BD Medication Delivery Solutions
1 Becton Drive
Franklin Lakes, NJ 07417
USA
bd.com

BD
Advancing the world of health

URGENT: Medical Device Product Advisory

Date: November 16, 2023

Product Name	Catalog No.	UDI-DI	Lot No.	Expiration Date	Product Package Size
BD PosiFlush™ Prefilled Saline Syringe with General Pump Compatibility (10mL Syringe with 10mL Saline Fill)	306547	30382903065470	3207548	30-Jun-2026	30 units / box, 480 units / case
			3207555	31-Jul-2026	
			3214826	31-Jul-2026	
			3226386	31-Jul-2026	
			3214828	31-Jul-2026	
			3226388	31-Jul-2026	
			3250302	31-Aug-2026	
			3250303	31-Aug-2026	
			3250304	31-Aug-2026	

For the Attention of:
Medical Director, Risk Manager, Medical Device Safety Officer, Nurse Manager

BD confirmed through customer complaints that an incorrect stopper was used in nine lots of 10mL BD PosiFlush™ Normal Saline Flush Syringes with General Pump Compatibility. The use of BD PosiFlush Prefilled Flush Syringes (catalog number 306547) with this stopper causes an increase in injection force, which has the potential to trigger alarms if used with a syringe pump.

Note: The product has been validated and is acceptable for manual use per IFU (instructions for use).

Clinical Risk Statement

The 10mL BD PosiFlush™ Normal Saline Flush Syringes with Pump Compatibility were produced using an incorrect stopper and may trigger syringe pump alarm. If the syringe pump alarms during patient use, this may lead to a delay in treatment due to response time to address the alarm and flush the full dose of medication into the blood stream.

If complications are encountered while using these products, the clinician can continue to flush the full dose of medication into the bloodstream manually. The product has been validated and is acceptable for manual use per IFU.

Healthcare facilities and providers should only use the impacted products for manual flush and discontinue use of the impacted products for syringe pump use.

To date there have been 40 complaints and no reported adverse events.

MDS-23-4914-FA

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Distribution:

BD distributed the affected lots beginning August 16, 2023. Our records indicate you may have received product from the affected lots.

Attachment

Attachment 1: Lot Number Identification

Please Take the Following Actions:

1. Immediately review your inventory for the affected product.
    a. If the product is used for syringe pumps, destroy all affected product subject to this field action following your institution's process for destruction.
    b. If the product is used for manual application, the product can continue to be used per IFU.
2. If the affected product was previously used on a patient, no further actions are needed.
3. If the affected product is currently in use with a syringe pump, replace the syringe with a non-impacted lot. Please note that healthcare facilities and providers should rely on their syringe pump manufacturer's IFU for the specific syringes that are compatible with their syringe pumps.
4. Share this field action notification with all users of the product within your facility network to ensure they are also aware of this field action.
5. Complete the attached Customer 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 per FDA requirements and subsequently process your product replacement if product is used on syringe pumps and has been discarded.
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 Fishers Lane, Rockville, MD 20852-9787

Actions Taken by BD:

1. BD has identified root cause and initiated corrective actions to prevent recurrence of this issue.
2. For syringe pump users, BD will provide replacement product for all discarded inventory. For manual users, the product can continue to be used per IFU.

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Contact Information:
If you require further assistance, please contact:

BD Contact	US Contact Information	Areas of Support
North American Regional Complaint Center	**Phone:** 1-844-8BD-LIFE (1-844-823-5433) Say "Recall" when prompted Mon–Fri 8:00am and 5:00pm CT **or** **Email:** productcomplaints@bd.com	Recall questions, 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,

Klaus Hoerauf, MD
VP, Global Medical Affairs

Michele Wootten
VP, Quality Management

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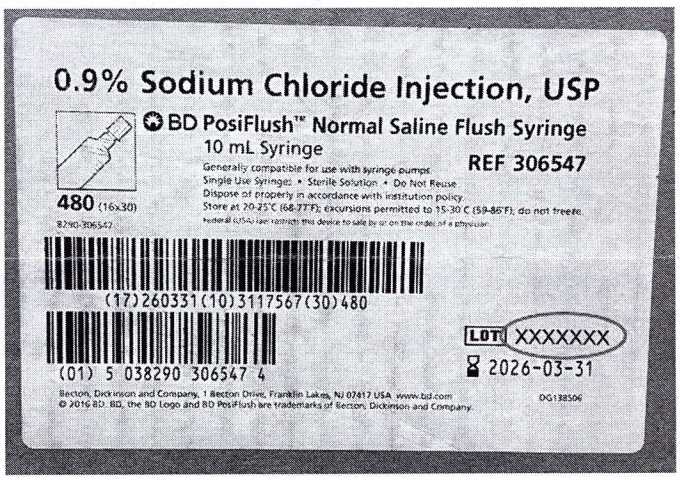
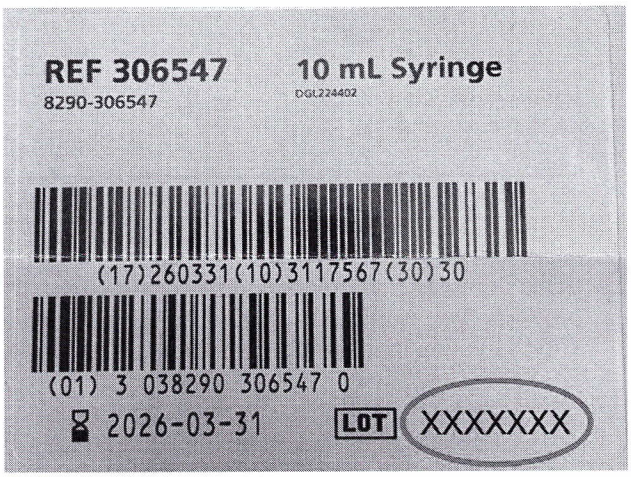
ATTACHMENT 1: Lot number identification on product

The lot number can be found on three areas of the product and its packaging.

Case carton:



Shelf carton:



Syringe label: