BEFORE THE UNITED STATES JUDICIAL PANEL ON MULTIDISTRICT LITIGATION

IN RE: BARD IMPLANTED PORT CATHETER PRODUCTS LIABILITY LITIGATION	MDL No. 3081

DEFENDANTS BECTON, DICKINSON AND COMPANY, C.R. BARD, INC. AND BARD ACCESS SYSTEMS, INC.'S MEMORANDUM IN OPPOSITION TO THE MOTION TO TRANSFER ACTIONS PURSUANT TO 28 U.S.C. § 1407

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Page(s)

Federal Cases

Statutes & Regulations

INTRODUCTION

Defendants Becton, Dickinson & Company, C.R. Bard, Inc., and Bard Access System, Inc. (collectively, "Defendants" or "Bard") respectfully submit this Memorandum in opposition to this Motion to Transfer Actions. This Motion arises from a coordinated attorney advertising campaign soliciting cases related to Bard's totally implantable venous access devices. Since their introduction about two decades ago, Bard has a proven track record of safety and efficacy in connection with the implantable port devices identified in this Motion, which facilitate the administration of chemotherapy and other life-saving treatments to hundreds of thousands of patients each year. In addition, Bard has a proven track record of effectively managing the modest litigation that has occurred with these devices over the years without formal consolidation. Nothing in Movants' application warrants departure from the ordinary litigation process, and Movants have failed to establish that transfer of these eleven actions is convenient for the parties and witnesses, and that it will promote the just and efficient conduct of these actions. 28 U.S.C. § 1407(a). The Panel should deny this Motion.

RELEVANT FACTUAL BACKGROUND

A. Bard's Implantable Ports are Safe and Effective Devices That Have Been Used by Medical Professionals for Decades

Bard's implantable ports are FDA-cleared Class II totally implantable venous access devices indicated for patient therapies requiring repeated access to the vascular system. *See* 21 C.F.R. § 880.5965. Totally implantable venous access devices have allowed millions of patients to receive chemotherapy, antibiotic therapy, parenteral nutrition and other life-sustaining treatment without the need for repeated, painful needle pricks that can cause serious damage to veins. Totally implantable venous access devices are offered for sale by a number of different manufacturers, and have provided an important means of venous access for critically ill patients since the 1980s.

Of the eleven pending actions, ten concern devices sold under the tradename "PowerPort." PowerPorts not only allow for infusions of medication and other therapies, but also allow for the power injection of contrast media for contrast-enhanced CT scans. In 2006, Bard introduced the first of its PowerPort family of devices. The eleventh action concerns a non-power-injection port sold under the tradename "BardPort." BardPort devices have been on the market for more than two decades.

PowerPorts, like all totally implantable venous access devices, consists of two primary components: an injection port with a self-sealing silicone septum and a radiopaque catheter. *See* Ex. A (Specification Sheet); Ex. B, at 1 (IFU). The injection port is generally implanted under the skin in the lateral region of the chest below the clavicle. *See* Ex. B, at 1-4. A catheter connected to the injection port is tunneled under the skin to an insertion point in a vein. *Id.* at 4-5. 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 where the medication or fluids are introduced via injection from the port. *Id.*

Importantly, "PowerPorts" consist of a number of devices with differing designs and configurations of injection ports and catheters that have been the subject of seven different premarket submissions to FDA pursuant to the 510(k) process, 21 U.S.C. § 360(k). There are presently eight "families" of PowerPort devices that, in turn, are comprised of dozens of configurations identifiable by assigned product codes or SKU numbers:

See Ex. A. The various configurations include injection port bodies of different shapes and materials, among other differences.

There are also different available catheter options, such as the Chronoflex™ and Groshong™ catheters that were allegedly implanted in the plaintiffs in these actions. *See* Ex. A. Chronoflex™ catheters are open-ended, polyurethane catheters, while Groshong™ catheters are closed-tip, silicone catheters with end-valves for fluid flow. Silicone and polyurethane catheters have different physical and chemical properties. As such, these catheters are subject to different design and specifications to ensure biodurability and biocompatibility. Chronoflex™ and Groshong™ catheters also differ in their concentration of barium sulfate, a radiopaque substance that allows it to be seen on diagnostic imaging such as x-ray, CT or MRI.

Additionally, a medical practitioner's vein selection for catheter insertion subjects the device to various anatomical conditions. For example, as commonly explained in the different Instructions for Use that accompany these devices, medical professionals are advised to avoid the risk of "pinch-off" syndrome. *See* Ex. B, at 1-3. Pinch-off occurs when the catheter becomes compressed between the clavicle and first rib, and the catheter severs as a result. *Id.* PowerPorts are contraindicated for catheter insertion in the subclavian vein medial to the border of the first rib. To prevent pinch-off, the IFUs advise practitioners to use the lateral subclavian vein or the internal jugular vein for catheter insertion. *Id.* The IFU also instructs physicians to avoid bending catheters during implantation, which "can compromise catheter patency." *Id.* at 3. Other factors may impact performance and wear, including but not limited to, how well the device is maintained. Bard's implantable ports, like other totally implantable venous access devices, must be properly maintained in order to minimize the risk of clot formation, blockage, and infection by regularly flushing the port and catheter with a specific saline solution depending on the type of catheter.

As with all totally implantable venous access devices, there are known risks of complication. Plaintiffs in the underlying actions complain of infection, thrombosis (blood clots),

fracture or breakage, and catheter embolism (migration). Importantly, all of these risks, which are associated with all totally implantable venous access devices, are clearly delineated in the IFUs for PowerPorts and in the medical literature:

Possible Complications

The use of a subcutaneous port provides an important means of venous access for critically ill patients. However, the potential exists for serious complications, including the following:

- Air Embolism
- Allergic Reaction
- Bleeding
- Brachial Plexus Injury
- Cardiac Arrhythmia
- Cardiac Puncture
- Cardiac Tamponade
- Catheter or Port Erosion Through the Skin
- Catheter Embolism
- Catheter Occlusion
- Catheter or port-related Sepsis
- Damage or Breakage due to Compression between the Clavicle and First Rib
- Device Rotation or Extrusion
- Endocarditis
- Extravasation
- Fibrin Sheath Formation
- Guidewire Fragment Embolism
- Hematoma
- Hemothorax
- Hydrothorax
- Infection, including but not limited to, pocket, catheter tunnel, and/or blood stream
- Inflammation, Necrosis, or Scarring of Skin Over Implant Area
- Intolerance or Reaction to Implanted Device
- Laceration of Vessels or Viscus
- Pain at or around port pocket site
- Perforation of Vessels or Viscus
- Pneumothorax
- Risks Normally Associated with Local or General Anesthesia, Surgery, and Post-Operative Recovery
- Spontaneous Catheter Tip Malposition or Retraction
- Thoracic Duct Injury
- Thromboembolism
- Vascular Thrombosis
- Vessel Erosion

These and other complications are well documented in medical literature and should be carefully considered before placing the port.

Id.[1] In the event of a complication, minimally invasive treatment is typically sufficient, and where a port must be removed, it is very common for a new port ***of the same make and model*** to be implanted. Thrombolytic agents and antibiotics can be used to successfully treat occlusions and infections, respectively.[2] Catheter fracture and migration, which are rare complications, are typically addressed by retrieving the distal end of the catheter intravenously via guidewire and snare without the need for anesthesia in most cases.[3]

[1] Bard cites to the IFU identified in *Divelbliss v. Bard Access Sys., Inc.*, No. 22-CV-00601 (D.N.M.), which was the first filed action and only one of the four cases in eleven total in which plaintiffs properly identified the device at issue. Although Bard's implanted ports are not subject to a single IFU, Bard's IFUs have uniformly warned of the risk of infection or sepsis, thrombosis, catheter embolism, and damage or breakage.

[2] *See* Thromboyltic therapy for central venous catheter occlusion, Hameatologica 97(5), 641–650. (May 2012); Clinical Practice Guidelines for the Diagnosis and Management of Intravascular Catheter-Related Infection: 2009 Update by the Infectious Diseases Society of America (2009).

[3] *See* Spontaneous fracture and migration of catheter of a totally implantable venous access port via internal jugular vein – a case report, J. of Cardiothoracic Surgery (2016) 11:50.

Given the minimally invasive and successful treatment options for addressing complications, it is unsurprising that litigation rarely results from a complication. And importantly, there has not been any landmark scientific studies questioning the overall safety profile of Bard's implantable ports. Nor have there been any FDA-issued recalls,[4] or other regulatory action taken by FDA related to PowerPort safety (such as warning letters or public health notifications).

B. Defendants Have Efficiently Managed Past Implantable Port Litigation Without an MDL, and Will Continue to Do So with Respect to the Pending and any Future Actions

Although Movants emphasize "the ubiquity of implanted port implantations in the United States," there are only eleven (11) pending actions. Mot. at 2. Indeed, there has only been eleven other actions involving Bard's port devices filed in the five years preceding this Motion. *See* Cert. of Counsel ¶ 5. Critically, Bard efficiently resolved those previously filed cases, without an MDL. *Id.* ¶¶ 6-9. Movants do not point to any fact warranting deviation from the normal litigation process.

Product liability litigation concerning Bard's implantable ports has been limited and pursued by only a few attorneys. Indeed, Movants' counsel in more than half of the pending actions, Adam Evans, was involved in the majority of the previously filed and resolved actions.[5] *See id.* ¶ 7. At one point, nine cases were simultaneously pending in nine different district courts spanning from California, to Indiana, to Georgia. *See id.* ¶ 6. Eight of those cases were filed by a single law firm. Defendants were able to coordinate discovery in those cases with plaintiffs' counsel and Mr. Evans without the need for any formal consolidation or centralization of cases. *Id.* ¶ 8.[6] *Id.* All

[4] There have been eight voluntary limited product recalls since 2015 involving certain lots of PowerPort devices, which is the earliest date that any of the plaintiffs had their port implanted. None of these small-scale recalls relates to Movants' allegations regarding catheter composition, nor do Movants argue that they are in anyway related to their claims.

[5] At the time of the prior cases, Mr. Evans was affiliated with the Brenes Law Group, P.C. In or about May 2022, Mr. Evans joined his current firm Dickerson Oxton, LLC.

[6] After these eight cases were resolved, two additional cases were filed shortly before the expiration of the applicable statutes of limitation. These cases were voluntarily dismissed

cases resolved prior to the exchange of expert disclosures. All cases, except one, resolved without taking a single deposition. *Id.* All cases resolved within one month to thirty-one months of filing, with an average duration of about eighteen months. *Id.* ¶ 9.

There is no indication that the parties will not be able to coordinate, efficiently litigate, and successfully resolve the now-pending actions as they have done in the past. Indeed, Movants advance the same theory of liability in the pending actions as Mr. Evans did in the prior actions: that Defendants' radiopaque agent, barium sulfate, is allegedly "known to reduce the material integrity of the catheter when it is not encapsulated, coated or otherwise separated from the catheter surface," which in turn can lead to complications. (*Compare* Mot. at 3 *with Duff v. C.R. Bard, Inc.*, Am. Compl. ¶¶ 18-23, No. 20-cv-60, ECF No. 20 (W.D. Ky. June 22, 2020) (alleging that "Defendants' manufacturing process . . . involved too high a concentration of barium sulfate particles" and that Defendants elected not to incorporate "design modifications to encapsulate the radiopaque compound").[7]

As discussed, no precipitating event spurred the newly filed actions. Instead, the principal driver for the eleven pending actions is counsel's intent to form an MDL in his home jurisdiction, the Western District of Missouri. In December 2022, Mr. Evans contacted Defendants to discuss port litigation, and advised Defendants that he was running a targeted digital advertising campaign with a consortium of other law firms with an eye towards filing an MDL application. Cert. of Counsel ¶ 10. At the time, there was only one pending action (not filed by Movants' counsel),

immediately upon Defendants' filing of motions to dismiss. The parties resolved the eleventh action shortly after pre-answer motion practice and the exchange of limited, core discovery.

[7] In fact, Mr. Evans filed at least five complaints in 2021 alleging identical theories of product defect related to the use of barium sulfate against another manufacturer of implantable venous access devices and did not move for formation of an MDL. *See, e.g.*, *Mora v. AngioDynamics, Inc.*, Compl. ¶¶ 28-31, No. 21-cv-10234, ECF No. 1-1 (D. Mass Feb. 11, 2021)).

Divelbliss v. Bard Access Sys., Inc., No. 22-CV-00601 (D.N.M.), which was subject to a fully briefed motion to dismiss.

This coordinated digital advertising campaign has resulted in several internet websites such as portcatheterlawsuit.com, which is hosted by Mr. Evans' law firm, that misrepresent the safety and efficacy of Bard's products by asserting recklessly that "patients with Bard implanted port devices may be at a higher risk of serious complications or injury due to the device." Cert. of Counsel ¶ 11, Ex. C. Other websites have already latched onto the filing of this Motion as part of their efforts to solicit new cases, falsely representing that "[d]esign problems with the Bard PowerPort have been linked to reports of serious injury," and that "Bard PowerPort settlements may become available." *Id.* Importantly, though, this targeted advertising campaign has not resulted in a cascade of newly filed actions. Despite this advertising campaign, only eleven actions have been filed in the last year. Nothing in Movants' application suggests that a wave of future cases is imminent, and the Panel should not credit any assertion regarding future filings.

C. The Eleven Pending Actions Involve Varied Alleged Complications, Individualized Causation Issues, and Different Devices

The pending actions all have unique characteristics that weigh against centralization. Different medical providers implanted different ports into each plaintiff between 2015 and 2022 for the delivery of vital medications to treat pre-existing medical conditions. Those plaintiffs allegedly experienced distinct complications, prompting medical intervention.[8]

Five of the eleven actions purportedly involve "infections"—a risk that is explicitly disclosed in Bard's IFUs for these devices and that is otherwise attendant to all medical procedures. These five actions involve at least three different devices implanted over a seven-year period and

[8] Movants are eight of the ten plaintiffs listed in the Motion. Defendants have removed an eleventh action from a state court. *See* Schedule of Actions, ECF No. 14-1.

only one of the five plaintiffs identifies the product code and the lot number in her Complaint. As for the specific factual allegations, common issues do not predominate given the significant variation as to when the infection occurred, the type of infection at issue, and the devices at issue. Further, more than half of these cases are facially barred by the statute of limitations, and another case raises a statute of limitations issue that may be able to be confirmed once plaintiff produces her medical records.[9] Ordinary litigation and informal coordination among the overlapping plaintiffs' counsel is appropriate for these cases.

Five of the eleven actions allege catheter fractures. These actions involve five different devices, are pending in four different jurisdictions, and involve fact-specific causation issues. For example, some of these cases allege insertion of the catheter through the right subclavian vein where the risk of pinch-off may be greater, while other cases allege insertion through the internal jugular vein.[10] And despite being pleaded as a "fracture" case, medical records produced in *Kelley*

[9] Movant Groves (W.D. Mo.) received a "Bard PowerPort® M.R.I Implantable Port" in November 2015. Less than a month later, she allegedly suffered an infection. Movant, by her counsel Danielle Rogers and Roman Balaban, filed her Complaint more than three years ***after*** the statute of limitations expired. Movant Beltz (W.D. Mo.) received a "Bard PowerPort ClearVue MRI Port" in July 2017. About six months later, she allegedly suffered an infection. Movant, by her counsel Adam Evans, filed her Complaint three months ***after*** the statute of limitations expired. Movant Elwell (D. Kan.) received a "Bard PowerPort ClearVue Implantable Port" in January 2015. Six years later, she allegedly suffered an infection. Movant, by her counsel Adam Evans and Roman Balaban, filed her Complaint four months ***after*** the statute of limitations expired. Movant Nelk (D.N.J.) received a "Bard PowerPort ClearVue Implantable Port" in February 2021. About two weeks later, she allegedly suffered an infection. Movant, by her counsel Adam Evans and Roman Balaban, filed her Complaint on the eve of the expiration of the statute of limitations.

[10] *Prentice* (D. Ariz.) ("BardPort M.R.I Implantable Port"); *Kelley* (W.D. Mo.) ("Bard PowerPort ClearVue ISP Implantable Port"); *Divelbliss* (D.N.M.) ("Bard PowerPort® isp M.R.I Implantable Port"); *Cabello* (D.N.J.) ("Bard Groshong© MRI implantable injection port"). The final case was not initially pleaded as a fracture case. In her initial pleading, Movant Cunningham (W.D. Mo.) alleged that she received a "Bard PowerPort M.R.I. Implantable Port," and that nearly three years later, she was allegedly suffered an infection. Movant, by her counsel Adam Evans, filed her Complaint just one week before the latest date that the statute of limitations would expire. In response to Bard's Motion to Dismiss, Movant Cunningham filed an Amended Complaint pursuant to Rule 15(a)(1)(B) and entirely changed the facts of her case: She now alleges that she suffered a

indicates that the catheter detached at the port following her breast reconstructive surgery, and therefore, did not "fracture." Because each of these actions may turn on whether the alleged fracture was the result of pinch-off or how the device was implanted, the subsequent maintenance of the implanted device, and plaintiffs' underlying medical treatment, these actions can be litigated in the ordinary course as Defendants have done in the past.

The final case alleges thromboembolism. The facts of this case are readily distinguishable from the pending actions given the type of alleged complication and the short time-period between insertion of the device and the occurrence of that complication.[11] In addition, the complaints allege injuries from different catheters: eight cases involve the insertion of polyurethane Chronoflex™ catheter, while three cases involve the insertion of a silicone Groshong™ catheter.

D. Defendants Have Proposed Informal Coordination

Although Defendants oppose formation of an MDL, they remain open to informal coordination. In response to Movants' request for a stay of all proceedings pending this Motion, Defendants have proposed that the parties proceed with pre-answer motion practice in each case and the exchange of "core" discovery: (1) Initial Disclosures; (2) plaintiffs' port-related treatment records (i.e., implant and explant records and any medical procedures related to the alleged complications); (3) Defendants' existing Medical Device Reports ("MDRs") to the FDA for each plaintiff; (4) the applicable 510(k) submissions; and (5) certain device-specific design documents.

---

catheter fracture—not an infection—and that the catheter was inserted in the right internal jugular vein—not the subclavian vein. Bard respectfully submits that the Panel should interpret this about-face by Movants' counsel for what it truly is: disinterest in vetting the substance of each case given the focal interest in boosting case numbers for this Motion.

[11] Movant Terry (W.D. Mo.) allegedly received a "Bard PowerPort ClearVue Implantable Port" in March 2022. Less than three weeks later in April 2022, Movant was admitted to the hospital for concerns of thrombosis.

Cert. of Counsel ¶ 16, Ex. D. As discussed, nothing in this Motion or pleaded in the present actions suggest that the parties' past success with informal coordination cannot be replicated here.

ARGUMENT

Section 1407 prescribes that "civil actions involving one or more common questions of fact . . . may be transferred to any district for coordinated or consolidated pretrial proceedings . . . upon [the Panel's] determination that transfers for such proceedings will be for the convenience of parties and witnesses and will promote the just and efficient conduct of such actions." 28 U.S.C. § 1407(a). Particularly in light of Defendants' track record of efficiently managing and resolving these actions without the need for centralization, Movants "bear a strong burden to show that the common questions of fact are so complex and the accompanying discovery so time-consuming that Section 1407 transfer would serve the convenience of the parties and witnesses and promote the just and efficient conduct of the litigation." *In re Raymond Lee Org., Inc. Sec. Litig.*, 446 F. Supp. 1266, 1268 (J.P.M.L. 1978). Movants fall woefully short of making that showing. Individualized issues will overwhelm the efficiencies, if any, to be gained from centralization.

The Panel has also stated that "centralization under Section 1407 should be the *last solution* after considered review of all other options." *In re: Best Buy Co., Inc., Cal. Song-Beverly Credit Card Act Litig.*, 804 F. Supp. 2d 1376, 1378 (J.P.M.L. 2011) (emphasis added). Informal coordination is a "practicable" alternative that will minimize any inconveniences to the parties or witnesses (i.e., cross-noticing depositions). *In re Belviq (Lorcaserin HCI) Prod. Liab. Litig.*, 555 F. Supp. 3d 1369, 1370-71 (J.P.M.L. 2021).

I. Individualized Factual Issues Concerning the Devices and the Alleged Injuries Predominate and Negate Any Perceived Efficiencies of an MDL.

"The existence of common questions of fact between actions is . . . but one condition precedent to transfer under Section 1407. Before a transfer will be ordered, the Panel must be

satisfied that all the statutory criteria have been met." *In re Drowning Incident at Quality Inn Ne., Washington, D. C., on May 3, 1974*, 405 F. Supp. 1304, 1306 (J.P.M.L. 1976) (internal citation omitted). Accordingly, it is not enough to just identify common questions of fact. The common issues must predominate over the highly individualized issues specific to each plaintiff to render centralization appropriate. *See* 28 U.S.C. § 1407(a); *In re Xytex Corp. Sperm Donor Prod. Liab. Litig.*, 223 F. Supp. 3d 1351, 1352 (J.P.M.L. 2016) (denying motion for centralization because "the[] common factual questions [did not] predominate over the plaintiff-specific factual and legal questions presented in these actions"). In other words, the common questions of fact must be "so complex . . . that Section 1407 transfer would serve the convenience of the parties and witnesses and promote the just and efficient conduct of the litigation." *In re Raymond Lee Org., Inc. Sec. Litig.*, 446 F. Supp. at 1268.

Movants do not come close to meeting this standard. They merely identify certain high-level "common questions" that are attendant to every products liability action involving a medical device: whether plaintiffs have established causation, and "whether Defendants acted negligently in the design, testing, manufacture, sale of these devices, whether Defendants should be strictly liable for injuries caused by these devices, and whether Defendants failed to satisfy their duty to warn healthcare providers of the risks posed by these products." Mot. at 8. Setting aside their conclusory allegations, the only commonality among plaintiffs is their theory of liability: that "the design of the catheter components of Defendants' products are rendered unreasonably dangerous by a common design element, and that said unreasonably dangerous condition caused Plaintiffs' injuries." Mot. at 7. That sweeping statement does not withstand scrutiny however, and Plaintiffs wholly fail to explain how "Centralization of the Actions will Minimize the Risk of Inconsistent Rulings." *Id.* at 6 (capitalization in original).

The individualized issues are abundant and predominate over those common questions. *See In re: Linear Gadolinium-Based Contrast Agents Prod. Liab. Litig.*, 341 F. Supp. 3d 1381, 1382 (J.P.M.L. 2018) (finding that "movants have failed to demonstrate that any common questions of fact and law are sufficiently complex or numerous to justify centralization" and noting that "the injuries alleged in each case appear to be highly plaintiff-specific"). Movants seek to form an MDL (1) involving disparate complications (fracture versus infection versus thrombosis) (2) caused by a number of different devices (which Plaintiffs have failed to adequately identify) (3) that allegedly occurred over a significantly different time period. These individualized factual issues "diminish the potential to achieve significant efficiencies in an MDL" because the parties may be required to, among other things, engage in product-specific discovery in each case, seek significant third-party discovery from the relevant medical providers, and retain specialized experts. *In re Belviq (Lorcaserin HCl) Prod. Liab. Litig.*, 555 F. Supp. 3d at 1370 (denying motion for centralization where "individualized factual issues concerning causation will predominate and diminish the potential to achieve significant efficiencies in an MDL").

Analysis of the pending actions evidences their lack of amenability to centralization. Discovery and trial in a catheter fracture action, such as *Divelbliss*, which involves the alleged fracture of a silicone Groshong catheter two-and-a-half years after implantation, will look very different than discovery and trial in *Nelk,* which involves the alleged occurrence of a bloodstream infection two weeks after implantation of a polyurethane Chronoflex catheter.

Discovery in *Divelbliss* will require fact-specific expert opinions from the parties on the proper implantation and maintenance of the PowerPort over the two-year period to rule-in and rule-out alternative causes of the alleged fracture, such as pinch-off or subpar maintenance of the device. There will also be fact-specific expert discovery regarding Ms. Divelbliss's contention that

her silicone Groshong catheter was defectively designed. Specifically, she contends that her catheter allegedly fractured two-and-a-half years after implantation at the location of a "radiopaque barium sulfate stripe" as a result of "improper mixing of barium sulfate particles within the silicone matrix." *Divelbliss v. Bard Access Sys., Inc.*, No. 22-cv-601, Compl. ¶¶ 16, 20, 64, ECF No. 26 (D.N.M.).

In contrast, fact and expert discovery in *Nelk* will be focused predominately on (1) whether sterile practices were followed by her medical providers, and (2) whether the barium sulfate in her polyurethane Chronoflex catheter "dissociated from the surface of the catheter" in just eleven days following implantation so as to create a "roughened catheter surface" and cause her "bloodstream infection." *Nelk v. Becton, Dickinson & Co.*, No. 23-cv-1173, Compl. ¶¶ 25, 30, 40-41, ECF No. 1 (D.N.J.). The trier-of-fact's highly fact-specific findings as to the existence of a fracture-related design defect and causation in *Divelbliss* will be of no moment to the trier-of-fact's determination in *Nelk*.

This same line of reasoning extends to the infection cases. From what can be discerned from the complaints that actually identify the infection at issue (most do not), Movants have not shown that centralization will minimize the risk of inconsistent rulings or promote the efficient conduct of these actions. For example, Movant Groves alleges that she developed "Staph Aureus Bacteremia, a blood infection[,] . . . [as] a result of seepage from the defective PowerPort catheter" less than a month after implantation of the port. *Groves v. Becton, Dickinson & Co.*, Compl. ¶¶ 60-61, No. 23-cv-6058, ECF No. 1 (W.D. Mo.). Movant Anderson, on the other hand, alleges that he "developed a fungemia infection" more than eighteen months after implantation of the port. *Anderson*, Compl. ¶¶ 40-41, No. 23-cv-316, ECF No. 1 (W.D.Mo.). Movants make no showing as

to how centralization of these actions involving disparate fact patterns will be convenient to anyone other than Movants' counsel who are pushing for the formation of this MDL.

Nor is there sufficient commonality with respect to issues related to Defendants' products and conduct. Movants fail to explain whether there are commonalities among the varied devices identified in the underlying Complaints, which identify eight different variations of devices and involve different catheters.

Lastly, Movants fail to carry their "strong burden" of "show[ing] that . . . the accompanying discovery [will be] so time-consuming that Section 1407 transfer would serve the convenience of the parties and witnesses and promote the just and efficient conduct of the litigation." *In re Raymond Lee Org., Inc. Sec. Litig.*, 446 F. Supp. at 1268. This is particularly true in these circumstances given the common discovery that the parties were able to efficiently exchange and coordinate in the prior actions and the fact that all prior cases over the last five years resolved without expert disclosures, and all, except one action, resolved without a single deposition.

For these reasons, these actions lack sufficient common questions of fact such that centralization would serve the convenience of the parties or promote the just and efficient conduct of this litigation.

II. The Minimal Number of Actions Filed and Their Procedural Posture Weigh Against Centralization

"The Panel has repeatedly stated 'where only a minimal number of actions are involved, the moving party generally bears a heavier burden of demonstrating the need for centralization.'" *In re Stivax Mktg. & Sales Pracs. Litig.*, __ F. Supp. 3d __, 2022 WL 17843106, at *1 (J.P.M.L. Dec. 12, 2022) (quoting *In re Transocean Ltd. Secs. Litig. (No. II)*, 753 F. Supp. 2d 1373, 1374 (J.P.M.L. 2010)). Such is the case here. The low number of pending actions weigh against centralization, and Plaintiffs have failed to carry their heavy burden of proving otherwise. *In re*

Covidien Hernia Mesh Prod. Liab. Litig., 481 F. Supp. 3d 1348, 1349 (J.P.M.L. 2020) (denying centralization of twelve actions pending in nine districts).

Relatedly, the Panel should reject Movants' reliance on the likelihood of future filings. The Panel has repeatedly reiterated that it is "'disinclined to take into account the mere possibility of future filings in [its] centralization calculus.'" *Id.* (quoting *In re Lipitor (Atorvastatin Calcium) Mktg., Sales Practices & Prods. Liab. Litig.*, 959 F. Supp. 2d 1375, 1376 (J.P.M.L. 2013)). That admonition is apt here in light of Movants' unsupported prediction that "thousands (and possibly tens of thousands) of similar follow-on cases are likely to be filed" in the future. Mot. at 9. As discussed, there has been no precipitating event that will lead to a wave of new litigation after decades of these devices' safe and effective use to administer lifesaving medications.

Plaintiffs cannot rely on the FDA's election to formally end its Alternative Summary Reporting ("ASR") program in June 2019,[12] or the unrelated cited journal article published in January 2021 evaluating purported long-term complications associated with unidentified port-a-catheters to suggest that future filings are imminent.[13] Mot. at 3-4. To the contrary, the low number of actions filed since these events underscores the lack of a need for an MDL.

---

[12] Defendants dispute any suggestion that their lawful submission of data through the FDA's ASR program was in any way improper. Under the ASR program, "manufacturers of certain devices could request an exemption from the requirement to file individual medical device reports for certain events that were well-known and well-established risks associated with a particular device and to instead submit quarterly summary reports of such events." FDA, Press Release, *Statement on agency's efforts to increase transparency in medical device reporting* (June 21, 2019). According to FDA, "[t]he ASR Program allowed the FDA to more efficiently review reports of well-known, well-understood adverse events, so [it] could focus on identifying and taking action on new safety signals and less understood risks." *Id.*

[13] Defendants further dispute the inference drawn by Movants from the cited journal article that port devices, and Bard's in particular, have a high complication rate. In the article, there is no mention of Bard devices and no mention that barium sulfate or any other design feature had anything to do with the complications reported. The study explicitly acknowledges its limitations including that the data reviewed "does not allow for control of individual variabilities such as surgeon expertise, procedural methods, and follow-up and treatment protocols, or any insight into

The Panel's analysis in *In re: Lipitor (Atorvastatin Calcium) Mktg., Sales Pracs. & Prod. Liab. Litig.*, 959 F. Supp. 2d at 1376, is on point:

> Although plaintiffs suggest that the number of Lipitor cases is likely to expand considerably, we are disinclined to take into account the mere possibility of future filings in our centralization calculus. That is particularly true here. Lipitor came to market in the late 1990's, and is one of the best-selling prescription drugs of all time. Virtually all the complaints in these actions cite a label change for the drug—as well as other statins—informing patients that increases in blood sugar levels had been reported with statin use. That label change, however, occurred in February 2012. Yet, more than a year later, only a relative handful of actions have been brought actually alleging a link between an individual's ingestion of Lipitor and the development of her type 2 diabetes.
>
> As always in this type of litigation, a highly individualized inquiry is necessary to determine whether any particular plaintiff developed type 2 diabetes as a result of taking Lipitor. Where few cases are filed, the balance tips toward allowing the regular litigation process to resolve those cases.

So too here. Bard's implantable ports have been on the market for two decades, and the plaintiffs in these actions all allege the occurrence of complications that are disclosed in the IFUs for these devices. Only a handful of actions have been filed in the four years since the FDA's withdrawal of the ASR program and the two years since the publication of the cited journal article. Given the highly individualized inquiry necessary to determine the cause of an infection, fracture, or

---

patient selection criteria. Various clinical factors, including but not limited to agents infused, heparin flushes, and systemic anticoagulation, are all variables that may further discern differences in complication rates within this cohort that we were unable to assess." S.I. Khalid, et al, *Outcomes following port-a-catheter placement in Medicare population*, Surgery Open Science 3 (2021) 39, 42. Contrary to the Khalid article that claims that 59% of the patients in that study experienced "any complication" with unidentified "port-a-catheter" devices, another study of patients implanted only with Bard M.R.I. Implantable Ports with open end 8 French polyurethane single lumen venous catheters found the "overall complication rate is consistent with data reported by several studies that range between 2 to 14.4%." Granziera et al., *Totally implantable venous access devices: retrospective analysis of different insertion techniques and predictors of complications in 796 devices implanted in a single institution*, BMC Surgery 2014, 14:27

thrombus and the low number of cases, the parties can and should rely on the regular litigation process and informal coordination.

Finally, the Panel has stated that "a history of early dismissals and settlements 'suggests that the advantages centralization typically affords—i.e., reducing duplicative discovery and motion practice, etc.—may not be relevant.'" *In re Hotel Booking Access for Individuals With Disabilities Litig.*, 521 F. Supp. 3d 1361, 1362 (J.P.M.L. 2021) (quoting *In re: ArrivalStar S.A. Fleet Mgmt. Sys. Patent Litig.*, 802 F. Supp. 2d 1378, 1379 (J.P.M.L. 2011)). Early dismissals and settlements has been the norm in the past implantable port litigation. Indeed, none of the previously filed cases by Mr. Evans or others over the last five years proceeded to expert disclosures, and only one case proceeded to deposition.

In sum, Movants have failed to carry their burden of demonstrating that centralization is appropriate here.

III. Informal Coordination is Possible and Preferred.

As the Panel has stated in the past, "[t]he presence of common counsel here should facilitate informal coordination of this relatively small number of actions." *In re Covidien Hernia Mesh Prod. Liab. Litig.*, 481 F. Supp. 3d at 1349 (citing *In re Cymbalta (Duloxetine) Prods. Liab. Litig.*, 65 F. Supp. 3d 1393, 1394 (J.P.M.L. 2014)). Here, Movants' counsel Adam Evans, with whom Defendants have previously litigated and successfully coordinated pending actions without centralization, represents plaintiffs in more than half of the pending actions. Mr. Evans has also advised Defendants that he is coordinating with other counsel, which is also reflected in the fact that he is co-counsel with Balaban Law, LLP and Ratzan Weissman & Boldt in certain cases. In addition, defense counsel is the same for all actions.

These considerations, including the fact that all of these actions are in their early stages, weigh against centralization. *See In re: Lipitor (Atorvastatin Calcium) Mktg., Sales Pracs. & Prod.*

Liab. Litig., 959 F. Supp. 2d at 1376 (denying centralization where "many of the actions involve common plaintiffs' counsel"; and defendants agreed "to appropriately coordinate any common discovery or other pretrial matters across the cases"); *In re Linear Gadolinium-Based Contrast Agents Prod. Liab. Litig.*, 341 F. Supp. 3d at 1382 ("[P]laintiffs in most actions are represented by a single law firm or firms that are working as co-counsel with that firm in other related actions. . . . Given the significant overlap in plaintiffs' counsel, alternatives to transfer exist that may minimize whatever possibilities there might be of duplicative discovery and/or inconsistent pretrial rulings."); *In re Belviq (Lorcaserin HCI) Prod. Liab. Litig.*, 555 F. Supp. 3d at 1370–71 (stating that informal coordination is "practicable" and likely "to minimize duplicative discovery through cooperative efforts" where "[a]ll actions are in their early stages"). To the extent that Movants' counsel state in their reply that they have a number of retained additional claimants who have not yet filed suit, voluntary coordination remains "a preferable alternative to centralization." *In re Qualitest Birth Control Prod. Liab. Litig.*, 38 F. Supp. 3d 1388, 1389 (J.P.M.L. 2014) (stating that, notwithstanding counsel's representation that "there are 113 additional claimants that have not yet filed suit," voluntary coordination remained a preferable alternative to centralization given that those "potential plaintiffs would be represented by movants' counsel").

IV. Centralization of these Actions in the Western District of Missouri Would Advance Only the Interests of Movants' Counsel

The Panel has taken into account whether "a Section 1407 motion appears intended to further the interests of particular counsel more than those of the statute." *In re CVS Caremark Corp. Wage and Hour Emp't Practices Litig.*, 684 F. Supp. 2d 1377, 1379 (J.P.M.L. 2010). Following Mr. Evans' call with Defendants in December 2022, Movants' counsel have been true to their word in seeking to file actions (many of which are plainly barred by the applicable statute of limitations and filed in improper venues) in an effort to tee up this Motion. The only connection

to Missouri is that it is the home state of some of Movants' counsel and certain plaintiffs. Despite Defendants' lack of any specific connection to the Western District of Missouri, Movants nonetheless seek to centralize all actions in that district.

The Panel should deny centralization for the reasons stated in this Memorandum. In the event that the Panel finds centralization to be warranted, the Western District of Missouri is not the appropriate transferee district given its lack of connection to Defendants' contacts.[14] Instead, Defendants respectfully request the Panel centralize and transfer the pending actions to either the District of Utah or the District of Arizona.

The District of Utah is an appropriate transferee court. Bard Access Systems is the principal manufacturer and distributor of Defendants' implantable ports, and is a Utah corporation with a principal place of business in Utah. A significant number of relevant witnesses and documents are located at Bard Access Systems' headquarters in Salt Lake City. No MDL is currently pending in that district, as opposed to the now five MDLs pending in the Western District of Missouri. The District of Arizona is also an appropriate transferee court. Bard Access Systems, Inc. has a significant business presence in Arizona where a number of prospective witnesses work out of Defendants' facility in Tempe, Arizona. Notably, the Honorable David G. Campbell effectively oversaw an MDL to completion related to C. R. Bard, Inc.'s inferior vena cava ("IVC") filter

[14] In the event that the Panel orders transfer to the Western District of Missouri, Defendants respectfully submit that the Honorable Brian C. Wimes is not an appropriate selection for the transferee judge. Judge Wimes may need to recuse himself from the pending actions due to Defendants separately retaining Shook Hardy & Bacon, LLP as local counsel, where Judge Wimes daughter is now working as a summer law clerk. Defendants intend to address this issue with His Honor and Movants' counsel separately. Furthermore, Judge Wimes was recently assigned another MDL by the Panel. *See In re: T-Mobile 2022 Customer Data Security Breach Litig.*, MDL No. 3073, ECF No. 59 (assigning MDL to Judge Wimes and noting that His Honor is separately presiding over MDL No. 3019).

products that at one point had more than 8,000 cases pending in the District of Arizona. *See In re: Bard IVC Filters Prods. Liab. Litig.*, No. 2:15-md-2641 (D. Ariz.).

CONCLUSION

For the foregoing reasons, Defendants respectfully request the Panel deny this Motion to Transfer Actions.

Dated: June 16, 2023 By: */s/ Edward J. Fanning*

McCARTER & ENGLISH, LLP
Edward J. Fanning
Wilfred P. Coronato
Christopher A. Rojao
Ryan M. Savercool
Four Gateway Center
100 Mulberry Street
Newark, New Jersey 07102
Telephone: (973) 639-8486
Fax: (973) 624-7070
efanning@mccarter.com

Attorneys for Defendants,
Becton, Dickinson and Company, C.R. Bard, Inc., and Bard Access Systems, Inc.

BEFORE THE UNITED STATES JUDICIAL PANEL ON MULTIDISTRICT LITIGATION

IN RE: BARD IMPLANTED PORT CATHETER PRODUCTS LIABILITY LITIGATION	MDL No. 3081 **CERTIFICATION OF COUNSEL IN SUPPORT OF DEFENDANTS' OPPOSITION TO THE MOTION TO TRANSFER ACTIONS**

EDWARD J. FANNING, ESQ., of full age, hereby certifies as follows:

1. I am a partner of the law firm of McCarter & English, LLP, attorneys for Defendants Becton, Dickson & Company; C.R. Bard., Inc.; and Bard Access Systems, Inc. ("Defendants" or "Bard"). I submit this Certification in support of Defendants' Opposition to the Motion to Transfer Actions.

2. This Motion arises from product liability litigation concerning Bard's implantable port devices. I, along with attorneys at McCarter & English, LLP, have defended Bard in the limited litigation that has arisen over the years involving these devices.

3. The various iterations and configurations of Bard's implantable port devices sold under the tradename "PowerPort" are set forth in a Specification Sheet that is attached hereto as **Exhibit A**.

4. Each PowerPort device is accompanied by a separate Instructions for Use ("IFU"). A copy of the IFU corresponding to the PowerPort M.R.I. Implantable Port identified by the plaintiff in *Divelbliss v. Bard Access Sys., Inc.*, No. 22-CV-00601 (D.N.M.), is attached hereto as **Exhibit B**.

5. Apart from the actions that are the subject of the Motion to Transfer Actions, there were only eleven other actions filed in the five years preceding this Motion.

6. At one point, nine cases were simultaneously pending in nine different district courts, which Defendants managed without formal consolidation. These cases were captioned: *Cruz v. C.R. Bard., Inc.*, No. 18-cv-2637 (S.D. Cal. Nov. 16, 2018); *Dixon v. C.R. Bard, Inc.*, No. 19-cv-4037 (S.D. Tex. Oct. 16, 2019); *Recker v. C.R. Bard, Inc.*, No. 19-cv-950 (W.D. Okla. Oct. 16, 2019); *Wright v. C.R. Bard, Inc.*, No. 19-cv-3029 (D. Md. Oct. 16, 2019); *Bradburn v. C.R. Bard, Inc.*, No. 19-cv-925 (N.D. Ind. Oct. 18, 2019); *Duff v. C.R. Bard, Inc.*, No. 20-cv-60 (W.D. Ky. Mar. 30, 2020); *Gorji v. C.R. Bard, Inc.*, No. 21-cv-3134 (D. Neb. June 6, 2021); *Camden v. C.R. Bard, Inc.*, No. 21-cv-3878 (S.D. Ohio July 1, 2021); *Mitchell v. C.R. Bard, Inc.*, No. 21-cv-5121 (N.D. Cal. Sept. 29, 2021).

7. Of those nine simultaneously pending actions, the Brenes Law Group, P.C., through its attorneys Troy Brenes and Adam Evans, filed eight of those actions. Mr. Evans is Movants' counsel in at least six of the actions that are the subject of this Motion to Transfer Actions.

8. Defendants were able to coordinate discovery in those eight cases with Mr. Evans without the need for an MDL. All cases resolved prior to the exchange of expert disclosures, and all cases, except one, resolved without taking a single deposition.

9. Apart from the eight cases filed by Mr. Evans' prior firm, only four cases were filed between June 2021 and August 2022. The first action was resolved after pre-answer motion practice and the exchange of limited discovery. *See Gorji v. C.R. Bard, Inc.*, No. 21-cv-3134 (D. Neb.). Two cases were voluntarily dismissed upon Defendants' filing of motions to dismiss. *See Hagwood v. C.R. Bard, Inc.*, No. 22-cv-2632 (N.D. Ga.); *Franks v. C.R. Bard, Inc.*, 22-cv-1665 (N.D. Ohio). The final case, which was not filed by Movants' counsel but is the first action listed in the Motion to Transfer Actions, was filed in July 2022 and has been the subject of a fully briefed motion to dismiss since December 2022. *See Divelbliss v. Bard Access Sys., Inc.*, No. 22-cv-601

(D.N.M.). All cases resolved within one month to thirty-one months of filing, with an average duration of about eighteen months.

10. In December 2022, Mr. Evans contacted Defendants, and advised the Undersigned that he was running a targeted digital advertising campaign with a consortium of other law firms with an eye toward filing an MDL application.

11. This coordinated digital advertising campaign has resulted in several internet websites such as portcatheterlawsuit.com, which is hosted by Mr. Evans' law firm. Other websites have already emphasized the filing of this Motion, such as https://www.aboutlawsuits.com/bard-powerport-lawsuit. A copy of these webpages is attached hereto as **Exhibit C**.

12. After the telephone call in December 2022, Mr. Evans, through his firm of Dickerson Oxton, LLC and alongside the law firms of Balaban Law, LLC and Ratazan, Weissman & Boldt, separately or jointly filed eight actions between February 10, 2023 and May 22, 2023. Movants' counsel then filed their Motion to Transfer Actions on May 24, 2023.

13. Movants advance the same theory of liability in the pending actions that Mr. Evans advanced in the prior, now dismissed actions: that Defendants' radiopaque agent, barium sulfate, is allegedly "known to reduce the material integrity of the catheter when it is not encapsulated, coated or otherwise separated from the catheter surface," which in turn can lead to complications. (*Compare* Mot. at 3 *with Duff v. C.R. Bard, Inc.*, Am. Compl. ¶¶ 18-23, No. 20-cv-60, ECF No. 20 (W.D. Ky. June 22, 2020) (alleging that "Defendants' manufacturing process . . . involved too high a concentration of barium sulfate particles" and that Defendants elected not to incorporate "design modifications to encapsulate the radiopaque compound").

14. In 2021, Mr. Evans filed at least five complaints alleging identical theories related to the use of barium sulfate against AngioDynamics, Inc., another manufacturer of implantable

venous access devices. *See, e.g.*, *Kingston v. AngioDynamics, Inc.*, Compl. ¶¶ 28-31, No. 21-cv-10234, ECF No. 1-3 (D. Mass Feb. 11, 2021) (alleging that "Defendants' manufacturing process . . . involved too high a concentration of barium sulfate particles" and that "Defendants elected not to incorporate" certain "design modifications").

15. On June 9, 2023, Mr. Evans emailed the Undersigned to seek Defendants' consent to a stay of all eleven actions pending the Panel's decision on this Motion.

16. On June 15, 2023, Defendants sent Movants' counsel a letter in response to the request for a stay, proposing that the parties proceed with pre-answer motion practice in each case and the exchange of "core" discovery. Defendants further proposed a meet and confer regarding informal coordination of the pending actions. A copy of Defendants' letter and the parties' emails are attached hereto as **Exhibit D**.

17. Nothing in the present actions suggest that the parties' prior informal coordination cannot be replicated here. However, in the event that centralization is ordered, transfer should be to either the District of Utah or the District of Arizona. Bard Access Systems is the principal manufacturer and distributor of Defendants' PowerPorts, and is a Utah corporation with a principal place of business in Utah. A significant number of relevant witnesses and documents are located at Bard Access Systems' headquarters in Salt Lake City Bard Access Systems, Inc. also has a significant business presence in Arizona where a number of prospective witnesses work and reside.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on: June 16, 2023

/s/ Edward J. Fanning

McCARTER & ENGLISH, LLP
Edward J. Fanning
Four Gateway Center
100 Mulberry Street
Newark, New Jersey 07102

Telephone: (973) 639-8486
Fax: (973) 624-7070
efanning@mccarter.com

Attorneys for Defendants,
Becton, Dickinson and Company, C.R. Bard, Inc., and Bard Access Systems, Inc.

Exhibit A

PowerPort™

Implantable Port

Specification Sheet

	PowerPort™ ClearVUE™ isp Implantable Port	PowerPort™ ClearVUE™ Slim Implantable Port	PowerPort™ isp M.R.I.™ Implantable Port	PowerPort™ M.R.I.™ Implantable Port	PowerPort™ duo M.R.I.™ Implantable Port	PowerPort™ isp Implantable Port	PowerPort™ Slim Implantable Port	PowerPort™ Implantable Port
								
Port								
Reservoir Material	Plastic w/ Silicone Overmold	Plastic	Plastic w/ Titanium Markers & Stem	Plastic w/ Titanium Markers & Stem	Plastic w/ Titanium Markers & Stem	Titanium	Titanium	Titanium
Profile	Intermediate	Low Profile	Intermediate	Full Size	Intermediate	Intermediate	Low Profile	Full Size
Base Diameter (mm)	29.0	28.0	29.0	32.0	29.0 x 39.0	30.0	28.0	32.0
Height (mm)	11.9	10.4	11.6	13.6	12.5	11.3	9.9	13.1
Internal Volume (mL)	0.6	0.4	0.6	0.6	0.6 Each Reservoir	0.6	0.5	0.6
Suture Mechanism	Silicone Overmold	Silicone-filled & Non-filled Suture Holes	Silicone-filled & Non-filled Suture Holes	Silicone-filled & Non-filled Suture Holes	Silicone-filled Suture Holes	Silicone-filled & Non-filled Suture Holes	Silicone-filled & Non-filled Suture Holes	Silicone-filled & Non-filled Suture Holes
Septum								
Bump Configuration	Modified & Smooth	Modified & Smooth	Regular & Modified	Regular	Modified	Regular & Modified	Modified	Regular
Diameter (mm)	13.0	8.9	13.0	13.0	13.0	13.0	8.9	12.7
Puncture								
19 Gauge Non-Coring Needle	208 punctures	208 punctures	208 punctures	208 punctures	208 punctures	208 punctures	208 punctures	208 punctures
Power Injection Flow Rate								
19 Gauge PowerLoc™ Needle	5 mL/sec	5 mL/sec	5 mL/sec	5 mL/sec	5 mL/sec	5 mL/sec	5 mL/sec	5 mL/sec
20 Gauge PowerLoc™ Needle	5 mL/sec	5 mL/sec	5 mL/sec	5 mL/sec	5 mL/sec	5 mL/sec	5 mL/sec	5 mL/sec
22 Gauge PowerLoc™ Needle	2 mL/sec	2 mL/sec	2 mL/sec	2 mL/sec	2 mL/sec	2 mL/sec	2 mL/sec	2 mL/sec

CONTINUED

BD

PowerPort™

Implantable Port

	PowerPort™ ClearVUE™ isp Implantable Port	PowerPort™ ClearVUE™ Slim Implantable Port	PowerPort™ isp M.R.I.™ Implantable Port	PowerPort™ M.R.I.™ Implantable Port	PowerPort™ duo M.R.I.™ Implantable Port	PowerPort™ isp Implantable Port	PowerPort™ Slim Implantable Port	PowerPort™ Implantable Port
• Catheter Depth Markings Every 1 cm • Gravity Flow Rate > 500 mL/h w/ 19 Gauge Non-Coring Needle • 28-Day Flushing Interval (Except where noted)								
MR Rating								
Safe/Conditional	MR	MR	MR	MR	MR	MR	MR	MR
Available Catheter Options (Attachable)								
6F Polyurethane, 45 cm Length ◆ ChronoFlex™ Catheter (1.3 mm I.D.) 0.7 mL volume (0.014 mL/cm)	◆	◆	◆			◆		
6F Polyurethane, 60 cm Length ◆ ChronoFlex™ Catheter (1.3 mm I.D.) 0.9 mL volume (0.014 mL/cm)							◆	
8F Polyurethane, 45 cm Length ◆ ChronoFlex™ Catheter (1.6 mm I.D.) 0.9 mL volume (0.02 mL/cm)	◆	◆	◆	◆		◆	◆	◆
9.5F Polyurethane, 45 cm Length ◆ ChronoFlex™ Catheter (1.5 mm I.D.) 0.9 mL volume (0.02 mL/cm/Lumen)					◆			
8F Silicone, 45 cm Length ◆ Groshong™ Catheter 90-Day Saline Flushing Interval (1.5 mm I.D.) 0.9 mL volume (0.02 mL/cm)			◆	◆		◆	◆	◆
9.6F Silicone, 45 cm Length ◆ Hickman™ Catheter (1.6 mm I.D.) 0.9 mL volume (0.02 mL/cm)			◆	◆				◆
Kit Configuration								
Intermediate/Microintroducer	Intermediate & Microintroducer	Intermediate & Microintroducer	Intermediate & Microintroducer	Intermediate & Microintroducer	Intermediate & Microintroducer	Intermediate & Microintroducer	Intermediate & Microintroducer	Intermediate & Microintroducer

PowerPort™ Implantable Port

Indications for Use: The PowerPort™ Implantable Port is indicated for patient therapies requiring repeated access to the vascular system. The port system can be used for infusion of medications, I.V. fluids, parenteral nutrition solutions, blood products, and for the withdrawal of blood samples. When used with a PowerLoc™ Brand Safety Infusion Set, the PowerPort™ device is indicated for power injection of contrast media. For power injection of contrast media, the maximum recommended rate is 5 mL/s.

Contraindications: This device is contraindicated for: · Catheter insertion in the subclavian vein medial to the border of the first rib, an area which is associated with higher rates of pinch-off. Port may be placed in lateral subclavian vein based on evaluation by a qualified practitioner. · When the presence of device-related infection, bacteremia, or septicemia is known or suspected. · When the patient's body size is insufficient for the size of the implanted device. · When the patient is known or is suspected to be allergic to materials contained in the device. The device is primarily comprised of silicone, polyacetal, polyetheretherketone, and/or titanium · If severe chronic obstructive lung disease exists. · If the prospective insertion site has been previously irradiated. · If the prospective placement site has previously suffered episodes of venous thrombosis or vascular surgical procedures. · If local tissue factors will prevent proper device stabilization and/or access.

Warnings: · Avoid vessel perforation · Do not power inject through a port system that exhibits signs of clavicle-first reib compression or pinch-off as it may result in port system failure · PowerPort™ Implantable Ports are only power injectable when accessed with a PowerLoc™ Brand Safety Infusion Set. · Failure to ensure patency of the catheter prior to power injection studies may result in port system failure · Exceeding maximum flow rate may result in port system failure and/or catheter tip displacement · PowerPort™ implantable port indication for power injection of contrast media implies the port's ability to withstand the procedure, but it does not imply appropriateness of the procedure for a particular patient nor for a particular infusion set. A suitably trained clinician is responsible for evaluating the health status of a patient as it pertains to a power injection procedure and for evaluating the suitability of any infusion set used to access the port. · Do not exceed a 300 psi pressure limit setting on the power injection machine, or the maximum recommended flow rate on the PowerLoc™ needle, if power injecting through the PowerPort™ implantable port. · If local pain, swelling or signs of extravasation are noted during power injection, the injection should be stopped immediately. Do not use a syringe smaller than 10ml to access the port. Flushing occluded catheters with small syringes can create excessive pressure within the port system.

Precautions: · Check patient's records, and ask patient, whether they have any known allergies to chemicals or materials that will be used during the placement procedure. · Fill (prime) the device with sterile normal saline solution to help avoid air embolism. · Carefully follow the connection technique given in the IFU to ensure proper catheter connection and to avoid catheter damage. · Care should be taken to avoid excessive force when accessing an implanted port.

Potential Adverse Reactions: · Air Embolism, Device rotation or extrusion, Allergic reactions, Extravasation, Catheter or port erosion through the skin, and Fibrin sheath formation

Please consult product labels and inserts for any indications, contraindications, hazards, warnings and precautions, and directions for use.

For technical inquiries, contact the BD Clinical Information Hotline at 800 555 7422.

www.bd.com | 1 800 321 4254 | 1625 W. 3rd Street Tempe, AZ 85281

BD-32067

MR Safe

MR Conditional: 3000 Gauss/cm

BD

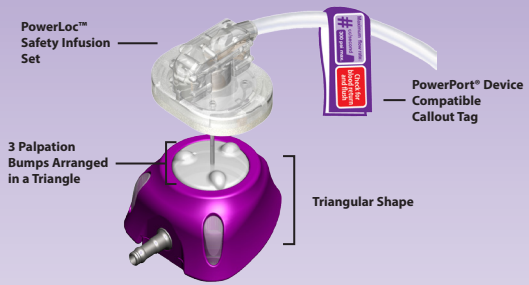
Exhibit B

PowerPort®

Implantable Port

Instructions For Use

PowerPort® Implantable Port Features



Examples of Radiopaque Identifiers

Radiopaque identifiers for PowerPort® devices aid in identification as a Bard power injectable port.

Description

The PowerPort® implantable port is an implantable access device designed to provide repeated access to the vascular system. Port access is performed by percutaneous needle insertion using a non-coring needle. Power injection is performed using a PowerLoc™ Safety Infusion Set only. The PowerPort® implantable port consists of two primary components: an injection port with a self-sealing silicone septum and a radiopaque catheter. Single lumen PowerPort® implantable ports can be identified subcutaneously by feeling the top of the septum which includes three palpation bumps arranged in a triangle and by palpating the sides of the port, which is also triangular. Dual lumen PowerPort® implantable ports can be identified subcutaneously by feeling the top of each septum; each septum features three palpation bumps arranged in a triangle. All materials are biocompatible, can be used with virtually all injectable solutions intended for medicinal use, including the power injection of contrast media. For implantable ports with Groshong® catheters, the Groshong® catheter valve helps provide security against blood reflux and air embolism into the port/catheter system. The Groshong® catheter may be flushed with normal saline, and it does not require heparin to maintain patency.

Indications For Use

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

When used with a PowerLoc™ Safety Infusion Set, the PowerPort® implantable port is indicated for power injection of contrast media. For power injection of contrast media, the maximum recommended infusion rate is 5 mL/s.

Contraindications, Warnings, and Precautions

Contraindications

This device is contraindicated for:

- Catheter insertion in the subclavian vein medial to the border of the first rib, an area which is associated with higher rates of pinch-off.[1,2] Port may be placed in lateral subclavian vein based on evaluation by a qualified practitioner.
- When the presence of device-related infection, bacteremia, or septicemia is known or suspected.
- When the patient's body size is insufficient for the size of the implanted device.
- When the patient is known or is suspected to be allergic to materials contained in the device. The device is primarily comprised of silicone, polyacetal, polyetheretherketone, and/or titanium.
- If severe chronic obstructive lung disease exists.
- If the prospective insertion site has been previously irradiated.
- If the prospective placement site has previously suffered episodes of venous thrombosis or vascular surgical procedures.
- If local tissue factors will prevent proper device stabilization and/or access.

Warnings

I. During Placement:

- Intended for Single Use. Do not reuse. Reuse and/or repackaging may create risk of patient or user infection, compromise the structural integrity and/or essential material and design characteristics of the device, which may lead to device failure and/or lead to injury, illness or death of the patient.
- Alcohol should not be used to soak or declot a polyurethane catheter because alcohol is known to degrade the polyurethane catheter over time with repeated and prolonged exposure.
- After use, this product may be a potential biohazard. Handle and discard in accordance with accepted medical practice and applicable local, state and federal laws and regulations.
- Place thumb over exposed opening of sheath or needle or attach syringe filled with sterile normal saline solution to minimize blood loss and prevent air embolism. The risk of air embolism is reduced by performing this part of the procedure with the patient performing the Valsalva maneuver and/or in Trendelenburg position.

- Do not suture catheter to port, port stem, or surrounding tissue. Any damage or constriction of catheter may compromise power injection performance and catheter integrity. Bard Access Systems, Inc. does not recommend suturing around the catheter as doing so could compress, kink, or damage catheter, including catheter fragmenting and/or fracturing.
- Do not manipulate a pre-assembled or pre-connected catheter/port connection, as the catheter could become disconnected from the port, or system damage could occur.
- Do not attempt to measure the patient's blood pressure on the arm in which a peripheral system is located, since catheter occlusion or other damage to the catheter could occur.
- Avoid vessel perforation.
- Do not power inject through a port system that exhibits signs of clavicle-first rib compression or pinch-off as it may result in port system failure.
- For implantable ports with Groshong® catheters, do not cut stylet. Withdraw stiffening stylet from catheter prior to cutting.
- Failure to completely advance the catheter on the dual lumen stem may result in subcutaneous leakage.

II. During Port Access:

- Do not use a syringe smaller than 10 mL. Flushing occluded catheters with small syringes can create excessive pressures within the port system.
- PowerPort® implantable ports are only power injectable when accessed with a PowerLoc™ Safety Infusion Set.
- Failure to warm contrast media to body temperature prior to power injection may result in port system failure.
- Failure to ensure patency of the catheter prior to power injection studies may result in port system failure.
- Power injector machine pressure limiting feature may not prevent over pressurization of an occluded catheter.
- Exceeding the maximum flow rate may result in port system failure and/or catheter tip displacement.
- PowerPort® implantable port indication for power injection of contrast media implies the port's ability to withstand the procedure, but it does not imply appropriateness of the procedure for a particular patient nor for a particular infusion set. A suitably trained clinician is responsible for evaluating the health status of a patient as it pertains to a power injection procedure and for evaluating the suitability of any infusion set used to access the port.
- Do not exceed a 300 psi pressure limit setting on the power injection machine, or the maximum recommended flow rate on the PowerLoc™ needle, if power injecting through the PowerPort® implantable port.
- If local pain, swelling or signs of extravasation are noted during power injection, the injection should be stopped immediately.

Signs of Pinch-off

Clinical:

- Difficulty with blood withdrawal
- Resistance to infusion of fluids
- Patient position changes required for infusion of fluids or blood withdrawal

Radiologic:

- Grade 1 or 2 distortion on chest X-ray. Pinch-off should be evaluated for degree of severity prior to explantation. Patients indicating any degree of catheter distortion at the clavicle/first rib area should be followed diligently. There are grades of pinch-off that should be recognized with appropriate chest x-ray as shown in the table at right.[3,4]

Grade	Severity	Recommended Action
Grade 0	No distortion	No action
Grade 1	Distortion present with luminal narrowing	Chest x-ray should be taken every one to three months to monitor progression of pinch-off to grade 2 distortion. Shoulder positioning during chest x-rays should be noted as it can contribute to changes in distortion grades.
Grade 2	Distortion present without luminal narrowing	Removal of the catheter should be considered.
Grade 3	Catheter transection or fracture	Prompt removal of the catheter.

Precautions

- Carefully read and follow all instructions in these instructions for use.
- Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.
- Only qualified healthcare practitioners should insert, manipulate and remove these devices.
- Avoid inadvertent puncture of the skin or fascia with the tip of the tunneler.
- If the guidewire must be withdrawn while the needle is inserted, remove both the needle and wire as a unit to prevent the needle from damaging or shearing the guidewire.
- Use only non-coring needles with the port.
- Prior to advancing the catheter lock, ensure that the catheter is properly positioned. A catheter not advanced to the proper region may not seat securely and lead to dislodgment and extravasation. The catheter must be straight with no sign of kinking. A slight pull on the catheter is sufficient to straighten it. Advancing the catheter lock over a kinked catheter may damage the catheter. Do not hold the catheter or cathlock with any instruments that could potentially damage either piece (e.g. hemostats).
- Follow universal precautions when inserting and maintaining the catheter.
- Follow all contraindications, warnings, precautions and instructions for all infusates as specified by their manufacturers.
- Precautions are intended to help avoid catheter damage and/or patient injury.

I. Prior to Placement:

- Examine package carefully before opening to confirm its integrity and that the expiration date has not passed. The device is supplied in a double sterile package and is non-pyrogenic. Do not use if package is damaged, opened or the expiration date has passed. Sterilized by ethylene oxide. Do not resterilize.
- Inspect kit for presence of all components.

- Check patient's records, and ask patient, whether they have any known allergies to chemicals or materials that will be used during the placement procedure.
- Fill (prime) the device with sterile normal saline solution to help avoid air embolism.
- When using an introducer kit, verify that the catheter fits easily through the introducer sheath.
- When utilizing port for arm placement, the port should not be placed in the axillary cavity.
- Bard Access Systems, Inc. recommends the use of components provided in the kit. If additional items are to be used, check for proper fit prior to utilization.
  Note: Port body, catheter and catheter lock cannot be replaced with components outside the provided kit.

II. During Placement:

- Do not allow accidental device contact with sharp instruments. Mechanical damage may occur. Use only smooth edged, atraumatic clamps or forceps.
- Take care not to perforate, tear, or fracture the catheter during placement. After assembling catheter to port, check assembly for leaks or damage.
- Do not use the catheter if there is any evidence of mechanical damage or leaking.
- Do not bend catheter at sharp angles during implantation. This can compromise catheter patency.
- Carefully follow the connection technique given in these instructions to ensure proper catheter connection and to avoid catheter damage.
- Do not use sutures to secure catheter to the port stem as it could collapse or damage the catheter.
- When using peel-apart introducers:
  - Carefully insert the introducer and catheter to avoid inadvertent penetration to vital structures in the thorax.
  - Avoid blood vessel damage by maintaining a catheter or dilator as internal support when using a peel-apart introducer.
  - Avoid sheath damage by simultaneously advancing the sheath and dilator as a single unit using a rotational motion.
- Never use a catheter lock that appears cracked or otherwise damaged.

III. After Placement:

- Encourage patient to keep patient ID card and present it to clinicians accessing their port.
- Care should be taken to avoid excessive force when accessing an implanted port.

Possible Complications

The use of a subcutaneous port provides an important means of venous access for critically ill patients. However, the potential exists for serious complications, including the following:

- Air Embolism
- Allergic Reaction
- Bleeding
- Brachial Plexus Injury
- Cardiac Arrhythmia
- Cardiac Puncture
- Cardiac Tamponade
- Catheter or Port Erosion Through the Skin
- Catheter Embolism
- Catheter Occlusion
- Catheter or port-related Sepsis
- Damage or Breakage due to Compression between the Clavicle and First Rib
- Device Rotation or Extrusion
- Endocarditis
- Extravasation
- Fibrin Sheath Formation
- Guidewire Fragment Embolism
- Hematoma
- Hemothorax
- Hydrothorax
- Infection, including but not limited to, pocket, catheter tunnel, and/or blood stream
- Inflammation, Necrosis, or Scarring of Skin Over Implant Area
- Intolerance or Reaction to Implanted Device
- Laceration of Vessels or Viscus
- Pain at or around port pocket site
- Perforation of Vessels or Viscus
- Pneumothorax
- Risks Normally Associated with Local or General Anesthesia, Surgery, and Post-Operative Recovery
- Spontaneous Catheter Tip Malposition or Retraction
- Thoracic Duct Injury
- Thromboembolism
- Vascular Thrombosis
- Vessel Erosion

These and other complications are well documented in medical literature and should be carefully considered before placing the port.

Implantation Instructions

Please read through complete implantation instructions before implanting port, noting "Contraindications, Warnings, and Precautions" and "Possible Complications" sections of this manual before beginning procedure.

Preventing Pinch-Off

The risk of pinch-off syndrome can be avoided by inserting the catheter via the internal jugular vein (IJ). Subclavian insertion of the catheter medial to the border of the first rib may cause catheter pinch-off, which in turn results in occlusion causing port system failure during power injection.

If you choose to insert the catheter into the subclavian vein, it should be inserted lateral to the border of the first rib or at the junction with the axillary vein because such insertion will avoid compression of the catheter, which can cause damage and even sever the catheter. The use of image guidance upon insertion is strongly recommended. A radiographic confirmation of catheter insertion should be made to ensure that the catheter is not being pinched.

Implantation Preparation

1. Select implantation procedure to be used.
2. Select the site for port placement.
   Note: Port pocket site selection should allow for port placement in an anatomic area that provides good port stability, does not interfere with patient mobility or daily activities, does not create pressure points, has not previously been irradiated, does not show signs of infection, and does not interfere with clothing. Ideally choose an implantation site in the lateral infraclavicular region for cosmesis and functionality. For arm port placement, port site should be distal to the desired vein insertion site. Patient's arm movement should be considered when determining the length of the catheter and the final tip location. Consider the amount of cutaneous tissue over the port septum, as excessive tissue will make access difficult. Conversely, too thin a tissue layer over the port may lead to tissue erosion. A tissue thickness of 0.5 cm to 2 cm is appropriate.
3. Complete patient implant record, including length of catheter implanted, product reorder number and lot number.
4. Perform adequate anesthesia.
5. Create sterile field and open tray.
6. Surgically prep and drape the implantation site.

7a. For Attachable Catheters: Flush each lumen of open-ended catheters with sterile normal saline, through the flushing connector and clamp the catheter closed several centimeters from the distal (port) end.
   Note: Clamped catheter segments will be cut off prior to attachment.

7b. For Pre-Attached Catheters: Use a non-coring needle to flush the port and catheter system with sterile normal saline.

7c. For Groshong® catheters: Flush catheter with sterile normal saline through the pre-loaded stylet connector.

8. Place patient in the Trendelenburg position with head turned away from the intended venipuncture site. For arm port placement, position the arm in an abducted, externally rotated position.
   Note: Recommended veins for arm placement are cephalic, basilic, or medial cubital basilic.
   Note: Recommended veins for chest placement are internal jugular or lateral subclavian. Refer to the "Warnings" section covering catheter pinch-off if inserting the catheter via the subclavian vein.

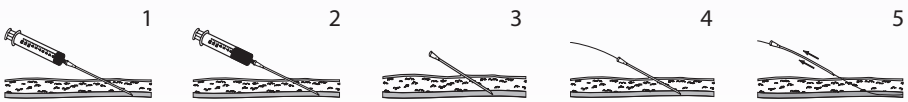
Percutaneous Procedure

1. Locate and access vessel with introducer needle attached to a syringe.
2. Aspirate gently as the insertion is made. If the artery is entered, withdraw the needle and apply manual pressure for several minutes. If the pleural space is entered, withdraw the needle and evaluate patient for possible pneumothorax.
3. When the vein has been entered, remove the syringe leaving the needle in place.
   Warning: Place thumb over exposed opening of sheath or needle or attach syringe filled with sterile normal saline solution to minimize blood loss and prevent air embolism. The risk of air embolism is reduced by performing this part of the procedure with the patient performing the Valsalva maneuver and/or in Trendelenburg position.

> *If using a micropuncture set*, insert the flexible end of the micropuncture guidewire into the introducer needle. Advance the guidewire as far as appropriate. Verify correct positioning, using fluoroscopy or appropriate technology. Gently withdraw and remove the needle, while holding the micropuncture guidewire in position. Advance the small sheath and dilator together as a unit over the micropuncture guidewire, using a slight rotational motion. Withdraw the dilator and guidewire, leaving the microintroducer sheath in place.

> **Caution:** If the guidewire must be withdrawn while the needle is inserted, remove both needle and wire as a unit to prevent the needle from damaging or shearing the guidewire.
> **Warning:** Place thumb over opening of sheath to minimize blood loss and prevent air embolism. The risk of air embolism is reduced by performing this part of the procedure with the patient performing the Valsalva maneuver and/or in Trendelenburg position.

4. Straighten "J" tip of standard guidewire with tip straightener and insert tapered end of tip straightener into the needle (or microintroducer sheath if using a micropuncture set).
   Note: Do not advance guidewire if obstruction is encountered.
5. Remove the tip straightener and advance the guidewire into the superior vena cava. Advance the guidewire as far as appropriate for the procedure. Verify correct positioning using fluoroscopy or appropriate technology.
6. Gently withdraw and remove needle (or microintroducer sheath if using micropuncture set).
   Caution: If the guidewire must be withdrawn while the needle is inserted, remove both the needle and wire as a unit to help prevent the needle from damaging or shearing the guidewire.

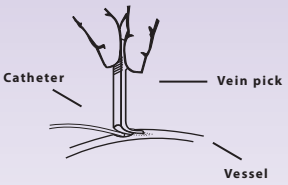


Peel-Apart Sheath Introducer Instructions

1. Advance the vessel dilator and sheath introducer as a unit over the exposed wire using a rotational motion. Advance it into the vein as a unit, leaving at least 2 cm of sheath exposed.
   Note: Placement may be facilitated by making a small incision to ease introduction of vessel dilator and sheath introducer.
   Warning: Avoid vessel perforation.

2. Release the locking mechanism and gently withdraw the vessel dilator and "J" wire, leaving the sheath in place.
   Warning: Place thumb over exposed opening of sheath to minimize blood loss and prevent air embolism. The risk of air embolism is reduced by performing this part of the procedure with the patient performing the Valsalva maneuver and/or in Trendelenburg position.
3. Insert catheter into the sheath. Advance the catheter through the sheath into the vessel to the desired infusion site. Catheters should be positioned with the catheter tip at the junction of the superior vena cava and the right atrium.
4. Verify correct catheter tip position using fluoroscopy or appropriate technology.
5. Grasp the two handles of the peel-apart sheath and pull outward and upward at the same time. Peel the sheath away from the catheter completely. Make sure the catheter is not dislodged from vessel.

Cut-Down Procedure



1. Use a cut-down incision to expose the entry vein of choice.
2. Perform vessel incision after vessel is isolated and stabilized to prevent bleeding and air embolism.
3. If using a vein pick, insert its tapered end through the incision and advance it into the vessel. Then slide the catheter tip into the grooved underside of the pick.
4. Advance the catheter tip into the vessel.
5. Withdraw the vein pick, if used.
6. Advance the catheter into the vessel to the desired infusion site.
   Note: Catheters should be positioned with the catheter tip at the junction of the superior vena cava and the right atruim. Verify correct catheter tip position using fluoroscopy or appropriate technology.

Catheter Tunneling Procedure

1. Create a subcutaneous pocket using blunt dissection.
   Note: Do a trial placement to verify that the pocket is large enough to accommodate the port and that the port does not lie beneath the incision.

Attachable Catheters

Create a subcutaneous tunnel from the venous site to the port pocket site using tunneler or long forceps per the following:

a. Make a small incision at the venous entry site.
b. Insert tip of tunneler into the small incision.
c. Form tunnel by advancing tip of tunneler from the venous entry site to the port pocket site.
   Caution: Avoid inadvertent puncture of the skin or fascia with the tip of the tunneler.
d. Remove catheter lock from the catheter. For implanted ports with Groshong® catheters, remove the catheter lock and stiffener stylet from the catheter prior to cutting catheter to appropriate length.
   Warning: Do not cut stiffening stylet. Withdraw stiffening stylet from catheter prior to cutting.
   Caution: Never use a catheter lock that appears cracked or otherwise damaged.
e. Attach end of catheter onto the tunneler barb with a twisting motion.
   Note: Barb threads must be completely covered by the catheter to adequately secure the catheter as it is pulled through the tunnel. A suture may be tied around the catheter between the tunneler body and the large barb to hold it more securely.
f. Pull the tunneler through to the port pocket site while gently holding the catheter.
   Note: The catheter must not be forced.
g. Cut off end of the catheter attached to tunneler.

Pre-Attached Catheters

Create subcutaneous tunnel from the port pocket site to the venous entrance site per the following:

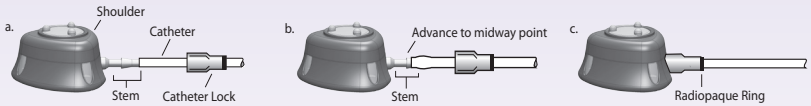
a. Form tunnel by advancing the tip of the tunneler from the port pocket site to the venous entry site.
   Caution: Avoid inadvertent puncture of the skin or fascia with the tip of the tunneler.
b. Connect the catheter tip into the end of the tunneler.
c. Pull the tunneler through to the venous entry site while gently holding the catheter.
   Note: The catheter must not be forced.
d. Cut off end of the catheter attached to tunneler.
e. Estimate the catheter length required for the tip placement at the junction of the superior vena cava and right atrium by placing the catheter on the chest along the venous path to the right atrium. Cut catheter to length at a 90˚ angle.

Connect Catheter To Port For Attachable Catheters

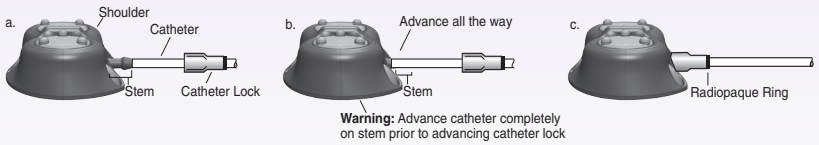
1. Flush all air from each lumen of the port body using a 10 mL syringe with a non-coring needle filled with sterile normal saline. Insert the needle through the septum and inject the fluid while pointing the stem up.
2. Cleanse all system components with irrigation solution.
   Caution: Prior to advancing the catheter lock, ensure that the catheter is properly positioned. A catheter not advanced to the proper region may not seat securely and lead to dislodgement and extravasation. The catheter must be straight with no sign of kinking. A slight pull on the catheter is sufficient to straighten it. Advancing the catheter lock over a kinked catheter may damage the catheter. Do not hold the catheter or cathlock with any instruments that could potentially damage either piece (e.g. hemostats).
3. Connect catheter to port:
   a. Place catheter lock back onto catheter, ensuring the black radiopaque ring on the catheter lock faces away from the port body.
   b. Cut the catheter to the proper length at a 90˚ angle, allowing sufficient slack for body movement and port connection. Check catheter for any damage. If any damage is noted, cut damaged section off before connecting catheter to port.
   Note: Ensure that no guidewires or stiffening wires remain in the catheter lumen prior to cutting and adjusting catheter to desired length.
   c. For single lumen ports, align port stem with catheter. When placing dual lumen ports, align the port stem with both lumens.
   Note: If the catheter and catheter lock are connected and then disconnected, the catheter end must be re-trimmed to ensure a secure re-connection. **Note:** When using the catheter lock, be sure the end containing a colored radiopaque ring faces away from the port. The catheter lock should be sufficient to secure catheter to port. **Note:** Sterile gauze may be used to facilitate stem to catheter connection.
   d. **For single lumen ports:** Advance catheter over port stem to midway point. **Note:** Advancing catheter too far along port stem could lead to "mushrooming" of tubing when the catheter lock is advanced. Should this occur, it is advisable to stop advancing the catheter lock, pull the catheter back along the stem away from the port, trim end of catheter and re-assemble the connection.
   e. **For dual lumen ports:** Advance catheter completely on stem prior to advancing catheter lock. **Warning:** Failure to completely advance the catheter on the dual lumen stem may result in subcutaneous leakage.

Warning: Do not suture catheter to port, port stem, or surrounding tissue. Any damage or constriction of catheter may compromise power injection performance and catheter integrity. Bard Access Systems, Inc. does not recommend suturing around the catheter as doing so could compress, kink, or damage catheter.

Single Lumen PowerPort® Implanted Port Device:



Dual Lumen PowerPort® Implanted Port Device:



Position Port And Close Incision Site

1. Place the port in the subcutaneous pocket away from the incision line. Secure the port to the underlying fascia using non-absorbable, monofilament sutures. Leave sufficient slack in the catheter to permit slight movement, and verify that the catheter is not kinked. This will reduce the risk of port migration and the possibility of it flipping over.
   Note: When suturing a port with a silicone port body, place suture through at least 2 mm of silicone.
2. After suturing the port in the pocket, flush the wound with an appropriate antibiotic solution, per institutional protocol.
3. Conduct flow studies on each lumen of the catheter using a non-coring needle and 10 mL syringe to confirm that the flow is not obstructed, that no leak exists, and that the catheter is correctly positioned.
4. Aspirate to confirm the ability to draw blood.
5. Flush and lock each lumen of the port system as described under heparin lock procedure for open-ended catheters or saline lock procedures for implantable ports with Groshong® catheters. Close clamp while injecting last 0.5 mL of flush solution.
   Caution: Remember that some patients may be hyper-sensitive to heparin or suffer from heparin induced thrombocytopenia (HIT). These patients must not have their port locked with heparinized saline.
6. Close the incision site, so that the port does not lie beneath the incision.
7. Apply dressing according to hospital practice.

Power Injection Procedure

1. Access the PowerPort® implantable port with a PowerLoc™ Safety Infusion Set. Make certain that the needle is long enough to be inserted fully within the port and that the needle tip has made contact with the bottom of the port reservoir.
   Warning: The PowerPort® implantable port is only power injectable when accessed with a PowerLoc™ Safety Infusion Set.
   Note: Follow institutional protocol to verify correct catheter tip position prior to power injection.
2. Attach a syringe filled with sterile normal saline.
3. Instruct the patient to assume the position they will be in during the power injection procedure, before checking for patency. If possible, the patient should receive power injection with his or her arm vertically above the shoulder with the palm of the hand on the face of the gantry during injection. This allows for uninterrupted passage of injected contrast through the axillary and subclavian veins at the thoracic outlet.
4. Aspirate for adequate blood return and vigorously flush the port with at least 10 mL of sterile normal saline.
   Warning: Failure to ensure patency of the catheter prior to power injection studies may result in port system failure.
5. Detach syringe.
6. Warm contrast media to body temperature.
7. Attach the power injection device to the PowerLoc™ Safety Infusion Set ensuring connection is secure. Check indicated flow rate of safety infusion set and confirm power injector settings.
   Warning: Do not exceed a 300 psi pressure limit setting on the power injection machine, or the maximum recommended flow rate on the PowerLoc™ needle, if power injecting through the PowerPort® implantable port.

PowerLoc™ Safety Infusion Set Gauge Size	19 Ga.	20 Ga.	22 Ga.
PowerLoc™ Safety Infusion Set Gauge Color	Cream	Yellow	Black
Maximum Recommended Flow Rate Setting	5 mL/s	5 mL/s	2 mL/s

8. Instruct the patient to communicate immediately any pain or change in feeling during the injection.
9. Inject contrast media warmed to body temperature, taking care not to exceed the flow rate limits.
   Warning: If local pain, swelling or signs of extravasation are noted, the injection should be stopped immediately.
   Warning: Exceeding the maximum flow rate may result in port system failure and/or catheter tip displacement.
10. Disconnect the power injection device.
11. After therapy completion, flush each lumen of the port per institutional protocol. Close clamp while injecting last 0.5 mL of flush solution.
12. Perform heparin lock procedure or saline lock procedures for implanted ports with Groshong® catheters. For dual lumen PowerPort® implantable ports, flush each lumen separately and perform locking procedures on each septum.
    Caution: Remember that some patients may be hyper-sensitive to heparin or suffer from heparin induced thrombocytopenia (HIT). These patients must not have their port locked with heparinized saline.
13. To remove PowerLoc™ Safety Infusion Set from the port, activate safety mechanism while withdrawing needle until you hear or feel a "click" at which time the needle should be captured within the safety mechanism of the PowerLoc™ Safety Infusion Set.

Determining Port System Volumes for Port Lock Procedures

For port system volumes and locking procedures, please refer to the packaging insert.

Heparin Lock Procedure For Open-Ended Catheters

To help prevent clot formation and catheter blockage, each lumen of the implanted ports with open-ended catheters should be filled with sterile heparinized saline after each use. If the port remains unused for long periods of time, the heparin lock should be changed at least once every 28 days.
Caution: Remember that some patients may be hyper-sensitive to heparin or suffer from heparin induced thrombocytopenia (HIT). These patients must not have their port locked with heparinized saline.

If the port catheter length is not known, the following are recommended flushing volumes for open-ended catheters, otherwise follow institutional protocol.

Flushing and Locking Volumes (each lumen)	
Procedure	**Volume**
When port not in use	5 mL heparinized saline every 28 days (100 U/mL)
After each infusion of medication or TPN	10 mL sterile normal saline then 5 mL heparinized saline (100 U/mL)
After blood withdrawl	20 mL sterile normal saline then 5 mL heparinized saline (100 U/mL)
After power injection of contrast media	10 mL sterile normal saline then 5 mL heparinized saline (100 U/mL)

Equipment:
- Non-coring needle
- 10 mL syringe filled with sterile saline per lumen
- 10 mL syringe filled with 5 mL heparinized saline (100 U/mL) per lumen

Note: Other concentrations of heparinized saline (10 to 1000 U/mL) have been found to be effective. Determination of proper concentration and volume should be based on patient's medical condition, laboratory tests, and prior experience.

Procedure:
1. Explain procedure to patient and prepare injection site.
2. Attach a 10 mL syringe filled with sterile normal saline to needle.
3. Aseptically locate and access port.
4. After therapy completion, flush port per institutional protocol, then lock with 5 mL 100 U/mL heparinized saline, or with port system volume calculated on "Determining Port System Volumes For Port Lock Procedures" insert. Close clamp while injecting last 0.5 mL of lock solution.

   Warning: Alcohol should not be used to soak or declot polyurethane catheters because alcohol is known to degrade the polyurethane catheters over time with repeated and prolonged exposure.

Saline Lock Procedure For Groshong® Catheters

To help prevent clot formation and catheter blockage, implanted ports with Groshong® catheters should be filled with sterile normal saline after each use. If the port remains unused for long periods of time, the saline lock should be changed by flushing at least once every 90 days.

If the port catheter length is not known, the following chart outlines the recommended flushing volumes for Groshong® catheters – otherwise follow institutional protocol.

Flushing and Locking Volumes (each lumen)	
Procedure	**Volume**
When port not in use	5 mL sterile normal saline every 90 days
After each infusion of medication or TPN	10 mL sterile normal saline
After blood withdrawl	20 mL sterile normal saline
After power injection of contrast media	10 mL sterile normal saline

Equipment:
- Non-coring needle
- 10 mL syringe filled with sterile normal saline

Procedure:
1. Explain procedure to patient and prepare injection site.
2. Attach a 10 mL syringe filled with sterile normal saline to needle.
3. Aseptically locate and access port.
4. After therapy completion, flush port per institutional protocol. Close clamp while injecting last 0.5 mL of flush solution.

References

1. Jacobs, D. M. et. al., "Anatomical and Morphological Evaluation of Pacemaker Lead Compression". PACE. 1993 Mar; 16(1):434-444.
2. Magney, J. E. et. al., "Anatomical Mechanisms Explaining Damage to Pacemaker Leads, Defibrillator Leads and Failure of Central Venous Catheters Adjacent to the Stemoclavicular Joint". PACE. 1993 Mar; 16(1):445-457.
3. Hinke, D,H.; Zandt-Stastny, D.A.; Goodman, L.R.; et.al. Pinch-off syndrome: A complication of implantable subclavian venous access devices. Radiology 177: 353-356, 1990.
4. Ingle, Rebecca; Nace, Corinne. "Venous Access Devices: Catheter Pinch-off and Fracture". 1993, Bard Access Systems, Inc.
5. Camp-Sorrell, Dawn. "Access Device Guidelines." 2nd Ed. Oncology Nursing Society, 2004.

Note: The PowerPort® device testing included at least 36 power injection cycles with a PowerLoc® Brand Safety Infusion Set and 11.8 cP viscosity contrast solution.

Further Reading

- See PowerPort® Implantable Port Nursing Guide and/or PowerPort® Implantable Port CT Guide for more details.
- Bard Access Systems, Inc. is proud to offer "Your Port Access Advantage"™ patient education module for helping patients select their best access option.
- www.powerportadvantage.com
- www.portadvantage.com
- www.veins4life.com

Contact Bard Peripheral Vascular's Sales Representative for more information about any of these products. An issued or revision date for these instructions is included for the user's information. In the event two years have elapsed between this date and product use, the user should contact Bard Peripheral Vascular, Inc. to see if additional product information is available.

Revised date: May 2014.

This product and packaging do not contain natural rubber latex

This product does not contain DEHP

Notes

BARD
ACCESS SYSTEMS

BARD | PERIPHERAL VASCULAR

Manufacturer:
Bard Access Systems, Inc.
605 North 5600 West
Salt Lake City, UT 84116 USA
801-522-5000
Clinical Information Hotline: 800-443-3385
www.bardaccess.com
www.portadvantage.com
www.veins4life.com

Distributed By:
Bard Peripheral Vascular, Inc.
1625 West Third Street
Tempe, AZ 85281 USA
480-894-9515
Clinical Information Hotline: 800-443-3385

0735583 1405R

Exhibit C

DICKERSONOXTON

ESP

(816) 368-5637
(913) 428-8220

MENU

FOR THOSE SEEKING COMPENSATION FOR THEIR INJURIES

PORT A CATHETER INJURY ATTORNEYS

Open and honest communication at all times +

Never a fee unless your case is won +

Our success rate is over 98% +

Investigating cases nationwide +

REQUEST YOUR FREE CONSULTATION

Implanted Port Injury Attorneys

At The Dickerson Oxton Law Firm, our experienced implanted port injury lawyers are dedicated to helping anybody who has suffered an injury due to issues associated with an implanted port device – also known as a port-a-cath. Implanted port installation is highly

Dickerson Oxton Law Firm today to discuss your case, and see how we can help you with your port-a-cath injury today.

WHY CHOOSE US?

The Dickerson Oxton Law Firm provides exceptional representation for those who have suffered an implanted port injury due to negligence or carelessness.

- We have extensive experience helping innocent victims of negligence seek justice and compensation for their injuries.
- We have a reputation for success, maintaining a 98% case success rate throughout the entire history of our law firm.
- We take a collaborative effort in every case, ensuring that our top minds are all working together to help you receive the maximum possible compensation.
- We represent clients on a contingency fee basis – there are no upfront costs, and you pay no legal fees if we do not secure a favorable verdict or settlement on your behalf.

WHY DO YOU NEED A LAWYER?

It is highly recommended to consult an experienced attorney before proceeding with a claim against a medical manufacturer. These cases often fall under the purview of product liability, also known as defective products. These types of cases can often be incredibly difficult to litigate, requiring a considerable amount of evidence and knowledge in order to succeed. An attorney with experience in product liability cases can assist you in these regards, conducting all litigation on your behalf to ensure you receive the maximum possible compensation for your needs.

DICKERSONOXTON

ESP

(816) 368-5637
(913) 428-8220

MENU

WHAT IS A PORT-A-CATH/IMPLANTED PORT?

A port-a-cath is an implanted device that makes it easier for a medical professional to access your veins. It consists of two parts:

- A catheter, a long tube that is inserted in your veins.
- A port, connected to the end of the catheter and implanted beneath the skin.

The port allows medical professionals to conveniently inject and/or extract fluids into the bloodstream without having to install an IV every time. It is made of a self-sealing material, typically silicone, so that it can withstand multiple punctures of a syringe to administer medication or fluids. Other port-a-caths may use special proprietary needles to prevent damage to the port.

WE HELP YOU AGAINST COMMON PORT-A-CATH BRANDS

Common manufacturers and brands of implanted port devices include:

Bard

- BardPort
- Bard PowerPort (including several sub-varieties)
- Bard SlimPort
- Bard M.R.I. Ports

Smiths Medical

- Port-a-Cath
- P.A.S. Port

Teleflex

- Arrow

WHO NEEDS AN IMPLANTED PORT?

An **implanted port** is highly recommended for those who require regular access to a vein for medication and/or therapy. They are most often implanted in patients diagnosed with cancer who require radiation therapy for treatment. Other uses include patients who require these on a regular basis:

- Blood transfusions
- Blood draws
- Antibiotic treatments
- Other IV treatments

COMMON ISSUES WITH IMPLANTED PORTS

Unfortunately, implanted ports are not permanent, and can be subject to different types of failures – all of which have the potential to cause serious, severe injury in patients. Some of

body, causing serious complications. This is most commonly due to a reduction in durability due to constant flexing – also known as flex fatigue. When this happens, the catheter typically breaks into multiple pieces and is swept throughout the circulatory system. In cases where it gets swept into the heart, emergency heart surgery may be required to remove the fragments. Additionally, this puts patients at a higher risk of a pulmonary embolism – a blockage in lung arteries that can cause significant permanent damage to a patients' lungs.

LONG-TERM RISK OF INFECTION

In time, as the catheter has a reduction in durability, it is possible for bacteria and other pathogens to permeate through the catheter. Often, these holes and cracks allow pathogens to slip through – but are often too small for the body's immune cells to pass through. This can result in severe infections that the body is not able to fight.

CATHETER MIGRATION/DISLODGEMENT

Similar to catheter fracture, a catheter has the potential to simply dislodge from the implanted port device and migrate to other parts of the body. Although this has the potential for serious injury, catheters that are dislodged often remain whole, so operations to remove them are less intensive and serious than catheter fractures.

WHO IS LIABLE?

In cases involving implanted port injuries and issues, it is often the manufacturer who may be held liable for any serious injuries that occur. Catheters in port-a-cath devices are made of materials such as silicone and polyurethane and no other reinforcements or additives to

been negligent in their actions – and therefore may be held fully accountable for their actions.

CONTACT US TODAY

If you or a loved one has suffered an injury due to a failed implanted port or port-a-cath device, please contact us immediately to discuss your case. We are committed to seeking the compensation you need and the justice you deserve.

To discuss the circumstances of your case, call our implanted port injury attorneys at **(816) 268-1960**. Or reach out to us via our online **contact form** to schedule a free consultation with us today to see how we can help.

Practice Areas

BARD PORT INJURIES

BARD POWER PORT INJURIES

BARD SLIM PORT INJURIES

DICKERSONOXTON

ESP

(816) 368-5637
(913) 428-8220

MENU

PENUMBRA JET / CATHETER LAWSUITS

PULMONARY EMBOLISM / BLOOD CLOTS

MIGRATION & DISLODGEMENT OF CATHETER

INFECTIONS CAUSED BY PORTS

COMMON ISSUES CAUSED BY PORTS

BEST OF THE BAR
KANSAS CITY BUSINESS JOURNAL

DICKERSONOXTON

ESP

(816) 368-5637
(913) 428-8220

MENU

“Everyone involved exceeded the scope of what their responsibilities t
open and honest, a degree of integrity exemplified by the firm

LEROY C. I CLIENT

MEET OUR TEAM

DICKERSONOXTON

ESP

(816) 368-5637
(913) 428-8220

MENU

PARTNER

CHELSEA DICKERSON

PARTNER

DICKERSONOXTON

ESP

(816) 368-5637
(913) 428-8220

MENU

& WE HAVE ANSWERS

FIRST NAME •

LAST NAME •

PHONE •

fields required •

EMAIL •

DICKERSONOXTON

ESP

(816) 368-5637
(913) 428-8220

MENU

SUBMIT

MISSOURI

T (816) 368-5637

F (816) 268-1965

KANSAS

T (913) 428-8220

F (913) 428-8224

DICKERSONOXTON

ESP

(816) 368-5637
(913) 428-8220

MENU

LAWSUIT STATUS: New Cases Being Accepted

What is the Bard PowerPort Lawsuit?

Bard PowerPort is an implanted port device, placed below the skin to provide a catheter port for delivery of medications.

Design defects with the Bard PowerPort may cause the catheter tube to crack, fracture or migrate resulting in serious and life-threatening injuries.

A number of **Bard PowerPort lawsuits** have been filed by individuals who suffered **infections, blood clots and other problems.**

Skip to main content

Who is Eligible for a Settlement Claim?

Bard PowerPort settlements may become available for individuals who received the implantable catheter port and experienced complications from a Bard PowerPort failure, including:

- Infection
- Blood Clots
- Perforations
- Catheter Fracture
- Wrongful Death

FIND OUT IF YOU ARE ELIGIBLE (/CONTACT/?INQUIRY=BARD-POWERPORT&ACTION=HUB-HERO)

UPDATED: June 2023 1 Comments

Bard PowerPort Lawsuit Overview

The FDA approved the Bard PowerPort in 2000, as a port cath device that is implanted under the skin to provide long-term and easy access to attach a catheter for the delivery of medication, intravenous fluids, parenteral nutrition solutions, and blood products.

Design problems with the Bard PowerPort have been linked to reports of serious injuries and deaths, after the catheter port material cracked, causing the catheter to fracture or migrate. These complications have resulted in severe infections, blood clots, cardiac punctures and many other life threatening injuries.

As a result of the apparent defective design of the implantable port, individuals are now pursuing **Bard PowerPort lawsuits(https://www.youhavealawyer.com/bard-powerport-lawsuit/)**, claiming the manufacturer knew the catheters were prone to surface degradation that would put patients at serious risk.

Skip to main content

Info on this Page About Bard Port Catheter Lawsuits:

1. **Who is eligible for a Bard PowerPort lawsuit?**

Who is eligible for a Bard PowerPort lawsuit?

Financial compensation may be available through a Bard catheter lawsuit for individuals who received an implantable PowerPort and suffered any of the following complications:

- Infections (sepsis or septic shock)
- Deep Vein Thrombosis (DVT)
- Hemorrhaging or Bleeding Injuries
- Cardiac/pericardial tamponade
- Cardiac arrhythmia
- Severe and persistent pain
- Perforations of tissues, vessels and organs
- Patient death
- Other injuries caused by fractured PowerPort catheter

Bard PowerPort Injury Lawyers are reviewing lawsuits involving problems caused by various Bard catheter failures. Attorneys are handling cases on a contingency fee basis, which means that there are no fees or expenses paid unless a settlement or lawsuit payout is received.

Skip to main content

LEARN MORE ABOUT

BARD POWERPORT LAWSUITS

Serious and life-threatening injuries have been linked to problems with Bard PowerPort. Lawsuits are now being pursued by individuals who suffered injuries from the implantable port catheter fracturing or migrating.

SEE IF YOU QUALIFY FOR A CLAIM

2023 Bard Port Lawsuit Updates

May 2023 Update: Given common questions raised in a number of complaints filed throughout the federal court system, a motion was filed with the U.S. Judicial Panel on Multidistrict Litigation (JPML), seeking to consolidate and **centralize all Bard implanted port lawsuits(https://www.aboutlawsuits.com/bard-powerport-lawsuit/bard-implanted-port-lawsuits-motion-to-centralize/)** before one judge for discovery and pretrial proceedings.

What is the Bard PowerPort device?

The Bard PowerPort ClearVue Implantable Port, is a vascular access device, which is implanted below the skin to provide a catheter port that allows easy delivery of medications to a patient's bloodstream. It consists mainly of an injection port, where the needle is inserted to deliver medications; and a polyurethane catheter tube that carries the drug into the blood vessel.

The injection port contains a raised area where the needle is inserted for faster delivery of the medication. The medications then travel through a catheter that is placed inside one of the large central veins that carry blood to the heart.

Skip to main content

Bard advertises that the PowerPort not only offers a faster and more convenient method of delivering medication or drawing blood, but that the PowerPort design can also withstand higher injection pressure. However, a growing number of individuals are now reporting serious injuries and Bard PowerPort complications that could have been avoided with an alternative catheter port.

What is wrong with Bard PowerPort devices?

The PowerPort catheter tubes are made of a material that may be prone to fissuring, cracking and fracturing. The catheter tubing is made of a flexible polyurethane polymer called Chronoflex, which is a mixture of polyurethane and barium sulfate.

Lawsuits indicate that problems with the Bard PowerPort stem from the use of high concentrations of barium sulfate, which is a chemical compound that is known to cause polyurethane's mechanical integrity to break down, resulting in microfractures, degradation, fissuring and cracking.

Improper mixing during the manufacturing process may result in pockets of barium sulfate and entrapped air being distributed through the catheter body and surfaces, according to complaints filed. This can result in catheter cracks, fissures and pits. Surface degradation may also increase the risk of thromboembolism or blood clots.

Problems with Bard PowerPort Were Known for Years

In a number of Bard PowerPort injury lawsuits, plaintiffs maintain that **Bard knew about PowerPort catheter fractures(https://www.aboutlawsuits.com/bard-powerport-lawsuit/lawsuits-bard-power-port-problems-withheld/)**, migrations and infections being reported among individuals with the implanted port device shortly after their product was introduced in 2000, yet failed to act.

Lawsuits indicate that serious and fatal injuries could have been avoided if a safer alternative design had been used, or a Bard PowerPort recall had been issued.

However, Bard Access Systems Inc., C.R. Bard, Inc. and Becton Dickson & Company failed to issue any warnings about the PowerPort problems for the medical community or initiate any post-marketing surveillance system to better identify reports of injury and death. Instead, the manufacturers concealed their knowledge about problems with the Bard catheters and continued to actively advertise the PowerPort as safe.

Skip to main content

Bard PowerPort Complications & Injuries

Bard catheter failures have been reported at high rates among individuals with the PowerPort. Some of the most frequently reported complications with Bard catheters include:

Bard PowerPort Catheter Fracture

Given the brittle composition of the Bard PowerPort, it is possible for small pieces of the plastic flexible tubing to break away into a patient's vascular system. The dislodged or fractured catheter tubing can present a series of potential life threatening health complications including;

- Blood clots
- Cardiac arrhythmia
- Cardiac Punctures
- Hematomas
- Pulmonary embolism
- Tearing of blood vessels

Bard PowerPort Catheter Migration

Bard catheter migration occurs when the flexible tube inserted into the body cavity or blood vessel moves from its original position to another unintended location in the body. This can lead to serious health consequences including;

- Obstruction of blood flow
- Infection
- Organ damage
- Catheter failure

Bard PowerPort Infection

Skip to main content

Individuals with a Bard catheter may be prone to infections due to the ability for bacteria to enter around the degraded or broken areas of the PowerPort. Bard PowerPort infections can lead to serious complications that can delay critical treatments. Common symptoms of a

catheter infection include;

- Fever & Chills
- Inflammation and Swelling
- Drainage or pus
- Changes in urine color or odor
- Confusion

SHARE YOUR STORY

Were you injured by a malfunctioning Bard PowerPort? Share your story with AboutLawsuits.com and have your comments reviewed by a lawyer to determine if you may be eligible for a lawsuit.

ADD COMMENTS

Is there a Bard PowerPort recall?

No. The medical device manufacturer has not issued a Bard PowerPort recall over the catheter risks.

Who is the Bard PowerPort lawsuit against?

The Bard PowerPort lawsuit is against the manufacturer, Becton Dickinson & Company, and its C.R. Bard and Bard Access Systems, Inc. subsidiaries.

Examples of Bard PowerPort Lawsuits

Bard PowerPort Wrongful Death Lawsuit:(https://www.aboutlawsuits.com/bard-powerport-lawsuit/bard-powerport-wrongful-death-lawsuit/) Christopher Cabello filed a wrongful death lawsuit on behalf of his deceased wife, Elizabeth, in the Superior Court of New Jersey Bergen County on May 18, 2023, claiming her death was largely caused by a defectively designed Bard

Skip to main content

PowerPort that fractured and leaked while undergoing treatment for bladder cancer. Cabello claims the fractured Bard PowerPort required Elizabeth to undergo major emergency surgery to remove the PowerPort, which was a substantial contributing factor to her death.

Bard PowerPort Infection Lawsuit(https://www.aboutlawsuits.com/bard-powerport-lawsuit/bard-powerpoint-infection-lawsuit/): Jean Cunningham filed a Bard PowerPort infection lawsuit in U.S. District Court for the Western District of Missouri on April 24, 2023, claiming the device contained a defective design that caused it to crack while she was undergoing treatment for multiple sclerosis. Cunningham states that as a result of the Bard PowerPort fracturing, she developed an infection that has lead to permanent injuries and the need for catheter replacement surgery.

Bard PowerPort Lawsuit Over Bloodstream Infection(https://www.aboutlawsuits.com/bard-powerport-lawsuit-catheter-infection/): Mary Nelk filed a catheter infection lawsuit in the U.S. District Court for the District of New Jersey on February 28, 2023, claiming the Bard PowerPort failed and caused her to develop a bloodstream infection. Nelk claims the defective design of Bard's catheters caused her multiple hospital admissions and have left her with severe and permanent injuries.

Bard PowerPort Thrombosis Lawsuit(https://www.aboutlawsuits.com/bard-powerport-deep-vein-thrombosis-lawsuit/): Patrice Terry filed a port-a-cath lawsuit in the U.S. District Court Western District of Missouri on February 10, 2023, claiming a fractured PowerPort device caused her to develop deep vein thrombosis (DVT) in the jugular vein. Terry states that she was required to undergo major surgery as she was receiving chemotherapy through the PowerPort device to treat her colon cancer.

Have a Bard PowerPort Injury Lawyer Review Your Case

If you or a loved one were injured by an implantable catheter port, submit information about your potential claim for review by a product liability lawyer to determine whether a Bard PowerPort settlement or lawsuit payout may be available.

Bard PowerPort injury lawyers provide free claim evaluations and consultations. There are no fees or expenses unless a recovery is obtained in your case.

Skip to main content

FREE CASE EVALUATION

If you or a loved one experienced an injury from a Bard PowerPort device, submit information for review by a lawyer to determine if you may be eligible for a Bard PowerPort settlement.

FIND OUT IF YOU QUALIFY(/CONTACT/?INQUIRY=BARDPOWERPORT&ACTION=HUB-BOTTOM-CTA)

Tags:

1 Comments

Paula May 16, 2023 at 5:06 pm

I have a power port that when then access the port they been having problems with the blood draw.Also the chemo they gave me has like burn my skin on my hand that cause my palms of my hands to completely peel. I am worried that that medicine might have been to strong for the port? Could that medicine damage the port .?my skin is red and irritated. Do these port have expiration dates how long s [Show More]

"*" indicates required fields

Share Your Comments

Skip to main content

First Name*

Last Name

Email Address*

Shared Comments*

I AUTHORIZE THE ABOVE COMMENTS BE POSTED ON THIS PAGE*

☐ YES ☐ NO

HAVE YOUR COMMENTS REVIEWED BY A LAWYER

Provide additional contact information if you want an attorney to review your comments and contact you about a potential case. **This information will not be published.**

Contact Phone #

Alt Phone #

Private Comments: Tell the lawyer about your case

NOTE: Providing information for review by an attorney does not form an attorney-client relationship.

Skip to main content

SUBMIT COMMENTS

Exhibit D

McCarter & English

Edward J. Fanning
Partner

T. 973-639-7927
F. 973-297-3868

efanning@mccarter.com

McCarter & English, LLP

Four Gateway Center
100 Mulberry Street
Newark, NJ 07102-4056

www.mccarter.com

June 15, 2023

VIA EMAIL

Adam M. Evans
DICKERSON OXTON
1100 Main St., Ste. 2550
Kansas City, MO 64105

Re: *In re: Bard Implanted Port Catheter Products Liability Litigation*
MDL No. 3081

Dear Counsel,

As you know, we represent Defendants Becton, Dickinson & Company, C.R. Bard. Inc., and Bard Access Systems, Inc. ("Defendants" or "Bard") in connection with the above-referenced application to the United States Judicial Panel on Multidistrict Litigation ("Panel"). We are in receipt of your inquiry as to whether Bard will consent to a stay of all proceedings in each of the eleven underlying civil actions pending the Panel's ruling on the Motion to Transfer Actions pursuant to 28 U.S.C. § 1407. Please accept this letter setting forth our counterproposal regarding a stay pending the Panel's decision and our proposal to informally coordinate certain discovery in each of these actions as an alternative to centralization.

A. Plaintiffs' Request for a Stay

Bard does not consent to a stay of *all* proceedings pending the Panel's decision. Instead, Bard proposes that the parties proceed with pre-answer motion practice, and limited "core" discovery in each civil action comprised of the following items:

1. Exchange of Initial Disclosures pursuant to Rule 26(a)(1);

2. Production of port-related medical records, including implant and explant records, and any treatment records related to the alleged complications at issue; and

3. The following categories of device-related documents, to the extent applicable, and following Plaintiffs' production of documents confirming product identification and the entry of a protective order or discovery confidentiality order:

    a. Section 510(k) premarket submission;

    b. Instructions for Use;

    c. Design History File;

    d. Device Master Record;

e. Device History Record; and

f. Bard's Complaint File pursuant to its Medical Device Reporting requirements.

Bard does not agree with your assertion that there is a risk of inconsistent rulings absent a stay. The eleven actions are pending in different jurisdictions, allege different complications, and present truly plaintiff-specific issues such as statute of limitations defenses. Bard also firmly believes that the Complaints allege a number of factually and legally deficient claims that will be uniformly dismissed under Rule 8 and Rule 12(b)(6)'s standards. These include the manufacturing defect claims (that some Plaintiffs have already dropped in amended pleadings), the breach of express warranty claims (no Plaintiff has identified any express warranty), the failure-to-warn claims (given, *inter alia*, that the IFU expressly discloses the risks of infection, thrombosis, fracture, and catheter embolism), and the consumer protection and fraudulent concealment claims (due to preemption and other defenses such as the learned-intermediary doctrine).

To the extent that Plaintiffs wish to save resources in connection with pre-answer motion practice, please let us know whether Plaintiffs will stipulate to the dismissal of all claims with the exception of the negligent and strict-liability design defect claims, assuming applicable state law recognizes both of these theories. Otherwise, pre-answer motion practice is necessary to expose the factually and legally deficient claims "at the point of minimum expenditure of time and money by the parties and the court." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 558 (2007).

With respect to discovery pending the Panel's ruling, the exchange of the materials identified herein will materially advance each lawsuit without undue burden on any party. To the extent that certain limited discovery from Bard may be common to more than one Plaintiff based on product identification,[1] Defendants will make common discovery available to those Plaintiffs.

Furthermore, this exchange of limited discovery will allow the parties to evaluate the strengths and weaknesses of the parties' claims and defenses. As you know from prior PowerPort lawsuits, the parties have a proven track record of efficiently resolving these claims upon a preliminary review of documents and without having to engage in depositions. There is no reason to deviate from past practices for the pending cases.

B. Informal Coordination of Discovery

Bard opposes transfer and centralization of the pending actions. Informal coordination is practicable in these actions. Beyond the discovery outlined herein, Bard is willing to permit Plaintiffs to cross-notice certain defense witness discovery depositions, and subject to judicial

[1] Product identification requires identification of the product code or SKU number, and the lot number. *See, e.g.*, *Kelley v. C.R. Bard, Inc.*, No. 23-cv-3044 (W.D. Mo.), Compl. ¶¶ 1, 33, ECF No. 11 (alleging that, "[o]n or about August 24, 2018, Plaintiff underwent placement of [a Bard Power-Port ClearVue ISP Implantable Port], reference number 5608062, lot number RECT1528."). Certain documents cannot be produced absent proper product identification, and certain documents may not exist for each Plaintiff. Bard reserves all rights to contest the discoverability of certain information, and provides the list of items as an effort to informally coordinate on the scope of discovery that is otherwise generally applicable to these actions.

approval, recommend that discovery proceed in each action on the same schedule. To the extent that Plaintiffs wish to confer regarding other alternatives to centralization, Bard is available to meet and regarding same.

* * *

Please advise whether you agree to this counterproposal in *Terry*, *Nelk*, *Beltz*, *Cunningham*, *Elwell*, *Anderson*, *Cabello*, *Prentice*, and *Groves*, in which you and your co-counsel, at Ratazan, Weissman & Boldt, Balaban Law, LLC, and Langdon & Emison, represent these plaintiffs either jointly or separately. We understand that you have been in contact with counsel in *Kelley* regarding a stay, and we have copied counsel in *Kelley* and *Divelbliss* regarding this counterproposal.

We are available at your convenience to discuss and look forward to hearing from you.

Very truly yours,

Edward J. Fanning, Jr.

cc: Charles N. Lakins, Esq.
Nicholas W. Allen, Esq.
Stuart N. Ratzan, Esq.
Kimberly L. Boldt, Esq.
Roman Balaban, Esq.
Brett A. Emison, Esq.
Danielle Rogers, Esq.

BEFORE THE UNITED STATES JUDICIAL PANEL ON MULTIDISTRICT LITIGATION

IN RE: BARD IMPLANTED PORT CATHETER PRODUCTS LIABILITY LITIGATION	MDL No. 3081

CERTIFICATION OF SERVICE

I hereby certify that on June 16, 2023, a copy of Defendants Becton, Dickinson & Company, C.R. Bard, Inc., and Bard Access System, Inc.'s Memorandum in Opposition to the Motion to Transfer Actions Pursuant to 28 U.S.C. § 1407 and Certification of Counsel was electronically filed via the Court's electronic filing system (CM/ECF) and served as indicated below to the following:

Divelbliss v. Bard Access Systems, Inc., et al., District of New Mexico, 1:22-cv-00601-DHU-KK

VIA ELECTRONIC MAIL

Charles N. Lakins, Esq.
LAKINS LAW FIRM, P.C.
P.O. Box 91357
Albuquerque, NM 87199
charles@lakinslawfirm.com
Counsel for Plaintiff Kimberly Divelbliss

Kelley v. C.R. Bard, Inc., et al., Western District of Missouri, 6:23-cv-03044-MDH

VIA ELECTRONIC MAIL

Nickolas W. Allen
DOUGLAS, HAUN & HEIDEMANN, P.C.
901 E. St. Louis St.
Suite 1200
Springfield, MO 65806
nick@dhhlawfirm.com
Counsel for Plaintiff Kriston Kelley

Terry v. Becton, Dickinson and Company, et al., Western District of Missouri, 4:23-cv-00100-BP

VIA ELECTRONIC MAIL

Adam M. Evans
Chelsea E. Dickerson
DICKERSON OXTON, LLC
1100 Main St., Suite 2550
Kansas City, MO 64105
aevans@dickersonoxton.com
cdickerson@dickersonoxton.com
Counsel for Plaintiff Patrice Terry

Nelk v. Becton, Dickinson and Company, et al., District of New Jersey, 2:23-cv-01173-SDW-MAH

VIA ELECTRONIC MAIL

Adam M. Evans
DICKERSON OXTON, LLC
1100 Main St., Suite 2550
Kansas City, MO 64105
aevans@dickersonoxton.com

Roman Balaban
Sarah A. Wolter
BALABAN LAW, LLC
8055 E. Tufts Ave, Suite 325
Denver, CO 80237
balaban@denverfirm.com
wolter@denverfirm.com
Counsel for Plaintiff Mary Nelk

Prentice v. Becton, Dickinson and Company, et al., District of Arizona, 2:23-cv-00627-ROS

VIA ELECTRONIC MAIL

Stuart N. Ratzan
Kimberly L. Boldt
RATZAN, WEISSMAN & BOLDT
2850 Tigertail Avenue, Suite 400
Coconut Grove, FL 33133
stuart@rwblawyers.com
kimberly@rwblawyers.com
Counsel for Plaintiff Lori Prentice

Beltz v. Becton, Dickinson and Company, et al., Western District of Missouri, 4:23-cv-00264-BP

VIA ELECTRONIC MAIL

Adam M. Evans
Chelsea E. Dickerson
DICKERSON OXTON, LLC
1100 Main St., Suite 2550
Kansas City, MO 64105
aevans@dickersonoxton.com
cdickerson@dickersonoxton.com

Stuart N. Ratzan
Kimberly L. Boldt
RATZAN, WEISSMAN & BOLDT
2850 Tigertail Avenue, Suite 400
Coconut Grove, FL 33133
stuart@rwblawyers.com
kimberly@rwblawyers.com
Counsel for Plaintiff Dana Beltz

Cunningham v. Becton, Dickinson and Company, et al., Western District of Missouri, 2:23-cv-04087-BCW

VIA ELECTRONIC MAIL

Adam M. Evans
Chelsea E. Dickerson
DICKERSON OXTON, LLC
1100 Main St., Suite 2550
Kansas City, MO 64105
aevans@dickersonoxton.com
cdickerson@dickersonoxton.com
Counsel for Plaintiff Jean Cunningham

Elwell v. Becton, Dickinson and Company, et al., District of Kansas, 2:23-cv-02197-JAR-GEB

VIA ELECTRONIC MAIL

Adam M. Evans
Chelsea E. Dickerson
DICKERSON OXTON, LLC
1100 Main St., Suite 2550
Kansas City, MO 64105
aevans@dickersonoxton.com
cdickerson@dickersonoxton.com

Roman Balaban
Sarah A. Wolter
Olga Y. Steinreich
Maxim Yefimenko
BALABAN LAW, LLC
8055 E. Tufts Ave, Suite 325
Denver, CO 80237
balaban@denverfirm.com
wolter@denverfirm.com
steinreich@denverfirm.com
yefimenko@denverfirm.com
Counsel for Plaintiff Shannon Elwell

Anderson v. Becton, Dickinson and Company, et al., Western District of Missouri, 4:23-cv-00316-BP

VIA ELECTRONIC MAIL

Adam M. Evans
Chelsea E. Dickerson
DICKERSON OXTON, LLC
1100 Main St., Suite 2550
Kansas City, MO 64105
aevans@dickersonoxton.com
cdickerson@dickersonoxton.com
Counsel for Plaintiff Vincent Anderson

Cabello v. C.R. Bard, Inc., et al., District of New Jersey, 2:23-cv-02859-MCA-JRA

VIA ELECTRONIC MAIL

Michael A. Galpern
JAVERBAUM WURGAFT HICKS KAHN WIKSTROM & SININS
Laurel Oak Corporate Center
1000 Haddonfield-Berlin Road
Suite 203
Voorhees, NJ 08043
mgalpern@lawjw.com
Counsel for Plaintiff Elizabeth Cabello, by and through her Representative Christopher Cabello

Groves v. Bard Access Systems, Inc., et al., Western District of Missouri, 5:23-cv-06058-DGK

VIA ELECTRONIC MAIL

Brett A. Emison
Danielle Rogers
LANGDON & EMISON
911 Main Street
P.O. Box 220
Lexington, MO 64067
brett@lelaw.com
danielle@lelaw.com
Counsel for Plaintiff Debbie Groves

Dated: June 16, 2023 By: */s/ Edward J. Fanning*

McCARTER & ENGLISH, LLP
Edward J. Fanning
Four Gateway Center
100 Mulberry Street
Newark, New Jersey 07102
Telephone: (973) 639-8486
Fax: (973) 624-7070
efanning@mccarter.com

Attorneys for Defendants,
Becton, Dickinson and Company, C.R. Bard, Inc., and Bard Access Systems, Inc.