Heraeus Medical

FSN Ref: FSN-HME-2025-02-EN

FSCA Ref: 201150082

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.

Dr. Thomas Kluge
Head of Technology
Person Responsible for Regulatory Compliance (Art. 15 EU MDR)
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04 December 2025

Urgent Field Safety Notice

Field Safety Corrective Action (FSCA) for PALACOS® and COPAL® pro systems marketed by Heraeus Medical GmbH

Heraeus reference:	FSCA Ref. 201150082
Commercial name	• PALACOS® R+G pro 40; PALACOS® R+G pro 60; PALACOS® R+G pro 80 • PALACOS® MV+G pro 40; PALACOS® MV+G pro 60; PALACOS® MV+G pro 80 • COPAL® G+C pro 40; COPAL® G+C pro 80
Material number(s)	• 5081273, 5081279, 5081280 • 5081281, 5081282, 5081283 • 5081284, 5081285
Affected batch(es)	All batches
Device type	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

In the course of our post-market activities, we have noted an increase of complaints regarding the breakage of the ampoules within our PALACOS® and COPAL® pro systems. An extensive investigation revealed that multiple factors have an impact on the ampoule breakage. An unfortunate combination of these influence factors can lead to unbreakable ampoules. We are currently conducting further rigorous tests, during which an initial remedy has been found. Our series of experiments have shown that the influence factors can be levelled out in most cases by a simple handling hack: Applying pressure with the palm over the neck of the ampoule casing when flexing it simplifies the ampoule breakage.

Figure 1: New pictogram for handling step no.3

This recommendation will be included in the instructions for use and labelling of the device, together with a new pictogram for this handling step. Furthermore, the handling guideline of the devices will be adapted, supported by a new training video.

POTENTIAL RISK

If none or not all ampoules break, the product cannot be used on the patient since no or no appropriate cement dough is formed. A slight delay in operating time caused by the time required to procure a replacement product may be the consequence for the patient. The instructions for use of the device state having at least one additional pack of the device available before commencing the operation.

Please note that only the preparation of the cement mix is impaired not the quality of the cement mix itself. As long as both ampoules broke, there is no risk for patients in whom the affected device has already been implanted.

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.fsca.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.
4. Heraeus Medical GmbH is fully cooperating with regulatory authorities and is committed to resolving this issue efficiently. For further details regarding this field safety notice, please contact your Heraeus Medical sales representative or distributor.

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:

Heraeus Medical GmbH
Vigilance & Safety
Philipp-Reis-Straße 8/13
D-61273 Wehrheim
+49 (0) 6181 35 2887
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-2025-02-EN
FSN date*	04 Dec 2025
Product/ device name*	PALACOS® R+G pro 40 PALACOS® R+G pro 60 PALACOS® R+G pro 80 PALACOS® MV+G pro 40 PALACOS® MV+G pro 60 PALACOS® MV+G pro 80 COPAL® G+C pro 40 COPAL® G+C pro 80
Catalogue/reference number (s)	5081273, 5081279, 5081280, 5081281, 5081282, 5081283,5081284, 5081285
Batch/serial number (s)	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	
☐	*I confirm receipt of the Field Safety Notice and that I read and understood its content.
☐	*The information has been brought to the attention of all relevant users and executed.
Print name*	
Signature*	
Date*	

4. Return Acknowledgement to Sender	
Email	hm.fsca.medical@heraeus.com
Customer helpline	+49 (0) 6181 35 2887
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*	05 Jan 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.

Field Safety Notice
Distributor Reply Form

1. Field Safety Notice (FSN) Information	
FSN reference number*	FSN-HME-2025-02-PT
FSN date*	04.12.2025
Product/ device name*	PALACOS® R+G pro 40 PALACOS® R+G pro 60 PALACOS® R+G pro 80 PALACOS® MV+G pro 40 PALACOS® MV+G pro 60 PALACOS® MV+G pro 80 COPAL® G+C pro 40 COPAL® G+C pro 80
Catalogue/reference number (s)	5081273, 5081279, 5081280, 5081281, 5081282, 5081283,5081284, 5081285
Batch/serial number (s)	All batches

2. Distributor Details	
Company name*	
Account number	
Address*	
Contact name*	
Title or function	
Telephone number*	
Email*	

3. Distributors Action Taken (Tick all that apply)		
☐	*I confirm receipt of the Field Safety Notice and that I read and understood its content.	
☐	I have identified customers that received or may have received this device	
☐	I have attached a customer list	
☐	I have informed the identified customers of this FSN	*Date of communication (DD/MM/YYYY):*
☐	I have received confirmation of reply from all identified customers	
Print name*		
Signature*		
Date*		

4. Return Acknowledgement to Sender	
Email	hm.fsca.medical@heraeus.com
Distributor/importer helpline	+49 (0) 6181 35 2887
Postal address	Heraeus Medical Vigilance & Safety Philipp-Reis-Str. 8/13 61273 Wehrheim Germany
Web portal	www.heraeus-medical.com
Deadline for returning the distributor reply form*	05.01.2026

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.