

Urgent Field Safety Notice

Product name: Mod. rev. neck lateral with screw 60

FSCA ID no.: FSCA 19/02

Type of action: Safety information

Bettlach, 11 March 2019

Issued by: Mathys Ltd Bettlach

Addressee: OR Management

CC: Purchasing Department

Affected product:


|  | Item number | Item description | Batch numbers |
|---|-------------|--------------------------------------|---------------|
| | 52.34.0021 | Mod. rev. neck lateral with screw 60 | 2239710 |

Table 1: Affected products of FSCA 19/02

Ladies and Gentlemen,

Mathys Ltd Bettlach hereby notifies you of a voluntary Field Safety Notice (FSN) affecting the item and batch numbers of the Mod. rev. neck lateral with screw 60 listed above.

According to our records, one of the devices involved in this FSN was implanted in your Hospital.

Description of the problem

Mathys received one (1) complaint where at the time of implant placement, the screw of the modular neck passed through the screw hole and could not be fixated.

Internal analysis showed a probable dimensional anomaly on the Mod. rev. neck lateral with screw 60 with lot numbers 2239710 and 2238537. The dimensional anomaly is shown in an over-dimensioning of the screw hole of the Revision neck that could allow the locking screw to entirely pass through the screw hole of the neck.

In total, 5 implants of the affected lot numbers were implanted. The following information is given to surgeons and hospitals where a neck & screw with one of the two lot numbers was implanted.

Information to Surgeons and Hospitals

Although the decision to inform patients is ultimately up to the surgeon, the purpose of this Field Safety Notice is to inform surgeons involved about the current status of investigation performed to allow them making the most appropriate monitoring of their patients.

Regarding the future clinical management of patients implanted with the specific Revision necks covered by this FSN, Mathys Ltd Bettlach does not recommend a preventive revision surgery. Based on the following:

- The locking screw is only a safety screw. Connection between the two modules does not rely on the screw fixation but mainly on the Morse tapers. By considering that neck-stem is a self-locking coupling, patient may have no problem at all;
- Increased micromotions at the stem-neck interface over time could potentially lead to fretting corrosion. According to literature, factors that influence micromotions are related to material couplings, design, weight of patient and level activity, assembly force, cleaning of tapers before assembly. If tapers have been coupled correctly in terms of strength and cleanliness during the surgery, the incidence of the screw will be minimal;
- Taper rotation as post-op complication could be experienced if surgeon did not adequately tight the taper during the surgery. This event, never reported to Mathys for lot numbers specified in table 1, is very unlikely to occur since it would have been visible few weeks after surgery. Lot numbers specified in table 1 have been instead implanted several months ago.

Surgeons are then advised to continue monitoring patients according to the standard clinical follow-up protocol and to act accordingly.

Immediate measures 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.
- 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 FSN)*
- 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 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 action.

Please notify Mathys AG Bettlach of any adverse event in connection with the Mod. rev. neck lateral with screw 60 or any other Mathys product. You can report adverse events to Mathys at vigilance@mathysmedical.com or via your local Mathys office.

We very much regret the inconvenience caused to you. If you have any further queries, please do not hesitate to contact us.

Mathys Ltd Bettlach



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Regulatory & Vigilance



Dominic Bachmann
Vigilance & Post Market Surveillance Manager
Regulatory & Vigilance

Confirmation form FSCA 19/02

Product name: Mod. rev. neck lateral with screw 60
FSCA ID no.: FSCA 19/02
Type of action: Safety information

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: