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

34209 Melsungen

Our reference: FSCA-2023-08-21

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Date: August 23, 2023

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.

Article	Article Number	Batch Number
PERFUSOR LINE, PVC, LL, 300 CM	8255253	23D10E8SM3
PERFUSOR LINE, PVC, LL, 300 CM	8255253	23D14E8SM3
PERFUSOR LEITUNG, PVC, LL, 250 CM	8255490	23D12E8SM3

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.

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 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.

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- 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 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	

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,