URGENT MEDICAL DEVICE RECALL

May 31, 2017

<table>
<thead>
<tr>
<th>Product Name</th>
<th>Catalog (Ref) No.</th>
<th>Lot No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>BD PrecisionGlide™ Needle 18G x 1&quot; RB</td>
<td>305195</td>
<td>6152995</td>
</tr>
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</table>

For the Attention of:
- Distributor

Description of the problem and health hazard(s):
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
You Need to Take the Following Actions:

- 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 distribution of the affected product. This recall only affects the Catalog (Ref) and lot number listed on the table above.

- If you have further distributed the recalled product, please notify any accounts or additional locations that may have received the recalled product from you. This recall is being conducted at the Distributor and End User levels. If you would like BD to notify your customers, please email your customer list within 3 business days to Becky_Saggau@bd.com. Please include the contact name, address, phone number, email address, and/or fax numbers for each customer. BD will notify these customers of the recall.

- If you have recalled product, please complete the attached Business Response Card and return the recalled product following the enclosed packing instruction. This is required so that BD may process your product credit.

- If you do not have recalled product, please complete the attached Business Response Card as well so that BD receives acknowledgement of your receipt of this recall notification.

Actions Taken by BD:

- A credit will be applied to your account for the affected product upon receipt of the recalled units.
Contact information

If you have questions or require further assistance, 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,

[Signature]

Leslie Robinson-Frye
Regulatory Compliance Manager
Business Response Card
BD PrecisionGlide™ Needle 18G x 1" RB

Please assist BD by promptly returning this form to:
Email: bd4354@stericycle.com
Fax No.: 855-544-4803

Facility: 

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:

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

☐ I have identified and notified all customers that purchased any affected product. Check below which method of notification was used (include date and method):
Date of Notification: 
Mail: _______; E-mail: _______; Fax: _______; Phone: _______

☐ I have identified and provided BD with a listing of all customers that purchased any affected product.
PACKING INSTRUCTIONS

Urgent Medical Device Recall

Product Return Instructions:

1. Please enclose the completed 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”.

MSS-17-988-FA

Page 5 of 8
Location of Product Identification

Urgent Medical Device Recall

Unit Level
Catalog Number

Lot Number
Shelf Carton Level

Catalog Number

Lot Number
Shipper Carton Level
(Generic Label)

Catalog Number

BD PrecisionGlide™ Needle
18G x 1 (1.2mm x 25mm)
Sterile • Do Not Reuse
Becton, Dickinson and Company, 1 Becton Drive, Franklin Lakes, NJ 07417 USA
BD, BD Logo and BD PrecisionGlide are trademarks of
Becton, Dickinson and Company. © 2010 BD. Made in USA. www.bd.com

1000 (10 x 100)

Lot Number

BD PrecisionGlide™ Needle
18G x 1 (1.2mm x 25mm)
Sterile • Do Not Reuse
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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](image1.png)  
![Figure 2- Cracked Hub](image2.png)
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](http://www.fda.gov/medwatch)
- Phone: 1-800-FDA-1088 (1-800-332-1088)
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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

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.

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 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.
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Urgent Medical Device Recall

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2. The simplest way to return product would be to access the following UPS website:

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<td><img src="image1" alt="Catalog Number Image" /></td>
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**Lot Number**

![Lot Number Image](image2)
### Catalog Number

![Catalog Number Image]

**BD PrecisionGlide™ Needle**

18G x 1 (1.2mm x 25mm)

Sterile • Do Not Reuse

1000 (10 x 100)

REF 305195

YYYY-MM-DD 1234567

### Lot Number

![Lot Number Image]

**BD PrecisionGlide™ Needle**

18G x 1 (1.2mm x 25mm)

Sterile • Do Not Reuse

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REF 305195

YYYY-MM-DD 1234567