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

July 1, 2020

UPDATED

URGENT: FIELD SAFETY NOTICE – MDS-20-1971

BD PosiFlush™ XS 10mL Syringe

REF: 306572 **Lot Numbers:** See Table 1 (page 3)

Type of Action: Recall

Attention: Clinical Personnel, Risk Managers, Biomedical Personnel

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

Dear Valued Customer,

In April 2020, BD issued an advisory Field Safety Notice to re-enforce the existing instruction that users of the **BD PosiFlush™ XS 10mL Syringes** (REF: 306572) should check the product package prior to use due to the potential that the device packaging may exhibit holes as a result of a manufacturing issue.

The approach to release an "advisory" Field Safety Notice at this time was agreed upon with the Health Products Regulatory Authority (HPRA), as the Lead Regulatory Authority. The combination of BD's reduced manufacturing capability and significant demand for the product due to COVID-19 led to the agreement between the HPRA and BD to issue the advisory notice in order to ensure that customers were not left without product during this global pandemic.

After a review and further discussions with the HPRA, both parties have agreed that as the impact of COVID-19 on EU healthcare facilities is now reducing, that this action is now being updated from an "advisory" to a "product recall" of any remaining product inventory. The impacted lot numbers are listed in Table 1, page 3. No additional lot numbers are impacted.

The risk associated with the defect has not increased since the previous Field Safety Notice. While the sterility of the outer syringe may be compromised for devices that have a hole in the packaging, the saline solution and the fluid path remain sterile due to the product design. The device incorporates a syringe sealing closure which comprises a stopper inserted into the end of the syringe tip. The syringe tip with the stopper, is covered with a threaded tip cap. These two features combine to create a sterile seal for the saline solution. The maintenance of the sterility of the saline solution does not depend on the packaging material.

Root Cause of Defect:

As an update, BD is still investigating the root cause of the packaging defect and the specific manufacturing line will not be used to manufacture devices until BD has identified the exact root cause and taken corrective actions within manufacturing to prevent a re-occurrence.

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Actions for customers to take:

1. Identify, quarantine, and destroy any of the impacted lots left in your inventory.

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

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

4. Return the completed customer response form to BDUKFieldAction@bd.com **as soon as possible or no later than 25th July, 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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UPDATED Customer Response Form – MDS-20-1971
BD PosiFlush™ XS 10mL Syringe (REF: 306572)

Please read in conjunction with the Field Safety Notice MDS-20-1971 and return the completed and signed form as soon as possible or **no later than July 25th, 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.

Tick the appropriate box below:

☐ We do not have any of the affected product in our possession.

OR

☐ We have units of the affected product and confirm that the following numbers of units have been destroyed & replacement product will be provided *(Please note there may be delays in the replacement product subject to product availability).*

Lot Number	Expiry Date	Quantity Destroyed	Lot Number	Expiry Date	Quantity Destroyed
9182101	30 Jun 2022		9232938	31 Jul 2022	
9185822	30 Jun 2022		9235407	31 Jul 2022	
9192691	30 Jun 2022		9239399	31 Aug 2022	
9199773	30 Jun 2022		9248167	31 Aug 2022	
9204191	30 Jun 2022		9255893	31 Aug 2022	
9213726	31 Jul 2022		9263969	31 Aug 2022	
9224747	31 Jul 2022				

Table 1: Impacted Lot Numbers & Expiry Dates

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.