

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

34209 Melsungen

Our Reference FSN-2023-01-20

Contact: [REDACTED]

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<http://www.bbraun.com>

Date: Jan 20, 2023

URGENT Field Safety Notice – Infusomat Space Transfusion Line - leakage

Dear Sir or Madam,

The B. Braun Melsungen AG has decided to proactively inform all customers on potential quality issues of 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
8270066SP-26	INF.SP.LINE,TRANS,PVC,LL,250CM-CIS/SA/AP	See Appendix II

Reason for the Information:

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 had already recalled 8 batches in two separate actions from the market in the 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 positive. Out of caution it has been decided to proactively inform all customers on potential quality issues of Infusomat Space Transfusion Lines in the course of a Field Safety Notice.

Chairwoman of the Supervisory Board:
Dr. Annette Beller

Executive Board:
Markus Strotmann
(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



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 organization and other concerned persons are informed about this Field Safety Notice.
- If you are a distributor, please forward this notification to your customers.
- It is recommended to proceed with currently ongoing treatments 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 at 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 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

Local contact 1

Name

Title

Email

telephone

Local contact 2

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,

APPENDIX I

Article Number	Article Name	Batch
8270066SP-01	INF.SP.LINE,TRANS,PVC,LL,250CM-EU	22N11E8ST5
8270066SP-01	INF.SP.LINE,TRANS,PVC,LL,250CM-EU	22M05E8ST5
8270066SP-01	INF.SP.LINE,TRANS,PVC,LL,250CM-EU	22N01E8ST5
8270066SP-01	INF.SP.LINE,TRANS,PVC,LL,250CM-EU	22M07E8ST5
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	22K07E8ST5
8270066SP-01	INF.SP.LINE,TRANS,PVC,LL,250CM-EU	22K03E8ST5
8270066SP-01	INF.SP.LINE,TRANS,PVC,LL,250CM-EU	22H25E8ST5
8270066SP-01	INF.SP.LINE,TRANS,PVC,LL,250CM-EU	22G11E8ST5
8270066SP-01	INF.SP.LINE,TRANS,PVC,LL,250CM-EU	22G09E8ST5
8270066SP-01	INF.SP.LINE,TRANS,PVC,LL,250CM-EU	22G03E8ST5
8270066SP-01	INF.SP.LINE,TRANS,PVC,LL,250CM-EU	22F22E8ST5
8270066SP-01	INF.SP.LINE,TRANS,PVC,LL,250CM-EU	22G01E8ST5
8270066SP-01	INF.SP.LINE,TRANS,PVC,LL,250CM-EU	22F19E8ST5
8270066SP-01	INF.SP.LINE,TRANS,PVC,LL,250CM-EU	22F19E8ST5
8270066SP-01	INF.SP.LINE,TRANS,PVC,LL,250CM-EU	22E21E8ST5
8270066SP-01	INF.SP.LINE,TRANS,PVC,LL,250CM-EU	22E11E8ST5
8270066SP-01	INF.SP.LINE,TRANS,PVC,LL,250CM-EU	22E07E8ST5
8270066SP-01	INF.SP.LINE,TRANS,PVC,LL,250CM-EU	22D11E8ST5
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	22B10E8ST5
8270066SP-01	INF.SP.LINE,TRANS,PVC,LL,250CM-EU	22B10E8ST5
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	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	21M20E8ST5
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	21L22E8ST5
8270066SP-01	INF.SP.LINE,TRANS,PVC,LL,250CM-EU	21L22E8ST5
8270066SP-01	INF.SP.LINE,TRANS,PVC,LL,250CM-EU	21L24E8ST5

Article Number	Article Name	Batch
8270066SP-01	INF.SP.LINE,TRANS,PVC,LL,250CM-EU	21G17E8ST5
8270066SP-01	INF.SP.LINE,TRANS,PVC,LL,250CM-EU	21G24E8ST5
8270066SP-01	INF.SP.LINE,TRANS,PVC,LL,250CM-EU	21G09E8ST5
8270066SP-01	INF.SP.LINE,TRANS,PVC,LL,250CM-EU	21G16E8ST5
8270066SP-01	INF.SP.LINE,TRANS,PVC,LL,250CM-EU	21G09E8ST5
8270066SP-01	INF.SP.LINE,TRANS,PVC,LL,250CM-EU	21F25E8ST5
8270066SP-01	INF.SP.LINE,TRANS,PVC,LL,250CM-EU	21F23E8ST5
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	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	21C19E8ST5
8270066SP-01	INF.SP.LINE,TRANS,PVC,LL,250CM-EU	21B26E8ST5
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	20M06E8ST5
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	20H24E8ST5
8270066SP-01	INF.SP.LINE,TRANS,PVC,LL,250CM-EU	20G08E8ST5
8270066SP-01	INF.SP.LINE,TRANS,PVC,LL,250CM-EU	20G22E8VT5
8270066SP-01	INF.SP.LINE,TRANS,PVC,LL,250CM-EU	20E20E8ST5

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APPENDIX II

Article Number	Article Name	Batch
8270066SP-26	INF.SP.LINE,TRANS,PVC,LL,250CM-CIS/SA/AP	22L06E8ST5
8270066SP-26	INF.SP.LINE,TRANS,PVC,LL,250CM-CIS/SA/AP	22G10E8ST5
8270066SP-26	INF.SP.LINE,TRANS,PVC,LL,250CM-CIS/SA/AP	22E09E8ST5
8270066SP-26	INF.SP.LINE,TRANS,PVC,LL,250CM-CIS/SA/AP	22G06E8ST5
8270066SP-26	INF.SP.LINE,TRANS,PVC,LL,250CM-CIS/SA/AP	22G08E8ST5
8270066SP-26	INF.SP.LINE,TRANS,PVC,LL,250CM-CIS/SA/AP	22F24E8ST5
8270066SP-26	INF.SP.LINE,TRANS,PVC,LL,250CM-CIS/SA/AP	22E18E8ST5
8270066SP-26	INF.SP.LINE,TRANS,PVC,LL,250CM-CIS/SA/AP	22E18E8ST5
8270066SP-26	INF.SP.LINE,TRANS,PVC,LL,250CM-CIS/SA/AP	22D13E8ST5
8270066SP-26	INF.SP.LINE,TRANS,PVC,LL,250CM-CIS/SA/AP	22D29E8VT5
8270066SP-26	INF.SP.LINE,TRANS,PVC,LL,250CM-CIS/SA/AP	22D28E8VT5
8270066SP-26	INF.SP.LINE,TRANS,PVC,LL,250CM-CIS/SA/AP	22D27E8VT5
8270066SP-26	INF.SP.LINE,TRANS,PVC,LL,250CM-CIS/SA/AP	22C10E8ST5
8270066SP-26	INF.SP.LINE,TRANS,PVC,LL,250CM-CIS/SA/AP	22B08E8ST5
8270066SP-26	INF.SP.LINE,TRANS,PVC,LL,250CM-CIS/SA/AP	21N02E8ST5
8270066SP-26	INF.SP.LINE,TRANS,PVC,LL,250CM-CIS/SA/AP	21M02E8ST5
8270066SP-26	INF.SP.LINE,TRANS,PVC,LL,250CM-CIS/SA/AP	21L26E8ST5
8270066SP-26	INF.SP.LINE,TRANS,PVC,LL,250CM-CIS/SA/AP	21L26E8ST5
8270066SP-26	INF.SP.LINE,TRANS,PVC,LL,250CM-CIS/SA/AP	21F16E8ST5
8270066SP-26	INF.SP.LINE,TRANS,PVC,LL,250CM-CIS/SA/AP	21E26E8ST5
8270066SP-26	INF.SP.LINE,TRANS,PVC,LL,250CM-CIS/SA/AP	21E17E8ST5
8270066SP-26	INF.SP.LINE,TRANS,PVC,LL,250CM-CIS/SA/AP	21E17E8ST5
8270066SP-26	INF.SP.LINE,TRANS,PVC,LL,250CM-CIS/SA/AP	21C05E8ST5
8270066SP-26	INF.SP.LINE,TRANS,PVC,LL,250CM-CIS/SA/AP	21A13E8ST5
8270066SP-26	INF.SP.LINE,TRANS,PVC,LL,250CM-CIS/SA/AP	20K09E8ST5