Bard Peripheral Vascular, Inc.
1625 W 3rd St.
Tempe, AZ 85281

www.bd.com

URGENT MEDICAL DEVICE RECALL

PowerPort™ duo M.R.I.™ Implantable Port Kits

March 25, 2021

For the Attention of: Recall Coordinator, Director of Nursing, Director of Purchasing, Director of Risk Management

"Dear Valued Customer,

This letter is to inform you of a Voluntary Medical Device Product Recall being conducted by Bard Access Systems, Inc., a wholly owned subsidiary of Becton, Dickinson and Company (BD). Multiple lots of POWERPORT ™ duo M.R.I. ™ Implantable Port are affected as outlined in the table below. Our records show that your facility has purchased one or more units from the affected lots distributed starting on September 17, 2020.

Product Name	Catalog Number	Lot Number	UDI (GTIN, DI + PI)	Exp. Date
PowerPort™ duo M.R.I. ™ Implantable Port with Attachable 9.5F Polyurethane Open-Ended Dual-Lumen Venous Catheter Intermediate Kit	1829500	REEU3063	(01)00801741027185(17)311221 (10)REEU3063	12/31/2021
		REEV0989	(01)00801741027185(17)310522 (10)REEV0989	5/31/2022
		REEV2633	(01)00801741027185(17)310322 (10)REEV2633	3/31/2022
		REEX1380	(01)00801741027185(17)310522 (10)REEX1380	5/31/2022
		REEZ1991	(01)00801741027185(17)310822 (10)REEZ1991	8/31/2022
PowerPort™ duo M.R.I. ™ Implantable Port with Attachable 9.5F Polyurethane Open-Ended Dual-Lumen Venous Catheter Microintroducer Kit	1829570	REEW1060	(01)00801741027192(17)310322 (10)REEW1060	3/31/2022
		REEX0568	(01)00801741027192(17)311221 (10)REEX0568	12/31/2021
		REEZ1841	(01)00801741027192(17)310822 (10)REEZ1841	8/31/2022
PowerPort™ duo M.R.I. ™ Implantable Port with Non-Bumped Septa and Attachable 9.5F Polyurethane Open-Ended Dual-Lumen Venous Catheter Intermediate Kit	5829502	REEV2356	(01)00801741027406(17)310522 (10)REEV2356	5/31/2022
		REEX1383	(01)00801741027406(17)310822 (10)REEX1383	8/31/2022
		REEX3996	(01)00801741027406(17)310522 (10)REEX3996	5/31/2022

Description of the problem and health hazard(s):

BD has recently received reports of difficulty in flushing, infusion, and / or aspiration, and septum dislodgements during use of the above referenced PowerPort duo M.R.I. Implantable Ports. An example of a dislodged septum can be seen in Figure 1, on the following page.

A dislodged septum can result in leakage of infusates into the port cavity of the patient where the implanted port resides. Depending on the detectability of the leak and the volume and type of infusate, this situation may lead to a varying degree of pain and injury to the patient. In the case of an irritant or vesicant solution, a leak could produce serious toxic and or necrotic injury requiring immediate intervention to remove the port and treat the underlying affected tissue. The difficulty and/or inability to flush, infuse or aspirate can cause a delay in therapy and/or additional medical intervention. Both product issues can lead to port abandonment and may require surgical removal and or replacement of the port.

Figure 1: Dislodged Septum

Existing Mitigations:

The PowerPort duo M.R.I. Implantable Ports instructions for use (IFU) instruct the clinician at the time of preparation for implantation and during the power injection procedure to “flush each lumen of open-ended catheters with sterile normal saline, through the flushing connector” and “aspirate for adequate blood return and vigorously flush the port with at least 10 mL of sterile normal saline”, “Do not use a syringe smaller than 10 mL”.

Adherence to the IFU as well as to existing good clinical practice protocols should mitigate the risk posed by this product issue, as it will ensure the proper functionality of the ports prior to infusion of treatment, including power injection.

If any difficulty is encountered in flushing, infusion, and / or aspiration with either lumen of an implanted port, the affected port lumen should be considered non-functional and the remaining lumen should be verified for patency. After evaluation a non-patent lumen should be abandoned. Clinicians and physicians should use sound medical judgement and a risk versus benefit assessment in each individual case to determine the appropriate time for explantation.

Please Take the Following Actions:

1. Please check all inventory locations within your institution for the specific catalog and lot numbers of the PowerPort duo M.R.I. Implantable Ports listed above and immediately destroy all affected product remaining in your possession.
2. Share this notice with any users of the product within your facilities to ensure they are also aware of this Urgent Medical Device Recall.
3. If you purchased this product from a distributor, contact your distributor for further instructions.
4. **Complete and return the attached Customer Response Form to the BD contact noted on the form** confirming acknowledgement of the recall notification, whether or not you have any affected product, so that BD may acknowledge your receipt of this notification and process any applicable replacement orders.

5. Report any adverse health consequences experienced with the use of this product to BD. Events may also be reported to the FDA's MedWatch Adverse Event Reporting program:
   Web: MedWatch website at www.fda.gov/medwatch
   Phone: 1-800-FDA-1088 (1-800-332-1088)
   Mail: MedWatch, HF-2, FDA, 5600 Fisher's Lane, Rockville, MD 20852-9787

BD Contact Information: If you require further assistance please contact:

BD Customer Support:	Contact Information
North American Regional Complaint Center	1-844-8BD- LIFE (1-844-823-5433) Say "Recall" when prompted M-F 8am -5pm CT

Actions Taken by BD:

1. BD will process replacement orders for all customers affected by the recall following receipt of the completed Customer Response Form.
2. Based on inventory levels there may be a delay of 6 weeks or more in the fulfillment of replacement orders. BD understands that supply interruptions can impact our customers' ability to provide the best care for their patients and takes this matter very seriously, as such we fulfill orders as quickly as possible.
3. BD has implemented actions to prevent recurrence of this product issue.

BD is committed to advancing the world of health. Our primary objectives are patient and user safety and providing you with quality products. We apologize for any inconvenience this issue may have caused and thank you in advance for helping us to resolve this matter as quickly and effectively as possible.

Sincerely,

J.D Meler, M.D.
Vice President, Medical Affairs
BD Peripheral Intervention

Gail Griffiths
Sr. Director, Post Market Quality

BD
Advancing the world of health

CUSTOMER RESPONSE FORM
PI-21-4079-FA
PowerPort™ duo M.R.I. ™ Implantable Port Kits

Please assist BD by promptly returning this form to:

BD Post Market Quality
Website: BD.com/PI-21-4079
Email: BDRC15@bd.com
Fax No.: 312-949-0369

Facility: _____
Please use full, current facility name. Do not use initials.

Street Address: _____

City:_____ State: _____ Zip: _____

Correction Response Form Completed By:	
Name:	
Title:	
Telephone No.	
Fax No.	
Email Address	

Please check the following options, as applicable:

☐ I have read and understood the attached notice and taken appropriate actions.

☐ We do not have any of the affected product(s) on hand.

☐ I certify that I have destroyed all affected product indicated below as available inventory at the time of receipt of this notification and request replacement.

Product Name **PowerPortTM duo M.R.I. ™ Implantable Port Catheter**	**Catalog No.**	**Lot No(s).**	**Quantity in Eaches**
with Attachable 9.5F Polyurethane Open-Ended Dual-Lumen Venous Catheter Intermediate Kit	1829500		
with Attachable 9.5F Polyurethane Open-Ended Dual-Lumen Venous Catheter Microintroducer Kit	1829570		
with Non-Bumped Septa and Attachable 9.5F Polyurethane Open-Ended Dual-Lumen Venous Catheter Intermediate Kit	5829502		

Please assist BD with assuring these communications are delivered to the appropriate person/function within your facility if that is not you.

Person/function responsible for the receipt and management of all recalls/corrections at your facility:

Name: _____
Phone: _____
Email: _____
Fax: _____