

Date:
July 10, 2018

Ref: FSN 2018-07-04 LS/STK

Urgent FIELD SAFETY NOTICE: Perifix Catheter Connector

To whom it may concern,

B. Braun Melsungen AG has decided to proactively inform customers of a voluntary FIELD SAFETY NOTICE regarding 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 anaesthesia procedural trays. For further manufacturing, the Perifix Catheter Connector is also distributed as bulk non-sterile packed units.

For a full list of affected products please refer to **Attachment 1**.

Reason for the voluntary Customer Information (Field Safety Notice)

The Perifix Catheter Connector is a connection device used by clinicians to provide various anaesthetic and fluid administration devices with a single, common access point to a catheter for delivery of anaesthetics. The connector is used in conjunction with the catheter for continuous administration of anaesthetic 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 severities.

Actions to be taken by the customer:

Our records show that your hospital / facility has received the Perifix Catheter Connector or one of the anaesthesia 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 organisation 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 and signing the attached 'Field Safety Notice Confirmation Form' and return this to B. Braun (fax no. 01-7091889).

Actions being taken by B. Braun:

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

The relevant regulatory authorities have been informed of this action.

If more information is needed, please contact:

Robert Egan
Business Unit Manager
B Braun Medical Ltd
Tel: 086-2606917
Email: rob.egan@bbraun.com

We appreciate your immediate attention and apologise for any inconvenience caused.

Yours sincerely,



Robert Egan
Business Unit Manager



Roberta Egan
Regulatory Affairs Manager

July 10, 2018

Field Safety Notice CONFIRMATION FORM**Perifix Catheter Connector**

Please complete this form and fax it back to Fax No. 01-7091889

We hereby confirm that we are aware of the Field Safety Notice from 10th July 2018 concerning the Perifix Catheter Connector.

Organisation:	
Address:	
Contact Name:	
Contact Phone Number:	
Contact e-mail address:	
Date and signature	

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

Attachment 1 to the Field Safety Notice of July 10, 2018
Perifix Catheter Connector

Product List

Article Number	Product Description
4430096	CELSITE ST304-19 ST SET PA/PUR 19G E/S
4477112	PROSET PERIFIX
4513150	PERIFIX CATHETER 0.45X0.85, 20G S-O
4513800	PERIFIX CATHETER CONNECTOR, 20/24G
4514017	PERIFIX 401 FILTER SET WITH LOR,G18
4514025	PERIFIX 402 FILTER SET WITH LOR,G16
4517504	PERIFIX® 750 SOFT TIP FILTER-SET+PINPAD
4556666	ESPOCAN W. PENCAN 27GX5" (0,42X127,5 MM)
4556674	ESPOCAN W. SPINOCAN 27GX5" (0,42X125,5 M
4556763	ESPOCAN W. DS + PENCAN 27GX5 3/8" (0,42X
4898115	CONTIPLEX C SET SH,15°,25GX7½"0.53X190MM
4898305	CONTIPLEX D SET SH,15°,18GX2 1/8",1,3X55
4898335	CONTIPLEX D SET SH 30°,18GX2 1/8",1.3X55
331691N	CONTIPLEX TUOHY SET,18GX2",1.3X50MM
331693N	CONTIPLEX TUOHY SET,18GX4",1.3X100MM
331694N	CONTIPLEX TUOHY SET,18GX6",1.3X150MM
331695N	CONTIPLEX TUOHY SET,18GX1½",1,3X40MM
4512014C	PERIFIX ONE PAED SET 20
4514017C	PERIFIX ONE 401 FILTER SET
4514513C	PERIFIX ONE 451 FILTER SET
4892410N	CONTIPLEX D SET,15°,20GX2 1/8", 1.1X55MM
4894235N	CONTIPLEX D SET,15°,18GX2 1/8", 1.3X55MM
4898610-27	CONT S ULT 360,20°18GX100MM-CIS/AP/EU/SA
4894243N	CONTIPLEX D SET,30°,18GX2 1/8", 1.3X55MM
4894391N	CONTIPLEX D SET,15°,18GX4 3/8",1.3X110MM
4898650-27	CONT. S ULT 360,20°18GX50MM-CIS/AP/EU/SA
4898704-01	CONTIPLEX TUOHY ULTRA 360,18GX40MM-EU
4898705-01	CONTIPLEX TUOHY ULTRA 360,18GX50MM-EU
4898710-01	CONTIPLEX TUOHY ULTRA 360,18GX100MM-EU
4898715-01	CONTIPLEX TUOHY ULTRA 360,18GX150MM-EU