Urgent Field Safety Notice

Product name:	**optimys® Opening Broach bent**
FSCA-ID-No.:	**FSCA 13/01**
Type of action:	**Safety Notice**

Bettlach, 24 September 2013

Addresser:	Mathys Ltd Bettlach
Addressee:	Orthopaedic surgeons

Details regarding the affected product:

Article number: 51.34.0079

Name: **optimys Opening Broach bent**

Lot numbers:

6053731	6054883	6057918	6059150	6060683

Description of the problem:

Mathys Ltd Bettlach (Mathys) has been notified of an incident in Switzerland where the optimys Opening Broach broke intraoperatively and the fragment was left in the bone. Investigations have shown that the instrument was not used in compliance with the instructions, and detailed exploration revealed that this was causal to the incident.

In the course of the investigations, it became apparent that the Opening Broach bent may exhibit surface defects in the hewn portion which may favour breakage in case of non-compliant usage.

Based on the findings, Mathys has decided as an immediate measure to send this Field Safety Notice to all users in order to call attention to the correct usage.

Potential hazards:

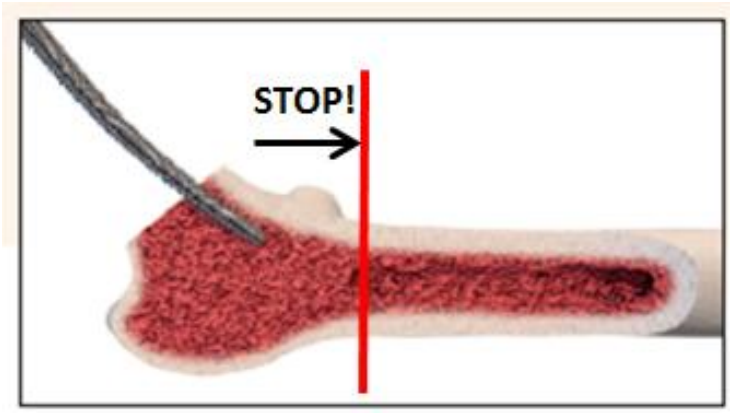
The risk of breakage with correct usage in compliance with the surgical technique is very low. Should an optimys Opening Broach nevertheless break during surgery, the fragment can be removed without problems. In this case, negative health consequences are unlikely to ensue.

Should the broken fragment still remain in the patient's body, the general risks associated with foreign bodies are present, particularly:

- chronic local irritation of the surrounding tissue
- delayed bacterial infection due to anachoresis and a resulting reduction of immunosurveillance
- local reactions leading to the formation of benign or malignant tumours
- migration of the foreign body

Note on correct usage according to the surgical technique

The optimys Opening Broach bent is intended **exclusively for opening the medullary canal**. The purpose is to create an optimal starting position for the bone-preserving rasping of the implant bed along the calcar arch. Opening of the medullary canal is performed manually close to the medial cortex. Further opening of the medullary canal through the metaphysis to the proximal diaphysis is performed along the calcar arch and facilitates the introduction and centring of the rasps that follow.



➔ **Use the optimys Opening Broach bent <u>only for opening down to the proximal diaphysis</u>.**

➔ **Any unintended further insertion involves a risk of breakage, and a broken off fragment would not be easily removable.**

Actions to be taken by the addressee:

- Please read this Field Safety Notice carefully.
- Please make sure that all relevant positions will be informed of this Field Safety Notice within your hospital.
- Replacement products made of material more suitable for the field of application are currently being manufactured. As soon as they become available, we will inform you and arrange for the replacement at your hospital.
- If you have any questions, please contact your local Mathys agency.
- Complete the response form attached and send it to the address specified:
  (You herewith avoid the delivery of further notifications through Mathys. Please also complete the form in case you are not using the optimys Opening Broach bent.)

Distribution of this Field Safety Notice:

Please ensure that all involved positions are informed of this Field Safety Notice within your organisation. Should affected devices have been passed on, make sure the corresponding organisations will be notified and instructed.

This Field Safety Notice should be kept until the action within your organisation has been terminated.

This notice has been notified to the corresponding competent authorities.

Mathys Ltd Bettlach

Stephan Affolter
Manager Vigilance
Regulatory Affairs & Vigilance