



Field Safety Notice

Notification regarding an information about the MRP-TITAN System

Reference

R-20220803-1

Affected Products

Article Number	Description	Batch
61211-02	Anchoring Stem Curved with Distal Interlocking Cementless, Ø 11 x 320 mm	N/A
61211-01	Anchoring Stem Curved with Distal Interlocking Cementless, Ø 11 x 260 mm	N/A
60913-02	Anchoring Stem Straight Cementless, Ø 13 x 200 mm	N/A
60913-03	Anchoring Stem Curved Cementless, Ø 13 x 200 mm	N/A

Description of the Situation

In the context of acquiring the certification of MRP-TITAN in accordance to Regulation (EU) 2017/745 (MDR) extended preclinical tests according to ISO 7206-4 taking into account ASTM F2996 were carried out in order to assess the component safety.

The above stated articles were subjected to the testing under laboratory conditions with the required loads. In the tests, isolated cases of stem breakage at the level of the embedment occurred (see Figure 1).

An increased risk of stem breakage could NOT be derived based on market observation.



Figure 1: Test setup and marking of embedment



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Die Präzision in Titan
für den Menschen

For regulatory reasons it is therefore necessary to establish a weight restriction of 65kg for the affected stems. The biomechanical stability with a correlating body weight of 65kg was confirmed on basis of performed testing in accordance to the normative requirements referenced above.

The information regarding the weight restriction is embedded within the instruction for use:

NOTE	<p><i>For the articles:</i></p> <ul style="list-style-type: none">- <i>Anchoring Stem Curved with Distal Interlocking Cementless, Ø 11 x 320 mm</i>- <i>Anchoring Stem Curved with Distal Interlocking Cementless, Ø 11 x 260 mm</i>- <i>Anchoring Stem Straight Cementless, Ø 13 x 200 mm</i>- <i>Anchoring Stem Curved Cementless, Ø 13 x 200 mm</i> <p><i>there is a restriction of the patient weight to 65 kg.</i></p>
 CAUTION	<p>Failure to observe the weight restriction:</p> <ul style="list-style-type: none">• Risk of injury due to implant fracture!• Impairment of component safety due to increased stress!➤ The weight limitation of the implants must be observed➤ The criterion should also be checked and observed during the follow-up examination

Clinical Effects

Possible postoperative stem breakage of the affected stems in case of being implanted in patients with a higher body weight than 65 kg, or patients presenting a higher body weight than 65kg within the lifespan of the medical devices.

Measures to be taken

- Please take the information into account in the context of the preoperative planning as well as the information and planned follow-up examinations of your patients.
- 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.
- We kindly ask you to confirm that you have read and understood this letter and to return the enclosed fax reply for documenting this safety notice within 5 working days.
- If you have any questions regarding the field safety notice, or regarding the measures to be taken please contact your sales representative.

Contact Persons

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