


Urgent Field Safety Notice

Product name: optimys stems lateral
FSCA ID no.: FSCA 15/04
Type of action: **Recall of incorrectly labelled batches**

Bettlach, 8 December 2015

Issued by: Mathys Ltd Bettlach
Addressee: OR Management
CC: Purchasing Department

Affected products:

 optimys stems lateral	Item number	Item description	Batch numbers
	52.34.0206	optimys stem lat. TAV 6 uncem.	2227869
	52.34.0207	optimys stem lat. TAV 7 uncem.	2227871

Ladies and Gentlemen,

Mathys Ltd Bettlach hereby notifies you of a voluntary Field Safety Corrective Action (FSCA) affecting the item and batch numbers of optimys stems lateral listed above. Our records indicate that you have received one or both of the affected batches and are therefore subject to this safety-relevant action.

Description of the problem

The packaging of the above mentioned article and batch numbers contains product and patient labels with the non-correct shelf-life expiration date 2015-09 (see Figure 1). The outer box is labelled with the correct shelf-life expiration date 2020-08 (see Figure 2).



Figure 1: Example of the incorrect patient labels inside the packaging



Figure 2: Example of the correct label on the cardboard box

Information relating to patient safety

In the event that the non-correct labelling goes undetected, there is no harm to the patient because the product's correct expiry date is August 2020.

In the improbable event that the user detects the non-conformance (non-correct expiration date) in the operating theatre, there are two possible scenarios.

The surgical staff might decide to confirm the expiry date of the product or request the same size implant from inventory, resulting in a longer surgical procedure.

If there is no second implant of the same size on stock, the surgeon might decide to continue surgery with an implant of a different size. In this case the patient would be treated with an implant size that does not correspond best with the patient's anatomy.

There is no risk to patients already implanted with an incorrectly labelled optimys stem.

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.
- **Immediately identify and quarantine all unused products carrying the item and batch numbers indicated above.**
- **Return any affected products as soon as possible.** A Mathys representative will contact you in order to support you with this procedure and organise the replacement.
- Third parties to whom affected products have been forwarded must be informed and instructed accordingly.
- 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 FSCA.)*
- 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 the return and replacement of the products, please contact the Mathys representative responsible for your organisation or your local Mathys office.
- 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 Ltd Bettlach of any adverse event in connection with the optimys stems 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



Head Regulatory & Vigilance
Regulatory & Quality Management



Vigilance & Post Market Surveillance Manager
Regulatory & Vigilance

Confirmation form FSCA 15/04

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Product name: optimys stems lateral
FSCA ID no.: FSCA 15/04
Type of action: **Recall of incorrectly labelled batches**

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: