B. Braun Medical Ltd

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10th January 2023

Ref : FSCA-2023-01-06 STK/AS

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

Dear Sir or Madam,

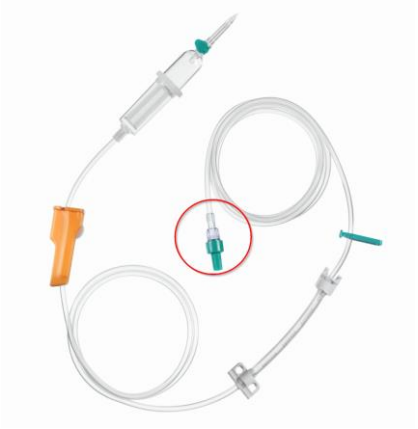
The B. Braun Melsungen AG has decided to proactively recall defined article batch combinations of Infusomat Space Transfusion Lines in the course of a Field Safety Corrective Action from the market:

Article Number	Article Name	Batch
8270066SP-01	INF.SP.LINE,TRANS,PVC,LL,250CM-EU	22F19E8ST5
8270066SP-01	INF.SP.LINE,TRANS,PVC,LL,250CM-EU	22G01E8ST5
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 batches 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 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

For Technical Issues	For stock/returns Issues
Kieren Bruce	Catherine Clulow
Associate Sales Specialist	Team Leader Product Complaints
Kieren.bruce@bbraun.com	recalls.uk@bbraun.com.
Tel: 07966 281 667	Tel : 0114 2259155

Please ensure that all users of the affected product are informed about this safety information in your organization. If you have distributed the products to a third party, please forward a copy of this information or inform the above-mentioned contact person. The Competent Authority MHRA has received a copy of this safety information.

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,

Karen Jackson
Head of Regulatory Affairs, QM and Environmental

Catherine Clulow
Team Leader Product Complaints

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Please complete this form and return to
Catherine Clulow
Fax: 0114 2259141
E-mail: recalls.uk@bbraun.com

FEEDBACK FORM

Article Number	Article Name	Batch
8270066SP-01	INF.SP.LINE,TRANS,PVC,LL,250CM-EU	22F19E8ST5
8270066SP-01	INF.SP.LINE,TRANS,PVC,LL,250CM-EU	22G01E8ST5
8270066SP-01	INF.SP.LINE,TRANS,PVC,LL,250CM-EU	22G03E8ST5
8270066SP-01	INF.SP.LINE,TRANS,PVC,LL,250CM-EU	22H25E8ST5

☐ *We have received the Field Safety Notice and confirm that we have no remaining products in stock.*

☐ *We have received the Field Safety Notice and confirm that we have quarantined the stock and wish to return the following:*

Product Code	*Quantity to be returned*	*Lot/Batch Number*

☐ *We have not shipped any products affected by this Field Safety Notice to third parties.*

☐ *We have notified our customers who are affected by this recall notice and we will contact our customers to arrange collection of any affected products for onward return to B Braun Medical Limited.*

NAME: .....

TELEPHONE NUMBER: .....

POSITION: .....

COMPANY NAME: .....