B. Braun Medical Ltd
Unit 8 Brookdale Road
Thorncliffe Park
Sheffield
S35 2PW
Tel (0114) 225 9000
Fax (0114) 225111 1
www.bbraun.co.uk

Date: 24th August 2026

Customer Notification

Distribute to Wholesaler / Hospital Level

Procedure Pack Label Discrepancy – ChloraPrep 1mL / 1.5mL

Internal Ref: RC/26/03
DMRC Ref: DMRC_PROC-40505255

Dear Customer,

B. Braun Medical Limited is writing to formally notify you of a labelling discrepancy identified on 10 batches of Procedure Packs.

Description of the Issue:

During a review of the product labelling, it was identified that the procedure pack label incorrectly states **ChloraPrep 1mL**, whereas the procedure pack contains **ChloraPrep 1.5mL.**

The discrepancy is therefore limited to the printed product description on the procedure pack label. The ChloraPrep product supplied within the affected procedure packs is the correct ChloraPrep 1.5mL presentation and the printed information on the ChloraPrep 1.5mL applicator is correct.

The affected batches are listed within Appendix A of this notification.

Risk and Impact Assessment:

An assessment of the discrepancy has been completed. Based on the assessment, the issue does not affect the quality, safety, intended performance or functionality of the procedure pack or the ChloraPrep product contained within it.

The ChloraPrep supplied within the affected procedure packs is the intended 1.5mL presentation and has not been substituted, altered or otherwise compromised. The identified issue is specifically a labelling discrepancy relating to the stated volume on the procedure pack label.

There is therefore no identified impact to product quality, safety or performance, and no patient harm or adverse patient impact has been identified as a result of this discrepancy. In addition, there is no impact on the clinical application of the products within the procedure pack as a result of this label discrepancy.

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Regulatory Assessment:

The issue has been assessed in accordance with our established quality and regulatory processes and has been communicated to the Medicines and Healthcare products Regulatory Agency (MHRA) – Defective Medicines Report Centre (DMRC).

Following review, the MHRA (DMRC) has agreed with the customer notification. This notification is therefore being issued to ensure that affected customer/s are formally informed of the discrepancy and can take the appropriate action within their own quality management systems.

Required Customer Action:

Upon receipt of this notification, we request that you:

- Ensure that relevant personnel are made aware of the labelling discrepancy. Where applicable, ensure that the discrepancy is considered during use of the affected procedure packs.
- Distribute this notification to your affected customers and supply chain.
- Continue to use the affected procedure packs in accordance with your established procedures, taking into consideration that the correct ChloraPrep presentation contained within the pack is 1.5mL.
- Notify B.Braun Medical Limited if you identify any additional concerns, discrepancies or patient-related events associated with the affected batches.

Healthcare professionals and service providers should note this notification below before supplying or using the procedure packs.

No product return or quarantine is required solely as a result of this labelling discrepancy.

Corrective and Preventive Actions:

We are initiating appropriate corrective and preventive actions within our quality management system to address the root cause of the labelling discrepancy and prevent recurrence.

These actions will include review of the relevant labelling controls, manufacturing documentation and verification processes associated with the procedure pack. The effectiveness of these actions will be assessed through our established quality system processes.

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Conclusion:

We recognise the importance of accurate and controlled labelling for procedure packs and apologise for any concern or inconvenience this discrepancy may cause.

Following our assessment and regulatory consultation, this issue has been classified as a customer notification. The MHRA (DMRC) has reviewed and agreed with no market action being required, and there is no identified impact to product quality, safety or performance and no identified patient harm resulting from this discrepancy. The shipper label and patient information leaflet (PIL) supplied with each batch are unaffected.

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 notification may cause.

Should you require any further information, please contact us using the details listed below:

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 007 381

Yours sincerely,

Tendai Chisambara
Medical Affairs Manager (Local Safety Officer)

Catherine Clulow
Local Vigilance Officer

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Appendix A

Batch Details: (UK Distributed Only) Procedure Pack Codes	Procedure Pack Batch / Lot Numbers
BRA44400	24F26
BRA44400	30F26
BRA44400	14G26
BRA44400	29G26
RMT552203	21G26
RML133053	21G26
RML133048	23G26
BRA41200	27G26
BRA44700	27G26
BRA44100	28G26

END OF LIST

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Customer Reply Form

1. Customer Notification	
Customer Notification Reference number*	RC/26/03
Customer Notification Date*	24th August 2026
Product/ Device name*	ChloraPrep 1mL / 1.5mL
Product Code(s)	1 - BRA44400, 2 - RMT552203 3 - RML133053 , 4 - RML133048 5 - BRA41200 6 - BRA44700 7 - BRA44100
Batch/Serial Number (s)	1 - 24F26, 2 - 30F26, 3 - 14G26 4 - 29G26, 5 - 21G26, 6 - 23G26 7 - 27G26, 8 - 28G26

2. Customer Details	
Healthcare Organisation Name*	
Organisation Address*	
Department/Unit	
Contact Name*	
Title or Function	
Telephone number*	
Email*	

3. Customer action undertaken on behalf of Healthcare Organisation		
☐	I confirm receipt of the Customer Notification 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.	
☐	I have a query please contact me (e.g. need for replacement of the product).	Customer to enter contact details if different from above and brief description of query
Print Name*		
Signature*		
Date*		

4. Return acknowledgement to sender	
Email	Recalls.uk@bbraun.com
Customer Helpline	0114 225 9155
Postal Address	B.Braun Medical Limited, Thorncliffe Park, S35 2PW
Web Portal	www.bbraun.com
Fax	0114 225 1111
Deadline for returning the customer reply form*	04/09/2026

Mandatory fields are marked with *

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It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN.

Your organisation's reply is the evidence we need to monitor the progress of the corrective actions.