
Urgent Field Safety Notice

Product name: chronOS Putty
FSCA-ID-No.: FSCA 12/01
Type of action: Recall

Bettlach, February 3rd 2012

Adresser: Mathys Ltd Bettlach

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

Details regarding the affected product:

See separate list on page 3.

Description of the problem:

Mathys Ltd Bettlach has initiated a Field Safety Corrective Action. The above mentioned articles of chronOS 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.
- Return the affected products to Mathys.

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



Director Business Units
Member Management Board



Manager Vigilance
Regulatory Affairs & Vigilance

List of affected chronOS Putty articles

Description	Article no.	Lot no.
chronOS Putty 1.0cc	710.601S	all
chronOS Putty 2.5cc	710.602S	all
chronOS Putty 5cc	710.603S	all
chronOS Putty 10cc	710.604S	all
chronOS Putty 1.0cc	710.701S	all
chronOS Putty 2.5cc	710.702S	all
chronOS Putty 5cc	710.703S	all
chronOS Putty 10cc	710.704S	all
chronOS Putty 1.0cc	710.801S	all
chronOS Putty 2.5cc	710.802S	all
chronOS Putty 5cc	710.803S	all
chronOS Putty 10cc	710.804S	all