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:** *6/1/2017*
Pages: *8* *(Including cover page)*	
Regarding: *BD PrecisionGlide Needle 18G X 1" RB Item #305915*	

Comments:

Dear Distributor,

Attached is a medical device recall we received from BD regarding the PrecisionGlide Needle. Our records indicate that you purchased this product 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

Djana Milliken

407 New Sanford Road, La Vergne, TN 37086
compliance@ndc-inc.com / Phone: 615-324-6375 / Fax: 615-229-6801

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URGENT MEDICAL DEVICE RECALL

May 31, 2017

Product Name	Catalog (Ref) No.	Lot No.
BD PrecisionGlide™ Needle 18G x 1" RB	305195	6152995

Dear Customer,

BD is conducting a product removal recall of lot 6152995 of the BD PrecisionGlide™ Needle 18G x 1" RB , Cat (Ref) 305195, due to hub damage resulting in breakage and/or leakage during use. An example of a defective damaged hub is shown below in Figures 1 through 4. BD distributed the affected recalled lot from September 9, 2016 to October 31, 2016.

Using a damaged device could result in the following health consequences or harms:

- Local or systemic effects due to exposure of the clinician to hazardous drugs during medication preparation
- Exposure of the clinician to blood/body fluid potentially containing bloodborne pathogens while aspirating blood/body fluids.

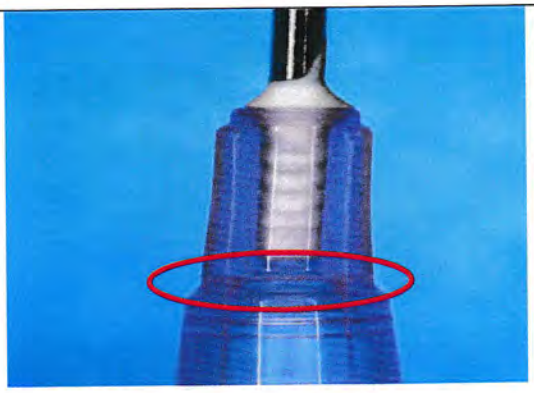

Figure 1- Cracked Hub

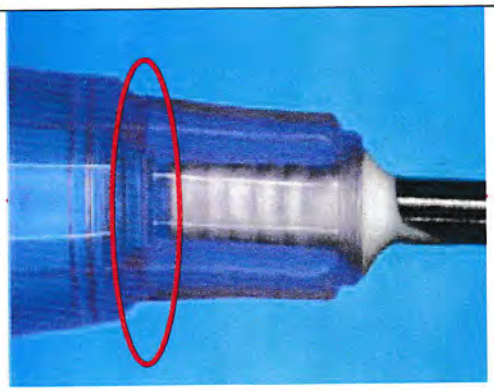

Figure 2- Cracked Hub

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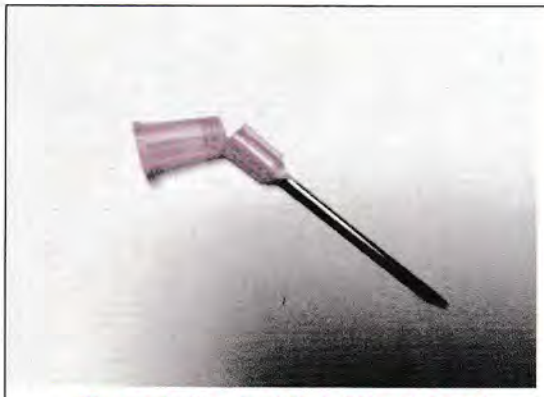

Figure 3- Cracked Hub (Worst Case)

Figure 4- Cracked Hub (Worst Case)

YOU NEED TO TAKE THE FOLLOWING ACTIONS:

1. Immediately review your inventory for the specific Catalog (Ref) and lot number listed above, see attached Location of Product Identification for assistance locating information. Quarantine product subject to the recall. Immediately discontinue the use and distribution of the affected product.
2. Complete the Business Response Card form and fax it back to BD at 855-544-4803 or email the completed form to bd4354@stericycle.com.
3. Return all affected products with the completed Business 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 Business Response Card form indicating you have zero (0) quantity and fax the completed form back to BD at 855-544-4803 or email the completed form to bd4354@stericycle.com.

CONTACT INFORMATION:

If you have any questions or require assistance with the return of the recalled product, please contact 855-215-4932 between 8AM and 5 PM ET, Monday through Friday.

No adverse events have been received by BD at this time. 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

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This recall is being conducted with the knowledge of the U.S. Food and Drug Administration. BD is committed to advancing the world of health. Our primary objectives are patient and user safety and providing you with quality products. We thank you in advance for helping us to assure patient safety by compliance with this product removal recall notification as quickly and effectively as possible.

Sincerely,

Bruce Culleton, MD
VP WW Medical Affairs
Medical and Procedural Solutions,
BD Medical

Gail Christie
VP WW Regulatory Affairs
Medical and Procedural Solutions,
BD Medical

MSS-17-988-FA

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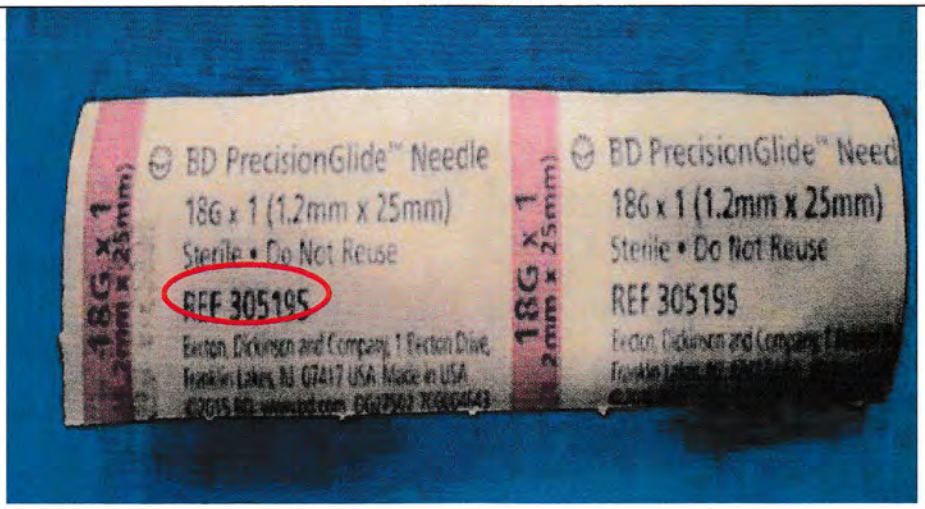
Location of Product Identification

Urgent Medical Device Recall

Unit Level



Lot Number

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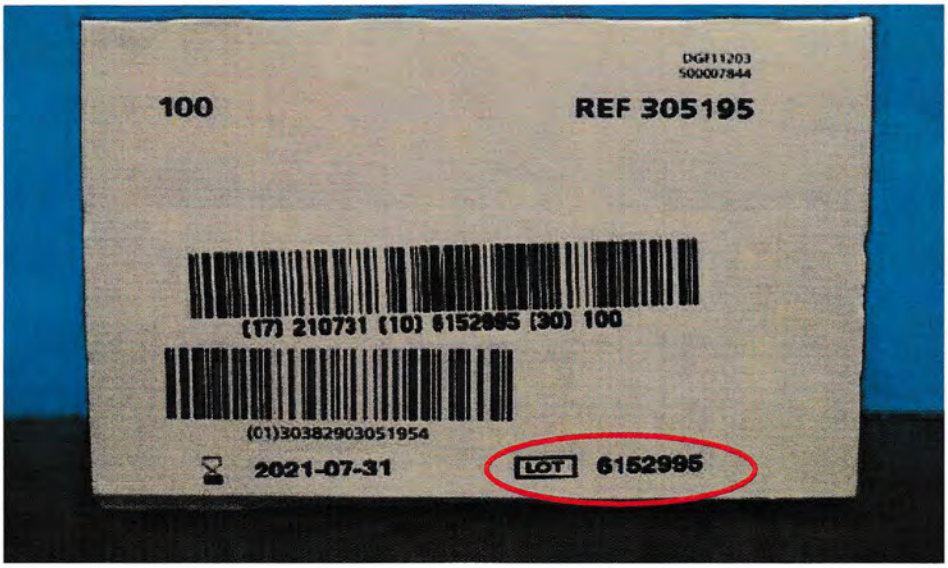
Shelf Carton Level

Catalog Number

Lot Number



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Shipper Carton Level
(*Generic Label*)

Catalog Number

Lot Number

6/1/2017

BD - Item # 305195

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

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: Djana Milliken
Fax #: 615.229-6801
Email: compliance@ndc-inc.com

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