

34209 Melsungen

Your reference:

Our reference: RECALL 2019-03-07 AS/LS

Contact:

TO WHOM IT MAY CONCERN

Fon: Phone number

Fax: Fax number

Email: E-Mail address

Internet: <http://www.bbraun.de>

Date: March 7, 2019

Urgent FIELD SAFETY NOTICE – Certofix® Quattro Recall

To whom it may concern,

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

The Certofix® Quattro catheters are distributed in various sterile procedural trays.

As the defect cannot be restricted, the whole Certofix® Quattro Product range has to be recalled.

Depending on the shelf-life of the products and the distribution on the market, the below mentioned batches have to be considered as initial batches. From then onwards all consecutive batches are affected.

Article No.	Article Name	Initial Batch	Expiry Date
4167767	CERTOFIX QUATTRO V 815	16AXXXXXX 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		
4167783-07	CERTOFIX QUATTRO V 830-EU/SA		
4167775S	CERTOFIX SAFETY QUATTRO S 820		
4167775S-07	CERTOFIX SAFETY QUATTRO S 820-EU/SA		

Chairman of Supervisory Board:
Prof. Dr. h.c. Ludwig Georg Braun

Executive Board:
Prof. Dr. Heinz-Walter Große
(Chairman)
Dr. Annette Beller
Anna Maria Braun, LL.M.

Dr. Meinrad Luga
Caroll H. Neubauer, LL.M.
Dr. Joachim Schulz
Markus Strotmann

Corporate Office: Melsungen
Register Court: Local Court Fritzlar
HRB 11 000
WEEE-Reg.-No. DE 42690900

Address:
B. Braun Melsungen AG
Carl-Braun-Straße 1
34212 Melsungen
Germany

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4167767P	CERTOFIX PROTECT QUATTRO V 815	4CXXXXXX / 14CXXXXXX or following	March 2019 or later
4167767P-07	CERTOFIX PROTECT QUATTRO V 815-EU/SA		
4167767P-S1	CERTOFIX PROTECT QUATTRO V815 - SET1		
4167775P	CERTOFIX PROTECT QUATTRO V 820		
4167775P-07	CERTOFIX PROTECT QUATTRO V 820-EU/SA		
4167775P-S1	CERTOFIX PROTECT QUATTRO V820 - SET1		
4167783P	CERTOFIX PROTECT QUATTRO V 830		
4167783P-07	CERTOFIX PROTECT QUATTRO V 830-EU/SA		
4167783P-S1	CERTOFIX PROTECT QUATTRO V830 - SET1		
4161094	PROSET CERTOFIX PROTECT QUATTRO V820	17CXXXXXX or following	March 19 or later
4161098	PROSET CERTOFIX PROTECT QUATTRO V815		
4161886	PROSET CERTOFIX QUATTRO V830		
4163492	PROSET CERTOFIX QUATTRO S820		
4168178	PROSET CERTOFIX QUATTRO S820		
4168894	PROSET CERTOFIX QUATTRO S830		
4167230SM	PROSET CERTOFIX SAFETY QUATTRO S820		
4167280SM	PROSET CERTOFIX SAFETY QUATTRO S830		
4167312SM	PROSET CERTOFIX SAFETY QUATTRO S830		
4167784S	PROSET CERTOFIX SAFETY QUATTRO S820		
4168030S	PROSET CERTOFIX SAFETY QUATTRO S820		
4161886P	PROSET CERTOFIX PROTECT QUATTRO V830		

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 side hole 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.



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Actions to be taken by the customer:

Our records have shown that your institution has received the affected Certofix® Quattro Catheter 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 organization 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.

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,