

BD - Recall of PosiFlush[™] SF Saline Flush Syringe

- On April 16, 2020, <u>BD announced</u> a voluntary, consumer-level medical device recall of multiple lots of <u>PosiFlush SF (sterile field)</u> saline flush because of 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.
- BD distributed the affected recalled lots between February 28, 2019 through March 2, 2020.

Product Description	NDC#	Lot# (Expiration Date)
BD PosiFlush SF Saline Flush Syringe 10 mL	08290-3065-53	8353952 (12/31/21);
		9011582 (12/31/21);
		9017875 (12/31/21);
		9024676 (01/31/22);
		9045702 (01/31/22);
		9060999 (02/28/22);
		9079716 (02/28/22);
		9127571 (02/28/22);
		9143529 (04/30/22);
		9156595 (05/31/22);
		9163601 (05/31/22)

- PosiFlush SF saline flush is intended to be used only for the flushing of indwelling vascular access devices.
- 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.
- To date, BD has not received any adverse event reports related to this recall.
- 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
 quidelines.
- Anyone with an existing inventory of the recalled product should stop distribution and quarantine the product immediately.
- Contact BD by phone at 1-888-364-2985 for further information regarding this recall.



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