ATTENTION: RISK MANAGER/MATERIALS MANAGER

URGENT MEDICAL DEVICE RECALL NOTIFICATION

Implantable Ports & GROSHONG® Central Venous Catheter

September XX, 2019

Dear Customer,

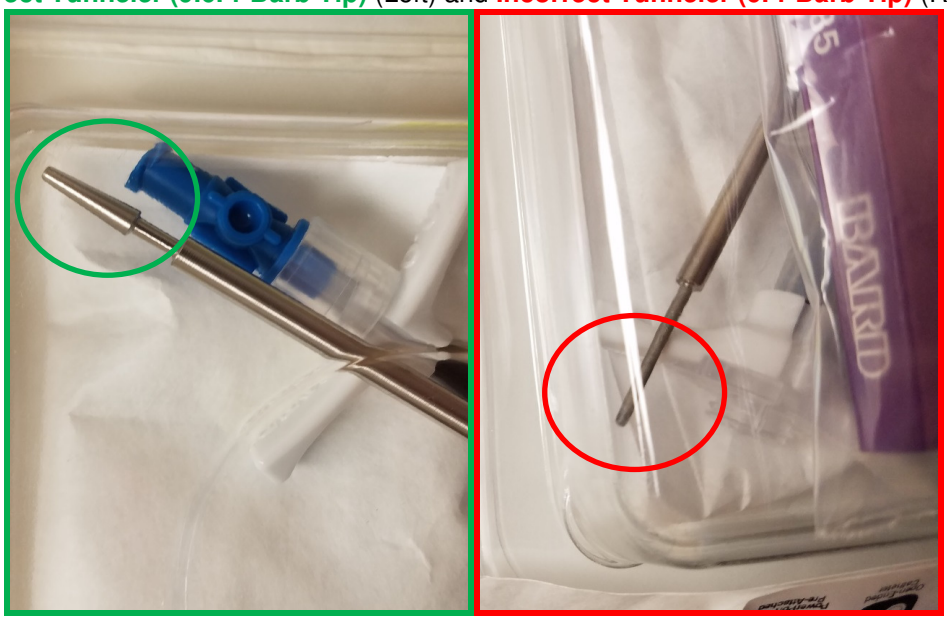
This letter is to inform you of a voluntary product recall issued by Bard Peripheral Vascular, Inc. (BPV), a wholly owned subsidiary of Becton, Dickinson and Company. Specific Implantable Port and GROSHONG® Central Venous Catheter product code / lot number combinations are affected as outlined in Attachment 3. Our records show that your facility has purchased one or more units from the affected lots.

All other product code / lot number combinations not listed in Attachment 3 can continue to be used by your facility as they are safe to use and are not affected by this product recall.

Reason for Recall:

BPV has identified that the product code / lot numbers listed in Attachment 3 may be at risk of incorrectly containing a tunneler with a barb tip meant to attach to a 6Fr catheter instead of the correct barb tip for a 9.6Fr catheter, as shown in the figures below.

Correct Tunneler (9.6Fr Barb Tip) (Left) and **Incorrect Tunneler (6Fr Barb Tip)** (Right)



Clinical Risk Statement:

The immediate health consequences include the potential that the user would not be able to attach the end of the catheter to the tunneler and need to get an appropriate tunneler to complete the procedure. In addition, there is the potential that the catheter could become dislodged from the tunneler during the advancement through the tunnel. In this case, the user would either pull the catheter back out and begin again or, if able, improvise and capture the end of the catheter (with the aid of a surgical clamp or hemostat) and complete the advancement into the port pocket. Overall, this represents a prolongation of

the procedure, may have an incremental risk of minor tissue injury, however, is unlikely to lead to a serious injury. There is no indication that this would lead to a long-term health consequence.

Required Actions:

Please find attached instructions detailing the steps we are requesting you take regarding this product. The Food & Drug Administration has been made aware of this action and as such records of completion are subject to verification by the FDA. **BPV must document your compliance with this action.**

We appreciate your cooperation and assistance in dealing with this matter and sincerely apologize for any inconvenience that may result from this action. If there is any assistance that you require regarding this action, please do not hesitate to contact your Bard representative.

Sincerely,

Garth Conrad
Vice President, Quality Assurance
Bard Peripheral Vascular, Inc

Attachment 1 – Instructions for Completing Required Actions
Attachment 2 – Recall and Effectiveness Check Form
Attachment 3 – Affected Product Code / Lot Number Combinations

Attachment 1

INSTRUCTIONS FOR COMPLETING REQUIRED ACTIONS

1. Our records show that your facility has purchased product codes affected by this voluntary recall. Do not use or further distribute any affected product.

2. Please check all inventory locations within your institution for affected product code / lot number combinations listed in the recall notice. If you have further distributed any of the product code / lot numbers, please immediately contact that location, advise them of the recall, forward these instructions and have them return the affected product to BPV.

3. Please remove any identified product from your shelves.

4. If you have used the affected product, complete and return the attached ***Recall and Effectiveness Check Form*** indicating no product will be returned.

Once the product affected by this recall has been removed from your inventory:

5. Fill out the ***Recall and Effectiveness Check Form.*** Be sure to state the quantities and lot numbers of each recalled product that you intend to return. It is extremely important that we receive this information.

6. Email the completed ***Recall and Effectiveness Check Form*** to BDPI.CustomerSupportCenter@bd.com or fax it to BPV at 1-800-994-6772.

7. Once the Recall and Effectiveness Check Form has been completed and emailed to BDPI.CustomerSupportCenter@bd.com or faxed to BPV at 1-800-994-6772 and all information has been verified, the BPV Customer Support Center will issue you a Return Authorization (XC) Number to facilitate the expedient return of the product. BPV will issue a replacement product for your returned product. Please call our BPV Customer Support Center at 1-800-321-4254 Option #5 (M-F 5am to 2pm MST) or email at BDPI.CustomerSupportCenter@bd.com with any questions.

8. A mailing label will be enclosed for your convenience to return the affected product. Please mark the outside package as "RECALLED PRODUCT" and include the XC number. All products should be returned to the following shipping address:

   Bard Peripheral Vascular, Inc.
   1415 W. 3rd Street
   Tempe, AZ 85281

9. Please report any new and/or previously unreported adverse events associated with this recall to the US Food and Drug Administration's ("FDA") MedWatch Program by phone at 1-800-FDA-1088; by fax at 1-800-FDA-0178; by mail to MedWatch, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857-9787; or on line at http://www.fda.gov/medwatch/report.htm.

Attachment 2

RECALL AND EFFECTIVENESS CHECK FORM

Implantable Ports & GROSHONG® Central Venous Catheter

Please complete this form and Fax to 1-800-994-6772. Contact our BPV Customer Support Center at 1-800-321-4254 Option #5 with any questions about the product return process.

Please PRINT your contact information and fill form out completely:

Name of facility:

Account #:

Address:

City: State: Zip:

Name:_____Title:_____

Phone:_____ Date:_____

Email:_____

1. Do you currently possess any of the affected lots of product? (*Please check both consignment and purchased inventory for possible locations of this affected product.*)

   Yes_____ No_____

2. If you have affected product, do you intend to return the affected product?

   Yes_____ If YES, Total # of Pieces to be returned: _____

Product Code	Lot Number	Qty to be Returned

No_____If NO, please provide reason for not returning. [ ] Used [ ] Destroyed [ ] Other

Return Authorization Number: XC # _____

Note: Return authorization number will be provided by our BPV Customer Support Center upon verification of the provided information.

Please email the completed form to BDPI.CustomerSupportCenter@bd.com or FAX completed form to:

Fax: 1-800-994-6772

Attn: BPV Customer Support Center
Customer Service
Bard Peripheral Vascular, Inc.

Attachment 2 – Affected Product Code / Lot Number Combinations

Product Name	Product Code	Lot Number
BARDPORT® M.R.I. Hard Base Implantable Port	0604550	RECR1431
BARDPORT® M.R.I. Implantable Port	0602680	RECR1439
	0602680	RECT0078
	0602680	RECU1067
	0602680	RECU2404
BARDPORT® Titanium Implantable Port	0602230	RECR2059
GROSHONG® 9.5F Dual-Lumen Central Venous Catheter	7726950	RECQ1106
	7726950	RECR2195
	7726954	RECU1837
POWERFLOW® 9.6Fr ChronoFlex Implantable Apheresis IV Port	A710962	RECR1499
POWERPORT® Implantable Port	1759600	RECS1276
	1759600	RECS2991
	1709600	RECT0088
	1709601	RECU1601
POWERPORT® isp M.R.I. Implantable Port	1859660	RECR0983
	1859660	RECR1885
	1859660	RECR2220
	1859660	RECS0030
	1859601	RECS0065
	1859660	RECS2758
	1859661	RECS2974
	1809660	RECT0092
	1809661	RECT0190
	1859660	RECU0481
	1859601	RECU2292
POWERPORT® M.R.I. Implantable Port	1809600	RECR1434
	1859600	RECR2072
	1859600	RECS1118
	1809600	RECT0091
	1809601	RECT0189
VACCESS® CT Power-Injectable Implantable Port	7496000	RECR0929
	7496000	RECR1511
	7496000	RECR1882
X-PORT® isp M.R.I. Implantable Port	0607550	RECR1508
	0657525	RECU1597