URGENT PRODUCT REMOVAL RECALL

May 25, 2017

<table>
<thead>
<tr>
<th>Product Name</th>
<th>Catalog (Ref) No.</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>6291768</td>
</tr>
</tbody>
</table>

For the Attention of:
- Pharmacy Prescribers and Staff

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, Cat (Ref) 328466, because some polybags in the lot 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. **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 lot from March 3, 2017 to April 24, 2017.

![Correct Polybag Label](image1)

![Incorrect Polybag Label](image2)

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.

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:

- Immediately review your inventory for the specific Catalog (Ref) and lot number listed 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 number listed on the table above.
- 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.
- Please notify consumers that may have received the recalled product from you. A copy of the recall letter for consumers is enclosed with this letter. BD will provide product replacement at no charge to consumers that have the affected recalled product. For assistance on how to return the recalled product and to obtain product replacement, please instruct your consumers to call BD at 1-888-345-5364 between 8 AM and 8 PM ET Monday through Friday.

Actions Taken by BD:

- For Retail Pharmacy – BD will replace the returned recalled product inventory.
- For Consumers – BD will provide a return kit and a voucher to be exchanged for product replacement at no charge. The voucher can be redeemed at their local retail pharmacy. The retail pharmacy will receive the product reimbursement at the same time the voucher is redeemed.
  - For Pharmacies that have questions related to the voucher program as well as how the consumer product reimbursement will occur once the voucher is redeemed at the retail pharmacy, please call BD at 1-888-345-5364 between 8 AM and 8 PM ET Monday through Friday.

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.

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
- 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:**

![BD Insulin Syringes](image)

- **Catalog (Ref) Number:** 328466
- **Lot Number:**

**Case Carton Side:**

- **Catalog (Ref) Number:** BD 328466
- **Lot Number:**

**Shelf Box:**

![BD Insulin Syringes](image)
Shelf Box:

Lot Number

Polybag:

Catalog (Ref) Number

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.

Instructions for use (To view a demo on-line visit www.bd.com/diabetes)

1. Wash hands and gather supplies. To open plunger, twist white cap to break seal, then pull off.
2. Place tip of insulin bottle with a BD® AluGuard® Insulin. If you are using closely insulin, swirl the bottle between your hands until it is uniformly cloudy. Never shake a bottle of insulin.
3. To expose needle, hold syringe cap, then pull straight off, being careful not to touch the needle or let needle touch anything.
4. Pull plunger down to let desired units of air into syringe, then hold air in the syringe equal to the amount of insulin you will take.
5. Push needle through the center of rubber top of insulin bottle and push plunger down completely.
6. Leave needle in the insulin bottle. Carefully pour insulin and syringe upside down, as the bottle is on top.
7. Pull plunger down slowly, aligning the thin black line of plunger with desired number of units on the syringe.

Lot Number
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:

<table>
<thead>
<tr>
<th>Product Name</th>
<th>Catalog No.</th>
<th>Lot No.</th>
<th>No. of Units</th>
</tr>
</thead>
<tbody>
<tr>
<td>BD Insulin Syringes with the BD Ultra-Fine™ needle ½mL 12.7mm 30G</td>
<td></td>
<td>6291766</td>
<td></td>
</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 consumers 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: _______
PACKING INSTRUCTIONS FOR RETAIL PHARMACIES

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".
URGENT MEDICAL DEVICE RECALL

May 25, 2017

<table>
<thead>
<tr>
<th>Product Name</th>
<th>NDC/HRI #</th>
<th>Catalog #</th>
<th>Lot #</th>
</tr>
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<tbody>
<tr>
<td>BD Insulin Syringes with the BD Ultra-Fine™ needle ½ mL 12.7mm 30G</td>
<td>08290-8466-01</td>
<td>328466</td>
<td>6291768</td>
</tr>
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</table>

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:**

*Catalog #: If you have individual polybags outside of the shelf box, you need to verify the lot number for any of the following catalogs: 328466 or 328468.*

• 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
URGENT MEDICAL DEVICE RECALL

May 25, 2017

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<tr>
<td>BD Insulin Syringes with the BD Ultra-Fine™ needle 1/2 mL 12.7mm 30G</td>
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For the Attention of:
- Medical Director, Risk Manager, Materials Manager

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 1/2 mL 12.7mm 30G, Cat (Ref) 328466, because some polybags in the lot are incorrectly labeled as BD Ultra-Fine™ needle 1/2 mL 8mm 31G, Cat (Ref) 328468. An example of the correct and incorrect labels are shown below in Figures 1 and 2. The shelf carton and case carton are correctly labeled as BD Insulin Syringes with the BD Ultra-Fine™ needle 1/2 mL 12.7mm 30G. BD distributed the affected recalled lot from March 3, 2017 to April 24, 2017.

![Correct Polybag Label](image1)

![Incorrect Polybag Label](image2)

The polybags of BD Insulin Syringes with the BD Ultra-Fine™ needle that are incorrectly labeled as 1/2 mL 8mm 31G, contain syringes that are 1/2 mL 12.7mm 30G.

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:

- Immediately review your inventory for the specific Catalog (Ref) and lot number listed 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 number 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.

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 ask 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  
BDDC-17-1013-FA

Mark Yale  
Sr Director Regulatory Compliance  
BD Medical
Attachment A: Catalog (Ref) and Lot identification:

Case Carton Front:

![Case Carton Front Image]

- Catalog (Ref) Number: 328466
- Lot Number: [Barcode]

Case Carton Side:

![Case Carton Side Image]

- Catalog (Ref) Number: 328466
- Lot Number: [Barcode]

Shelf Box:

![Shelf Box Image]

- Catalog (Ref) Number: [Barcode]
**Shelf Box:**

![Image of BD Insulin Syringes with the BD Ultra-Fine™ needle]

- **Lot Number:**

**Polybag:**

![Image of BD Insulin Syringes with the BD Ultra-Fine™ needle in a polybag]

- **Catalog (Ref) Number**

**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.

**Instructions for use:**

1. Wash hands and gather supplies. To expose syringe, hold white cap to break seal, then pull off.
2. Remove top of insulin bottle with a BD™ Alu-coll Flow Lock. If you are using a cloudy insulin, swivel the bottle between your hands until it is uniformly cloudy. Never shake a bottle of insulin.
3. To expose needle, twist cap off. Then push plunger, being careful not to touch the needle or let needle touch anything.
4. Pull plunger down to let desired units of insulin enter the syringe. Make sure that the amount of insulin you will take.
5. Push needle through the center of rubber top of insulin bottle and push plunger down completely.
6. Leave needle in the insulin bottle. Carefully turn bottle and syringe upside down, so the bottle is on top.
7. Push plunger down slowly, aligning the thin black line of plunger with desired number of units on the syringe.

- **Lot Number:**
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.: ____________________________

<table>
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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.
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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.
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.

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   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".