Urgent Field Safety Notice

Product name: **Affinis Inverse Drill-bit 2.5, Gen2**
Affinis Inverse Drill-bit 3.2, Gen2

FSCA ID №: **FSCA 24/01**

Type of action: **Recall of batches**

Bettlach, March 26, 2024

Issued by: Mathys Ltd Bettlach

Addressees: All customers of the Affinis Inverse Drill-bit System including:
Orthopaedic surgeons
OR management

Affected products:

Product	Item №	Item description	Batch №
	61.34.0184	Affinis Inverse Drill-bit 2.5, Gen2	All batch numbers lower than 2277885
	61.34.0185	Affinis Inverse Drill-bit 3.2, Gen2	All batch numbers lower than 2277886

Table 1: Products affected by FSCA 24/01

Dear Sir or Madam:

Mathys Ltd Bettlach is carrying out a Field Safety Corrective Action (FSCA) for the Affinis Inverse Drill-bit 2.5, Gen2 and the Affinis Inverse Drill-bit 3.2, Gen2. Our records indicate that you have received or are using one or several of the affected devices.

Description of the problem:

Our global post-market monitoring system has observed that a number of Affinis Inverse Drill-bits have broken during surgery and, in some cases, the tip of the drill-bit has remained in the patient. A new design of the affected Drill-bits has already been placed on the market and this recall only affects the Drill-bits with the old design.

Possible hazards:

A) The breakage of the drill may lead to an injury to the patient or the surgeon. There is a risk of unwanted tissue destruction and/or additional blood loss and/or a minor delay in surgical procedure.

B) If the surgeon detects that a part of the drill has broken off, the part can be located and removed. It is easily visible with a C-arm. This leads to a minor delay in surgical procedure.

C) If the missing part goes undetected and remains inside the patient's bone or tissue there are several possible scenarios:

- The part may remain in the patient without creating any side effect or harm to the patient. No medical re-intervention is necessary.
- The part may remain in the patient and present potential harm to the patient. It may cause soft tissue damage and/or internal bleeding. An urgent medical re-intervention will be necessary.
- The part may lead to an adverse reaction of the patient such as an inflammation as the drill is not made of implant grade steel. A medical re-intervention might become necessary in this case.
- The part is not MR safe and may represent a danger for the patient when a MRI analysis is needed. A medical re-intervention would be necessary before the MRI analysis is performed.

D) The part may be located in the intended path of a fixation screw. A shorter length of screw would have to be selected or the screw put at a slightly different angle. This might result in a lower primary stability and could potentially lead to early loosening.
This potential harm is rated as small. The surgeon will always be capable of finding a secure screw fixation.

Please take the following measures immediately:

- Read this Field Safety Notice carefully. Inform all relevant departments and positions.
- Immediately identify and quarantine all unused products with the affected item and batch number (see „Affected Products")..
- Immediately separate out all products with the affected item and batch number (see „Affected Products"). A Mathys representative will contact you to organise the return of the products.
- Inform and instruct any third parties to whom affected products were transferred.
- Fill out the enclosed confirmation form. Return it to the indicated address or hand it over to your Mathys representative. After that, Mathys won't send further reminders concerning this Field Safety Notice.
- Observe the present Field Safety Notice until the action has been completed within your organisation. Keep a copy of this Field Safety Notice.

Please contact your Mathys representative or your local Mathys office in case of any questions regarding the return of the products.
Please contact us via vigilance@mathysmedical.com for any other questions regarding this Field Safety Notice.

Information on materiovigilance:

Mathys informed the competent national authorities about this Field Safety Corrective Action. Please inform Mathys Ltd Bettlach about any adverse events concerning the affected products or any other Mathys products via vigilance@mathysmedical.com or your local Mathys office.

We apologise for any inconvenience this may cause. We are 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 24/01

Urgent Field Safety Notice

Product name: **Affinis Inverse Drill-bit 2.5, Gen2**
Affinis Inverse Drill-bit 3.2, Gen2

FSCA ID №: **FSCA 2401**

Type of action: **Recall of batches lower than 2277886**

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 to the following address:

Email: