



URGENT PRODUCT RECALL

Catalog (Ref) #	Product Description	Lot Number
367342	23 G x .75 in. BD Vacutainer® Push Button Blood Collection Set with 12 in. Tubing	See list provided p.3

August 8, 2016

Dear Customer:

BD is conducting a voluntary recall of limited lots of BD Vacutainer® Push Button Blood Collection Sets associated with product catalog number 367342. BD has received multiple reports of units associated with these lots exhibiting separation of front and rear barrels upon activation of the safety feature, which retracts the needle. Barrel separation can result in an exposed needle, which may lead to accidental needle sticks or leakage of blood, which may result in exposure to blood borne pathogens.

This recall is limited to the specific lot numbers listed in the table included in this letter. The lot number can be found on the individual unit label, the shelf label and the case label. Sample graphics showing the location of the catalog and lot numbers on the unit, shelf and case labels are included to assist you in identifying the recalled lots within your control. BD distributed the affected recall lots beginning February 9, 2016.

YOU NEED TO TAKE THE FOLLOWING ACTIONS:

1. Immediately review your inventory for the specific Catalog (Ref) and lot numbers listed in the table on p. 3 of this Letter, and quarantine the product subject to the recall.
2. Complete the Recall Response Form and fax it back to BD at **1-866-913-0661** or email to **bd6835@stericycle.com**.

3. Return all affected products with the completed Recall Response Form following the instruction on the enclosed packing instruction. Upon receipt of the returned product, BD will issue product replacement.

NOTE: Even if you do not have any of the affected lot in your inventory, please complete the Recall Response Form indicating you have zero (0) quantity and fax the completed form back to BD at 1-866-913-0661 or email the completed form to bd6835@stericycle.com.

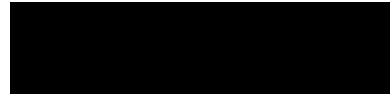
If you have any questions or require assistance with the return of the recalled product and/or availability of replacement product, please contact **1-888-628-0732 between 8AM and 5 PM ET Monday through Friday.**

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,



Ana K. Stankovic, MD, PhD, MSPH
WW VP Medical Affairs
BD Life Sciences - Preanalytical
Systems



Matthew Kelleher
Regulatory Compliance Manager
BD Life Sciences - Preanalytical
Systems

BD VACUTAINER® Push Button Blood Collection Set
Catalog Number 367342

Affected Lot Numbers

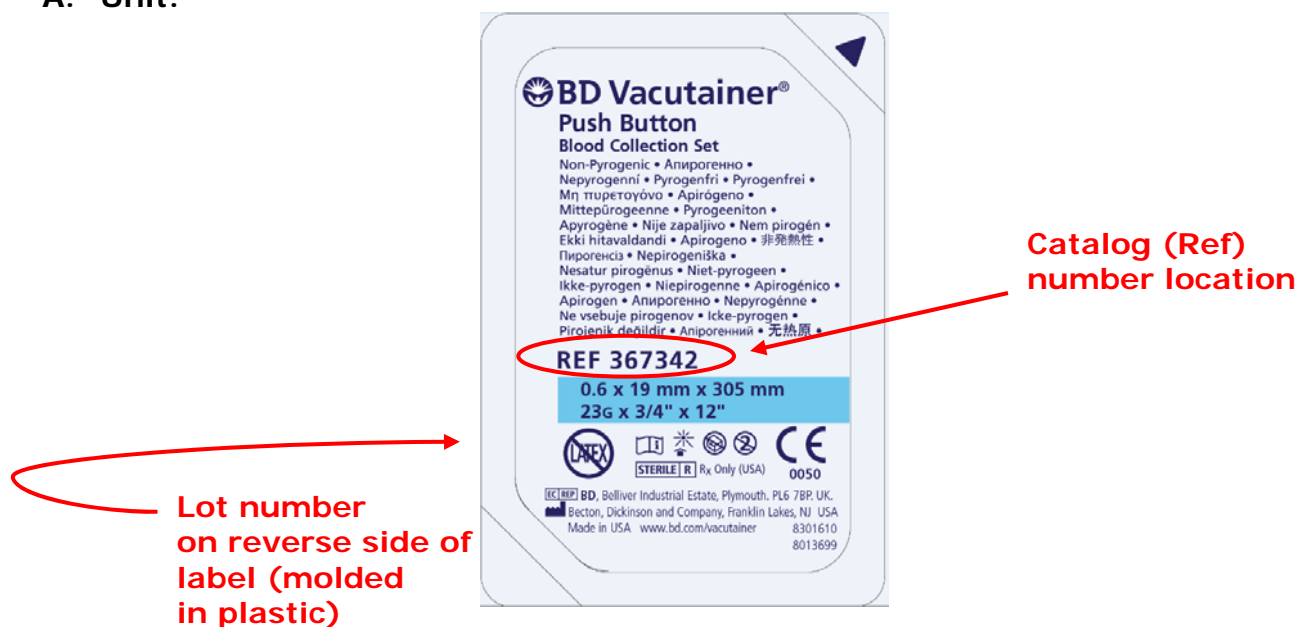
The expiration date for all affected lots is 12/31/2017.

Lot Number
5355531
5355533
5356681
5356682
6006629
6006630
6006631
6006633
6006634
6006650

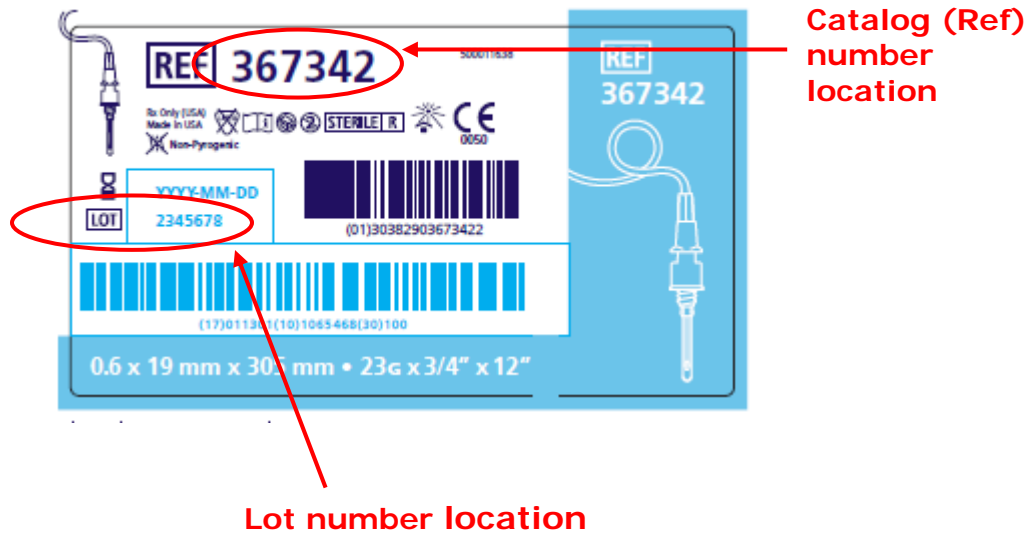
Label Sample BD VACUTAINER® Push Button Blood Collection Set

Recall Catalog (Ref) / Lot Identification Sample

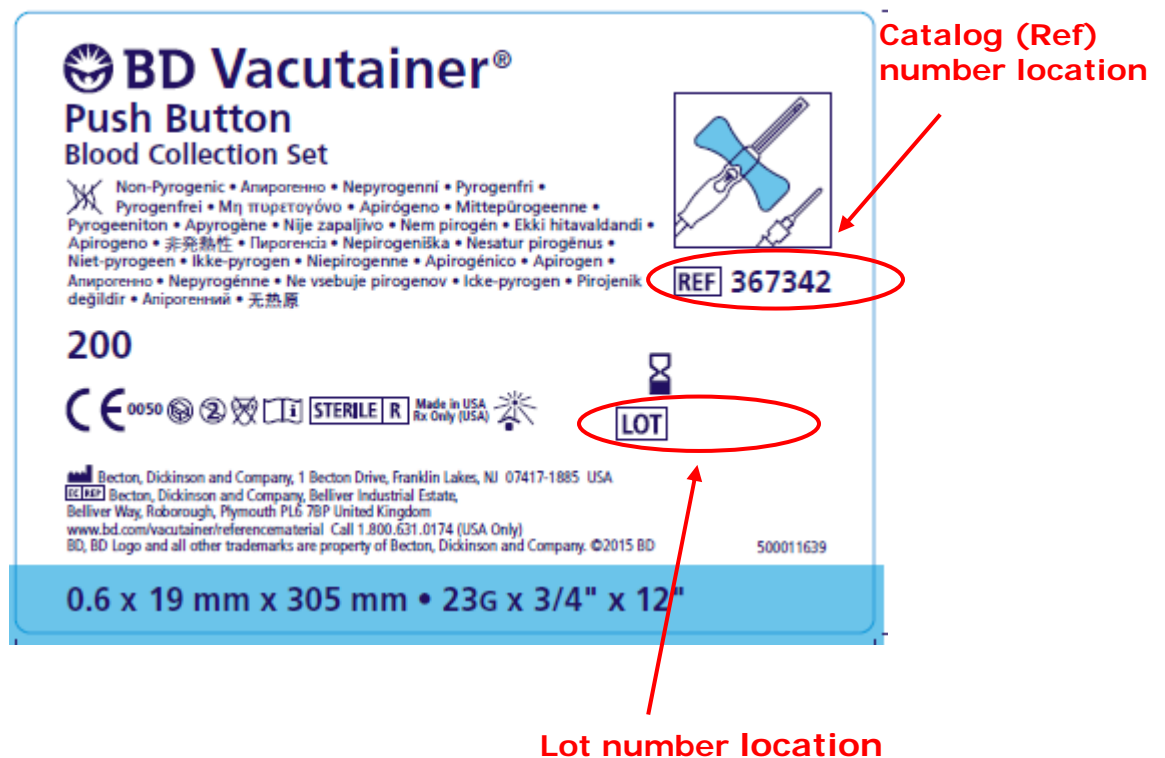
A. Unit:



B. Shelf:



C. Case:



Recall Response Form

BD VACUTAINER® Push Button Blood Collection Set

Catalog (Ref) #	Lot Numbers
367342	5355531, 5355533, 5356681, 5356682, 6006629, 6006630, 6006631, 6006633, 6006634, 6006650

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 product replacement.

Fax the completed form to BD at 1-866-913-0661 or email the completed form to bd6835@stericycle.com.

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

Required Information:

Business Name : _____

Phone Number: _____

Address/City/State/Zip : _____

Lot Number and Quantity Returned (units) : _____

Completed by: (Print Name/Signature/Date) _____

BD Office Use Only

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 or email above and return the product per the packing instruction.)

Please enclose the completed form with the return product shipment.

PACKING INSTRUCTIONS

BD VACUTAINER® Push Button Blood Collection Set Recall

Product Return Instructions:

1. Please enclose the complete Recall Response Form 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: **OER739**.

Product should be returned to:

Returns Team, ref. PAS-16-841-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. PAS-16-841-FA

BD c/o Cass Info Systems

PO Box 67

St. Louis, MO 63166-0067

4. Upon receipt of returned product, BD will provide product replacement. 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".