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

Date:
February 02, 2024

Ref: FSCA-2024-01-31

URGENT Field Safety Corrective Action – Original Perfusor® Line

Dear Sir/Madam,

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.

Article	Article Number	Batch Number
PERFUSOR LINE, PVC, LL, 200 CM	8722862	23E25E8SB5
PERFUSOR LINE, PVC, LL, 200 CM	8722862	23F01E8SB5
PERFUSOR LINE, PVC, LL, 200 CM	8722862	23F13E8SB5
PERFUSOR LINE, PVC, LL, 150 CM	8722960	23E27E8SB5
PERFUSOR LINE, PVC, LL, 150 CM	8722960	23F10E8SB4
PERFUSOR LINE, PVC, LL, 150 CM	8722960	23F12E8SB4

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.

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 articles anymore.
- It is not necessary to exchange devices from the above mentioned batches, which are currently in use, if you did not experience difficulties during the connection.
- 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 Confirmation Form by **Friday 9th February**, or sooner if possible.*

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
Automated Infusion Ecosystem Business Manager
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,

burkdeie Digitally signed by burkdeie
Date: 2024.02.02 13:07:24 Z

Declan Burke
Automated Infusion Ecosystem Business Manager

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Date: 2024.02.02 12:59:25 Z

Roberta Egan
Regulatory Affairs Manager