"AMENDED" URGENT MEDICAL DEVICE RECALL

August 30, 2017

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

For the Attention of:

- Medical Director, Risk Manager, Materials Manager

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. An example of the correct and incorrect labels are shown below in Figures 1 and 2.

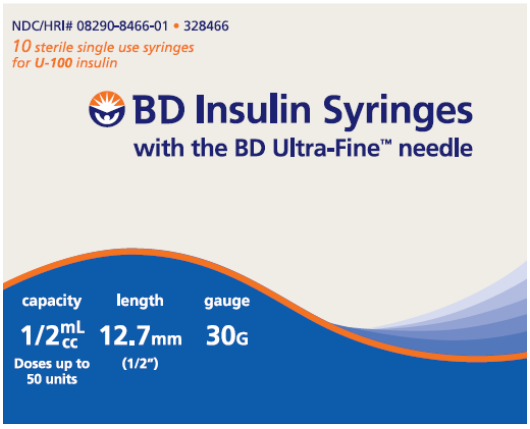


Figure 1: Correct Polybag Label

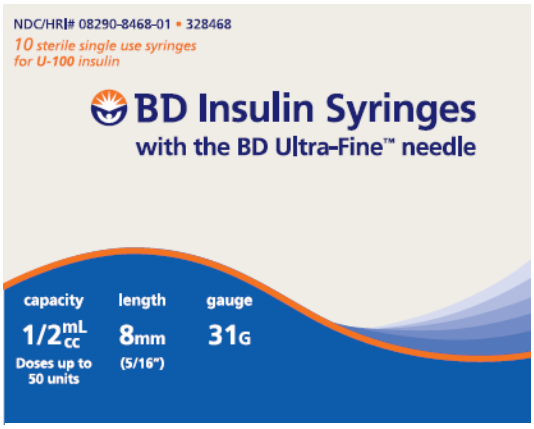


Figure 2: Incorrect Polybag Label

The shelf carton and case carton are correctly labeled as BD Insulin Syringes with the BD Ultra-Fine™ needle ½mL 12.7mm 30G. BD distributed the affected recalled lots from February 15, 2017 to May 17, 2017. **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.**

You Need to Take the Following Actions:

- Immediately review your inventory for the specific Catalog (Ref) and lot numbers listed on the table above, and quarantine product subject to the recall. Immediately discontinue the distribution of the affected product. This recall only affects the Catalog (Ref) and lot numbers listed on the table above. Please share this recall notification with all users of the product to ensure they are also aware of the recall.
- This recall is being conducted at the wholesaler/hospital/retail/consumer level.
    - **Important Note: Hospital/Retail/Consumers that have individual polybags outside of the shelf box need to verify the lot number for any of the following catalogs: 328466 or 328468 as indicated in Attachment A.**
- 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 replacement.
- If you do not have recalled product, please complete the attached Business Response Card as well so that BD receives an acknowledgement of your receipt of this recall notification.

Actions Taken by BD:

- BD will replace the returned recalled product inventory.

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.

One adverse event report has 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

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.

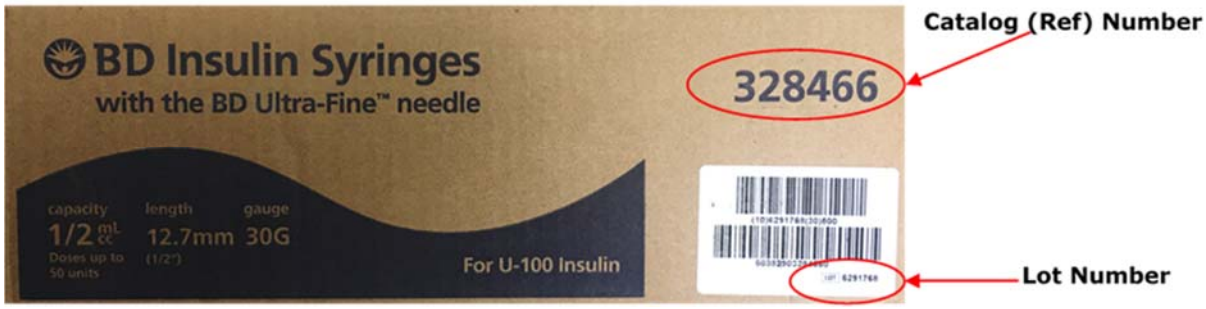
Sincerely,

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

Mark Yale
Sr Director Regulatory Compliance
BD Medical

Attachment A: Catalog (Ref) and Lot Identification:

Case Carton Front:

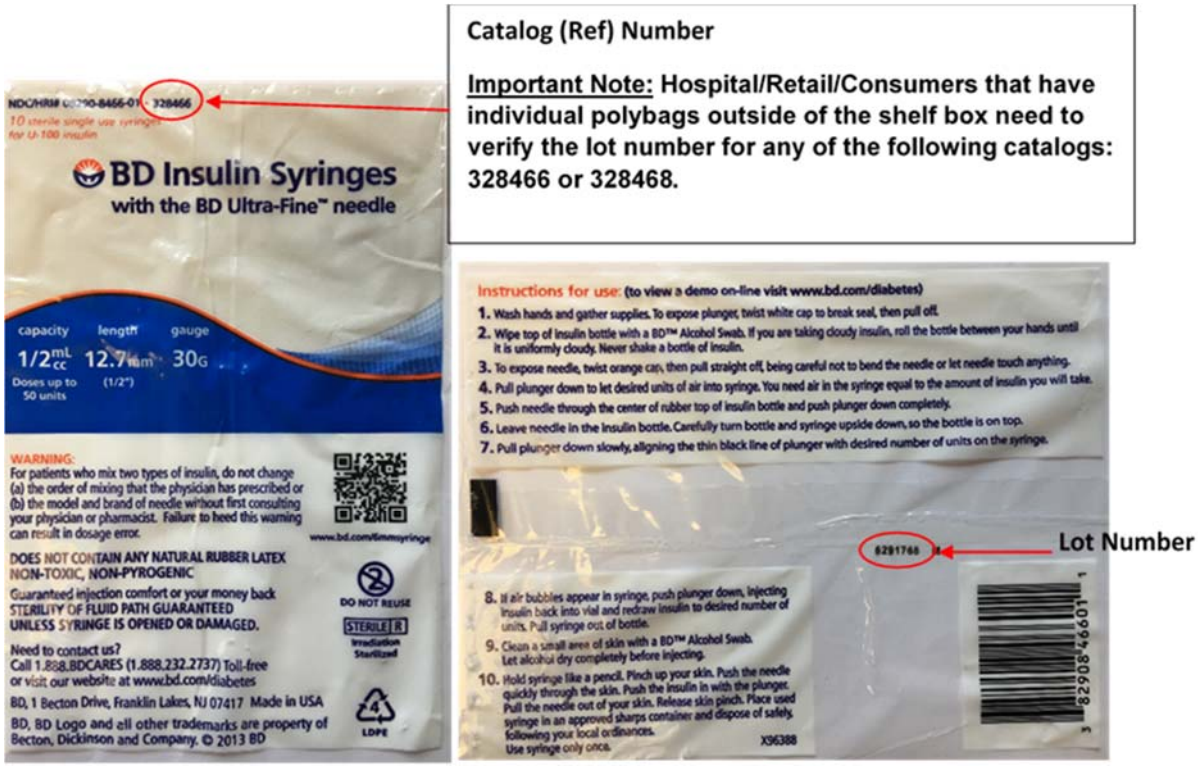


Case Carton Side:

Shelf Box:

Shelf Box:

Polybag:



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 Removal 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:

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

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

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".