

B. Braun Melsungen AG
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Safety Officer Medical Devices

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Our reference:

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Date: March 18, 2018

TO WHOM IT MAY CONCERN

Field Safety Notice

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, we the 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
8713231	Connection Lead SP (12V)	CW 40/17 to CW 43/18

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 observed as the connection lead has no power output, thus not charging the pump. This failure can be easily detected by observing the LED indication of the Connection Lead which signs the cable is functional or not.



Figure 1 Green LED indication of function

Chairman of Supervisory Board:
Prof. Dr. h.c. Ludwig Georg Braun

Executive Board:
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(Chairman)
Dr. Annette Beller
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Register Court: Local Court Fittzlar
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Considering the area of application of the Connection Lead, there is a potential risk for a delay 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, we will exchange the affected cables which are under warranty conditions.

For the time being, we would like to point out that precautions with the cables produced in the signed batches need to be taken, especially when having pumps on board in transport settings as specified in the *Actions to be taken* section below.

How to identify affected Connection Leads

Affected Connection Leads have been manufactured by our supplier in the period from October 2017 until September 2018. 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 between **CW 40/17 and CW 43/18**.

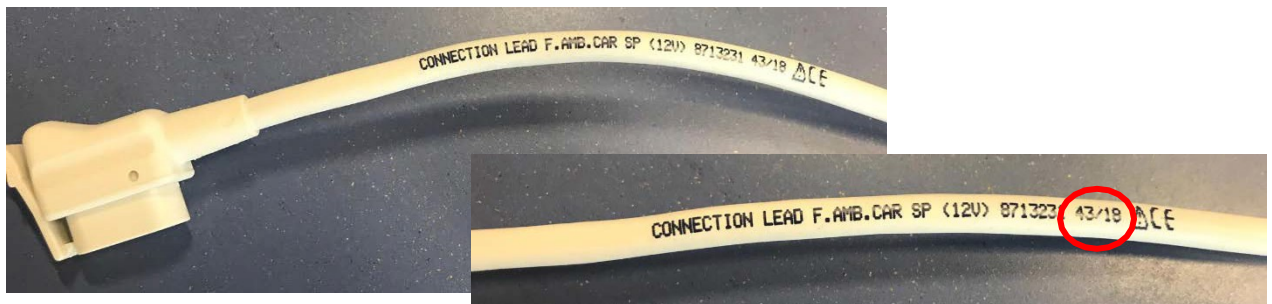


Figure 2 Indication of production date

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Actions to be taken

- Confirm the receipt of this information.
- 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 functionality of the Connection Leads prior to usage (by observing the LED). In case of identified damage, please do not use it anymore.
- 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.
- For exchange of affected Connection Leads, please contact your local sales representative for further information on availability and replacement.

If more information is needed, please contact your local representative

Local contact 1

Name

Title

Email

telephone

Local contact 2

Kindly accept our apologies for any inconvenience.

Yours sincerely,