
Urgent Field Safety Notice

Product name: cycIOS Putty
FSCA-ID-No.: FSCA 12/02
Type of action: Recall

Bettlach, February 7th 2012

Adresser: Mathys Ltd Bettlach

Addressee: Trust Chief Executives, General Manager, Surgery Management, Safety Delegate, OR staff.

Details regarding the affected product:

Bezeichnung	Artikel Nummer	Lot-Nummern
cycIOS Putty 1cc	59.37.2425	all
cycIOS Putty 5cc	59.37.2426	all
cycIOS Putty 10cc	59.37.2427	all

Description of the problem:

Mathys Ltd Bettlach has initiated a Field Safety Corrective Action. The above mentioned articles of cycIOS Putty are being recalled from the market.

An assessment of the instruction for using (IFU) has shown a misleading description on how to open the packaging. When opening the packaging as described, there might be a contamination of the sterile personnel and surgical field through the receipt of a non-sterile packaging. Please note that this is a hypothetical scenario as Mathys Ltd Bettlach has not received any reports of related incidents.

Actions to be taken by the addressee:

- Stop using the affected products.
- Quarantine the affected products.
- Your local sales representative is going to contact you regarding the return of affected items.

Distribution of this Field Safety Notice:

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

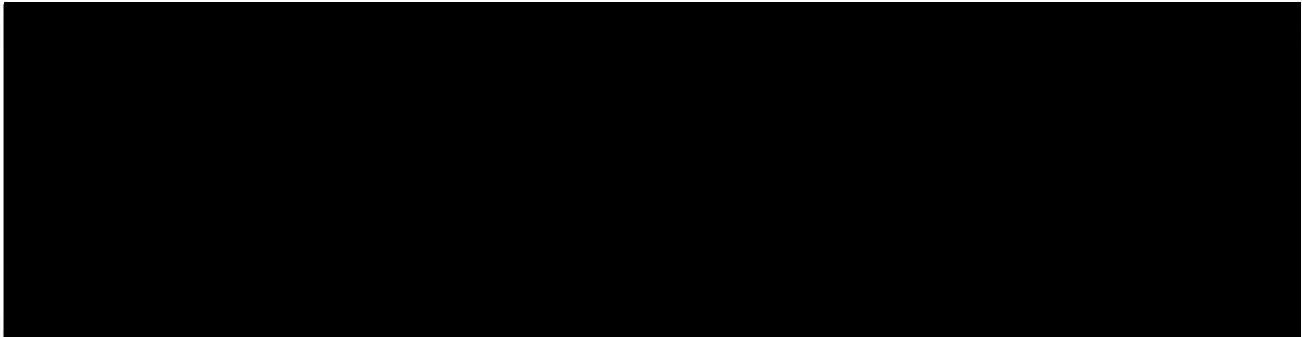
This Field Safety Notice should be kept until the action within your organisation has been terminated.

Contact reference person:

Stephan Affolter
Manager Vigilance
Regulatory Affairs & Vigilance
vigilance@mathysmedical.com

This notice has been notified to the corresponding competent authorities.

Mathys Ltd Bettlach



Response Form FSCA 12/02

Urgent Field Safety Notice

Product name: cyclIOS Putty
FSCA-ID-No.: FSCA 12/02
Type of action: Recall

Return of medical devices

Please fill in:

Customer ID _____
Hospital _____
Postcode, place _____
Person responsible
(Name/Position) _____

- We have checked our stock. The following articles were quarantined and returned to Mathys Ltd Bettlach. We herewith consider the recall as finished within our organization.

Description	Article-Nr.	Quantity quarantined and returned to Mathys
cyclIOS Putty 1cc	59.37.2425	
cyclIOS Putty 5cc	59.37.2426	
cyclIOS Putty 10cc	59.37.2427	

Place/Date: _____

Signature: _____

Please send the completed form per email or fax to the address mentioned below:

vigilance@mathysmedical.com
+41 (0)32 644 11 64