

## **URGENT MEDICAL DEVICE RECALL**

May 31, 2017

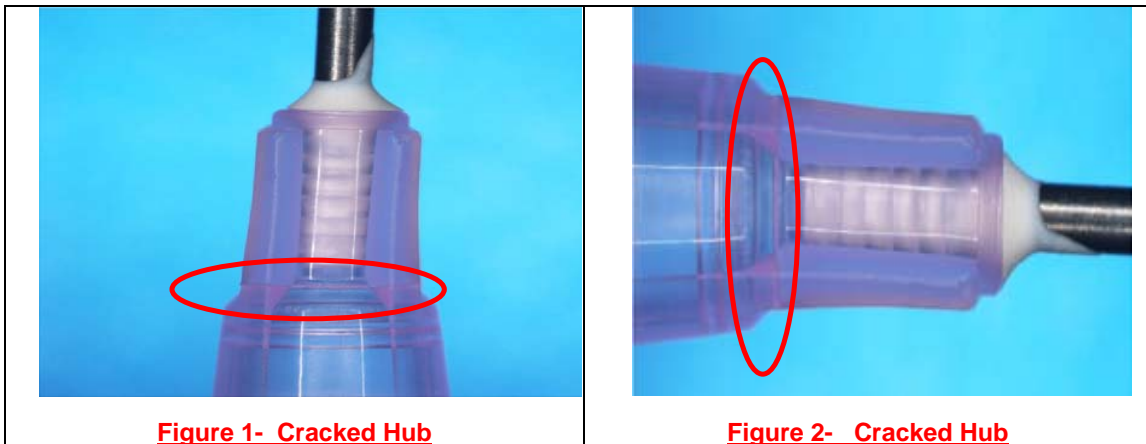
<b>Product Name</b>	<b>Catalog (Ref) No.</b>	<b>Lot No.</b>
BD PrecisionGlide™ Needle 18G x 1" RB	305195	6152995

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.

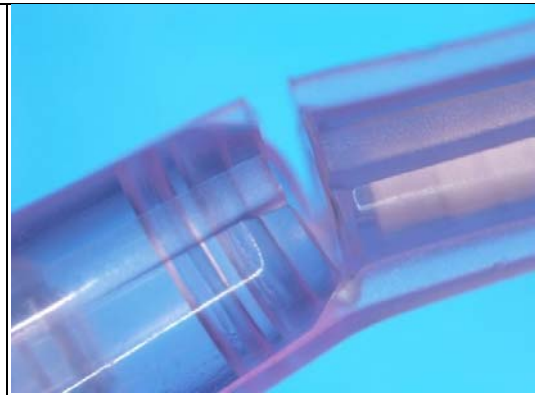
Using a damaged device could result in the following health consequences or harms:

- 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 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](mailto: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](mailto: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](http://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 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

## Business Response Card

### Urgent Medical Device Recall

<b>Cat (Ref) #</b>
305195

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 855-544-4803 or email the completed form to [bd4354@stericycle.com](mailto:bd4354@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.

<b>Required Information:</b>	
Business Name:	Phone Number:
Address/City/State/Zip :	
Lot Number and Quantity Returned (units) :	
Completed by: (Print Name/Signature/Date)	
<b>BD Office Use Only:</b>	
Lot Number and Quantity Returned (units) :	

I have **NO** affected product (Fill out and return this form to BD at fax/e-mail above).

**YES**, I have affected product (Fill out and 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.***

## PACKING INSTRUCTIONS

### Urgent Medical Device Recall

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**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: OER739.

**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.

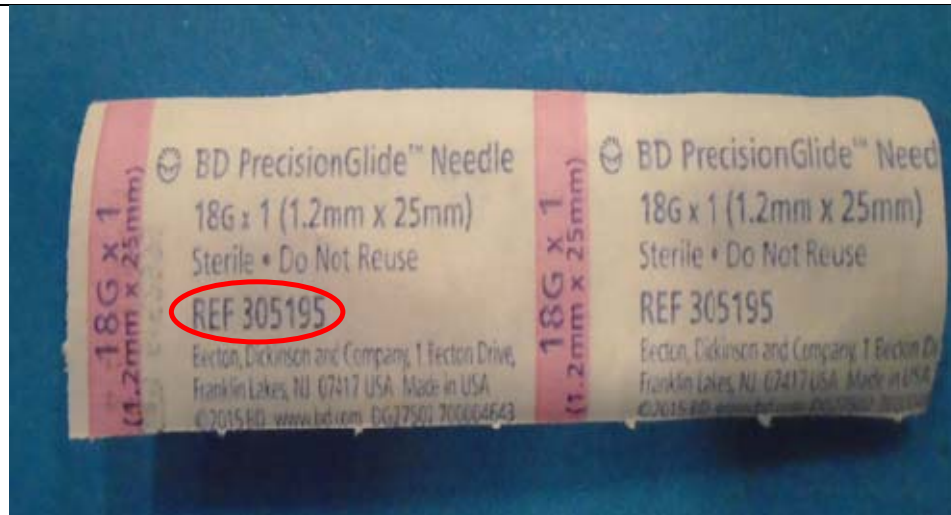
**DO NOT SHIP FREIGHT COLLECT**

**Our warehouse cannot receive products shipped "freight collect".**

## Location of Product Identification

### Urgent Medical Device Recall

#### Unit Level



#### Lot Number

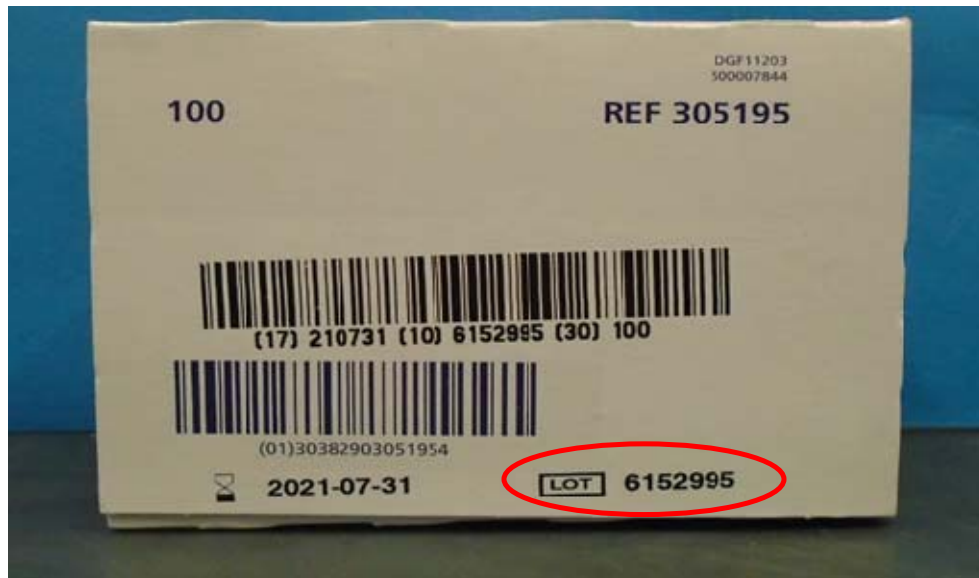


**Shelf Carton Level**

Catalog Number



Lot Number



**Shipper Carton Level  
(Generic Label)**

Catalog Number



Lot Number

