Heraeus

Medical

FSN Ref: FSN-HME-2025-03-EN

FSCA Ref: 201153339

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For Attention of:

Doctors and operating staff in orthopaedic surgery and trauma surgery.

21. November 2025

Urgent Field Safety Notice

Field Safety Corrective Action (FSCA) for PALAMIX® uno marketed by Heraeus Medical GmbH

Heraeus reference:	FSCA Ref. 201153339
Commercial name	PALAMIX® uno
Material number(s)	66057893
Affected batch(es)	222898R
Device type	Mixing and application system
Intended purpose	PALAMIX® uno is intended for mixing bone cement of various viscosities under vacuum

Dear Valued Customer,

Heraeus Medical GmbH is committed to ensure the highest standards of safety and quality in all our products. Regrettably, we must inform you that products from a specific batch of our mixing and application system are being recalled, as described in more detail below.

REASON FOR THE RECALL

Some products of batch 222898R of our PALAMIX® uno system, that were in quarantine, were accidentally withdrawn from storage, shipped to the United Kingdom and distributed to customers before they were released.

POTENTIAL RISK

These products do not meet the specified requirements and have not been tested by our Quality Control Department.

We cannot therefore completely rule out possible risks to patients and have decided to recall the entire batch as a precautionary measure.

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 the recall.
2. Immediate Discontinuation and Quarantine:
   Ensure that no affected product is used for patient treatment: Cease use, identify, and quarantine any stock of 66057893 PALAMIX® uno, batch 222898R
3. Handover of products to your Heraeus sales team
4. Report an incident:
   Please ensure close monitoring of patients for which the product was used and report a potential incident.
5. Please complete the attached **customer reply form** and send it to hm.fsca.medical@heraeus.com within five (5) calendar days. This form must be returned even if you no longer use the affected batch.

Heraeus Medical GmbH is committed to resolve this issue efficiently and is equally informing the regulatory authorities thereof. This field safety notice will be submitted to the MHRA along with the FSCA report.

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

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