B. Braun Medical Ltd.
3 Naas Road Industrial Park
Dublin 12
e-mail:
productcomplaints.ie@bbraun.com
http://www.bbraun.com

Date:
January 16, 2023

Ref: FSCA-2023-01-12

URGENT Field Safety Corrective Action – Original Perfusor® Line

Dear Sir/Madam,

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/batch 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 organisation 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 and signing the attached Confirmation Form and return this to B. Braun using the contact details provided.

*Please return the completed form by **Friday 20th January 2023**, or sooner if possible.*

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A member of B. Braun Medical will then be in touch with you to organise collection of any quarantined units. Please enclose a copy of the Confirmation Form with this collection.

Credit will be provided for any affected product returned.

The Health Products Regulatory Authority has been informed of this action.

If more information is needed please contact:

Declan Burke
Hospital Solutions Consultant
B. Braun Medical Ltd
Tel: 086 2529912
Email: declan.burke@bbraun.com

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,

mcguciie Digitally signed by mcguciie Date: 2023.01.16 10:50:17 Z

Ciarán McGuinness
Digital Health & Healthcare Technology Lead

eganroie Digitally signed by eganroie Date: 2023.01.16 10:36:05 Z

Roberta Egan
Regulatory Affairs Manager

Appendix 1 – List of affected article/batch combinations

Article Number	Article Name	Batch
8255067	PERFUSOR LINE, PE, LL, 100 CM	22B02E8SC6
		22C06E8SC6
		22D02E8SC6
		22E09E8SC6
		22F04E8SC6
8722935	PERFUSOR LEITUNG, PE, LL, 150 CM	22B11E8SC6
		22B18E8SC6
		22B23E8SC6
		22D30E8SC6
		22E04E8SC6
		22E20E8SC6
		22E30E8SC6
		22F12E8SC6
8723060	PERFUSOR LINE, PE, LL, 200 CM	22B20E8SC6
		22D06E8SC6
		22E22E8SC6