

Heraeus Medical GmbH · Philipp-Reis-Str. 8/13 · 61273 Wehrheim

For Attention of:
Doctors and operating staff in orthopaedic surgery and
trauma surgery.

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Field Safety Notice

Field Safety Corrective Action (FSCA) for PALAMIX[®] uno and PALAMIX[®] duo mixing systems marketed by Heraeus Medical GmbH

Heraeus reference:	201194884
Commercial name	PALAMIX [®] uno PALAMIX [®] duo
Material number(s)	PALAMIX [®] uno: 66057893 PALAMIX [®] duo: 66057897
Affected batch(es)	PALAMIX [®] uno: all batches with numbers below 223060 PALAMIX [®] duo: all batches with numbers below 520215
Device type	PALAMIX [®] is an orthopaedic vacuum mixing and application system for bone cements. PALAMIX [®] is available in two sizes: PALAMIX [®] uno and PALAMIX [®] duo and they are suitable for automatic collection of bone cement within the mixing cartridge under vacuum.
Intended purpose	PALAMIX [®] is intended for mixing bone cement with different viscosities under vacuum

Dear Valued Customer,

Heraeus Medical GmbH is committed to ensure the highest standards of safety and quality in all our products. To keep your satisfaction with our products high, Heraeus Medical would like to inform you of an important update regarding the PALAMIX® vacuum mixing system.

REASON FOR THE SAFETY ADVICE

Based on long-term stability testing, we have determined that in units older than 1.5 years (17 months) the mixing rod may, in rare cases, come loose from its lock during the mixing process.

This finding concerns only functional performance at the end of the original three-year shelf life and does not affect any safety-relevant characteristics. No incidents or malfunctions have been reported from use. Accordingly, no risk to patients or users has been identified at any time. However, based on the results of the long-term stability study, the shelf life had to be reduced, but this does not involve any change to the design, performance or handling of PALAMIX®. Your usual mixing process and clinical workflow will remain unaffected.

As part of our continuous quality assurance, the shelf life of PALAMIX® has therefore been reduced from three years to 17 months with immediate effect. From batch number 223060 for PALAMIX® uno and 520215 for PALAMIX® duo, the new shelf life of 1.5 years will be indicated on the product label.

With this notification, relabelling of earlier batches is not required, as all safety-related criteria continue to be fully met.

POTENTIAL RISK

The malfunction causes the mixing rod to come loose, resulting in a loss of functionality at the end of the three-year shelf life. This makes it impossible to mix the cement. The potential damage is limited to delays in the operating room. In the instructions for use, we point out that an additional pack of PALAMIX® should always be available in the operating room. In addition, it must be ensured that the bone cement intended for the procedure is available in sufficient quantity and in the correct variant in the operating room. No additional risk to patients, users, or third parties has been identified due to the shortened shelf life.

ACTION TO BE TAKEN BY THE HOSPITAL AND MEDICAL STAFF

1. Read this Field Safety Notice and ensure that all relevant hospital departments are informed about its content.
2. Please complete the attached customer reply form and send it to hm.fsc.medical@heraeus.com within five (5) calendar days. This form must be returned even if you no longer use the device.
3. Keep a copy of the attached customer reply form with your records in the event of a compliance audit of your facility.

We regret any inconvenience caused by this action and value your cooperation and commitment to patient safety.

This field safety notice was submitted to your local authority in context of the FSCA authority report.

Please do not hesitate to contact us if you should have any questions on this matter, using the contact details below.

Contact Details:

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Yours sincerely

Heraeus Medical GmbH