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B. Braun Melsungen AG
Division Hospital Care

TO WHOM IT MAY CONCERN

Your reference	Our reference	Tel. +49/56 61/71-	Fax +49/56 61/71-	Date
	RECALL 2014-03-28 LS/DJ			March 28, 2014

Urgent FIELD SAFETY NOTICE – Cavafix Recall

To whom it may concern,

we, the B. Braun Melsungen AG have decided to recall the following products in the context of a FIELD SAFETY CORRECTIVE ACTION from the market:

Article Number	Article Name	Batch
4152557	CAVAFIX CERTO 255CM G16 45CM G18 LL	all
4152573	CAVAFIX CERTO 257 7CM G16 45CM G18 LL	all
4152751	CAVAFIX CERTO 275 LOCK	all
4153359	CAVAFIX CERTO 335 LOCK	all
4153383	CAVAFIX CERTO 338 8CM G14 32CM G16 LL	all
4153553	CAVAFIX CERTO 355, LOCK	all
4153588	CAVAFIX CERTO 358 8CM G14 45CM G16 LL	all
4153758	CAVAFIX CERTO 375 5CM G14 70CM G16 LL	all
4153766	CAVAFIX CERTO 375, LOCK	all
4154550	CAVAFIX CERTO 455 5CM G12 45CM G14 LL	all
4154584	CAVAFIX CERTO 458 8CM G12 45CM G14 LL	all
4154754	CAVAFIX CERTO 475 5CM G12 70CM G14 LL	all
4172574	CAVAFIX CERTO W SPLITTOCAN 257 16GX7CM 1	all
4173350	CAVAFIX CERTO WITH SPLITTOCAN 335 32CM G	all
4173384	CAVAFIX CERTO WITH SPLITTOCAN 338 32CM G	all
4173554	CAVAFIX CERTO WITH SPLITTOCAN 355 45CM G	all
4173589	CAVAFIX CERTO WITH SPLITTOCAN 358 45CM G	all
4173759	CAVAFIX 375 70CM G16 LL	all
4180550	CAVAFIX CERTODYN 355	all
4180755	CAVAFIX CERTODYN 375	all
4180550A	CAVAFIX CERTODYN 355-SA	all
4180755A	CAVAFIX CERTODYN 375	all

Reason for the Recall

In the course of internal quality checks we discovered that during aging of these products it may come to a blooming of stabilizers of the catheter material on the surface of the

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catheters. Up to now, no harm or any other adverse patient outcome which could be associated to the above described observation has been reported to the B. Braun Melsungen AG. Nevertheless, we have decided to recall the affected products from the market.

Actions to be taken by the USER

Our records show that your hospital has received potentially affected Cavafix catheters as specified in the table above.

We kindly ask you to initiate the following activities immediately and with priority:

- Identify, quarantine and return affected devices.
- Do not use affected devices anymore.
- Affected devices currently in use do not need to be replaced.
- Inform the responsible personnel in the affected facilities .
- Confirm the receipt of this information.

If more information is needed, please contact

Local contact 1	Local contact 2
Name	
Title	
Email	
telephone	

Kindly accept our apologies for any inconveniences.

Yours sincerely,