BD Medical
1 Becton Drive
Franklin Lakes, NJ 07417
USA

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URGENT MEDICAL DEVICE RECALL

BD POSIFLUSH™ HEPARIN LOCK FLUSH SYRINGES
BD™ PRE-FILLED NORMAL SALINE SYRINGES

April 20, 2018

Product Name	Catalog (REF) Number
BD PosiFlush™ Heparin Lock Flush Syringes	306509, 306510, 306511, 306512, 306513, 306514, 306515, 306516, 306517, 306521, 306525, 306528, 306531
BD™ Pre-Filled Normal Saline Syringes	306500, 306502, 306503, 306504, 306505, 306507, 306508, 306518

For the Attention of:

- Risk Manager, Materials Manager, Infection Control, Medical Director, Medical Device Safety Officer, Director of Nursing, Nursing Education, Pharmacy Directors

Description of the problem and health hazard(s):

Out of an abundance of caution and in the interest of public health, BD is voluntarily recalling certain lots of BD PosiFlush™ Heparin Lock Flush and BD™ Pre-Filled Normal Saline Flush syringes due to a potential for contamination with *Serratia marcescens* bacterium. BD was notified by the U.S. Food and Drug Administration (FDA) and Centers for Disease Control and Prevention (CDC) about a potential epidemiological link between catheter related blood stream infections and the *S. marcescens* bacterium.

Specifically, the FDA and CDC identified a potential connection between reports of infection in a small number of patients caused by *S. marcescens* across multiple states. CDC's initial investigation found that affected patients had received treatment using certain BD flush products.

To date, there is no evidence of BD flush product testing positive for this bacterium. Investigations are ongoing by BD, FDA, and CDC.

This recall only affects the product Catalog (REF) and lot numbers listed in Attachment A: *List of Recall Catalog Numbers and Lot Numbers*, all from a single manufacturing site.

No products other than those listed in the Attachment A are affected by this recall.

Examples of the product labels are provided in Attachment B to aid you with the identification of the affected product.

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YOU NEED TO TAKE THE FOLLOWING ACTIONS:

1. Immediately review your inventory for the specific Catalog (Ref) and Lot numbers listed in Attachment A, discontinue use and quarantine product subject to the recall.

2. Complete the Customer Recall Response Form and fax it to BD at **1-855-620-5693** or email to **BD5689@stericycle.com.** Even if you do not have any of the affected lot(s) in your inventory, please complete the Customer Recall Response Form indicating you have zero (0) quantity and return as indicated above.

3. If you have inventory of the recalled product, please return the product following the enclosed packing instructions. This is required so that BD may process your product replacement upon receipt of the recalled product.

4. Share this notice with all users of the product within your facility to ensure awareness.

Contact Information

If you have questions or require further assistance, please contact 1-866-660-8973 between 8 AM and 5 PM ET Monday through Friday.

Any adverse health consequences experienced with the use of this product should be reported to BD and may 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

This recall is being conducted with the knowledge of the FDA. Patient safety and product quality are top priorities at BD, and the company takes any potential product issue very seriously. Our primary objective is to provide you with quality products that are safe for patients and users. We thank you in advance for complying with this medical device recall notification as quickly and effectively as possible.

Sincerely,

Klaus Hoerauf, MD
VP Global Medical Affairs
BD Medication Delivery Solutions

Gail Griffiths
Sr. Director Corporate Regulatory Compliance
BD US Region

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Attachment A
List of Recall Catalog (REF) and Lot Numbers

Product Name	UDI	Catalog (Ref) No.	First Lot Number Affected	Last Lot Number Affected	Product Package Size
BD™ Pre-Filled Normal Saline Syringe	(01)50382903065009	306500	708111D	735212A	120 units per case (30 units per shelf box)
BD™ Pre-Filled Normal Saline Syringe	(01)50382903065023	306502	706012B	734511C	120 units per case (30 units per shelf box)
BD™ Pre-Filled Normal Saline Syringe	(01)50382903065030	306503	706512B	730611C	120 units per case (30 units per shelf box)
BD™ Pre-Filled Normal Saline Syringe	(01)50382903065047	306504	714312C	735212C	120 units per case (30 units per shelf box)
BD™ Pre-Filled Normal Saline Syringe	(01)50382903065054	306505	714511C	730411C	120 units per case (30 units per shelf box)
BD™ Pre-Filled Normal Saline Syringe	(01)50382903065078	306507	705311B	735211C	120 units per case (30 units per shelf box)
BD™ Pre-Filled Normal Saline Syringe	(01)50382903065085	306508	706211B	734211C	120 units per case (30 units per shelf box)
BD PosiFlush™ Heparin Lock Flush Syringe	(01)50382903065092	306509	710272N	734111N	120 units per case (30 units per shelf box)
BD PosiFlush™ Heparin Lock Flush Syringe	(01)50382903065108	306510	707672N	735222N	120 units per case (30 units per shelf box)
BD PosiFlush™ Heparin Lock Flush Syringe	(01)50382903065115	306511	707671N	735221N	120 units per case (30 units per shelf box)
BD PosiFlush™ Heparin Lock Flush Syringe	(01)50382903065122	306512	710271N	733811N	120 units per case (30 units per shelf box)
BD PosiFlush™ Heparin Lock Flush Syringe	(01)50382903065139	306513	707471N	735211N	120 units per case (30 units per shelf box)
BD PosiFlush™ Heparin Lock Flush Syringe	(01)50382903065146	306514	708782N	734211N	120 units per case (30 units per shelf box)
BD PosiFlush™ Heparin Lock Flush Syringe	(01)50382903065153	306515	707971N	735311N	120 units per case (30 units per shelf box)
BD PosiFlush™ Heparin Lock Flush Syringe	(01)50382903065160	306516	708071N	730612N	120 units per case (30 units per shelf box)

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Product Name	UDI	Catalog (Ref) No.	First Lot Number Affected	Last Lot Number Affected	Product Package Size
BD PosiFlush™ Heparin Lock Flush Syringe	(01)50382903065177	306517	710371N	734221N	120 units per case (30 units per shelf box)
BD™ Pre-Filled Normal Saline Syringe with Blunt Plastic Cannula	(01)50382903065184	306518	715013C	735211A	120 units per case (30 units per shelf box)
BD PosiFlush™ Heparin Lock Flush Syringe	(01)50382903065214	306521	710071N	731921N	120 units per case (30 units per shelf box)
BD PosiFlush™ Heparin Lock Flush Syringe with Blunt Plastic Cannula	(01)50382903065252	306525	713772N	734011N	120 units per case (30 units per shelf box)
BD PosiFlush™ Heparin Lock Flush Syringe	(01)50382903065283	306528	710372N	719121N	120 units per case (30 units per shelf box)
BD PosiFlush™ Heparin Lock Flush Syringe with Blunt Plastic Cannula	(01)50382903065313	306531	716091N	733421N	120 units per case (30 units per shelf box)

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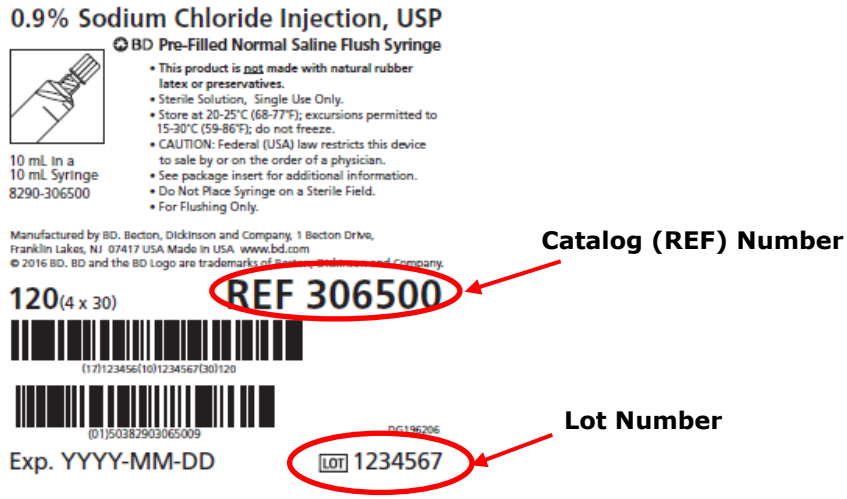
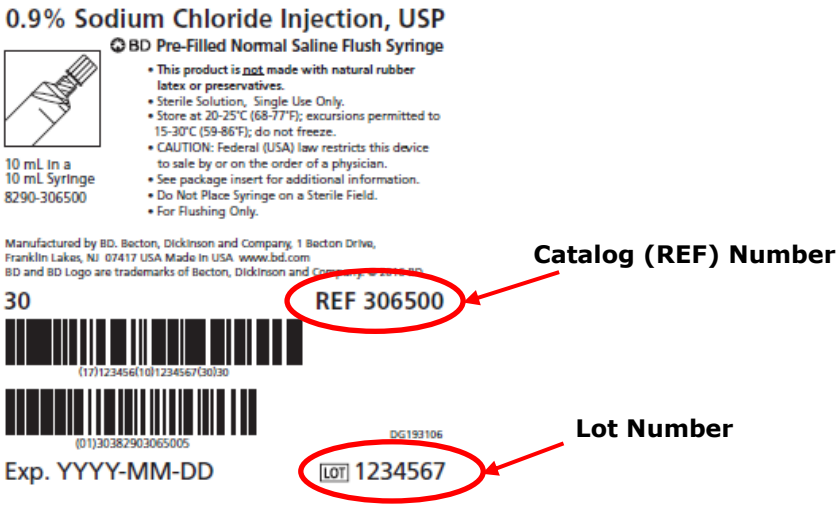
Attachment B
Medical Device Recall Catalog (Ref) and Lot Numbers Identification Sample:

Example for Saline:

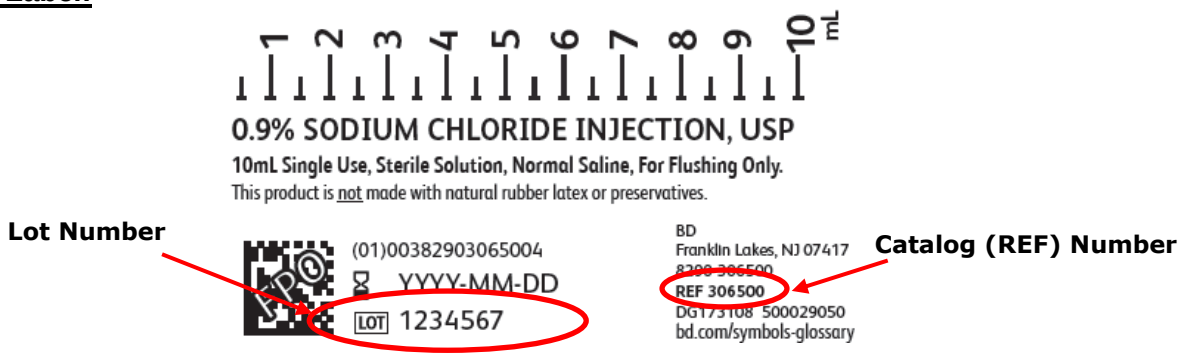
Case Label:



Shelf Box Label:



Unit Label:



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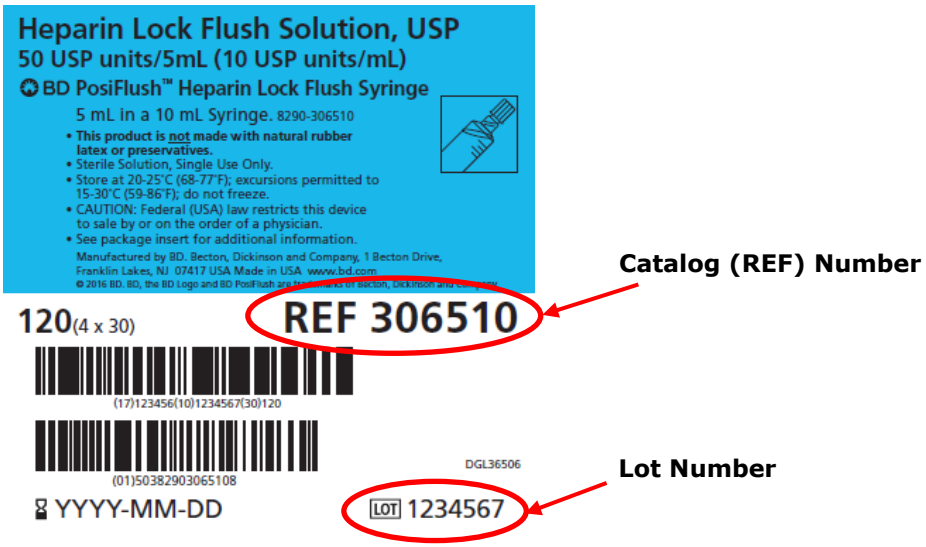
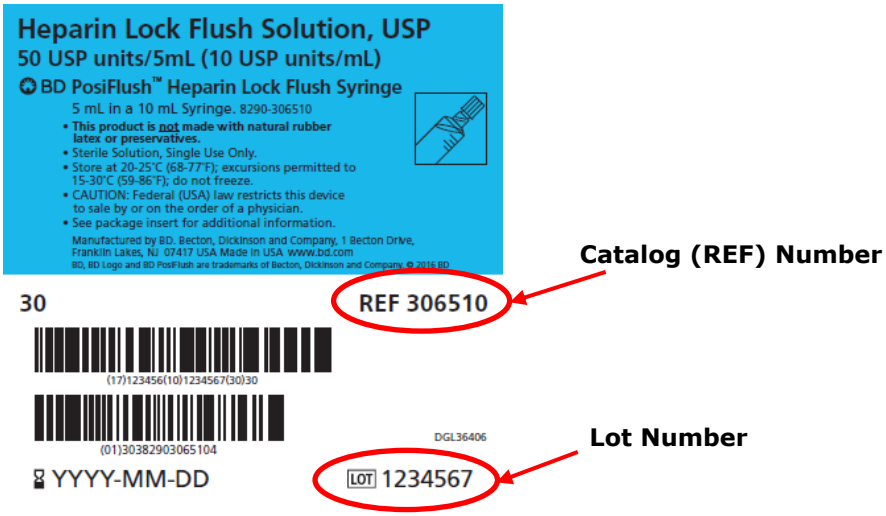
Example for 10 unit Heparin:

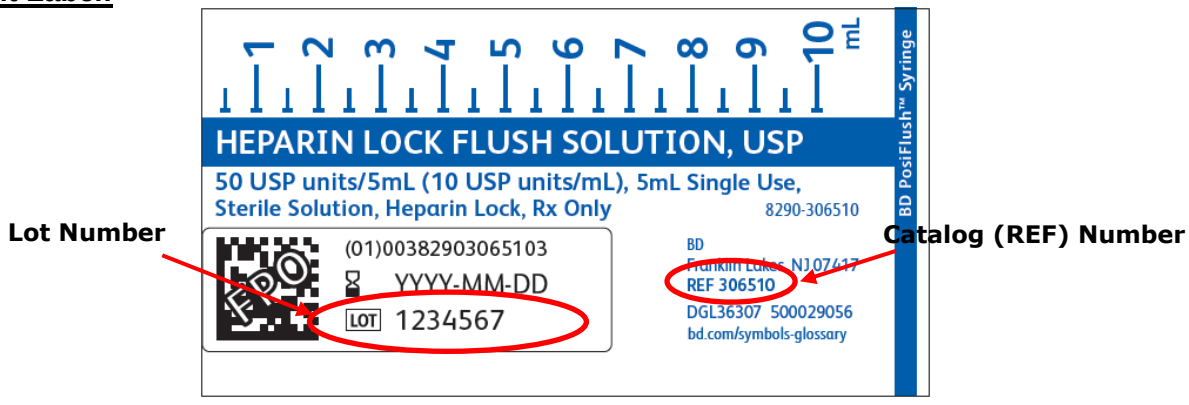
Case Label:



Shelf Box Label:



Unit Label:



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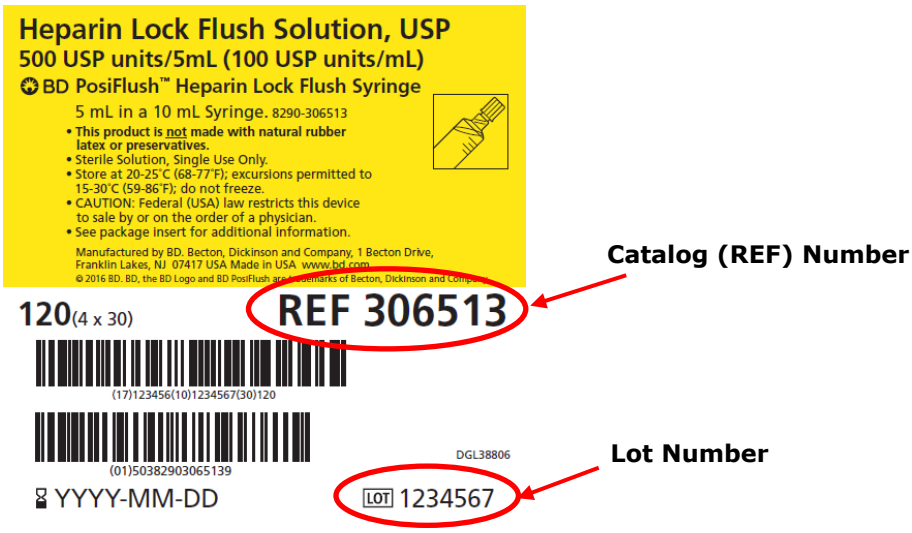
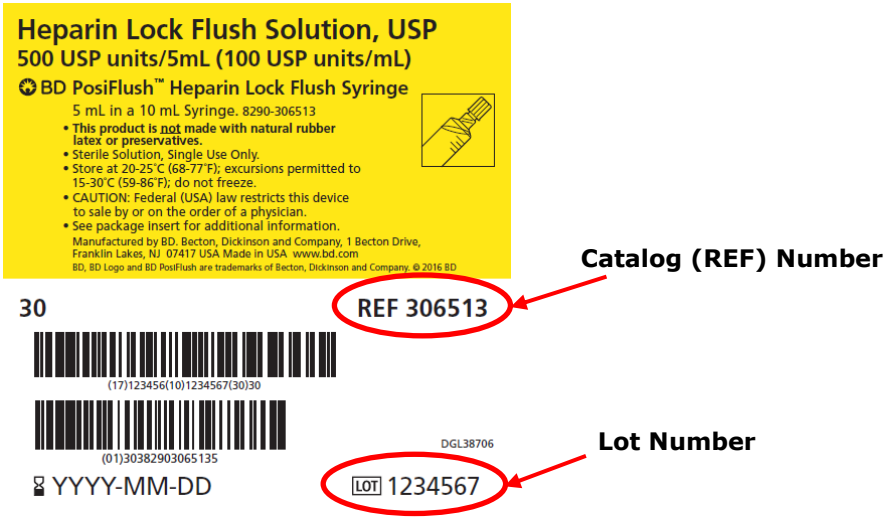
Example for 100 unit Heparin:

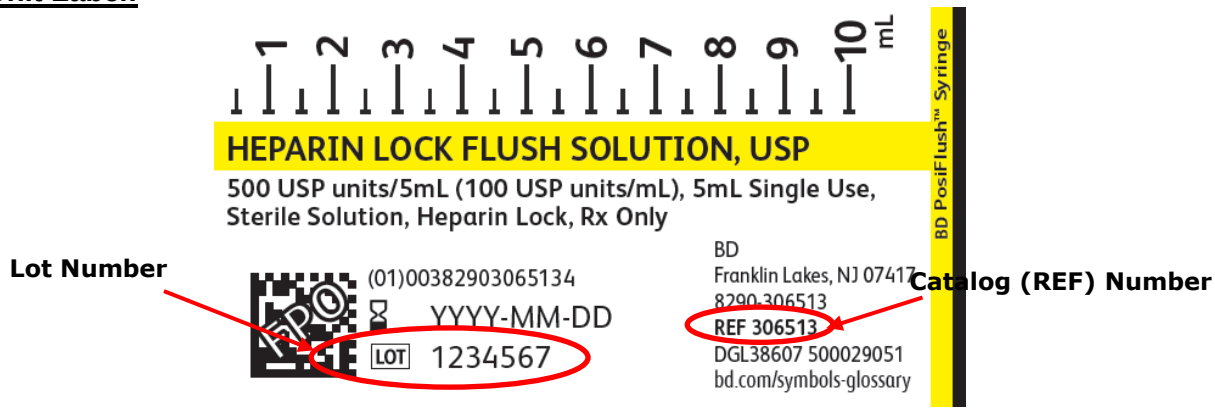
Case Label:



Shelf Box Label:



Unit Label:



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Customer Recall Response Form

BD PosiFlush™ Heparin Lock Flush Syringes
BD™ Pre-Filled Normal Saline Syringes

Please assist BD by promptly returning this form to:

BD
Email: BD5689@stericycle.com
Fax No.: 1-855-620-5693

Facility: _____
Please use full, current facility name. Do not use initials.
Street Address: _____

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

Contact Person: _____

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

Fax No.: _____

Name:	
Title:	
Signature/Date:	

☐ I have read and understood the contents of this product recall notification and confirm that our product inventory has been checked. Please select one of the following:
- ☐ We do not have any of the affected product(s) on hand.
- ☐ We have the following affected product in our inventory:

Product Name	Catalog No.	Lot No.	No. of Units

☐ I certify that I have returned all affected product indicated above as available inventory at the time of receipt of this notification.

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PACKING INSTRUCTIONS

Urgent Medical Device Recall

Product Return Instructions:

1. Please enclose the completed Customer 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 ID: bdapi, Password: bdapi

   When you access the site, you can select among 4 UPS options. If you select the options, "Display Return Label Only" or "Display and E-mail Label", 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
   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
   BD c/o Cass Info Systems
   PO Box 67
   St. Louis, MO 63166-0067

4. Upon receipt of returned product BD will issue a 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".