B BRAUN

B. Braun Melsungen AG
Division Hospital Care
Safety Officer Medical Devices

34209 Melsungen
Germany

Your reference:
Our reference: RECALL 2016-12-21 LS/STK

Contact:

Fon: 05661 71-2769
Fax: 05661 75-2769
Email: ludwig.schuetz@bbraun.com
Internet: http://www.bbraun.de

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TO WHOM IT MAY CONCERN

Urgent FIELD SAFETY NOTICE – Certofix Duo Certofix Trio Drucafix

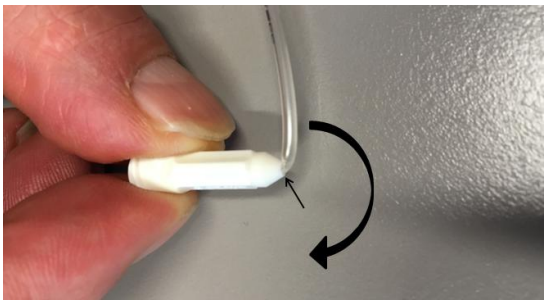
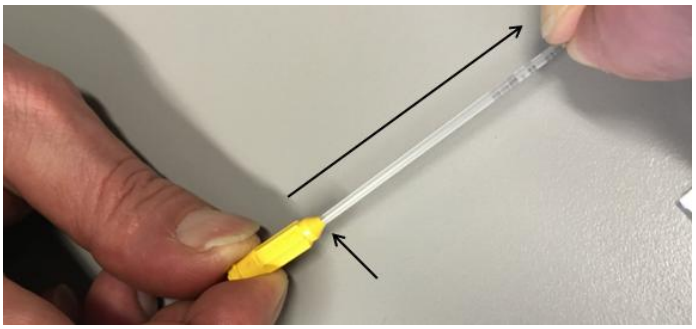
To whom it may concern,

we, the B. Braun Melsungen AG have decided to conduct a FIELD SAFETY CORRECTIVE ACTION for the following products:

Article Number	Article Name	Batch
4161211	CERTOFIX DUO V 720	16M15A8551
4161319	CERTOFIX DUO V 730	16M21A8551
4163214	CERTOFIX TRIO V720	16M17A8551
		16M16A8551
4163306	CERTOFIX TRIO S 730	16M18A8551
4164158	CERTOFIX DUO S 715	16M24A8551
4167385	CERTOFIX DUO S 720	16M18A8551
4167408	CERTOFIX TRIO S 720	16M28A8551
4162200E	CERTOFIX DUO 720	16M21A8551
		16M22A8551
4163206E	CERTOFIX TRIO 720	16M11A8551
4167408S	CERTOFIX SAFETY TRIO S 720	16M08A8551
4166906	CERTOFIX DUO PAED S 408	16M24A8551
4166922	CERTOFIX DUO PAED S 413	16M18A8551
227599	DRUCAFIX WITH SPLITTOCAN	16L20A8701
		16L07A8701
4162153	CERTOFIX TRIO V 715	16M22A8551
		16M24A8551
		16M25A8551

Reason for the FSCA:
During production we observed in an isolated case that a female Luer connector was not fully connected to the extension line of the Certofix Catheter. Upon further intensive testing, we could identify the root cause of the defect and are able to limit a possible occurrence of the failure to the below listed product/batch combinations. The failure appears only at white and yellow luer connectors and occurs at a very low rate. The failure can be identified by the user.

A disconnection of the Luer connector from the extension line has the potential to cause air embolism and other serious patient harm. We therefore advise to discontinue usage of the affected product/batch combinations OR - in case of an undersupply situation - identify potentially affected products according to the below described procedure.

In case of an undersupply situation, the user has the opportunity to identify full functionality of the Certofix catheter.
1. Fold the yellow and white luer cone versus the extension line by at least 90°. 
2. Pull on the yellow and white luer cone (away from the extension line). 
3. Visually inspect the connection between the luer cone and the extensionline for a potential opening.
4. After priming inspect the connection between the luer cone and the extensionline for potential leakage.
5. If no openings or leakages are identified, the Certofix catheter can be safely used.

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Actions to be taken

Our records have shown that your hospital has received affected Certofix/Drucafix Catheter batches as mentioned in the table above.

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

- Please identify, quarantine and return affected devices.
- In case of an undersupply situation, please inspect the catheters for the potential failure and continue using until the undersupply situation has ended.
- Should an affected product/batch combination be in use in a patient, please inspect the catheter according to the above described procedure. If no defects are found the catheter can be safely used.
- In case a defect catheter is identified please do not take any attempt to repair the catheter. A defect catheter is not useable anymore.
- Should a defect be identified, please file a complaint via your contact partner to the B.Braun Melsungen AG.
- Please inform the responsible personnel/user staff in the affected facilities .
- Please confirm the receipt of this information.

If more information is needed, please contact

Local contact 1
Name
Title
Email
telephone

Local contact 2

Kindly accept our apologies for any inconveniences.

Yours sincerely,