

TO WHOM IT MAY CONCERN

Your reference

Our reference

Tel. +49/56 61/71-

Fax +49/56 61/71-

Date

January 14, 2014

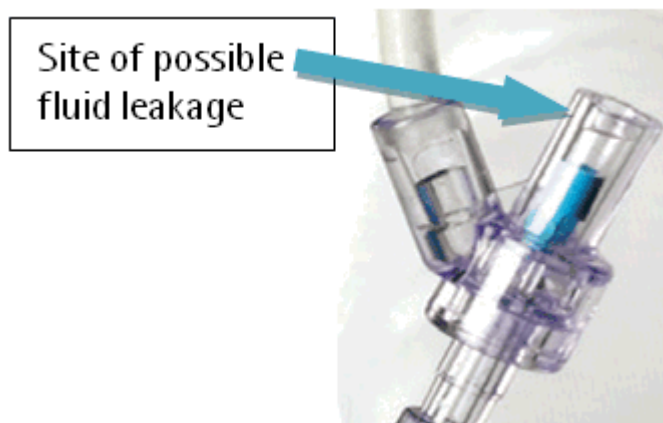
Cyto-Set

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)



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).

Chairman of Supervisory Board:
Prof. Dr. h.c. Ludwig Georg Braun**Executive Board:**
Prof. Dr. Heinz-Walter Große
(Chairman)
Dr. Annette Beller
Otto Philipp BraunProf. Dr. Hanns-Peter Knaebel
Dr. Meinrad Lugan
Caroll H. Neubauer, LL.M.
Markus Strotmann
(Deputy member)**Corporate Office: Melsungen**
Register Court: Local Court Fritzlar
HRB 11 000
WEEE-Reg.-No. DE 42690900**Address:**
B. Braun Melsungen AG
Carl-Braun-Straße 1
34212 Melsungen
Germany

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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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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

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Date

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Cyto-Set Field Safety Corrective Action

Effected products see Annex 2 and Annex 3

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)



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.

In order to ensure product availability and safe use of these products, strictly adhere to the following advice:

Chairman of Supervisory Board:
Prof. Dr. h.c. Ludwig Georg Braun

Executive Board:
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(Chairman)
Dr. Annette Beller
Otto Philipp Braun

Prof. Dr. Hanns-Peter Knaebel
Dr. Meinrad Lugan
Caroll H. Neubauer, LL.M.
Markus Strotmann
(Deputy member)

Corporate Office: Melsungen
Register Court: Local Court Fritzlar
HRB 11 000
WEEE-Reg.-No. DE 42690900

Address:
B. Braun Melsungen AG
Carl-Braun-Straße 1
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Cyto-Set (for product list see Annex 2)	Cyto-Set Mix (for product list see Annex 3)
<ol style="list-style-type: none">1. Strictly perform re-capping of the Safsite valve after use as already instructed in IfU.2. Use always straight Safsite valve to be installed on top of the distal Y-shaped Safsite valve downstream from the pump segment. These straight Safsite valves will be provided free of charge by B. Braun and are not affected by the leakage issue.3. Strictly follow the recommendations given in the IfU and keep system closed for disposal. Do not disassemble any side infusion devices from Safsite ports above the drip chamber in the main line.	<ol style="list-style-type: none">1. Strictly perform re-capping of the Safsite valve after use as already instructed in IfU.2. Use always straight Safsite valves to be installed on top of the affected Y-shaped Safsite valves. These straight Safsite valves will be provided free of charge by B. Braun and are not affected by the leakage issue.

Our records show that your hospital has received **Cyto-Set devices** from the specific batches listed in the Annexes 2 and 3.

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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No Annex 1 in this letter

Annex 2:

Article number	Article text	Batch
8250911SP	PROSET CYTO-SET TYP SPACE M. 3X SAFSITE	3M183400B1
		3M023400B1
		3M023400B1
		3L183400B1
		3L183400B1
		3K24340000
		3K15340000
		3K15340000
		3K02340000
		3K02340000
		3K02340000
8250915SP	CYTO-SET INF.SPAC W.3 SAFSITE/BCV/OPAQ.	3L14340000
		3L12340000
		3K29340000
8250910SP	CYTO-SET INFUSOMAT SPACE M. 3 SAFSITE	3M103400H2
		3M093400H2
		3L273400H2
		3L193400H2
		3L07340000
		3L04340000
		3K24340000
		3K16340000
		3K09340000
		3K14340000
		3K09340000
3K02340000		
8250916SP	CYTO-SET INF.SPAC W.3 SAFSITE/UV-PROT.	3L253400H2
		3L06340000
		3K03340000
8250913SP	CYTO-SET INFUSOMAT SPACE M.3 SAFSITE/BCV	3M123400H2
		3L223400H2
		3L06340000
		3K31340000
8250855SP	PROSET CYTO-SET TYP SPACE MIT 2X SAFSITE	3M103400B1

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Article number	Article text	Batch
		3M113400B1
		3L223400B1
		3K14340000
		3K07340000
8250655SP	PROSET CYTO-SET SPACE LINE 3X SAFSITE	3K22340000
8250812SP	CYTO-SET INFUSOMAT SPACE M. 5 SAFSITE	3M163400H2
		3M133400H2
		3M063400H2
		3L183400H2
		3L293400H2
		3L283400H2
		3L213400H2
		3L183400H2
		3L15340000
		3K17340000
		3I30340000
8250819SP	CYTO-SET INFUSOMAT SPACE, UV-PROT.	3M113400H2
		3L283400H2
		3L203400H2
		3L12340000
		3I26340000
8250813SP	CYTO-SET INFUSOMAT SPACE MIT RSV	3M093400H2
		3M073400H2
		3L263400H2
		3L193400H2
		3L203400H2
		3L13340000
		3L05340000
		3K28340000
		3K21340000
		3K09340000
		3K08340000
		3K01340000
		3I27340000
8250955SP	PROSET CYTO-SET TYP SPACE MIT 4X SAFSITE	3M103400B1
		3L183400B1
		3K30340000

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Article number	Article text	Batch
		3K11340000
		3I30340000
8250413SP	CYTO-SET INFUSOMAT SPACE 0,2 MY FILTER	3M163400B1
		3L15340000
		3L06340000
		3I30340000
8250356SP	PROSET INFUSOMAT SPACE LINE 2X SAFSITE	3M063400B1
		3K28340000
8250755SP	PROSET CYTO-SET SPACE LINE 1X SAFSITE	3L203400B1
		3L253400B1
		3L193400B1
		3I30340000
8250814SP	PROSET CYTO-SET TYP SPACE M. 5X SAFSITE	3M033400B1
		3L11340000
		3L05340000
		3K21340000
		3K16340000
		3K08340000
8250817SP	CYTO-SET INFUSOMAT SPACE W. 5 NF VENTILE	3K30340000
8250839SP	INFUSOMAT SPACE LTG. M. NUTRIFIX 1000ML	3M113400B1
		3M023400B1
		3L183400B1
		3L05340000
		3K30340000
		3K28340000
		3K17340000

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Article number	Article text	Batch
4182725	PROSET CYTO-SET MIX M. RV (1X=10 STCK)	3M093400B1
		3L273400B1
		3L06340000
		3K25340000
		3K11340000
		3K03340000
4182726	PROSET CYTO-SET MIX	3L273400B1
		3L12340000
4188925	PROSET CYTO-SET MIX M. RV UND 0,2µM F.	3M063400B1
		3L11340000
		3K25340000
		3K14340000
4188926	PROSET CYTO-SET MIX M. 0,2µm FILTER	3L06340000
A2901N	CYTO-SET MIX	3M163400H2
		3M193400H2
		3M123400H2
		3M103400H2
		3M093400H2
		3L253400H2
		3L14340000
		3L193400H2
		3L08340000
		3K09340000
		3K07340000
A29023N	CYTO-SET MIX MIT BCV UND 0,2 MY FILTER	3M133400B1
		3M043400B1
		3K30340000
		3K25340000
		3K08340000
A2902N	CYTO-SET MIX MIT RSV	3M163400H2
		3M033400H2
		3M073400H2
		3M023400H2
		3L283400H2
		3L253400H2
		3K29340000

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Article number	Article text	Batch
		3K28340000
		3K22340000
		3K21340000
		3K14340000
		3K07340000
		3K03340000
		3I30340000
A2905N	CYTO-SET MIX WITH BCV - UV PROT.	3M173400B1
		3M133400B1
		3L223400B1
		3K16340000