

B. Braun Melsungen AG
Division Hospital Care
Safety Officer Medical Devices
34209 Melsungen

Our Reference: FSCA-2022-07-25
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Date: Jul 25, 2022

URGENT Field Safety Corrective Action – Perfusor Line PE

Dear Sir or Madam,

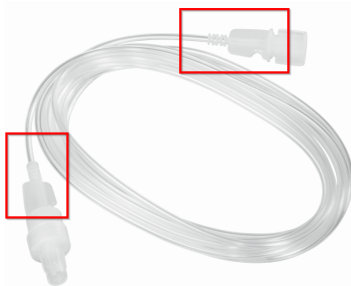
The **B. Braun Melsungen AG** has decided to proactively recall the below batch of Perfusor Line PE in the course of a Field Safety Corrective action from the market.

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 be limited to the above mentioned batch. No other batches or products are affected.

Chairwoman of the Supervisory Board:
Dr. Annette Beller

Executive Board:
Markus Strotmann
(Chairman)
Priv.-Doz. Dr. Stefan Ruppert
Jürgen Stühl

Corporate Office: Melsungen
Register Court:
Local Court Fritzlar
HRB 11 000
WEEE-Reg.-No. DE 42690900

Address:
B. Braun Melsungen AG
Carl-Braun-Straße 1
34212 Melsungen
Germany



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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

Local contact 1

Local contact 2

Name

Title

Email

telephone

Kindly accept our apologies for any inconveniences caused and thank you in advance for your cooperation to resolve this matter quickly.

Yours sincerely,