B. Braun Singapore Pte Ltd
Company Reg No.: 198703127H
GST Reg No.: M2-0078143-X

17 Dec 2015

FIELD SAFETY NOTICE – Certofix Quattro Recall

Dear Customer,

We, B. Braun Singapore Pte Ltd, have decided to recall the following products in the context of a FIELD SAFETY CORRECTIVE ACTION from the market:

Article Number	Article Name	Batch
4167767	CERTOFIX QUATTRO V 815	all
4167775	CERTOFIX QUATTRO V 820	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.

Actions to be taken by the USER

Our records show that your hospital has received potentially affected CERTOFIX QUATTRO 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.
- 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 .
- Confirm the receipt of this information.

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Kindly accept our apologies for any inconveniences.

Yours sincerely,

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