

Sempach, 27. March 2019

FIELD SAFETY NOTICE (FSN)**Please inform immediately all affected departments and customers!****Subject** **Connection Lead / SP (12V) for Infusomat® Space,
Infusomat® Space P and Perfusor® Space**

Dear valued customer,

The safety of patients and users as well as the reliability of our infusion pumps are top priorities for B. Braun.

Therefore, B. Braun Melsungen AG have decided to inform you in the context of a voluntary Field Safety Notice about an observed failure with the following product:

Article Number	Article Name	Batch Coding
8713231	Connection Lead / SP (12V) (Anschlusskabel 12V)	CW 40/17 bis CW 43/18

The affected Connection Lead is used to power the following three articles: *Infusomat® Space* (8713070), *Infusomat® Space P* (8713050), and *Perfusor® Space* (8713030).

Reason for the FSN

In the course of post market surveillance activities it has been observed that the Connection Leads are potentially affected by a malfunction which has a correlation to massive temperature fluctuations.

The malfunction can be easily detected by observing the LED indication. In case the LED indication does not shine in "green", the pump does not get any power supply and is running accordingly in battery mode, see figure.



Figure 1 Green LED indication of function

The problem particularly affects Connection Lead that are used on board or under transport conditions.

Considering the area of application of the Connection Lead, there is a potential risk for an abort of therapy in patient transport situations.

In the meantime, our supplier has started the production of optimized cables followed by 100% stress tests before shipment and we expect to normalize the supply situation during the month of April 2019. From then onwards, the affected cables which are under warranty conditions will be exchanged.

How to identify affected Connection Leads

The production date is indicated as week and year (WW/YY), and is specified on the pump connector ending of the cable (see figure 2 below).

The affected Connection Leads were produced by our supplier between **CW 40/17 and CW 43/18**.



Figure 2 Indication of production date

Please take the following measures urgently and immediately:

- Review this FSN in its entirety and ensure that all users of the above mentioned products in your organization and other concerned persons are informed about this FSN.
If you are a distributor please forward this FSN to affected customers.
- Please observe storage conditions, as it has been identified that there is a correlation between low temperatures and the damage in the Connection Lead.
- We recommend to confirm the functionality of the Connection Leads prior to usage (by observing the LED). In case of identified damage, please do not use it anymore.
- For exchange of affected Connection Leads, please contact B. Braun Medical AG Technical Service & Support (You find the contact details on the answer form.)

Customer

Regardless on the above mentioned, for critical transport situations in general we recommend always to check if the battery capacity is sufficient for the necessary transport conditions. Additionally, we also recommend to have an alternative replacement battery pack available on board.

According to our delivery database, we have also delivered goods of the affected batches to your house. We ask you to check or use the still available **Connection Lead / SP (12V)** according to the procedure described above.

Further, we require your confirmation of receipt of this letter. Please complete the answer form in the appendix and send it completely filled out to the address given therein.

The present measure (FSN) is coordinated with Swissmedic.

If you have any questions regarding this Field Safety Notice (FSN), please contact our product management:

Contact	Function	Contact Details
Patrick Wyss	Product Manager	patrick.wyss@bbraun.com Direct: +41 58 258 52 91 Mobile: +41 79 789 27 22

We thank you for your understanding and apologize for the inconvenience.

Friendly greetings

B. Braun Medical AG

Dr. Anja Wolf-Neumann
QP / QM Manager CH-Sales Divisions

Patrick Wyss
Product Manager AIS

Customer

ANSWER

Please return to:

B. Braun Medical AG Technical Service & Support
Tel. / Fax : +41 58 258 71 51 / +41 58 258 63 59
Email technical-support.ch@bbraun.com

We ask you to confirm receipt of this letter (FSN) as follows:

I have received and read the letter (FSN) **dated 27 March 2019** concerning **Connection Lead / SP (12V)** and have taken the appropriate measures.

Organization	
Address	
Contact person	
Tel. kontakt	
Email kontakt	
Date and signature	

For general inquiries please contact:

B. Braun Medical AG
Technical Service & Support
Tel.: +41 58 258 71 51
Email: technical-support.ch@bbraun.com

Customer