

B. Braun Melsungen AG
Division Hospital Care
Quality & Environment Management

34209 Melsungen

Your reference:

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

Contact:

TO WHOM IT MAY CONCERN

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Perifix® Catheter Connector

Dear valued customer,

This follow-up notice is intended to provide you with additional information regarding the steps which B. Braun is taking to address concerns with our Perifix® Catheter Connectors.

BACKGROUND

In July 2018, B. Braun informed all customers of a voluntary, Field Safety Notice (FSN) involving our Perifix® Catheter Connectors 2.0 (PCC 2.0) and the potential for them to not remain closed during use. This issue may lead to reports of leakage or disconnection of the catheter from the catheter connector.

INFORMATION

1. PROGRESS OF DESIGN & MATERIAL CHANGE

After having performed a thorough root-cause analysis it became apparent that the reported problems of the Perifix® Catheter Connector 2.0 need to be addressed by a design and material change.

The geometric design has been modified to prevent unintended opening of the connector. In addition, a more rigid polypropylene has been used for the lower part of the connector.

The last necessary steps for CE-marking are currently ongoing. CE-mark is currently anticipated for August 2019.

2. ROLLOUT OF THE REDESIGNED VERSION

After CE-marking of the redesigned Perifix® Catheter Connector, it will immediately go into serial production. In a first instance it is planned to provide single sterile packed PCC 2.1 to allow use with

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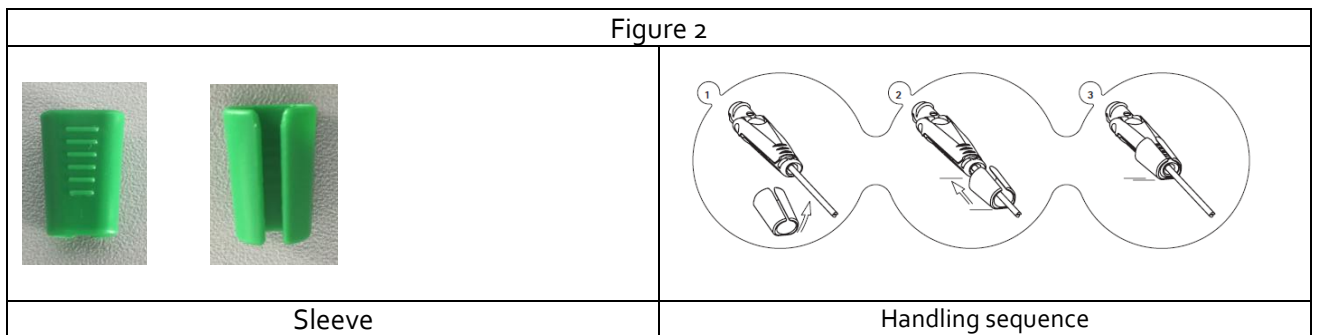
Perifix® Sets already stocked in your hospitals in order to avoid any risk of shortage. Availability for this is planned for Oct-2019.

In parallel we will start manufacturing the Perifix® Sets including the new PCC 2.1 starting with the highest volume product lines first This is to ensure market supply to the largest possible extent in a short timeframe.

The new PCC 2.1 will then be added to the more specialized and lower volume products. The majority of products is currently expected to be available with PCC 2.1 by Feb-2020 in the EU market.

3. ALTERNATIVE MEASURE PROPOSED BY WAITING FOR THE ROLLOUT

We can provide you with a sleeve to insert on the Perifix® Catheter Connector (See Figure 2). It will be made available to you free of charge, after ordering it to your Sales Representative.



Kindly accept our apologies for any inconveniences.

Yours sincerely,