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Date:
February 01, 2023

Ref: FSN-2023-01-20

URGENT Field Safety Notice – Infusomat Space Transfusion Line – leakage

Dear Sir/Madam,

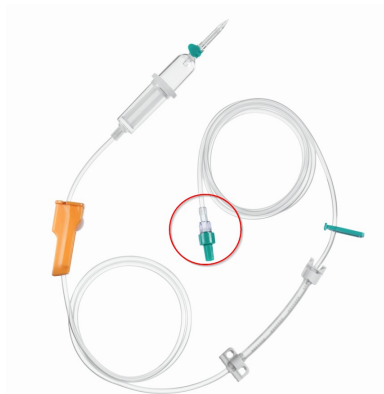
B. Braun Melsungen AG has decided to proactively inform all customers of potential quality issues with Infusomat Space Transfusion Lines in the course of a Field Safety Notice:

| Article Number | Article Name | Batch |
|----------------|-----------------------------------|----------------|
| 8270066SP-01 | INF.SP.LINE,TRANS,PVC,LL,250CM-EU | See Appendix I |

Reason for the Recall

In the course of our Post Market Surveillance activities and internal controls, we identified quality issues specifically referring to the gluing connection between the tube and the patients' Luer connector as indicated on the picture below. In clinical practice this issue may be observed as leakage. They do occur discontinuously and some batches are more affected than others.

Due to the discontinuous occurrence of leakages, B. Braun has already recalled 8 batches in two separate actions from the market in recent months (FSCA-2023-01-06 and FSCA 2022-02-07). Subsequently, the overall remaining risk has been reviewed and balanced against the benefits, including market supply and treatment opportunities with transfusion lines, and has been found to be positive. Out of caution it has been decided to proactively inform all customers of potential quality issues with Infusomat Space Transfusion Lines in the course of a Field Safety Notice.



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.

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.

- Continue currently ongoing treatment with affected devices.
- Treatment with the affected article is possible. However, please observe the connection between tube and patient connector during priming of the line for leakage. In case of a leakage, please change the line and file a complaint with B. Braun.
- Mechanical stress from repeated movement, or similar, at the Luer might lead to a delayed leakage. Therefore repeatedly observe for leakage during the entire usage of the product.
- If you can switch from pump-driven treatment to gravity-treatment, you also may want to consider the opportunity of using alternative products designed for gravity transfusion treatment.

- 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 ***Tuesday 7th February 2023***, or sooner if possible.

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,

Ciarán McGuinness
Digital Health & Healthcare Technology Lead

Roberta Egan
Regulatory Affairs Manager

APPENDIX I

| Article Number | Article Name | Batch |
|-----------------------|-----------------------------------|--------------|
| 8270066SP-01 | INF.SP.LINE,TRANS,PVC,LL,250CM-EU | 22M07E8ST5 |
| 8270066SP-01 | INF.SP.LINE,TRANS,PVC,LL,250CM-EU | 22L25E8ST5 |
| 8270066SP-01 | INF.SP.LINE,TRANS,PVC,LL,250CM-EU | 22L12E8ST5 |
| 8270066SP-01 | INF.SP.LINE,TRANS,PVC,LL,250CM-EU | 22L04E8ST5 |
| 8270066SP-01 | INF.SP.LINE,TRANS,PVC,LL,250CM-EU | 22K07E8ST5 |
| 8270066SP-01 | INF.SP.LINE,TRANS,PVC,LL,250CM-EU | 22K03E8ST5 |
| 8270066SP-01 | INF.SP.LINE,TRANS,PVC,LL,250CM-EU | 22G11E8ST5 |
| 8270066SP-01 | INF.SP.LINE,TRANS,PVC,LL,250CM-EU | 22C08E8ST5 |
| 8270066SP-01 | INF.SP.LINE,TRANS,PVC,LL,250CM-EU | 22C18E8ST5 |
| 8270066SP-01 | INF.SP.LINE,TRANS,PVC,LL,250CM-EU | 22A29E8ST5 |
| 8270066SP-01 | INF.SP.LINE,TRANS,PVC,LL,250CM-EU | 22A11E8ST5 |
| 8270066SP-01 | INF.SP.LINE,TRANS,PVC,LL,250CM-EU | 22A04E8ST5 |
| 8270066SP-01 | INF.SP.LINE,TRANS,PVC,LL,250CM-EU | 21M20E8ST5 |
| 8270066SP-01 | INF.SP.LINE,TRANS,PVC,LL,250CM-EU | 21M21E8ST5 |
| 8270066SP-01 | INF.SP.LINE,TRANS,PVC,LL,250CM-EU | 21M18E8ST5 |
| 8270066SP-01 | INF.SP.LINE,TRANS,PVC,LL,250CM-EU | 21M04E8ST5 |
| 8270066SP-01 | INF.SP.LINE,TRANS,PVC,LL,250CM-EU | 21L24E8ST5 |
| 8270066SP-01 | INF.SP.LINE,TRANS,PVC,LL,250CM-EU | 21G09E8ST5 |
| 8270066SP-01 | INF.SP.LINE,TRANS,PVC,LL,250CM-EU | 21F07E8ST5 |
| 8270066SP-01 | INF.SP.LINE,TRANS,PVC,LL,250CM-EU | 21E19E8ST5 |
| 8270066SP-01 | INF.SP.LINE,TRANS,PVC,LL,250CM-EU | 21E03E8ST5 |
| 8270066SP-01 | INF.SP.LINE,TRANS,PVC,LL,250CM-EU | 21D21E8ST5 |
| 8270066SP-01 | INF.SP.LINE,TRANS,PVC,LL,250CM-EU | 21C25E8ST5 |
| 8270066SP-01 | INF.SP.LINE,TRANS,PVC,LL,250CM-EU | 21C19E8ST5 |
| 8270066SP-01 | INF.SP.LINE,TRANS,PVC,LL,250CM-EU | 21A15E8ST5 |
| 8270066SP-01 | INF.SP.LINE,TRANS,PVC,LL,250CM-EU | 20M30E8ST5 |
| 8270066SP-01 | INF.SP.LINE,TRANS,PVC,LL,250CM-EU | 20M27E8ST5 |
| 8270066SP-01 | INF.SP.LINE,TRANS,PVC,LL,250CM-EU | 20M26E8ST5 |
| 8270066SP-01 | INF.SP.LINE,TRANS,PVC,LL,250CM-EU | 20K07E8ST5 |
| 8270066SP-01 | INF.SP.LINE,TRANS,PVC,LL,250CM-EU | 20K04E8ST5 |
| 8270066SP-01 | INF.SP.LINE,TRANS,PVC,LL,250CM-EU | 20H31E8ST5 |
| 8270066SP-01 | INF.SP.LINE,TRANS,PVC,LL,250CM-EU | 20K02E8ST5 |
| 8270066SP-01 | INF.SP.LINE,TRANS,PVC,LL,250CM-EU | 20H27E8ST5 |
| 8270066SP-01 | INF.SP.LINE,TRANS,PVC,LL,250CM-EU | 20G08E8ST5 |