Bard Limited
Forest House, Tilgate Forest Business Park
Brighton Road, Crawley
West Sussex, RH11 9BP
England, UK.

[Contact Name]

[Department/Title]
[Hospital Name]
[Address Line 1]
[Town/City]
[Postal Code]
[Country]

[Date]

Reference: FA2015-52

URGENT FIELD SAFETY NOTICE
Bard TruGuide® Disposable Coaxial Biopsy Needles

Dear [Contact Name]

This letter is to inform you of a Field Safety Corrective Action for a product removal initiated by Bard Peripheral Vascular (Bard), 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 below in Table 1.

Table 1: Affected Product Code / Lot Number Combinations

Part Number	Lot Number
C2016B	REXB1529
C2016B	REXC1632

Reason for Field Safety Notice (FSN):

Bard has confirmed that the product code / lot number combinations listed above in Table 1 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 may contain a 17 gauge blunt tip stylet.

Our records show that your facility has purchased one or more units of the affected product. All other product codes not listed in this Field Safety Notice 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 potential hazard associated with attempting to proceed in the placement of the coaxial utilising 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.

Please be aware that your Competent Authority is being notified of this Field Safety Corrective Action. As part of this action, we require that you follow the instructions below and notify Bard of your compliance with this Field Safety Corrective Action.

Required actions for you and your Healthcare Facility:

1. **Do not use or further distribute any Bard TruGuide® Disposable Coaxial Biopsy Needles listed above in Table 1.**
2. Check all your storage locations for the **Bard TruGuide® Disposable Coaxial Biopsy Needles listed above in Table 1**.
3. Pass this Field Safety Notice to all those who need to be aware of it within your organisation and to any organisation where the potentially affected devices have been transferred.
4. Please remove any identified product from your shelves and segregate appropriately.
5. If you have further distributed to your customers any **Bard TruGuide® Disposable Coaxial Biopsy Needles** product please immediately contact that location, advise them of the recall and have them return the affected product to your facility.
    - Once the affected product has been returned to your facility please contact your local Bard representative.
6. Before returning the product to Bard, mark the outside package as "RECALLED PRODUCT" and include the RGA number reference number FA2015-52.

Once the product affected by this recall has been removed from your inventory;
Please complete the attached Reply Effectiveness Check Form and fax to [Local Fax Number].
Alternatively this can be emailed to xxxxxxx@crbard.com

Note: It is extremely important that we receive this information. If you cannot fax or email the form please telephone your local Bard Customer Service Representative and report the required information verbally.

We appreciate your cooperation and assistance in dealing with this matter and sincerely apologize for any inconvenience that may result from this action. Should you have any questions or require assistance in this matter, please contact your local sales specialist or local Bard Customer Service Representative on [Tel #]

Yours faithfully.
For and on behalf of C. R. Bard, Inc.

[Signature]

REFERENCE: FA2015-52 **RGA #** _____

REPLY EFFECTIVENESS CHECK FORM

Bard TruGuide® Disposable Coaxial Biopsy Needles

It is important that the Bard TruGuide® Disposable Coaxial Biopsy Needles be immediately removed from your inventory and isolated from use.

Please complete this form and fax to [Local Fax Number].
Alternatively this can be emailed to xxxxx@crbard.com

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 ☐

Part Number	Lot Number
C2016B	REXB1529
C2016B	REXC1632

2. Have you further distributed any of the affected lots to your customers?

   Yes ☐ No ☐

   ☐ If you answered Yes, please tick this box to confirm you have notifed these customers of the Field Safety Corrective Action and had them return any affected product to you.

3. If the answer to Question 1 is YES, please list Product Codes, Lot Numbers and Quantity being returned by completing the table below:

Customer Name	Customer PO#	Actual Ship Date	Item Code	Lot#	Quantity Ordered	Quantity to Return	ACTUAL QTY RETURNED (BARD ONLY)
[Pre-populated field]	[Pre-populated field]	[Pre-populated field]	[Pre-populated field]	[Pre-populated field]	[Pre-populated field]		
[Pre-populated field]	[Pre-populated field]	[Pre-populated field]	[Pre-populated field]	[Pre-populated field]	[Pre-populated field]		

Please PRINT Your Contact Information and fill form out completely	
Name	
Title	
Name of Account / Hospital	[Pre-populated field]
Contact Phone Number	
Date	
Signature	

Please return completed form and any affected product to:
[Local Contact Name]
[Local Contact Title]
[Bard® XYZ (Insert IBC Name / Address / Country]
[Tel: (Local Tel #)] [Fax: (Local Fax #)] [Email: (name@crbard.com