BD (C.R. Bard) Urology and Critical Care
8195 Industrial Blvd
Covington, GA 30014
www.bd.com

URGENT Medical Device Correction – Update Letter

BD (C.R. Bard, Inc.) Bard® Minnesota Four Lumen Esophagogastric Tamponade Tube, Bard® Blakemore Esophageal-Nasogastric Tube (Child, Intermediate, and Adult), Bard® Single Intragastric Linton Balloon Tube

May 19, 2025

For the Attention of: Recall Coordinator, Director of Nursing, Director of Purchasing, Director of Risk Management

The purpose of this revised letter is to inform you C.R. Bard® Urology and Critical Care, a wholly owned subsidiary of Becton, Dickinson and Company (BD) is voluntarily initiating a correction for the devices listed below. All lot numbers of unexpired product listed in Attachment 2 (Affected Product) are impacted by this recall and include the following products:

- Bard® Minnesota Four Lumen Esophagogastric Tamponade Tube
- Bard® Blakemore Esophageal-Nasogastric Tube (Child, Intermediate, and Adult)
- Bard® Single Intragastric Linton Balloon Tube

Please read this entire letter as we have provided more detail that will assist you in proper use of the product.

Description of the problem:

BD (C. R. Bard, Inc.) is taking this action because we have become aware through customer complaints of serious adverse events and one patient death that users are potentially unable to, or are finding it difficult, to remove the plastic plugs in order to inflate the gastric and/or esophageal balloons. In some cases, the devices may become damaged during removal of the plastic plugs.

Serious injuries and/or death potentially could occur if users are unable or find it difficult to remove the plastic plugs in a timely manner, or device damage occurs during removal of the plastic plugs, and a replacement device is not readily available. There have been reports of eighteen (18) complaints from December 2021 to March 2025 with two (2) complaints of serious injury and one (1) patient death.

Clinical Impact:

Potential health consequences may include delay in diagnosis, delay in treatment, and need for a replacement device. Delays in diagnosis and treatment may result in the onset or prolongation of hypotension and its potential short and long-term complications, up to and including death. This issue may also result in additional and unexpected diagnostic and/or medical/surgical intervention which was not previously planned as physicians attempt to manage the bleeding. User dissatisfaction with the product is also possible.

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Advice for Clinical Users:

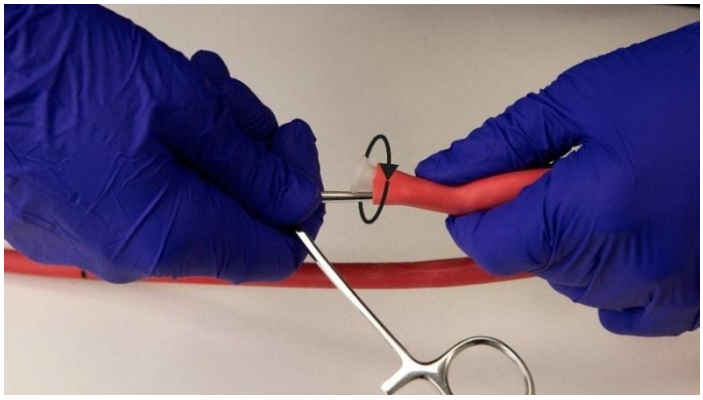
Users can continue to use the devices and should review and follow the instructions for removal of the plastic plugs provided in this medical device correction letter to avoid potential health consequences in the future.

Users are advised to store 5" Straight Smooth Jaw Hemostat with the affected devices for immediate availability to be used for plastic plug removal. Users are advised to maintain available secondary balloon tamponade devices for immediate replacement if the primary device is damaged during plastic plug removal.

Plastic Plug Removal Instructions:

Users should follow the instructions below to remove the plastic plugs as the first step in preparing the device for use in patients.

1. Remove plastic plugs and set aside to remain with the device.
    a. To aid in plug removal, fully open the 5" Straight Smooth Jaw Hemostats and insert one hemostat jaw between the plug and the rubber lumen. While hemostat jaw is inserted, rotate the jaw around the plug's circumference. Remove hemostat, then the plug.



Following removal of the plastic plugs, test the balloons for evidence of air leaks prior to proceeding with the remaining steps required for placement as described in the original instructions for use (IFU).

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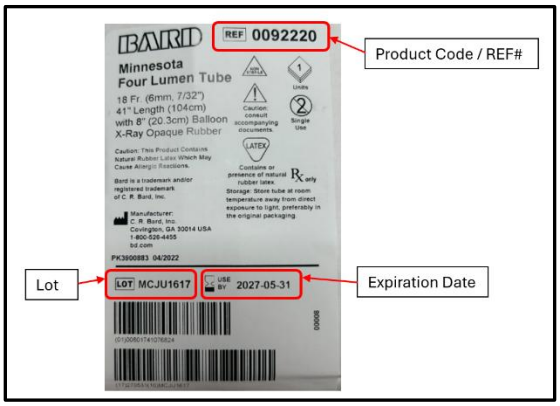
Distribution Timeframe and Label Photo:

You are receiving this notification because our records indicate that you have received product that is still within expiration date. The photo below shows the product label and the location of the product code (REF#) and lot number (LOT) information. Please refer to the photo below.



Please Take the Following Actions:

1. **Follow the above plastic plug removal instructions.**
2. **Post this notice where the devices are stored.**
3. Please confirm posting at all inventory locations within your institution for BD (C.R Bard) Bard® Minnesota Four Lumen Esophagogastric Tamponade Tubes, Bard® Blakemore Esophageal-Nasogastric Tubes (Child, Intermediate, and Adult), and Bard® Single Intragastric Linton Balloon Tubes.
4. Share this notice with any users of the product within your facilities or with any interfacility users where product was transferred, to ensure they are also aware of this Medical Device Correction.
5. **If you have already responded to the prior notification, you do not need to respond to this updated notice.** If you have not responded, please complete and return the attached Customer Response Form to the BD contact noted on the form confirming acknowledgement of this notification, **whether or not you have any affected product**, so that BD may confirm your receipt of this notification. See Attachment 1 (Customer Response Form).
6. Report any adverse health consequences experienced with the use of this product to BD. Events may also be reported to the FDA's MedWatch Adverse Event Reporting program via:

   Web: MedWatch website at www.fda.gov/medwatch
   Phone: 1-800-FDA-1088 (1-800-332-1088)
   Mail: MedWatch, HF-2, FDA, 5600 Fisher's Lane, Rockville, MD 20852-9787

7. Report any complaints experienced with the use of this product to BD via the North American Regional Complaint Center:
   Phone: 1-844-8BD-LIFE (1-844-823-5433) say "Product Complaints" when prompted
   Mon–Fri 8:00am and 5:00pm CT
   Email: productcomplaints@bd.com

Affected Product:

Please see Attachment 2 for affected product information.

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Actions Taken by BD:

BD will continue to distribute these devices. BD is investigating the cause of the issue and will implement corrective actions based on the investigation results.

Actions To Be Taken by BD:

BD will continue to provide this Correction Notice until the product instructions for use (IFU) have been updated through the regulatory clearance process. BD will provide a status communication on our progress by October 2025.

Contact Information: If you require further assistance please contact:

BD Contact	Contact Information	Areas of Support
BD Medical Information Services	Available 24/7 Select #2 when prompted 1-800-555-7422 or Email: medical.information@bd.com	Product Use Inquiries
BD Technical Support	1-844-8BD-LIFE (1-844-823-5433) Say "Product Complaint" when prompted M-F 8am - 5pm CT or Email: productcomplaints@bd.com	Product Complaints, Technical Support
Recall Customer Response Forms	BDRC51@bd.com	Mail for receipt of customer response forms

BD is committed to advancing the world of health. Our primary objectives are patient and user safety and providing you with quality products. We apologize for any inconvenience this issue may have caused and thank you in advance for helping us to resolve this matter as quickly and effectively as possible.

Sincerely,

Gerald Denny

Gerald Denny
Vice President, Medical Affairs
BD UCC

Elizabeth Gaipa

Elizabeth Gaipa
Vice President, Quality Management
BD UCC

Enclosures:
Attachment 1 – Customer Response Form
Attachment 2 – Affected Product

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CUSTOMER RESPONSE FORM
(UCC-25-5238)
BD (C.R. Bard Inc.) Bard® Minnesota Four Lumen Esophagogastric Tamponade Tube, Bard® Blakemore Esophageal-Nasogastric Tube (Child, Intermediate, and Adult), Bard® Single Intragastric Linton Balloon Tube

Please assist BD by acknowledging this field action using one of the following methods:

WebSite: https://bdx.my.site.com/CC360/s/impactedproducts?rn=UCC-25-5238
Email: BDRC51@bd.com
Fax No.: 312-949-0071

Facility:_____
Please use full, current facility name. Do not use initials.

Street Address:_____

City:_____ State: _____ Zip:_____

Field action Response Form Completed By:	
Name:	
Title:	
Telephone No.	
Fax No.	
Email Address	

Please check all that apply:

☐ I have read and understood the attached notice and taken appropriate actions.

☐ We do not have any of the affected product(s) on hand.

Please assist BD with assuring these communications are delivered to the appropriate person/function within your facility if that is not you.

Person/function responsible for the receipt and management of all recalls/corrections at your facility:

Name: _____

Phone: _____

Email: _____

Fax: _____

Attachment 1

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Attachment 2- Affected Product

Product Name (Brand Name as per labelling)	Catalog No.	Lot No., Serial No., or Software Version	UDI-DI	Expiration Date DD-MMM-YYYY	Product Package Size
Bard® Minnesota Four Lumen Esophagogastric Tamponade Tube	0092220	All Lots within expiration date	(01)00801741076824	All Lots Within Expiry	Eaches
Bard® Blakemore Esophageal-Nasogastric Tube (Adult)	0092100	All Lots within expiration date	(01)00801741076800	All Lots Within Expiry	Eaches
Bard® Blakemore Esophageal-Nasogastric Tube (Child)	0092110	All Lots within expiration date	(01)00801741076817	All Lots Within Expiry	Eaches
Bard® Blakemore Esophageal-Nasogastric Tube (Intermediate)	0092300	All Lots within expiration date	(01)00801741076831	All Lots Within Expiry	Eaches
Bard® Single Intragastric Linton Balloon Tube	0092740	All Lots within expiration date	(01)00801741076848	All Lots Within Expiry	Eaches