

URGENT MEDICAL DEVICE RECALL

May 25, 2017

Product Name	NDC/HRI #	Catalog #	Lot #
BD Insulin Syringes with the BD Ultra-Fine™ needle ½ mL 12.7mm 30G	08290-8466-01	328466	6291768

For the Attention of:

- Patient, Consumer

Description of the problem and health hazard(s):

BD is conducting a product removal recall of lot 6291768 of the BD Insulin Syringes with the BD Ultra-Fine™ needle ½mL 12.7mm 30G, Catalog # 328466, because some polybags in the lot are incorrectly labeled as BD Ultra-Fine™ needle ½mL 8mm 31G, Catalog # 328468. ***The shelf carton is correctly labeled as BD Insulin Syringes with the BD Ultra-Fine™ needle ½mL 12.7mm 30G.*** The affected recalled lot was distributed from March 3, 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. 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.

You Need to Take the Following Actions:

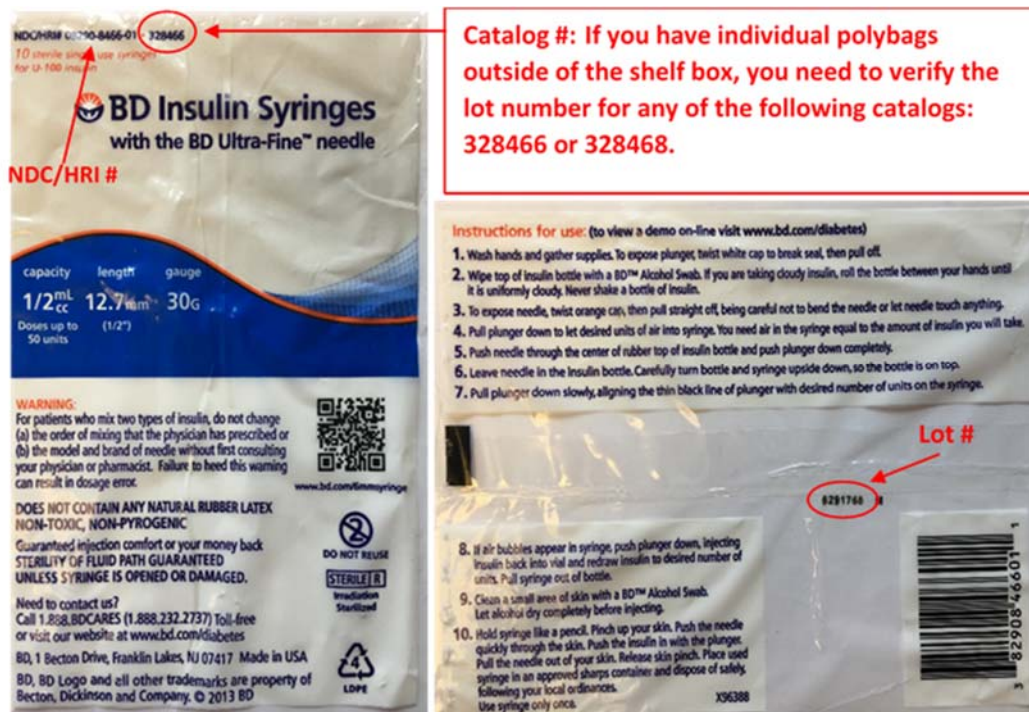
- Please verify if you have the affected recalled product. To determine if you have the affected recalled product, please review the catalog and lot number in the shelf box as shown below.

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:



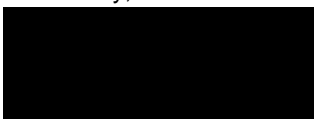
- If you don't have the lot number indicated on the table above, your product is not affected by this recall. **If you have the recalled product, please contact BD at 1-888-345-5364 between 8 AM and 8 PM ET Monday through Friday.** BD will assist you with the return of the recalled product and how to obtain product replacement at no charge.

Contact Information

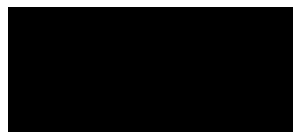
If you have questions or require further assistance, please contact 1-888-345-5364 between 8 AM and 8 PM ET Monday through Friday.

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