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

HOMECARE CUSTOMER NOTIFICATION

Reference: FA2015-23

URGENT FIELD SAFETY NOTICE

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

Dear Valued Customer,

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

Reason for Recall:

BMD has initiated the recall of certain lots of **Magic^{3TM} Hydrophilic-coated Female Intermittent Catheter products** as they may 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. Attachment 2 can help to find the Product Code and Lot Number information on your catheter.

Your distributor's records show that you may have 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 this occurred, the patient may require medical intervention.

If you have already used any affected product there are no additional actions you need to take. As with the use of any catheter, it is recommended that you consult a physician if symptoms or signs of an infection are present. You should consult your physician if you experience any of the following symptoms; fever, pain, or burning sensation upon voiding.

Required actions for you:

1. **Do not use any of the product code / lot number combinations listed in Attachment 1.**
2. Check all your storage locations for the affected batches of **Magic^{3TM} Hydrophilic-coated Female Intermittent Catheter** devices with the product code / lot number listed in Attachment 1. The photos contained in Attachment 2 can help to locate the Product Code and Lot Number of you catheter.
3. Contact your distributor to arrange the return of any affected units you may have.

Should you have any questions or require assistance in this matter, please contact your provider of the products.

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

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

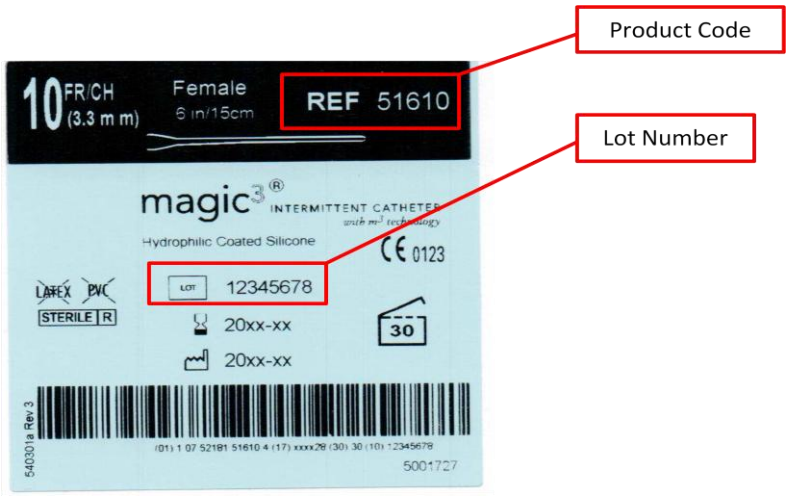
[Signature]

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^{3TM} 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