

Urgent Field Safety Corrective Action - Certofix Quattro Recall

Dear All,

We have decided to recall the following products in the context of a FIELD SAFETY CORRECTIVE ACTION from the market:

Article Number	Article Name	Batch
4167775S	CERTOFIX SAFETY QUATTRO S 820	all
4167767	CERTOFIX QUATTRO V 815	all
4167775	CERTOFIX QUATTRO V 820	all
4167783	CERTOFIX QUATTRO V 830	all
4163443	PROSET CERTOFIX-QUATTRO S830 (APOPLF.)	all
4168894	PROSET CERTOFIX QUATTRO S830	all
4163492	PROSET CERTOFIX QUATTRO S820	all
4168208	PROSET CERTOFIX QUATTRO S830	all
4167784S	PROSET CERTOFIX SAFETY QUATTRO S820	all
4168178	PROSET CERTOFIX QUATTRO S820	all
4167772S	PROSET CERTOFIX SAFETY QUATTRO S820	all
4163443	PROSET CERTOFIX-QUATTRO S830	all
4164038	PROSET CERTOFIX-QUATTRO S820	all
4169960	CERTOFIX QUATTRO S820 W/O ECD DEDUCT	all
4169972	CERTOFIX QUATTRO S830 W/O ECD DEDUCTION	all

Reason for the Recall

In the course of internal quality checks we discovered that in CERTOFIX QUATTRO minor inter-lumen connections may occur with a very low frequency. The potential inter-lumen connections are fully embedded into the plastic material of the bifurcation hub and a leakage to outside can be excluded. Up to now, no harm or any other adverse patient outcome 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.

Catheters other than the above specified CERTOFIX QUATTRO type are not affected.

Action needed from you:

1. Please translate the below attached Field Safety Notice into your local language and forward it to your affected customers immediately.

2. The hospital has to confirm the receipt of the Field Safety Notice and to initiate the following activities immediately and with priority:

- identify, quarantine and return affected devices
- not use affected devices anymore
- Patients with affected devices in place should be monitored carefully. If clinically uneventful, an exchange of the device is not indicated

- inform the responsible personnel in the affected facilities

3. Please ensure a balance of distributed and returned goods and keep the records.

4. Affected goods which are stored in your warehouse and which are returned by the customer shall be stored locally until further notice.

5. Please be advised that this FSCA must be reported by yourselves to your local Health Authority.

6. Please keep all correspondence with local health authorities on file and confirm the completion of your activities by email to us.

7. Please confirm the receipt of this information.

Please note that no new stock will be available before end of January 2016.

You are kindly requested to acknowledge the receipt of this e-mail.

Please accept our apologies for any inconveniences.

We thank you very much for your cooperation.

Yours sincerely,

B. Braun Melsungen AG

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