Heraeus

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Urgent Safety Information

Recommendation on the sterile removal of the primary cement powder bag

PALACOS® and COPAL® bone cements

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	Product description	Catalogue number
PALACOS® R	High viscosity bone cement without gentamicin	66017777 66017778
PALACOS® R+G	High viscosity bone cement with gentamicin	66017776 66017775 66017772 66017771 66017747
PALACOS® MV	Medium viscosity bone cement without gentamicin	66031982 66031984
PALACOS® MV+G	Medium viscosity bone cement with gentamicin	66032000 66031998 66031996 66031995 66031993
PALACOS® LV	Low viscosity bone cement without gentamicin	66017788 66037893
PALACOS® LV+G	Low viscosity bone cement with gentamicin	66017787 66037894
PALACOS® fast R+G	Fast curing bone cement with gentamicin	66056768
COPAL® G+C	High viscosity bone cement with gentamicin and clindamycin	66017790
COPAL® G+V	High viscosity bone cement with gentamicin and vancomycin	66038973

Description of the problem including the identified cause:

In individual cases, the secondary bag (polyethylene paper bag) of the bone cement products specified in the list may tear on opening, making sterile removal of the primary bag (cement powder bag) difficult. The reduced ability of the secondary bag to be torn open that is described here occurs due to the excessive tensile strength of the sealed seam. Given identical sealing parameters, the batches of packaging material affected exhibit higher tensile strength of the sealed seams, which all however conform with the applicable standards.

The packaging materials used are subject to minor fluctuations within the scope of the defined specifications, such that the effect of the ability of the bag to be torn open may fluctuate across batches. Tests have also demonstrated that pulling the bag apart abruptly may lead to the problems described.

The sterility of the cement is not affected by these problems. A strong sealed seam ensures a sterile product. The strong sealed seam can adversely affect the ability to tear open and in turn handle the cement powder bag. Should the bag tear on opening, this will impair sterile removal of the primary bag and the product may have to be discarded. A slight delay in operating time caused by the time required to procure a replacement product may be the consequence for the patient. The current worldwide rate/incidence of this problem is below 0.02%.

In order for us to ensure sterility while still allowing the bag to be opened easily, Heraeus Medical is currently investigating new materials and sealing processes. Based on the applicable requirements for validation and approval, this will take some time.

What measures can the recipient take?

To further minimise the effect of reduced ability of the secondary bag to be torn open, we recommend that you grasp as much area of the piece of foil and paper as possible. As you do so, you should hold the paper/foil in the middle of the bag between your thumb and index/middle fingers.

Use the surface of the thumb down to the ball of the thumb and the finger surfaces (not the fingertips) to grasp the foil and paper (see photo).

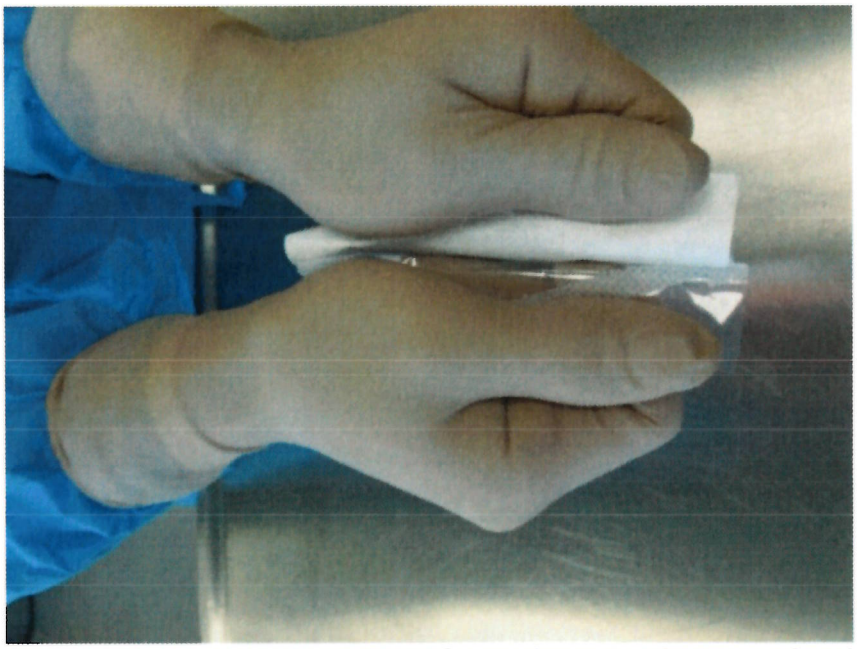

Photo: Recommended technique for tearing open the secondary bag

Photo: Product part description

No.	Name	Sterile
1	Aluminium bag	No
2	Secondary bag (polyethylene paper bag)	No
3	Unsterile label	No
4	Primary bag (cement powder bag)	Yes

Disseminating the information described here:

In your organisation, please ensure that all users of the above-described products and other persons who need to be informed receive knowledge of this "Urgent Safety Information". If you have passed on the products to third parties, please send them a copy of this information or inform the contact person below.

The Federal Institute for Drugs and Medical Devices (BfArM) has received a copy of this "Urgent safety information".

Please do not hesitate to contact us if you should have any questions on this matter, using the contact details below.

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Yours sincerely

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