“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 ½mL 12.7mm 30G</td>
<td>328466</td>
<td>08290-3284-66</td>
<td>08290-8466-01</td>
<td>6291768</td>
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<td>6312558</td>
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<td>6340590</td>
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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