Urgent Field Safety Notice

Product name: **balanSys Ligament Tensor**

FSCA ID no.: **FSCA 18/02**

Type of action: **FSN / Recall of affected batch numbers**

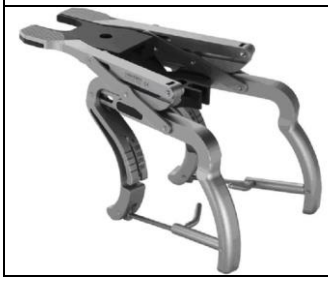
Bettlach, 08 March 2018

Issued by: Mathys Ltd Bettlach

Addressee: OR Management
CC: Purchasing Department

Mathys Ltd Bettlach hereby notifies you of a voluntary Field Safety Corrective Action (FSCA) affecting the item and batch numbers of the balanSys Ligament Tensor listed below. Our records indicate that you have received one or more of the affected batches and are therefore subject to this safety-relevant action.

Affected products:

Product	Item number	Item description	Batch numbers
	71.02.3018	balanSys Ligament Tensor	2205708; 2205708N01; 2205708N02

Description of the problem:

Mathys Ltd Bettlach has received a report that a rivet on a balanSys ligament tensioner was missing. This was detected during the checking of loan instruments. The rivet is made of stainless steel and consists of two parts, a stem and a cap. In a worst-case scenario, it is possible that a rivet that comes loose could fall intraoperatively into the situs.

It has been established that only Lots 2205708, 2205708N01 and 2205708N02 were affected, where a total of 11 units were produced. In total, 9 units went onto the market. All the affected items required rework which could possibly result in a rivet coming loose due to sub-optimal riveting during the rework.

For this reason, Mathys Ltd Bettlach decided to recall the affected batch numbers of the balanSys Ligament Tensor. All affected items at your facility will be replaced with devices not affected by this issue.

Potential hazards:

The following hazardous scenarios may lead to serious patient harm if a rivet becomes loose during surgery without the surgeon noticing it:

1. The undetected loss of the rivet may result in erroneous readings of the ligament tension. Therefore, the knee components may be implanted with incorrect varus / valgus or internal / external rotation and hence lead to problems of misoriented implant positioning (for example, altered kinematics, pain, higher wear, early aseptic loosening).

2. If the missing rivet goes undetected at the time of surgery and remains in the situs, it will only be detected at the first post-operative X-ray, resulting in a medical re-intervention.

Immediate actions to be taken by the customer:

- Read this Field Safety Notice carefully and make sure that all relevant departments and positions are informed of its content.

- **Immediately identify and quarantine all unused products carrying the item and batch number indicated above.**

- **Return any affected products as soon as possible.** A Mathys representative will contact you to support you with this procedure and organise the replacement.

- Third parties to whom affected products have been forwarded must be informed and instructed accordingly.

- Please complete the enclosed confirmation form and return it to the address indicated or hand it over to your Mathys representative. *(This will stop Mathys from sending you further reminders concerning this FSCA.)*

- The present Field Safety Notice must be observed until the action has been completed within your organisation. Please keep a copy of this Field Safety Notice.

- For questions regarding the return and replacement of the products, please contact the Mathys representative responsible for your organisation or your local Mathys office.

- For questions regarding this Field Safety Notice, please contact us at the following address: vigilance@mathysmedical.com

Information on materiovigilance:

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

Please notify Mathys Ltd Bettlach of any adverse event related to the affected product or any other Mathys product. You can report adverse events to Mathys at vigilance@mathysmedical.com or via your local Mathys office.

We apologize for any inconvenience this may cause. If you have any further queries, please do not hesitate to contact us.

Mathys Ltd Bettlach

Stephan Müller
Director Regulatory Affairs & Quality Management
Regulatory & Quality Management

Abir Roy
Vigilance & Post Market Surveillance Manager
Regulatory & Vigilance

Confirmation form FSCA 18/02

Product name:	**balanSys Ligament Tensor**
FSCA ID no.:	**FSCA 18/02**
Type of action:	**FSN / Recall of affected batch numbers**

Confirmation of receipt

Please complete:

Customer no. _____

Hospital _____

Post code, town _____

Contact (Name/position) _____

By completing and returning the present form I confirm that I have received and read this Field Safety Notice:

☐ Our stocks do not contain any affected products.

☐ Our stocks contain the following affected products.

Item number	Batch	Number of units

Place/date: _____ Signature: _____

Please return this form by e-mail or fax to the following address:
e-mail:
fax: