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B. Braun Avitum AG

Am Buschberg 1
34212 Melsungen

Contact:

Fon:
Fax:
Email:
Internet:

Date: July 08, 2022

Urgent Field Safety Notice

Diacap® α Polysulfone LO PS 18 and HI PS 18, Diacap® Pro 16H, 16L and 19L

Leakage at the dialysis fluid side with potential balance deviation

R-2022-002

Absender:
B. Braun Organisation

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

Affected Medical Devices:

Article Description *(please customize)*	**Article Code** *(please customize)*	**Batch** *(please customize)*
Diacap® α Polysulfone LO PS 18	7203550	990530621 990550621 990560621 990420421 990510521
Diacap® α Polysulfone HI PS 18	7203657	990520521 990540621
Diacap® Pro 16H	720DH16	990460421

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Diacap® Pro 16L	720DL16	990500521 990490521
Diacap® Pro 19L	720DL19	990480421 990440421 990450421 990470421 990570621

Description of the Problem, Root Cause and Corrective Measures:

In the course of our market surveillance, we became aware that the above-mentioned dialyzers may leak on the dialysis fluid side. In case of a leakage, the dialysis fluid escapes between the cap and the housing.

All leakages that have occurred on the market, were detected during the preparation phase and there was no adverse effect on patients. However, it cannot be excluded that a balance deviation may occur if the leakage is detected only during therapy.

The leakage is due to a deviation in the production process. The cause of the deviation was identified and the potentially affected dialyzers 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.
2) Confirm the receipt of this Field Safety Notice on the enclosed confirmation form.
3) Additionally record on the enclosed confirmation 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 filled out and signed confirmation form in a timely manner to the fax number or e-mail address given on the form.

At the next delivery the quarantined products will be exchanged according to your information given on the return fax. For returned products you will of course receive a credit note.

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:

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National contact

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-2022-002

You received the Diacap® dialyzers listed in the table below.

Please fill out this form including the table completely.

Please return the form immediately to the following fax number or e-mail address.

Please enter the fax number and/or e-mail address of the national contact person

The result of the inventory check due to this Urgent Field Safety Notice is as follows:

Article Description *(Please customize)*	**Article Code** *(Please customize)*	**Batch** *(Please customize)*	**Amount Received**	**Amount Used**	**Amount to be Returned**
Diacap® α Polysulfone LO PS 18	7203550	990530621			
		990550621			
		990560621			
		990420421			
		990510521			
Diacap® α Polysulfone HI PS 18	7203657	990520521			
		990540621			
Diacap® Pro 16H	720DH16	990460421			
Diacap® Pro 16L	720DL16	990500521			
		990490521			
Diacap® Pro 19L	720DL19	990480421			
		990440421			
		990450421			
		990470421			

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Article Description *(Please customize)*	**Article Code** *(Please customize)*	**Batch** *(Please customize)*	**Amount Received**	**Amount Used**	**Amount to be Returned**
		990570621			

Herewith, we confirm that we received and noticed the Field Safety Notice from 2022-07-xx concerning the above mentioned medical devices. The Field Safety Notice was distributed and communicated within our organisation.

Name: _____

Address: _____

Phone number _____

Date and Signature: _____

Stamp: