Rochester Medical,
(Subsidiary of Bard Medical Division)
One Rochester Medical Drive
Stewartville,
MN 55976

[Contact Name]

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

[Date]

Reference: FA2015-23

URGENT FIELD SAFETY NOTICE

Magic^{3TM} Hydrophilic-coated Female Intermittent Catheters

Dear [Contact Name]

This letter is to inform you of a Field Safety Corrective Action initiated by Bard Medical Division (BMD), a wholly owned subsidiary of C.R. Bard, Inc.

Reason for Field Safety Notice:

BMD has identified that certain lots of Magic^{3TM} Hydrophilic-coated Female Intermittent Catheter products be at risk of having a small void in the package seal and therefore product sterility may be affected.

Specific product code / lot number combinations of Magic^{3TM} Hydrophilic-coated Female Intermittent Catheters 10-16 Fr as well as the Magic^{3TM} Hydrophilic-coated Female Intermittent Catheter 14 Fr included in an Insertion Supply Kit are affected as listed 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 not affected by this Field Safety Corrective Action.

Clinical Risk Statement:

The catheter is intended for urinary bladder drainage in patients requiring catheterisation, including self-catheterisation, for management of incontinence, voiding dysfunction, or surgical procedures as a result of pre-existing or acute conditions such as Spina Bifida, spinal trauma, or others. Use of non-sterile Magic^{3TM} Female Intermittent Catheters could introduce microorganisms to the urinary tract during a catheterisation procedure which may lead to a varying degree of risk including localised and/or systemic infectious complications ranging from urinary tract infection to urosepsis. In the event infections or other complications were to occur, the patient may require medical intervention.

If affected product has already been used, it is advisable to monitor the patient for symptoms and signs of localised and/or systemic infection. Symptoms could include fever, pain, or burning sensation upon voiding. As with the use of any catheter, it is recommended that the patient consult a physician if symptoms or signs of an infection are present.

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Please be aware that your Competent Authority is being notified of this Field Safety Corrective Action. Our records show that your facility has purchased product affected therefore, 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 facility:

1. **Do not further distribute any of the product code / lot number combinations listed in Attachment 1.**
2. Check all inventory locations within your institution for the affected batches of **Magic^{3TM} Hydrophilic-coated Female Intermittent Catheter** devices with the product code / lot number listed in Attachment 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.
5. If you have further distributed to your customers any of the devices with the product code / lot number combinations listed in Attachment 1, please immediately contact that location, advise them of the recall and have them return the affected product to your facility.
    - Your notification should include a copy of the attached Customer Letter, including the customer Effectiveness Check Form
6. Once the affected product has been returned to your facility please contact your local Bard representative. Before returning the product to Bard, mark the outside package as "RECALLED PRODUCT" and include the RGA number reference number FA2015-23.

Once the product affected by this recall has been removed from your inventory and the actions as listed above have been completed;
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.

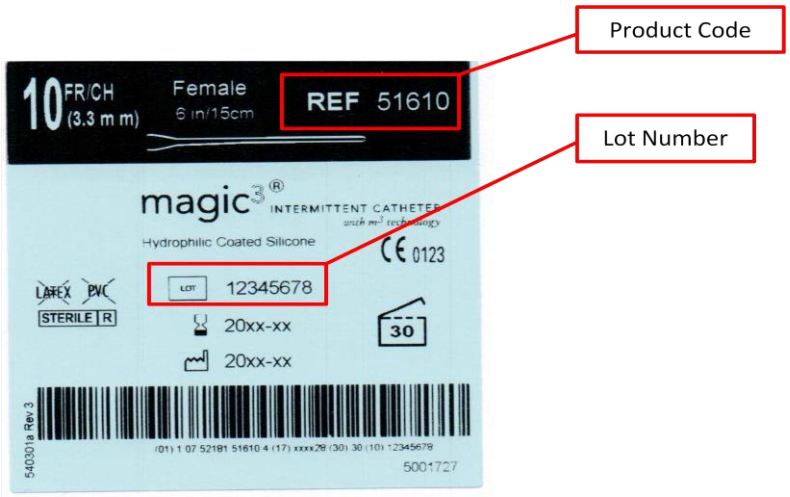
[Signature]

Attachment 1: Product Codes / Lot Numbers of affected devices

Product Code	Product Description	Lot Number
51610	Magic^3 + Hydrophilic Female Length (6") – 10 Fr	73600023
51612	Magic^3 + Hydrophilic Female Length (6") – 12 Fr	73600014 73600079 73600110 73600128 73600219
51614	Magic^3 + Hydrophilic Female Length (6") – 14 Fr	73600003 73600006 73600007 73600011 73600012 73600013 73600016 73600017 73600020 73600021 73600024 73600080 73600081 73600082 73600095 73600096 73600097 73600123 73600124 73600125 73600126 73600144 73600145 73600163 73600164 73600167 73600181 73600196 73600217 73600218
51616	Magic^3 + Hydrophilic Female Length (6") – 16 Fr	73600015 73600068 73600129
51614S	Magic^3 + Hydrophilic Female Length (6") – with Insertion Supply Kit – 14 Fr	53620387 53621274 53621279

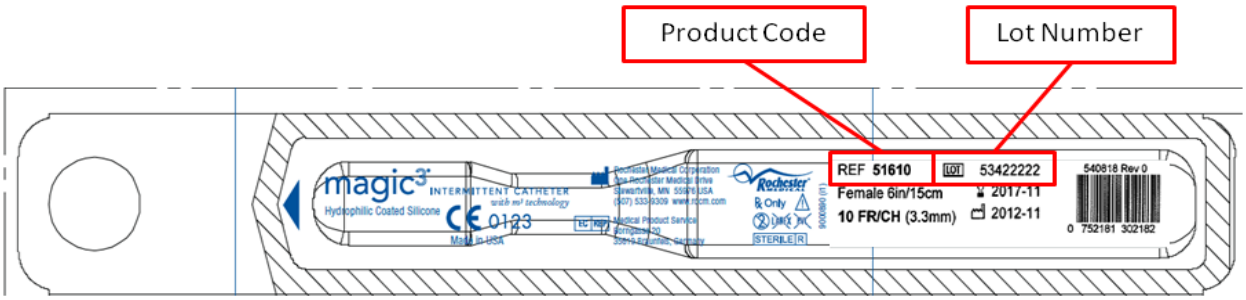
Attachment 2: Identifying Product Codes and Lot numbers for your Magic^{3} + Hydrophilic Female Length (6") Sizes 10-16Fr catheters and Insertion Kits:

Box Label for Magic^{3TM} Hydrophilic-coated Female Intermittent Catheters 10-16 Fr



Box Label for Insertion Supply Kit

Package label for Magic^{3TM} Hydrophilic-coated Female Intermittent Catheters 10-16 Fr



REFERENCE: FA2015-23 **RGA #** _____

REPLY EFFECTIVENESS CHECK FORM

Magic^{3TM} Hydrophilic-coated Female Intermittent Catheters

It is important that the Product Code / Lot Number combination of the **Magic^{3TM} Hydrophilic-coated Female Intermittent Catheters** listed in Attachment 1 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 ☐

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)

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

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)