

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

34209 Melsungen

Our Reference FSCA-2023-01-12
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Date: Jan 12, 2023

URGENT Field Safety Corrective Action – Original Perfusor® Line

Dear Sir or Madam,

The 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 batches 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 organization 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.

Chairwoman of the Supervisory Board:
Dr. Annette Beller

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

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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- 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

Name

Title

Email

telephone

Local contact 2

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,

Appendix 1 – List of affected article-batch combinations

Article Number	Article Name	Batch
8250146	PERFUSOR LINE, PE, LL, 300 CM	22A27E8SC3
8255067	PERFUSOR LINE, PE, LL, 100 CM	22B02E8SC6
8722935	PERFUSOR LINE, PE, LL, 150 CM	22B09E8SC6
8723010	PERFUSOR LINE, OPAQUE , PE, LL,150CM	22B09E9SC6
8722935	PERFUSOR LINE, PE, LL, 150 CM	22B11E8SC6
8723017	PERFUSOR LINE, UV-PROTECT, PE, LL,150CM	22B12E8SC6
8722935-20	PERFUSOR LINE, PE, LL, 150 CM-CIS	22B14E8SC6
8722935	PERFUSOR LINE, PE, LL, 150 CM	22B15E8SC6
8722935	PERFUSOR LINE, PE, LL, 150 CM	22B18E8SC6
8723060	PERFUSOR LINE, PE, LL, 200 CM	22B20E8SC6
8722935-20	PERFUSOR LINE, PE, LL, 150 CM-CIS	22B21E8SC6
8722935	PERFUSOR LINE, PE, LL, 150 CM	22B22E8SC6
8722935	PERFUSOR LINE, PE, LL, 150 CM	22B23E8SC6
8723060	PERFUSOR LINE, PE, LL, 200 CM	22B24E8SC6
8723060	PERFUSOR LINE, PE, LL, 200 CM	22B25E8SC6
8272565	PERFUSOR LINE, PE, LL, 250 CM	22C03E8SC3
8723026	PERFUSOR LINE,PE,MAGENTA TUBE,LL,200cm	22C03E8SC6
8250146	PERFUSOR LINE, PE, LL, 300 CM	22C04E8SC3
8723018	PERFUSOR LINE, UV-PROT. PE, LL, 200CM	22C04E8SC6
8250146	PERFUSOR LINE, PE, LL, 300 CM	22C05E8SC3
8723060	PERFUSOR LINE, PE, LL, 200 CM	22C05E8SC6
8272565	PERFUSOR LINE, PE, LL, 250 CM	22C06E8SC3
8255067	PERFUSOR LINE, PE, LL, 100 CM	22C06E8SC6
8723017	PERFUSOR LINE, UV-PROTECT, PE, LL,150CM	22C07E8SC6
8722935	PERFUSOR LINE, PE, LL, 150 CM	22C09E8SC6
8723060	PERFUSOR LINE, PE, LL, 200 CM	22C11E8SC6
8722935	PERFUSOR LINE, PE, LL, 150 CM	22C12E8SC6
8723060	PERFUSOR LINE, PE, LL, 200 CM	22C17E8SC6
8929055E	PERFUS. PE 1x2 MAGENTA LL 2,00M NST BULK	22C19E0SC3
8723018	PERFUSOR LINE, UV-PROT. PE, LL, 200CM	22C19E8SC6
8723017-20	PERFUSOR LINE,UV-PROTECT,PE,LL,150CM-CIS	22C21E8SC6
8723024	PERFUSOR LINE, PE, GREEN TUBE, LL, 200CM	22C24E8SC6
8723060	PERFUSOR LINE, PE, LL, 200 CM	22C25E8SC6
8723060	PERFUSOR LINE, PE, LL, 200 CM	22C27E8SC6
8723018	PERFUSOR LINE, UV-PROT. PE, LL, 200CM	22C29E8SC6
8723021	PERFUSOR LINE, PE, BLUE TUBE, LL, 200CM	22C30E8SC6
8723017-20	PERFUSOR LINE,UV-PROTECT,PE,LL,150CM-CIS	22C30E8SC6
8723060	PERFUSOR LINE, PE, LL, 200 CM	22C31E8SC6
8272565	PERFUSOR LINE, PE, LL, 250 CM	22D01E8SC3

Article Number	Article Name	Batch
8723060	PERFUSOR LINE, PE, LL, 200 CM	22D01E8SC6
8255067	PERFUSOR LINE, PE, LL, 100 CM	22D02E8SC6
8723060	PERFUSOR LINE, PE, LL, 200 CM	22D03E8SC6
8723025	PERFUSOR LINE,PE,MAGENTA TUBE,LL,150cm	22D04E8SC6
8723060	PERFUSOR LINE, PE, LL, 200 CM	22D06E8SC6
8723017	PERFUSOR LINE, UV-PROTECT, PE, LL,150CM	22D08E8SC6
8723060	PERFUSOR LINE, PE, LL, 200 CM	22D09E8SC6
8722935	PERFUSOR LINE, PE, LL, 150 CM	22D10E8SC6
8722935	PERFUSOR LINE, PE, LL, 150 CM	22D12E8SC6
8723060	PERFUSOR LINE, PE, LL, 200 CM	22D13E8SC6
8722935	PERFUSOR LINE, PE, LL, 150 CM	22D14E8SC6
8723060	PERFUSOR LINE, PE, LL, 200 CM	22D16E8SC6
8722935	PERFUSOR LINE, PE, LL, 150 CM	22D18E8SC6
8250146	PERFUSOR LINE, PE, LL, 300 CM	22D19E8SC3
8722935-20	PERFUSOR LINE, PE, LL, 150 CM-CIS	22D19E8SC6
8723060	PERFUSOR LINE, PE, LL, 200 CM	22D21E8SC6
8272565	PERFUSOR LINE, PE, LL, 250 CM	22D25E8SC3
8723017	PERFUSOR LINE, UV-PROTECT, PE, LL,150CM	22D26E8SC6
8250146	PERFUSOR LINE, PE, LL, 300 CM	22D27E8SC3
8255067	PERFUSOR LINE, PE, LL, 100 CM	22D27E8SC6
8723060	PERFUSOR LINE, PE, LL, 200 CM	22D28E8SC6
8722935	PERFUSOR LINE, PE, LL, 150 CM	22D30E8SC6
8723017	PERFUSOR LINE, UV-PROTECT, PE, LL,150CM	22E02E8SC6
8722935	PERFUSOR LINE, PE, LL, 150 CM	22E04E8SC6
8722935	PERFUSOR LINE, PE, LL, 150 CM	22E06E8SC6
8272565	PERFUSOR LINE, PE, LL, 250 CM	22E09E8SC3
8255067	PERFUSOR LINE, PE, LL, 100 CM	22E09E8SC6
8723017	PERFUSOR LINE, UV-PROTECT, PE, LL,150CM	22E10E8SC6
8250146	PERFUSOR LINE, PE, LL, 300 CM	22E11E8SC3
8723060	PERFUSOR LINE, PE, LL, 200 CM	22E12E8SC6
8723026	PERFUSOR LINE,PE,MAGENTA TUBE,LL,200cm	22E16E8SC6
8722935-20	PERFUSOR LINE, PE, LL, 150 CM-CIS	22E18E8SC6
8722935	PERFUSOR LINE, PE, LL, 150 CM	22E20E8SC6
8723060	PERFUSOR LINE, PE, LL, 200 CM	22E22E8SC6
8722935	PERFUSOR LINE, PE, LL, 150 CM	22E24E8SC6
8723017-20	PERFUSOR LINE,UV-PROTECT,PE,LL,150CM-CIS	22E26E8SC6
8722935	PERFUSOR LINE, PE, LL, 150 CM	22E28E8SC6
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8255067	PERFUSOR LINE, PE, LL, 100 CM	22F04E8SC6
8722935	PERFUSOR LINE, PE, LL, 150 CM	22F06E8SC6

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Article Number	Article Name	Batch
8722935	PERFUSOR LINE, PE, LL, 150 CM	22F12E8SC6