BD Medical
1 Becton Drive
Franklin Lakes, NJ 07417
USA
bd.com

URGENT MEDICAL DEVICE RECALL

BD PosiFlush™ SF Saline Flush Syringe 10mL

Date: April 16, 2020

Product Name	UDI	Catalog (Ref) No.	Lot No.	Exp. Date	Shelf Box Quantity
BD PosiFlush™ SF Saline Flush Syringe 10mL	50382903065535	306553	8353952 9011582 9017875 9024676 9045702 9060999 9079716 9127571 9143529 9156595 9163601	2021-12-31 2021-12-31 2021-12-31 2022-01-31 2022-01-31 2022-02-28 2022-02-28 2022-02-28 2022-04-30 2022-05-31 2022-05-31	30

For the Attention of:
Patient, Consumer

Description of the problem and health hazard(s):
BD is conducting a voluntary medical device recall for multiple lots of the BD PosiFlush™ SF (Sterile Field) Saline Flush Syringe 10mL identified in the Table above. This product has been confirmed to exhibit holes in the packaging, which impacts package integrity and potentially compromises a sterile field. While the sterility of the outer surface of the syringe may be compromised, the saline solution and the sterile path of the syringe are not impacted.

When used in a sterile field, the compromised sterility due to holes in the packaging may increase the risk of infection to a patient, potentially leading to medical intervention and/or life-threatening injury. If the issue is identified prior to use and the syringe is discarded per standard clinical practice, this may lead to a delay or interruption of treatment and user dissatisfaction or annoyance.

This recall affects the catalog and specific lot numbers referenced in this notification. This recall does not affect any other products or lots. The lot number can be found on the syringe and case label.

There have been no reports of adverse events, injuries or deaths related to this recall to date.

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BD continues to manufacture the BD PosiFlush™ SF Saline Flush Syringe product and replacement orders will be prioritized. As BD does not have an alternative sterile product, this may cause a slight delay in the fulfillment of replacement product. BD understands that supply interruptions can impact our customers' ability to provide the best care for their patients and takes this matter very seriously. If BD product is not available, customers may look for an equivalent sterile prefilled product in the marketplace. Lastly, as an alternate practice, clinicians may choose to draw up normal saline for a sterile field using a sterile syringe and sterile needle as described in the "Association of Surgical Technologists Guidelines for Safe Medication Practices in the Perioperative Area" and following their hospital guidelines.

BD has taken immediate action to maximize production for this product to help reduce the impact to our customers.

Please Take the Following Actions:

1. Please verify if you have the affected recalled product. To determine if you have the affected recalled product, please review the catalog and lot number on the shelf box.
2. If you have individual syringes outside of the shelf box you need to verify the catalog and lot number.
3. Discard all product subject to the recall. If you don't have any of the catalog and lot numbers indicated on the table included in Attachment A, your product is not affected by this recall.
4. If you have the recalled product, or additional questions regarding this recall, please contact BD at 888-364-2985 between 8 AM and 5 PM ET Monday through Friday. BD will assist you with instructions on how to obtain product replacement at no charge.
5. 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

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 Medical Affairs
BD Medication Delivery Solutions

Gail Griffiths
Sr. Director Regulatory Compliance
BD US Region