

**B. Braun Melsungen AG**  
**Division Hospital Care**  
**Safety Officer Medical Devices**

34209 Melsungen

Our reference: FSCA 2022-02-07 STK/AS

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Date: February 07, 2022

TO WHOM IT MAY CONCERN

## 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:

**Chairwoman of the Supervisory Board:**  
Dr. Annette Beller

**Executive Board:**  
Dr. Meinrad Lugan  
(Chairman)  
Priv.-Doz. Dr. Stefan Ruppert  
Jürgen Stihl

**Corporate Office: Melsungen**  
Register Court:  
Local Court Fritzlar  
HRB 11 000  
WEEE-Reg.-No. DE 42690900

**Address:**  
B. Braun Melsungen AG  
Carl-Braun-Straße 1  
34212 Melsungen  
Germany



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- 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.

If more information is needed, please contact

Local contact 1

Local contact 2

Name

Title

Email

telephone

Kindly accept our apologies for any inconveniences.

Yours sincerely,