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

TO WHOM IT MAY CONCERN

Date:
February 08, 2022

Ref: FSCA 2022-02-07 STK/AS

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

Dear Sir/Madam,

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 the tube and patient connector might be inadequate. Due to temporary deviations in production, the glue was supplied insufficiently, resulting in leakage of the device between the 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 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 by **Friday 11th February 2022**, 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:

Ciarán McGuinness
Digital Health & Healthcare Technology Lead
B. Braun Medical Ltd
Tel: 086- 2588019
Email: ciaran.mcguinness@bbraun.com

We appreciate your immediate attention and apologise for any inconvenience caused.

Yours sincerely,

mcguciie Digitally signed by mcguciie Date: 2022.02.08 12:43:52 Z

Ciarán McGuinness
Digital Health & Healthcare Technology Lead

eganroie Digitally signed by eganroie Date: 2022.02.08 12:37:54 Z

Roberta Egan
Regulatory Affairs Manager