

**Customer Address**

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**Field Safety Notice**

**Field Safety Corrective Action / Recall  
A/V Set DEHP-free PVC for Dialog**

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2015-10-26

**From**

**B. Braun National Organization / Distributor**

**To**

Users, operators, distributors and patients who were supplied with the following product.

**Affected Medical Devices**

Art. No.	Article Description	Batch
7211034	A/V SET DEHP-FREE PVC FOR DIALOG W/HDF	15C20980

**Description of the Problem, Root Cause and Corrective Measures**

During continuous post-market surveillance we became aware of a disconnection of the female Luer-Lock connector from the venous side of the Single-Needle adapter leading to blood loss for the patient. The dialysis machine had triggered an alarm indicating the disconnection and the incident had no consequences for the patient.

The investigation showed that the Luer-Lock connector was not glued to the tube of the Single-Needle adapter.



Affected component

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Page 2 Field Safety Notice 2015-10-26

The component is produced by a supplier in a fully automatic process where components not meeting the specifications and not checked are automatically discarded by the machine. The above mentioned case led us to recognise, that due to a specific failure of the equipment which occurred once for a short term and only during the production of this single component batch, the affected component was not automatically discarded.

The component batch in question was built into the above mentioned product. The vast majority of the these products was used in the market without any further complaint.

As a precaution, we will exchange all products in which this single component batch was used.

**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 Notice. 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** have been notified of the Field Safety Corrective Action / Recall.

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

## **National contact**

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

Best regards,

**Please fill in your signature, job title, etc here**

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Page 3 Field Safety Notice 2015-10-26

## Confirmation of Receipt of the Field Safety Notice

R-2015-003

### A/V Set DEHP-free PVC for Dialog

Art. No.	Article Description	Batch
7211034	A/V SET DEHP-FREE PVC FOR DIALOG W/HDF	15C20980

Please fill in this form and return it by fax immediately to the fax number

**Please fill in your fax number**

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

Article No.	Batch No.	Amount Received	Amount Used	Amount to be Returned
		xxxxxxxx		
		xxxxxxxx		

Herewith, we confirm that we received and noticed the Field Safety Notice from **date** concerning the above mentioned A/V sets for Dialog and the Single-Needle adapter. The Field Safety Notice was distributed and communicated within our organisation.

Name: \_\_\_\_\_

Phone number \_\_\_\_\_

Date and Signature: \_\_\_\_\_

Stamp: