B. Braun Medical Ltd.
3 Naas Road Industrial Park
Dublin 12
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http://www.bbraun.com

Date:
March 08, 2019

Ref: RECALL 2019-03-07 AS/LS

Urgent FIELD SAFETY NOTICE: Certofix® Quattro Recall

To whom it may concern,

B. Braun Melsungen AG has decided to recall the CERTOFIX® QUATTRO PRODUCT RANGE in the context of a FIELD SAFETY CORRECTIVE ACTION from the market.

As the defect cannot be restricted, the whole Certofix® Quattro Product range has to be recalled. Batches of the below listed products with batch numbers from 16AXXXXXXX onwards are affected.

Article No.	Article Name	Initial Batch	Expiry Date
4167767	CERTOFIX QUATTRO V 815	**16A**XXXXXXX or following	January 2021 or later
4167775	CERTOFIX QUATTRO V 820		
4167783	CERTOFIX QUATTRO V 830		
4167767-07	CERTOFIX QUATTRO V 815-EU/SA		
4167775-07	CERTOFIX QUATTRO V 820-EU/SA		

Reason for the Recall

Certofix® Quattro is a four-lumen catheter for catheterization of the superior vena cava using the Seldinger technique. Central venous catheters are well known and routinely used for central vein puncture and establishing access to the blood system of a patient to deliver infusion solutions, blood or pharmaceuticals in carrier solutions or monitoring systemic pressure.

In order to avoid accumulation of blood or fluid in the dead space between the side hole the and catheter tip, the lumen is closed with a plug.

In the course of our internal quality and post market surveillance activities we have found that this plug may not stay in its intended position. This deviation is caused by supplier related component quality issues.

While no serious injuries to patients, users, or third parties have been reported to date, there is a remaining risk of an undersupply, infusion of the plug into the patient and thrombus formation up to embolism.

All other Certofix® catheter variants (Mono, Duo, Trio, Quinto) are **not** affected as the lumen closure has a different design and is completely produced in-house.

Actions to be taken by the customer:
Our records show that your hospital / facility has received affected Certofix® Quattro Catheters as specified above.

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

- Review this Field Safety Notice in its entirety and ensure that all users of the above mentioned products in your organisation and other concerned persons are informed about this Field Safety Corrective Action. If you are a distributor, please forward this correction notification to your customers.
- Identify, quarantine and return affected goods.
- Do not use affected devices anymore.
- Already placed catheters can stay in situ until therapy is finished depending on individual risk benefit assessment. Check channels for patency.
- Confirm receipt of this information by completing and signing the attached 'Field Safety Notice Confirmation Form' and return this to B. Braun (fax no. 01-7091889).

The Health Products Regulatory Authority has been informed of this action.

If more information is needed, please contact:

Robert Egan
Business Unit Manager
B Braun Medical Ltd
Tel: 086-2606917
Email: rob.egan@bbraun.com

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

Yours sincerely,

Robert Egan
Business Unit Manager

Roberta Egan
Regulatory Affairs Manager

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March 08, 2019

Field Safety Notice CONFIRMATION FORM

Certofix® Quattro

Please complete this form and fax it back to Fax No. 01-7091889

1. **We hereby confirm that we are aware of the Field Safety Notice from 8th March 2019 concerning the Certofix® Quattro.**
2. **Please mark accordingly:**
   - ☐ We do not have any of the affected product in stock.
   - ☐ We will return the following products:

Article No.	Article Name	Batch Number	Quantity to be returned
4167767	CERTOFIX QUATTRO V 815		
4167775	CERTOFIX QUATTRO V 820		
4167783	CERTOFIX QUATTRO V 830		
4167767-07	CERTOFIX QUATTRO V 815-EU/SA		
4167775-07	CERTOFIX QUATTRO V 820-EU/SA		

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