

TO WHOM IT MAY CONCERN

CC Chairman Medical Board and relevant Head of
Departments

Date: 11 July 2018

Urgent FIELD SAFETY NOTICE: Perifix Catheter Connector

To whom it may concern,

On behalf of B. Braun Melsungen AG, we 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 list of affected products in Singapore, please refer to **Attachment1**.

Please note that there may be other affected identifiers that are affected globally and that recipient of this notice should check with product owner in the event the device is obtained from an overseas dealer.

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.

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

600 North Bridge Road
#15-05 Parkview Square
Singapore 188778

Tel : (65) 6213 0933

Fax : (65) 6213 0930

<http://www.bbraun.com.sg>

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

Loo Bee Keong
General Manager (Sales)

DID:(+65)62130960
Tel:(+65)62130933
Fax:(+65)62130930
Mobile: [REDACTED]

Christina Loh
Assistant Sales Manager

DID:(+65)62130949
Tel:(+65)62130933
Fax:(+65)62130930
Mobile: [REDACTED]

Kindly accept our apologies for any inconveniences.

Yours sincerely,

[REDACTED]

Loo Bee Keong
General Manager (Sales)

Attachment 1

Article	Device description
4510305	PERIFIX 901
4513258C	PERIFIX ONE 0.60X1.05, 19G S-O
4512006C	PERIFIX ONE PAED SET 18
4514025	PERIFIX 402 FILTER SET WITH LOR,G16
4050176	ESPOCAN KIT WITH PENCAN G27,DOCKING SYS
4898130	CONTIPLEX C SET SH,30°,25GX7½"0.53X190MM
331691NC	CONTIPLEX TUOHY ULTRA, 18GX2", 1.3X50MM
4898750NC	CONTIPLEX S ULTRA ,20°,18GX2", 1.3X50MM
4898752NC	CONTIPLEX S ULTRA ,20°,18GX4", 1.3X100MM
331693NC	CONTIPLEX TUOHY ULTRA, 18GX4", 1.3X100MM
4050177	PERIFIX KIT G18 FOR KKWCH SINGAPORE Y40

Appendix 1

- 1) Place the catheter according to internal hygiene policies.
- 2) Connect catheter and verify catheter placement per product instructions.
- 3) Fix the catheter.
- 4) Take an adhesive tape available in the hospital.
- 5) Begin wrapping the tape around the catheter connector starting from the bottom of the distal end.



Figure 1

- 6) Continue wrapping the tape along the length of the connector.

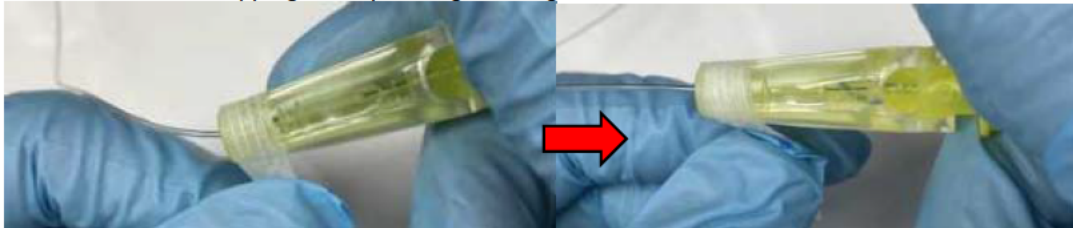


Figure 2

Figure 3

- 7) To maintain secure closure of the Catheter Connector, the tape should cover approximately 1/3 of the length of the connector.



Figure 4

Confirmation of Receipt of Urgent Field Safety Notice

Please fill in this form and return it by fax immediately to the fax number or email to hui_min.teng@bbraun.com

+65 62130930

We hereby confirm that we are aware of the above Field Safety Notice. The Field Safety Notice was communicated within our organization.

Name:

Phone Number

Date and Signature:

Company Stamp:

Received by:

Name, date & sign