



PETER-BREHM
Die Präzision in Titan
für den Menschen

Field Safety Notice

Information on intraoperative handling of the MRP-TITAN® screw M6

Reference	R-20200217-3
Affected products	
Article Number	Designation
60901-04	Screw M6 short
60901-07	Screw M6 long
97021-55-1	Allen Key SW 5 Ball Head

Description of situation

Based on new information, PETER BREHM GmbH identified two possible risk factors in the intraoperative handling of the screw M6:

1. Contaminated thread with blood

New test results indicate dried blood on the thread of the M6 screw or in the internal thread of the anchoring stem may cause screw breaks. The dried blood in the thread blocks the screw before it is fully seated. When securing with a tightening torque of 25 Nm, the screw M6 may break.

2. Not using of the gold-colored Allen key SW5 ball head

Also, PETER BREHM GmbH has been informed the mandated gold-colored Allen key SW5 ball head (item no.: 97021-55-1) is not always used intraoperatively. By not using the gold-colored Allen key SW5 ball head (item no.: 97021-55-1) transversal forces can occur, whereby the screw M6 will not completely screwed in axially and can block it. During the following securing with a tightening torque of 25 Nm, the blocking can lead to a breakage of the screw M6 in worst case.



Please note the detailed descriptions in the instructions for use:

- Instruction for use LBL609; Page 6 ff.
- Surgical technique LBL 609-51; Page 36 ff.
- InfoFlip LBL 681-70; "DOS AND DON'TS"



PETER-BREHM
Die Präzision in Titan
für den Menschen

Clinical effects

If a screw M6 breaks and the screw fragment cannot be removed from the internal thread of the cone a prolonged operating time > 30 minutes may be necessary due to the required shaft replacement.

If the morse taper junction is not properly secured with the screw M6 according to the instructions for use, there is the possible risk of postoperative taper connection fracture of the hip shaft.

Measures to be implemented

1. If the thread is contaminated with blood

- Before screwing in the connecting rod, make sure that it is free of soil to avoid contamination of the internal thread in the anchoring stem.
- It is also important to ensure that the screw M6 itself is free of contamination before it is screwed in.
- Before screwing in the screw M6, ensure the internal thread of the anchoring stem is still free of contamination. Therefore, the internal thread must be thoroughly rinsed with at least 100 ml saline solution (NaCl 0.9%) using a syringe. Make certain the thread is not damaged by the flushing.

2. Use of the gold-colored Allen key SW5 ball head

- The screw M6 must **always** be attached with the gold-colored Allen key SW5 ball head (item no.: 97021 55-1) and screwed in as far as possible with little effort. Only then secure the screw M6 in conjunction with the torque limiter.

3. Additional information on cleaning the plug-cone connection

- We would like to emphasize the Instruction for use (IFU), which mandates the following text with regard prior to tensioning the morse taper junction:

Carefully clean (rinse with NaCl 0.9%) and dry prior to assembly of the morse taper junction.

We received the information and ensure that all users of the mentioned products or other people to inform are aware of this Field Safety Corrective Action. The outlined actions will be taken.

We would ask you to return the enclosed fax response to us within **10 workdays** as documentation of this Safety Information.

Contacts

If you have any further questions on this measure or on substitute products, please contact the sales agent who is responsible for you.

Customer Service International: +49 9135 – 7103 – 669

Team Leader F&E Hip: Christian Zucker
Phone: +49 9135 – 7103 – 41
E-Mail: christian.zucker@peter-brehm.de

Safety Officer for Medical Products
Tel: +49 9135 – 7103 – 993
E-Mail: sbm@peter-brehm.de