

Urgent safety information

COPAL® knee moulds size L with two different expiry dates

Sender:

HERAEUS Medical GmbH
Philipp-Reis-Straße 8/13
61273 Wehrheim
Germany

Recipients:

Doctors and operating staff in orthopaedic surgery and trauma surgery.

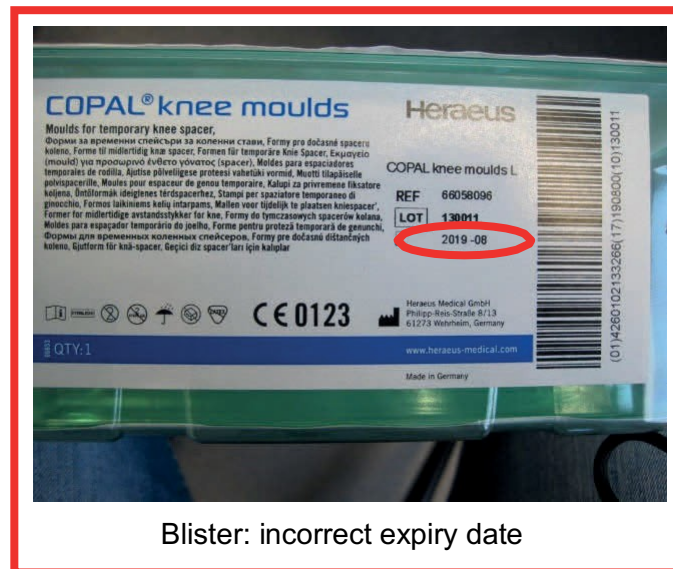
Identification of the medical devices affected:

Product name	Versions	Product name	Catalogue number	Batch
COPAL® knee moulds	Size L	Moulds for temporary knee spacers	66058096	130011



Description of the problem including the identified cause:

Since 23 November 2016 COPAL® knee moulds size L have been supplied that are labelled with two different expiry dates. While the patient sticker and the outer carton have the correct expiry date of 08/2018, the blister is incorrectly labelled with an expiry date of 08/2019. As the following pictures illustrate, you can find the correct expiry date (08/2018) on the patient sticker and the outer carton.



There is therefore no risk for users and patients who have already had COPAL® knee moulds used to create temporary knee spacers. There is also no risk for users and patients associated with using the COPAL® knee moulds up to the end of August 2018. After the correct expiry date of 08/2018 has elapsed, the COPAL® knee moulds must no longer be used.

What measures must be taken by the recipients?

To prevent any risks for patients, users and third parties, we request that you check your stocks for the affected COPAL® knee moulds size L from batch 130011. **If you should still have stocks, we request that you register these with Heraeus Medical GmbH using the attached confirmation of receipt.** Customer Service at Heraeus Medical GmbH will then contact you and organise to collect the goods. Heraeus Medical GmbH offers replacement for the affected goods COPAL® knee moulds size L free of charge.

Please complete the confirmation of receipt attached and send it to technicalsupport.medical@heraeus.com **before 15.08.2018. The confirmation of receipt must be returned even if there are no longer any affected products in your facility.**

Keep a copy of the confirmation of receipt in your documents.

Dissemination of the information described here:

Please ensure that all users of the above-named products and other relevant persons in your organisation receive this urgent safety information. If you have supplied the product to third parties, please forward a copy of this information to these third parties. Please inform us of any contact with third parties for additional collection by providing us with the contact details of the third party in the confirmation of receipt.

The signatory confirms that this safety information has been reported to the relevant regulatory authority.

If you have any questions relating to this issue, please contact Dr Thomas Kluge using the contact details given below.

Contact:

Heraeus Medical GmbH
Philipp-Reis-Straße 8/13
61273 Wehrheim
Germany
Fax + 49 (0) 6181 35 2916
www.heraeus-medical.com
Dr Thomas Kluge
Email: thomas.kluge@heraeus.com

Yours sincerely


pp Dr Thomas Kluge
Head of Technology & Safety Officer


pp Lothar Kiontke
Head of Marketing

Confirmation of receipt

Product: COPAL® knee moulds (size L), batch 130011

Note: This form must be sent back to Heraeus Medical GmbH even if you have no stocks of COPAL® knee moulds (size L) from batch 130011.

With my signature I confirm that the necessary measures in accordance with the safety information have been taken.

- ☐ I have read and understood the safety information. I have informed other affected users of the COPAL® knee moulds about the safety information.
- ☐ The stocks in our facility have been checked and we no longer have any stocks of COPAL® knee moulds (size L) from batch 130011.
- ☐ We still have _____ COPAL® knee moulds (size L) from batch 130011 in our stocks. These must be collected by Heraeus Medical GmbH. I would like the returned COPAL® knee moulds size L to be replaced free of charge.

- ☐ The COPAL® knee moulds were passed on to third parties. I have forwarded a copy of this safety information to these third parties. The contact details of the third parties are:

Hospital of third party: _____

Address of third party: _____

Contact person of third party: _____ Function: _____

Email of third party: _____ Tel: _____ Fax: _____

Your hospital: _____

Your address: _____

Your name: _____ Function: _____

Your email: _____ Tel: _____ Fax: _____

Stamp of the hospital

Date, signature

Please send the completed form to us by email, fax or mail before **15.08.2018** to:

Heraeus Medical GmbH
Philipp-Reis-Straße 8/13
61273 Germany
Germany

Technical Support
Email: Technicalsupport.medical@heraeus.com
Fax: + 49 (0) 6181 35 2916