B. Braun Avitum AG

Am Buschberg 1
34212 Melsungen

Contact:

Fon:
Fax:
Email:
Internet:

Date: March xx, 2025

Urgent Field Safety Notice

Single Needle Cross Over/Single Needle Bloodlines
for Dialog+ and Dialog iQ dialysis machines

Potential of particles in venous expansion chamber

R-2025-002

Absender:
B. Braun Organisation

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

Affected Medical Devices:

Article Code (please customize)	**Article Description** (please customize)	**Batch** (please customize)
7211127	DIASTREAM IQ PREMIUM HD SNCO	22A13534P 22B08534P 22B17534P 22C28534P 22D19534P 22E04534P 22E10534P 22F07534P 22F27534P 22H03534P 22H10534P 22H22534P 22H23534P 22I28534P 22K18534P 22L03534P 22M01534P 22M02534P 22M12534P 23B15534P 23B16534P 23C09534P 23D03F5PA0 23E09F5PA0

		23F02F5PA0 23H04F5PA0 23H23F5PA0 23K05F5PA0 23K27F5PA0 23L11F5PA0 23M07F5PA0 24A10F5PA0 24A24F5PA0 24B20F5PA0 24C06F5PA0 24C13F5PA0 24D17F5PA0 24D24F5PA0 24D25F5PA0 24E15F5PA0 24E17F5PA0 24F25F5PA0 24F26F5PA0 24G01F5PA0 24G03F5PA0 24H14F5PA0 24H22F5PA0 24K18F5PA0 24L21F5PA0 24M20F5PA0 24N05F5PA0 24N09F5PA0 25A10F5PA0 25A13F5PA0
7211270	DIASTREAM HD SN	22F21534P 22H12534P 22I13534P 22L08534P 22M08534P 23C08534P
7211271	DIASTREAM PREMIUM HD SNCO	23D25F5PA0
7211272	DIASTREAM ECOPRIME HD SNCO	22E31534P 22G04534P 22H16534P 22H29534P 22K05534P 22K25534P 22L18534P 22M06534P 23B22534P 23C14534P 23C28534P 23D25F5PA0 23E16F5PA0 23F15F5PA0 23K20F5PA0 23L19F5PA0 23L30F5PA0 24A17F5PA0 24A30F5PA0 24B27F5PA0 24D03F5PA0 24D23F5PA0 24E22F5PA0 24F19F5PA0 24G03F5PA0 24H13F5PA0 24K11F5PA0 24L14F5PA0 24M27F5PA0
7211349	DIASTREAM CLASSIC HD SNCO	22C21534P 22D11534P 22E17534P 22F14534P 22F29534P

		22G25534P 22I13534P 22K13534P 22L08534P 22L22534P 23B07534P 23D13F5PA0 23F07F5PA0 23F08F5PA0 23K14F5PA0 23L04F5PA0 23L24F5PA0 24A19F5PA0 24A31F5PA0 24B29F5PA0 24D10F5PA0 24E23F5PA0 24F20F5PA0 24L15F5PA0 24M26F5PA0
7211475	SN CO A/V SET WITH POD DIALOG IQ (CN)	23C01534P 23E23F5PA0 24C07F5PA0 24E15F5PA0 24H02F5PA0 24M08F5PA0

Description of the Problem, Root Cause and Corrective Measures:

In the course of internal quality control, we became aware that in rare cases there might be a particle in the venous expansion chamber. The particle consists of the material of the filter inside the chamber. It cannot be excluded that the particle reaches the patient's bloodstream.

No presence of a small particle inside the venous expansion chamber became known from the market.

The potential failure is due to a deviation in the production process. The potentially affected batches could be identified unequivocally.

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

1) Check whether you have the above-mentioned product in stock, and quarantine it.
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 potentially affected 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.
5) Until you receive new bloodlines please proceed as follows:
   - Check whether you can already switch potentially affected patients to double-needle therapy so that you can use standard AV bloodline sets.
     OR
   - Switch from Single-Needle Cross-Over therapy to Single-Needle Valve. For Single Needle Valve use a normal AV bloodline set plus Y single needle adapter (depending on the current setting of the vascular

access), and proceed as described in the respective section in the instruction for use. Adapt the physician's prescription for the patient's Single Needle therapy accordingly.

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 organization 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 and/or a therapy adaptation, please contact:

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

Confirmation of Receipt of the Field Safety Notice R-2025-002

You received Single Needle Cross Over/Single Needle Bloodlines 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	Article Code	Batch	Amount Received	Amount Used	Amount to be Returned
(please customize)	(please customize)	(please customize)			

Herewith, we confirm that we received and noticed the Field Safety Notice from 2025-03-xx concerning the above mentioned medical devices. The Field Safety Notice was distributed and communicated within our organization.

Name: _____

Address: _____

Phone number _____

Date and Signature: _____

Stamp: