B BRAUN

B. Braun Medical Ltd.
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Dublin 12
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http://www.bbraun.com

Date
December 17, 2015

Urgent FIELD SAFETY NOTICE – Certofix Quattro Recall

Article Number	Device Name	Batch
4167767	CERTOFIX QUATTRO V 815	All
4167775	CERTOFIX QUATTRO V 820	All
4167783	CERTOFIX QUATTRO V 830	All

Dear Sir/Madam,

B. Braun Melsungen AG has decided to recall the above listed products in the context of a FIELD SAFETY CORRECTIVE ACTION from the market.

Reason for the Recall
In the course of internal quality checks it was 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 with the above described observation has been reported to B. Braun. 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.

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- Inform the responsible personnel in the affected departments/facilities.
- Complete and sign the enclosed 'Recall Confirmation Form' and fax this back to us (fax no. 01-7091889) to confirm that you have received this notice and advise the quantity of affected product to be returned.

*Please return the completed form by **Wednesday 23rd December 2015**, or sooner if possible.*

A member of B. Braun Medical will then be in touch with you to organise collection of any quarantined units. Please enclose the Batch Recall Confirmation Form with this collection.

Credit will be provided for any affected product returned.

If more information is needed, please contact:

Robert Egan
Business Unit Manager
Medical Technologies Division
Telephone: 086 2606917
Email: rob.egan@bbraun.com

We appreciate your immediate attention and apologise for any inconvenience caused.

Yours sincerely,

Bill Proctor
Commercial Manager

Roberta Egan
Roberta Egan
Regulatory Affairs Manager

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December 17, 2015

RECALL CONFIRMATION FORM

Certofix Quattro

Please complete this form, even if you do not have any of the concerned product and fax this form back to Fax No. 01-7091889

1. **We acknowledge receipt of the recall-notification from B. Braun Medical.**
2. **Please mark accordingly:**
   - ☐ We do not have any of the affected product in stock.
   - ☐ We will return the following products:

Article Number	Device Name	Batch Number	Quantity to be Returned
4167767	CERTOFIX QUATTRO V 815		
4167775	CERTOFIX QUATTRO V 820		
4167783	CERTOFIX QUATTRO V 830		

Hospital:	
Address:	
Contact Name:	
Contact Phone Number:	
Contact e-mail address:	
Date and signature	