BD Medical Delivery Solutions
1 Becton Drive
Franklin Lakes, NJ 07417
USA

bd.com

URGENT MEDICAL DEVICE RECALL

SmartSite Syringe Administration Set

February 28, 2019

Product Name	UDI	Cat. No.	Lot No.	Exp. Date	Case Pack
SmartSite Syringe Administration Set	50885403234352	10798696	18046218	04/18/2021	50

For the Attention of:

- Medical Director, Risk Manager, Medical Device Safety Officer, Nurse Manager

Description of the problem and health hazard(s):

BD is conducting a voluntary medical device recall of SmartSite Syringe Administration Set (lot number referenced in the table above). The recall is being conducted due to leaking of the syringe administration set, which may result in delay or interruption of infusion, under-infusion, contamination of the fluid path and HCP exposure to infusates. The following is an illustration showing the location of the leaks: The following is an illustration showing the location of the leaks:

During infusion or priming, a leak (Identified as 1 droplet at approximately every 10 seconds) is observed in the tubing to the filter engagement. Either in the outlet port (lower red circle) or the inlet port (top red circle).

The risk of severe harm occurring could be high, primarily when used in Neo Intensive Care Unit (NICU) settings; where patients may be immunocompromised, where medications are considered critical therapies, and where a loss of a small volume could be significant.

This defect is isolated to the specified Catalog and Lot Number listed in the table above. BD distributed the affected lots beginning on May 11, 2018. Our records indicate you may have received product from the above-referenced lot.

Please Take the Following Actions:

1. Immediately review your inventory for the specific Catalogue (Ref) and lot number listed above. Destroy all product subject to the recall following your institution's process for destruction.

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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 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 and provide product replacement.

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.
   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

Actions Taken by BD:

1. Corrective actions have been initiated to prevent recurrence of the identified root cause.
2. BD will provide replacement for all discarded inventory.

Contact Information

If you require further assistance, please contact:

BD Contact	US Contact Information
Customer Advocacy	Phone: 888-812-3266 Phone hours: 24 hours a day, 7 days a week Email: customerfeedback@bd.com

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
BD Medication Delivery Solutions

William David
Sr. Director, Quality & Regulatory Compliance
BD EMEA Region

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CUSTOMER RESPONSE FORM

MDS-19-1433-FA
BD SmartSite Syringe Administration Set

Please assist BD by promptly returning this form to: BD Regulatory Compliance
Email: BDRC8@bd.com or
Fax No.: 312-949-0217 or regulatory_compliance_fax3@bd.com
Facility: _____

Please use full, current facility name. Do not use initials.

Street Address: _____

City:_____ **State**: _____ **Zip**: _____

Contact Person: _____

Telephone No.: _____**Email Address**: _____

Fax No.: _____

☐ I have read and understood the attached notice.

Name:	
Title:	
Signature/Date:	

☐ We do not have any of the affected product(s) on hand.

☐ I certify that all impacted units on hand have been discarded and request replacement for the following units.

Product Name	**Catalog No.**	**Lot No.**	**Units (Qty. in each's)**
BD SmartSite Syringe Administration Set	10798696	18046218	