Urgent Field Safety Notice

Product name: **balanSys REV Stem Screw**

FSCA ID N2: **FSCA 22/01**

Type of action: **Field Safety Notice:**
Reminder to all customers of the balanSys Revision System to follow the surgical technique to ensure correct implantation of the balanSys REV Stem Screw

Bettlach, March 28th, 2022

Issued by: Mathys Ud Bettlach

Addressees: All customers of the balanSys Revision System including:
Orthopaedic surgeons
OR management

Affected products:

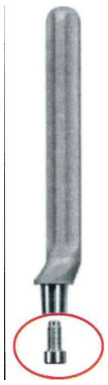
Product	Item N2	Item description	Batch N2
	79.15.0062	balanSys REV Stem Screw	all

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.

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.

Postoperative screw loosening may be caused by failure to follow the surgical technique of the balanSys Revision System, which indicates that the balanSys REV Stem Screw must be retightened after insertion of the implant with the impactor, as the previously applied pre-tension may have been reduced by the hammer strokes.

Internal investigations have shown that all batch numbers are affected.

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 remind all customers via Field Safety Notice to follow the surgical technique of the balanSys Revision System.

Potential hazards and patient care:

Potential hazards caused by failure to follow the surgical technique of the balanSys Revision System may include:

- 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

As long as the patient does not consult his or her physician after surgery due to symptoms that would indicate one of the incidents listed above and would require revision surgery, it is assumed that the screw has been tightened according to the surgical technique.

Patients operated with balanSys REVISION therefore do not require additional observation by the physician and can be examined as part of regular follow-up care according to the clinic's rules.

Field Safety Notice by Mathys Ltd Bettlach

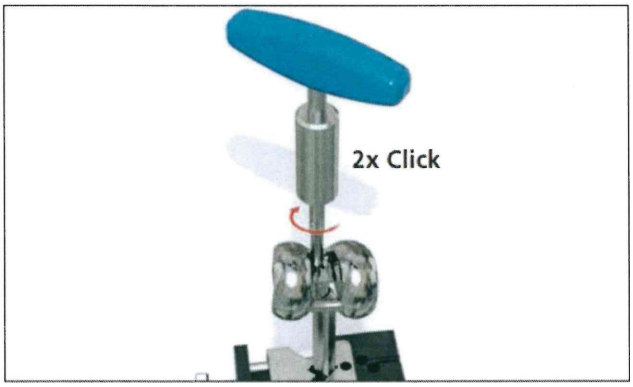
The present Field Safety Notice serves to point out to follow the surgical technique of the balanSys Revision System with special attention to tighten the balanSys REV Stem Screw again after insertion of the implant with the impactor, as the previously applied pre-tension may have been reduced by the hammer strokes.

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 sterns to the other components. Primary stability is ensured by a cone, secondary stability by an additional screw loek.

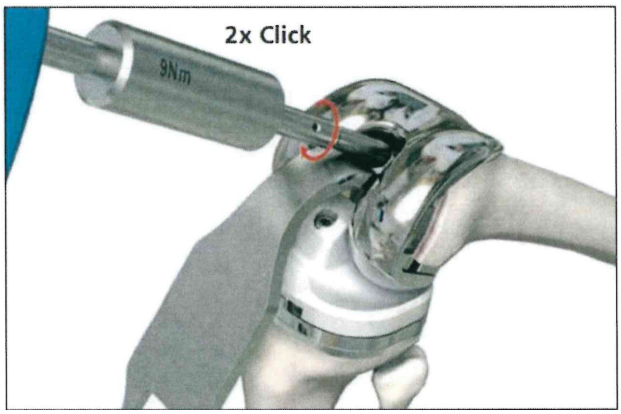
The screw must be tightened with the torque wrench supplied (Figure 1). **After insertion of the implant with the impactor, the screw must be tightened again,** as the previously applied pre-tension may have been reduced by the hammer strokes (Figure 2). The complete procedure is described in the surgical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



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

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

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



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).

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

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

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 wil/ stop Mathys trom 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

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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: