Urgent Field Safety Notice

Product designation:	**Affinis Inverse glenosphere 39**
FSCA ID №:	**FSCA 20/01**
Type of action:	**Recall of one batch**

Bettlach, 14-JAN-2020

Issued by:	Mathys Ltd Bettlach
Addressees:	Orthopaedic surgeons OR management
CC:	Purchasing department

Affected products:

Product	Item №	Item description	Batch №
	60.30.3039	Affinis Inverse glenosphere 39	2267919

Table 1: Products affected by FSCA 20/01

Ladies and Gentlemen:

Mathys Ltd Bettlach hereby informs you of a voluntary Field Safety Corrective Action (FSCA) concerning the item listed (Affinis Inverse glenosphere 39, Batch 2267919).

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

Description of the problem:

Implants of the batch indicated may fail to comply with the valid specification. In individual implants, the central borehole of the glenosphere may have been drilled too small. In these products, the fixation screw does not properly fit through the borehole. In these cases, the glenosphere cannot be used or fixated correctly.
Mathys is aware of two reports of this type from the market. Internal investigations have shown that only individual items of the batch are affected.

Only the batch listed in Table 1 is affected by this action. A total of 48 items of this batch were delivered.

Possible dangers:

Due to this manufacturing error, the implant cannot be used correctly. In the absence of another, equivalent implant of the same size (vitamys or PE), it may become necessary to use an implant of another size instead. This can lead to “overstuffing” or “understuffing”, increasing the likelihood of premature revision surgery.

If a glenosphere is implanted without a fixation screw, the implant is fixated only by a “snap-in mechanism”. The risk of loosening of the glenosphere is therefore increased.

The defect is not present in all products of this batch. In the case of products already implanted, it can be assumed that the implants do comply with the valid specification and there is no increased risk for the patient.

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 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 implants.
- 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.)*
- Please observe the present Field Safety Notice until the action has been completed within your organisation. 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 further questions regarding this Field Safety Corrective Action Notice, feel free to 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.

Inform 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. We will be glad to answer any further questions you may have.

Mathys Ltd Bettlach

Peter Münger
Head of Medical Affairs
Quality Management & Regulatory Affairs

Dominic Bachmann
Vigilance & Post Market Surveillance Manager
Quality Management & Regulatory Affairs

MATHYS
European Orthopaedics

Confirmation form FSCA 20/01

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Confirmation of receipt

Please enter the following:

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.**
- **I do not have any affected products in store anymore.**

☐ Our stocks do not contain any affected products.

☐ The following affected products have been replaced and/or returned:

Item №	Batch	Number of units

Place/date: _____ Signature: _____

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