

Date: 8th June, 2026

Ref: PHFSN2026-3 & RC/26/01

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 B. Braun Medical Ltd packs containing affected item – BD ChloraPrep Clear 1ml Applicator |
| Type of action | Identify all affected stock and organise a return to B. Braun Medical Ltd. |
| 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-00023775 |
| 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 Ltd 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 have identified a potential breach of sterility relating to the paper lidding material of the ChloroPrep applicator showing wrinkling.

Therefore, as the MAH, BD have decided to initiate this recall and we are recalling the potential affected products from the market which include 399 Procedure Pack Batches as per Appendix C. There is no patient harm reported.

Hazard giving rise to the FSCA:

ChloroPrep 1ml applicators with paper lidding may present a risk to sterile barrier integrity due to wrinkling of the lidding, which could increase the risk of microbial contamination.

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: 0797 200 738

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* | PHFSN2026-3 & RC/26/01 |
| Product/ Device name | ChloraPrep 1ml Applicators |
| Product Code(s) | Batch / Serial Number (s) |
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| 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 recalls.uk@bbraun.com

| 1. Field Safety Notice (FSN) information | |
|--|----------------------------|
| FSN Reference number* | PHFSN2026-3 & RC/26/01 |
| 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 | |
|---|---|
| <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. 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/Batch numbers

UK Distributed Only:

| Finished Product Name | Lot/Batch Number |
|-----------------------|---|
| BRA17000 | 07L23, 05A24, 26B24, 08D24, 25F24 |
| BRA17100 | 30L23, 15B24, 15C24, 09D24, 08E24, 25F24, 20H24, 03M24, 23A25 |
| BRA17200 | 24K23, 01L23, 18M23, 15A24, 16B24, 12C24, 12D24, 17E24, 04F24, 03G24, 09J24 |
| BRA17300 | 01M23, 19B24, 19C24, 08E24, 28F24, 03J24 |
| BRA17400 | 16L23, 18M23, 23B24, 20C24, 09D24, 13F24 |
| BRA23300 | 07L23, 18M23, 29A24, 19B24, 15D24, 10E24, 11F24, 19G24, 14H24, 27L24, 22A25, 07E25, 06F25, 04G25 |
| BRA35400 | 23D25 |
| BRA40600 | 15E24, 30E24, 05G24, 27L24, 05M24, 30A25, 23D25, 15E25, 07F25 |
| BRA40700 | 05C24, 21C24, 18D24, 07E24, 07F24, 12G24, 08H24, 03J24, 27L24, 07A25, 30A25, 08H25, 15H25, 18C25, 18F25, 23D25, 16E25, 09F25, 08G25 |
| BRA41100 | 24A24, 22B24, 16D24, 20E24, 24G24, 01H24, 30H24, 12L24, 18M24, 19C25, 19F25, 25D25, 19E25, 12F25, 27L25 |
| BRA41200 | 05C24, 18D24, 17E24, 20L24, 06B25, 19F25 |
| BRA43200 | 20B24, 16D24, 05G24, 09A25, 04D25, 19F25, 23E25 |
| BRA43300 | 01G24, 28A25 |
| BRA43400 | 27A25 |
| BRA43500 | 03M24 |
| BRA43600 | 27A25 |
| BRA43700 | 23E24, 24A25 |
| BRA43900 | 06A25 |
| BRA44000 | 21C24, 25D24, 20E24, 13F24, 23G24, 21H24, 29K24, 27L24, 08A25, 19F25, 29C25, 24D25, 16E25, 06F25 |
| BRA44100 | 23A24, 02A24, 24D24, 17E24, 16G24, 29H24, 10J24, 02A24, 30A24, 14H25, 20F25, 26B25, 19F25, 28C25, 24D25, 10F25 |
| BRA44400 | 28C24, 01G25, 13H25, 14H25, 17B25, 24F25, 25F25, 31C25, 02G25, 07D25, 11H25, 13F25, 15H25, 04F25, 11F25 |
| BRA44500 | 08C24, 02D24, 11L24, 11M24, 09A25, 08H25, 14H25, 19B25, 30F25, 13H25, 15H25, 20C25, 30G25, 01G25, 10D25, 11H25, 17H25, 25F25, 19E25, 29E25, 09G25 |
| BRA44700 | 15E25 |
| BRA46200 | 07C24, 30G24 |
| BRA47500 | 30D25 |
| BRA47600 | 01E25 |
| BRA47700 | 02E25 |

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|-----------|---|
| BRA47800 | 01E25 |
| BRA47900 | 02E25, 18G25 |
| BRA48000 | 06E25, 04H25 |
| BRA48100 | 30D25 |
| RML133046 | 20L23, 30A24, 15B24, 15C24, 24D24, 20E24, 07F24, 26F24, 09H24, 10J24, 25L24, 03M24, 23A25, 07E25, 11F25 |
| RML133047 | 27K23, 27L23, 21M23, 10A24, 27B24, 10D24, 24E24, 05F24, 18G24, 12H24, 05L24, 21L24, 23M24, 20A25, 26C25, 29G25, 28D25, 13E25, 27E25, 15G25, 16F25 |
| RML133048 | 02L23, 17L23, 20M23, 05A24, 28B24, 27C24, 19D24, 22E24, 12F24, 25G24, 15H24, 15L24, 02A25, 28A25, 17F25, 27C25, 29G25, 17D25, 14E25, 04F25, 18G25 |
| RML133049 | 14L23, 20M23, 31A24, 23B24, 09D24, 13F24, 30G24, 29H24, 08L24, 04M24, 24A25, 06B25, 14H25, 18F25, 28C25, 30D25, 15E25, 03G25 |
| RML133051 | 30L23, 14B24, 20E24, 03M24 |
| RML133052 | 19K23, 01L23, 30L23, 10A24, 15B24, 25C24, 23E24, 13J24, 04L24, 20M24, 24A25, 07B25, 28G25, 28D25, 12E25, 15G25, 16F25 |
| RML133053 | 04M23, 18A24, 29B24, 08D24, 22E24, 02G24, 15H24, 06L24, 27L24, 02A25, 27A25, 13B25, 22G25, 16D25, 14E25 |
| RML133054 | 19M23, 19A24, 23D24, 07L24, 04M24, 24A25, 02G25 |
| RMT552201 | 17L23, 09H24 |
| RMT552202 | 07L23, 20L23, 08D24, 21E24, 31E24, 17G24, 09H24, 29H24, 04L24, 25L24, 23F25, 24G25, 25C25, 17D25, 06F25, 04G25 |
| RMT552203 | 07L23, 20L23, 19A24, 15B24, 15C24, 09D24, 07F24, 10J24, 23A25, 07C25, 23F25, 24G25, 04F25, 04G25 |
| RMT552204 | 23K23, 24L23, 26K23, 19M23, 17A24, 26B24, 13C24, 24D24, 03F24, 03G24, 09H24, 06J24, 18M24, 17A25, 01G25, 23G25, 27B25, 09E25, 11G25 |
| RMT552205 | 25K23, 17L23, 03L23, 20M23, 25A24, 19C24, 22D24, 09E24, 10F24, 22G24, 16H24, 04J24, 07L24, 26L24, 03A25, 29A25, 01G25, 08H25, 17C25, 22D25, 14E25, 11F25, 07G25 |
| RMT552217 | 15L23, 30A24, 23B24, 24D24, 08E24, 13F24, 17G24, 30G24, 13L24, 04M24, 23A25, 02G25, 07C25 |

Appendix D

Affected ChloroPrep Applicator Lot/Batch Number

| | |
|---------|---------|
| 3159868 | 4040372 |
| 3190805 | 4064041 |
| 3228288 | 4067186 |
| 3233854 | 4099831 |
| 3256418 | 4130874 |
| 3257922 | 4149180 |
| 3273737 | 4162297 |
| 3283056 | 4170706 |
| 3286267 | 4177395 |
| 3289924 | 4204928 |
| 3290280 | 4204929 |
| 3304205 | 4275219 |
| 3306702 | 4291372 |
| 3317604 | 4292282 |
| 3340337 | 4306522 |
| 3340340 | 4306524 |
| 3342376 | 5010338 |
| 4008825 | 5010594 |
| 4040369 | 5035764 |

End of List