

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

34209 Melsungen
Germany

Your reference:
Our reference: FSN 2019-05-22 AS/SK

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Date: May 22, 2019

TO WHOM IT MAY CONCERN

Field Safety Notice

Connection Lead SP (12V) for Infusomat Space, Infusomat Space P and Perfusor Space

Dear valued customer,

In the Field Safety Notice from March 2019 (FSN 2019-03-18 AS/LS) we had informed that some of the 12 V Connection Lead SP distributed to the market may potentially be defect. After implementation of technical corrections including stress tests and 100% end-control, new products were delivered to the market. Unfortunately it appears that also some of the newly delivered products are non-functional. The root cause is currently unknown, but there seem to be factors during use that were so far not addressed in our previous corrective measures.

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

Article Number	Article Name	Batch
8713231	Connection Lead SP (12V)	CW 07/19 to CW 16/19

Reason for the FSN

In the course of post market surveillance activities it has been observed that the Connection Leads are potentially non-functional. 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. In addition the battery symbol in the pump screen shows whether or not the pump is connected to mains power supply.

Chairman of Supervisory Board:
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Executive Board:
Anna Maria Braun, LL.M.
(Chief Executive Officer)
Dr. Annette Beller
Dr. Meinrad Lugan

Caroll H. Neubauer, LL.M.
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Corporate Office: Melsungen
Register Court: Local Court Fritzlar
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Figure 1 Green LED indication of function

At the moment there are indications that the root cause of the problem is associated to massive temperature fluctuations. However, there seem to be factors during use that are not fully understood and were so far not addressed in our previous corrective measures.

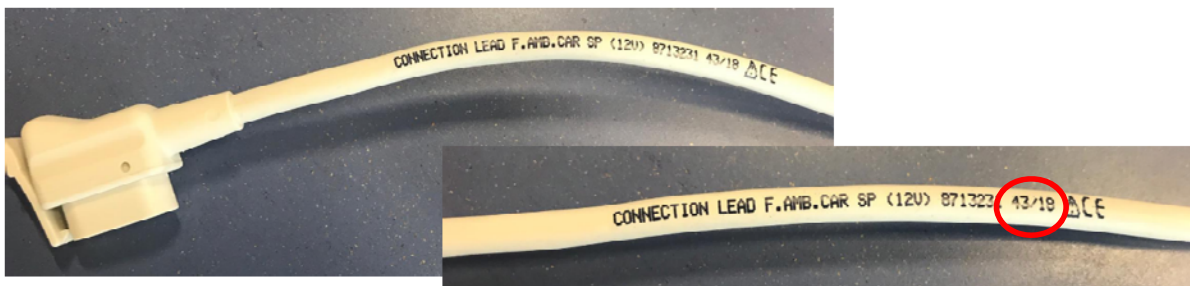
Considering the area of application of the Connection Lead, there is a potential risk for a delay of therapy in patient transport situations.

We are working with high priority to identify all related factors to provide a satisfactory solution as soon as possible. We assume finalisation of adequate corrective measures and normalisation of the supply situation latest by Q3 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 February 2019 until May 2019. 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 07/19 and CW 16/19**.



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Figure 2 Indication of production date

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 there is a likely 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, as described in the IfU we always recommend to have a second pump in transport situation 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,