ATTENTION: RISK MANAGER/MATERIALS MANAGER

URGENT MEDICAL DEVICE RECALL NOTIFICATION

SEEKER® Crossing Support Catheter

Product Code	Lot Number
SK15035M	VTBY0563
SK15014	VTBZ0193

April 16, 2018

Dear Valued 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 product code / lot number combinations of SEEKER® Crossing Support Catheters are affected as outlined above. Our records show that your facility has purchased one or more of the affected product code / lot number combinations.

All other product code / lot number combinations not listed above 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 number combinations listed above may be at risk of having detectable levels of bacterial endotoxin present on the packaging hoop that the catheter is packaged in. The bacterial endotoxin levels for the catheters are within acceptable levels; however, if bacterial endotoxins are present on the packaging hoops it may have the potential for cross-contamination in a clinical setting.

Clinical Risk Statement:
Exposure to bacterial endotoxin can have a varying degree of risk of patient harm, including a potentially life-threatening event. Even low levels of bacterial endotoxin exposure have been known to elicit an immune response. The responses can include, but are not limited to, fever-inducing (pyrogenicity), an impact to white blood cell activity (leukopenia or leukocytosis), multi-organ impact, and severe systemic shock. Long-term responses can be associated with intractable low-level inflammatory responses.

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,

[redacted]

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

Attachment 1 – Instructions for Completing the Required Actions
Attachment 2 – Recall and Effectiveness Check Form

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. Please call our BPV Customer Support Center at 1-800-321-4254 Option #5 (M-F 6am to 3pm MST) or email at BPV.CustomerSupportCenter@crbard.com. Once 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 provide a replacement for your returned product.

7. Email the completed ***Recall and Effectiveness Check Form*** to BPV.CustomerSupportCenter@crbard.com or fax it to BPV at 1-800-994-6772. If you cannot email or FAX the form, please call the BPV Customer Support Center at 1-800-321-4254 Option #5 and report the required information verbally.

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

SEEKER® Crossing Support 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:_____

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
SK15035M	VTBY0563	
SK15014	VTBZ0193	

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 BPV.CustomerSupportCenter@crbard.com or FAX completed form to:

Fax: 1-800-994-6772

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