

Date: 23rd July 2026

Ref: PHFSCA2026-4 & RC/26/02

Urgent Field Safety Notice / Product Recall Notice

270480 - ChloraPrep 1mL Applicators (See Appendix D for affected lot numbers)

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

Subject: Product Recall – Risk to sterile barrier

Device Type/Affected Product	Various Packs manufactured by B. Braun Medical Limited (Affected item – BD ChloraPrep Clear 1ml Applicator)
Type of action	Identify all affected stock and place into quarantine
B. Braun Medical Limited Ref:	PHFSCA2026-4 & RC/26/02 - JULY
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
Manufacturer SRN	GB-PR-000023775
UDI-DI	5033241PACKEDCLEANPACKSND
FSN Type	New

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

Catherine Clulow
B Braun Medical Ltd
Thorncliffe Park
Sheffield
S35 2PW
Email: recalls.uk@bbraun.com
Tel: 0114 225 9155

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.

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 have identified a potential risk to sterile barrier integrity due to potential open or incomplete seals on the applicator packaging.

Therefore, as the MAH, BD have decided to initiate this recall, and we are recalling the potential affected products from the market which include 278 Procedure Pack Batches as per Appendix C. There is no patient harm reported.

Hazard giving rise to the FSCA:

ChloraPrep 1ml applicators are potentially at risk of a compromised sterile barrier due to open/incomplete seals. This has been identified from customer complaints however, no adverse incidents have been reported.

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 Ltd 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

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 – Cannulation Packs
Marketing Manager
Infusion and Vascular Access
Rachel.kent@bbraun.com
Tel: 07772 115 887

Nikki Elston – Regional Anaesthesia Block Packs'
Product Manager Anaesthesia
nikki.elston@bbraun.com
Tel: 07972 007381

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,



Tendai Chisambara
Medical Affairs Manager (Local Safety Officer)



Catherine Clulow
Local Vigilance Officer

Appendix A

Distributor Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number*	PHFSN2026-4 & RC/26/02 - JULY
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)	
☐	*I confirm the receipt, the reading and understanding of the Notice.
☐	*I have informed the identified customers of this Notice. Date of Communication:
☐	*I have received confirmation of reply from all identified customers / hospitals.
☐	*I have identified & quarantined the affected devices Add quantity, Sales/Invoice number, Lot.
☐	Neither I nor any of my customers have any affected devices in inventory
Print Name*	
Signature*	
Date *	

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

1. Field Safety Notice (FSN) information	
FSN Reference number*	PHFSN2026-4 & RC/26/02 - JULY
Product/ Device name*	ChloraPrep 1ml Applicators
Product Code(s)*	Batch / Serial Number(s)*

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

3. Customer action taken on behalf of Healthcare Organisation	
☐	*I confirm receipt of the Notice and that I read and understood its content.
☐	*The information and required actions have been brought to the attention of all relevant users and executed.
☐	*Affected devices have been quarantined and are available for return.
	Please provide quantity and batch details
☐	Other Action (Define):
☐	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/Batch numbers – JULY 2026

UK Distributed Only:

Finished Product Name	Lot/Batch Number
BRA17000	05H25, 02K25
BRA17100	11H25, 24K25
BRA23300	05C25, 08H25, 11H25, 13L25, 25L25, 12A26, 02C26, 24C26, 15E26
BRA40600	10C25, 15H25, 14H25, 28C25, 22G25, 22H25, 08J25, 02K25, 06L25, 13A26, 09B26, 27B26, 08D26, 30D26
BRA40700	09H25, 10C25, 14H25, 08H25, 15H25, 18C25, 18F25, 03K25, 06L25, 13A26, 09B26, 10C26, 07E26
BRA41100	14B25, 14H25, 19C25, 19F25, 27L25, 22G25, 25H25, 02J25, 03K25, 06L25, 06B26, 11E26, 15F26
BRA41200	08K25, 20L25, 14A26, 10B26
BRA44000	21G25, 29H25, 05J25, 06K25, 07L25, 03M25, 14A26, 10B26, 09D26
BRA44100	14H25, 20F25, 26B25, 23G25, 28H25, 08K25, 19L25, 27K25, 16M25, 15A26, 03B26, 27B26, 30D26, 17F26
BRA44400	01G25, 13H25, 14H25, 17B25, 24F25, 02G25, 07D25, 11F25, 11H25, 13F25, 15H25, 24G25, 21L25, 10D26
BRA44500	08H25, 14H25, 19B25, 28L25, 30F25, 13H25, 15H25, 20C25, 29L25, 30G25, 01G25, 10D25, 11H25, 17H25, 25F25, 08J25, 03L25, 10M25, 22M25, 11B26, 12C26, 13D26, 03E26
BRA44700	28H25, 07A26, 15E26
BRA46200	20B26
BRA47500	02J25, 22J25, 17L25, 02M25, 09A26, 18B26, 31C26, 16F26
BRA47600	04H25, 22J25, 14L25, 01M25, 15D26, 18E26
BRA47700	05H25, 19H25, 23J25, 14K25, 27K25, 08M25, 09A26, 16B26, 09C26, 01D26, 13E26
BRA47800	05H25, 14K25, 19M25
BRA47900	18G25, 04H25, 02J25, 23J25, 03K25
BRA48000	04H25, 04J25, 15K25, 13L25, 19A26, 09C26, 15D26, 29D26
BRA48100	03L25, 07A26, 20C26, 17F26
RML133046	21G25, 06H25, 10J25, 13K25, 17L25, 12A26, 06B26, 03C26, 08D26, 07E26
RML133047	16F25, 26C25, 29G25, 15H25, 08K25, 28K25, 03M25, 07A26, 17B26, 04C26, 25C26, 12E26
RML133048	05C25, 28G25, 17F25, 27C25, 29G25, 12H25, 30J25, 14L25, 28L25, 19M25, 18C26, 02D26, 14E26
RML133049	06B25, 14H25, 22H25, 17L25, 01M25, 19B26, 18C26, 31C26
RML133051	06H25, 03C26, 07E26
RML133052	07B25, 16F25, 28G25, 10K25, 24K25

RML133053	13B25, 22G25, 17G25, 13H25, 01K25, 14L25
RML133054	22H25, 22J25, 25L25, 09C26, 31C26
RMT552202	23J24, 25G25, 06C25, 26G25, 23F25, 24G25, 25C25, 10J25, 25L25, 12A26, 01E26
RMT552203	07C25, 23F25, 24G25, 06H25, 10J25, 13K25, 27L25
RMT552204	17J24, 22G25, 01G25, 23G25, 27B25, 21H25, 10K25, 27K25, 04M25, 08A26, 09C26, 30C26, 05E26
RMT552205	01G25, 08H25, 17C25, 13H25, 02K25, 13L25, 26L25, 13A26, 11C26, 07D26, 06E26
RMT552217	22H25, 10J25, 13K25, 18L25, 02M25, 09A26
GWA-00100	24K25

End of List

Appendix D

Affected ChloroPrep Applicator Lot/Batch Number

5073773	5231297
5073779	5251499
5076832	5255466
5076836	5255470
5080296	5258986
5133559	5258990
5167712	5290981
5191436	5309467
5191438	5314932
5204121	5351461
5204132	

End of List