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B. Braun Avitum AG

Contact:

Mobile:
Phone
E-Mail:
Internet:

Datum:

Customer
Address

Urgent Field Safety Notice

Dialyser xevonta Lo 18, xevonta Hi 18, xevonta Hi 20

Cap leakage during therapy

R-2020-001

From:
B Braun National Organization

To:
Users, operators, distributors and patients who were supplied with the following products.

Affected Medical Devices:

(please customize the articles)	**Article Codes** *(please customize the codes)*	**Batch Numbers** *(please customize the batch numbers)*
XEVONTA DIALYSER LO 18, GAMMA	**7204550**	
XEVONTA DIALYSER LO 18 AP, GAMMA	**72045500**	
XEVONTA DIALYSER HI 18, GAMMA	**7204657**	
XEVONTA DIALYSER HI 18 AP, GAMMA	**72046570**	

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XEVONTA DIALYSER HI 20, GAMMA	**7204665**	
XEVONTA DIALYSER HI 20 AP, GAMMA	**72046650**	

Description of the Problem, Root Cause and Corrective Measures

In the course of our post market surveillance we became aware of occasional leakages at one of the blood caps of the above mentioned dialysers. The leakages occurred during preparation phase of the dialysis machine and some during therapy. The blood loss was marginal and without any health consequences for the patients.

The leakage is located between housing and blood cap of the dialyser due to a deviation in the production process. The root cause of the deviation is clearly defined and potentially affected dialysers could be identified unequivocally.

Due to this field safety notice, we kindly ask you to take the following measures:

1) Check whether you have above mentioned products in stock, and quarantine them. The isolated products will be exchanged according to your information on the fax form.
2) Confirm the receipt of this Field Safety Notice on the enclosed fax form.
3) Additionally record on the enclosed fax form the received amount of products with the above mentioned batch number/s as well as the amount used and the amount to be returned.
4) Return the completed form in a timely manner to the fax number given on the form.

At the next delivery the quarantined products will be exchanged according to your information given on the return fax.

(Please adapt the above information if necessary).

Distribution of Information:

Please make sure that all users of the above mentioned products in your organisation and other concerned persons are informed about this Field Safety Corrective Action. If you have forwarded the products to a third party, please forward a copy of the Field Safety Notice to them or inform the contact person mentioned below.

Please retain this Field Safety Notice until you have completed all the above measures.

The National Competent Authority has been notified of this Field Safety Corrective Action.

If you have any questions regarding this Field Safety Notice, please contact:

National contact

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We apologize for the inconvenience caused by this Field Safety Corrective Action and thank you for your understanding and co-operation.

Best regards,

Please fill in your signature, job title, etc here

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Confirmation of Receipt of the Field Safety Notice
R-2020-001

You received the xevonta dialysers listed in the table below.

Please fill in this form and table completely. Return it immediately to the following fax number or e-mail address

Please fill in your local fax number and e-mail

The result of the inspection of our stock in consequence of this Field Safety Notice is as follows:

Article Code	**Batch No.**	**Amount Received**	**Amount Used**	**Amount to be Returned**
(please customize the article codes)	*(please customize the batch numbers)*	xxxxxxxxx		
xxxxxxxxx	xxxxxxxxx	xxxxxxxxx		

Herewith, we confirm that we received and noticed the Field Safety Notice from **date** concerning the above mentioned medical devices. The Field Safety Notice was distributed and communicated within our organisation.

Name: _____

Phone number _____

Date and Signature: _____

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Stamp: