

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

Dr. Thomas Kluge
Head of Technology
Person Responsible for Regulatory
Compliance (Art. 15 EU MDR)
+49 6181 35 2513
hm.fsc.medical@heraeus.com
www.heraeus-medical.com

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

For Attention of

Doctors and operating staff in orthopaedic surgery and
trauma surgery.

8. September 2026

Urgent Field Safety Notice

Field Safety Corrective Action (FSCA) for PALACOS® und COPAL® pro Systeme distributed by Heraeus Medical GmbH

Heraeus reference	FSCA Ref. 201281227
Product names	• PALACOS® R+G pro 40/60/80 • PALACOS® MV+G pro 40/60/80 • COPAL® G+C pro 40/80
Catalogue numbers	All catalogue numbers
Affected batches	All batches
Device types	Radiopaque, poly(methyl methacrylate)-based (PMMA) bone cement, pre-filled into a mixing and application system, suitable for use with or without vacuum (ready to mix).
Intended purpose	PMMA bone cement intended for stable anchoring of total or partial joint endoprostheses in living bone.

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, we would like to inform you about an additional product advice regarding our PALACOS® and COPAL® pro systems.

REASON FOR THE SAFETY ADVICE

As part of our post-market activities, we have been informed of isolated cases of monomer liquid leaking from the pro system.

Assessments carried out to date have shown that the affected product can continue to be used as intended. Only the product that has leaked needs to be discarded.

Nevertheless, it cannot be entirely ruled out that users may come into contact with monomer liquid whilst handling the product. As a background, most countries have established sufficient occupational safety guidance for eye protection during surgical procedures. Moreover, eye protection control information is already part of the PALACOS® and COPAL® pro safety data sheets. Nevertheless, we have decided to expand the safety precautions as an additional layer of protection in the Instructions for Use.

The updated recommendation will be included in the next revision of the Instructions for Use. Until this updated documentation is available, users are advised to follow the measures described in this FSN.

POTENTIAL RISK

If monomer liquid leaks from the pro system, it may come into unintended contact with the user's skin or eyes. In the event of eye contact, there is a risk of temporary irritation, redness, a burning sensation or other local symptoms, which may require medical attention.

Wearing eye protection whilst handling the product reduces the likelihood of eye contact and helps to further minimize the residual risk.

ACTION TO BE TAKEN BY THE HOSPITAL AND MEDICAL STAFF

1. Please read this Field Safety Notice carefully and ensure that all relevant hospital departments are made aware of their contents.
2. **Ensure that suitable eye protection is worn whenever the system is being operated, in accordance with the applicable health and safety regulations.**
3. **Please complete the attached reply form and send it to hm.fsca.medical@heraeus.com by email within five (5) calendar days of receiving these instructions.** This form must be returned even if you are no longer using the product.
4. Keep a copy of the attached response form with your records in case your organization is subject to a compliance audit.

As previously mentioned, the product can continue to be used as intended. There is no need to exchange or return the product.

This Field Safety Notice has been submitted to your local authority as part of the notification regarding the Field Safety Corrective Action.

We thank you for your support in implementing this safety measure. If you have any questions or require assistance, please do not hesitate to contact us at any time.

Contact details:

Heraeus Medical GmbH
Vigilance & Safety
Philipp-Reis-Straße 8/13
D-61273 Wehrheim
hm.fsca.medical@heraeus.com
www.heraeus-medical.com

Yours sincerely

Heraeus Medical GmbH

Field Safety Notice Customer Reply Form

1. Field Safety Notice (FSN) Information	
FSN reference number	FSN-HME-2026-02-EN
FSN date	20 August 2026
Product name*	PALACOS® R+G pro 40/60/80 PALACOS® MV+G pro 40/60/80 COPAL® G+C pro 40/80
Catalogue number(s)	All catalogue numbers
Batch(es)	All batches

2. Customer Details	
Account number	
Healthcare organisation name*	
Organisation address*	
Department/unit	
Contact name*	
Title or function	
Telephone number*	
Email*	

3. Customer's Action Undertaken on Behalf of Healthcare Organisation	
By signing below, I confirm that I have received the Field Safety Notice and that I have read and understood its contents. The information has been brought to the attention of all relevant users and executed.	
Print name*	
Signature*	
Date*	

4. Please return the completed and signed customer reply form to:	
Email	hm.fsca.medical@heraeus.com
Postal address	Heraeus Medical Vigilance & Safety Philipp-Reis-Str. 8/13 61273 Wehrheim Germany
Web portal	www.heraeus-medical.com
Deadline for returning the customer reply form*	28 August 2026

Mandatory fields are marked with *

It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN.

Your organisation's reply is the evidence we need to monitor the progress of the corrective actions.