Heraeus

Medical

FSN-HME-2026-01-DE

FSCA Ref: 201194884

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

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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20. März 2026

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 online response form within five (5) business days. This form must be completed even if not affected, or you no longer use the device.
3. You will receive a copy of the response you submitted to the email address you provided to retain for your records.

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

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Medical

URGENT: Field Safety Notice

Customer Response Form

FSCA Ref: 201194884
FSN Reference Number: FSN-HME-2026-01-EN
FSN DATE: 12 March 2026
Product/Device Name: PALAMIX® uno & PALAMIX® duo

Catalogue/Reference number(s):
PALAMIX® uno: 66057893 & PALAMIX® duo: 66057897

Batch/Serial number(s):

PALAMIX® uno: all batches with numbers below 223060
PALAMIX® duo: all batches with numbers below 520215

To support regulatory tracking, submit a response even if NOT affected by this notification

Please review the notification and submit a response **within 5 business days** of receipt.

Account Information

* Facility Name		* Address	
* Heraeus Account Number (if unknown, please submit N/A)		* City	
* Department		State/Province/Region	
		* Area/Zip/Postal Code	
		* Country	

Acknowledgement

* I confirm receipt of the Field Safety Notice and that I have read and understood its content	☐
* The information has been brought to the attention of all relevant users and executed.	☐

Respondent submitted by

* First Name		* Telephone Number	
* Last Name		* Email Address	
* Role			

Signature

* Signature	
* Date	
* By completing and signing this form, it is certified that all of the information provided on this form is true and complete.	Yes

* Please click the '**Submit**' button located at the top to Submit your response.

Heraeus has partnered with IQVIA MedTech to assist in this Notification. For any assistance in submitting a response, please contact IQVIA MedTech using the information below:

Phone:
U.S.A +1 213 845 0364
All other countries: +44 1995 910912
Email: HeraeusPALAMIX@iqvia.com
Privacy Policy

Thank you for completing the response form. You will receive a copy to the email address provided for your records.