

URGENT MEDICAL DEVICE REMOVAL

October 31, 2025

Dear Valued McKesson Customer:

BD has notified McKesson Medical-Surgical Inc. (MMS) of an Urgent Medical Device Product Removal regarding specific lot(s) of their Luer Tip Caps. This notice has been issued because BD has confirmed through internal testing that certain BD Luer Tip Cap trays failed routine biocompatibility testing. Affected product first shipped March 14, 2025.

For questions regarding this notification, please contact BD at **(844) 823-5433**.

A review of our records indicates that your company may have purchased items included in this notification. Carefully review the information in this letter and follow the instructions provided below.

Refer to the table for a list of affected item(s) distributed by McKesson Medical-Surgical

MMS #	MFG Catalog #	Description	Affected Lot(s)	Exp. Date
362562	308341	CAP, SYR DISP STR (10/PK)	5029670 5034211 5041975	12/31/2029 01/31/2030 01/31/2030

McKesson Customer Instructions:

- 1.) Immediately discontinue use of any product matching the affected item(s) and lot number(s) listed in the item table. If you have no products matching the affected item(s) and lot number(s), no further action is needed.
- 2.) A copy of the Urgent Medical Device Removal from BD has been included for reference.
- 3.) If you have product affected by this notice, fill out the McKesson Reply Form and return it to our Corporate Customer Service Center via email at MMSRecalls@McKesson.com or fax at **(866) 871-0270**. To ensure timely credit to your account and support the completion of this notice, please respond within 30 days.
 - **Please note:** Any product returned in addition to or in lieu of affected product will be destroyed, without issuance of a credit. The affected product lot numbers are listed in the item table. Once the product is returned, credit will be issued to you.
 - **Please place a new order for replacement product if there is an immediate need.**
- 4.) If you have further distributed any of the item(s) referenced in this notification, provide your accounts with a copy of this notification and request that they return the affected product directly to you.

We sincerely apologize for any inconvenience this notice may have caused you and your staff. If you have any questions about information provided in this communication, please contact our **McKesson Medical-Surgical Recall Message Center** at MMSRecalls@McKesson.com or call **(800) 688-8840**.

Thank you for your prompt attention,

McKesson Medical-Surgical Inc.

McKesson Medical-Surgical Inc.
Medical Device Removal Reply Form: RC-2025-217
BD - Luer Tip Caps

October 31, 2025

Complete this reply form and return all pages immediately via email to MMSRecalls@McKesson.com or fax at **(866) 871-0270** should you have affected product.

To ensure timely credit to your account and support the completion of this notice, please respond within 30 days.

Date: _____ Ship to Acct Number: _____

Your Name: _____ Email Address: _____

Phone Number: _____ Fax Number: _____

Account Name: _____

Address: _____

City, State Zip: _____

I acknowledge that I DO HAVE product affected by this notification and have followed the instructions for return.

Qty	Unit of Measure	Affected Lot #(s)	MMS #	MFG Catalog #	Description
			362562	308341	CAP, SYR DISP STR (10/PK)

*Return Affected lot numbers only

*** Any product returned in addition to or in lieu of affected product will be destroyed, without issuance of a credit. The affected lot numbers are listed on the McKesson customer letter.**

If you are on a McKesson truck route, a delivery professional will pick up the affected products, otherwise you will receive UPS return label(s) via email or fax.

I am on a McKesson truck route, please schedule a delivery professional pick up.

Please send my UPS/Return label by Fax or Email. Number of UPS Parcels to be returned: _____

If you have any questions about information provided in this communication, please contact the McKesson Recall Message Center at MMSRecalls@McKesson.com or call (800) 688-8840.

URGENT: Medical Device Product Removal

MDS-25-5357-FA

BD Luer Tip Caps

Type of Action: Product Removal

Date: October 14, 2025

Affected Product

Product Name	Catalog No.	Lot No.	Expiration Date	UDI-DI	Product Package Size
BD Luer Tip Caps	308341	5029670	31Dec2029	(01)50382903083416	10 caps per tray/ 200 trays per case
		5034211	31Jan2030		
		5041975	31Jan2030		

For the Attention of: BD Product Distributor

Description of the problem:

BD has confirmed through internal testing that certain BD Luer Tip Cap trays failed routine biocompatibility testing.

Clinical Impact:

Although the tip cap covers a small surface area of the syringe and does not come in direct contact with patients there is the potential that the failure of a biocompatibility test may have varying consequences ranging from no harm or clinical impact to potential for sensitization, irritation, pyrogenicity, acute systemic toxicity or hemolysis depending on the nature of and duration of contact with the syringe.

For clinicians who may have already used the affected syringe tip cap trays, use discretion in managing patients who may have been impacted.

To date, there have been no reported complaints or adverse events related to this issue.

Please Take the Following Actions:

1. Cease use and destroy any unused affected product according to your facilities regulations. BD will provide credit for all product destroyed.
2. Identify all customers within your distribution network that purchased any affected product as defined in this notification. Provide a copy of the attached customer letter to all customers to advise them of this field action notification on BD's behalf.
3. ~~Complete the attached Distributor Response Form and return to the BD contact noted on the form whether or not you have any of the impacted material so that BD may acknowledge your receipt of this notification.~~
4. 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

5. 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

Product Distribution Time Frame:

BD distributed the affected lots from March 14, 2025 through June 24, 2025. Our records indicate you may have received product from the affected lot(s).

Actions Taken by BD:

BD is continuing to investigate the root cause and will take action to prevent reoccurrence of this issue.

Contact Information:

If you require further assistance, please contact:

BD Contact	Contact Information	Areas of Support
Recall Customer Response Forms	Email: BDRC26@bd.com	Email for receipt of customer response forms
North American Regional ComplaintCenter	<p>Phone: 1-844-8BD-LIFE (1-844-823-5433) Say "Product Complaints" when prompted Mon–Fri 8:00am and 5:00pm CT</p> <p>or</p> <p>Email: productcomplaints@bd.com</p>	Product Complaints, Technical Questions

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 you and thank you in advance for helping us to resolve this matter as quickly and effectively as possible.

Sincerely,



VP Medical Affairs



VP Quality Management