B|BRAUN

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

34209 Melsungen

Our Reference FSCA-2023-01-11

Contact: Dr. Stephan Krause

Fon: +49 5661 71-1339
Fax: +49 5661 71-
Email: stephan.krause@bbraun.com
Internet: http://www.bbraun.com

Date: Jan 11, 2023

URGENT Field Safety Corrective Action – ProSet Intrafix® SafeSet

Dear Sir or Madam,

The B. Braun Melsungen AG has decided to proactively recall the below listed article/batch combinations of ProSet Intrafix® SafeSet in the course of a Field Safety Corrective Action from the market:

Article Number	Article Name	Batch
4187009	ProSet Intrafix® SafeSet	21D28F0000
4187009	ProSet Intrafix® SafeSet	22G27F0000
4187009	ProSet Intrafix® SafeSet	22K17F0000

Reason for the Recall
In the course of our Post Market Surveillance activities, we identified the risk for leakages within the mentioned article of the indicated batches.

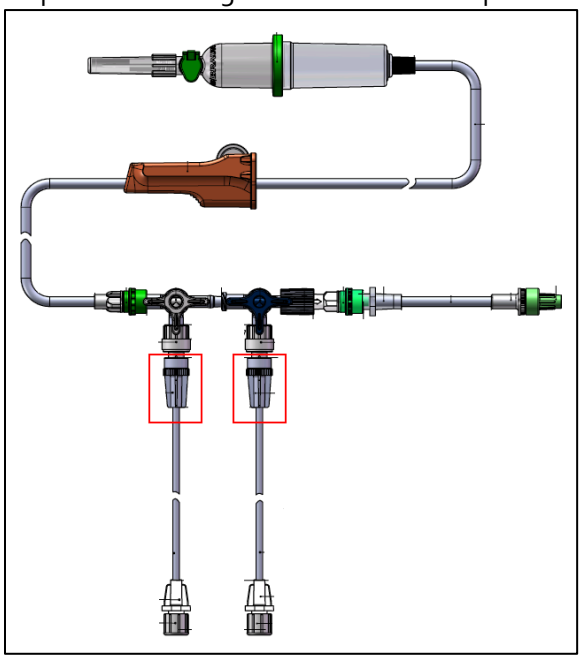
The deviation might harbour the risk for the patient of microbial contamination, under supply, open patient access, or air infusion. A potential consequence for the healthcare worker is given by contact to hazardous drugs.

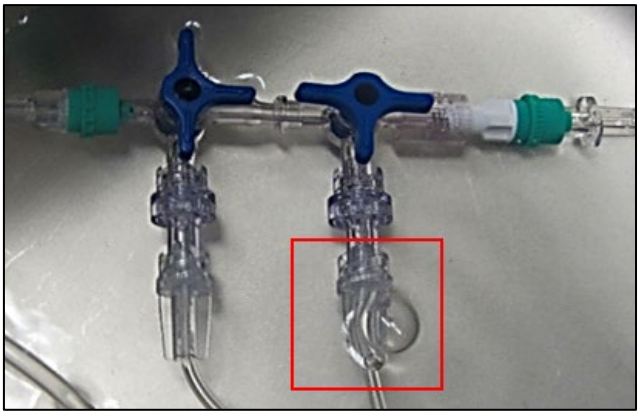
Based on the current state of the root-cause analysis and post market data, the effect can be limited to the above mentioned article batches combinations.

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

B|BRAUN

The potential leakage is indicated on the picture below:





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

Local contact 2

. . .

B|BRAUN

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,