

Our Reference FSCA-2022-12-07

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URGENT Field Safety Corrective Action – PROSET INFUSION SET - leakage

Dear Sir or Madam,

The B. Braun Melsungen AG has decided to proactively recall defined article/batch combinations of PROSET INFUSION SETs with Discofix C in the course of a Field Safety Corrective Action from the market:

Article Number	Article Name	Batch
4087930	PROSET DISCOFIX C-MANIFOLD SET 3-GANG	22K08F0000
4168894	PROSET CERTOFIX QUATTRO S830	22L19A8001
4180038	PROSET INTRAFIX PRIMELINE	22K05F0000
4180120	PROSET DISCOFIX C MANIFOLD 3-GANG	22H30F0000
4183450	PROSET INTRAFIX SAFESET	22H30F0000
4183925	PROSET ORIGINAL PERFUSOR LINE	22H31F0000
4183927	PROSET INFUSIONS-SET M. 0,2MM	22K07F0000
4183945	PROSET INFUSION-SET	22K05F0000
4185687	PROSET INFUSION SET FOR INFUSION THERAPY	22K06F0000
4187006	PROSET INTRAFIX SAFESET	22K01F0000
4187008	PROSET INTRAFIX PRIMELINE	22K05F0000
4187010	PROSET INTRAFIX PRIMELINE	22H31F0000
4187527	PROSET DISCOFIX C-STOPCOCK-SET	22K07F0000
4187879	PROSET DISCOFIX C-MANIFOLD SET 3-GANG	22H30F0000
4187879	PROSET DISCOFIX C-MANIFOLD SET 3-GANG	22K14F0000
4187911	PROSET DISCOFIX C-STOPCOCK-SET	22K14F0000
4188110	PROSET INTRAFIX SAFESET	22H26F0000
4188110	PROSET INTRAFIX SAFESET	22H30F0000
4188114	PROSET INTRAFIX SAFESET	22H31F0000

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

Article Number	Article Name	Batch
4188116	PROSET INTRAFIX SAFESET	22K06F0000
4188120	PROSET INTRAFIX SAFESET	22H29F0000
4188120	PROSET INTRAFIX SAFESET	22K08F0000
4800362	PROSET VITREKTOMIE SET	22L05A7001
4182189SP	PROSET DISCOFIX C 3GANG/SPACELINE	22K02F0000

Reason for the Recall

In the course of our Post Market Surveillance activities, we identified the risk for leakages on the Discifix C in the above mentioned article batch combinations.

The potential leakage is indicated on the picture below:



Whilst no injuries to patients, users, or third parties have been reported to date, 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.

In view of the identified risks, we decided to recall all affected devices from the market.

Based on internal controls and available post market data, the effect can be limited to the above mentioned article batches combinations. No other batches or products are affected.

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.
- 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,