

Date : 23rd May 2025**Urgent Field Safety Notice / Product Recall Notice****270480 - ChloraPrep 1ml Applicators**
(Batch numbers : 4108755, 4120319, 4257774, 4257778, 4275220 & 4276059)

FAO: Risk Managers Responsible for Vigilance and all Department Managers.

Subject: Product Recall – Faulty Seal on packing of ChloraPrep applicator

Device Type/Affected Product	Various B. Braun Medical Limited Packs Affected item – BD ChloraPrep Clear 1ml Applicator
Type of action	Identify all affected stock and organise return to B. Braun Medical Limited
Product code and LOT Number (Device Model)	See Appendix C
Clinical Purpose of the device	Various intended uses – see product code list in Appendix C
UDI-DI	5033241PACKEDCLEANPACKSND
FSN Type	New

Contact details of local representative (name, e-mail, telephone, address etc.) *

B Braun Medical Limited
Thorncliffe Park
Sheffield
S35 2PW
Email : recalls.uk@bbraun.com, Tel: 0114 225900

Dear Customer,

We are writing to inform you that B.Braun Medical Limited is initiating a product recall for the batches listed in Appendix C. Our records indicate that your facility may have received products from these potentially affected batches.

This recall is being conducted at the request of the Marketing Authorisation Holder concerning the medicinal product included within the procedure pack.

Please note that our manufacture site has implemented stringent quality control measures during the packaging of these batches. These measures included a 100% inspection process, which ensured that any defective units were identified and removed prior to market release. This process was carried out with the full knowledge and agreement of the Marketing Authorisation Holder, without any objections raised.

For detailed product codes and batch information, please refer to Appendix C. Should you have any questions or require further assistance, please do not hesitate to contact us.

Please follow the instructions as detailed on page 2.

Description of the Product Problem:

The Manufacturer and Marketing Authorisation Holder (MAH) of the Medicinal Product (Beckton Dickinson UK Ltd) have identified issues with the packaging seal of the ChloraPrep applicator.

Therefore, as the MAH, BD have decided to initiate this recall and as they are recalling the potential affected products from the market which include Eighty-Six (86) Procedure Pack Batches as per Appendix C. There is no patient harm reported.

Hazard giving rise to the FSCA:

If the seal on the packaging of the applicator is faulty this may lead to the applicator device becoming contaminated, potentially leading to increased risk of infection for the patient.

Actions to be taken by the Distributor:

1. Please forward this Field Safety Notice (FSN) to any affected customers.
2. Identify and quarantine all affected batches and contact B.Braun Medical Limited at recalls.uk@bbraun.com to organise the return of affected product. Please provide detailed information on product code, batch numbers and quantities.
3. Complete and return the attached form (**Appendix A**) to confirm that you have read and understood the contents of this FSN.

Actions to be taken by the User / Hospital:

1. Review this Field Safety Notice (FSN) in its entirety and ensure all users of the affected devices in your organisation and other concerned persons are informed about this Field Safety Notice (FSN).
2. Please identify all affected, unused product in your stock / inventory.
3. **Do not use the Product / Pack.**
4. **Contact B. Braun Medical Limited to organise the return of the affected products / packs.**
5. Please complete the customer response form (**Appendix B**) to confirm that you have read and understood the contents of this Field Safety Notice (FSN) and send it to your supplier of the products and email a copy to recalls.uk@bbraun.com
6. **Transmission of this Field Safety Notice:**

This notice needs to be passed on to all those who need to be aware within your organisation or to any organisation where the potentially affected Packs have been transferred.

Please pass this notice to other organisations on which this action has an impact.

Please maintain awareness on this notice until all required actions have been taken within your organisation.

Please report all related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback.

B Braun Medical Limited are committed to providing quality products to our customers and ensuring patient safety, and we sincerely apologise for any inconvenience this notice may cause.

If you have any questions regarding this Field Safety Notice and/or a therapy adaptation, please contact:

For technical information
Rachel Kent
Marketing Manager
Infusion and Vascular Access
Rachel.kent@bbraun.com
Tel: 07772 115887

For stock/returns issues
Catherine Clulow
Local Vigilance Officer
recalls.uk@bbraun.com
Tel: 0114 2259155

We apologise for the inconvenience caused by this Field Safety Notice and thank you for your understanding and co-operation.

Yours sincerely,



Sarah Wilson
Regulatory, Quality and Vigilance Senior Manager



Catherine Clulow
Local Vigilance Officer

Appendix A

Distributor Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number*	PHFSN2025-2 & RC/25/01
Product/ Device name	ChloraPrep 1ml Applicators
Product Code(s)	Batch / Serial Number (s)

2. Distributor Details	
Company Name*	
Account Number	
Address*	
Shipping address if different to above	
Contact Name*	
Title or Function	
Telephone number*	
Email*	

3. Distributors / Importers (tick all that apply)	
<input type="checkbox"/>	*I confirm the receipt, the reading and understanding of the Notice.
<input type="checkbox"/>	*I have informed the identified customers of this Notice. Date of Communication:
<input type="checkbox"/>	*I have received confirmation of reply from all identified customers / hospitals.
<input type="checkbox"/>	*I have identified & quarantined the affected devices Add quantity, Sales/Invoice number, Lot.
<input type="checkbox"/>	Neither I nor any of my customers has any affected devices in inventory
Print Name*	
Signature*	
Date *	

Return the completed form to recalls.uk@bbraun.com

Mandatory fields are marked with *

Appendix B

End User (Hospital / Clinic) Reply Form

Please complete this form and return to your supplier and email a copy to Pennine Healthcare

Email: recalls.uk@bbraun.com

4. Field Safety Notice (FSN) information	
FSN Reference number*	PHFSN2025-2 & RC/25/01
Product/ Device name*	ChloraPrep 1ml Applicators
Product Code(s)*	Batch / Serial Number(s)*

5. Customer Details	
Healthcare Organisation Name*	
Organisation Address*	
Department/Unit	
Shipping address if different to above	
Contact Name*	
Title or Function	
Telephone number*	
Email*	

6. Customer action taken on behalf of Healthcare Organisation	
<input type="checkbox"/>	*I confirm receipt of the Notice and that I read and understood its content.
<input type="checkbox"/>	*The information and required actions have been brought to the attention of all relevant users and executed.
<input type="checkbox"/>	*Affected devices have been quarantined and are available for return/ destruction
	Please provide quantity and batch details
<input type="checkbox"/>	Other Action (Define):
<input type="checkbox"/>	I do not have any devices affected.
Print Name*	
Signature*	
Date*	

Return the completed form to recalls.uk@bbraun.com

Mandatory fields are marked with *

Appendix C

Affected Product codes and Lot numbers

UK Distributed Only:

Finished Product Name	Batch Number
BRA17000	06C25
BRA23300	05C25, 24J24, 14K24
BRA35200	11C25, 18J24, 25K24
BRA35300	11C25, 11K24, 30J24
BRA35400	10C25, 29K24, 30J24, 31C25
BRA40600	10C25, 21K24, 28C25
BRA40700	10C25, 18C25
BRA41100	14B25, 19C25, 25K24
BRA41200	06B25
BRA43200	29K24, 04D25
BRA43300	07D25, 15K24, 24J24, 26B25
BRA43400	03C25, 04D25
BRA43500	25B25, 26C25
BRA43600	14K24
BRA43700	07B25, 04D25
BRA43900	04D25, 07C25, 28C25, 30J24
BRA44000	12C25, 27J24, 29C25, 29K24
BRA44100	24K24, 26B25, 28C25
BRA44400	07D25, 11J24, 17B25, 31C25
BRA44500	09K24, 10D25, 18J24, 19B25, 20C25, 21K24
BRA44700	29K24, 10C25
RML133046	07C25
RML133047	13J24, 10B25, 26C25
RML133048	02K24, 05C25, 08K24, 15K24, 27C25
RML133049	06B25, 23J24, 28C25
RML133052	13J24, 07B25
RML133053	01K24, 13B25
RMT552202	23J24, 06C25, 25C25
RMT552203	07C25
RMT552204	17J24, 27B25
RMT552205	25J24, 17C25
RMT552217	24J24, 18K24, 07C25

End of list