



PETER-BREHM
Die Präzision in Titan
für den Menschen

Field Safety Notice

Notification regarding a voluntary product recall

Reference R-20210701-4

Affected Products

Article Number	Description	LOT
42305-03	TIBIA Component UC + SC Cemented; Size: 5, Left	403079
42403-03	TIBIA Component UC + SC Cemented; Size:3, Right	403097

Description of the Situation

Due to a customer feedback it became aware that the sterile barrier was labeled falsely. A TIBIA Component UC+SC cemented, Size: 3, Right has been labeled mistakenly as a TIBIA Component UC + SC cemented, Size: 5, Left on the sterile barrier. The product within the packaging including the direct marking of the product match with the label on the outer packaging (cardboard box). In analogy, it is assumed that a TIBIA Component UC+SC cemented, Size: 5, Left has been labeled mistakenly as TIBIA Component UC+SC cemented, Size: 3, Right on the sterile barrier.

It is assumed that there has been a mix-up during the packaging process, whereby the sterile barrier labels had been mistakenly reversed for these two LOT numbers.

Illustration of the mistakenly labeling:



Fig. 1: Labeling of the outer packaging (Cardboard box)



Fig. 2: Labeling of the sterile barrier

As a precautionary measure, PETER BREHM GmbH has decided to recall all affected products with the LOT 403097 and LOT 403079 of the TIBIA Component UC+SC Cemented; Size:3, Right and the TIBIA Component UC+SC Cemented; Size: 5, Left.



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Clinical Effects

In case the falsely labeled TIBIA Component UC + SC cemented is identified, an OR time extension of <30 minutes might occur. The device itself matches the label on the outer packaging (cardboard box) as well as the patient labels and the direct marking of the device is correct, therefore no clinical impact on the instrumentation intraoperatively or in context with postoperative identification.

If any of the affected products have already been implanted, there is no increased risk to the patient postoperatively. The traceability of the products is also ensured.

Measures to be taken

- Please ensure that within your organization all users of the above-mentioned products and all other persons to be informed, are made aware of this field safety notice.
- Please check your stock immediately and ensure that the affected products are no longer used.
- Please return all affected products address stated in the following. You will immediately receive a replacement free of charge.

PETER BREHM GmbH
Complaint Management
Am Mühlberg 30
91085 Weisendorf
Germany

- Please return the enclosed fax reply for documenting this safety notice to us within 5 working days, even if you do not have any of the listed products in stock. This will prevent us from sending you unnecessary further messages regarding this issue.
- If you have any questions regarding the field safety notice, measures to be taken or possible replacement products, please contact your sales representative.

Contact Persons

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