

URGENT MEDICAL DEVICE RECALL
BD POSIFLUSH™ PRE-FILLED NORMAL SALINE SYRINGE

October 2019

Product Name	Cat. No. (Ref)	Lot Nos.	Exp. Date
BD Posiflush™ Pre-Filled Normal Saline Syringes	306547	9142881	30-April-2022
	306575	9175971	30-June-2022

For the Attention of: Customer

Description of the problem and health hazard(s):

BD is initiating a voluntary recall for the BD Posiflush™ Pre-Filled Normal Saline Syringes catalog and lot numbers referenced in the table above. The lots are being recalled as BD has become aware that a limited number of syringes labeled “Posiflush Experimental Product” and “Not for Human Use” being mixed with standard BD Posiflush™ Pre-Filled Normal Saline Syringes. BD has not received any reports of related adverse events and has confirmed that these syringes were manufactured and sterilized in accordance with our normal manufacturing process, perform as intended and do not pose any risk to health. BD is voluntarily recalling these devices to avoid confusion on the part of the user.

Distribution of the affected lots was between June - September, 2019. Our records indicate you may have received the affected product.

Please Take the Following Actions:

1. Immediately review your inventory for the specific Catalogue (Ref) and lot numbers listed above. Destroy all product subject to the recall following your institution’s process for destruction.
2. Share this recall notification with all users of the product within your facility to ensure that they are also aware of this recall.
3. Complete the attached Customer Response Form and return to the contact noted on the form **whether or not you have any of the impacted material** so that your receipt of this notification may be acknowledged.

Actions Taken by BD:

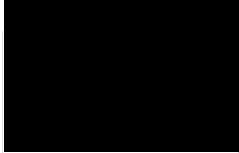
1. Corrective actions have been initiated to prevent recurrence of the identified root cause.
2. Your distributor will issue credit to you for product destroyed, once they receive the response form.

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

Contact	Contact Information
Customer/Technical support	(866) 979-9408

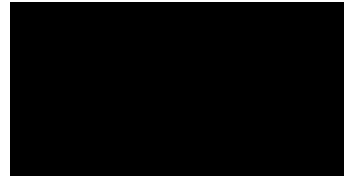
BD is committed to advancing the world of health. Our primary objectives are patient and user safety and providing you with quality products. We apologize for any inconvenience this issue may have caused you and thank you in advance for helping us to resolve this matter as quickly and effectively as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

Sincerely,



For

Blair Johnston
Vice President
Medication Delivery Solutions (MDS)
BECTON DICKINSON CANADA INC.



Patricia Norman
Director
Regulatory Affairs & Quality Management
BECTON DICKINSON CANADA INC.