1030 Eskdale Road
Winnersh Triangle
Wokingham
RG41 5TS
www.BD.com

April 21, 2020

URGENT: FIELD SAFETY NOTICE – MDS-20-1971

BD PosiFlush™ XS 10mL Syringe

REF: 306572

Type of Action: Advisory

Attention: Clinical Personnel, Risk Managers, Biomedical Personnel

This letter contains important information which requires your **immediate** attention.

Dear valued Customer,

BD is issuing an advisory Field Safety Notice for the **BD PosiFlush™ XS 10mL Syringes** (REF: 306572) and according to our distribution records your organisation may have received the impacted devices which were shipped by BD from August 6th, 2019 to March 6th, 2020.

Description of the Problem

BD has become aware through customer feedback that a percentage of **BD PosiFlush™ XS 10mL Syringes** (REF: 306572) have the potential to exhibit holes in the packaging, which impacts package integrity and potentially compromises the external sterility of the syringe. This issue is estimated to affect *less* than 1 in 10 devices manufactured. Please refer to Figure 1 below for an example of the issue and the location of the defect. While the sterility of the outer surface of the syringe may be compromised, the saline solution and the fluid path remain sterile.

Figure 1: Example of location of defect

The Instructions for Use enclosed with all BD PosiFlush™ XS 10mL Syringes advises Users to inspect the product prior to use to ensure integrity of the blister pack.

This Field Safety Notice is being issued to reinforce the Instructions for Use which state "***Do not use if unit package or content is damaged***."

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BD has attributed the cause of the packaging defect to a specific manufacturing line and is taking steps to identify the root cause and will implement corrective actions within manufacturing to prevent a re-occurrence.

Actions for customers to take:

1. Circulate this Field Safety Notice to all those within your organisation that may use the BD PosiFlush™ XS 10mL Syringes (REF: 306572).

2. Ensure Users are aware of the Instructions for Use which state "*Do not use if unit package or content is damaged*".

3. If any of the blister packs in your inventory contain holes or defects, dispose of the product per your normal process.

4. If you have further distributed the device/s, please identify those users and notify them at once of this Field Safety Notice.

5. Return the completed customer response form to BDUKFieldAction@bd.com **as soon as possible or no later than April 30th, 2020.**

Contact Reference Person

If you have any questions about the device, please contact BDUKFieldAction@bd.com.

BD confirms that the appropriate regulatory agencies have been informed of these actions.

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

Sincerely,

William David
Sr. Director, Quality Compliance, EMEA Quality Compliance

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Customer Response Form – MDS-20-1971
BD PosiFlush™ XS 10mL Syringe (REF: 306572)

Please read in conjunction with the advisory Field Safety Notice MDS-20-1971 and return the completed and signed form as soon as possible or **no later than April 30th, 2020** to BDUKFieldAction@bd.com.

By signing below, you confirm this notice has been read, understood and that all recommended actions have been implemented as required.

Name of Trust *(if applicable)*			
Name of all Facilities / Hospitals covered by this response *(e.g. other hospitals within your Trust)*			
Facility / Hospital address			
Postcode			
Telephone number		**E-mail address**	
Name			
Signature		**Date**	

This form must be returned to BD before this action can be considered closed for your account.
Please return your completed and signed Response Form to BDUKFieldAction@bd.com.