

## URGENT PRODUCT RECALL

Cat (Ref) #	Cat (Ref) #	Cat (Ref) #
301997	309571	309657
305062	309580	
305917	309604	

September 15, 2016

Dear Customer:

BD is conducting a voluntary product recall of several BD catalogs of Luer-Lok $^{\text{TM}}$  Syringes, Luer-Lok $^{\text{TM}}$  Syringes with Needles, and SafetyGlide $^{\text{TM}}$  Needle, since the sterility of the product cannot be assured. This may result in increased risk of infection. No adverse event has 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 included in Attachment A: List of Recall Catalogs and Lots. BD distributed the affected recalled lots from April 2016 to August 2016.

### YOU NEED TO TAKE THE FOLLOWING ACTIONS:

- Immediately review your inventory for the specific Catalog (Ref) and lot numbers listed above, and quarantine product subject to the recall. Immediately discontinue the use and distribution of the affected product.
- Complete the Recall Response Card form and fax it back to BD at 1-866-918-8735 or email the completed form to bd6968@stericycle.com.
- 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 issue product replacement.

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 1-866-918-8735 or email the completed form to bd6968@stericycle.com.

If you have any questions or require assistance with the return of the recalled product, please contact **1-866-913-0667** 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,



Bruce Culleton, MD VP WW Med Affairs Med & Procedural Sol BD Medical



Sergio Gadaleta Sr VP Regulatory Affairs Medical Segment, BD Medical

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## Attachment A: List of Recall Catalogs and Lots

Catalog (Ref) #	Product Description	Lot Number	Expiration Date
301997	DD 10ml Curings Lucy Lak M Tin	6060756	No Exp Date
	BD 10ml Syringe Luer-Lok™ Tip	6082533	No Exp Date
305062	BD 5ml Syringe Luer-Lok™ Tip with Blunt Fill Needle 18G x 1 1/2 (1.2mm x 40mm)	6204878	2021-07
305917	BD SafetyGlide™ Injection Needle	6022838	2021-01
309571	BD 3ml Syringe Luer-Lok™ Tip with BD PrecisionGlide™ Needle 23G x 1 (0.6mm x 25mm)	6117580	2021-03
309580	BD 3ml Syringe Luer-Lok™ Tip with BD PrecisionGlide™ Needle 18G x 1 1/2 (1.2mm x 40mm)	6090832	2021-03
		6176715	2021-06
309604	BD 10ml Syringe Luer-Lok™ Tip	6061746	2021-02
		6082982	2021-02
		6089821	2021-03
		6117858	2021-04
		6117863	2021-04
		6117889	2021-04
		6117891	2021-04
		6146962	2021-04
		6173697	2021-05
		6173767	2021-06
		6173779	2021-06
		6208614	2021-07
309657	BD 3ml Syringe Luer-Lok™ Tip	6113717	2021-04
		6209890	2021-07

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## Recall Response Card Voluntary Recall

Cat (Ref) #	Cat (Ref) #	Cat (Ref) #
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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 **1-866-918-8735** or email the completed form to **bd6968@stericycle.com**.

Please return only product from the lots referenced in the recall 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 <u>NO</u> affected product (Fill out and re	turn this form to BD at fax/e-mail above).
YES, I have affected product (Fill out and I	return this form to BD at fax/e-mail above and return the
product per the packing instruction.)	

Please enclose the completed form with the return product shipment.

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# PACKING INSTRUCTIONS Voluntary Recall

#### **Product Return Instructions:**

- 1. Please enclose the complete Business 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 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 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".

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