B. Braun Medical Ltd.
3 Naas Road Industrial Park
Dublin 12
e-mail:
productcomplaints.ie@bbraun.com
http://www.bbraun.com

Date:
December 21, 2023

Ref: FSCA-2023-12-20

URGENT Field Safety Corrective Action

Introducer Needle – hub detached

Dear Sir/Madam,

B. Braun Melsungen AG has decided to proactively recall the defined article/batch combinations 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 harbour 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/batch 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 organisation 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 and signing the attached Confirmation Form and return this to B. Braun using the contact details provided.

Please return the completed form as soon as possible.

A member of B. Braun Medical will then be in touch with you to organise collection of any quarantined units. Please enclose a copy of the Confirmation Form with this collection.

Credit will be provided for any affected product returned.

The Health Products Regulatory Authority has been informed of this action.

If more information is needed please contact:

Rob Egan
Strategic Partnership Lead
B. Braun Medical Ltd
Tel: 086 2606017
Email: rob.egan@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,

egarobie Digitally signed by egarobie Date: 2023.12.21 11:53:41 Z

Rob Egan
Strategic Partnership Lead

eganroie Digitally signed by eganroie Date: 2023.12.21 09:46:54 Z

Roberta Egan
Regulatory Affairs Manager

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ANNEX – List of affected article/batch combinations

Article Number	Article Name	Batch
4459016	PROSET PENCAN G25	23E08A8001
4459016	PROSET PENCAN G25	23G12A8001
4459035	PROSET PENCAN G25	23F15A8001
4459035	PROSET PENCAN G25	23K12A8001
4502043-13	PENCAN 25GX3 1/2" (88MM)M.FK-EU/AP/SA	23E24H8B05
4505000-13	FUEHRUNGSK. 20GX1 3/8" (35MM)-EU/AP/SA	22G28G8841