

URGENT MEDICAL DEVICE RECALL**BD 18Gx1-1/2IN Thin Wall (TW) Precision Glide Needles**

February 4, 2019

Product Name	Cat. No.	Lot No.	Exp. Date	Case Pack
18Gx1-1/2IN TW Precision Glide Needles	302032	8173135	2023-06	1000

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 one lot of 18Gx1-1/2IN TW Precision Glide Needles. The recall is being conducted due to a limited amount of 18Gx1-1/2IN TW Blunt Fill Needles (Catalog# 300204) being mixed in with the above referenced lot of Precision Glide Needles. Due to the obvious difference in the two needles (pointed vs. blunt tip) it is likely that a clinician would notice the incorrect needle prior to use. As a result, the potential for any health impact is expected to be minimal.

BD distributed the affected lot from August 24, 2018 through December 5, 2018. Our records indicate you may have received product from the above-referenced lot.

Please Take the Following Actions:

1. Immediately review your inventory for the specific Catalogue (Ref) and lot number 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 if required.

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.

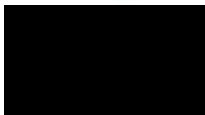
Contact Information

If you require further assistance, please contact:

BD Contact	Contact Information
Customer/Technical Support	BD Office Telephone: Monday – Friday between the hours of 8:00am and 5:00pm (EST)

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 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

CUSTOMER RESPONSE FORM
BD 18Gx1-1/2IN Thin Wall (TW) Precision Glide Needles
MDS-19-1421-FA

Please assist BD by promptly returning this form to: **BD Regulatory Compliance**

Email: _____

Fax No.: _____

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.)
18Gx1-1/2IN TW Precision Glide Needles	302032	8173135	

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