Becton Dickinson & Company (BD) Recalls SmartSite Syringe Administration Set Due to Risk of Leaks

The FDA has identified this as a Class I recall, the most serious type of recall. Use of these devices may cause serious injuries or death.

Recalled Product

- Becton Dickinson (BD) SmartSite Syringe Administration Set
- Model/Catalog Number: 10798696
- Serial/Lot Numbers: 18046218
- Manufacturing Dates: April 18, 2018
- Distribution Dates: May 11, 2018 to September 14, 2018
- Devices Recalled in the U.S.: 2,900
- Date Initiated by Firm: February 22, 2019

Device Use

Becton Dickinson's (BD) SmartSite Syringe Administration Sets are used with an infusion pump to deliver fluids including medications, blood and blood products into a patient's body in a controlled manner. The pump administers fluid into a patient's vein or other cleared routes of administration via an infusion tubing set. The infusion sets are intended to be used with the BD Alaris or Medley Syringe Pumps, Module 8110. The devices are used in hospitals and other health care facilities.

This product is primarily used to provide critical therapies to patients in the Neonatal Intensive Care Unit (NICU).

Reason for Recall

BD is recalling its SmartSite Syringe Administration Sets due to leaking of the sets which may result in under-infusion of critical medications, delay or interruption of infusions, contamination of the fluid paths and/or health care provider exposures to hazardous medications.

Delayed infusion or under-infusion of life-sustaining medications could result in serious adverse health consequences, particularly for very low birth-weight babies (micro-preemies). Additionally, contamination of the fluid path could result in an increased risk of infection for

patients.

To date, BD has not received any reports of serious injury or death due to the malfunction of this device.

Who May be Affected

- Hospitals and health care professionals using BD's SmartSite Syringe Administration Set.
- Patients who may receive fluids, medications, blood, or blood products using BD's SmartSite Syringe Administration Set.

What to Do

On February 28, 2019, BD sent customers an "Urgent Medical Device Recall (https://www.bd.com/documents/alerts/CustomerLetter_SmartSiteSyringe.pdf) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)" letter. The letter instructed customers to:

- Immediately review their inventory for products of the affected catalogue and lot number. Customers are instructed to destroy all products affected by this recall according to their institution's process.
- Share the recall letter with all healthcare staff who use this product within their facility to ensure that they are aware of this recall.
- Complete the attached "Customer Response Form" to facilitate shipment of replacement product to the customer.
- Report any adverse health consequences experienced with the use of this product to BD and to the FDA's MedWatch Adverse Event Reporting Program (/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program).

Contact Information

Customers who have questions or require additional assistance regarding this recall should contact BD's 24-hour helpline at 1-888-812-3266 or email customerfeedback@bd.com (mailto:customerfeedback@bd.com).

How do I report a problem?

Health care professionals and consumers may report adverse reactions or quality problems they experience using these devices to MedWatch: The FDA Safety Information and Adverse Event Reporting Program (https://www.accessdata.fda.gov/scripts/medwatch/index.cfm). Health care professionals employed by facilities that are subject to FDA's user facility reporting

requirements (/medical-devices/postmarket-requirements-devices/mandatory-reporting-requirements-manufacturers-importers-and-device-user-facilities) should follow the reporting procedures established by their facilities.

More information

- Class 1 Device Recall - BD SmartSite Syringe Administration Set (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=171256)