Michael A. Galpern
JAVERBAUM WURGAFT HICKS KHAN WIKSTROM & SININS, P.C.
1000 Haddonfield-Berlin Road, Suite 203
Voorhees, NJ 08043
Fax: (856) 702-6640
Phone: (856) 596-4100
Email: mgalpern@lawjw.com

Jennifer P. Elwell
BERGER MONTAGUE PC
1818 Market Street, Suite 3600
Philadelphia, PA 19103
Fax: (215) 875-4620
Phone: (215) 875-3000
Email: jelwell@bm.net

Christopher J. Geddis
MAZIE SLATER KATZ & FREEMAN, LLC
103 Eisenhower Parkway
Roseland, NJ 07068
Fax: (973) 228-0303
Phone: (973) 228-9898
Email: cgeddis@mazieslater.com

Co-Liaison Counsel for Plaintiffs

IN RE: Bard Implanted Port Catheter Products Liability Litigation	SUPERIOR COURT OF NEW JERSEY LAW DIVISION: BERGEN COUNTY Master Docket No. BER-L-2403-25 MCL No. 640 **MASTER LONG-FORM COMPLAINT AND JURY TRIAL DEMAND** (Applies to All Actions)

Plaintiffs in this consolidated action, by and through Plaintiffs' Co-Liaison Counsel, hereby file this Master Long-Form Complaint and Jury Trial Demand ("Master Complaint") against Defendants Becton, Dickinson and Company; C.R. Bard, Inc.; Bard Access Systems, Inc.; and Bard Peripheral Vascular, Inc. (collectively, "Defendants").

Plaintiffs seek judgment against Defendants for personal injuries and sequelae thereto sustained from Defendants' unreasonably dangerous implanted port catheter ("IPC") devices.

Plaintiffs intend this Master Complaint to achieve efficiency and economy by presenting certain common allegations and common questions of law and fact that generally pertain to Plaintiffs in this MCL. This Master Complaint is created for the convenience of the Court and all parties to give notice of allegations that some or all Plaintiffs in cases consolidated in this MCL allege against Defendants—whether those Plaintiffs' claims are for personal injury or wrongful death, and whether brought by an individual alleging injury or beneficiaries of claims for wrongful death of a Plaintiff or Plaintiff's decedent. Plaintiffs plead all counts of this Master Complaint in the broadest sense and pursuant to all applicable laws and choice-of-law principles.[1] For these reasons, this Master Complaint is solely an administrative device, not an operative pleading that consolidates the separate claims of Plaintiffs. Accordingly, this Master Complaint will become operative only when a Plaintiff incorporates it by reference in his or her Short-Form Complaint.

This Master Complaint does not necessarily include all claims asserted in all actions filed in, transferred to, or removed to this Court. Each Plaintiff will adopt this Master Complaint and the causes of action alleged herein by and through a separate Short-Form Complaint. Any individual facts, jurisdictional allegations, and/or additional legal claims of an individual Plaintiff may be set forth as necessary in the Short-Form Complaint. This Master Complaint does not constitute a waiver or dismissal of any allegations or claims asserted in those individual actions, and no Plaintiff relinquishes the right to amend his or her individual claims to include additional claims as discovery continues. This proposed master complaint is intended to be read expansively, and is intended to incorporate but not be limited to, every plaintiff cause of action pending in the MDL litigation, unlesss such

[1] Plaintiffs' claims arise under common law and/or statutory authority, as allowed by law.

cause of action is expressly non-cognizable in New Jersey, or expressly withdrawn or waived by plaintiffs in the MCL.

Accordingly, Plaintiffs in MCL 640 allege as follows:

INTRODUCTION

1. Plaintiffs bring this action for personal-injury and/or wrongful-death damages suffered by an injured or deceased party or parties as a direct and proximate result of that party being implanted with an IPC manufactured by Defendants.

2. The subject devices include but are not limited to the following products (collectively, "Bard IPCs"):

a. BardPort M.R.I. Implantable Port;
b. BardPort M.R.I. Low-Profile Implantable Port;
c. BardPort Titanium Dome Implantable Port;
d. BardPort Titanium Implantable Port;
e. M.R.I. Plastic Dual Lumen Port;
f. M.R.I. Ultra SlimPort Implantable Port;
g. Peritoneal Titanium Port;
h. PowerFlow Implantable Apheresis IV Port;
i. PowerPort ClearVUE isp Implantable Port;
j. PowerPort ClearVUE Slim Implantable Port;
k. PowerPort duo M.R.I. Implantable Port;
l. PowerPort Implantable Port;
m. PowerPort isp Implantable Port;
n. PowerPort isp M.R.I. Implantable Port;
o. PowerPort M.R.I. Implantable Port;
p. PowerPort Slim Implantable Port;
q. PowerPort VUE M.R.I. Implantable Port;
r. PowerPort VUE Titanium Implantable Port;
s. SlimPort Dual-Lumen Rosenblatt Implantable Port;

t. Titanium Low-Profile Port;

u. Titanium SlimPort Implantable Port;

v. Vaccess CT Low-Profile Titanium Power-Injectable Port;

w. Vaccess CT Power-Injectable Implantable Port;

x. X-Port isp M.R.I. Implantable Port; and

y. X-Port Low-Profile Titanium Port.

3. Plaintiffs' claims for damages all relate to Defendants' designing, researching, developing, licensing, testing, assembling, manufacturing, labeling, packaging, promoting, marketing, advertising, distributing, supplying, and/or selling Bard IPCs.

4. Defendants were aware of the defects and risks of Bard IPCs but nonetheless supplied these dangerously defective products to Plaintiffs without Plaintiffs or their physicians having any knowledge of those defects and risks.

5. Bard IPCs reached Plaintiffs and Plaintiffs' healthcare providers without substantial change in condition from the time they left Defendants' possession and control.

6. Plaintiffs and Plaintiffs' healthcare providers used Bard IPCs in the manner in which they were intended.

7. Defendants are solely responsible for any alleged defect in Bard IPCs regarding their design, warning and/or instruction, and manufacture.

8. Bard IPCs have caused Plaintiffs to suffer myriad complications, including but not limited to catheter fracture, migration, and/or perforation; infection; thrombosis; and even death.

9. Indeed, published and peer-reviewed scientific literature makes clear that "[IPCs] are not benign and represent an unnatural physiologic state leading to the progressive development of several complications."[2]

[2] Khalid et al., *Outcomes following port-a-catheter placement in the Medicare population*, Surg. Open Sci. 3 (2021) 39-43.

PARTIES

10. Plaintiffs are those persons and estates that have brought or will bring actions seeking personal-injury and/or wrongful-death damages caused by Bard IPCs. The identities and citizenship of individual Plaintiffs will be identified in their respective Short-Form Complaints.

11. Plaintiffs are persons injured, killed, or otherwise harmed by Bard IPCs. Depending on the law applicable to a particular Plaintiff's claims, Plaintiffs may include deceased individuals and/or their spouses, children, parents, heirs, survivors, administrators, executors, or personal representatives, as well as injured individuals and/or their spouses, children, parents, next friends, legal guardians, conservators, or other authorized representatives.

12. Defendant Becton, Dickinson and Company ("BD") is a New Jersey corporation with a principal place of business at 1 Becton Drive in Franklin Lakes, New Jersey.

13. BD is a citizen of New Jersey for diversity-of-citizenship purposes.

14. BD is the parent company of Defendants C.R. Bard; Bard Access Systems, Inc.; and Bard Peripheral Vascular, Inc.

15. BD conducts business throughout the United States, including the State of Arizona.

16. At all relevant times, BD has been 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 Bard IPCs, to be implanted in patients throughout the United States, including the State of New Jersey and Plaintiffs' states of residence, implant, and/or injury.

17. Defendant C.R. Bard, Inc. ("C.R. Bard") is a New Jersey corporation with its principal place of business located at 1 Becton Drive in Franklin Lakes, New Jersey.

18. C.R. Bard is a citizen of New Jersey for diversity-of-citizenship purposes.

19. C.R. Bard is a wholly-owned subsidiary of BD.

20. C.R. Bard conducts business throughout the United States, including the State of New Jersey.

21. At all relevant times, C.R. Bard has been 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 Bard IPCs, to be implanted in patients throughout the United States, including the State of New Jersey and Plaintiffs' respective states of residence, implant, and/or injury.

22. Defendant Bard Access Systems, Inc. ("BAS") is a Utah corporation with its principal place of business located at 605 North 5600 West in Salt Lake City, Utah.

23. BAS is a citizen of Utah for diversity-of-citizenship purposes.

24. BAS is a wholly-owned subsidiary of BD.

25. BAS is a wholly-owned subsidiary of C.R. Bard, Inc.

26. BAS operates under the business trade name C.R. Bard, Inc.

27. According to Defendants, BAS was or "is the principal manufacturer and distributor" of Bard IPCs.[3]

28. BAS conducts business throughout the United States, including the State of New Jersey.

29. At all relevant times, BAS has been 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 Bard IPCs, to be implanted in patients throughout the United States, including the State of New Jersey and Plaintiffs' states of residence, implant, and/or injury.

[3] JPML Dkt. 20 at 23.

30. Defendant Bard Peripheral Vascular, Inc. ("BPV") is an Arizona corporation with its principal place of business located at 1625 West 3rd Street in Tempe, Arizona.

31. BPV is a citizen of Arizona for diversity-of-citizenship purposes.

32. BPV is a wholly-owned subsidiary of BD.

33. BPV is a wholly-owned subsidiary of C.R. Bard, Inc.

34. BPV operates under the business trade name C.R. Bard, Inc.

35. BPV operates under the business trade name SenoRx, Inc.

36. According to Defendants, BPV "distributed" Bard IPCs.[4]

37. BPV conducts business throughout the United States, including the State of New Jersey.

38. At all relevant times, BPV has been 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 Bard IPCs, to be implanted in patients throughout the United States, including the State of Arizona and Plaintiffs' states of residence, implant, and/or injury.

BD Acquires C.R. Bard, BAS, and BPV

39. On or about April 23, 2017, BD entered into a Merger Agreement under which BD would acquire C.R. Bard and its subsidiaries, BAS and BPV.

40. On or about December 29, 2017, BD completed its acquisition of C.R. Bard and its subsidiaries, BAS and BPV.

41. C.R. Bard's product offerings were taken over by and integrated into BD's Interventional and Medical segments.

42. BAS's product offerings were taken over by and integrated into BD's Interventional and Medical segments.

[4] https://www.bd.com/content/dam/bd-assets/na/peripheral-intervention/documents/instructions-for-use/BAW0738034.pdf.

43. BPV's product offerings were taken over by and integrated into BD's Interventional and Medical segments.

44. BD created the new Interventional segment to include a majority of C.R. Bard, BAS, and BPV product offerings, including Bard IPCs.

45. Today, BD is the parent company of C.R. Bard, BAS, and BPV.

46. "BD," "C.R. Bard," "BAS, "BPV," and "Defendants" include any and all parent companies, subsidiaries, affiliates, divisions, franchises, partners, joint venturers, and organizational units of any kind; their predecessors, successors, and assigns; their officers, directors, employees, agents, representatives; and any and all other persons acting on their behalf.

47. John Does are the fictitious names of corporations, partnerships, or other entities, the true identity of which are unknown to plaintiffs at the present time despite due diligence, who are responsible for the negligent manufacture, testing, distribution, and/or marketing of the products at issue.

48. John Roes are the fictitious names of individuals, the true identity of whom are unknown to plaintiffs at the present time despite due diligence, who are responsible for the negligent manufacture, testing, distribution, and/or marketing of the products at issue.

JURISDICTION AND VENUE

49. This Court has jurisdiction over this action pursuant to Constitution Article VI 3,2 which grants the Superior Court "original jurisdiction throughout the State in all cases." The statutes under which this action is brought do not contravene this choice of venue.

50. This Court has personal jurisdiction over Defendants because all Defendants are present and doing business within New Jersey and have continuous and systematic contacts in New Jersey, including Bergen County.

51. Additionally, this Court has personal jurisdiction over BD and C.R. Bard because BD and C.R. Bard are citizens of New Jersey and their principle place of business is in New Jersey.

52. Specifically, Defendants engaged in the following contacts in the state of New Jersey:

a. Conducted business in the state of New Jersey;

b. Regularly solicited business in the state of New Jersey;

c. Specifically transacted and conducted business in the state of New Jersey with respect to Bard IPCs;

d. Targeted medical professionals in the state of New Jersey for the sale and use of Bard IPCs to be sold to and/or used by medical personnel within the state of New Jersey;

e. Engaged in substantial and continuing contact with the state of New Jersey;

f. Derived substantial revenue from goods used and consumed within the state of New Jersey;

g. Purposefully directed their business activities, particularly with respect to Bard IPCs, to the state of New Jersey;

h. Purposely placed Bard IPCs into the stream of commerce in the state of New Jersey;

i. Expected or reasonably should have expected that Bard IPCs would reach the state of New Jersey and be purchased and used by individuals in the state of New Jersey;

j. Anticipated or reasonably should have anticipated that Bard IPCs would reach the state of New Jersey and be purchased and used by individuals in the state of New Jersey;

k. Engaged in a persistent course of conduct in the state of New Jersey with respect to Bard IPCs;

l. Committed a tort in whole or in part in the state of New Jersey;

m. Reasonably expected or should have expected their acts to have consequences within the state of New Jersey; and/or

n. Intended to serve the market of the state of New Jersey and therefore purposely availed themselves of jurisdiction there.

o. Upon information and belief, there are many additional examples of other contacts within the State, which will be explored through discovery.

53. Pursuant to the Supreme Court of New Jersey's Notice and Order of Approval of MCL Designation of Bard Implanted Port Catheter Products Litigation filed

on October 15, 2024 [5], venue for actions alleging injuries by Bard IPCs is proper in Bergen County for centralized case management by Superior Court Judge Gregg A. Padovano.

54. Venue is proper in this Court under New Jersey Rule of Court 4:3-2(b) because all Defendants regularly conduct business in New Jersey and Bergen County and a substantial part of the events or omissions giving rise to the claims occurred here.

FACTUAL ALLEGATIONS

Implanted Port Catheters

55. Defendants "offer a diverse portfolio of power injectable and non-power injectable vascular access ports."[6]

56. These port devices, including Bard IPCs, are also known as "ports," "implanted port catheters," "port-a-caths," "mediports," or "totally implantable vascular/venous access devices."

57. The first IPC was introduced in 1982.[7]

58. IPCs are intended to provide access to a patient's vascular system (i.e., the circulatory system made up of blood vessels), specifically for patients who require repeated and/or long-term venous access.

59. IPCs may be used for the delivery of intravenous ("IV") fluids; medication such as the administration of chemotherapy or immunotherapy; or total parenteral nutrition.

60. According to Defendants, more than 90% of patients with IPCs use their IPC for cancer treatment.[8]

61. IPCs may also be used for blood-product administration and blood withdrawals, among other uses.

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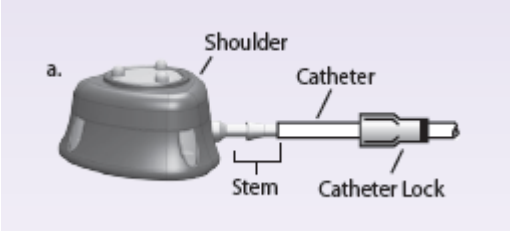
[5] Notice and Order - Approval of MCL Designation of Bard Implanted Port Catheter Products Litigation | NJ Courts.

[6] https://www.bd.com/en-eu/offerings/capabilities/vascular-access/port-devices-and-needles/implantable-port-devices.

[7] Tumay & Guner, *Availability of totally implantable venous access devices in cancer is high in the long term: a seven-year follow-up study*, Supportive Care in Cancer (2021) 29:3531-3538.

[8] https://www.accessdata.fda.gov/cdrh_docs/pdf18/K181446.pdf.

62. IPCs consist of two main components: an injection port and a catheter.[9]



63. The IPC's first component is called a "port" or "port body," referring to an opening for the passage of fluid.

64. Injection ports vary in shape, profile, material, size, volume, and access angle.

65. All ports, however, have a raised center, or "septum," where the needle is inserted for access to the patient's vascular system.

66. Ports may have one or two septa, the latter of which allows for simultaneous access with two needles.[10]

67. The number of septa is sometimes indicated by the terms "single lumen" or "dual lumen."

68. The port body may be made of plastic, silicone, or titanium.

69. Connected to the port is the IPC's second component: a small, flexible tube called a "catheter."

70. According to Defendants, "[t]he catheters used with infusion ports are essentially the same design as externalized, stand-alone intravascular catheters."[11]

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[9] JPML Dkt. 20-3 at 8.
[10] JPML Dkt. 20-2 at 2.
[11] https://www.accessdata.fda.gov/cdrh_docs/pdf15/K153359.pdf.

71. The catheter is connected to the port with a "cathlock."

72. The catheter may be "pre-attached," meaning it comes connected to the port, or "attachable," meaning it may be attached to the port by the physician during implantation.

73. Various catheter options exist, including but not limited to the ChronoFlex and Groshong catheters discussed further below.

74. Catheters may be made of silicone and/or polyurethane.

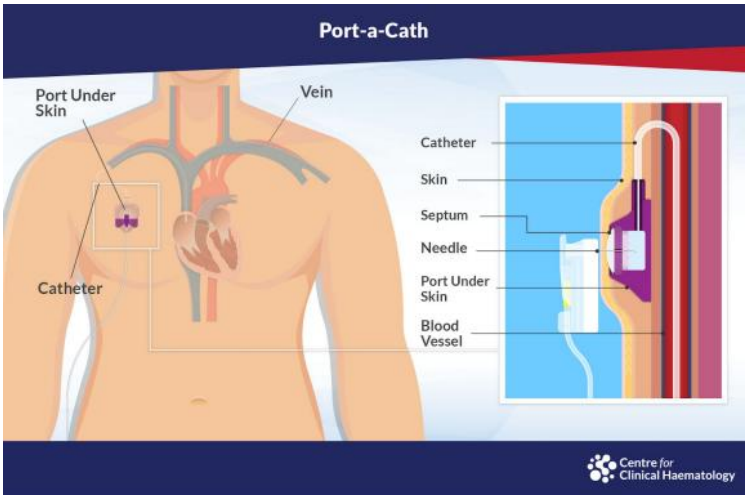
75. Catheters may also vary in width to conform to the patient's anatomy.

76. The unit of measurement for the catheter component of an IPC is the "Fr," which is based on the French Scale measurement system and is determined by multiplying the catheter's diameter by 3.

77. For example, if a catheter has a diameter of 3.2mm, then the size is 9.6 Fr.

78. IPCs are surgically placed subcutaneously (i.e., beneath the skin).

79. IPCs are often implanted in the lateral region of the chest beneath the clavicle.



80. The catheter is either tunneled under the skin until it reaches an insertion point in the designated vein, or the catheter is inserted directly into the vein and advanced through the blood vessels to the proper location.

81. In many cases, the tip of the catheter is advanced from its insertion point to the junction of the superior vena cava and the right atrium of the heart.

82. An interventional radiologist or vascular surgeon typically performs the implant surgery.

83. A nurse or radiological technologist then accesses the IPC to administer medical treatment.

Defendants' Development of IPC Devices and Technologies

84. Defendants began designing and developing various IPCs, including some Bard IPCs, in the 1980s.

85. Since then, Defendants have patented or licensed various patents relating to Bard IPCs, including but not limited to:

a. Patent No. 5,167,638 (Subcutaneous Multiple-Access Port), filed on July 9, 1991;

b. Patent No. 5,360,407 (Implantable Dual Access Port with Tactile Ridge for Position Sensing), filed on August 29, 1991;

c. Patent No. 5,399,168 (Implantable Plural Fluid Cavity Port), filed on July 29, 1992; and

d. Patent No. 6,213,973 (Vascular Access Port with Elongated Septum), filed on January 12, 1998.

86. Defendants have registered various trademarks relating to Bard IPCs, including but not limited to:

a. Groshong, first used in commerce on or around October 1987, and registered on April 28, 1992, and September 13, 2005;

b. BardPort, first used in commerce on or around January 31, 1994, and registered on August 20, 1996;

c. SlimPort, first used in commerce on or around August 14, 1996, and registered on April 7, 1998, and April 12, 2005;

d. ClearVue, first used in commerce on or around July 22, 2004, and registered on April 11, 2006, and November 13, 2012; and

e. PowerPort, first used in commerce on or around August 1, 2006, and registered on November 28, 2006.

87. Some Bard IPCs are denominated "Slim" or "Low-Profile" to describe the port's reduced dimensions, including the following Bard IPCs:

a. BardPort M.R.I. Low-Profile Implantable Port;

b. M.R.I. Ultra SlimPort Implantable Port;

c. PowerPort ClearVUE Slim Implantable Port;

d. PowerPort Slim Implantable Port;

e. SlimPort Dual-Lumen Rosenblatt Implantable Port;

f. Titanium SlimPort Implantable Port;

g. Titanium Low-Profile Port;

h. Vaccess CT Low-Profile Titanium Power-Injectable Port; and

i. X-Port Low-Profile Titanium Port.

88. Other Bard IPCs are denominated "isp" to refer to an "intermediate sized port," including the following Bard IPCs:

a. PowerPort isp Implantable Port;

b. PowerPort ClearVUE isp Implantable Port;

c. X-Port isp M.R.I. Implantable Port; and

d. PowerPort isp M.R.I. Implantable Port.

89. Still other Bard IPCs are denominated "M.R.I.," signaling their plastic port material, including the following Bard IPCs:

a. PowerPort M.R.I. Implantable Port;

b. PowerPort duo M.R.I. Implantable Port;

c. PowerPort VUE M.R.I. Implantable Port;

d. X-Port isp M.R.I. Implantable Port;

e. M.R.I. Ultra SlimPort Implantable Port;

f. M.R.I. Plastic Dual Lumen Port;

g. PowerPort isp M.R.I. Implantable Port;

h. BardPort M.R.I. Implantable Port; and

i. BardPort M.R.I. Low-Profile Implantable Port.

90. And some Bard IPCs are denominated "PowerPort," "PowerFlow," or "Power-Injectable" to signify the device is power-injectable, as described further below, including the following Bard IPCs:

a. PowerPort Implantable Port;

b. PowerPort isp Implantable Port;

c. PowerPort M.R.I. Implantable Port;

d. PowerPort duo M.R.I. Implantable Port;

e. PowerPort ClearVUE Slim Implantable Port;

f. PowerPort ClearVUE isp Implantable Port;

g. PowerPort VUE M.R.I. Implantable Port;

h. PowerPort VUE Titanium Implantable Port;

i. PowerPort isp M.R.I. Implantable Port;

j. PowerPort Slim Implantable Port;

k. Vaccess CT Power-Injectable Implantable Port;

l. Vaccess CT Low-Profile Titanium Power-Injectable Port; and

m. PowerFlow Implantable Apheresis IV Port.

91. Regardless of their denomination, these Bard IPCs have three raised "palpation bumps" in a triangular configuration to distinguish them as power-injectable.[12]

92. In addition, all Bard IPCs are "radiopaque," meaning visible during diagnostic imaging such as an X-ray, computed tomography ("CT scan"), or magnetic resonance imaging ("M.R.I.").

[12] JPML Dkt. 20-2 at 3.

93. The port bodies of Bard IPCs are radiopaque, containing special markers or identifiers.[13]

94. The catheters of Bard IPCs are also radiopaque due to the use of barium sulfate ($BaSO_4$), as described further below.

Defendants' Development of Power-Injectable IPCs

95. Beginning in the mid-2000s, Defendants designed and developed various "power-injectable" IPCs.

96. Power-injectable ports allow for contrast material to be injected at a higher rate than by hand injection, facilitating medical imaging.

97. Power-injectable ports were first made commercially available to the medical community in 2006.

98. The United States Food and Drug Administration ("FDA") cleared Defendants' PowerPort Implanted Titanium Port with 8 Fr ChronoFlex Catheter on July 14, 2006 (K060812), as detailed further below.

99. Defendants' power-injectable ports include but are not limited to the following Bard IPCs:

a. PowerPort Implantable Port;

b. PowerPort isp Implantable Port;

c. PowerPort M.R.I. Implantable Port;

[13] JPML Dkt. 20-3 at 3.

d. PowerPort duo M.R.I. Implantable Port;

e. PowerPort ClearVUE Slim Implantable Port;

f. PowerPort ClearVUE isp Implantable Port;

g. PowerPort isp M.R.I. Implantable Port;

h. PowerPort Slim Implantable Port;

i. Vaccess CT Power-Injectable Implantable Port;

j. Vaccess CT Low-Profile Titanium Power-Injectable Port; and

k. PowerFlow Implantable Apheresis IV Port.

Defendants' Regulatory Clearance of Non-Power-Injectable IPC Devices

100. The FDA classifies IPCs as Class II devices. *See* 21 C.F.R. § 880.5965.

101. As Class II devices, IPCs are subject to the 510(k) clearance process.

102. A 510(k) is a premarket submission made to the FDA to demonstrate that the new device to be marketed is substantially equivalent to an existing "predicate" device, which was either marketed prior to the enactment of the 1976 Medical Device Amendments to the Food, Drug, and Cosmetic Act or is the subject of an independent 510(k) clearance.

103. If the new device is substantially equivalent to the predicate, 510(k) permits the marketing of the device without formal review for the safety and efficacy of the device.

104. Through the 510(k) process, IPCs are cleared, not approved, by the FDA.

105. The FDA has explained:

> A manufacturer can obtain an FDA finding of 'substantial equivalence' by submitting a pre-market 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 FDA (as opposed to 'approved' by the agency under a PMA). A pre-market notification submitted under 510(k) is thus entirely different from a PMA, which must include data sufficient to demonstrate that the device is safe and effective.[14]

106. The Supreme Court has similarly explained:

> 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 only 20 hours. . . . As one

[14] *Horn v. Thoratec Corp.*, 376 F.3d 163, 167 (3d Cir. 2004).

> commentator noted: "The attraction of substantial equivalence to manufacturers is clear. Section 510(k) notification requires little information, rarely elicits a negative response from the FDA, and gets processed very quickly."[15]

107. Defendants' 510(k) submissions for Bard IPCs are subject to the following FDA special control: Guidance on 510(k) Submissions for Implanted Infusion Ports (Oct. 1990) ("1990 Guidance").[16]

108. The 1990 Guidance does not dictate a particular design for Bard IPCs.

109. The 1990 Guidance does not dictate the content of the labeling for Bard IPCs.

110. Defendants' 510(k) submissions for Bard IPCs are also subject to the following FDA special control: Guidance on Premarket Notification [510(k)] Submission for Short-Term and Long-Term Intravascular Catheters (Mar. 16, 1995) ("1995 Guidance").[17]

111. The 1995 Guidance does not dictate a particular design for Bard IPCs.

112. The 1995 Guidance does not dictate the content of the labeling for Bard IPCs.

113. Bard IPCs are not subject to any other FDA special controls besides the 1990 Guidance and 1995 Guidance.

114. The **Titanium Low-Profile Port** is one of Defendants' Bard IPCs.

a. On or around January 23, 1987, C.R. Bard sought 510(k) clearance for the Hickman Titanium Subcutaneous Port, claiming its substantial equivalence to a predicate device.

b. The FDA cleared the Hickman Titanium Subcutaneous Port on April 15, 1987 (K870260).

c. On information and belief, 510(k) number K870260 corresponds to the Titanium Low-Profile Port.

d. On or around February 7, 2005, BAS sought 510(k) clearance for the BardPort Implanted Port (Trade Name: Titanium Low-Profile Port), claiming its substantial equivalence to the BardPort Implanted Port (K870260).

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[15] *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 478-79 (1996) (quoting Adler, The 1976 Medical Device Amendments: A Step in the Right Direction Needs Another Step in the Right Direction, 43 Food Drug Cosm. L.J. 511, 516 (1988)).

[16] https://www.fda.gov/media/72495/download.

[17] https://www.fda.gov/media/72722/download.

e. The FDA cleared the BardPort Implanted Port on April 18, 2005 (K050310).

f. On information and belief, 510(k) number K050310 corresponds to the Titanium Low-Profile Port.

g. Defendants sell the Titanium Low-Profile Port under the following Stock Keeping Unit ("SKU")/model numbers, including but not limited to: 0602180, 0602190, 0605490, 0605510, 0606100, 0606150, 0606200.[18]

115. The **SlimPort Dual-Lumen Rosenblatt Implantable Port** is one of Defendants' Bard IPCs.

a. On or around September 30, 1996, BAS sought 510(k) clearance for the SlimPort Dual Low Profile Implanted Port, claiming its substantial equivalence to the Plastic Attachable Dual Port as a predicate device.

b. The FDA cleared the SlimPort Dual Low Profile Implanted Port on March 6, 1997 (K964066).

c. On information and belief, 510(k) number K964066 corresponds to the SlimPort Dual-Lumen Rosenblatt Implantable Port.

d. Defendants sell the SlimPort Dual-Lumen Rosenblatt Implantable Port under the following SKU/model numbers, including but not limited to: 0604970, 0624970, 0654970.[19]

116. The **X-Port isp M.R.I. Implantable Port** is one of Defendants' Bard IPCs.

a. On or around September 6, 2002, BAS sought 510(k) clearance for the BardPort Implanted Port (Trade Name: X-Port isp), claiming its substantial equivalence to the BardPort Implanted Port (Trade Name: Hickman Plastic Subcutaneous Port) as a predicate device.

b. The FDA cleared the BardPort Implanted Port (Trade Name: X-Port isp) on September 25, 2002 (K022983).

c. On information and belief, 510(k) number K022983 corresponds to the X-Port isp M.R.I. Implantable Port.

d. On or around February 5, 2016, BAS sought 510(k) clearance for the X-Port Implanted Port, claiming its substantial equivalence to the BardPort X-Port isp Port as a predicate device.

e. The FDA cleared the X-Port Implanted Port on May 20, 2016 (K153359).

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[18] *See, e.g.*, https://www.bd.com/en-us/products-and-solutions/products/product-page.0602180#overview.

[19] *See, e.g.*, https://www.bd.com/en-eu/slimport-dual-lumen-rosenblatt-implantable-port/0604970ce?return=true.

f. On information and belief, 510(k) number K153359 corresponds to the X-Port isp M.R.I. Implantable Port.

g. Defendants sell the X-Port isp M.R.I. Implantable Port under the following SKU/model numbers, including but not limited to: 0607500, 0607510, 0607520, 0607530, 0607540, 0607550, 0607555, 0657500, 0657510, 0657520, 0657525, 7707540, 7757540.[20]

117. The **X-Port Low-Profile Titanium Port** is one of Defendants' Bard IPCs.

a. On information and belief, 510(k) number K022983 also corresponds to the X-Port Low-Profile Titanium Port.

b. On information and belief, 510(k) number K153359 also corresponds to the X-Port Low-Profile Titanium Port.

c. Defendants sell the X-Port Low-Profile Titanium Port under the following SKU/model numbers, including but not limited to: 0655870, 0605840, 0605850.[21]

118. The **Titanium SlimPort Implantable Port** is one of Defendants' Bard IPCs.

a. On or around August 24, 1992, BAS sought 510(k) clearance for the Plastic Low Profile Subcutaneous Port, claiming its substantial equivalence to a predicate device.

b. The FDA cleared the Plastic Low Profile Subcutaneous Port on October 4, 1993 (K924250).

c. On information and belief, 510(k) number K924250 corresponds to the Titanium SlimPort Implantable Port.

d. On information and belief, 510(k) number K153359 corresponds to the Titanium SlimPort Implantable Port.

e. Defendants sell the Titanium SlimPort Implantable Port under the following SKU/model numbers, including but not limited to: 0605550, 0605560, 0655510.[22]

119. The **M.R.I. Ultra SlimPort Implantable Port** is one of Defendants' Bard IPCs.

a. On information and belief, 510(k) number K924250 also corresponds to the M.R.I. Ultra SlimPort Implantable Port.

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[20] *See, e.g.*, https://www.bd.com/en-us/products-and-solutions/products/product-page.0607510.
[21] *See, e.g.*, https://www.bd.com/en-us/products-and-solutions/products/product-page.0655870.
[22] *See, e.g.*, https://www.bd.com/en-us/products-and-solutions/products/product-page.0605550.

b. On information and belief, 510(k) number K153359 corresponds to the M.R.I. Ultra SlimPort Implantable Port.

c. Defendants sell the M.R.I. Ultra SlimPort Implantable Port under the following SKU/model numbers, including but not limited to: 0605640, 0655640.[23]

120. The **M.R.I. Plastic Dual Lumen Port** is one of Defendants' Bard IPCs.

a. On information and belief, Defendants never sought 510(k) clearance of the M.R.I. Plastic Dual Lumen Port.

b. On information and belief, the M.R.I. Plastic Dual Lumen Port never received 510(k) clearance.

c. Defendants sell the M.R.I. Plastic Dual Lumen Port under the following SKU/model numbers, including but not limited to: 0603500, 0605920, 0605930, 0607100, 0607200, 0615460.[24]

121. The **BardPort M.R.I. Implantable Port** is one of Defendants' Bard IPCs.

a. On information and belief, 510(k) number K050310 also corresponds to the BardPort M.R.I. Implantable Port.

b. Defendants sell the BardPort M.R.I. Implantable Port under the following SKU/model numbers, including but not limited to: 0602610, 0602620, 0602640, 0602650, 0602660, 0602670, 0602680, 0602690, 0602830, 0602833, 0602840, 0602843, 0605400, 0605420, 0607173.[25]

122. The **BardPort M.R.I. Low-Profile Implantable Port** is one of Defendants' Bard IPCs.

a. On information and belief, 510(k) number K050310 also corresponds to the BardPort M.R.I. Low-Profile Implantable Port.

b. Defendants sell the BardPort M.R.I. Low-Profile Implantable Port under the following SKU/model numbers, including but not limited to: 0603830, 0603840, 0603870, 0603880, 6603880.[26]

123. The **BardPort Titanium Implantable Port** is one of Defendants' Bard IPCs.

a. On information and belief, 510(k) number K870260 corresponds to the BardPort Titanium Implantable Port.

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[23] *See, e.g.*, https://www.bd.com/en-us/products-and-solutions/products/product-page.0605640.
[24] *See, e.g.*, https://www.bd.com/en-us/products-and-solutions/products/product-page.0605920.
[25] *See, e.g.*, https://www.westcmr.com/0602680-we1-0602680.
[26] *See, e.g.*, https://www.westcmr.com/0605420-we1-0605420.

b. On information and belief, 510(k) number K050310 also corresponds to the BardPort Titanium Implantable Port.

c. Defendants sell the BardPort Titanium Implantable Port under the following SKU/model numbers, including but not limited to: 0602230, 0602240, 0602270, 0602290, 0603000, 0602820, 0605300, 0605320, 0607301, 0607302, 0602210, 0602260, 0602280, 0602810.[27]

124. The **BardPort Titanium Dome Implantable Port** is one of Defendants' Bard IPCs.

a. On information and belief, 510(k) number K870260 corresponds to the BardPort Titanium Implantable Port.

b. On information and belief, 510(k) number K050310 also corresponds to the BardPort Titanium Implantable Port.

c. Defendants sell the BardPort Titanium Dome Implantable Port under the following SKU/model numbers, including but not limited to: 0602850, 0602860, 0602870.[28]

125. The **Peritoneal Titanium Port** is one of Defendants' power-injectable Bard IPCs.

a. On information and belief, 510(k) number K050310 also corresponds to the Peritoneal Titanium Port.

b. Defendants sell the Peritoneal Titanium Port under the following SKU/model numbers, including but not limited to: 0603000, 0603006.[29]

Defendants' Regulatory Clearance of Power-Injectable IPCs

126. The **PowerPort Implantable Port** is one of Defendants' power-injectable Bard IPCs.

a. On or around March 23, 2006, BAS sought 510(k) clearance for the PowerPort Implanted Titanium Port with 8 Fr ChronoFlex Catheter, claiming its substantial equivalence to the 5 Fr Dual Lumen PowerPICC Catheter, PowerPort Implanted Titanium Port with 8 Fr ChronoFlex Catheter, and MiniLoc Safety Infusion Set as predicate devices.

b. The FDA cleared the PowerPort Implanted Titanium Port with 8 Fr ChronoFlex Catheter on July 14, 2006 (K060812).

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[27] *See, e.g.*, https://www.westcmr.com/0602230-we1-0602230.
[28] *See, e.g.*, https://www.esutures.com/product/0-in-date/102-bard/1060-ports/46334155-bardport-titanium-dome-implantable-port-8f-0602850/.
[29] *See, e.g.*, https://www.bd.com/en-us/products-and-solutions/products/product-page.0603000.

c. On information and belief, 510(k) number K060812 corresponds to the PowerPort Implantable Port.

d. On or around May 30, 2008, BAS sought 510(k) clearance for the PowerPort Implanted Port with Groshong Catheter, claiming its substantial equivalence to the PowerPort Implanted Titanium Port as a predicate device.

e. The FDA cleared the PowerPort Implanted Port with Groshong Catheter on June 4, 2008 (K081311).

f. On information and belief, 510(k) number K081311 corresponds to the PowerPort Implantable Port.

g. On or around July 3, 2019, BAS sought 510(k) clearance for the PowerPort Implantable Port, claiming its substantial equivalence to the PowerPort Implanted Port with Groshong Catheter, MRI PowerPort Implanted Port with 9.6 Fr Silicone Catheter, and the PowerPort Implanted Titanium Port with 8 Fr ChronoFlex Polyurethane Catheter as predicate devices.

h. The FDA cleared the PowerPort Implantable Port on July 8, 2019 (K181446).

i. On information and belief, 510(k) number K181446 corresponds to the PowerPort Implantable Port.

j. Defendants sell the PowerPort Implantable Port under the following SKU/model numbers, including but not limited to: 1708000, 1708001, 1708070, 1708071, 1709600, 1709601, 1759600, 1759601, 1778000, 1778001, 1778070, 1778071.[30]

127. The **PowerPort M.R.I. Implantable Port** is one of Defendants' power-injectable Bard IPCs.

a. On or around November 6, 2006, BAS sought 510(k) clearance for the PowerPort Implanted Polymeric Port with 8 Fr ChronoFlex Catheter, claiming its substantial equivalence to the PowerPort Implanted Titanium Port with 8 Fr ChronoFlex Catheter as a predicate device.

b. The FDA cleared the PowerPort Implanted Polymeric Port with 8 Fr ChronoFlex Catheter on January 25, 2007 (K063377).

c. On information and belief, 510(k) number K063377 corresponds to the PowerPort M.R.I. Implantable Port.

d. On or around December 3, 2007, BAS sought 510(k) clearance for the MRI PowerPort Implanted Port with 9.6 Fr Silicone Catheter, claiming its substantial equivalence to the MRI PowerPort Polymeric Implanted Port with 8 Fr ChronoFlex Polyurethane Catheter as a predicate device.

[30] *See, e.g.*, https://www.bd.com/en-us/products-and-solutions/products/product-page.1708000.

e. The FDA cleared the MRI PowerPort Implanted Port with 9.6 Fr Silicone Catheter on December 19, 2007 (K073423).

f. On information and belief, 510(k) number K073423 corresponds to the PowerPort M.R.I. Implantable Port.

g. On or around July 3, 2019, BAS sought 510(k) clearance for the PowerPort M.R.I. Implantable Port, claiming its substantial equivalence to the MRI PowerPort Implanted Port with 9.6 Fr Silicone Catheter and the PowerPort Implanted Polymeric Port with 8 Fr ChronoFlex Catheter as predicate devices.

h. The FDA cleared the PowerPort M.R.I. Implantable Port on July 8, 2019 (K181446).

i. On information and belief, 510(k) number K181446 corresponds to the PowerPort M.R.I. Implantable Port.

j. Defendants sell the PowerPort M.R.I. Implantable Port under the following SKU/model numbers, including but not limited to: 1808000, 1808001, 1808002, 1808070, 1808071, 1808300, 1809600, 1809601, 1809670, 1859600, 1859601, 1878000, 1878001, 1878070, 1878071.[31]

128. The **PowerPort isp Implantable Port** is one of Defendants' power-injectable Bard IPCs.

a. On or around August 8, 2007, BAS sought 510(k) clearance for the Titanium PowerPort isp Implanted Port with 8 Fr ChronoFlex Polyurethane Catheter, claiming its substantial equivalence to the Titanium PowerPort Implanted Port with 8 Fr ChronoFlex Polyurethane Catheter and the MRI PowerPort Polymeric Implanted Port with 8 Fr ChronoFlex Polyurethane Catheter as predicate devices.

b. The FDA cleared the Titanium PowerPort isp Implanted Port with 8 Fr ChronoFlex Polyurethane Catheter on November 1, 2007 (K072215).

c. On information and belief, 510(k) number K072215 corresponds to the PowerPort isp Implantable Port.

d. On or around August 28, 2007, BAS sought 510(k) clearance for the Titanium PowerPort isp Implanted Port with 6 Fr ChronoFlex Polyurethane Catheter, claiming its substantial equivalence to the Titanium PowerPort Implanted Port with 8 Fr ChronoFlex Polyurethane Catheter and the MRI PowerPort Polymeric Implanted Port with 8 Fr. ChronoFlex Polyurethane Catheter as predicate devices.

e. The FDA cleared the Titanium PowerPort isp Implanted Port with 6 Fr ChronoFlex Polyurethane Catheter on November 14, 2007 (K072549).

[31] *See, e.g.*, https://www.bd.com/en-us/products-and-solutions/products/product-page.1808000.

f. On information and belief, 510(k) number K072549 corresponds to the PowerPort isp Implantable Port.

g. On or around July 3, 2019, BAS sought 510(k) clearance for the PowerPort isp Implantable Port, claiming its substantial equivalence to the PowerPort Implanted Port with Groshong Catheter and Titanium PowerPort isp Implanted Port with 6 Fr ChronoFlex Polyurethane Catheter as predicate devices.

h. The FDA cleared the PowerPort isp Implantable Port on July 8, 2019 (K181446).

i. On information and belief, 510(k) number K181446 corresponds to the PowerPort isp Implantable Port.

j. Defendants sell the PowerPort isp Implantable Port under the following SKU/model numbers, including but not limited to: 1706050, 1706051, 1706060, 1706061, 1708050, 1708051, 1708060, 1708061, 1708160, 1708550, 1708551, 1708560, 1708561, 4708060, 4708061, 4708560, 4708561, CP00001, CP00002, CP00003, CP00009.[32]

129. The **PowerPort duo M.R.I. Implantable Port** is one of Defendants' power-injectable Bard IPCs.

a. On or around February 20, 2009, BAS sought 510(k) clearance for the PowerPort duo M.R.I. Implanted Port with 9.5 Fr Dual Lumen (D/L) ChronoFlex Polyurethane Catheter, claiming its substantial equivalence to the PowerPort M.R.I. Implanted Port with 8.0 Fr ChronoFlex Polyurethane Catheter and the X-Port duo Implanted Port with 9.5 Fr Dual Lumen D/L ChronoFlex Polyurethane Catheter as predicate devices.

b. The FDA cleared the PowerPort duo M.R.I. Implanted Port with 9.5 Fr Dual Lumen (D/L) ChronoFlex Polyurethane Catheter on March 27, 2009 (K090512).

c. On information and belief, 510(k) number K090512 corresponds to the PowerPort duo M.R.I. Implantable Port.

d. On or around July 3, 2019, BAS sought 510(k) clearance for the PowerPort duo M.R.I. Implantable Port, claiming its substantial equivalence to the PowerPort duo M.R.I. Implanted Port with 9.5 Fr Dual Lumen ChronoFlex Polyurethane Catheter as a predicate device.

e. The FDA cleared the PowerPort duo M.R.I. Implantable Port on July 8, 2019 (K181446).

f. On information and belief, 510(k) number K181446 corresponds to the PowerPort duo M.R.I. Implantable Port.

[32] *See, e.g.*, https://www.bd.com/en-us/products-and-solutions/products/product-page.1706050.

g. Defendants sell the PowerPort duo M.R.I. Implantable Port under the following SKU/model numbers, including but not limited to: 1829500, 1829570, 5829500, 5829502.[33]

130. The **PowerPort ClearVUE Slim Implantable Port** is one of Defendants' power-injectable Bard IPCs.

a. On or around September 19, 2012, BAS sought 510(k) clearance for the PowerPort ClearVUE Slim Implantable Port with 8F Polyurethane Catheter, claiming its substantial equivalence to the Titanium PowerPort isp with 8F Polyurethane Catheter as a predicate device.

b. The FDA cleared the PowerPort ClearVUE Slim Implantable Port with 8F Polyurethane Catheter on November 15, 2012 (K122899).

c. On information and belief, 510(k) number K122899 corresponds to the PowerPort ClearVUE Slim Implantable Port.

d. On or around July 3, 2019, BAS sought 510(k) clearance for the PowerPort ClearVUE Slim Implantable Port, claiming its substantial equivalence to the PowerPort ClearVUE Slim Implantable Port with 8 Fr Polyurethane Catheter as a predicate device.

e. The FDA cleared the PowerPort ClearVUE Slim Implantable Port on July 8, 2019 (K181446).

f. On information and belief, 510(k) number K181446 corresponds to the PowerPort ClearVUE Slim Implantable Port.

g. Defendants sell the PowerPort ClearVUE Slim Implantable Port under the following SKU/model numbers, including but not limited to: 1616000, 1616001, 1616070, 1616071, 1616300, 1616380, 1618000, 1618001, 1618070, 1618300, 1618380, 1676301, 1678300, 1678301, 5616000, 5616300, 5618000, 5618300, 5676300, 5676301, 5678300, 5678301, CP00005.[34]

131. The **PowerPort ClearVUE isp Implantable Port** is one of Defendants' power-injectable Bard IPCs.

a. On or around July 3, 2019, BAS sought 510(k) clearance for the PowerPort ClearVUE isp Implantable Port, claiming its substantial equivalence to the PowerPort Implanted Polymeric Port with 8 Fr ChronoFlex Catheter as a predicate device.

[33] *See, e.g.*, https://www.bd.com/en-us/products-and-solutions/products/product-page.1829500.
[34] *See, e.g.*, https://www.bd.com/en-us/products-and-solutions/products/product-page.1616000.

b. The FDA cleared the PowerPort ClearVUE isp Implantable Port on July 8, 2019 (K181446).

c. On information and belief, 510(k) number K181446 corresponds to the PowerPort ClearVUE isp Implantable Port.

d. Defendants sell the PowerPort ClearVUE isp Implantable Port under the following SKU/model numbers, including but not limited to: 1606052, 1606062, 1606362, 1606382, 1608052, 1608062, 1608362, 1608382, 1666362, 1668362, 1676300, 5606362, 5608062, 5608362, 5666362, 5668362, CP00004.[35]

132. The **PowerPort VUE M.R.I. Implantable Port** is one of Defendants' power-injectable Bard IPCs.

a. On or around July 3, 2019, BAS sought 510(k) clearance for the PowerPort VUE M.R.I. Implantable Port, claiming its substantial equivalence to the PowerPort Implanted Polymeric Port with 8 Fr ChronoFlex Catheter as a predicate device.

b. The FDA cleared the PowerPort VUE M.R.I. Implantable Port on July 8, 2019 (K181446).

c. On information and belief, 510(k) number K181446 corresponds to the PowerPort VUE M.R.I. Implantable Port.

d. Defendants sell the PowerPort VUE M.R.I. Implantable Port under the following SKU/model numbers, including but not limited to: 1806052, 1806062, 1808052, 1808062.[36]

133. The **PowerPort VUE Titanium Implantable Port** is one of Defendants' power-injectable Bard IPCs.

a. On or around July 3, 2019, BAS sought 510(k) clearance for the PowerPort VUE Implantable Port, claiming its substantial equivalence to the Titanium PowerPort isp Implanted Port with 6 Fr ChronoFlex Polyurethane Catheter as a predicate device.

b. The FDA cleared the PowerPort VUE Implantable Port on July 8, 2019 (K181446).

c. On information and belief, 510(k) number K181446 corresponds to the PowerPort VUE Titanium Implantable Port.

[35] *See, e.g.*, https://www.bd.com/en-us/products-and-solutions/products/product-page.1606052.

[36] *See, e.g.*, https://accessgudid.nlm.nih.gov/devices/00801741026935.

d. Defendants sell the PowerPort VUE Titanium Implantable Port under the following SKU/model numbers, including but not limited to: 1706052, 1706062, 1708052, 1708062.[37]

134. The **PowerPort isp M.R.I. Implantable Port** is one of Defendants' power-injectable Bard IPCs.

a. On or around July 3, 2019, BAS sought 510(k) clearance for the PowerPort isp M.R.I. Implantable Port, claiming its substantial equivalence to the MRI PowerPort Implanted Port with 9.6 Fr. Silicone Catheter and the PowerPort Implanted Polymeric Port with 8 Fr ChronoFlex Catheter as predicate devices.

b. The FDA cleared the PowerPort isp M.R.I. Implantable Port on July 8, 2019 (K181446).

c. On information and belief, 510(k) number K181446 corresponds to the PowerPort isp M.R.I. Implantable Port.

d. Defendants sell the PowerPort isp M.R.I. Implantable Port under the following SKU/model numbers, including but not limited to: 1806050, 1806051, 1806060, 1806061, 1808050, 1808051, 1808060, 1808061, 1808069, 1808360, 1808550, 1808551, 1808560, 1808561, 1809660, 1809661, 1859660, 1859661, 4808060, 4808061, 4808560, 4808561, 9808560.[38]

135. The **PowerPort Slim Implantable Port** is one of Defendants' power-injectable Bard IPCs.

a. On or around July 3, 2019, BAS sought 510(k) clearance for the PowerPort Slim Implantable Port, claiming its substantial equivalence to the PowerPort Implanted Port with Groshong Catheter, Titanium PowerPort isp Implanted Port with 6 Fr ChronoFlex Polyurethane Catheter, and Titanium PowerPort isp Implanted Port with 8 Fr ChronoFlex Polyurethane Cathether as predicate devices.

b. The FDA cleared the PowerPort Slim Implantable Port on July 8, 2019 (K181446).

c. On information and belief, 510(k) number K181446 corresponds to the PowerPort Slim Implantable Port.

d. Defendants sell the PowerPort Slim Implantable Port under the following SKU/model numbers, including but not limited to: 1716000, 1716001,

[37] *See, e.g.*, https://accessgudid.nlm.nih.gov/devices/00801741026539.
[38] *See, e.g.*, https://www.esutures.com/product/1-expired/102-bard/1060-ports/46247187-bard-powerport-isp-m.r.i.-implantable-port-6f-1806050/.

1716070, 1716071, 1716080, 1718000, 1718001, 1718070, 1718500, 1718501, 1718570, 1718571, CP00008.[39]

136. The **Vaccess CT Power-Injectable Implantable Port** is one of Defendants' power-injectable Bard IPCs.

a. On or around July 3, 2019, BAS sought 510(k) clearance for the Vaccess CT Power-Injectable Port, claiming its substantial equivalence to the PowerPort Implanted Polymeric Port with 8 Fr ChronoFlex Catheter and Titanium PowerPort isp Implanted Port with 6 Fr ChronoFlex Polyurethane Catheter as predicate devices.

b. The FDA cleared the Vaccess CT Power-Injectable Port on July 8, 2019 (K181446).

c. On information and belief, 510(k) number K181446 corresponds to the Vaccess CT Power-Injectable Port.

d. Defendants sell the Vaccess CT Power-Injectable Port under the following SKU/model numbers, including but not limited to: 7460000, 7480000, 7496000.[40]

137. The **Vaccess CT Low-Profile Titanium Power-Injectable Port** is one of Defendants' power-injectable Bard IPCs.

a. On or around July 3, 2019, BAS sought 510(k) clearance for the Vaccess CT Low-Profile Titanium Power-Injectable Port, claiming its substantial equivalence to the Titanium PowerPort isp Implanted Port with 6 Fr ChronoFlex Polyurethane Catheter and the Titanium PowerPort isp Implanted Port with 8 Fr ChronoFlex Polyurethane Catheter as predicate devices.

b. The FDA cleared the Vaccess CT Low-Profile Titanium Power-Injectable Port on July 8, 2019 (K181446).

c. On information and belief, 510(k) number K181446 corresponds to the Vaccess CT Low-Profile Titanium Power-Injectable Port.

d. Defendants sell the Vaccess CT Low-Profile Titanium Power-Injectable Port under the following SKU/model numbers, including but not limited to: 7360000, 7360001, 7380000.[41]

[39] *See, e.g.*, https://www.esutures.com/product/0-in-date/102-bard/1060-ports/46267717-bard-powerport-slim-implantable-port-6f-intermediate-1716000/.
[40] *See, e.g.*, https://accessgudid.nlm.nih.gov/devices/00801741027468.
[41] *See, e.g.*, https://accessgudid.nlm.nih.gov/devices/00801741027437.

138. The **PowerFlow Implantable Apheresis IV Port** is one of Defendants' power-injectable Bard IPCs.

a. On or around April 14, 2017, BAS sought 510(k) clearance for the PowerFlow Implantable Apheresis IV Port with 9.6 Fr ChronoFlex Catheter, claiming its substantial equivalence to the Bard CathLink 20 Titanium Port with Attachable Polyurethane Catheter.

b. The FDA cleared the PowerFlow Implantable Apheresis IV Port on April 17, 2017 (K163001).

c. On information and belief, 510(k) number K1630001 corresponds to the PowerFlow Implantable Apheresis IV Port.

d. Defendants sell the PowerFlow Implantable Apheresis IV Port under the following SKU/model numbers, including but not limited to: A710962.[42]

Defendants' Development of Barium-Sulfate Catheters

139. Barium sulfate is a radiopaque substance, meaning it is visible during diagnostic imaging.

140. Defendants designed and manufactured Bard IPCs with catheters comprised of a polymeric mixture of barium sulfate with polyurethane and/or silicone.

141. Some Bard IPCs have catheters comprised of a polymeric mixture of barium sulfate and polyurethane called "ChronoFlex."

a. On or around March 23, 2006, BAS sought 510(k) clearance for the PowerPort Implanted Titanium Port with 8 Fr ChronoFlex Catheter, claiming its substantial equivalence to, *inter alia*, the PowerPort Implanted Titanium Port with 8 Fr ChronoFlex Catheter (K050310) as a predicate device.

b. The predicate device that BAS identified had been cleared with a 6.6 Fr and 9.6 Fr Open-Ended Silicone Intravascular Catheter, not a ChronoFlex Catheter.

c. BAS's 510(k) application for the PowerPort Implanted Titanium Port with 8 Fr ChronoFlex Catheter did not identify the differences in the ChronoFlex catheter.

d. The FDA cleared the PowerPort Implanted Titanium Port with 8 Fr ChronoFlex Catheter on July 14, 2006 (K060812).

[42] *See, e.g.*, https://www.bd.com/en-us/products-and-solutions/products/product-page.A710962.

e. On information and belief, 510(k) number K060812 is the first 510(k) clearance of an IPC including ChronoFlex.

f. 510(k) number K050310 did not involve ChronoFlex.

g. On or around November 6, 2006, BAS sought 510(k) clearance for the PowerPort Implanted Polymeric Port with 8 Fr ChronoFlex Catheter, claiming its substantial equivalence to the PowerPort Implanted Titanium Port with 8 Fr ChronoFlex Catheter (K060812) as a predicate device.

h. The FDA cleared the PowerPort Implanted Polymeric Port with 8 Fr ChronoFlex Catheter on January 25, 2007 (K063377).

142. Defendants specifically advertise that their IPCs include the ChronoFlex catheter, including but not limited to the following Bard IPCs:

a. M.R.I. Ultra SlimPort Implantable Port;[43]

b. PowerFlow Implantable Apheresis IV Port;[44]

c. PowerPort ClearVUE isp Implantable Port;[45]

d. PowerPort ClearVUE Slim Implantable Port;[46]

e. PowerPort duo M.R.I. Implantable Port;[47]

f. PowerPort Implantable Port;[48]

g. PowerPort isp Implantable Port;[49]

h. PowerPort M.R.I. Implantable Port;[50]

i. Titanium Low-Profile Port;[51]

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[43] *See, e.g.*, https://www.bd.com/en-us/products-and-solutions/products/product-page.0605640#specifications.
[44] *See, e.g.*, https://www.bd.com/en-us/products-and-solutions/products/product-page.A710962#overview.
[45] *See, e.g.*, https://www.bd.com/en-us/products-and-solutions/products/product-page.1606052#specifications.
[46] *See, e.g.*, https://www.bd.com/en-us/products-and-solutions/products/product-page.1616000#specifications.
[47] *See, e.g.*, https://www.bd.com/en-us/products-and-solutions/products/product-page.1829500#specifications.
[48] *See, e.g.*, https://www.bd.com/en-us/products-and-solutions/products/product-page.1708001#specifications.
[49] *See, e.g.*, https://www.bd.com/en-us/products-and-solutions/products/product-page.1706050#specifications.
[50] *See, e.g.*, https://www.bd.com/en-us/products-and-solutions/products/product-page.1808000#specifications.
[51] *See, e.g.*, https://www.bd.com/en-us/products-and-solutions/products/product-page.0605490#specifications.

j. Titanium SlimPort Implantable Port;[52]

k. X-Port isp M.R.I. Implantable Port;[53]

l. X-Port Low-Profile Titanium Port;[54] and

m. PowerFlow Implantable Apheresis IV Port.[55]

143. All of Defendants' ChronoFlex catheters contain barium sulfate.

144. In contrast to ChronoFlex catheters (which are comprised of a polymeric mixture of barium sulfate and polyurethane), some Bard IPCs have catheters comprised of a polymeric mixture of barium sulfate and silicone.

145. Defendants' Groshong catheter is one such example.

146. Indeed, all of Defendants' Groshong catheters contain barium sulfate.

147. On information and belief, other Bard IPCs are alternatively comprised of a polymeric mixture of barium sulfate with silicone and polyurethane.

148. Regardless of the model, all Bard IPCs are comprised of a polymeric mixture containing barium sulfate.

149. Barium sulfate reduces the mechanical integrity of polyurethane in vivo.

150. Scientists have found that "the roughness and thrombogenicity of various catheters is associated with the presence of radiopaque particles embedded in the catheters."[56]

151. When exposed to the bloodstream, barium-sulfate particles dissociate from the surface of the polyurethane catheter over time.

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[52] *See, e.g.*, https://www.bd.com/en-us/products-and-solutions/products/product-page.0605550#specifications.

[53] *See, e.g.*, https://www.bd.com/en-us/products-and-solutions/products/product-page.0607510#specifications.

[54] *See, e.g.*, https://www.bd.com/en-us/products-and-solutions/products/product-page.0655870#specifications.

[55] *See* https://www.bd.com/en-us/products-and-solutions/products/product-families/powerflow-implantable-apheresis-iv-port#overview.

[56] Wildgruber et al., *Polyurethane versus silicone catheters for central venous port devices implanted at the forearm*, Euro. J. Cancer 59 (2016) 113-124.

152. This exposure alters the catheter's polymeric structure and degrades its mechanical properties.

153. Scientific literature shows that when barium-sulfate impregnated catheters are "expos[ed] … to the bloodstream," it causes "[barium sulfate] particle release, resulting in surface irregularities."[57]

154. Thus, "it is … obvious that the choice of the material itself and subsequent degradation when exposed to the bloodstream has significant impact on catheter durability and catheter-related complications."[58]

155. The mechanical integrity of the barium-sulfate impregnated polyurethane is also affected by the concentration of barium sulfate.

156. The mechanical integrity of the barium-sulfate impregnated polyurethane is further affected by the homogeneity of the modified polymer.

157. In addition, barium sulfate reduces the mechanical integrity of silicone in vivo.

158. When exposed to the bloodstream, the barium-sulfate particles dissociate from the surface of the silicone catheter over time.

159. This exposure alters the catheter's polymeric structure and degrades its mechanical properties.

160. The mechanical integrity of the barium-sulfate impregnated silicone is also affected by the concentration of barium sulfate.

161. The mechanical integrity of the barium-sulfate impregnated silicone is further affected by the homogeneity of the modified polymer.

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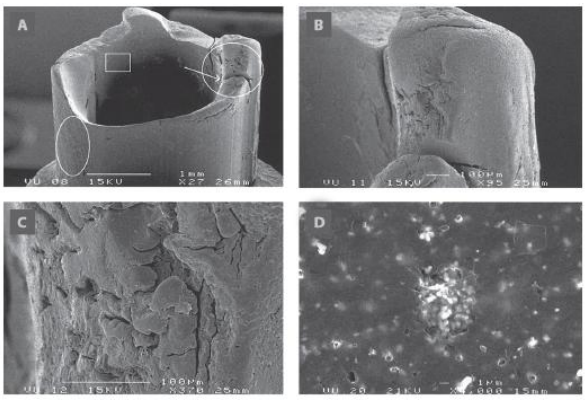
[57] Verbeke et al., *The role of polymer surface degradation and barium sulphate release in the pathogenesis of catheter-related infection*, Nephrol. Dial. Transpl. 25 (2010) 1207-1213.

[58] Wildgruber et al., *Polyurethane versus silicone catheters for central venous port devices implanted at the forearm*, Euro. J. Cancer 59 (2016) 113-124.

162. When the barium sulfate degrades in vivo, it causes cracks, fissures, divots, and/or pitting on the surface of the catheter.[59]



163. These cracks, fissures, divots, and/or pitting on the catheter's surface can cause catheter fracture.

164. Scientific literature shows that "the loss of barium sulphate filler particles near the surface of the catheter … results in preformed microscopic notches, which act as predetermined sites of fracture" and "complete mechanical failure."[60]

165. These cracks, fissures, divots, and pitting on the surface of the catheter can also harbor microbes.

166. Microbes on the surface of the catheter can cause infection.

167. Scientific literature shows that "[barium sulfate] particle release result[s] in surface irregularities predisposing to bacterial proliferation."[61]

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[59] Weijmer, M.C., *Strategies to reduce hemodialysis catheter-related complications* (2007) 69.

[60] Braun et al., *Mechanic and surface properties of central-venous port catheters after removal: A comparison of polyurethane and silicon rubber materials*, J. Mech. Behav. Biomed. Mats. 64 (2016) 281-291.

[61] Verbeke et al., *The role of polymer surface degradation and barium sulphate release in the pathogenesis of catheter-related infection*, Nephrol. Dial. Transpl. 25 (2010) 1207-1213.

168. Due to "continuous contact of the catheter with the tissues and the patient fluids," a biofilm is formed on the catheter, "which is a perfect environment for the development of infection."[62]

169. "[S]urface roughness" further "leads to enhanced bacterial colonization by providing shelter."[63]

170. Cracks, fissures, divots, and/or pitting on the surface of the catheter can also cause thrombosis by permitting the collection and proliferation of fibrinous material present in the bloodstream.

171. Indeed, "roughness of the catheter surface … promotes thrombogenicity."[64]

172. Additionally, collection of fibrinous material on the surface of a biomaterial potentiates infection by creating a hospitable surface environment for pathogens including bacteria and fungi.

173. In sum, "[IPC] implantations are associated with risk of infection and of thrombovascular, mechanical, and arrhythmogenic complications."[65]

174. "Surface irregularities resulting from the release of [barium sulfate] may represent a common causative pathway for these complications" and many others.[66]

175. At all relevant times, Defendants could have designed the catheters of Bard IPCs with radiopaque materials other than barium sulfate.

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[62] Nycz et al., *Surface analysis of long-term hemodialysis catheters made of carbothane before and after implantation in the patients' bodies*, Acta of Bioeng. & Biomech. 20 (2018) 47-53.

[63] *Id.*

[64] Verbeke et al., *The role of polymer surface degradation and barium sulphate release in the pathogenesis of catheter-related infection*, Nephrol. Dial. Transpl. 25 (2010) 1207-1213.

[65] Khalid et al., *Outcomes following port-a-catheter placement in the Medicare population*, Surg. Open Sci. 3 (2021) 39-43.

[66] Verbeke et al., *The role of polymer surface degradation and barium sulphate release in the pathogenesis of catheter-related infection*, Nephrol. Dial. Transpl. 25 (2010) 1207-1213.

a. Alternative radiopaque materials that are "widely used … for medical devices" include bismuth (Bi) and tungsten (W).[67]

b. On information and belief, Defendants could have obtained alternative radiopaque biomaterials from AdvanSource Biomaterials Corporation.

c. AdvanSource Biomaterials Corporation supplied Defendants with ChronoFlex.

176. At all relevant times, Defendants could have sheathed the catheters of Bard IPCs.

a. As early as 1982, in Patent No. 4,469,483, Baxter Travenol Laboratories patented a catheter with "three spaced, longitudinal radiopaque stripes made of barium sulfate" that were "generally encapsulated by the polytetrafluoroethylene of the catheter"—"basically solid lines of finely divided barium sulfate surrounded by the plastic material."

b. In or around 2007, medical device manufacturer Medtronic designed a catheter that was "fabricated from radiopaque silicone elastomer tubing with a barium-impregnated core," but Medtronic "encapsulated" the barium-sulfate core "in a clear silicone outer sheath."[68]

c. C.R. Bard had been assigned rights to Patent No. 8,636,794, first patented circa 2006, which disclosed a radiopaque graft device "comprising a layer of synthetic non-metallic material having a first surface and a second surface spaced apart from the first surface," with "a radiopaque marker at least partially embedded in the layer," whether that radiopaque marker consists of tantalum powder or barium sulfate.

177. At all relevant times, Defendants could have coated the catheter of Bard IPCs with a surface-modifying additive, functional coating, or antimicrobial coating.

a. In 2010, published and peer-reviewed scientific literature noted that "[barium-sulfate] release can be prevented by [surface-modifying additive] coating" and that "[o]btaining a smoother surface by [surface-modifying additive] coating thus reduces susceptibility to bacterial adhesion."[69]

178. Because Bard IPCs' catheters are not sheathed or otherwise coated, the barium sulfate on the catheter's surface contacts the patient's bloodstream.

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[67] Tilak M. Shah, *Radiopaque polymer formulations for medical devices*, Med. Plastics & Biomaterials (2000).

[68] https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K073139.

[69] Verbeke et al., *The role of polymer surface degradation and barium sulphate release in the pathogenesis of catheter-related infection*, Nephrol. Dial. Transpl. 25 (2010) 1207-1213.

179. Bard IPCs' labeling, including but not limited to the instructions for use, failed to warn about the fact that Bard IPCs' catheters were comprised of a polymeric mixture containing barium sulfate.

180. Defendants otherwise concealed and failed to warn about the fact that Bard IPCs' catheters were comprised of a polymeric mixture containing barium sulfate.

181. Bard IPCs' labeling, including but not limited to the instructions for use, failed to warn about the fact that barium sulfate disassociates from the catheter surface in vivo.

182. Defendants otherwise concealed and failed to warn about the fact that barium sulfate disassociates from the catheter surface in vivo.

183. Bard IPCs' labeling, including but not limited to the instructions for use, failed to warn about the fact that when barium sulfate disassociates, it causes injury, including but not limited to catheter fracture, infection, and thrombosis.

184. Defendants otherwise concealed and failed to warn about the fact that when barium sulfate disassociates, it causes injury, including but not limited to catheter fracture, infection, and thrombosis.

Defendants' Development of Port Reservoirs

185. Defendants manufacture several Bard IPCs utilizing polyoxymethylene ("POM") in the construction of the port reservoir, including but not limited to:

a. PowerPort M.R.I Implantable Port; and

b. X-Port isp M.R.I. Implantable Port.

186. POM is an acetal thermoplastic polymer material.

187. POM is commonly marketed under the trade name Delrin.

188. POM is a lower-cost material in comparison to titanium.

189. POM is known to undergo oxidative degradation, which is the disintegration of macromolecules by the action of oxygen on the substrate.

190. POM is known to undergo oxidative degradation during processing.

191. POM is known to undergo oxidative degradation in vivo.

192. POM is known to undergo oxidative degradation when exposed to radiography.

193. Oxidative degradation reduces the mechanical properties of the polymer.

194. Oxidative degradation results in the release of toxic formaldehyde as a degradation product.

195. The formulation of POM that Defendants utilize in the manufacture of their plastic Bard IPCs is Delrin 500 NC010.

196. Delrin 500 NC010 is provided by DuPont.

197. DuPont Delrin 500 NC010 comes with a Medical Caution Statement that prohibits its use for "applications involving permanent implantation in the human body" as well as "permanent contact with internal body fluid or tissues."[70]

198. DuPont Delrin 500 NC010 comes with a Medical Caution Statement that further prohibits its use for "medical applications involving brief or temporary implantation in the human body or contact with internal body fluid or tissues" absent explicit permission from DuPont.[71]

199. Delrin 500 NC010 is not compliant with the applicable specification standards for POM used in medical devices, including ASTM F1855-00.

200. Defendants' manufacturing process for the POM-containing Bard IPCs lack adequate measures to stabilize the POM to prevent oxidative degradation.

201. Reduction of the mechanical properties of POM precipitate physical degradation of the surface of the polymer, including formation of cracks, fissures, and other physical defects.

202. As detailed above, such surface defects increase the risk of fracture, infection, and thrombosis.

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[70] https://www.fluoroprecision.co.uk/pdf/medical-statement.pdf; https://www.campusplastics.com/campus/en/datasheet/Delrin%C2%AE+500P+NC010/DuPont+Engineering+Polymers/52/b50aa2c1.

[71] *Id.*

203. Colonization of the POM surface defects by bacteria often leads to formation of biofilm in the port reservoir and catheter.

204. At all relevant times, Defendants could have designed Bard IPCs with more stable plastic materials, including but not limited to:

a. Manufacturing the plastic port reservoir using POM stabilized with an effective ensemble of antioxidant additives, including hindered phenolic antioxidant and a secondary thermostabilizer such as a phosphite ester;

b. Manufacturing the plastic port reservoir using ultra-high molecular weight polyethylene ("UHMWP"); or

c. Manufacturing the plastic port reservoir with a formulation of POM that renders it suitable for medical applications.

205. In addition, as noted above, many Bard IPCs have a port reservoir with three raised palpation bumps on the anterior surface of the septum.

206. The stated purpose of the palpation bumps is to aid in identification of Bard IPC as a power-injectable device.

207. After implantation, the palpation bumps cause undue compression stress on the tissue of the subcutaneous pocket into which the port is placed.

208. Such compression stress leads to ulceration and tissue necrosis, which potentiates port infections and catheter infections.

209. Such compression stress leads to ulceration and tissue necrosis, which causes erosion of the port through the patient's skin.

210. The incidence of tissue erosion associated with Bard IPCs is unreasonably high, such that multiple medical institutions, including Massachusetts General Hospital, have implemented policies prohibiting the placement of ports with palpation bumps due to the high rate of erosion.[72]

211. At all relevant times, Defendants could have designed Bard IPCs without palpation bumps to reduce the risk of port infections, catheter infections, and erosion.

[72] *E.g.*, https://www.mghpcs.org/EED/CL/Assets/documents/modules/central-line-portal-infusion-lecture-2018.pdf.

Post-Market Performance Reveals That Bard IPCs Fail to Perform as Expected

212. Soon after Bard IPCs were introduced to market, Defendants received reports from patients and healthcare providers reporting that Bard IPCs harbored bacteria and/or caused infection.

213. Defendants also received reports from patients and healthcare providers reporting that Bard IPCs fractured, migrated, and/or perforated tissues, vessels, and/or organs.

214. Defendants also received reports from patients and healthcare providers reporting that Bard IPCs caused thromboembolism (blood clots).

215. Reports of these injuries in the absence of medical provider error were recorded and reported to Defendants prior to the implantation of Bard IPC in Plaintiffs.

216. Defendants intentionally concealed the frequency, quantity, and nature of these reports from Plaintiffs and Plaintiffs' healthcare providers.

217. Defendants failed to establish, maintain, and conduct an adequate post-market surveillance system.

218. Ultimately, Defendants failed to recall Bard IPCs from the market.

219. Although Defendants conducted a limited recall of approximately 360 BardPort Titanium Implantable Ports, Defendants never recalled the entire line of Bard IPCs.[73]

Defendants Knew or Should Have Known Bard IPCs Were Defective and Dangerous

220. According to Defendants' Code of Conduct, Defendants know that to "[e]nsur[e] product safety and quality," they must "[f]ollow quality system regulations, standards, policies and procedures, and good manufacturing practices."[74]

221. Defendants also know that "[w]hen patient safety is involved," as with IPCs, "attention to detail" and "consistency at each step" is "require[d]."[75]

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[73] *See* https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRes/res.cfm?id=179814.
[74] https://www.bd.com/documents/corporate/BD_Code-of-Conduct_EN.pdf.
[75] https://www.bd.com/en-us/products-and-solutions/products/product-families/bd-port-access-kits-and-needles.

222. Defendants violated their Code of Conduct by "[b]ypassing quality controls" and "tak[ing] shortcuts that comprise the quality [and] safety of [their] products," including Bard IPCs.[76]

223. On information and belief, Defendants failed to perform (or failed to adequately perform) tests to ensure the safety the palpation-bump design used in Bard IPCs.

224. On information and belief, Defendants failed to perform (or failed to adequately perform) test to ensure the biodurability and biocompatibility of POM used in Bard IPCs.

225. On information and belief, Defendants failed to perform (or failed to adequately perform) tests to ensure the biodurability and biocompatibility of barium-sulfate impregnated catheters used in Bard IPCs.

226. For example, Defendants failed to test (or failed to adequately test) the performance of barium-sulfate impregnated catheters when exposed to the bloodstream.

227. On information and belief, Defendants' techniques for mixing or integrating barium sulfate with the polyurethane and/or silicone polymer were inadequate.

228. Defendants' manufacturing process resulted in too high a concentration of barium-sulfate particles.

229. This improper mixing caused improperly high viscosity of the raw polyurethane and/or silicone before polymerization and improper mixing of barium-sulfate particles within the polymer matrix.

230. This improper mixing also caused pockets of barium sulfate and entrapped air throughout the catheter, including on its inner and outer surfaces.

231. On information and belief, Defendants' temperature for polymerization was inadequate.

[76] https://www.bd.com/documents/corporate/BD_Code-of-Conduct_EN.pdf

232. On information and belief, as a result of the foregoing acts and omissions, some catheters were out of specification for the proper concentration of barium sulfate (i.e., too much or too little barium sulfate, even if homogeneously distributed throughout the surface of the catheter).

233. On information and belief, as a result of the foregoing acts and omissions, some catheters were out of specification for the proper distribution of barium sulfate (i.e., non-uniform distribution of the barium sulfate throughout, resulting in areas of over- or under-concentration).

234. On information and belief, Defendants failed to perform (or failed to adequately perform) quality-control tests to ensure the specified concentration of the barium sulfate in Bard IPCs.

235. On information and belief, Defendants failed to perform (or failed to adequately perform) quality-control tests to ensure the homogeneity of the barium sulfate throughout Bard IPCs.

236. Defendants knew or should have known that Bard IPCs, even if made in conformance with Defendants' specifications, were defective in design.

237. Rather than alter the design of Bard IPCs to make them safer, Defendants chose to continue their efforts to promote their defective products.

238. Defendants knew or should have known that Bard IPCs, even if made in conformance with Defendants' specifications, were defective because Defendants failed to provide adequate warnings and/or instructions.

239. Rather than warn patients and healthcare providers of the dangers associated with Bard IPCs, Defendants chose to continue their efforts to promote their defective products.

240. Defendants knew or should have known that Bard IPCs had a substantially higher failure rate than other similar devices on the market, yet Defendants failed to warn of that fact.

a. Defendants knew or should have known that Bard IPCs had a substantially higher risk of fracture, migration, and/or perforation and resulting injury than other similar venous access devices on the market, yet Defendants failed to warn of that fact.

b. Defendants knew or should have known that Bard IPCs had a substantially higher risk of infection and resulting injury than other similar venous access devices on the market, yet Defendants failed to warn of that fact.

c. Defendants knew or should have known that Bard IPCs had a substantially higher risk of thrombosis and resulting injury than other similar venous access devices on the market, yet Defendants failed to warn of that fact.

Defendants Misrepresented Bard IPCs' Benefits and Concealed Their Risks

241. According to Defendants' Code of Conduct, "do[ing] what is right" means "mak[ing] accurate [and] truthful claims" about Bard IPCs "backed up by appropriate product testing or clinical data."[77]

242. Despite Defendants' knowledge of injury reports, Defendants continued to actively and aggressively market Bard IPCs as safe.

243. Defendants thus violated their Code of Conduct by "[m]ak[ing] claims that are not supported by appropriate product testing or clinical data," "[e]xaggerat[ing] the benefits of [their] products," and "hid[ing] the potential risks of using them."[78]

244. In addition, Defendants falsely claimed that their ChronoFlex polyurethane catheters were less likely to fracture than other venous access devices.

a. For example, Defendants claimed their "ChronoFlex polyurethane catheter[s] ha[ve] less propensity for surface biodegradation, making [them] more resistant to environmental stress cracking."[79]

b. On information and belief, this is false because Defendants' ChronoFlex catheters had a greater propensity for fracture than other catheters.

c. Defendants concealed and failed to warn about the fact that Bard IPCs suffered from design and/or manufacturing defects with regard to barium sulfate and/or POM that increased the risk of fracture.

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[77] https://www.bd.com/content/dam/bd-assets/bd-com/en-us/document/policy/code-of-conduct/code-of-conduct-english.pdf.
[78] *Id.*
[79] *E.g.*, https://healthdocbox.com/amp/75754235-Incontinence/Ports-setting-the-standard-with-a-comprehensive-family-of-ports.html.

245. Defendants falsely claimed that the risk of IPC fracture is limited to physician or patient error.

a. For example, Defendants stated "[c]atheter dislodgement" can be caused by "poor site selection, loosening of the catheter due to inadequate stabilization and lack of proper securement, as well as patient manipulation such as arm or body movement."[80]

b. Defendants also represented that "the potential exists for serious complications, including … [catheter] [d]amage or [b]reakage," but this warning was limited to fracture "due to [c]ompression between the [c]lavicle and [f]irst [r]ib," otherwise known as "pinch-off syndrome."[81]

c. The foregoing statements are false because the risk of IPC fracture is not limited to physician or patient error.

d. Defendants concealed and failed to warn about the fact that the catheter may become damaged or break due to device's degradation with regard to barium sulfate and/or POM.

246. Defendants falsely claimed that Bard IPCs were less likely to become infected than external catheters.

a. For example, Defendants claimed that IPCs "[m]ay have less potential for infection than external catheters."[82]

b. On information and belief, this is false because Bard IPCs had a greater risk of infection than external catheters.

c. Defendants concealed and failed to warn about the fact that Bard IPCs suffered from design and/or manufacturing defects with regard to barium sulfate, POM, and/or palpation bumps that increased the risk of infection.

247. Defendants falsely claimed that the risk of IPC infection is limited to physician or patient error.

a. For example, Defendants stated "catheter-related bloodstream infection[s]" can be caused by "breaking asepsis during insertion or care and maintenance; seeding bacteria from another site of infection; and ingress of bacteria due to non-intact dressing or suboptimal insertion site."[83]

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[80] *E.g.*, https://www.bd.com/en-us/products-and-solutions/solutions/vascular-access-management#accordion-7e44b2e42b-item-ba31e5ea28.

[81] *E.g.*, JPML Dkt. 20-3 at 5.

[82] *E.g.*, https://portready.com/infusion-therapy/healthcare-professionals/.

[83] *E.g.*, https://www.bd.com/en-us/products-and-solutions/solutions/vascular-access-management#accordion-7e44b2e42b-item-ba31e5ea28.

b. This is false because the risk of Bard IPC infection is not limited to physician or patient error.

c. Defendants concealed and failed to warn about the fact that the port and/or catheter may become infected due to device degradation with regard to barium sulfate and/or POM, or due to palpation bumps.

248. Defendants falsely claimed Bard IPCs were biocompatible.

a. For example, Defendants claimed the Titanium SlimPort Implantable Port was "[b]iocompatible."[84]

b. For example, Defendants' Instruction for Use for the PowerPort Implantable Port stated that "[a]ll materials are biocompatible."[85]

c. For example, Defendants' Instructions for Use for the BardPort, SlimPort, and X-Port IPCs stated that "[a]ll materials are biocompatible."[86]

d. For example, Defendants claimed the composition of "[m]edical-grade radiopaque silicone construction [of Bard IPCs] ensures biocompatibility."[87]

e. The foregoing statements are false because, as designed, the barium sulfate is not biocompatible.

f. The foregoing statements are false because, as designed, the POM is not biocompatible.

g. Defendants concealed and failed to warn about the fact that barium sulfate was not biocompatible.

h. Defendants concealed and failed to warn about the fact that POM was not biocompatible.

249. Defendants falsely claimed that Bard IPCs were durable.

a. For example, Defendants claimed that their "ChronoFlex polyurethane catheters have been proven to exhibit superior biodurability compared with other polyurethane catheters."[88]

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[84] *E.g.*, https://www.bd.com/en-us/products-and-solutions/products/product-page.0605550#overview.
[85] *E.g.*, JPML Dkt. 20-3 at 3.
[86] *E.g.*, https://www.bd.com/content/dam/bd-assets/na/peripheral-intervention/documents/instructions-for-use/BAW0738034.pdf.
[87] *E.g.*, https://healthdocbox.com/amp/75754235-Incontinence/Ports-setting-the-standard-with-a-comprehensive-family-of-ports.html.
[88] *E.g.*, *id.*

b. For example, Defendants claimed the PowerPort ClearVUE Implantable Port was made of a "[d]urable plastic port and ChronoFlex Polyurethane Catheter."[89]

c. For example, Defendants claimed the Titanium SlimPort Implantable Port was "[d]urable."[90]

d. The foregoing statements are false because Bard IPCs are not durable with regard to barium sulfate and/or POM.

e. Defendants concealed and failed to warn about the fact that Bard IPCs were not durable.

250. Defendants falsely claimed that Bard IPCs were safe and effective for long-term use.

a. For example, Defendants claimed that Bard IPCs "[c]an remain in place and be functional for many years."[91]

b. For example, Defendants claimed that the PowerPort Implantable Port "can stay in place as long as [the patient's] doctor determines that [the patient] need[s] it."[92]

c. For example, Defendants claimed that the PowerPort ClearVue Implantable Port "enable[s] uninterrupted imaging and treatment."[93]

d. For example, Defendants claimed that the PowerFlow Implantable Apheresis IV Port was "designed for long device life" and "[o]ptimized for [l]ong [d]evice [l]ife."[94]

e. The foregoing statements are false because Bard IPCs failed to function as advertised, often requiring early explantation before the end of the device's intended useful safe life.

f. Defendants concealed and failed to warn about the fact that Bard IPCs are at a higher risk of complications, including but not limited to infection and fracture, that jeopardize the device's intended useful safe life.

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[89] *E.g.*, https://www.bd.com/en-us/products-and-solutions/products/product-families/powerport-clearvue-implantable-ports.
[90] *E.g.*, https://www.bd.com/en-us/products-and-solutions/products/product-page.0605550#overview.
[91] *E.g.*, https://portready.com/infusion-therapy/healthcare-professionals/.
[92] *E.g.*, https://www.bd.com/assets/documents/guides/user-guides/PI_PV_PowerPort-Implantable-Port-Patient-Guide_UG_EN.pdf.
[93] *E.g.*, https://www.bd.com/en-us/products-and-solutions/products/product-families/powerport-clearvue-implantable-ports.
[94] *E.g.*, https://portready.com/apheresis-therapy/healthcare-professionals/.

251. Defendants falsely claimed that Bard IPCs could withstand repeated venous access.

a. For example, Defendants claimed that the PowerPort Implantable Port can withstand "208 punctures."[95]

b. This is false because, on information and belief, Defendants' IPCs often failed before 208 accesses.

c. For example, Defendants claimed that the Titanium Dome Implanted Port could "withstand[] more than 2,000 punctures with a 22 gauge non-coring needle and 1,000 punctures with a 19 gauge non-coring needle."[96]

d. This is false because, on information and belief, Bard IPCs often failed before 1,000 or 2,000 accesses.

e. For example, Defendants claimed that the PowerFlow Implantable Apheresis IV Port would withstand "up to 1,000 accesses."[97]

f. This is false because, on information and belief, Bard IPCs often failed before 1,000 accesses.

g. Defendants concealed and failed to warn about the fact that Bard IPCs had insufficient structural integrity to withstand repeated, long-term use.

252. Defendants falsely claimed that Bard IPCs were cosmetically appealing.

a. For example, Defendants claimed the PowerPort isp Implantable Port was "[c]osmetically appealing with compact size."[98]

b. For example, Defendants claimed the Titanium SlimPort Implantable Port was "[c]osmetically more appealing" and "[l]ess noticeable" with its "[r]educed incision … size."[99]

[95] *E.g.*, https://www.bd.com/assets/documents/PDH/BDPI_PowerFlow_BD-19821_PowerFlow-vs-Ports-Tech-Sheet.pdf.
[96] *E.g.*, https://medic-kart.com/shop/bard-dome-implantable-port-titanium-single-lumen-port-with-attachable-8fr-goshoring-catheter/.
[97] *E.g.*, https://www.bd.com/en-us/products-and-solutions/products/product-families/powerflow-implantable-apheresis-iv-port.
[98] *E.g.*, https://www.bd.com/en-us/products-and-solutions/products/product-page.1706050#overview.
[99] *E.g.*, https://www.bd.com/en-us/products-and-solutions/products/product-page.0605550#overview.

c. For example, Defendants claimed the PowerPort ClearVUE Slim Implantable Port is "[i]deal for … cosmetically-minded patient[s]" and its "[s]hape aids in the formation of small incisions."[100]

d. Defendants concealed and failed to warn about the fact that Bard IPCs may become infected, requiring explantation and disfigurement.

253. Defendants falsely claimed that they conduct adequate post-market surveillance to ensure patient safety.

a. For example, Defendants claim that they "monitor[ed] product performance" to "identify[] early warning signs of potential quality issues."[101]

b. For example, Defendants claim that they use "data-driven insights [that] may trigger [Defendants] to initiate field actions to protect patient safety."[102]

c. The foregoing statements are false because Defendants disregarded post-market evidence of device failure and failed to recall or redesign Bard IPCs.

d. Defendants concealed and failed to warn about the fact that they did not conduct adequate post-market surveillance.

254. Defendants concealed—and continue to conceal—the likelihood of complications caused by Bard IPCs from Plaintiffs and Plaintiffs' healthcare providers.

255. Defendants concealed—and continue to conceal—the severity of complications caused by Bard IPCs from Plaintiffs and Plaintiffs' healthcare providers.

256. Defendants concealed—and continue to conceal—their knowledge of Bard IPCs' defects and dangers from Plaintiffs and Plaintiffs' healthcare providers.

Defendants Caused Plaintiffs' Injuries

257. Plaintiffs were implanted with Bard IPCs.

258. Plaintiffs relied upon Defendants' warranties, representations, and concealment to Plaintiffs' detriment.

259. Plaintiffs' healthcare providers relied upon Defendants' warranties, misrepresentations, and concealment to Plaintiffs' detriment.

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[100] *E.g.*, https://www.bd.com/assets/documents/pdh/initial/BPV-PRT1-0316-0015-v1.1-ClearVUE-Family-Brochure.pdf.
[101] *E.g.*, https://www.bd.com/en-us/about-bd/quality-at-bd#product.
[102] *E.g.*, *id.*

260. As a direct and proximate result of using Bard IPCs, Plaintiffs suffered severe and life-threatening complications, including but not limited to:

a. Catheter fracture;

b. Catheter migration;

c. Catheter perforation of vessels and/or organs, including the heart;

d. Infection;

e. Thromboembolism; and/or

f. Death.

261. These complications were often accompanied by and associated with reports of other severe and life-threatening patient injuries, including but not limited to:

a. Hemorrhage;

b. Pulmonary embolism;

c. Hematomas;

d. Cardiac/pericardial tamponade;

e. Cardiac arrhythmia and other symptoms similar to myocardial infarction;

f. Sepsis, including septic shock and/or organ failure;

g. Severe and persistent pain; and

h. Death.

262. As a direct and proximate result of using Bard IPCs and suffering the foregoing complications, Plaintiffs required medical treatment, including but not limited to:

a. Hospitalization;

b. Emergent surgery or catheterization to remove catheter fragments;

c. Antibiotic treatment;

d. Explantation of Bard IPCs; and/or

e. Implantation of a replacement IPC or other venous access device.

263. As a direct and proximate result of having Bard IPCs implanted in them, Plaintiffs have suffered permanent and continuous injuries and damages.

264. The injuries suffered and damages sought by Plaintiffs ("Injuries and Damages") may include, without limitation: wrongful death of a spouse, child, parent, or other legally-cognizable relationship; bodily injuries of any type (including, without limitation, catheter fracture, migration, perforation of vessels and/or organs, infection, thromboembolic events, and cardiovascular injuries); past and future pain and suffering, emotional distress, mental anguish, and loss of enjoyment of life; past and future disability and impairment; scarring, disfigurement, and dismemberment; diminished capacity; loss of consortium; hedonic damages; increased risk of future severe and permanent injuries; ongoing fear and anxiety from future injuries, including but not limited to cardiac tamponade; past and future medical expenses and caregiving costs; past and future lost wages and loss of earning capacity; and any other form of damages under the law of any forum which governs any individual case.

265. Had Plaintiffs known the truth about Bard IPCs, Plaintiffs would not have consented to implantation of those devices.

266. Had Plaintiffs' healthcare providers known the truth about Bard IPCs, Plaintiffs' healthcare providers would not have prescribed Bard IPCs nor implanted them in Plaintiffs.

COUNT I: DESIGN DEFECT – STRICT LIABILITY

267. Plaintiffs restate the allegations above as if fully rewritten herein.

268. Plaintiffs plead this claim under the New Jersey Products Liability Act, N.J.S.A. 2A:58-C, *et. seq*.

269. At all relevant times, Defendants developed, designed, tested, manufactured, packaged, labeled, marketed, advertised, distributed, sold, and otherwise placed Bard IPCs into the stream of commerce for use by consumers, such as Plaintiffs, in the United States.

270. Plaintiffs were foreseeable users of Bard IPCs.

271. Bard IPCs were expected to and did reach Defendants' intended consumers, handlers, and persons coming into contact with the product without substantial change in the condition in which they were developed, designed, tested, manufactured, packaged, labeled, marketed, advertised, distributed, and sold by Defendants.

272. At all relevant times, Bard IPCs contained a defective and unreasonably dangerous condition because they are defective in design and are dangerous for use by the public in general and Plaintiffs in particular.

273. These design defects include but are not limited to the use of barium sulfate in the catheter; the absence of sheathing or coating surrounding the catheter; the use of POM in the port reservoir; the presence of palpation bumps; and a design that could not withstand repeated, long-term use as advertised.

274. These design defects existed even if Defendants exercised reasonable care.

275. Bard IPCs, as developed, designed, tested, manufactured, packaged, labeled, marketed, advertised, distributed, and sold by Defendants, are defective in design and formulation and unreasonably dangerous because the foreseeable risks exceeded the alleged benefits associated with their use.

276. Bard IPCs, as developed, designed, tested, manufactured, packaged, labeled, marketed, advertised, distributed, and sold by Defendants, are defective in design and formulation and unreasonably dangerous because Bard IPCs were more dangerous than the ordinary customer would expect.

277. Defendants knew that the design defects made Bard IPCs unreasonably dangerous to Plaintiffs.

278. It was unreasonable for a manufacturer with such knowledge to place Bard IPCs on the market without changing the design.

279. At the time Bard IPCs left Defendants' possession and control, Bard IPCs contained a defective and unreasonably dangerous condition.

280. At the time Plaintiffs used Bard IPCs, Bard IPCs contained a defective and unreasonably dangerous condition.

281. Physicians implanted Bard IPCs as instructed via the Instructions for Use and in a foreseeable manner as normally intended, recommended, promoted, and marketed by Defendants.

282. Plaintiffs received and utilized Bard IPCs in a foreseeable manner as normally intended, recommended, promoted, and marketed by Defendants.

283. At the time Defendants placed Bard IPCs into the stream of commerce, safer alternative designs existed that were attainable, available, and feasible commercially, technologically, and scientifically.

284. These safer alternative designs would have prevented and/or mitigated the harm resulting in Plaintiffs' Injuries and Damages without substantially impairing the reasonably anticipated or intended function of Bard IPCs.

285. The defective and unreasonably dangerous condition of Bard IPCs was a substantial factor in causing Plaintiffs' Injuries and Damages.

286. The Plaintiffs' Injuries and Damages would not have happened or occurred had Bard IPCs not been defective and unreasonably dangerous.

287. As a direct and proximate result of the defective and unreasonably dangerous condition of Bard IPCs, Plaintiffs suffered Injuries and Damages.

288. Plaintiffs in the consolidated case *In re: Bard Implanted Port Catheter Products Liability Litigation* (MDL 3081), 2:23-md-03081-DGC (USDC D. Arizona) served general (non-bellwether specific) reports from experts which explain in detail Plaintiffs' allegations as to Bard IPCs. Plaintiffs incorporate by reference each of the general expert reports and allegations as if set forth herein.

COUNT II: FAILURE TO WARN/INSTRUCT – STRICT LIABILITY

289. Plaintiffs restate the allegations above as if fully rewritten herein.

290. Plaintiffs plead this claim under the New Jersey Products Liability Act, N.J.S.A. 2A:58-C, *et. seq*.

291. At all relevant times, Defendants developed, designed, tested, manufactured, packaged, labeled, marketed, advertised, distributed, sold, and otherwise placed Bard IPCs

into the stream of commerce for use by consumers, such as Plaintiffs, via their physicians, in the United States.

292. Plaintiffs, via their physicians, were foreseeable users of Bard IPCs.

293. Bard IPCs were expected to and did reach Defendants' intended consumers, handlers, and persons coming into contact with the product without substantial change in the condition in which they were developed, designed, tested, manufactured, packaged, labeled, marketed, advertised, distributed, and sold by Defendants.

294. At all relevant times, Bard IPCs contained a defective and unreasonably dangerous condition because they were defective in warnings and/or instructions, including during any training sessions or similar instructive events or processes with Plaintiffs' healthcare providers, and through all marketing and sales related documents and communications, including via sales representatives, provided to Plaintiffs' healthcare providers, and were dangerous for use by the public in general and Plaintiffs in particular.

295. These informational defects include, but are not limited to, failing to warn (or inadequately warning) about the risk of fracture, infection, and thrombosis from the use of barium sulfate in the catheter; the risk of fracture, infection, and thrombosis from the use of POM in the port reservoir; the risk of necrosis and infection from the presence of palpation bumps; and the limited life expectancy of Bard IPCs.

296. These informational defects existed even if Defendants exercised reasonable care.

297. Bard IPCs, as developed, designed, tested, manufactured, packaged, labeled, marketed, advertised, distributed, and sold by Defendants, were defective in warnings and/or instructions and unreasonably dangerous because the foreseeable risks exceeded the alleged benefits associated with the use of Bard IPCs.

298. Bard IPCs, as developed, designed, tested, manufactured, packaged, labeled, marketed, advertised, distributed, and sold by Defendants, were defective in warnings and/or instructions and unreasonably dangerous because Bard IPCs are more dangerous

than the ordinary customer would expect, and the true risk-benefit profile was not disclosed.

299. Defendants knew that the warnings and/or instructions defects made Bard IPCs unreasonably dangerous to Plaintiffs.

300. At the time Bard IPCs left Defendants' possession and control, Bard IPCs contained a defective and unreasonably dangerous condition.

301. At the time Plaintiffs and their physicians used Bard IPCs, Bard IPCs contained a defective and unreasonably dangerous condition.

302. Physicians implanted Bard IPCs as instructed via the Instructions for Use and in a foreseeable manner as normally intended, recommended, promoted, and marketed by Defendants, including during any training sessions or similar instructive events or processes with Plaintiffs' healthcare providers, and through all marketing and sales related documents and communications, including via sales representatives, provided to Plaintiffs' healthcare providers.

303. Plaintiffs received and utilized Bard IPCs in a foreseeable manner as normally intended, recommended, promoted, and marketed by Defendants, including during any training sessions or similar instructive events or processes with Plaintiffs' healthcare providers, and through all marketing and sales related documents and communications, including via sales representatives, provided to Plaintiffs' healthcare providers.

304. At the time Defendants placed their defective and unreasonably dangerous Bard IPCs into the stream of commerce, they could have and should have provided alternative warnings and/or instructions and information, including during any training sessions or similar instructive events or processes with Plaintiffs' healthcare providers, and through all marketing and sales related documents and communications, including via sales representatives, provided to Plaintiffs' healthcare providers that were attainable, available, and feasible commercially, technologically, and scientifically.

305. These alternative warnings and/or instructions and information would have prevented and/or mitigated the harm resulting in Plaintiffs' Injuries and Damages without substantially impairing the reasonably anticipated or intended function of Bard IPCs.

306. Had Plaintiffs received proper or adequate warnings and/or instructions as to the risks of Bard IPCs, Plaintiffs would have heeded the warnings and/or instructions.

307. Had Plaintiffs and their physicians received proper or adequate warnings and/or instructions as to the risks of Bard IPCs, including during any training sessions or similar instructive events or processes with Plaintiffs' healthcare providers, and through all marketing and sales related documents and communications, including via sales representatives provided to Plaintiffs' healthcare providers, Plaintiffs' healthcare providers would have heeded the warnings and/or instructions.

308. The defective and unreasonably dangerous condition of Bard IPCs was a substantial factor in causing Plaintiffs' Injuries and Damages.

309. The Plaintiffs' Injuries and Damages would not have occurred had Bard IPCs not been defective and unreasonably dangerous.

310. As a direct and proximate result of the defective and unreasonably dangerous condition of Bard IPCs, Plaintiffs suffered Injuries and Damages.

311. Plaintiffs in the consolidated case *In re: Bard Implanted Port Catheter Products Liability Litigation* (MDL 3081), 2:23-md-03081-DGC (USDC D. Arizona) served general (non-bellwether specific) reports from experts which explain in detail Plaintiffs' allegations as to Bard IPCs. Plaintiffs incorporate by reference each of the general expert reports and allegations as if set forth herein.

COUNT III: MANUFACTURING DEFECT – STRICT LIABILITY

312. Plaintiffs restate the allegations above as if fully rewritten herein.

313. Plaintiffs plead this claim under the New Jersey Products Liability Act, N.J.S.A. 2A:58-C, *et. seq*.

314. At all relevant times, Defendants developed, designed, tested, manufactured, packaged, labeled, marketed, advertised, distributed, sold, and otherwise placed Bard IPCs into the stream of commerce for use by consumers, such as Plaintiffs, in the United States.

315. Plaintiffs were foreseeable users of Bard IPCs.

316. Bard IPCs were expected to and did reach Defendants' intended consumers, handlers, and persons coming into contact with the product without substantial change in the condition in which they were developed, designed, tested, manufactured, packaged, labeled, marketed, advertised, distributed, and sold by Defendants.

317. At all relevant times, Bard IPCs contained a defective and unreasonably dangerous condition because they were defective in manufacturing and were dangerous for use by the public in general and Plaintiffs in particular.

318. These manufacturing defects include but are not limited to deviating from Defendants' design or specifications for (1) the concentration of barium sulfate in the catheter and (2) the homogeneous barium sulfate distribution throughout the catheter.

319. These manufacturing defects existed even if Defendants exercised reasonable care.

320. Bard IPCs, as developed, designed, tested, manufactured, packaged, labeled, marketed, advertised, distributed, and sold by Defendants, were defective in manufacturing and unreasonably dangerous because Bard IPCs contained a condition that Defendants did not intend.

321. Bard IPCs, as developed, designed, tested, manufactured, packaged, labeled, marketed, advertised, distributed, and sold by Defendants, were defective in manufacturing and unreasonably dangerous because Bard IPCs were more dangerous than the ordinary customer would expect.

322. Defendants knew that the manufacturing defects made Bard IPCs unreasonably dangerous to Plaintiffs.

323. At the time Bard IPCs left Defendants' possession and control, Bard IPCs contained a defective and unreasonably dangerous condition.

324. At the time Plaintiffs used Bard IPCs, Bard IPCs contained a defective and unreasonably dangerous condition.

325. Physicians implanted Bard IPCs as instructed via the Instructions for Use and in a foreseeable manner as normally intended, recommended, promoted, and marketed by Defendants.

326. Plaintiffs received and utilized Bard IPCs in a foreseeable manner as normally intended, recommended, promoted, and marketed by Defendants.

327. At the time Defendants placed their defective and unreasonably dangerous Bard IPCs into the stream of commerce, there were safer alternative designs that were attainable, available, and feasible commercially, technologically, and scientifically.

328. These safer alternative designs would have prevented and/or mitigated the harm resulting in Plaintiffs' Injuries and Damages without substantially impairing the reasonably anticipated or intended function of Bard IPCs.

329. The defective and unreasonably dangerous condition of Bard IPCs was a substantial factor in causing Plaintiffs' Injuries and Damages.

330. The Plaintiffs' Injuries and Damages would not have happened or occurred had Bard IPCs not been defective and unreasonably dangerous.

331. As a direct and proximate result of the defective and unreasonably dangerous condition of Bard IPCs, Plaintiffs suffered Injuries and Damages.

332. Plaintiffs in the consolidated case *In re: Bard Implanted Port Catheter Products Liability Litigation* (MDL 3081), 2:23-md-03081-DGC (USDC D. Arizona) served reports from general (non-bellwether specific) experts which explain in detail Plaintiffs' allegations as to Bard IPCs. Plaintiffs incorporate by reference each of the reports and allegations as if set forth herein.

COUNT IV: BREACH OF EXPRESS WARRANTY

333. Plaintiffs restate the allegations above as if fully rewritten herein.

334. Plaintiffs, through their medical providers, purchased Bard IPCs from Defendants.

335. At all relevant times, Defendants were merchants of goods of the kind including medical devices and implanted port catheters (i.e., Bard IPCs).

336. At the time and place of sale, distribution, and supply of Bard IPCs to Plaintiffs, as well as other consumer and the medical community, Defendants expressly represented and warranted that Bard IPCs were, among other things:

a. Safe and effective for their intended use;

b. Well-tolerated, efficacious, and fit for their intended purpose;

c. Of merchantable quality;

d. Did not produce any unwarned-of dangerous side effects; and

e. Adequately tested.

337. Defendants expressly represented and warranted that, among other things:

a. ChronoFlex catheters were less likely to fracture than other venous access devices, as described further in Paragraph 326;

b. The risk of IPC fracture is limited to physician or patient error, as described further in Paragraph 327;

c. Bard IPCs were less likely to become infected than external catheters, as described further in Paragraph 328;

d. The risk of IPC infection is limited to physician or patient error, as described further in Paragraph 329;

e. Bard IPCs were biocompatible, as described further in Paragraph 330;

f. Bard IPCs were durable, as described further in Paragraph 331;

g. Bard IPCs were safe and effective for long-term use, as described further in Paragraph 332;

h. Bard IPCs could withstand repeated venous access, as described further in Paragraph 333;

i. Bard IPCs were cosmetically appealing, as described further in Paragraph 334; and

j. Defendants conduct adequate post-market surveillance to ensure patient safety, as described further in Paragraph 335.

338. These warranties came in one or more of the following forms:

a. publicly made written and verbal assurances of safety;

b. press releases, media dissemination, or uniform promotional information intended to create demand for Bard IPCs, but which contained misrepresentations and failed to warn of the risks of using the product;

c. verbal assurances made by Defendants' consumer relations personnel about the safety of Bard IPCs, which also downplayed the risks associated with the product; and

d. false, misleading, and inadequate written information and packaging supplied by Defendants.

339. When Defendants made these express warranties, they knew the intended purposes of Bard IPCs and warranted Bard IPCs to be in all respects safe and proper for such purposes.

340. Defendants drafted the documents and/or made statements upon which these warranty claims were based and, in doing so, defined the terms of those warranties.

341. At the time of Plaintiffs' purchase from Defendants, Bard IPCs were not in a merchantable condition and were not fit for their intended purpose.

342. Defendants breached their express warranties insofar as Bard IPCs, among other things:

a. Did not conform to Defendants' promises, descriptions, or affirmations;

b. Were not adequately packaged, labeled, promoted, and/or fit for the ordinary purpose for which they were intended;

c. Were designed in such a manner so as to be prone to an unreasonably high incidence of fracture, migration, and/or perforation of vessels and organs; infection; thrombosis; and necrosis;

d. Were manufactured in such a manner that the catheter was inadequately, improperly, and inappropriately constituted, causing it to degrade; and

e. Carried a risk of use outweighed any benefit.

343. Defendants' breach of express warranty was a substantial factor in causing Plaintiffs' Injuries and Damages.

344. The Plaintiffs' Injuries and Damages would not have happened or occurred had Defendants not breached their express warranties.

345. As a direct and proximate result of Defendants' breach of their express warranties, Plaintiffs suffered Injuries and Damages.

346. Plaintiffs in the consolidated case *In re: Bard Implanted Port Catheter Products Liability Litigation* (MDL 3081), 2:23-md-03081-DGC (USDC D. Arizona) served reports from general (non-bellwether specific) experts which explain in detail Plaintiffs' allegations as to Bard IPCs. Plaintiffs incorporate by reference each of the reports and allegations as if set forth herein.

COUNT V: VIOLATION OF THE NEW JERSEY CONSUMER FRAUD ACT

347. Plaintiffs restate the allegations above as if fully rewritten herein.

348. The acts and practices engaged in by Defendants constitute unlawful, unfair and/or fraudulent business practices in violation of the New Jersey Consumer Fraud Act, N.J.S.A. § 56:8-2, *et. seq.*

349. Unlawful, unfair and/or fraudulent business practices engaged in by Defendants and in violation of N.J.S.A. § 56:8-2, *et. seq.* include but are not limited to the following:

a. Representing that Bard IPCs have sponsorship, approval, characteristics, ingredients, uses, or benefits that they do not have;

b. Representing that Bard IPCs were of a particular quality, standard, or grade that they were not;

c. Advertising Bard IPCs with the intent not to sell them as advertised;

d. Using fraud, false pretenses, false promises, misrepresentations, misleading statements, or other deceptive practices relating to Bard IPCs;

e. Making material assertions, representations, or statements of fact in advertisements relating to Bard IPCs that are untrue, deceptive, or misleading; and

f. Engaging in fraudulent, unfair, and/or deceptive conduct relating to Bard IPCs that creates a likelihood of confusion or misunderstanding.

350. Defendants have a statutory duty to refrain from fraudulent, unfair, and/or deceptive acts or trade practices in the sale and promotion of Bard IPCs.

351. Defendants' fraudulent, unfair, and/or deceptive representations and material omissions to Plaintiffs and Plaintiffs' healthcare providers constituted consumer fraud and/or unfair and deceptive consumer sales practices in violation of N.J. Stat. Ann. §§ 56:8-1, *et seq*.

352. Under N.J. Stat. Ann. §§ 56:8-1, *et seq*., Defendants are the suppliers, manufacturers, advertisers, and sellers of Bard IPCs who are subject to liability under such legislation for fraudulent, unfair, and/or deceptive consumer sales practices.

353. Plaintiffs' purchase of Bard IPCs constitutes a sale within the meaning of N.J. Stat. Ann. §§ 56:8-1, *et seq*.

354. Plaintiffs are consumers within the meaning of N.J. Stat. Ann. §§ 56:8-1, *et seq*.

355. Defendants knowingly, deliberately, willfully, and/or wantonly engaged in unfair, unconscionable, deceptive, fraudulent, and misleading acts or practices in violation of N.J. Stat. Ann. §§ 56:8-1, *et seq*.

356. Defendants' conduct was willful, outrageous, immoral, unethical, oppressive, unscrupulous, unconscionable, and substantially injurious to Plaintiffs.

357. Defendants had actual knowledge of the defective and dangerous condition of Bard IPCs and failed to take any action to cure those conditions.

358. The actions and omissions of Defendants are uncured or incurable.

359. Defendants induced Plaintiffs to purchase and/or pay for Bard IPCs through their fraudulent, unfair, and/or deceptive acts or trade practices.

360. Plaintiffs and Plaintiffs' healthcare providers relied upon Defendants' misrepresentations and omissions in deciding to use Bard IPCs instead of another vascular access device.

361. Plaintiffs purchased and/or used Bard IPCs and suffered ascertainable losses, including their Injuries and Damages, as a result of Defendants' actions in violation of these consumer-protection laws.

362. Defendants' actions in violation of N.J. Stat. Ann. §§ 56:8-1, *et seq*. were a substantial factor in causing Plaintiffs' Injuries and Damages.

363. Had Defendants not engaged in the fraudulent, unfair, and/or deceptive conduct described herein, neither Plaintiffs nor their healthcare providers would have purchased and/or paid for Bard IPCs.

364. Nor would Plaintiffs have suffered physical and economic harm, including their Injuries and Damages, as a result of using Bard IPCs.

365. The Plaintiffs' Injuries and Damages would not have happened or occurred had Defendants not violated N.J. Stat. Ann. §§ 56:8-1, *et seq*.

366. As a direct and proximate result of Defendants' violations of N.J. Stat. Ann. §§ 56:8-1, *et seq*., Plaintiffs suffered Injuries and Damages and seek all available damages, compensatory and exemplary, under N.J. Stat. Ann. §§ 56:8-1, *et seq*.

367. Plaintiffs in the consolidated case *In re: Bard Implanted Port Catheter Products Liability Litigation* (MDL 3081), 2:23-md-03081-DGC (USDC D. Arizona) served general (non-bellwether specific) reports from experts which explain in detail Plaintiffs' allegations as to Bard IPCs. Plaintiffs incorporate by reference each of the general expert reports and allegations as if set forth herein.

COUNT VI: LOSS OF CONSORTIUM

368. Plaintiffs restate the allegations above as if fully rewritten herein.

369. At all relevant times, Plaintiffs' spouses ("Spouse Plaintiffs") and/or family members ("Family-Member Plaintiffs") and/or domestic partners ("Domestic-Partner Plaintiffs") have suffered injuries and losses as a result of Plaintiffs' injuries.

370. For the reasons set forth herein, Spouse Plaintiffs, Family Member Plaintiffs, and/or Domestic Partner Plaintiffs have necessarily paid and have become liable to pay for medical aid, treatment, and medications and will necessarily incur further expenses of a similar nature in the future as a direct and proximate result of Defendants' misconduct.

371. For the reasons set forth herein, Spouse Plaintiffs, Family-Member Plaintiffs, and/or Domestic-Partner Plaintiffs have suffered and will continue to suffer the loss of their

loved ones' support, companionship, services, society, love, and affection due to Plaintiffs' Injuries and Damages caused by Bard IPCs.

372. For Spouse Plaintiffs, Plaintiffs allege their marital relationship has been impaired and depreciated, and the marital association between husband and wife has been altered.

373. Spouse Plaintiffs, Family-Member Plaintiffs, and/or Domestic-Partner Plaintiffs have suffered great emotional pain and mental anguish.

374. Bard IPCs were a substantial factor in causing the Injuries and Damages of Spouse Plaintiffs, Family-Member Plaintiffs, and/or Domestic-Partner Plaintiffs.

375. As a direct and proximate result of the defective and unreasonably dangerous condition of Bard IPCs and Defendants' acts and/or omissions, Spouse Plaintiffs, Family-Member Plaintiffs, and/or Domestic-Partner Plaintiffs suffered Injuries and Damages.

376. Plaintiffs in the consolidated case *In re: Bard Implanted Port Catheter Products Liability Litigation* (MDL 3081), 2:23-md-03081-DGC (USDC D. Arizona) served general (non-bellwether specific) reports from experts which explain in detail Plaintiffs' allegations as to Bard IPCs. Plaintiffs incorporate by reference each of the general expert reports and allegations as if set forth herein.

COUNT VII: WRONGFUL DEATH

377. Plaintiffs restate the allegations above as if fully rewritten herein.

378. As a direct and proximate result of Defendants' acts and/or omissions, Plaintiffs' Decedents used Bard IPCs and ultimately died.

379. Plaintiffs' Decedents are survived by various family members, named and unnamed.

380. As a direct and proximate result of the defective and unreasonably dangerous condition of Bard IPCs and Defendants' acts and/or omissions, Plaintiffs' Decedents' beneficiaries have incurred hospital, nursing, and medical expenses, as well as funeral expenses and estate-administration expenses.

381. As a direct and proximate result of the defective and unreasonably dangerous condition of Bard IPCs and Defendants' acts and/or omissions, Plaintiffs' Decedents' heirs and family have been deprived of Plaintiffs' Decedents' future aid, income, assistance, services, companionship, society, affection, and financial support, and Plaintiffs have suffered Injuries and Damages.

382. Where authorized under relevant state law, Plaintiffs' Decedents' spouses, beneficiaries, administrators, and/or lawful representatives of Plaintiffs' Decedents' estates bring this claim on behalf of themselves and as the Plaintiffs' Decedents' lawful heirs and/or beneficiaries for the Plaintiffs' Decedents' wrongful death.

383. Plaintiffs in the consolidated case *In re: Bard Implanted Port Catheter Products Liability Litigation* (MDL 3081), 2:23-md-03081-DGC (USDC D. Arizona) served general (non-bellwether specific) reports from experts which explain in detail Plaintiffs' allegations as to Bard IPCs. Plaintiffs incorporate by reference each of the general expert reports and allegations as if set forth herein.

COUNT VIII: SURVIVAL

384. Plaintiffs restate the allegations above as if fully rewritten herein.

385. As a direct and proximate result of the defective and unreasonably dangerous condition of Bard IPCs and Defendants' acts and/or omissions, Plaintiffs' Decedents suffered Injuries and Damages prior to Plaintiffs' Decedents' deaths.

386. Plaintiffs' Decedents' spouses, beneficiaries, administrators, and/or lawful representatives of Plaintiffs' Decedents' estates seek all Injuries and Damages that Plaintiffs' Decedents suffered as a result of Bard IPCs.

387. Plaintiffs in the consolidated case *In re: Bard Implanted Port Catheter Products Liability Litigation* (MDL 3081), 2:23-md-03081-DGC (USDC D. Arizona) served general (non-bellwether specific) reports from experts which explain in detail Plaintiffs' allegations as to Bard IPCs. Plaintiffs incorporate by reference each of the general expert reports and allegations as if set forth herein.

PUNITIVE DAMAGES

388. Plaintiffs restate the allegations above as if fully rewritten herein.

389. Defendants have acted willfully, wantonly, recklessly and with evil motive, malice, conscious indifference, and deliberate disregard for the substantial risk of physical harm and/or death to consumers, such as Plaintiffs, including but not limited to:

a. By failing to disclose material facts regarding the dangers and serious safety concerns of Bard IPCs;

b. By concealing and suppressing material facts regarding the dangers and serious health and/or safety concerns of Bard IPCs;

c. By failing to disclose the truth and making false representations with the purpose of deceiving Plaintiffs and lulling them into using and relying upon Bard IPCs; and

d. By falsely representing the qualities and characteristics of Bard IPCs to the public and Plaintiffs.

390. Defendants' conduct is grossly negligent and reprehensible, evidencing an evil motive, and was undertaken for pecuniary gain.

391. Such conduct justifies an award of punitive or exemplary damages in an amount sufficient to punish Defendants' conduct and deter like conduct by Defendants and other similarly situated persons and entities in the future.

392. Plaintiffs in the consolidated case *In re: Bard Implanted Port Catheter Products Liability Litigation* (MDL 3081), 2:23-md-03081-DGC (USDC D. Arizona) served general (non-bellwether specific) reports from experts which explain in detail Plaintiffs' allegations as to Bard IPCs. Plaintiffs incorporate by reference each of the general expert reports and allegations as if set forth herein.

TIMELINESS AND TOLLING OF STATUTES OF LIMITATION AND REPOSE

393. Plaintiffs restate the allegations above as if fully rewritten herein.

394. Plaintiffs are within the applicable statute of limitations for their claims because Plaintiffs and Plaintiffs' healthcare providers did not discover (and could not discover through the exercise of reasonable diligence) that Bard IPCs caused their Injuries and Damages because, at the time of those Injuries and Damages, the cause was unknown.

395. Plaintiffs are within the applicable statute of limitations for their claims because Plaintiffs and Plaintiffs' healthcare providers did not discover (and could not discover through the exercise of reasonable diligence) the defective and unreasonably dangerous condition of their Bard IPCs.

396. Plaintiffs did not suspect and had no reason to suspect that Bard IPCs caused their Injuries and Damages until less than the applicable limitations period prior to the filing of this action.

397. Plaintiffs' ignorance of the defective and unreasonably dangerous nature of Bard IPCs, and the causal connection between these defects and Plaintiffs' Injuries and Damages, is due in large part to Defendants' acts and omissions in fraudulently concealing information from the public and misrepresenting and/or downplaying the serious threat to public safety its products present.

398. To this day, Defendants claim to "never mislead [their] customers."[103]

399. Defendants' fraudulent concealment has tolled the running of any statute of limitations.

400. Through their affirmative representations and omissions, Defendants actively concealed from Plaintiffs the risks associated with the defects of Bard IPCs and that Bard IPCs caused their Injuries and Damages.

401. Through their ongoing affirmative misrepresentations and omissions, Defendants committed continual tortious and fraudulent acts.

402. In addition, Defendants are estopped from relying on any statutes of limitation or repose by virtue of their unclean hands, acts of fraudulent concealment, affirmative misrepresentations, and omissions.

403. Such conduct includes intentional concealment from Plaintiffs, Plaintiffs' healthcare providers, and the public of material information that Bard IPCs are not safe or effective and carry with them the risks and dangerous defects described above.

[103] https://www.bd.com/content/dam/bd-assets/bd-com/en-us/document/policy/code-of-conduct/code-of-conduct-english.pdf.

404. Defendants had a duty to disclose the fact that Bard IPCs are not safe or effective, are not as safe as other venous access devices on the market, are defective and unreasonably dangerous, and that their implantation and use carried with them the serious risk of developing fracture, migration, and/or perforation; infection; thrombosis; or death.

405. As a result of Defendants' fraudulent concealment, Plaintiffs were unaware and could not have reasonably known or learned through reasonable diligence that they had been exposed to the defects and risks alleged herein and that those defects and risks were the direct and proximate result of Defendants' acts and omissions. Additionally, Plaintiffs are within the applicable statute of limitations for their claims because the COVID-19 state of emergency tolled the running of the applicable statute of limitations, including but not limited to as set forth in N.J. Order (Mar. 17, 2020). [104]

406. Plaintiffs invoke the doctrines of Res Ipsa Loquitor, Apparent agency and Respondeat Superior.

JURY DEMAND

Plaintiffs hereby demand a trial by jury on all counts and issues so triable.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs demand judgment against Defendants for:

A. Compensatory damages, including without limitation: past and future medical expenses; past and future pain and suffering, emotional distress, mental anguish, loss of enjoyment of life, and disability; disfigurement; past and future loss of consortium; past and future lost wages, including loss of earnings and loss of earning capacity; funeral and burial expenses; and other consequential damages as allowed by law;

B. Injunctive relief as the Court deems equitable, just, and proper, including but not limited to enjoining Defendants from continuing the unlawful practices as set forth herein and requiring Defendants to conduct a corrective advertising campaign;

C. Punitive or exemplary damages;

D. Disgorgement of profits;

[104] https://www.nelsonmullins.com/storage/PLLEdLH0yX9SjG3YPDCVU6gwqbfSjA9Q9audPs5Z.pdf.

E. Restitution;

F. Statutory damages, where authorized;

G. Any and all applicable statutory and civil penalties, as allowed by law;

H. Costs and expenses of suit;

I. Reasonable attorneys' fees, where authorized;

J. Pre-judgment interest as allowed by law;

K. Post-judgment interest at the highest applicable statutory or common-law rate from the date of judgment until satisfaction of judgment;

L. Any other interest recoverable under the law of any action pending in this MCL; and

M. Any such other additional and further relief as Plaintiffs may be entitled to at law or in equity.

NOTICE PURSUANT TO RULES 1:5-l(a) AND 4:17-4(c)

Please take notice that the undersigned attorneys, counsel for Plaintiffs, do hereby demand, pursuant to Rules 1:5-l(a) and 4:17-4(c), that each party herein serving pleadings and interrogatories and receiving answers thereto, serve copies of all such pleadings and answered interrogatories received from any party, including any documents, papers and other material referred to therein, upon the undersigned attorneys, please take notice that this is a continuing demand.

ANTI- SPOLIATION/PRESERVATION WARNING

The term "you," "your" or "yours" as used herein shall refer to you (the recipient of this letter), as well any and all affiliates, subsidiaries, agents, employees, representatives, officers, and/or officials thereof, and any and all named defendants in this matter, its affiliates and/or subsidiaries, its employees, representatives and/or agents and officials, as well as any and all individuals responsible for the custody and control of the below information, including but not limited to those individual's administrative assistants, secretaries, agents, employees, information technology personnel and third-party vendors.

You are directed from this point forward to prevent any uspoliation", defined as alteration, change, updating, periodic destruction of, editing or deletion of, any of the information which is set forth hereafter.

If you cause any such alteration, destruction or change, directed or allow it to occur, you will be potentially charged with discovery rule violations for which sanctions may be imposed.

Further, the Complaint may be amended to add purposeful and/or reckless or negligent destruction or spoliation of evidence. Finally, we may ask for specific instructions to the jury to find certain facts to your disadvantage by virtue of the destroyed or inaccessible evidence.

Please be advised that you are hereby directed to prevent any spoliation of all records and/or recordings related to and/or regarding this patient for the past ten (10) years, including but not limited to any and all, medical records, time logs, videos, quality control reports, morbidity and mortality reports, morbidity and mortality statements, and any and all reports made to local, state, and/or federal agencies.

Electronically Stored Information

In terms of electronically stored information, you are directed to prevent any destructive, alterative or other change to any web pages, virtual profiles or identities (including *but not limited to* Myspace, Facebook, Instagram, Pinterest, Twitter, Tumblr, Linkedln, Snapchat, Google Plus+, Flickr, Vine, About.me, etc. or any other social media-based web profile or networking site account.), emails, voice messages, text messages, instant messages or messaging systems, pertaining in any way to this controversy or to the parties or witnesses, recordings, digital recordings, media images and videos, temporary memory, memory sticks, portable memory devices, laptops or computers, CDs, DVDs, USB devices, databases, computer activity logs, internet browsing history (including cookies), network access and server activity logs, word processing files and file fragments, back-up and archival files, imaging and facsimile files, electronic calendar and scheduling program files and file fragments as well as any other contact and relationship management data (e.g., Outlook, ACT!), electronic spreadsheet files and file fragments, related to this matter. This includes a request that such information not be modified, altered or deleted as a result of data compression or disk fragmentation (or other optimizations procedures), which processes you are hereby directed to suspend until such time as that data can be preserved, copied and produced.

You are directed to not modify, alter or delete-or allow modifications, alterations or deletions to be made to-any such electronically stored information unless an exact replica or "mirror image" has been made and will be preserved and made accessible for purposes of discovery in this litigation and unless, in addition, an activity log of all document modifications already made to any electronically stored information is maintained.

Electronic documents and the storage media on which they reside contain relevant, discoverable information beyond that which may be found in printed documents.

Therefore, even where a paper copy exists, we will seek all documents in their electronic form along with information about those documents contained on the media. We also will seek paper printouts of only those documents that contain unique information after they were printed out (such as paper documents containing hand writing, signatures, marginalia, drawings, annotations, highlighting and redactions) along with any paper documents for which no corresponding electronic files exist.

You are further directed to preserve and not destroy all passwords, decryption procedures (including, if necessary, the software to decrypt the files); network access codes, manuals, tutorials, written instructions, decompression or reconstruction software, and any and all other information and things necessary to access, view and (if necessary) reconstruct the electronic data we will request through discovery.

Paper Information

In terms of paper information, you are directed to preserve any and all contracts and contract drafts, emails, memos and drafts of memos, handbooks (past and present), policies (past and present) and drafts, employment files, pay stubs or duplicates, spreadsheets, lists, reports, documents, notes, correspondence, photographs, investigative information or other documents which pertain in any way to the controversy, parties or witnesses in this matter.

RULE 4:5-1 CERTIFICATION

I hereby certify that to the best of my knowledge the matter in controversy is the subject of numerous other actions. On October 15, 2024, the Supreme Court designated all cases involving Bard Implanted Port Catheter Products as a Multicounty Litigation (MCL) and assigned this MCL to Judge Gregg A. Padovano in Bergen County for centralized case management.

I hereby certify that the foregoing statements made by me are true. I am aware of any of the foregoing statements made by me are willfully false, I am subject to punishment.

Dated: February 13, 2026

Respectfully submitted,

/s/ Michael A. Galpern
Michael A. Galpern
Javerbaum Wurgaft Hicks
Khan Wikstrom and Sinins, P.C.
1000 Haddonfield-Berlin Road, Suite 203
Voorhees, NJ 08043
Fax: (856) 702-6640
Phone: (856) 596-4100
Email: mgalpern@lawjw.com

/s/ Jennifer P. Elwell
Jennifer P. Elwell
Berger Montague PC
1818 Market Street, Suite 3600
Philadelphia, PA 19103
Fax: (215) 875-4620
Phone: (215) 875-3000
Email: jelwell@bm.net

/s/ Christopher J. Geddis
Christopher J. Geddis
Mazie Slater Katz & Freeman, LLC
103 Eisenhower Parkway
Roseland, NJ 07068
Fax: (973) 228-0303
Phone: (973) 228-9898
Email: cgeddis@mazieslater.com

Co-Liaison Counsel for Plaintiffs

EXHIBIT A

Brand Name	Model Number/Product Code
BardPort M.R.I. Implantable Port	0602610, 0602620, 0602640, 0602650, 0602660, 0602670, 0602680, 0602690, 0602830, 0602833, 0602840, 0602843, 0605400, 0605420, 0607173
BardPort M.R.I. Low-Profile Implantable Port	0603830, 0603840, 0603870, 0603880, 6603880
BardPort Titanium Dome Implantable Port	0602850, 0602860, 0602870
BardPort Titanium Implantable Port	0602230, 0602240, 0602270, 0602290, 0603000, 0602820, 0605300, 0605320, 0607301, 0607302, 0602210, 0602260, 0602280, 0602810
M.R.I. Plastic Dual Lumen Port	0603500, 0605920, 0605930, 0607100, 0607200, 0615460
M.R.I. Ultra SlimPort Implantable Port	0605640, 0655640
Peritoneal Titanium Port	0603000, 0603006
PowerFlow Implantable Apheresis IV Port	A710962
PowerPort ClearVUE isp Implantable Port	1606052, 1606062, 1606362, 1606382, 1608052, 1608062, 1608362, 1608382, 1666362, 1668362, 1676300, 5606362, 5608062, 5608362, 5666362, 5668362, CP00004

PowerPort ClearVUE Slim Implantable Port	1616000, 1616001, 1616070, 1616071, 1616300, 1616380, 1618000, 1618001, 1618070, 1618300, 1618380, 1676301, 1678300, 1678301, 5616000, 5616300, 5618000, 5618300, 5676300, 5676301, 5678300, 5678301, CP00005
PowerPort duo M.R.I. Implantable Port	1829500, 1829570, 5829500, 5829502
PowerPort Implantable Port	1708000, 1708001, 1708070, 1708071, 1709600, 1709601, 1759600, 1759601, 1778000, 1778001, 1778070, 1778071
PowerPort isp Implantable Port	1706050, 1706051, 1706060, 1706061, 1708050, 1708051, 1708060, 1708061, 1708160, 1708550, 1708551, 1708560, 1708561, 4708060, 4708061, 4708560, 4708561, CP00001, CP00002, CP00003, CP00009
PowerPort isp M.R.I. Implantable Port	1806050, 1806051, 1806060, 1806061, 1808050, 1808051, 1808060, 1808061, 1808069, 1808360, 1808550, 1808551, 1808560, 1808561, 1809660, 1809661, 1859660, 1859661, 4808060, 4808061, 4808560, 4808561, 9808560
PowerPort M.R.I. Implantable Port	1808000, 1808001, 1808002, 1808070, 1808071, 1808300, 1809600, 1809601, 1809670, 1859600, 1859601, 1878000, 1878001, 1878070, 1878071

PowerPort Slim Implantable Port	1716000, 1716001, 1716070, 1716071, 1716080, 1718000, 1718001, 1718070, 1718500, 1718501, 1718570, 1718571, CP00008
PowerPort VUE M.R.I. Implantable Port	1806052, 1806062, 1808052, 1808062
PowerPort VUE Titanium Implantable Port	1706052, 1706062, 1708052, 1708062
SlimPort Dual-Lumen Rosenblatt Implantable Port	0604970, 0624970, 0654970
Titanium Low-Profile Port	0602180, 0602190, 0605490, 0605510, 0606100, 0606150, 0606200
Titanium SlimPort Implantable Port	0605550, 0605560, 0655510
Vaccess CT Low-Profile Titanium Power-Injectable Port	7360000, 7360001, 7380000
Vaccess CT Power-Injectable Implantable Port	7460000, 7480000, 7496000
X-Port isp M.R.I. Implantable Port	0607500, 0607510, 0607520, 0607530, 0607540, 0607550, 0607555, 0657500, 0657510, 0657520, 0657525, 7707540, 7757540
X-Port Low-Profile Titanium Port	0655870, 0605840, 0605850