B. Braun Medical Ltd

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Date 6th February 2024

Ref: FSCA-2024-01-31

URGENT Field Safety Corrective Action – Original Perfusor® Line

Dear Valued Customer,

The B. Braun Melsungen AG has decided to proactively recall the below referenced batches of Original Perfusor® Line in the course of a Field Safety Corrective Action from the market.

Material Description	Product Code	Batch
PERFUSOR LINE, PVC, LL, 50 CM	8255172	23F20E8SB4
PERFUSOR LINE, PVC, LL, 300 CM	8255253	23E26E8SM3
PERFUSOR LINE, PVC, LL, 300 CM	8255253	23F06E8SM3
PERFUSOR LINE, PVC, LL, 300 CM	8255253	23F12E8SM3
PERFUSOR LINE, PVC, LL, 200 CM	8722862	23E25E8SB5
PERFUSOR LINE, PVC, LL, 200 CM	8722862	23F11E8SB5
PERFUSOR LINE, PVC, LL, 150 CM	8722960	23F12E8SB4
PERFUSOR LINE, PVC, LL, 150 CM	8722960	23E31E8SB5

Reason for the Recall
In the course of our regular post market surveillance activities, we identified the risk, that the male Luer connectors of the above-mentioned article batch combinations show dimensional deviations. This could have the effect, that a tight and safe connection to other products is not possible.

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 given article batch combinations.

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

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Actions to be taken:
Our records have shown that your institution has received the affected articles.

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 articles anymore.
- It is not necessary to exchange devices which are currently in use, other than those from the above-mentioned batches, if you did not experience difficulties during the connection.
- Confirm receipt of this information by completing the attached confirmation slip and return this to B. Braun using the contact details provided.

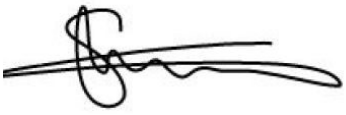
For technical information
Ian Parsons
Associate Product Manager and Analyst
Ian.parsons@bbraun.com
Tel: 07808 716079

for stock/returns issues
Catherine Clulow
Local Vigilance and Project Coordinator
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,



c clulow

Simba Mavhunga
Regulatory and Business Development Manager

Catherine Clulow
Local Vigilance and Project Coordinator

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

FEEDBACK FORM

Material Description	Product Code	Batch
PERFUSOR LINE, PVC, LL, 50 CM	8255172	23F20E8SB4
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PERFUSOR LINE, PVC, LL, 150 CM	8722960	23E31E8SB5

☐ *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:*

Product Code	***Quantity to be returned***	***Lot/Batch Number***

☐ *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.*

NAME: .....

TELEPHONE NUMBER.....

POSITION: ……..

COMPANY NAME……