

## URGENT VOLUNTARY PRODUCT RECALL



Catalog (Ref) #	Product Description	Lot Number
385100	BD Q-Syte™ Luer Access Split Septum	4128925
		4128926

February 18, 2015

Dear Customer:

BD is conducting a voluntary recall of the BD Q-Syte™ Luer Access Split Septum (Catalog (Ref) #385100) since some units may have the silicone septum torn. This defect may result in leakage of infusate/medication or blood. In addition, there is a potential risk for air to enter the bloodstream which could result in air embolism. No adverse events have been reported for this issue at this time. BD is actively working on implementing corrective actions to address this issue.

This recall only affects the Catalog (Ref) # and lot numbers listed on the table above. BD distributed the two affected recalled lots from July 2014 through present. A copy of the label showing the location of the catalog (Ref) and lot number is attached to assist you in identifying the recalled lots in your control.

### **YOU NEED TO TAKE THE FOLLOWING ACTIONS:**

1. Immediately review your inventory for the specific Catalog (Ref) and lot numbers listed above, and quarantine product subject to the recall.
2. Complete the Recall Response Card form and fax it back to BD at **1-201-847-6990**.
3. Return all affected products with the completed Recall Response Card form following the instruction on the enclosed packing instruction. Upon receipt of the returned product, BD will send you replacement product.

**NOTE: If you do not have any of the affected lots in your inventory, please complete the Recall Response Card form indicating you have zero (0) quantity and fax the completed form back to BD at **1-201-847-6990**.**

If you have any questions or require assistance with the return of the recalled product and/or availability of replacement product, please contact BD Customer Service at **1-888-237-2762 option 3**.

The safety and well-being of patients and healthcare workers is the primary objective for BD and we aim to ensure that only the highest quality product is used by our customers. 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,

Randall K. Jones MD  
WW Medical Director, BD Medical  
BD Medical – Medical Surgical Systems

Karen Y. Smith  
Director of Regulatory Compliance  
BD Medical – Medical Surgical Systems

**BD Q-Syte™ Luer Access Split Septum  
Voluntary Recall Catalog (Ref) / Lot Identification Sample**

**A. Case:**

**Catalog (Ref) number location**

REF **385100** 200

**Luer Access Split-Septum**



(17)051200(10)YJJSSS(30)0200



(01)50382903851008

YYYY-MM

ASSEMBLED IN MEXICO

LOT **YJJSSS**

D14253-6 (12-06)

**Lot number location**

**B. Shelf:**

**Catalog (Ref) number location**

REF **385100** 50

**Luer Access Split-Septum**



(17)051200(10)YJJSSS(30)50



(01)50382903851004

YYYY-MM

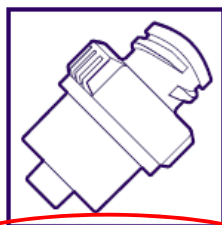
ASSEMBLED IN MEXICO

LOT **YJJSSS**

D14251-5 (12-05)

**Lot number location**

**C. Unit:**



**REF 385100**



**BD Q-Syte™ 0.16 ml**

STERILE EO 2 ⚠️ Ⓢ CE 0086 Rx ONLY

U.S. Patents: 6,171,287

Becton Dickinson Infusion Therapy Systems Inc.,  
9450 South State Street, Sandy, Utah 84070, USA.

Assembled in Mexico, H3768-7

**Catalog (Ref) number location**

# Recall Response Card

## BD Q-Syte™ Luer Access Split Septum Voluntary Recall

Catalog (Ref) #	Product Description	Lot Number
385100	BD Q-Syte™ Luer Access Split Septum	4128925
		4128926

**Check inventory and complete the information below, even if you do not have the affected product.**  
*Failure to complete all sections of this page may result in improper or delayed delivery of replacement product.*

**Fax the completed form to 1-201-847-6990.**

Please return only product from the lots referenced in the recalled letter, you will only receive replacement product for the recalled product that you return.

<b>Required Information:</b>	
_____ Business Name :	_____ Phone Number:
_____ Address/City/State/Zip :	
_____ Lot Number and Quantity Returned (units) :	
_____ Completed by: (Print Name/Signature/Date)	
<b>BD Office Use Only</b>	
_____ Lot Number and Quantity Returned (units) :	

- I have **NO** affected product (Fill out and return this form to BD at fax above).
- YES**, I have affected product (Fill out and return this form to BD at fax above and return the product per the packing instruction.)

**Please enclose the completed form with the return product shipment.**

# PACKING INSTRUCTIONS

## BD Q-Syte™ Luer Access Split Septum Voluntary Recall

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### Product Return Instructions:

1. Please enclose the complete Recall Response Card with the shipment.
2. The simplest way to return product would be to access the following UPS website: <http://returns.upsrow.com>  
login: **bdapi**, Password: **bdapi**

When you access the site, you can select among 3 UPS shipping options. If you select the initial option, “Display Return Label Only”, you can give the package to a UPS person who stops at your site or drop it off at a UPS location. If you select either of the remaining two options, a UPS person will stop by your location specifically to pick up the package. You need to enter the returned product reorder number, lot number and quantity on the website.

**Note:** If you are not returning product, also indicate this on the website.

3. If you do not have access to the internet you can call UPS at 1-800-PICK-UPS (742-5877) and arrange for a pick-up using the following charge number specific to this recall: **0ER739**.

Product should be returned to:

**Returns Team, ref. MSS-15-531-FA**  
**BD Distribution Center**  
**DOOR #2**  
130 Four Oaks Parkway  
Four Oaks, NC 27524

For shipments over 150 pounds - utilize UPS Ground Freight. UPS Freight Customer Service can be contacted at 1-800-333-7400. When arranging the pick-up of freight, please specify 3rd party billing as follows:

**Returns Team, ref. MSS-15-531-FA**  
**BD c/o Cass Info Systems**  
PO Box 67  
St. Louis, MO 63166-0067

4. Upon receipt of returned product BD will provide replacement product. A returned goods authorization is NOT required for this recall return process

**DO NOT SHIP FREIGHT COLLECT**  
**Our warehouse cannot receive products shipped “freight collect”.**