

Urgent Field Safety Notice

Product name: balanSys REV Stem Screw

FSCA ID No: FSCA 22/01

Type of action: Field Safety Notice

Bettlach, 15 March 2022

Issued by: Mathys Ltd Bettlach

Addressees: Orthopaedic surgeons
OR management

Affected products:


Product	Item No	Item description	Batch No
	79.15.0062	balanSys REV Stem Screw	all

Table 1: Products affected by FSCA 22/01

Ladies and Gentlemen:

Mathys Ltd Bettlach hereby informs you of a voluntary Field Safety Corrective Action (FSCA) concerning the product listed above.

Data from global post-marketing surveillance show eight (8) reports since 2009 regarding postoperative screw loosening.

Description of the problem:

Data from global post-market monitoring show that the femoral screw of the balanSys Rev Stem may loosen post-operatively.

Root cause analysis and definition of preventive and corrective measures have already been initiated by Mathys Ltd Bettlach.

Internal investigations have shown that all batch numbers are affected.

Potential hazards:

- The patient must undergo another surgery for removal of the loosened screw and insertion of a new screw into the femoral component
- Scratches in the polyethylene inlay or the femoral component can lead to increased PE abrasion
- Increased risk of loosening of the primary connection between stem and implant

Safety measure taken by Mathys Ltd Bettlach

The present Field Safety Notice serves to point out the correct surgical technique. After insertion of the implant with the impactor, the screw must be tightened again, as the previously applied pre-tension may have been reduced by the hammer strokes.

In the period from 2009 to February 2022, 8 relevant vigilance cases were reported to Mathys Ltd Bettlach. Although the probability of occurrence is very low (0.048%/y), Mathys Ltd Bettlach has decided to implement this voluntary Field Safety Corrective Action.

We would like to draw your attention to the current surgical technique.

Assembly of the implants is a crucial part of every revision knee surgery. Correct application is important for reliable and long-lasting restoration; each step must be done correctly.

The balanSys Revision consists of a two-stage locking mechanism that connects the stems to the other components. Primary stability is ensured by a cone, secondary stability by an additional screw lock.

The screw must be tightened with the torque wrench supplied (Figure 1). **After insertion of the implant with the impactor, the screw must be tightened again**, as the previously applied pre-tension may have been reduced by the hammer strokes (Figure 2). The complete procedure is described in the surgical technique. This is of crucial importance, as unscrewing of the screw is prevented only by correct application of torque and pre-tension.

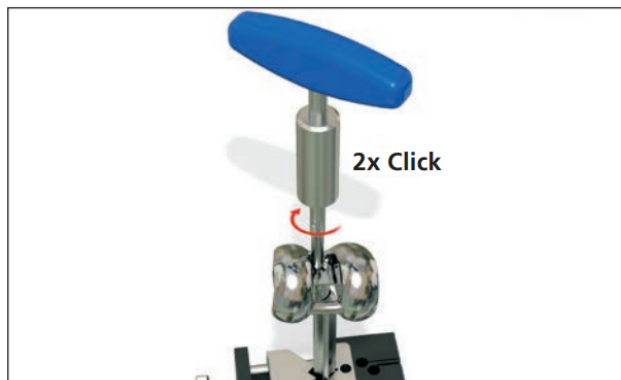


Figure 1: The screw must be tightened with the torque wrench included in the scope of delivery

Tighten the stem screw with the Torque Wrench (18.410-RAL5002) with 2 clicks.



After implantation, the stem screw must be re-tightened since the screw can loosen during impaction!



Figure 2: After insertion of the implant with the impactor, the screw must be tightened again

Insert the Neck Stopper Curved (79.02.0750) into the box of the femur component.

Tighten the stem screw of the component with the Torque Wrench 3.5 with 2 clicks while counteracting the torque with the Neck Stopper Curved (79.02.0750).



After implantation, the stem screw must be re-tightened with the Torque Wrench (18.410-RAL5002) with 2 clicks.

Measures to be taken by the customers:

- Read this Field Safety Notice carefully and make sure that all relevant departments and position holders are informed of its content.
- Inform and instruct any 3rd parties to whom affected products have been passed on.
- Please complete the enclosed confirmation form and return it to the address provided, or hand it to your Mathys representative. *(This will stop Mathys from sending you further reminders concerning this FSCA.)*
- Please observe the present Field Safety Notice until the action has been completed within your organisation. Keep a copy of this Field Safety Notice.
- For questions regarding this Field Safety Notice, please contact us at the following address:
vigilance@mathysmedical.com

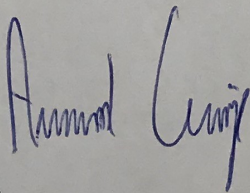
Information on materiovigilance:

The competent national authorities have been notified of this Field Safety Corrective Action.

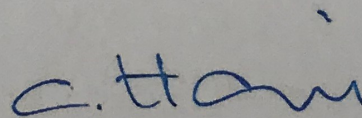
Please notify Mathys Ltd Bettlach of any adverse event in connection with the affected products or any other Mathys product. You can report adverse events to vigilance@mathysmedical.com or contact Mathys Ltd Bettlach via your local Mathys branch.

We apologise for any inconvenience this may cause and will be glad to answer any further questions you may have.

Mathys Ltd Bettlach



Armand Linge
Person Responsible for Regulatory Compliance
Quality Management & Regulatory Affairs



Cornelia Hari
Vigilance & Post Market Surveillance Manager
Quality Management & Regulatory Affairs

Confirmation form FSCA 22/01

Urgent Field Safety Notice

Product name: balanSys REV Stem Screw

FSCA ID №: FSCA 22/01

Type of action: Field Safety Notice

Confirmation of receipt

Please complete:

Customer № _____

Hospital _____

Post code, town _____

Contact _____

(Name/position)

By filling out and returning the present form sheet, I confirm that I have received and read this Field Safety Notice:

Place/ Date: _____

Signature: _____

Please return this form by email or fax to the following address:

Email:

Fax: