B. Braun Medical Ltd

Unit 8 Brookdale Road
Thorncliffe Park
Sheffield
S35 2PW
Tel (0114) 225 9000
Fax (0114) 225 111 1
www.bbraun.co.uk

8th February 2022

Ref : FSCA 2022-02-07 STK/AS

Urgent FIELD SAFETY NOTICE – Infusomat® Space Line (Transfusion)

Dear Sir or Madam,

The B. Braun Melsungen AG has decided to proactively recall the below batches of Infusomat® Space Line (Transfusion) 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	21F23E8ST5 21F25E8ST5 21G16E8ST5 21G17E8ST5

Reason for the Recall

In the course of our post market surveillance activities we identified that the gluing connection between tube and patient connector might be inadequate. Due to temporary deviations in the production, the glue was supplied insufficiently, resulting in leakage of the device between patient connector and tube.

This might harbour the theoretical risk for microbial contamination, under supply, open patient access or air infusion.
Based on the identified risks, we decided to proactively recall all affected devices from the market.

The effect is limited to the above mentioned batches. No other batches or products are affected.

Actions to be taken

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 customer.
- 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.

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If more information is needed, please contact

For Technical Issues
Ben Huckle
Product Manager
ben.huckle@bbraun.com
Tel 07972 007338

For Stock/Returns Issues
Catherine Clulow
Team Leader Product Complaints
productcomplaints.bbmuk@bbraun.com
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 apologise for any inconvenience this may cause and thank you very much for your support.

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: productcomplaints.bbmuk@bbraun.com

FEEDBACK FORM

Article Number	Article Name	Batch
8270066SP-01	INF.SP.LINE,TRANS,PVC,LL,250CM-EU	21F23E8ST5 21F25E8ST5 21G16E8ST5 21G17E8ST5

☐ *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……