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15 **UNITED STATES DISTRICT COURT**
16 **CENTRAL DISTRICT OF CALIFORNIA**

17 JACQUILINE HIATT,

18 Plaintiff,

19 vs.

20 ICU MEDICAL, INC., successor in
21 interest by merger to SMITHS
22 MEDICAL ASD, INC.,

23 Defendant.
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27
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Case No.

**COMPLAINT FOR DAMAGES
ACTION**

DEMAND FOR JURY TRIAL

1 COMES NOW the Plaintiff, Jacqueline Hiatt, (hereinafter “Plaintiff”), by and
2 through her undersigned counsel, and brings this Complaint against ICU MEDICAL,
3 INC., successor in interest by merger to SMITHS MEDICAL ASD, INC.
4 (“Defendant”), and alleges as follows:

5 1. This is an action for damages arising out of failures relating to Defendant’s
6 design, development, testing, assembling, manufacturing, packaging, promoting,
7 marketing, distribution, supplying, and/or selling the defective implantable vascular
8 access device sold under the trade name of Port-A-Cath II Power P.A.C. (hereinafter
9 “Power P.A.C.” or “Defective Device”).

10 **PARTIES**

11 2. At all times material, Plaintiff, Jacqueline Hiatt is an adult resident and
12 citizen of Hamilton County, Indiana, and claims damages as set forth below.

13 3. Defendant ICU Medical, Inc. (“ICU Medical”) is a Delaware corporation
14 with its principal place of business located in San Clemente, California. ICU Medical
15 is engaged in the business of researching, developing, designing, licensing,
16 manufacturing, distributing, supplying, selling, marketing, and introducing into
17 interstate commerce, either directly or indirectly through third parties or related
18 entities, its medical devices, including the Power P.A.C.

19 4. Defendant ICU Medical, Inc. (“ICU Medical”) is a Delaware corporation
20 that, based upon public filings made by Defendant, merged with and became a legal
21 successor in interest to Smiths Medical ASD, Inc. (“Smiths Medical”) on July 24, 2024.
22 The merger occurred after the implantation and removal of the defective port that is the
23 subject of Plaintiff’s claim. Smiths Medical conducted business throughout the United
24 States, including the State of California, and is a wholly owned subsidiary of ICU
25 Medical. Smiths Medical is engaged in the business of researching, developing,
26 designing, licensing, manufacturing, distributing, supplying, selling, marketing, and
27 introducing into interstate commerce, either directly or indirectly through third parties
28 or related entities, its medical devices, including the Power P.A.C.

1 5. Upon representation by the Defendant and upon information and belief,
2 Smiths Medical's assets and liabilities were assumed by ICU Medical as part of the
3 merger, which occurred after Plaintiff's implant and explant, and ICU Medical is
4 therefore the successor in interest responsible for Smiths Medical's liabilities relating
5 to the device at issue.

6 **JURISDICTION AND VENUE**

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

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

16 8. Defendant has and continues to conduct substantial business in the State
17 of California and in this District, distribute vascular access products in this District,
18 receive substantial compensation and profits from sales of vascular access products in
19 this District, and made material omissions and misrepresentations and breaches of
20 warranties in this District, so as to subject them to *in personam* jurisdiction in this
21 District.

22 9. Consistent with the Due Process Clause of the Fifth and Fourteenth
23 Amendments, this Court has *in personam* jurisdiction over Defendant because
24 Defendant is present in the State of California, such that requiring an appearance does
25 not offend traditional notices of fair and substantial justice.

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PRODUCT BACKGROUND

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

11. The Power P.A.C. is one of several varieties of implanted port catheters (IPCs) that has been designed, manufactured, marketed, and sold by Defendant.

12. According to Defendant, the Power P.A.C. 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.

13. The intended purpose of the Power P.A.C. 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.

14. The Power P.A.C. is a system consisting of two primary components: an injection port and catheter which includes additives intended to make it radiopaque.

15. 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.

16. The Power P.A.C. 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.

17. The product's catheter is comprised of a polymer and a barium sulfate radiopacity agent.

18. Barium sulfate is known to contribute to reduction of the mechanical integrity of polymers *in vivo* as the particles of barium sulfate dissociate from the

1 surface of the catheter over time, leaving microfractures and other alterations of the
2 polymeric structure and degrading the mechanical properties of the polyurethane.

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

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

11 21. This defect in the manufacturing process led to a heterogeneous modified
12 polymer which led to an irregular catheter surface replete with fissure, pits and cracks
13 as well as sections of the catheter lumen which contain more than 30% barium sulfate
14 by weight, reducing the catheter strength at those loci.

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

18 23. The relationship between catheter surface irregularities, polymer
19 degradation, and microbial biofilm formation is well recognized in the medical and
20 scientific literature concerning vascular access devices. Published research has
21 demonstrated that increased catheter surface roughness and polymer degradation
22 significantly increase bacterial adhesion, thrombus formation, and biofilm
23 development on intravascular devices. These biofilms serve as a reservoir for persistent
24 infection and are a well-recognized cause of catheter-related bloodstream infections
25 ("CRBSIs") and other port-related infections.

26 24. Although the surface degradation and resultant mechanical failure can be
27 reduced or avoided with design modifications (e.g., using a higher grade radiopacity
28 compound and/or encapsulating the admixed polymer within polyurethane), Defendant

1 elected not to incorporate those design elements into the Power P.A.C.

2 25. Among the most common and concerning complications associated with
3 IPCs, such as the Power P.A.C. system, are IPC-related infections.

4 26. There are several types of IPC-related infections. The most common and
5 severe are CRBSIs, or CLABSIs, which occur when microorganisms, typically bacteria
6 or fungi, colonize the surface of the catheter and enter the bloodstream.¹

7 27. IPC pocket infections refer to an infection localized in the subcutaneous
8 pocket where the port is implanted. These types of infections most often occur within
9 a few days of implantation.² If clinical signs appear in the IPC pocket after that time-
10 frame, then it is most commonly related to a CRBSI.³

11 28. The least common IPC-related infections are tunnel infections which
12 occur when an infection occurs along the subcutaneous tunnel created for the
13 placement of the central venous catheter.⁴

14 29. IPC-related infections occur through a multi-step process that begins with
15 device conditioning followed by microbial contamination, microbial adherence and
16 biofilm formation, and ultimately progresses to localized infection and/or bloodstream
17 infection. Biofilm formation on IPCs is particularly problematic because of the
18 frequent use and long-term placement of these devices. Microbial contamination,
19 colonization, and biofilm formation on catheter surfaces can begin as early as 24 hrs.
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23 ¹ Teichgräber, UKM., Gebauer, B., Saleh, A. Outcome analysis in 3,160 implantations of
24 radiologically guided placements of totally implantable central venous port systems. *European*
Radiology. 2011;21(6):1224–1232.

25 ² Machat, S., et al. Complications of central venous port systems: a pictorial review. *Insights into*
imaging. 2019; 10(1):86; Gominet, M., et al. Central Venous Catheters & Biofilms: Where Do We
26 Stand in 2017? *APMS* 125:365-375 (2017).

27 ³ Baang JH, Inagaki K, Nagel J, et al. Inpatient Diagnosis and Treatment of Catheter-Related
28 Bloodstream Infection [Internet]. Ann Arbor (MI): Michigan Medicine University of Michigan; 2023
Jan.

⁴ Machat, S., et al. Complications of central venous port systems: a pictorial review. *Insights into*
imaging. 2019; 10(1):86; Gominet, M., et al. Central Venous Catheters & Biofilms: Where Do We
Stand in 2017? *APMS* 125:365-375 (2017).

1 after insertion.⁵

2 30. Vascular access device (VAD), like Defendant's IPC, infections are
3 closely linked to the development of biofilms on the surface of the foreign body.⁶
4 Approximately 60% of hospital acquired infections (HAIs) worldwide are believed to
5 be caused by micro-organisms forming biofilms on medical devices.⁷

6 31. Once the biofilm is established, it serves as a reservoir for persistent
7 infection. Biofilms are notoriously difficult to eradicate due to their resistance to both
8 the host's immune system and antimicrobial therapy.⁸ In most instances, antimicrobial
9 therapy is not sufficient to treat these infections, as antimicrobials will not
10 remove/eliminate the biofilms and their embedded micro-organisms and thus device
11 removal is required.⁹

12 32. Although not an absolute requirement for microbial adhesion, the initial
13 adhesion of proteins to the surface of a foreign body (also called conditioning) and
14 thrombosis promotes biofilm formation. Immediately after insertion, a conditioning
15 film composed of organic macromolecules from body fluids, such as fibrinogen,
16 fibronectin, vitronectin, thrombospondin, glucose, and pyruvate, coats the catheter
17 surface.¹⁰ This is a natural response to a foreign body; however, this film unfortunately
18 provides an ideal environment for microbial attachment.¹¹

19
20 ⁵ Donlan, R. M. Biofilms and device-associated infections. *Emerging infectious diseases*. Centers for
21 Disease Control and Prevention, 2002;7(2), p. 277; Gominet, M., et al. Central Venous Catheters &
22 Biofilms: Where Do We Stand in 2017? *APMS* 125:365-375 (2017).

⁶ Bustos, M. D., et al. Long-term Catheterization: current approaches in the diagnosis and treatment
23 of port-related infections. *Infection and Drug Resistance* 2014;7 25-35.

⁷ Treter, J., Macedo, a J. Catheters: a suitable surface for biofilm formation. *Science against microbial
24 pathogens: communicating current research and technological advances; Formatex* 2011:835-842.

⁸ Gominet et al. (2017); Bustos et al. (2014)

⁹ Kojic, EM and Darouiche, RO. Candida Infections of Medical Devices. *Clin. Microbiol. Rev.* 2004;
25 17 (2):255-267.; Mack, D., et al. Biofilm formation in medical device-related infection. *Int. J. Artif.
26 Organs.* 2006; 29 (4):343-59.

¹⁰ Fletcher, S. Catheter-related bloodstream infection, *Continuing Education in Anaesthesia Critical
27 Care & Pain*, 2005;5(2), pp. 49-51; Gominet, M., et al. Central Venous Catheters & Biofilms: Where
28 Do We Stand in 2017? *APMS* 125:365-375 (2017).

¹¹ Gominet, M., et al. Central Venous Catheters & Biofilms: Where Do We Stand in 2017? *APMS*
125:365-375 (2017); Nycz, A., et al. Surface Analysis of Long-Term Hemodialysis Catheters Made
of Carbothane (Poly(carbonate)urethane) Before and After Implantation in Patients' Bodies. *Act of
Bioengineering & BioMechanics.* 2018; 20(2).

33. This protein adhesion facilitates microbial adhesion in multiple ways. Protein adhesion creates more surface area for bacteria adhesion.¹² Protein adhesion allows bacteria to adhere to more diverse surfaces.¹³ Proteins within the thrombus can attract microbial species.¹⁴ Protein adhesion increases the risk of both biofilm formation and thrombosis, which are closely interconnected and create a reinforcing cycle.¹⁵

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

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

a. Surface roughness promotes biofilm formation and increases the risk of infection.

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

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

¹² Palmer, J, Flint, S and Brooks, J. Bacterial cell attachment, the beginning of a biofilm. Journal of Industrial Microbiology and Biotechnology. 2007; 34(9):577–588.

¹³ Li, Q., et al. Zwitterionic Biomaterials. Chemical Reviews. 2022; 122(23):17073–17154.

¹⁴ Mohammad, SF. Enhanced risk of infection with device-associated thrombi. ASAIO journal. 2000; 46(6):S63–S68; Mehall, JR., et al. Fibrin sheath enhances central venous catheter infection. Critical care medicine. 2002; 30(4):908–912; Neoh, KG., et al. Surface modification strategies for combating catheter-related complications: recent advances and challenges. Journal of Materials Chemistry B. 2017; 5(11):2045–2067.

¹⁵ Galloway, S. et al., Long-term central venous access, 92 British Journal of Anaesthesia 722 (2004); Fletcher, S. Catheter-related bloodstream infection, Continuing Education in Anaesthesia Critical Care & Pain, 2005;5(2), pp. 49–51; van Rooden, CJ., Schippers, EF., et al. Infectious complications of central venous catheters increase the risk of catheter-related thrombosis in hematology patients: a prospective study. Journal of Clinical Oncology. American Society of Clinical Oncology; 2005;23(12):2655–2660; Smith, RS., Zhang, Z., Bouchard, M., et al. Vascular catheters with a nonleaching poly-sulfobetaine surface modification reduce thrombus formation and microbial attachment. Science Translational Medicine. 2012;4(153); Busch JD, Vens M, Mahler C, Herrmann J, Adam G, Ittrich H. Complication Rates Observed in Silicone and Polyurethane Catheters of Totally Implanted Central Venous Access Devices Implanted in the Upper Arm. J Vasc Interv Radiol. 2017 Aug;28(8):1177-1183; Neoh, KG., et al. Surface modification strategies for combating catheter-related complications: recent advances and challenges. Journal of Materials Chemistry B. 2017; 5(11):2045–2067.

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

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

a. Antimicrobial catheters prevent and/or reduce the risk of CRBSI by preventing or reducing bacterial colonization and biofilm formation on catheter surfaces through traditional bactericidal (lethal) or bacteriostatic (inhibitory) mechanisms.¹⁶

b. Catheters with non-fouling coatings and substrates reduce risk of CRBSI by inhibiting its triggers—protein adsorption, bacterial adhesion, and biofilm formation on catheter surfaces.¹⁷

c. Catheters that incorporate both non-fouling coatings or additives (preventing protein adsorption and bacterial adhesion) *and* antimicrobial agents (killing bacteria) reduce the risk of CRBSI.¹⁸

37. Defendant's IPCs design, such as the Power P.A.C., increase the risk of infection.

a. Defendant's IPCs have rough and variable surfaces.

b. Defendant's uncoated IPCs permit rather than inhibit microbial

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

¹⁷ Li, Q., et al. Zwitterionic Biomaterials. Chemical Reviews. 2022; 122(23):17073–17154; Zhang, Z., et al. Blood compatibility of surfaces with superlow protein adsorption. Biomaterials. 2008;29(32):4285–4291.

¹⁸ Zander, Becker. Antimicrobial and Antifouling Strategies for Polymeric Medical Devices. ACS Macro Letters. 2018;7(1):16-25; Li, Q., et al. Zwitterionic Biomaterials. Chemical Reviews. 2022; 122(23):17073–17154; Neoh, KG., et al. Surface modification strategies for combating catheter-related complications: recent advances and challenges. Journal of Materials Chemistry B. 2017; 5(11):2045–2067; Singha, P., Locklin, J., Handa, H. Multipronged Approach to Combat Catheter-Associated Infections and Thrombosis by Combining Nitric Oxide and a Polyzwitterion: A 7-Day In Vivo Study In a Rabbit Model. ACS Appl. Mater. Interfaces 2020;12:907-9079.

1 adhesion, thus increasing the risk of infection.

2 c. Defendant's uncoated IPCs permit rather than inhibit thrombus
3 accumulation which increases risk of infection.

4 d. Defendant's IPCs are impregnated with barium sulfate which
5 increases the risk of CRBSI.

6 e. Defendant's IPCs are prone to degradation which increases the risk
7 of biofilm formation.

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

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

12 38. If Defendant had incorporated safer alternative designs, then the incidence
13 of IPC-related infections would have been reduced.

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

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

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

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

25 39. At all times relevant, Defendant misrepresented the safety of the Power
26 P.A.C. system, and negligently designed, manufactured, prepared, compounded,
27 assembled, processed, labeled, marketed, distributed, and sold the Power P.A.C.
28 system as a safe and effective device to be surgically implanted to provide repeated

1 access to the vascular system for the delivery of medications, intravenous fluids,
2 parenteral nutrition solutions, and blood products.

3 40. At all times relevant to this action, Defendant knew and had reason to
4 know, that the Power P.A.C. was not safe for the patients for whom they were
5 prescribed and implanted, because once implanted the device was prone to infection,
6 thrombosis, fracturing, perforating internal vasculature, and otherwise malfunctioning.

7 41. At all times relevant to this action, Defendant knew and had reason to
8 know that patients implanted with a Power P.A.C. port had an increased risk of
9 suffering life threatening injuries, including but not limited to: death; fracture; sepsis;
10 thrombosis; thromboembolic events; hemorrhage; cardiac/pericardial tamponade
11 (pressure caused by a collection of blood in the area around the heart); cardiac
12 arrhythmia and other symptoms similar to myocardial infarction; severe and persistent
13 pain; and perforations of tissue, vessels and organs, or the need for additional surgeries
14 to remove the defective device.

15 42. Shortly after entering the market, Defendant began receiving numerous
16 adverse event reports indicating that the Power P.A.C. could experience housing-
17 reservoir separations. Based on these events, Defendant issued a Class I recall in early
18 2025 and advised providers to monitor for device defects. While specific reports of
19 fractured fragments migrating to internal organs or vasculature perforation have been
20 alleged in patient litigation, these serious complications have not been substantively
21 described in public recall documentation. Any such occurrences would likely stem
22 from the core defect of port separation.

23 43. Smiths Medical, in issuing the FDA Class I recall, confirmed that Power
24 P.A.C. housing-reservoir separations ‘may cause serious adverse health consequences’
25 — including **therapy disruption, tissue or skin damage, air embolism, and even**
26 **death** in the most serious cases. The recall notification also recommended clinical
27 monitoring for signs of device failure. While additional patient-level harms have been
28 alleged in litigation, the recall itself does not document cardiac tamponade, vessel or

1 organ perforations, hemorrhage, or arrhythmias as verified outcomes.

2 44. Defendant was aware or should have been aware that the Power P.A.C.
3 had a substantially higher failure rate than other similar products on the market, yet
4 Defendant failed to warn consumers of this fact. The subsequent Class I recall issued
5 by Smiths Medical relating to separation defects in the Power P.A.C. system further
6 confirms that Defendant had knowledge of serious device performance issues affecting
7 the safety and reliability of the product.

8 45. Defendant had a continuing duty under federal law and applicable FDA
9 regulations to monitor post-market performance of the Power P.A.C., investigate
10 adverse events, and timely report known device failures and complications to the FDA
11 through the Medical Device Reporting (“MDR”) system. Upon information and belief,
12 Defendant received adverse event reports and other information reflecting device
13 failures and infection complications associated with the Power P.A.C., yet failed to
14 adequately investigate, report, and disclose this information to regulators, physicians,
15 and patients. Had Defendant properly reported and disclosed these adverse events and
16 device failures, physicians would have been able to more accurately assess the risks of
17 the Power P.A.C. and could have selected safer alternative vascular access devices.

18 46. Defendant also intentionally concealed the severity of complications
19 caused by the Power P.A.C. and the likelihood of these events occurring.

20 47. Rather than alter the design of the Power P.A.C. to make it safer or
21 adequately warn physicians of the dangers associated with the Power P.A.C.,
22 Defendant continued to actively and aggressively market the Power P.A.C. as safe,
23 despite their knowledge of numerous reports of catheter fracture and associated
24 injuries.

25 48. Moreover, Defendant concealed—and continues to conceal—its
26 knowledge of the Power P.A.C.’s dangerous propensity to precipitate infection.
27 Defendant further concealed its knowledge that the catheter design caused these
28 failures and that these failures cause serious injuries.

1 49. The conduct of Defendant, as alleged in this Complaint, constitutes
2 willful, wanton, gross, and outrageous corporate conduct that demonstrates a conscious
3 disregard for the safety of Plaintiff. Defendant had actual knowledge of the dangers
4 presented by the Power P.A.C. System, yet consciously failed to act reasonably to:

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

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

9 c. Recall the Power P.A.C. System from the market.

10 50. Implantable port catheter systems such as the Power P.A.C. are associated
11 with a spectrum of device-related complications when defects in design, materials, or
12 manufacturing are present. These complications include, but are not limited to, catheter
13 degradation, fracture or separation, thrombus formation, infection, catheter-related
14 bloodstream infection (CRBSI), embolization of device fragments, vascular injury, and
15 the need for surgical removal or replacement of the device. The defects described
16 herein substantially increase the likelihood of these complications occurring during
17 normal and foreseeable use of the device.

18 **SPECIFIC FACTUAL ALLEGATIONS AS TO JACQUINE HIATT**

19 51. On or about December 18, 2023, Plaintiff underwent placement of the
20 Port-A-Cath II Power P.A.C., catalog number 21-4483-24, lot number 4420780. The
21 device was implanted by Dr. Jon Silvio Cardinal, M.D., at Community Hospital North,
22 in Indianapolis, Indiana, to facilitate palliative systemic chemotherapy and intravenous
23 access related to Plaintiff's metastatic anal cancer treatment.

24 52. The identification of the Power P.A.C. device described herein is based
25 on Plaintiff's medical records, operative reports, device tracking information, and other
26 healthcare documentation presently available to Plaintiff. To the extent additional
27 identifying information regarding the device—including catalog numbers, lot numbers,
28 serial numbers, manufacturing records, or distribution records—is within the

1 possession, custody, or control of Defendant or third parties, Plaintiff will seek such
2 information through discovery and reserves the right to amend these allegations as
3 necessary.

4 53. Defendant, directly and through its agents, apparent agents, servants, or
5 employees designed, manufactured, marketed, advertised, distributed, and sold the
6 Power P.A.C. that was implanted in Plaintiff.

7 54. Defendant manufactured, sold, and/or distributed the Power P.A.C. to
8 Plaintiff, through her doctors, to be used for chemotherapy administration and blood
9 draws.

10 55. On or about April 6, 2024, Plaintiff underwent a CT scan of the chest
11 with contrast after experiencing symptoms at the port site including redness, swelling,
12 and tenderness. Imaging revealed soft tissue inflammation in the left upper chest wall
13 adjacent to the implanted port, consistent with possible cellulitis or port-related
14 infection.

15 56. On or about April 9, 2024, Plaintiff presented to the hospital with
16 erythema, edema, and pain overlying the port site, and physicians expressed concern
17 for infection associated with the implanted port device. Infectious disease specialists
18 were consulted and recommended extraction of the implanted port due to suspected
19 infection.

20 57. On or about April 11, 2024, Plaintiff's defective port was removed by
21 Dr. Jon Silvio Cardinal, M.D., at Community Hospital North, in Indianapolis, Indiana.
22 Pathology examination documented the gross removal of the implanted port and
23 catheter, confirming extraction of the device. The removal of the implanted Power
24 P.A.C. device was medically necessary due to the suspected device-related infection
25 and associated complications at the port site.

26 58. Plaintiff required intravenous antibiotics during hospitalization and was
27 later transitioned to oral antibiotics upon discharge on or about April 13, 2024.

28

1 Following removal of the device, Plaintiff experienced significant improvement in
2 erythema, swelling, and pain at the port site.

3 59. Due to the need for continued chemotherapy and venous access, Plaintiff
4 later required implantation of another port device on April 26, 2024 in the right
5 subclavian chest.

6 60. As a direct and proximate result of the defective port device implanted on
7 December 18, 2023, Plaintiff suffered infection, pain, inflammation, surgical removal
8 of the device, hospitalization, and additional medical treatment.

9 61. At all times, the Power P.A.C. was utilized and implanted in a manner
10 foreseeable to Defendant, as Defendant generated the instructions for use and created
11 procedures for implanting the product.

12 62. The Power P.A.C. implanted in Plaintiff was in the same or substantially
13 similar condition as when it left the possession of Defendant and in the condition
14 directed by and expected by Defendant.

15 63. Plaintiff and her physicians foreseeably used and implanted the Power
16 P.A.C. and did not misuse or alter the Power P.A.C. in an unforeseeable manner.

17 64. Defendant advertised, promoted, marketed, sold, and distributed the
18 Power P.A.C. as a safe medical device when Defendant knew or should have known
19 the Power P.A.C. was not safe for its intended purposes and that the product could
20 cause serious medical problems.

21 65. Defendant had sole access to material facts concerning the defective
22 nature of the Power P.A.C. product and its propensity to cause serious and dangerous
23 side effects.

24 66. In reliance on Defendant's representations, Plaintiff's doctor was induced
25 to and did use the Power P.A.C.

26 67. As a result of having the Power P.A.C. implanted, Plaintiff has
27 experienced significant mental and physical pain and suffering, has sustained
28 permanent injury, and has suffered financial or economic loss, including, but not

1 limited to, obligations for medical services and expenses, and present and future lost
2 wages.

3 68. Defendant's Power P.A.C. was marketed to the medical community and
4 to patients as a safe, effective, reliable, medical devices implanted by safe and
5 effective, minimally invasive surgical techniques for the treatment of medical
6 conditions, and as safer and more effective as compared to the traditional products and
7 procedures for treatment and other competing Vascular Access Devices.

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

15 70. The injuries, conditions, and complications suffered due to Defendant's
16 Power P.A.C. include but are not limited to infection; necrosis; fracture and leakage;
17 blood clots; cardiac/pericardial tamponade; cardiac arrhythmia and other symptoms
18 similar to myocardial infarction; severe and persistent pain; perforations of tissue,
19 vessels and organs; and even death.

20 71. Despite diligent investigation by Plaintiff into the cause of her injuries,
21 including consultations with her medical providers, Plaintiff did not discover, and
22 could not reasonably have discovered through the exercise of due diligence, the nature
23 of her injuries and their causal relationship to the Product until a date within the
24 applicable statute of limitations. Accordingly, under the discovery rule, Plaintiff's
25 claims were timely filed.

26 72. Plaintiff did not become aware of Defendant's wrongful conduct,
27 including but not limited to the defective design and/or manufacturing of the Product,
28 until a time within the applicable statute of limitations. Even with the exercise of

1 reasonable diligence, Plaintiff could not have discovered this conduct earlier.
2 Therefore, application of the discovery rule confirms that this action was filed within
3 the statutory limitations period.

4 73. Defendant was negligent toward Plaintiff in the following respects:

5 a. Defendant failed to incorporate safer alternative designs in the
6 Power P.A.C. that would have prevented IPC-related blood clots.

7 b. Defendant failed to design and establish a safe, effective procedure
8 for removal of Power P.A.C.; therefore, in the event of a failure, injury, or
9 complications it is difficult to safely remove Power P.A.C.

10 c. Defendant provided incomplete, insufficient, and misleading
11 information to physicians in order to increase the number of physicians using
12 Power P.A.C. for the purpose of increasing their sales. By so doing, Defendant
13 caused the dissemination of inadequate and misleading information to patients,
14 including the Plaintiff.

15 74. At the time of her operation, Plaintiff was not informed of, and had no
16 knowledge of the complaints, known complications, and risks associated with Power
17 P.A.C., including but not limited to the extent of seriousness of the danger of blood
18 clots, fracture and infection.

19 75. Plaintiff was never informed by Defendant of the defective and dangerous
20 nature of Power P.A.C.

21 76. At the time of her implant, neither Plaintiff nor Plaintiff's physicians were
22 aware of the defective and dangerous condition of Power P.A.C.

23 77. As a result of the Defendant's actions and inactions, Plaintiff has been
24 injured and has sustained economic and non-economic damages, both in the past and
25 future, including for pain and suffering and medical expenses.

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FIRST CAUSE OF ACTION

NEGLIGENCE

(Against Defendant ICU Medical)

78. Plaintiff incorporates paragraphs 1 through 73 as if set out fully herein.

79. The Defendant owed Plaintiff a duty to exercise reasonable care when designing, manufacturing, marketing, advertising, distributing, selling, and conducting post-market surveillance of the Power P.A.C.

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

a. Failing to properly and thoroughly test the Power P.A.C. 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 Power P.A.C.;

c. Failing to conduct sufficient post-market testing and surveillance of the Power P.A.C.;

d. Failing to comply with state and federal regulations concerning the study, testing, design, development, manufacture, inspection, production, advertisement, marketing, promotion, distribution, and/or sale of the Power P.A.C.;

e. Designing, manufacturing, marketing, advertising, distributing, and selling the Power P.A.C. to consumers, including Plaintiff, without an adequate warning of the significant and dangerous risks of the Power P.A.C. and without proper instruction to avoid the harm which could foreseeably occur as a result of using the device;

f. Failing to exercise due care when advertising and promoting the Power P.A.C.; and

g. Negligently continuing to manufacture, market, advertise, and

1 distribute the Power P.A.C. after Defendant knew or should have known of its
2 adverse effects.

3 81. As a direct, actual, and proximate cause of the Defendant's actions,
4 omissions, and misrepresentations, Plaintiff has been injured and has sustained
5 economic and non-economic damages, both in the past and future, including for pain
6 and suffering and medical expenses.

7 82. In performing the foregoing acts, omissions, and misrepresentations,
8 Defendant acted grossly negligent, fraudulently, and with malice.

9 **SECOND CAUSE OF ACTION**

10 **STRICT PRODUCTS LIABILITY – FAILURE TO WARN**

11 (Against Defendant ICU Medical)

12 83. Plaintiff incorporates paragraphs 1 through 73 as if set out fully herein.

13 84. Defendant designed, set specifications, manufactured, assembled,
14 processed, marketed, labeled, distributed, and sold the Power P.A.C., including the one
15 implanted in Plaintiff, into the stream of commerce and in the course of the same,
16 directly advertised and marketed the device to consumers or persons responsible for
17 consumers, and therefore had a duty to warn of the risk of harm associated with the use
18 of the device and to provide adequate instructions on the safe and proper use of the
19 device.

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

28 86. Defendant knew or should have known at the time they manufactured,

1 labeled, distributed and sold the Power P.A.C. that was implanted into Plaintiff that the
2 Power P.A.C. posed a significant and higher risk than other similar devices of device
3 failure and resulting serious injuries.

4 87. Defendant failed to timely and reasonably warn of material facts regarding
5 the safety and efficacy of the Power P.A.C.; no reasonable health care provider,
6 including Plaintiff's, and no reasonable patient would have used the device in the
7 manner directed, had those facts been made known to the prescribing healthcare
8 providers or the consumers of the device.

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

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

15 90. The Power P.A.C., which was designed, manufactured, prepared,
16 compounded, assembled, processed, marketed, labeled, distributed, and sold into the
17 stream of commerce by Defendant, was defective at the time of release into the stream
18 of commerce due to inadequate warnings, labeling and/or instructions accompanying
19 the product.

20 91. When Plaintiff was implanted with the device, Defendant failed to provide
21 adequate warnings, instructions, or labels regarding the severity and extent of health
22 risks posed by the device, as discussed herein.

23 92. Defendant intentionally underreported the number and nature of adverse
24 events associated with fracture and migration of the devices to Plaintiff's health care
25 providers, as well as the FDA.

26 93. Upon information and belief, neither Plaintiff nor her health care
27 providers knew of the substantial danger associated with the intended and foreseeable
28 use of the device as described herein.

1 94. Plaintiff and her health care providers used the Power P.A.C. in a normal,
2 customary, intended, and foreseeable manner, namely as a surgically placed device
3 used to make it easier to deliver medications directly into the patient's bloodstream.

4 95. Upon information and belief, the defective and dangerous condition of the
5 device, including the one implanted into Plaintiff, existed at the time they were
6 manufactured, prepared, compounded, assembled, processed, marketed, labeled,
7 distributed, and sold by Defendant to distributors and/or healthcare professionals or
8 organizations.

9 96. Upon information and belief, the device implanted in Plaintiff was in the
10 same condition as when it was manufactured, inspected, marketed, labeled, promoted,
11 distributed and sold by Defendant.

12 97. Defendant's lack of sufficient warning and/or instructions was the direct
13 and proximate cause of Plaintiff's serious physical injuries, and economic damages in
14 an amount to be determined at trial. Had Defendant provided adequate warnings,
15 Plaintiff and her physicians would not have used the device.

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

20 99. In performing the foregoing acts, omissions, and misrepresentations,
21 Defendant acted grossly negligent, fraudulently, and with malice.

22 **THIRD CAUSE OF ACTION**

23 **STRICT PRODUCTS LIABILITY – DESIGN DEFECT**

24 (Against Defendant ICU Medical)

25 100. Plaintiff incorporates paragraphs 1 through 73 as if set out fully herein.

26 101. Defendant supplied, manufactured, sold, distributed and/or otherwise
27 placed into the stream of commerce the Power P.A.C. implanted into Plaintiff.

28 102. The Power P.A.C. implanted in the Plaintiff was not reasonably safe for

1 its intended use and was defective with respect to its design.

2 103. The Power P.A.C. was in a defective condition and was defective in its
3 design in that when it left the possession and control of Defendant, it was not safe for
4 its anticipated use and safer, more reasonable alternative designs existed that could
5 have been utilized by Defendant.

6 104. The Power P.A.C. was unreasonably dangerous to the user or consumer,
7 taking into consideration the utility of said product and the risks involved in its use.
8 The foreseeable risks associated with the design of the product were more dangerous
9 than a reasonably prudent consumer such as Plaintiff and/or her physicians would
10 expect when the product was used for its normal and intended purpose.

11 105. The Power P.A.C. was expected to and did reach the consumer without
12 substantial change in the condition in which it was supplied, distributed, sold and/or
13 otherwise placed into the stream of commerce.

14 106. A reasonably prudent medical device manufacturer would have
15 recognized the defective design of the Power P.A.C. and not placed it into the stream
16 of commerce.

17 107. The design defects in the Power P.A.C. were not known, knowable and/or
18 reasonably apparent to Plaintiff and/or her physician or discoverable upon any
19 reasonable examination.

20 108. The Power P.A.C. was used and implanted in the manner in which it was
21 intended to be used and implanted by Defendant pursuant to the instructions for use
22 and the product specifications provided by Defendant.

23 109. As a direct, actual, and proximate cause of the Defendant's actions,
24 omissions, and misrepresentations, Plaintiff has been injured and has sustained
25 economic and non-economic damages, both in the past and future, including for pain
26 and suffering and medical expenses.

27 110. In performing the foregoing acts, omissions, and misrepresentations,
28 Defendant acted grossly negligent, fraudulently, and with malice.

FOURTH CAUSE OF ACTION
BREACH OF IMPLIED WARRANTY

(Against Defendant ICU Medical)

111. Plaintiff incorporates paragraphs 1 through 73 as if set out fully herein.

112. Defendant impliedly warranted that the Power P.A.C. was merchantable and fit for the ordinary purposes for which it was intended.

113. When the Power P.A.C. was implanted in the Plaintiff, it was being used for the ordinary purposes for which it was intended.

114. The Plaintiff, individually and/or by and through her physician, relied upon Defendant's implied warranties of merchantability in consenting to have the Power P.A.C. implanted in her.

115. Privity exists between Plaintiff and Defendant 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.

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

117. Defendant breached these implied warranties of merchantability because the Power P.A.C. 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. Defendant's manufacturing process in constructing the catheter of the Power P.A.C. implanted in Plaintiff involved too high of a concentration of barium sulfate particles for the polymer formulation, which led to improperly high viscosity of the admixed polyurethane before polymerization and causing improper mixing of barium sulfate particles within the polymer matrix;

b. Defendant knew or should have known barium sulfate is known to contribute to a reduction in the mechanical integrity of the silicone in its product,

1 the Power P.A.C., as the barium sulfate particles dissociate from the surface of
2 the catheter over time; and

3 c. These defects led to a heterogenous modified polymer that included
4 microfractures and weakened areas at the location of the higher barium sulfate
5 concentration that ultimately led to the collection and proliferation of blood
6 products, thereby drastically increasing the risk of biofilm, thrombosis,
7 infection, sepsis and fracture.

8 118. Defendant's breaches of their implied warranties resulted in the
9 implantation of an unreasonably dangerous and defective product, the Power P.A.C.,
10 into Plaintiff's body, placing said Plaintiff's health and safety in jeopardy.

11 119. The Power P.A.C. was sold to the Plaintiff's health care providers for
12 implantation in patients, such as Plaintiff.

13 120. As a direct, actual, and proximate cause of the Defendant's actions,
14 omissions, and misrepresentations, Plaintiff has been injured and has sustained
15 economic and non-economic damages, both in the past and future, including for pain
16 and suffering and medical expenses.

17 121. Upon information and belief, Plaintiff's healthcare providers sent notice
18 to Defendant of the adverse event that occurred to Plaintiff and thus, the nonconformity
19 of the Power P.A.C., within a reasonable period of time following discovery of the
20 breach of warranty and before suit was filed.

21 **FIFTH CAUSE OF ACTION**

22 **BREACH OF EXPRESS WARRANTY**

23 (Against Defendant ICU Medical)

24 (Cal. Com. Code § 2313; *Hauter v. Zogarts*, 534 P.2d 377 (Cal. 1975); 21 U.S.C. §
25 352; 21 C.F.R. § 801.6; *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238 (1984);
26 *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996))

27 122. Plaintiff incorporates paragraphs 1 through 73 as if set out fully herein.

28 123. On or before December 18, 2023, and prior to Plaintiff's implantation,

1 Defendant ICU Medical distributed and promoted written materials concerning its
2 Power P.A.C. implantable port-catheter system to hospitals, surgeons, and patients,
3 including Plaintiff and her implanting physician. These written materials included
4 Instructions for Use (IFUs), patient guides, product brochures, and marketing literature.
5 One such document was titled “Understanding Your Power P.A.C. Port System”,
6 which expressly stated:

7 “The Power P.A.C. has been clinically tested and proven safe
8 for long-term intravenous therapy and is specifically
9 designed to reduce the risk of infection and thrombosis
10 compared to competing implantable ports.”
11

12 This statement, among others, was presented as an unequivocal guarantee of the
13 product’s safety, fitness for its intended use, and superiority over other available port-
14 catheter systems. Upon information and belief, these written representations were
15 included in Defendant’s Instructions for Use and promotional materials supplied to the
16 hospital and physicians involved in Plaintiff’s treatment and were available to
17 Plaintiff’s implanting physician prior to selecting and implanting the device.

18 124. These express warranties were made in writing and formed part of the
19 basis of the bargain. Plaintiff’s implanting physician and Plaintiff relied on Defendant’s
20 written assurances regarding the safety and performance of the Power P.A.C. in
21 selecting and consenting to implantation of the device. Without these written
22 assurances, neither Plaintiff nor her physician would have chosen the Power P.A.C.
23 over other available port systems.

24 125. These express warranties included, but were not limited to:

25 a. Written representations that the Power P.A.C. system had been
26 “clinically tested and proven safe for long-term intravenous therapy.”

27 b. Written assurances that the device’s design was intended to reduce
28 fracture, infection and thrombosis, improving patient safety compared to

1 competitors.

2 c. Statements in product literature that the device was regulated and
3 manufactured in compliance with applicable federal law, implying a superior
4 safety profile and reliability.

5 d. Comparative claims that ICU Medical's Power P.A.C. "offers
6 superior protection against infection and complications compared to competing
7 implantable port systems."

8 126. These written warranties were false and misleading at the time they were
9 made. In reality, the Power P.A.C. system had not been properly tested in its final
10 configuration, contained unvalidated design and material changes, and carried a known
11 but undisclosed risk of catheter surface defects, biofilm formation, serious infections,
12 sepsis, and device fracture. ICU Medical's written materials omitted known adverse
13 effects, including infection, stroke, and heart attack, thereby rendering the product
14 labeling and brochures misleading. As a result, Plaintiff and her physician were
15 deprived of accurate information and relied on false written guarantees of safety and
16 efficacy.

17 127. Plaintiff alleges on information and belief that ICU Medical distributed
18 the above-described written materials, including product brochures, Instructions for
19 Use, and patient guides containing express warranty language, to hospitals, surgeons,
20 and patients throughout the United States, including the facility where Plaintiff's
21 procedure occurred, before December 18, 2023. Because these materials are in
22 Defendant's exclusive possession and control, Plaintiff cannot at this stage provide
23 copies of every specific document. Plaintiff will identify and attach the precise
24 warranty statements once ICU Medical produces these materials during discovery. This
25 allegation is based on industry custom and practice, the uniform marketing and labeling
26 requirements for Class III medical devices, and the promotional literature already
27 identified by Defendant in related litigation and regulatory submissions.

28 128. These warranties were false. At the time of sale and implantation:

- 1 a. The device had not been tested in its final configuration;
- 2 b. Its design and component composition had been substantively
- 3 altered through unvalidated PMA Supplements;
- 4 c. Its clinical safety for patients with autoimmune conditions had not
- 5 been demonstrated; and
- 6 d. Known adverse effects, including infection, stroke and heart
- 7 attack had been omitted from product disclosures.

8 129. The Power P.A.C. system did not conform to ICU Medical's express
9 representations and was not of the quality or safety promised at the time of sale.

10 130. Plaintiff relied on these warranties in choosing to proceed with
11 implantation, and her healthcare providers relied on ICU Medical's literature, IFUs, and
12 representative support in recommending the device. These written representations
13 were a substantial factor in the decision to select and implant the Power P.A.C. device
14 in Plaintiff.

15 131. California law recognizes a cause of action for breach of express warranty
16 under Cal. Com. Code § 2313 where a seller's affirmations of fact or promises form
17 part of the basis of the bargain. (*Hauter v. Zogarts*, 534 P.2d 377, 382–83 (Cal. 1975)).

18 132. ICU Medical's breach of its express warranties was a substantial factor in
19 causing Plaintiff's injuries. The device failed to perform as warranted, and Plaintiff
20 suffered infection, pain, inflammation, and required surgical removal of the device.

21 133. As a result of the device failure, Plaintiff suffered internal injury, required
22 surgical removal of the device, and incurred substantial medical expenses.

23 134. Plaintiff's device failed, contrary to Defendant's express assurances of
24 safety and durability.

25 135. Plaintiff's implanting physician and Plaintiff herself relied on these
26 representations when selecting and implanting the device.

27 136. This claim is not preempted. Express warranty liability arises from
28 Defendant's own voluntary statements and representations and does not impose any

1 additional or different federal requirements. (*Lohr*, 518 U.S. at 503; *Silkwood*, 464 U.S.
2 at 256).

3 137. The Defendant is in a superior position to identify and produce its own
4 express warranties and representations. Plaintiff intends to seek these materials during
5 the discovery process.

6 138. On information and belief, Defendant expressly warranted through its
7 product labeling and promotional materials that the device was safe for subcutaneous
8 use. These materials are in Defendant's possession and will be identified more
9 precisely once discovery commences.

10 **SIXTH CAUSE OF ACTION**
11 **FRAUDULENT CONCEALMENT**

12 (Against Defendant ICU Medical)

13 139. Plaintiff incorporates paragraphs 1 through 73 as if set out fully herein.

14 140. Defendant made false statements and representations to Plaintiff and her
15 healthcare providers concerning the Power P.A.C. product implanted in Plaintiff.

16 141. Defendant engaged in and fraudulently concealed information with
17 respect to the Power P.A.C. in the following respects:

18 a. Defendant represented through the labeling, advertising, marketing
19 materials, seminar presentations, publications, notice letters, and regulatory
20 submissions that the Power P.A.C. was safe and fraudulently withheld and
21 concealed information about the substantial risks of using the Power P.A.C.,
22 including but not limited to, its heightened propensity to precipitate infection,
23 and cause complications;

24 b. Defendant represented that the Power P.A.C. was safer than other
25 alternative systems and fraudulently concealed information which demonstrated
26 that the Power P.A.C. was not safer than alternatives available on the market;

27 c. Defendant concealed that it knew these devices were fracturing and
28 migrating from causes other than the manner in which the implanting physician

1 implanted the device; and

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

4 142. Defendant had knowledge that the representations they made concerning
5 the Power P.A.C., as stated above, were false.

6 143. Defendant had sole access to material facts concerning the dangers and
7 unreasonable risks of the Power P.A.C.

8 144. The concealment of information by the Defendant about the risks of the
9 Power P.A.C. was intentional.

10 145. The concealment of information and the misrepresentations about the
11 Power P.A.C. was made by the Defendant with the intent that Plaintiff's health care
12 providers and Plaintiff rely upon them.

13 146. Plaintiff and her physicians relied upon the representations and were
14 unaware of the substantial risks of the Power P.A.C. which the Defendant concealed
15 from the public, including Plaintiff and her physicians.

16 147. As a direct and proximate result of the Defendant's actions, omissions and
17 misrepresentations, Plaintiff has been injured and has sustained economic and non-
18 economic damages, both in the past and future, including for pain and suffering and
19 medical expenses.

20 148. The Defendant acted with oppression, fraud, and malice towards Plaintiff.

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

23 **PRAYER**

24 **WHEREFORE**, Plaintiff prays for judgment against Defendant as follows:

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

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

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

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

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

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

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

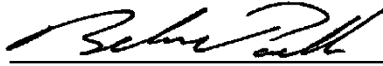
10 **DEMAND FOR JURY TRIAL**

11 Plaintiff hereby demands trial by jury on all issues.

12 Dated: March 26, 2026

Respectfully submitted,

13 WISNER BAUM, LLP

14 

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