ATTENTION: RISK MANAGER/MATERIALS MANAGER

URGENT MEDICAL DEVICE RECALL NOTIFICATION

BARD TRUGUIDE® Disposable Coaxial Biopsy Needles

Part Number	Lot Number
C2016B	REWL0924
C2016B	REXA1695
C2016B	REXB1529
C2016B	REXC1632

February 4, 2016

Dear Valued Customer,

This letter is to inform you of a voluntary recall initiated by Bard Peripheral Vascular, Inc. (BPV), a wholly owned subsidiary of C.R. Bard, Inc. Specific product code / lot number combinations of Bard TruGuide® Disposable Coaxial Biopsy Needles 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:

Bard Peripheral Vascular (BPV) has confirmed that the product code / lot number combination listed above may be at risk of having an incorrectly sized blunt tip stylet within its packaging that will not pass through the coaxial. Specifically, the product should contain a 19 gauge blunt tip stylet when the actual packaged product contains a 17 gauge blunt tip stylet.

Clinical Risk Statement:

The potential hazard associated with attempting to proceed in the placement of the coaxial utilizing the sharp trocar stylet, instead of the intended optional blunt tip stylet, may be variable depending on the anatomical location of the biopsy and may pose an incremental risk of unintended injury to tissue, vasculature, or other organs. If the affected device has already been safely used, then no further product related action is required.

Required Actions:

Please find the attached instructions detailing the steps we are asking you to 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 need regarding this action please do not hesitate to contact your Bard representative.

Sincerely,

Garth Conrad
Vice President, Quality Assurance
Bard Peripheral Vascular

1415 West 3rd Street • Tempe, AZ 85281
Tel: 1-800-321-4254 Option #2 Ext 2501 • Fax: 1-800-994-6772 • www.bardpv.com

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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 combination 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 have in stock. It is extremely important that we receive this information even if you no longer have possession of the recalled product.

6. Please call our Recall Coordinator Raye Seisinger at 1-800-321-4254 Option #2 Ext 2501 (M-F 6am to 3pm MST) or email at raye.seisinger@crbard.com. Once all information has been verified, the Recall Coordinator will issue you either a Return Authorization (XC) Number or Consignment Recall Number (XH) to facilitate the expedient return of the product. BPV will provide replacement product for your returned product.

7. Fax the ***Recall and Effectiveness Check Form*** to BPV at 1-800-994-6772. If you cannot FAX the form, please call the BPV recall coordinator (Raye Seisinger, at 1-800-321-4254 Option #2 Ext 2501) and report the required information verbally.

8. A mailing label is enclosed for your convenience to return the affected product. Please mark the outside package as "RECALLED PRODUCT" and include the XC or XH 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.

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RECALL AND EFFECTIVENESS CHECK FORM
BARD TRUGUIDE® Disposable Coaxial Biopsy Needles

Please complete this form and Fax to 1-800-994-6772. Contact BPV Recall Coordinator, Raye Seisinger, at 1-800-321-4254 Option #2 Ext 2501 with any questions about the product return process.

Please PRINT your contact information and fill form out completely:

Name:_____ Title:_____

Phone:_____ Date:_____

Name of facility:_____ Account #:_____

Address:_____

City: _____ State: _____ Zip:_____

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
C2016B	REWL0924	
C2016B	REXA1695	
C2016B	REXB1529	
C2016B	REXC1632	

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

Return Authorization Number: XC or XH # _____

Note: Return authorization number will be provided by the recall coordinator upon verification of the provided information.

Please fax completed form to: **Fax: 1-800-994-6772**

Attn: Recall Coordinator / Raye Seisinger
Customer Service
Bard Peripheral Vascular, Inc.

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