

TO WHOM IT MAY  
CONCERN

Your reference  
2014

Our reference

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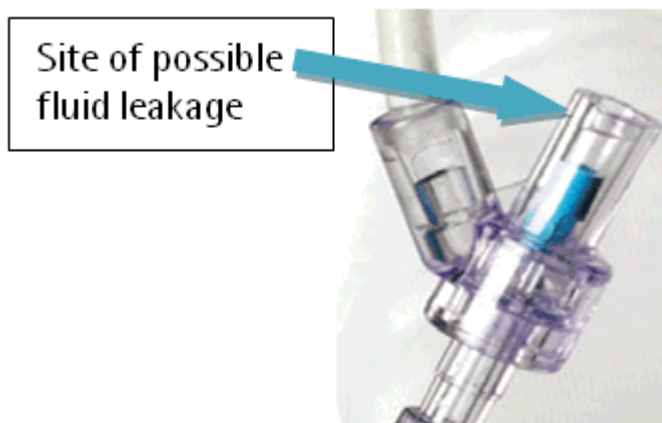
Date  
January 14,

## Cyto-Set Field Safety Corrective Action - Recall

**Affected products see Annex 1**

Dear Sirs,

In the course of internal quality checks we have found that these IV-sets may leak in some cases after disconnection at the Y-shaped Safsite valve, due to an incomplete closing of the valve. (see picture)



**Chairman of Supervisory Board:**    **Executive Board:**

Prof. Dr. h.c. Ludwig Georg Braun  
Court: Local Court Fritztlar

(Chairman)  
Dr. Annette Beller  
Otto Philipp Braun

Prof. Dr. Heinz-Walter Große  
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Page 2 to the letter of January 14, 2014 to  
TO WHOM IT MAY CONCERN

The silicone disc is not returning into closed position after disconnection of male Luer cone counterparts. Valves, unused or fully connected do not show this defect.

Nevertheless we have decided to recall the concerned, below listed batches as a preventive measure (see Annex 1).

Our records show that your hospital has received **Cyto-Set devices** from the specific batches listed in Annex 1. Please do not use devices of these batches and send them back.

Please forward this information to the users within your hospital immediately.

Please accept our apologies for any inconveniences.

We kindly ask you to confirm the receipt of this information. Should you have any questions, please call your local B. Braun contact person under Tel xxx-xxxx.

Yours sincerely,

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Page 3 to the letter of January 14, 2014 to  
TO WHOM IT MAY CONCERN

## Annex 1

Article number	Article name	Batch
4091051	PROSET VERBINDUNGSLEITUNG MIT SAFESITE	3L293400B1
4186578	PROSET DISCOFIX-HB 3-F. M. INTRAPUR PLUS	3K24340000
A1686	CYTO-SET INFUSION M. 3 SAFSITE	3L223400H2
		3L11340000
		3K30340000
		3K14340000
		3I13340000
A1685SNF	CYTO-SET INFUSION	3L04340000
		3K04340000
A1672SO	CYTO-SET PUMP ADAPTER	3K07340000
A1685SNF	CYTO-SET INFUSION	3L04340000
		3K04340000
A1686	CYTO-SET INFUSION M. 3 SAFSITE	3M103400H2
		3L223400H2
		3L11340000
		3K30340000
		3K14340000
A25001	PROSET TRANSFUSIONSSYSTEM M. 2X SAFESITE	3L293400B1
		3L08340000
		3K15340000
A25002	PROSET TRANSFUSIONSSYSTEM	3M173400B4
		3M103400B4
		3M043400B4
		3L263400B4
		3L193400B4
		3L11340000
		3L06340000
		3K25340000
		3K16340000
		3K15340000
		3K12340000
		3K07340000
3K02340000		