CONSUMER LEVEL RECALL

9/5/17

Dear Member,

In May 25, 2017, BD initiated a product recall for Catalog (Ref) 328466, Lot 6291768, since some polybags in the lot were incorrectly labeled as BD Ultra-Fine™ needle ½mL 8mm 31G, Cat (Ref) 328468. After further investigation, BD identified that two additional lots were also mislabeled with the same condition.

As a result, BD is expanding the product removal recall of the BD Insulin Syringes with the BD Ultra-Fine™ needle ½ ml 12.7mm 30G, Cat (Ref) 328466, to include all lots listed in the table below. Using a 12.7mm needle for injection when an 8mm was intended, could result in an increased risk of an inadvertent intramuscular injection, which may lead to unanticipated hypoglycemia.

PRODUCTS RECALLED BY BD

<table>
<thead>
<tr>
<th>MUTUAL ITEM #</th>
<th>PRODUCT</th>
<th>ITEM #</th>
<th>LOT #S</th>
</tr>
</thead>
<tbody>
<tr>
<td>287-714</td>
<td>BD SYRINGE ULTRAFINE 1/2CC 30G</td>
<td>328466</td>
<td>6291768,6312558</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>6340590</td>
</tr>
</tbody>
</table>

With this recall, you are asked to:
- Check your products for the affected lots.
- Immediately discontinue distribution of the products being recalled.
- **DO NOT RETURN THE PRODUCT TO MUTUAL DRUG**
- A business response form and detailed instructions for returning product as well as a patient letter can be downloaded by logging onto https://www.mdmembers.com/ and going to the Recalls section.
- Contact Brent Slaughter if you have additional questions
CLASS I RECALL
ACKNOWLEDGEMENT

9/5/17

Dear Member,

In May 25, 2017, BD initiated a product recall for Catalog (Ref) 328466, Lot 6291768, since some polybags in the lot were incorrectly labeled as BD Ultra-Fine™ needle ½mL 8mm 31G, Cat (Ref) 328468. After further investigation, BD identified that two additional lots were also mislabeled with the same condition.

As a result, BD is expanding the product removal recall of the BD Insulin Syringes with the BD Ultra-Fine™ needle ½ ml 12.7mm 30G, Cat (Ref) 328466, to include lots 6291768, 6312558 and 6340590. Using a 12.7mm needle for injection when an 8mm was intended, could result in an increased risk of an inadvertent intramuscular injection, which may lead to unanticipated hypoglycemia.

Please acknowledge receipt of this Class I Recall and return this letter to NC Mutual Wholesale Drug. You may return by fax to (919) 596-1453 or by e-mail to: bslaught@mutualdrug.com

Store Name____________________________________   Customer #____________________

Printed Name_________________________________________________________________

Signature_____________________________________________________________________

Date________________________________
"AMENDED" URGENT MEDICAL DEVICE RECALL

August 30, 2017

<table>
<thead>
<tr>
<th>Product Name</th>
<th>Catalog (Ref) No.</th>
<th>NDC/HRI # in Shelf Box</th>
<th>NDC/HRI # in Polybag</th>
<th>Lot No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>BD Insulin Syringes with the BD Ultra-Fine™ needle ½ mL 12.7mm 30G</td>
<td>328466</td>
<td>08290-3284-66</td>
<td>08290-8466-01</td>
<td>6291768</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>6312558</td>
</tr>
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<td></td>
<td></td>
<td></td>
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<td>6340590</td>
</tr>
</tbody>
</table>

For the Attention of:
- Patient, Consumer

Description of the problem and health hazard(s):
In May 25, 2017, BD initiated a product recall for Catalog (Ref) 328466, Lot 6291768, since some polybags in the lot were incorrectly labeled as BD Ultra-Fine™ needle ½mL 8mm 31G, Cat (Ref) 328468. After further investigation, BD identified that two additional lots were also mislabeled with the same condition. As a result, BD is expanding the product removal recall of the BD Insulin Syringes with the BD Ultra-Fine™ needle ½mL 12.7mm 30G, Cat (Ref) 328466, to include all lots listed in the table above. Using a 12.7mm needle for injection when an 8mm was intended, could result in an increased risk of an inadvertent intramuscular injection, which may lead to unanticipated hypoglycemia.

The recall is being conducted since some polybags in the lots are incorrectly labeled as BD Ultra-Fine™ needle ½mL 8mm 31G, Cat (Ref) 328468. The shelf carton and case carton are correctly labeled as BD Insulin Syringes with the BD Ultra-Fine™ needle ½mL 12.7mm 30G. The affected recalled lots were distributed from February 15, 2017 to present.

The polybags of BD Insulin Syringes with the BD Ultra-Fine™ needle that are incorrectly labeled as ½mL 8mm 31G, contain syringes that are ½mL 12.7mm 30G. This may represent a health hazard to patients using the product affected by this recall.

You Need to Take the Following Actions:
- Please verify if you have the affected recalled product. To determine if you have the affected recalled product, please review the catalog and lot number in the shelf box as shown below.
Shelf Box:

- If you have individual polybags outside of the shelf box, you need to verify the catalog and lot number as shown below.

Polybag:

- If you don’t have any of the lot numbers indicated on the table above, your product is not affected by this recall. If you have the recalled product, please contact BD at 1-888-345-5364 between 8 AM and 8 PM ET Monday through Friday. BD will assist you with the return of the recalled product and how to obtain product replacement at no charge.
Contact Information
If you have questions or require further assistance, please contact 1-888-345-5364 between 8 AM and 8 PM ET Monday through Friday.

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,

Laurence Hirsch, MD  
VP Global Medical Affairs  
BD Medical – Diabetes Care

Mark Yale  
Sr Director Regulatory Compliance  
BD Medical
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 issue a credit to your account. 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”.

BDDC-17-1013-FA
Business Response Card
BD Insulin Syringes with the BD Ultra-Fine™ needle ½mL 12.7mm 30G

Please assist BD by promptly returning this form to:
BD
Email: bd7385@stericycle.com
Fax No.: 1-888-349-1319

Facility: ____________________________________________________________
Please use full, current facility name. Do not use initials.

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:

<table>
<thead>
<tr>
<th>Product Name</th>
<th>Catalog (Ref) No.</th>
<th>NDC/HRI # in Shelf Box</th>
<th>NDC/HRI # in Polybag</th>
<th>Lot No.</th>
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<tr>
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</tr>
</tbody>
</table>

☐ 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.

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