

Urgent Field Safety Notice

Product name: Straight cup positioner
Curved cup positioner

FSCA ID №: FSCA 22/02

Type of action: Recall of all batches

Bettlach, October 27th, 2022

Issued by: Mathys Ltd Bettlach

Addressees: Orthopaedic surgeons
(Users of the curved/straight cup positioner)
OR management

Affected products:



Product	Item №	Item description	Batch №
	51.34.1112	Curved cup positioner	All
	51.34.1114	Straight cup positioner	All

Table 1: Products affected by FSCA 22/02

Created / Revised by: 03.06.2020 Formanowski, Vera	Reviewed by: 04.06.2020 Soland, Carole	Approved by: 04.06.2020 Muenger, Peter	
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Dear Sir or Madam:

Mathys Ltd Bettlach hereby informs you about a *Field Safety Corrective Action* (FSCA) which Mathys Ltd Bettlach is carrying out and which concerns the items listed (curved and straight cup positioner).

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

Description of the problem:

Data from global post-market monitoring show that intraoperative breakage of the instrument can occur with the items listed in Table 1.

The locking rings have a clearance (by design) in the groove of the locking device, which allows movement of the locking rings and leads to shear stresses acting unilaterally on the locking rings. The unilateral support and shear stresses may cause the part to break under loading situations.

Possible hazards:

The following scenarios could occur due to breakage of the rings followed by the instrument falling apart:

In the **most likely scenario**, the locking ring inside the instrument breaks intraoperatively, and the instrument then disintegrates into several distinct parts. Fragments that may fall into the patient are detected and removed during surgery. Extension of the procedure by a few minutes. Fragments are removed immediately or detected and removed with imaging equipment during surgery.

Potential harm to the patient and/or user:

- Extension of the procedure by a few minutes.
- If a fracture is detected, the broken piece can be located and removed during surgery.

In a **worst-case scenario**, the locking ring inside the instrument breaks intraoperatively, and the instrument then disintegrates into several distinct parts, with metal fragments falling into the patient. During surgery, not all fragments can be detected in the patient and removed. Follow-up surgery to remove the fragments, or fragments remaining in the patient.

Potential harm to the patient and/or user:

- Metal part remains in situ; the broken part is detected only after surgery (X-ray, CT). Follow-up surgery to remove the part, or the part or parts remain in the patient.
- It is unlikely that the fracture will go undetected, as the instrument cannot be used any further and the fracture will be clearly visible as the instrument falls apart. The fragments can be seen on intraoperative radiographies and are removed with an additional procedure.

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.
- Inform and instruct any third parties to whom affected products were transferred.
- Fill out 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.)*
- 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 other questions regarding this Field Safety Corrective Action 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 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
Medical Affairs



Armand Linge
PRRC
Regulatory Affairs

Confirmation form FSCA 22/02

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Product name: Straight cup positioner
Curved cup positioner

FSCA ID №: FSCA 22/02

Type of action: Recall of all batches

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.
- 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: