



PETER-BREHM
Die Präzision in Titan
für den Menschen

Field Safety Corrective Action

Notification of a voluntary product recall

Reference | R-20190301-4

Affected products

| Article Number | Designation | LOT |
|----------------|--|----------|
| 54860-15-1 | TRIAL Titanium Shell left with strap 60 mm | 15006263 |

Description of situation

Due to a manufacturing fault the incorrect size was inadvertently marked on one batch of Trial Titanium Shell left with strap 60 mm. The instruments serve the intra-surgical size estimation during selection of the original implant. Incorrect size determination of the original implant can therefore result intra-surgically. For this reason this lot is being recalled.



The Trial Titanium Shell Ø 60 mm marked with: Ø 64L, Article Number: 54864-15-1, LOT: 15006263, is being recalled (PICTURE).

Clinical effects

A potentially incorrect size estimation will most probably be noticed during the implantation of the original implants. In the worst case an incorrect size estimation can result in an increase in the operation time \geq 30 minutes. The supply quality with the original implant is not impaired as a result because an implant position with primary stability always has to be achieved, irrespective of the stem diameter.

There is no short- or long-term danger of damage to the health of patients at whom an Titanium Shell left with strap 60 mm has already been implanted.

Measures to be implemented

- Please ensure that this safety information is brought to the attention of all the users of the products mentioned above as well as all other persons who are to be informed in your organization.
- Please check your stocks immediately and ensure that the affected products are no longer used.
- Please return all the affected products to the following address. You will receive a free replacement immediately afterwards.



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- We would ask you to return the enclosed fax response to us within 5 workdays as documentation of this Safety Information, even if you do not have any of the listed products on stock. This measure ensures that we do not unnecessarily send you any further messages about this topic.
- If you have any further questions on this measure or on substitute products, please contact the sales agent who is responsible for you.

Contacts

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