BD Medical Delivery Solutions
1 Becton Drive
Franklin Lakes, NJ 07417
USA

bd.com

URGENT MEDICAL DEVICE RECALL

BD 3ml Luer-Lok Syringe and BD 3ml Safety-Lok Syringe

February 1, 2019

Product Name	UDI	Cat. No.	Lot No.	Exp. Date	Case Pack
BD 3mL Luer-Lok Syringe	30382903096573	309657	8303571	31-Oct-2023	800
BD 3mL Safety-Lok Syringe	30382903096061	309606	8307694	31-Oct-2023	800

For the Attention of:

- Distributor

Description of the problem and health hazard(s):

BD is conducting a voluntary medical device recall of 3ml Luer-Lok Syringes and 3ml Safety-Lok Syringes (lot numbers referenced in the table above). The recall is being conducted due to the syringes having scale markings printed in varying degrees, resulting in missing and/or partially printed scale numbers and scale lines. Although this defect would most likely be noticeable to the user, minimizing the impact to health, in a worst-case scenario, it could result in a potential mis-dose volume of up to 0.5ml. This defect is isolated to the specified Catalog and Lot Numbers listed in the table above.

BD distributed the affected lots between November 16, 2018 and January 4, 2019. Our records indicate you may have product from the above-referenced lots.

Please Take the Following Actions:

1. Immediately review your inventory for the specific Catalogue (Ref) and lot numbers listed above. Return all product subject to recall according to the Packing Instructions enclosed.

2. Identify all your customers that purchased any affected product, as defined in this recall notification. E-mail an excel file listing of all customers to **BDRC7@bd.com**, within 72 hours of receipt of this letter.

3. Complete the attached Wholesaler/Distributor Response Form and return to the BD contact noted on the form whether or not you have any of the impacted material so that BD may acknowledge your receipt of this notification and process your credit accordingly.

4. Report any adverse health consequences experienced with the use of this product to BD. Events may also 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

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Actions Taken by BD:

1. BD will provide a credit for all returned inventory.
2. Corrective actions have been initiated to prevent recurrence of the identified root cause.

Contact Information

If you require further assistance, please contact:

BD Contact	US Contact Information	OUS Support
Customer/Technical Support	**888-237-2762 OPT 3, OPT 2** Monday – Friday between 8:00am and 5:00pm (EST)	**For customers outside the US, contact your local BD representative or distributor.**

BD is committed to advancing the world of health. Our primary objectives are patient and user safety and providing you with quality products. We apologize for any inconvenience this issue may have caused you and thank you in advance for helping us to resolve this matter as quickly and effectively as possible.

Sincerely,

Klaus Hoerauf, MD
VP Global Medical Affairs
BD Medication Delivery Solutions

Gail Griffiths
Sr. Director Corporate Regulatory Compliance
BD US Region

Kim. K. @ BD
410-316-4418

Per Kim. K. @ BD
Retail Level Recall
NO Customer Notifications will be sent from our D.C's.
MFG will send out Notifications.
Per their request
2/4 @ 11:30 LH

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WHOLESALER/DISTRIBUTOR RESPONSE FORM

MDS-19-1431-FA

BD 3ml Luer-Lok Syringe & BD 3ml Safety-Lok Syringe

Please assist BD by promptly returning this form to: BD Regulatory Compliance
Email: BDRC7@bd.com
Fax No.: 312-949-0217

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

Street Address: _____

City: _____ **State:** _____ **Zip:** _____

Contact Person: _____

Telephone No.: _____ **Email Address:** _____

Fax No.: _____

☐ I have read and understood the attached notice.

Name:	
Title:	
Signature/Date:	

☐ We do not have any of the affected product(s) on hand.
☐ We had the following units on hand and request credit.

Product Name	Catalog No.	Lot No.	Units (Qty.)
BD 3ml Luer-Lok Syringe	309657	8303571	
BD 3ml Safety-Lok Syringe	309606	8307694	

☐ 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 provided BD with an excel file listing all customers (and their contact information) for all that purchased any affected product.

☐ We decline to provide a customer list to BD and have notified our customer on the following date: ___

_____.

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PACKING INSTRUCTIONS

Urgent Medical Device Recall

Product Return Instructions:

1. Please enclose the completed Customer Recall Response Form with the shipment.

2. The simplest way to return product would be to access the following UPS website and log in:
   http://row.ups.com/
   Company Alias: bdapi
   Login ID: MDS-19-1431
   Password: MDS-19-1431

   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: MDS-19-1431
   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. 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".

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For the Attention of:

- Medical Director, Risk Manager, Medical Device Safety Officer, Nurse Manager

Description of the problem and health hazard(s):

BD is conducting a voluntary medical device recall of 3ml Luer-Lok Syringes and 3ml Safety-Lok Syringes (lot numbers referenced in the table above). The recall is being conducted due to the syringes having scale markings printed in varying degrees, resulting in missing and/or partially printed scale numbers and scale lines. Although this defect would most likely be noticeable to the user, minimizing the impact to health, in a worst-case scenario, it could result in a potential mis-dose volume of up to 0.5ml. This defect is isolated to the specified Catalog and Lot Numbers listed in the table above.

BD distributed the affected lots beginning on November 16, 2018. Our records indicate you may have received product from the above-referenced lots.

Please Take the Following Actions:

1. Immediately review your inventory for the specific Catalogue (Ref) and lot numbers listed above. Destroy all product subject to the recall following your institution's process for destruction.

2. Share this recall notification with all users of the product within your facility to ensure that they are also aware of this recall.

3. Complete the attached Customer Response Form and return to the BD contact noted on the form whether or not you have any of the impacted material so that BD may acknowledge your receipt of this notification and process your product replacement.

4. Report any adverse health consequences experienced with the use of this product to BD. Events may also 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

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Actions Taken by BD:

1. Corrective actions have been initiated to prevent recurrence of the identified root cause.
2. BD will provide replacement for all discarded inventory.

Contact Information

If you require further assistance, please contact:

BD Contact	US Contact Information	OUS Support
Customer/Technical Support	**888-237-2762 OPT 3, OPT 2** Monday – Friday between the hours of 8:00am and 5:00pm (EST)	**For customers outside the US, contact your local BD representative or distributor**

BD is committed to advancing the world of health. Our primary objectives are patient and user safety and providing you with quality products. We apologize for any inconvenience this issue may have caused you and thank you in advance for helping us to resolve this matter as quickly and effectively as possible.

Sincerely,

Klaus Hoerauf, MD
VP, Global Medical Affairs
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Gail Griffiths
Sr. Director, Corporate Regulatory Compliance
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CUSTOMER RESPONSE FORM

MDS-19-1431-FA

BD 3ml Luer-Lok Syringe and BD 3ml Safety-Lok Syringe

Please assist BD by promptly returning this form to: BD Regulatory Compliance
Email: BDRC7@bd.com or
Fax No.: 312-949-0217

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

Street Address: _____

City:_____ **State:** _____ **Zip:** _____

Contact Person: _____

Telephone No.: _____**Email Address:** _____

Fax No.: _____

☐ I have read and understood the attached notice.

Name:	
Title:	
Signature/Date:	

☐ We do not have any of the affected product(s) on hand.

☐ We have the following units on hand and request replacement.

Product Name	**Catalog No.**	**Lot No.**	**Units (Qty.)**
BD 3ml Luer-Lok Syringe	309657	8303571	
BD 3ml Safety-Lok Syringe	309606	8307694	

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