragments.

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

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

100. 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. These damages have occurred in the past and will continue into the future.

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

FIFTH CAUSE OF ACTION

BREACH OF EXPRESS WARRANTY

(Against Defendants AngioDynamics and Navilyst)

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

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

104. The Vortex 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.

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

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

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

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

109. 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.

110. 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 Vortex, within a reasonable period of time following discovery of the breach of warranty and

before suit was filed.

SIXTH CAUSE OF ACTION

FRAUDULENT CONCEALMENT

(Against Defendants AngioDynamics and Navilyst)

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

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

113. Defendants engaged in and fraudulently concealed information with respect to the Vortex in the following particulars:

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

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

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

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

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

115. Defendants had sole access to material facts concerning the dangers and unreasonable risks of the Vortex.

116. The concealment of information by the Defendants about the risks of the Vortex was intentional.

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

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

119. 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.

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

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

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

SEVENTH CAUSE OF ACTION

DECEPTIVE TRADE PRACTICES AND CONSUMER PROTECTION ACT

(Against Defendants AngioDynamics and Navilyst)

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

124. The acts and practices engaged in by Defendants constitute unlawful, unfair, deceptive, and/or fraudulent business or trade practices in violation of the Deceptive Trade Practices-Consumer Protection Act, Tex. Bus. & Com. Code Ann. § 17.41, *et seq.* (the "DTPA").

125. Defendants engaged in in unlawful practices, including deception, false promises, misrepresentation, and/or concealment, suppression, or omission of material facts in connection with the sale, distribution, and/or advertisement of the Vortex in violation of the DTPA.

126. Defendants further engaged in unfair, unconscionable, deceptive, deliberately misleading, false, and/or deceptive acts and practices, all in violation of the DTPA, and as further described herein, including, but not limited to, misrepresenting that the Vortex was reasonably safe for use and failing to adequately disclose the substantial risk of fracture, migration and harm the product entailed given the large number of adverse events Defendants knew or should have been aware of but did not adequately disclose to Plaintiff.

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

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

129. As a result of Defendants' conduct, Plaintiff suffered actual damages in that the

product she purchased was misrepresented and worth far less than the product she thought she had purchased, had Defendants' representations been true.

PUNITIVE DAMAGES

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

131. Defendants had knowledge of, and were in possession of evidence demonstrating that, the Vortex caused serious physical side effects. Defendants continued to market said product by providing false and misleading information with regard to the product's safety and efficacy to the regulatory agencies, the medical community, and consumers of the device, notwithstanding Defendants' knowledge of the true serious side effects of the Vortex, Defendants failed to provide accurate information and warnings to the healthcare community that would have dissuaded physicians from surgically implanting the Vortex and consumers from agreeing to being implanted

with the Vortex, thus depriving physicians and consumers from weighing the true risks against the benefits of prescribing and implanting the Vortex.

132. As a direct, proximate, and legal result of Defendants' acts and omissions as described herein, and Plaintiff's implantation with Defendants' defective product, Plaintiff suffered, and will continue to suffer, the injuries and damages described herein.

WHEREFORE, Plaintiffs 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 just and proper.

PRAYER

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

a. Judgment be entered against all Defendant on all causes of action of this Complaint;

b. Plaintiff be awarded her full, fair, and complete recovery for all claims and causes of action relevant to this action;

c. Plaintiff be awarded general damages according to proof at the time of trial;

d. Plaintiff be awarded damages, including past, present, and future, medical expenses according to proof at the time of trial;

e. Plaintiff be awarded damages and attorney fees in connection with Plaintiff's claims under Deceptive Trade Practices-Consumer Protection Act, Tex. Bus. & Com. Code Ann. § 17.41, *et seq.* (the "DTPA");

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

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

h. Awarding the costs and the expenses of this litigation to the Plaintiff.

i. 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/ Alex Barlow

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