B. Braun Medical Ltd

Unit 8 Brookdale Road
Thorncliffe Park
Sheffield
S35 2PW
Tel (0114) 225 9000
Fax (0114) 225 1111
www.bbraun.co.uk

27th July 2022

Ref : FSCA 2022-07-25

NHS Logistics Bridgwater
Rosemary Myers
Unit 6 Express Park, Bristol Road
Bridgwater
TA6 4RN

URGENT Field Safety Corrective Action – Perfusor Line PE

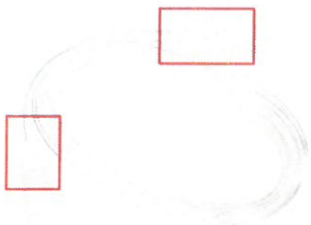
Dear Sir or Madam,

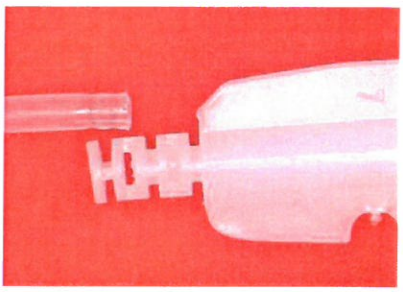
The **B. Braun Melsungen AG** has decided to proactively recall the below batch of Perfusor Line PE in the course of a Field Safety Corrective action from the market.

This FSN addresses **Supply Chain and Clinicians** of affected customers.

Article Number	Article Name	Batch
8723060	PERFUSOR LINE, PE, LL, 200 CM	22C25E8SC6

Reason for the Recall
In the course of our regular post market surveillance activities, we identified the risk, that luer connectors may detach from the Perfusor Line (see pictures). The deviation harbours the risk for the patient of microbial contamination, under supply, open patient access, or air infusion.





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

Based on additional internal controls and the post market observations the effect can limited to the above-mentioned batch. No other batches or products are affected.

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Actions to be taken
Our records have shown that your institution has received the affected article/batch combination.

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 customer.
- 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

Technical Issues	For Stock/Return Issues
Ian Parsons	Catherine Clulow
Associate Product Manager & Analyst	Team Leader Product Complaints
ian.parsons@bbraun.com	productcomplaints.bbmuk@bbraun.com
Tel: 07808 716079	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

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

FEEDBACK FORM

Article Number	Article Name	Batch
8723060	PERFUSOR LINE, PE, LL, 200 CM	22C25E8SC6

☐ *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.....