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

Date:
January 10, 2023

Ref: FSCA-2023-01-06

URGENT Field Safety Corrective Action – Infusomat Space Transfusion Line – leakage

Dear Sir/Madam,

B. Braun Melsungen AG has decided to proactively recall defined article/batch combinations of Infusomat Space Transfusion Lines in the course of a Field Safety Corrective Action from the market:

Article Number	Article Name	Batch
8270066SP-01	INF.SP.LINE,TRANS,PVC,LL,250CM-EU	22G03E8ST5
8270066SP-01	INF.SP.LINE,TRANS,PVC,LL,250CM-EU	22H25E8ST5

Reason for the Recall
In the course of our post market surveillance activities, we identified the risk for leakages on the above mentioned article/batch combinations. The potential leakage is located between the tube and the patients' Luer connector as indicated on the picture below:

Whilst no serious 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.

In view of the identified risks, we decided to recall the above listed devices from the market.

Based on internal controls and available post market data, the effect can be limited to the above mentioned article/batch combinations.

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.
- It is recommended to exchange devices from the above mentioned batches, which are currently in use.
- 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 by **Friday 13th January 2023**, or sooner if 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:

Declan Burke
Hospital Solutions Consultant
B. Braun Medical Ltd
Tel: 086 2529912
Email: declan.burke@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,

mcguciie Digitally signed by mcguciie Date: 2023.01.10 12:32:18 Z

Ciarán McGuinness
Digital Health & Healthcare Technology Lead

eganroie Digitally signed by eganroie Date: 2023.01.10 12:16:19 Z

Roberta Egan
Regulatory Affairs Manager