

16th January 2023

Ref : FSCA-2023-01-12

## **URGENT Field Safety Corrective Action – Original Perfusor® Line**

Dear Sir or Madam,

The B. Braun Melsungen AG has decided to proactively recall the article/batch combinations of Original Perfusor® Line listed within Appendix 1 in the course of a Field Safety Corrective Action from the market.

### Reason for the Recall

In the course of our Post Market Surveillance activities, we identified the risk for holes and leakages in the listed article batch combinations of Original Perfusor® Line.

The deviation might harbour the risk for the patient of microbial contamination, under supply, open patient access, or air infusion. A potential consequence for the healthcare worker is given by contact to hazardous drugs.

Based on internal controls and available post market data, the effect can be limited to the listed article batches combinations.

In view of the identified risks, we decided to recall all affected devices from the market.

### Actions to be taken

Our records have shown that your institution has received one or more of the affected article batch combinations.

We kindly ask you to initiate the following activities immediately and with priority:

- Review this Field Safety Notice in its entirety and ensure that all users of the above-mentioned product in your organization and other concerned persons are informed about this Field Safety Notice.
- If you are a distributor, please forward this correction notification to your customers.
- Identify, quarantine, and return affected articles.
- Do not use affected devices anymore.
- It is recommended to exchange devices from the above-mentioned batches, which are currently in use.
- Confirm receipt of this information by completing the attached confirmation slip and return this to B. Braun using the contact details provided.

If more information is needed or you require devices for replacement, please contact

For technical information

Ian Parsons

Associate Product Manager & Analyst

ian.parsons@bbraun.com

Tel: 07808 716 079

For stock/returns issues

Catherine Clulow

Team Leader Product Complaints

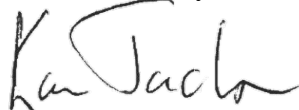
recalls.uk@bbraun.com

Tel: 0114 2259155

Please ensure that all users of the affected product are informed about this safety information in your organization. If you have distributed the products to a third party, please forward a copy of this information or inform the above-mentioned contact person. The Competent Authority MHRA has received a copy of this safety information.

We believe in improving people's health through everything we do. Patient and user safety is our highest priority. Kindly accept our apologies for any inconveniences caused and thank you in advance for your cooperation to resolve this matter quickly

Yours sincerely,



Karen Jackson

Head of Regulatory Affairs, QM and Environmental



Catherine Clulow

Team Leader Product Complaints

**Appendix 1 – List of affected article-batch combinations**

| <b>Article Number</b> | <b>Article Name</b>                     | <b>Batch</b> |
|-----------------------|---|--------------|
| 8722935               | PERFUSOR LINE, PE, LL, 150 CM           | 22C12E8SC6   |
| 8722935               | PERFUSOR LINE, PE, LL, 150 CM           | 22D14E8SC6   |
| 8722935               | PERFUSOR LINE, PE, LL, 150 CM           | 22D30E8SC6   |
| 8722935               | PERFUSOR LINE, PE, LL, 150 CM           | 22F12E8SC6   |
| 8723017               | PERFUSOR LINE, UV-PROTECT, PE, LL,150CM | 22B12E8SC6   |
| 8723017               | PERFUSOR LINE, UV-PROTECT, PE, LL,150CM | 22D08E8SC6   |
| 8723017               | PERFUSOR LINE, UV-PROTECT, PE, LL,150CM | 22D26E8SC6   |
| 8723017               | PERFUSOR LINE, UV-PROTECT, PE, LL,150CM | 22E02E8SC6   |
| 8723017               | PERFUSOR LINE, UV-PROTECT, PE, LL,150CM | 22E10E8SC6   |
| 8723060               | PERFUSOR LINE, PE, LL, 200 CM           | 22B24E8SC6   |
| 8723060               | PERFUSOR LINE, PE, LL, 200 CM           | 22C05E8SC6   |
| 8723060               | PERFUSOR LINE, PE, LL, 200 CM           | 22C11E8SC6   |
| 8723060               | PERFUSOR LINE, PE, LL, 200 CM           | 22C17E8SC6   |
| 8723060               | PERFUSOR LINE, PE, LL, 200 CM           | 22C25E8SC6   |
| 8723060               | PERFUSOR LINE, PE, LL, 200 CM           | 22D01E8SC6   |
| 8723060               | PERFUSOR LINE, PE, LL, 200 CM           | 22D09E8SC6   |
| 8723060               | PERFUSOR LINE, PE, LL, 200 CM           | 22D13E8SC6   |
| 8723060               | PERFUSOR LINE, PE, LL, 200 CM           | 22D16E8SC6   |

Please complete this form and return to  
 Catherine Clulow  
 Fax: 0114 2259141  
 E-mail: [recalls.uk@bbraun.com](mailto:recalls.uk@bbraun.com)

| <b>FEEDBACK FORM</b>  |   |              |
|-----------------------|---|--------------|
| <b>Article Number</b> | <b>Article Name</b>                     | <b>Batch</b> |
| 8722935               | PERFUSOR LINE, PE, LL, 150 CM           | 22C12E8SC6   |
| 8722935               | PERFUSOR LINE, PE, LL, 150 CM           | 22D14E8SC6   |
| 8722935               | PERFUSOR LINE, PE, LL, 150 CM           | 22D30E8SC6   |
| 8722935               | PERFUSOR LINE, PE, LL, 150 CM           | 22F12E8SC6   |
| 8723017               | PERFUSOR LINE, UV-PROTECT, PE, LL,150CM | 22B12E8SC6   |
| 8723017               | PERFUSOR LINE, UV-PROTECT, PE, LL,150CM | 22D08E8SC6   |
| 8723017               | PERFUSOR LINE, UV-PROTECT, PE, LL,150CM | 22D26E8SC6   |
| 8723017               | PERFUSOR LINE, UV-PROTECT, PE, LL,150CM | 22E02E8SC6   |
| 8723017               | PERFUSOR LINE, UV-PROTECT, PE, LL,150CM | 22E10E8SC6   |
| 8723060               | PERFUSOR LINE, PE, LL, 200 CM           | 22B24E8SC6   |
| 8723060               | PERFUSOR LINE, PE, LL, 200 CM           | 22C05E8SC6   |
| 8723060               | PERFUSOR LINE, PE, LL, 200 CM           | 22C11E8SC6   |
| 8723060               | PERFUSOR LINE, PE, LL, 200 CM           | 22C17E8SC6   |
| 8723060               | PERFUSOR LINE, PE, LL, 200 CM           | 22C25E8SC6   |
| 8723060               | PERFUSOR LINE, PE, LL, 200 CM           | 22D01E8SC6   |
| 8723060               | PERFUSOR LINE, PE, LL, 200 CM           | 22D09E8SC6   |
| 8723060               | PERFUSOR LINE, PE, LL, 200 CM           | 22D13E8SC6   |
| 8723060               | PERFUSOR LINE, PE, LL, 200 CM           | 22D16E8SC6   |

*We have received the Field Safety Notice and confirm that we have no remaining products in stock.*

*We have received the Field Safety Notice and confirm that we have quarantined the stock and wish to return the following:*

| <i><b>Product Code</b></i> | <i><b>Quantity to be returned</b></i> | <i><b>Lot/Batch Number</b></i> |
|----------------------------|---------------------------------------|--------------------------------|
|                            |                                       |                                |
|                            |                                       |                                |
|                            |                                       |                                |
|                            |                                       |                                |

*We have not shipped any products affected by this Field Safety Notice to third parties.*

*We have notified our customers who are affected by this recall notice, and we will contact our customers to arrange collection of any affected products for onward return to B Braun Medical Limited.*



**B. Braun Medical Ltd**

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Thornccliffe Park  
Sheffield  
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Fax (0114) 225 111 1  
[www.bbraun.co.uk](http://www.bbraun.co.uk)

*NAME:* .....

*TELEPHONE NUMBER:* .....

*POSITION:* .....

*COMPANY NAME:* .....