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: FA2017-51

URGENT FIELD SAFETY NOTICE

Intermittent Catheters – Catheter caught in seal

Dear [Contact Name]

This letter is to inform you of a voluntary Field Safety Corrective Action initiated by Bard, involving specific lots of Rochester Medical catheters - **Magic3®, HydroSil Gripper** and Personal Intermittent Catheters (16" and 10" lengths). The affected product code/ lot numbers are listed in Attachment 1 to this FSN.

Reason for Field Safety Notice (FSN):

Bard has identified that the product code / lot number combination identified in Attachment 1 may have a sterile barrier breach where the catheter may be caught in the seal or protruding from the seal of the packaging, and potentially, have the catheter tip cut.

Only the product / lot number combinations listed in Attachment 1 are affected by this Field Safety Notice.

Our records show that your facility has purchased one or more units of the affected product code/lot number combinations. All other product code / lot number combinations 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:

It is reasonable to assume that some of the affected catheters will be used by an unaware patient; the highest severity associated with this adverse event resulting from use of the device could be a potential injury to the patient's urethral meatus or the patient's urethra very likely resulting in pain and discomfort during the initial and subsequent catheter insertions, and a potential for a urinary tract infection.

If the affected product 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.

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Required actions for you and your Healthcare Facility:

1. **Do not use or further distribute any of the product code/lot number combinations listed in Attachment 1.**
2. Check all your storage locations for the **product code/lot number combinations listed in Attachment 1**.
3. Immediately remove any identified product code/lot number combinations from your shelves and segregate appropriately.
4. 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.
5. If you have further distributed to your customers any of the affected product code/lot number combinations please immediately contact that location, advise them of the recall and have them return the affected product to your facility.
6. Before returning the product to Bard, mark the outside package as “RECALLED PRODUCT” and include the RGA number reference number FA2017-51.

Once the product affected by this recall has been removed from your inventory and/or returned to your facility:
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]

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REPLY EFFECTIVENESS CHECK FORM

It is important that the product listed in Attachment 1 to this FSN 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 lot of product listed in Attachment 1 above? (*Please check both consignment and purchased inventory for possible locations of this affected product.*)

   Yes ☐ No ☐

2. Have you further distributed any of the affected lot of product 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 the 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]		

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