Heraeus

COPAL® exchange G hip

Preformed PMMA hip spacer containing Gentamicin

Instructions for use

COPAL® exchange G hip

1. Product description
Preformed PMMA hip spacer containing gentamicin.
COPAL® exchange G hip is a temporary hip spacer implant as part of two-stage septic endoprosthesis revision based on bone cement.
COPAL® exchange G hip spacer resembles a hemi-endoprosthesis consisting of bone cement with a core of AISI 316L stainless steel. The hip spacer can be used in both the right and the left hip joint. The spacer function provides that after removal of the endoprosthesis the existing joint space is retained and contraction of the musculature and the surrounding tissues is reduced.
COPAL® exchange G hip spacer contains gentamicin. Gentamicin reduces the risk for bacterial colonisation of the device and is released into the fluid surrounding the joint.
COPAL® exchange G hip spacer is colored with the food colorant E141 (chlorophyll-copper complex) and contains the X-ray contrast medium calcium carbonate.

2. Package contents & composition
COPAL® exchange G hip spacer is available in 10 different sizes.

Size	Head size	Shaft length
S short	46 mm	135 mm
M short	54 mm	135 mm
L short	60 mm	135 mm
XL short	65 mm	135 mm
S medium	46 mm	184 mm
M medium	54 mm	184 mm
S long	46 mm	251 mm
M long	54 mm	251 mm
L long	60 mm	251 mm
XL long	65 mm	251 mm

A **COPAL® exchange G hip** package contains a double blister with a sterile prefabricated hip component. The outer blister is unsterile on the outside and sterile on the inside. Inside the outer blister is a sterile inner blister that contains the spacer. Both blisters are sealed with Tyvek.

Composition:
COPAL® exchange G hip spacer consists of a steel core coated with bone cement containing gentamicin.
Polymer ingredients: polymethylmethacrylate, calcium carbonate, benzoyl peroxide, N,N-Dimethyl-p-toluidine, hydroquinone, colorant E141, gentamicin (as gentamicin sulfate)
Steel core component: AISI 316L stainless steel

Size	Gentamicin base (in g)
S short	1.2
M short	1.6
L short	2.1
XL short	2.4
S medium	1.2
M medium	1.3
S long	1.3
M long	1.8
L long	2.2
XL long	2.5

3. Indications
COPAL® exchange G hip spacer (polymethylmethacrylate/gentamicin) is indicated for temporary use (maximum of 180 days) as a total hip replacement (THR) in skeletally mature patients undergoing a two-stage procedure due to a septic process. The device is inserted into the femoral medullary canal and acetabular cavity following removal of the existing implant and radical debridement. The device is assigned to be used in conjunction with systemic antimicrobial antibiotic therapy (standard treatment approach to an infection).
COPAL® exchange G hip spacer is not intended for use for more than 180 days, at which time it must be explanted, and a permanent device implanted, or another appropriate treatment performed (e.g., resection arthroplasty, fusion etc.). **COPAL® exchange G hip spacer** is only indicated for patients who will consistently use traditional mobility assist devices (e.g. crutches, walkers, canes) throughout the implantation period.

4. Contraindications and restrictions on use
COPAL® exchange G hip spacer must not be used on the patient
- if it is known or supposed that the patient is hypersensitive to ingredients of the spacer
- in patients with severe renal insufficiency
- in the case of active local or systemic infection with gentamicin-resistant germs which has not yet been fully treated

COPAL® exchange G hip spacer must not be used on patients in whom
- the state of health precludes two-stage endoprosthesis revision
- the loss of bone tissue from the proximal femur and/or the acetabulum is so extensive that anchoring the spacer with bone cement is not possible

- the bone quality has been so negatively affected, by osteoporosis, for example, that loosening or migration of the spacer or an inadequate mechanical weight-bearing capacity of the bone bed can be expected
- the musculature and ligaments do not have sufficient functional competence or there are neuromuscular or vascular disorders present
- myasthenia gravis has been diagnosed
- osteosynthesis material may interfere with the bearing of the hip spacer and acetabulum
- an additional systemic and/or chronic infection is present
- the infected hip endoprosthesis cannot be removed either fully or in part
- there is no total hip replacement present and the infection is secondary to trauma, septic arthritis or other diseases that require surgical treatment
- the skeleton is not yet mature

Since there is no clinical experience with children or adolescents, it is recommended that
COPAL® exchange G hip spacer should not be used with children or adolescents.

5. Side effects
General side effects
Complications which may occur with every surgical procedure are conceivable.
The following side effects are possible when using
COPAL® exchange G hip spacer:
- Damage to the femur and acetabulum
- Damage to the surrounding blood vessels and nerves
- Dislocation of the joint or the spacer
- Change to the surrounding tissue
- Difference in leg lengths
- Damage to the bone cement coating due to a disproportionately high mechanical load

Gentamicin
Where gentamicin is used, it is possible, in principle, for the antibiotic to trigger typical side effects:
- Damage to the auditory and vestibular nerves
- Nephrotoxicity
- Neuromuscular blockade
- Rarely paresthesia, tetany and muscle weakness
- Rarely allergic reactions (exanthema, urticaria, anaphylactic reactions)

Like all aminoglycosides, gentamicin is also potentially nephrotoxic and/or ototoxic.
Although an accumulation is hardly to be expected because of the minimal systemic concentration, caution is advised and serum levels of gentamicin should be monitored in patients with severe renal impairment.
As gentamicin has neuromuscular blocking properties, caution is advised with patients:
- having a history of neuromuscular disease
- treated concomitantly with the administration of muscle relaxants

Allergic reactions may occur regardless of the dosage.

Disclaimer
It has not been clinically proven that the antibiotic effect of the drug gentamicin holds for the gentamicin-loaded spacer.

6. Interactions
The following interactions are unlikely to occur on account of the very low gentamicin serum levels reached. Owing to the administration of muscle relaxants and ether, the neuromuscular blocking properties of gentamicin may be intensified. Simultaneous use of gentamicin and strong diuretics such as ethacrynic acid or furosemide may intensify the ototoxic effect of gentamicin.

7. Warnings, precautions and relevant information
User
Before working with **COPAL® exchange G hip spacer** users should be thoroughly familiar with its properties and use. In addition, users must make themselves familiar with bone cement used to fix the spacer. The instructions for use for all the products (**PALACOS®** bone cement) used must be noted beforehand.
Before inserting **COPAL® exchange G hip spacer**, the suitable size should be determined intraoperatively with the help of **COPAL® exchange G** Trials.

The user must adjust pre-operatively to the anticipated situation (e.g. defect type and expected stability of the bone bed) and have appropriate instruments at hand.
COPAL® exchange G hip spacer contains no instruments.
COPAL® exchange G hip spacer may only be used if it is undamaged. The spacer must not be positioned with force or by striking with a hammer or similar instruments.

Patient
After surgery, the patient may only stand up, walk and sit down with the help of walking aids with partial weight bearing. The patient must be informed of this beforehand and warned that there is an increased risk for breakage or disclocation of the spacer with full-weight bearing or high levels of activity. If the function of the musculature and the ligaments is limited, the use of an orthesis to stabilise the joint function may be helpful. The decision as to whether and to what extent partial weight bearing can occur is made by the surgeon and should be determined by the anatomical situation, the health status of the patient and the stability of the spacer after insertion.

Pregnancy and lactation
No sufficient data is available regarding the use of gentamicin in pregnant and lactating women in order to assess a possible health risk. Gentamicin is known to cross the placenta. Ototoxicity and nephrotoxicity in the fetus is a potential hazard. In view of this data, the benefits for the mother should be weighed against the potential risk to the child before using **COPAL® exchange G hip spacer** during pregnancy and lactation.

8. Use

General information

COPAL® exchange G hip spacer is intended for single use and must not be re-used or resterilized.
COPAL® exchange G hip spacer must not be mechanically reworked.

Opening

The blister must only be opened under sterile conditions. For this purpose, the inner blister is available sterile after the removal of the outer blister Tyvek. If the sterile barrier is damaged, the **COPAL® exchange G hip spacer** must not be used and must be disposed of.

Preparation

Before using the **COPAL® exchange G hip spacer**, it should be checked for any damage and completeness.
When using **COPAL® exchange G hip spacer**, the prepared bone should be carefully cleaned and dried before the spacer is placed.

Fixation with **PALACOS®** bone cement is used primarily to stabilize the spacer. Deep penetration of the bone cement into the bone structure is not desirable and can make subsequent explantation of the spacer more difficult. Excess bone cement must be removed. After the bone cement used for fixation is set, the joint space must be cleaned of any bone cement particles. During the cleaning, the spacer should not come into contact with aqueous solution nor should the pulse lavage touch the spacer because any substances present in the bone cement may be flushed out as a result.

Anomalies

COPAL® exchange G hip should not be used if the spacer has cracks or broken-off components.

Incompatibilities

Not known according to current knowledge.

Disposal

An explanted **COPAL® exchange G hip spacer** and the outer packaging can be disposed of with regular hospital waste. Please comply with local environmental legislation and waste disposal regulations.

Explantation

The **COPAL® exchange G hip spacer** may remain in the patient for a maximum of 180 days and must then be explanted. In explantation, bone cement should be completely removed. After the explantation, the hip joint must be provided with an appropriate hip endoprosthesis or another suitable treatment (e.g. arthrodesis of the hip joint) must be carried out.

9. Storage

COPAL® exchange G hip spacer must be stored unopened and protected from light at a maximum temperature of 25 °C (77 °F) in a dry, clean place in the original packaging.

10. Shelf life

The shelf life is shown on the folding box and the outer blister. **COPAL® exchange G hip spacer** must not be used after the indicated expiration date.

11. Sterility

COPAL® exchange G hip spacer is sterile and was sterilized using ethylene oxide. The contents of unused, opened or damaged packs must not be re-sterilized and must be discarded.

12. MRI Safety Information

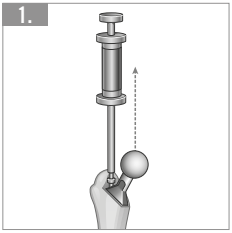
The **COPAL® exchange G hip spacer** has not been evaluated for safety in the MR environment. It has not been tested for heating or unwanted movement in the MR environment. The safety of **COPAL® exchange G hip spacer** in the MR environment is unknown. Performing an MR exam on a person who has this medical device may result in injury or device malfunction.

13. Caution

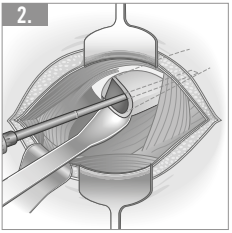
Federal law restricts this device to sale, distribution, and use by or on the order of a physician.

Revision status: 2022-01

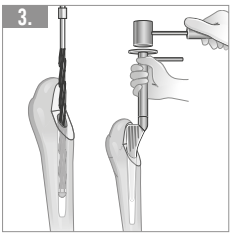
Example of implantation of the spacer



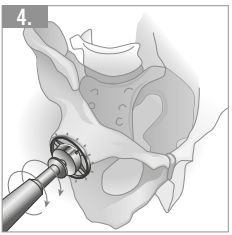
Remove the infected implant and residual cement.



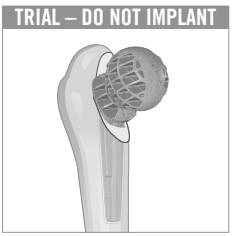
Thoroughly debride and irrigate canal to remove residual cement and tissue.



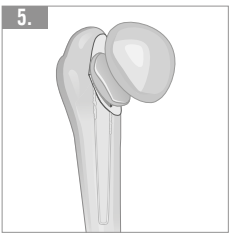
Ream and broach canal to create space for spacer.



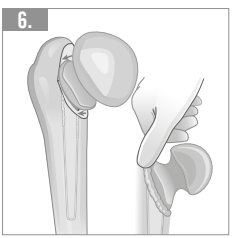
Thoroughly debride the acetabulum. For an optimal fit it may be necessary to mill out the acetabulum.



COPAL® exhange G hip Trial shall be inserted into the femoral canal to verify stem fit. Once properly seated, the hip joint may be deduced to determine correct fit in the acetabular cavity. After the correct size is identified, **COPAL® exhange G hip** Trials must be removed from the cavity as trials must not be implanted.



After determining the suitable size, coat the upper third of selected stem spacer with fresh, doughy cement.



If necessary, fill proximal gaps with cement to reduce the risk of dislocation.

SYMBOLS


Manufacturer

Do not store above 25 °C (77 °F)

Sterilized using ethylene oxide


Consult instructions for use


Do not re-use


Use by date

Batch code


Keep away from sunlight


Keep dry

Do not resterilize


Do not use if package is damaged

Catalogue number

Federal law restricts this device to sale, distribution, and use by or on the order of a physician

Heraeus

Heraeus Medical GmbH
Philipp-Reis-Straße 8/13
61273 Wehrheim, Germany
Phone: + 49 (0) 6181 35 33 99
www.heraeus-medical.com