

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

Your reference:  
Our reference: FSN 2018-07-04 LS/STK

Contact:

## TO WHOM IT MAY CONCERN

Fon:  
Fax:  
Email:  
Internet: <http://www.bbraun.de>

Date: July 05, 2018

## Urgent FIELD SAFETY NOTICE: Perifix Catheter Connector

To whom it may concern,

We, the B. Braun Melsungen AG, have decided to proactively inform our customers in the context of a voluntary FIELD SAFETY NOTICE on a problem with the **Perifix Catheter Connector**. This FSN is being executed as a correction and not a product removal.

The Perifix Catheter Connector is distributed as a single sterile packed unit, and in various sterile anesthesia procedural trays. For further manufacturing the Perifix Catheter Connector is also distributed as bulk non-sterile packed unit.

For a full list of affected products please refer to **Attachment1**.

### Reason for the voluntary Customer Information (Field Safety Notice)

The Perifix Catheter Connector is a connection device used by clinicians to provide various anesthetic and fluid administration devices with a single, common access point to a catheter for delivery of anesthetics. The connector is used in conjunction with the catheter for continuous administration of anesthetic fluids. In the course of our regular post market surveillance activities we have found that the Perifix Catheter Connector may not remain closed during use. In some cases this has led to leakage or disconnection of the catheter from the Perifix Catheter Connector.

While no serious injuries to patients, users, or third parties have been reported to date, there is a possibility of contamination of the catheter or delay of anaesthesia of different severity.

### Actions to be taken by the customer:

Our records have shown that your institution has received the Perifix Catheter Connector or one of the anesthesia kits containing the connector.

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

Executive Board:  
Prof. Dr. Heinz-Walter Große  
(Chairman)  
Dr. Annette Beller  
Anna Maria Braun, L.L.M.

Dr. Meinrad Lugin  
Caroll H. Neubauer, LL.M.  
Dr. Joachim Schulz  
Markus Strotmann

Corporate Office: Melsungen  
Register Court: Local Court Fritzlar  
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Carl-Braun-Straße 1  
34212 Melsungen  
Germany

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We kindly ask you to initiate the following activities immediately and with priority:

- Review this Medical Device Correction Notification in its entirety and ensure that all users of the above mentioned products in your organization and other concerned persons are informed about this Medical Device Correction –Notification. If you are a distributor, please forward this correction notification to your customers.
- In case you encounter any of the described issues we recommend to secure the catheter with adhesive tape as described in Appendix 1.
- Confirm receipt of this information by completing the attached confirmation slip and return this to B. Braun using the contact details provided.

Actions being taken by B. Braun:

B. Braun is working with highest priority to implement a solution for the above described problem of the Perifix Catheter Connector. B.Braun will provide a communication to customers on the status in September 2018.

If more information is needed, please contact

**Local contact 1**

Name

Title

Email

telephone

**Local contact 2**

Kindly accept our apologies for any inconveniences.

Yours sincerely,