

B. Braun Melsungen AG  
Safety Officer Medical Devices  
34209 Melsungen

Your reference: FSCA-2023-12-20

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Internet: <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, ProSets Pencan** and **Pencan** containing the Introducer Needle as listed in the ANNEX 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:

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

- 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.
- 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

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,

Article Number	Article Name	Batch
4458966	PROSET PENCAN G25	23D21A8001
4458966	PROSET PENCAN G25	23E04A8001
4458966	PROSET PENCAN G25	23G03A8001
4458966	PROSET PENCAN G25	23L23A8001
4459016	PROSET PENCAN G25	23E08A8001
4459016	PROSET PENCAN G25	23G12A8001
4459035	PROSET PENCAN G25	23F15A8001
4459035	PROSET PENCAN G25	23K12A8001
4471791	PROSET PENCAN G25	23H02A8001
4477802	PROSET PENCAN G25	23D20A8001
4477802	PROSET PENCAN G25	23G04A8001
4477802	PROSET PENCAN G25	23L20A8001
4477883	PROSET PENCAN G25	23F07A8001
4477883	PROSET PENCAN G25	23F27A8001
8850322	PROSET PENCAN G25	23E03A8001
8850322	PROSET PENCAN G25	23F27A8001
8850322	PROSET PENCAN G25	23K28A8001
8850326	PROSET PENCAN G25	23E10A8001
8850326	PROSET PENCAN G25	23G03A8001
8850326	PROSET PENCAN G25	23K21A8001
8850361	PROSET PENCAN G25	23E30A8001
8850361	PROSET PENCAN G25	23F07A8001
8850361	PROSET PENCAN G25	23G12A8001
8850361	PROSET PENCAN G25	23H08A8001
8850361	PROSET PENCAN G25	23K29A8001
8850380	PROSET PENCAN G25	23F13A8001
8850380	PROSET PENCAN G25	23H09A8001
8850380	PROSET PENCAN G25	23L24A8001
8850396	PROSET PENCAN G25	23E02A8001
8850396	PROSET PENCAN G25	23F29A8001
8850396	PROSET PENCAN G25	23G07A8001
8850416	PROSET PENCAN G25	23E02A8001
8850416	PROSET PENCAN G25	23G03A8001
8850416	PROSET PENCAN G25	23L18A8001
8850474	PROSET PENCAN G25	23E17A8001
8850474	PROSET PENCAN G25	23F21A8001
8850474	PROSET PENCAN G25	23K18A8001
8850474	PROSET PENCAN G25	23L05A8001

8850474	PROSET PENCAN G25	23L17A8001
8850478	PROSET PENCAN G25	23E05A8001
8850478	PROSET PENCAN G25	23F23A8001
8850478	PROSET PENCAN G25	23H04A8001
8850495	PROSET PENCAN G25	23F16A8001
8850495	PROSET PENCAN G25	23G05A8001
8850501	PROSET PENCAN G25	23E17A8001
8850501	PROSET PENCAN G25	23F27A8001
8850552	PROSET PENCAN G25	23E17A8001
8850552	PROSET PENCAN G25	23F07A8001
8850552	PROSET PENCAN G25	23K06A8001
8851403	PROSET PENCAN G25	23E11A8001
8851403	PROSET PENCAN G25	23G05A8001
4451226S	PROSET PENCAN SAFETY G25	23F29A8001
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