Becton Dickinson UK Ltd
1030 Eskdale Road, Winnersh
Wokingham RG41 5TS
United Kingdom

19th May 2025

Direct Healthcare Professional Communication

BD ChloraPrep™ Clear - 1mL Applicator: Recall of affected batches due to packaging defect and subsequent risk of contamination

URGENT: MEDICINES RECALL SUR-25-5188-FA

ChloraPrep 1mL Clear

Sterile Solution/Applicator

REF: 270480

Lot Numbers: 4099824, 4099828, 4108755, 4108759, 4116445, 4120316, 4120319, 4121513, 4121515, 4255105, 4255107, 4255108, 4257774, 4257778, 4257776, 4257777, 4259473, 4275220, 4276062, 4276059, 4276075, 4276079,

Type of Action: Removal (Recall)

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

Dear Customer

Summary

We wish to advise you that for below batches REF: 270480 **BD ChloraPrep™ Clear - 1mL Applicator**, PL 05920/0002 - 0001 are being recalled.

This recall is going to Hospital level.

This action has been agreed with the Medicines and Healthcare Products Regulatory Agency (link)

Some units exhibit an open seal on the packaging of the applicator. This defect would increase the risk of the applicator device being contaminated with pathogens, which would lead to increased infection rates for the patients.

Background

The reason for the recall is that based on customer feedback, BD has determined that the affected product may exhibit an open seal on the packaging of the applicator.

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This recall is specific to the list mentioned below. No other lots of BD ChloraPrep™ Clear - 1mL Applicator product are impacted.

Affected LOT batch numbers

Batch No.	Expiry Date	Pack Size	First Distributed
4099824	30-Apr-27	60 applicators	18/07/2024
4099828	30-Apr-27	60 applicators	24/07/2024
4108755	30-Apr-27	60 applicators	15/08/2024
4108759	30-Apr-27	60 applicators	11/09/2024
4116445	30-Apr-27	60 applicators	30/07/2024
4120316	30-Apr-27	60 applicators	05/08/2024
4120319	30-Apr-27	60 applicators	12/08/2024
4121513	30-Apr-27	60 applicators	14/08/2024
4121515	30-Apr-27	60 applicators	14/08/2024
4255105	30-Sep-27	60 applicators	24/02/2025
4255107	30-Sep-27	60 applicators	06/01/2025
4255108	30-Sep-27	60 applicators	17/02/2025
4257774	30-Sep-27	60 applicators	23/01/2025
4257778	30-Sep-27	60 applicators	23/01/2025
4257776	30-Sep-27	60 applicators	13/01/2025
4257777	30-Sep-27	60 applicators	20/01/2025
4259473	30-Sep-27	60 applicators	13/01/2025
4275220	31-Oct-27	60 applicators	19/02/2025
4276062	31-Oct-27	60 applicators	03/03/2025
4276059	31-Oct-27	60 applicators	19/02/2025
4276075	31-Oct-27	60 applicators	19/02/2025
4276079	31-Oct-27	60 applicators	10/03/2025

Table 1: Affected batch numbers

Advice for Healthcare Professionals:

- Immediately discontinue use of the BD ChloraPrep™ Clear 1 mL Applicators from above listed lots and select an appropriate equivalent product to prepare the patient's skin prior to surgery.
- It is recommended that treating clinicians use their discretion in managing patients and/or users who may be at risk.

Actions to be taken

1. Please immediately discontinue use of the affected lots. Check all inventory locations within your facility and quarantine until disposal.
2. This recall notice should be shared with anyone who needs to be aware within your organization and forwarded to any organization where affected products have been transferred.

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3. Complete the attached Response Form and return it to the contact noted on the form indicating whether or not you have any of the affected lots so that BD may acknowledge your receipt of this notification.
4. Indicate on the response form the quantity from the affected lots identified at your facility and confirm that this product inventory was returned.

Call for Reporting

Please continue to report suspected adverse drug reactions (ADRs) to the MHRA through the Yellow Card scheme.

Please report:

- all suspected ADRs that are serious or result in harm. Serious reactions are those that are fatal, life-threatening, disabling or incapacitating, those that cause a congenital abnormality or result in hospitalisation, and those that are considered medically significant for any other reason
- all suspected ADRs associated with new drugs and vaccines identified by the black triangle ▼

You can report via:

- the Yellow Card website
- the free Yellow Card app available from the Apple App Store or Google Play Store
- some clinical IT systems (EMIS/SystmOne/Vision/MiDatabank) for healthcare professionals

Alternatively, you can report a suspected side effect to the Yellow Card scheme by calling 0800 731 6789 for free, Monday to Friday between 9am and 5pm.

When reporting please provide as much information as possible, including information about medical history, any concomitant medication, timing onset, treatment dates, and product brand name.

Company contact point

For all medical information enquiries and information on this product, please email safetyinformation@bd.com, or telephone 08000437546. For stock control enquiries please email info@insightbio.com, or telephone 01707351330.

Yours faithfully

Signed by:
Javier Franch
Signer Name: Javier Franch
Signing Reason: I approve this document
Signing Time: 19-May-2025 | 6:23:01 AM PDT
DBBE11F3FCA548408ECC00C94DFE28E5
19-May-2025

Javier Franch
BD Associate Director,
Global Pharma Quality

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Customer Response Form –

Field Action Reference Number

SUR-25-5188-FA

REF: 270480

Return to your supplier as soon as possible or **no later than the 21st May 2025**

- **I confirm this Field Safety 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 as listed in **Table 1** in our facility. Affected product has been used.

OR

☐ We have the following units of the affected product as listed in **Table 1** in our possession and I confirm that the units have been returned *(Please complete the table below with the lot number and the number of units returned. <<**Replacement/credit**>> product will only be sent on completion and return of this form).*

REF:	Lot Number/s:	Units returned *(insert quantity below)*

*This form must be returned to BD before this action can be considered closed for your account.*If you were forwarded this Field Safety Notice via a distributor/3rd party, please return your completed form to that organisation for reconciliation purposes.*

Account/Organisation Name:	
Department *(if applicable)*:	
Address:	
Postcode:	**City:**
Contact Name:	
Job Title:	
Contact Telephone Number:	**Contact E-mail Address:**
Signature:	**Date:**

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Appendix 1 - Product Code / Lot number Identification (if applicable)

Carton Labels (front and side) for REF 270480

Applicator Label for REF 270480: