

Your reference: FSCA-2023-12-20

Contact: Dr. Stephan Krause

Fon: +49 5661 71-1339

Fax:

Email: stephan.krause@bbraun.comInternet: <http://www.bbraun.com>

Date: December 20, 2023

URGENT Field Safety Corrective Action– Introducer Needle – hub detached

Dear Sir or Madam,

The B.Braun Melsungen AG has decided to proactively recall the defined article/batch combination of the *Introducer Needle, Pencan* containing the Introducer Needle as listed below, in the course of a Field Safety Corrective Action from the market.

Reason for the Information

In the course of Post Market Surveillance activities and our internal quality checks, we identified that in a subset of the defined article batch combinations the gluing between the hub and the steel cannula might disconnect during use.

The deviation might harbor the risk of Hazards of microbial contamination, foreign matter entry, malpositioning, mechanical hazards and delay of therapy ranging from no clinical effect up to serious patient injury.

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

The effect can be limited to the defined 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.

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

- 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.
- 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, please contact

Sara Lorentzen or Winnie Iisager by Email:

Sara.lorentzen@bbarun.com

Winnie.iisager@bbraun.com

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,

B. Braun

Article Number	Article Name	Batch
4502043-13	PENCAN 25GX3 1/2" (88MM)M.FK-EU/AP/SA	23E24H8B05
4502116-13	PENCAN 25GX4" (103MM) M. FK-EU/AP/SA	23E30H8B04
4505000-13	FUEHRUNGSK. 20GX1 3/8" (35MM)-EU/AP/SA	22G28G8841