Bard Medical Division
C.R. Bard, Inc.
8195 Industrial Blvd.
Covington, GA 30014

URGENT: MEDICAL DEVICE PRODUCT RECALL

(Month Day, Year)

Dear Valued Customer,

This letter is to inform you of a voluntary Medical Device Product Recall initiated by Bard Medical Division (BMD), a wholly owned subsidiary of C.R. Bard, Inc. involving one (1) lot of the X-Force™ Nephrostomy Balloon Dilation Catheter Kit identified below. Distribution of this lot began in April 2015. If you have lots other than the one listed below, they are safe to use and you do not have to return them. Our records show that your facility has purchased at least one unit of sale for this product code / lot number combination.

Product Code	Description	Lot Number	Expiration Date
996081	X-Force™ Nephrostomy Balloon Dilation Catheter Kit With Inflation Device, PTFE Sheath, 8 mm X 15 cm	BMZCE039	2018-12-31

Reason for Recall:

Bard Medical Division (BMD) has identified that the product code / lot number combination identified above may have 30 Fr sheath instead of the appropriate 24Fr sheath.

Clinical Risk Statement:

The X-FORCE® Nephrostomy Balloon Dilation Catheter is a dual lumen catheter indicated for recommended use in the dilation of the nephrostomy tract and for placement of a working sheath.

In the most likely event, trained and experienced medical personnel would visually inspect the X-Force™ Nephrostomy Balloon Dilation Catheter Kit labeled 24Fr as required per the Instructions for Use, likely notice the 30Fr sheath, and discard or return the kit to the manufacturer prior to starting a procedure.

In the event that trained and experienced medical personnel were to use the 24Fr X-Force™ Nephrostomy Balloon Dilation Catheter and then realize that a 30Fr sheath was provided in the kit instead of the 24Fr sheath as indicated on the label, a correct 30Fr sheath would have to be procured in order to complete the intended procedure, possibly resulting in an unintended prolongation of the procedure.

Action required:

- Immediately examine your inventory and quarantine product subject to this recall. Please refer to Attachment 1 to help you locate the affected product and lot number. Do not use or further distribute any affected product.
- Please complete and return the accompanying Recall & Effectiveness Check Form attached to this letter regardless of whether or not you have any of the affected product. Additional instructions for product return are contained on the form. Upon receipt of the form indicating there is product to return, the BMD Recall Coordinator will issue you a return authorization number for return of the affected product.
- If you have further distributed any units of the affected lot, please identify your customers and notify them at once of this product recall by forwarding a copy of this letter: Your notification should include a copy of this letter and the accompanying enclosures.

This recall should be carried out to the user level.

This product recall is being made with the knowledge of the Food and Drug administration.

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

Sincerely,

_____
Vice President Quality Assurance
Bard Medical Division

Enclosures (2):

1. Sample Product Labeling
2. Recall & Effectiveness Check Form

Attachment 1

Identifying Product Code and Lot number for your X-Force™ Nephrostomy Balloon Dilation Catheter Kit with Inflation Device, PTFE Sheath, 8 mm X 15 cm:

The product labels will indicate product code REF 996081 and LOT BMZCE039.

Figure 1: Product Label (Carton)

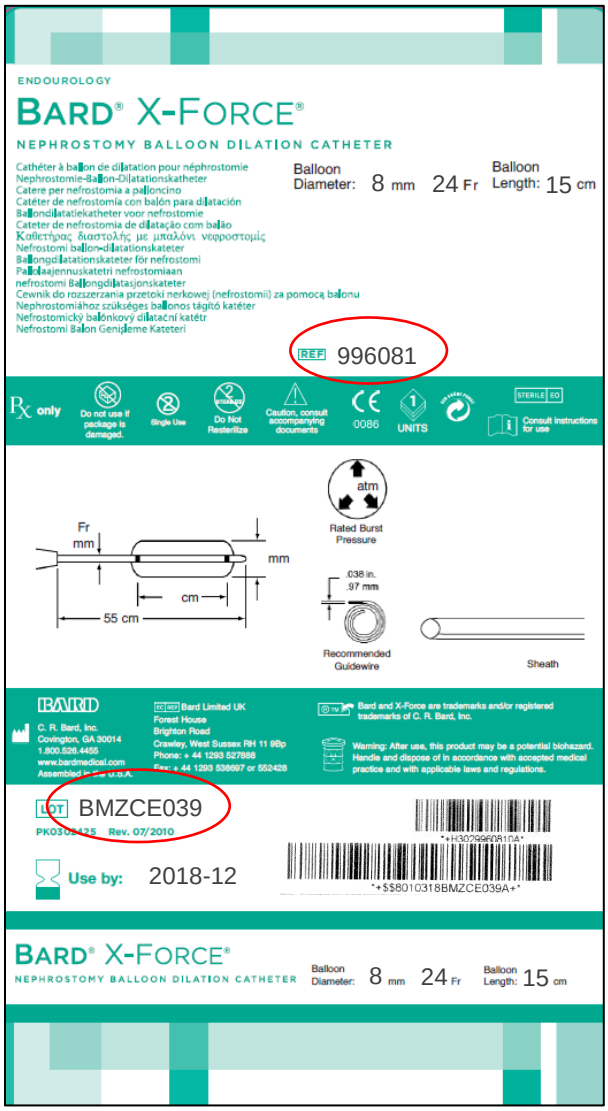
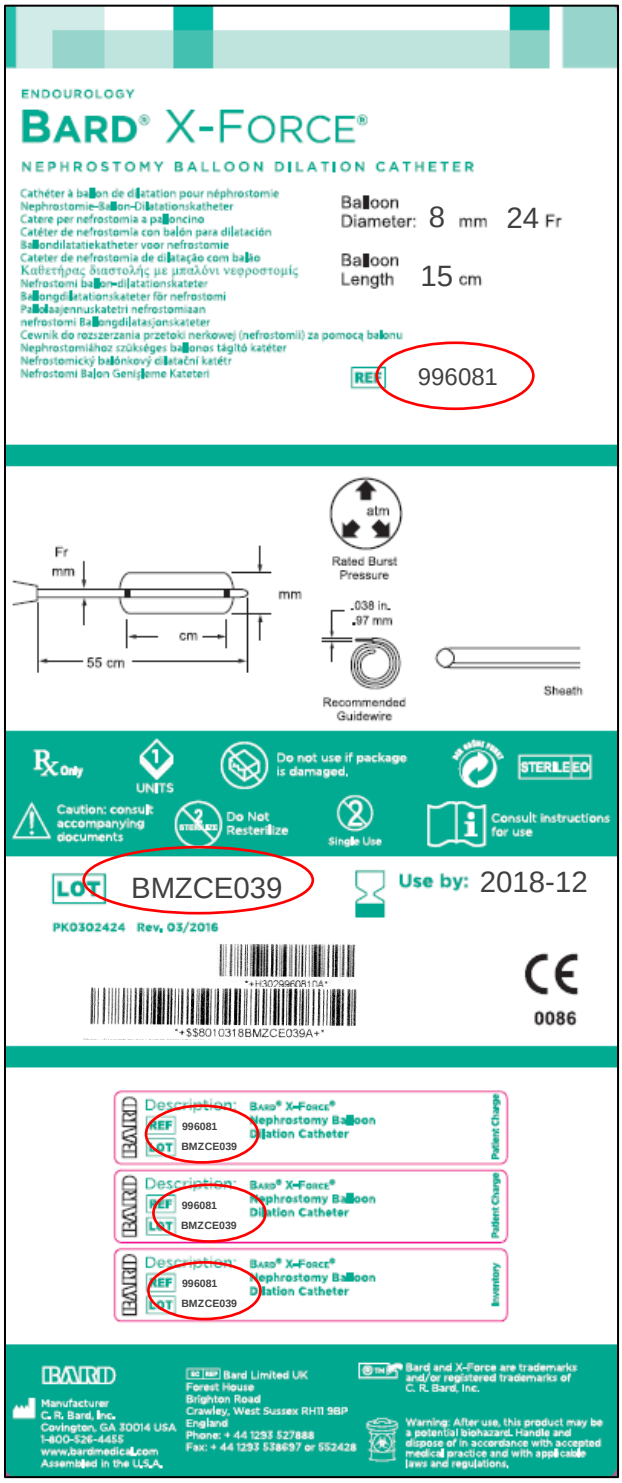


Figure 2: Product Label (Pouch)



RECALL & EFFECTIVENESS CHECK FORM

X-Force™ Nephrostomy Balloon Dilation Catheter Kit with Inflation Device, PTFE Sheath, 8 mm X 15 cm

Do not use or further distribute any of the affected product.

Please complete this form by <date> and fax to 1-770-784-6469 or email a scanned copy to BMD.FieldAction@crbard.com .

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1. Do you currently possess any of the affected product listed below? Indicate quantity below.

Product Code	Description	Lot Number	Quantity
996081	X-Force™ Nephrostomy Balloon Dilation Catheter Kit With Inflation Device, PTFE Sheath, 8 mm X 15 cm	BMZCE039	

2. If you have affected product, please contact the BMD Recall Coordinator via phone at 1-800-793-8110 or email BMD.FieldAction@crbard.com to obtain a return authorization number (RCL #).

RCL # _____

3. **Please PRINT CLEARLY Your Complete Contact Information**: Date:_____

Name:_____Title:_____

Phone_____ Email_____ *(for shipping label)*

Facility Name:_____Account # _____

Address_____ City: _____ State: _____ZIP_____

4. **Fax this form to 1-770-784-6469 or email a scanned copy to** BMD.FieldAction@crbard.com**.**
Attn: Recall Coordinator