

Urgent Field Safety Notice

Product name: balanSys Femur Holder
FSCA ID №: FSCA 19/01
Type of action: Recall of all items from batch 2247596

Bettlach, 14-MAR-2019

Issued by: Mathys Ltd Bettlach
Addressee: Orthopaedic surgeons
(Users of the balanSys Femur Holder)
OR management
CC: Purchasing Department
Affected products:


Product	Item №	Item description	Batch №
 balanSys Femur Holder	71.34.1014	balanSys Femur Holder	2247596

Table 1: Products affected by FSCA 19/01

Ladies and Gentlemen:

Mathys Ltd Bettlach hereby informs you of a voluntary Field Safety Corrective Action (FSCA) concerning the listed item (balanSys Femur Holder) from the Leggera Instrument Set.

Our records indicate that you have received one or several of the affected devices.

Description of the problem:

Global post-market surveillance data show two reports of fractures of a metal claw of the balanSys Femur Holder (item № 71.34.1014) with batch № 2247596.

Examinations at our manufacturer's have shown that there is a production error affecting all items in this lot. During the thermal treatment of the material used, a deviation in the process was identified that leads to a change in the material characteristics and thus to an increased risk of breakage at the place of the claw. A total of 29 items from this batch were delivered to the market.

Only the specified batch (2247596) is affected by this measure. Mathys Ltd Bettlach is not aware of anything to suggest that other lot numbers might have the same problem.

Possible dangers:

Due to the material defect, an increased risk of the claw of the femur holder breaking off must be expected. In the event of an unnoticed intraoperative fracture, there is a risk of the fragment remaining in situ.

The resulting sharp edge at the fracture point moreover represents an increased risk to the users of the instrument.

Immediate measures to be taken by the customers:

- 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 № indicated above.
- Immediately separate out all the products carrying the item and batch №s indicated above (see “Affected Products”). A Mathys representative will contact you in order to support you with this procedure and organise the return of the instruments.
- Any 3rd 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.
- Should you have any questions regarding the return of the products, please contact the Mathys representative responsible for your organisation or your local Mathys office.
- For any other questions regarding this Field Safety Corrective Action Notice, please contact us at the following address: vigilance@mathysmedical.com

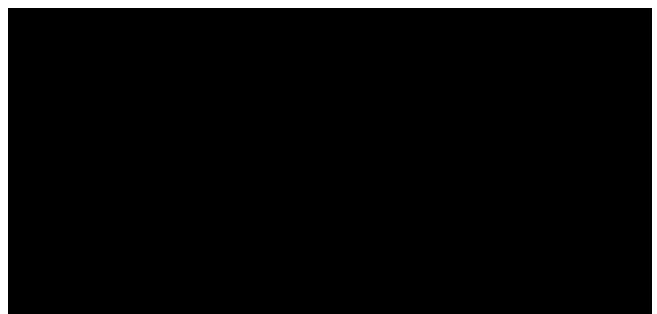
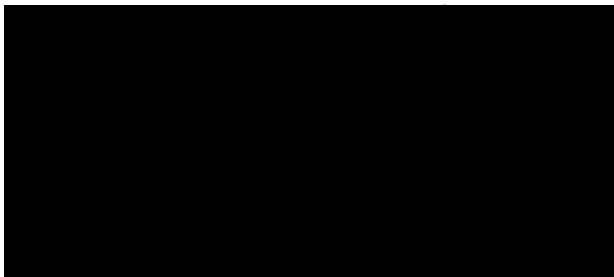
Information on materiovigilance:

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

Please notify Mathys Ltd Bettlach of any adverse event in connection with 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 apologise for any inconvenience this may cause. If you have any further queries, please do not hesitate to contact us.

Mathys Ltd Bettlach



Confirmation form FSCA 19/01

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Product name: balanSys Femur Holder
FSCA ID №: FSCA 19/01
Type of action: Recall of all items from batch 2247596

Confirmation of receipt

Please complete:

Customer № _____
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 №	Batch	Number of units

Place/date: _____

Signature: _____

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

Email:

Fax: