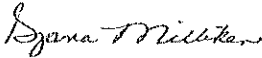




Delivering Efficiency to Healthcare



FAX COVER

From: National Distribution & Contracting, Inc. Djana Milliken – Compliance ***URGENT*** ***This is being faxed/emailed to the "bill to" account for your company. Please distribute to any/all branches.***	
To: Purchasing or Regulations Department	Date: 9/19/2016
Pages: <u>4</u> (Including cover page)	
Regarding: BD Urgent Product Recall	
Comments: Dear Distributor, Attached is a letter we received from BD Medical regarding a product recall. Our records indicate that you have purchased at least one of these products from us. Please read attached letter and check your inventory for any affected product with listed lot number. If you have any of this product in stock please fill out attached "Request for return" form, so that we can issue you a RGA for return. Also, please make note that no credit will be issued without an RGA. If you have any questions please feel free to contact me. It is very important that we receive a response, a record of receipt is very important in documentation of these types of notices. Additionally, if you have distributed these products to your customers, please advise them of the recall, and have return any affected product to you. Thanks,  Djana Milliken	



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™ Syringes, Luer-Lok™ Syringes with Needles, and SafetyGlide™ 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:

1. 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.
2. 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



Attachment A: List of Recall Catalogs and Lots

Catalog (Ref) #	Product Description	Lot Number	Expiration Date
301997	BD 10ml Syringe Luer-Lok™ Tip	6060756	No Exp Date
		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



9/19/2016

BD Medical Urgent Product Recall

Please fill out and fax/email this distributor form within 10 business days, even if you do not have the recalled product.

Please complete and fax to: 615-229-6801 Or email to: Compliance@ndc-inc.com

REQUEST FOR RETURN FORM

Customer Information

Account No. _____

Account Name _____

Address _____

City/State/Zip _____

Contact Name _____

Phone No. _____

Fax No. _____

Email _____

Inventory Information

Catalog #	
	301997
	305062
	309571
	309580
	309604
	309657

Item number	Lot number	Expiration date	Quantity to return

- I have read and understood the information within the accompanying notification. All relevant customers/ personnel have been informed of its contents, any necessary actions taken and records retained as part of our documentation.
- We have inspected our inventory and have no product related to this recall

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

Returned Completed form to:

Fax #:
Email:

Djana Milliken
615.229-6801
compliance@ndc-inc.com

Delivering Efficiency to Healthcare®

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