

Attention: Risk Manager/Materials Manager

**URGENT MEDICAL DEVICE RECALL NOTIFICATION**

**Bard® MAX-CORE Disposable CORE BIOPSY INSTRUMENT**

April xx, 2015

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.

**Reason for Recall:**

Bard Peripheral Vascular (BPV) has confirmed that the product code / lot number combination listed in Attachment 1 may be at risk of having self-activation-related issues.

**Specific product code / lot number combinations of Bard® Max-Core Disposable Core Biopsy Instruments are affected as outlined in Attachment 1. 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 in Attachment 1 can continue to be used by your facility as they are safe to use and are not affected by this product recall.**

**Clinical Risk Statement**

The harm associated with potential self-activation during use may pose an incremental increase in the risk associated with biopsy procedures. This includes prolonging the procedure, requiring the use of an additional device, or minor tissue injury to the patient if the device fails to fire. Potential self-activation, may potentially lead to inadvertent injury to deep tissue or structures, blood vessels or adjacent critical organs. In addition, a used device may pose an incremental risk of bloodborne contamination to the user if self-activated. In the event this occurred, the patient or user may require urgent medical or surgical intervention and the user is to follow facility procedures for inadvertent needle sticks or injury.

If the affected device has already been used, no further product related action is required. Please refer to the Recall and Effectiveness Check Form completion requirement below.

**Instructions:**

**Do not use or further distribute any affected product.**

- Our records show that your facility has purchased product codes affected by this voluntary recall.
- We ask that you check all inventory locations within your institution for Bard® Max-Core Disposable Core Biopsy Instruments with product code / lot number combination listed in Attachment 1.
  - If you have further distributed any of the product code / lot numbers listed in Attachment 1, please immediately contact that location, advise them of the recall and have them return the affected product to BPV (address listed below).
- Please remove any identified product in Attachment 1 from your shelves.
- If you have used the affected product from Attachment 1, complete and return the attached **Recall and Effectiveness Check Form** indicating no product will be returned.

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>.

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

- 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.
- Please call our Recall Coordinator Randy Hopkins at 1-800-321-4254 Option #2 Ext 2988 (M-F 7am to 4pm MST) or email at [randy.hopkins@crbard.com](mailto:randy.hopkins@crbard.com). The Recall Coordinator will issue you either a Return Authorization (RCL) Number or Consignment Recall Number (CRC) to facilitate the expedient return of the product.
- Fax the **Recall and Effectiveness Check Form** to BPV at 1-800-994-6772
- BPV will provide replacement product for your returned product.

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

Bard Peripheral Vascular, Inc.  
1415 W. 3<sup>rd</sup> Street  
Tempe, AZ 85281

FDA has been notified of this recall.

#### **FDA Required Recall Reconciliation**

FDA requires detailed reconciliation of all recalled product. Please complete the enclosed **Recall and Effectiveness Check Form** and fax to the attention of Recall Coordinator in Customer Service at 1-800-994-6772, even if you no longer have possession of the recalled product. If you cannot FAX the forms, please call the BPV telephone number provided below on the form and report the required information verbally. Be sure to state the quantities and lot numbers of each product that you have in your stock.

**It is extremely important that we receive this information.** BPV must document your compliance with this voluntary recall. Facilities that receive this communication must immediately carry out the instructions set forth in this communication and extend the recall to its consignees, as applicable.

We appreciate your cooperation and assistance in dealing with this matter and sincerely apologize for any inconvenience that may result from this action.

Sincerely,

Chad Modra  
Vice President, Quality Assurance  
Bard Peripheral Vascular

**RECALL AND EFFECTIVENESS CHECK FORM**  
**Bard® Max-Core Disposable Core Biopsy Instrument**

**It is important that the product code / lot number combinations of Bard® Max-Core Disposable Core Biopsy Instruments listed in Attachment 1 be immediately removed from your inventory and isolated from use.**

**Please complete this form and fax to 1-800-994-6772.**

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

**Please PRINT Your Contact Information and fill form out completely:**

Name: \_\_\_\_\_ Title: \_\_\_\_\_

Phone \_\_\_\_\_ Date: \_\_\_\_\_

Name of Account/Hospital: \_\_\_\_\_ Account # \_\_\_\_\_

Address \_\_\_\_\_ City: \_\_\_\_\_ State: \_\_\_\_\_ ZIP \_\_\_\_\_

RCL or CRC # \_\_\_\_\_

**Please Fax completed form to: Fax: 1-800-994-6772 Attn: Recall Coordinator / Randy Hopkins  
 Customer Service  
 Bard Peripheral Vascular, Inc.**

**Please call Call BPV Recall coordinator Randy Hopkins at 1-800-321-4254 Option #2 Ext 2988 with any questions about the product return process.**