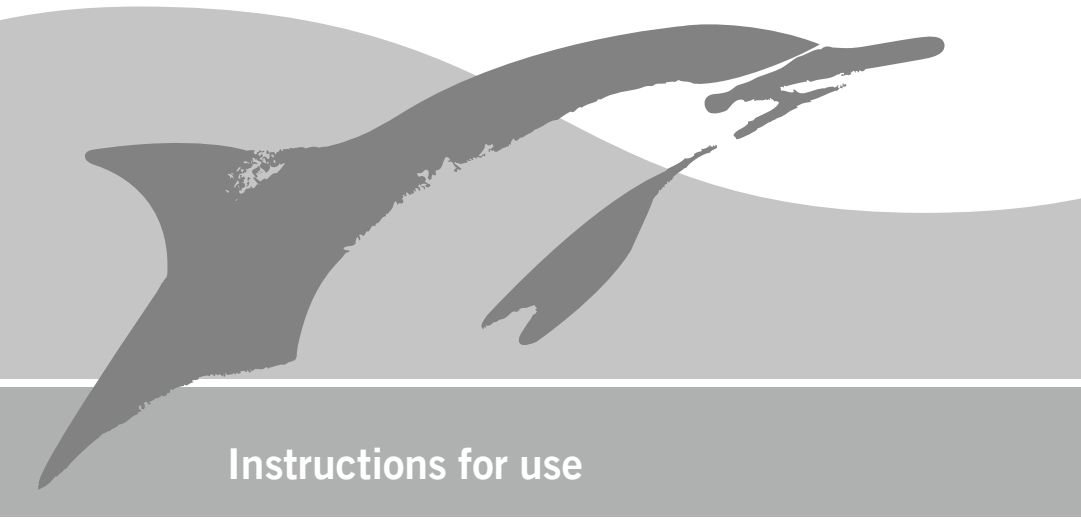
Heraeus

Medical

COPAL® exchange G hip

Preformed PMMA hip spacer containing Gentamicin



Instructions for use

℞ Only

COPAL® exchange G hip

EN **Instructions for use** **3**
(Revision status: 2024-02-13)

1 General information

1.1 Device description

COPAL® exchange G hip spacer provides patients, undergoing a two-stage revision procedure for an infected total joint, a temporary implant to 1) allow for partial weight bearing and 2) provide an approximate natural range of motion. The devices also maintain a patient's soft tissue and joint space, preventing further complications such as muscular contraction.
COPAL® exchange G hip spacer is placed into the joint to maintain normal joint space and alignment. The spacer provides patient comfort and limited mobility while the infection is being treated. **COPAL® exchange G hip spacer** is made with bone cement containing gentamicin. Gentamicin reduces the risk for bacterial colonization of the device and is released into the fluid surrounding the joint.
COPAL® exchange G hip spacer is a temporary joint prosthesis designed to temporarily replace an infected implant during a total hip arthroplasty and provide the patient with limited mobility and predictable, consistent local antibiotic release.
COPAL® exchange G hip spacer is intended for single-use and is supplied sterile.
COPAL® exchange G hip spacer can be used in both the right and the left hip joint.
COPAL® exchange G hip spacer is made of fully formed polymethylmethacrylate (radiopaque PMMA with gentamicin) and contains an inner stainless steel (AISI 316L) reinforcing structure. The mass used in the filling of the molds (the PMMA unformed resin) is prepared from a powder component and a liquid component. It contains the Xray contrast medium calcium carbonate. To improve visibility in the surgical field, it has been colored with chlorophyll-copper-complex (E141).

1.2 Device sizes and packaging

Device sizes

COPAL® exchange G hip spacer is available in 8 different sizes: three stem sizes (short, medium, and long) that are 135, 184 and 251 mm in length with three different head diameters (46 mm, 54 mm, and 60 mm).

Size	Head size	Shaft length
S short	46 mm	135 mm
M short	54 mm	135 mm
L short	60 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

Additionally, **COPAL® exchange G hip spacer** XL short and long is available on special request.
COPAL® exchange G hip spacer XL short comprises of 65 mm head size and 135 mm stem length.
COPAL® exchange G hip spacer XL long comprises of 65 mm head size and 251 mm stem length.

Package content

- 1 **COPAL® exchange G hip spacer**
- 1 set of product stickers for documentation
- 1 instructions for use
- 1 surgical technique

Packaging design

A **COPAL® exchange G hip** package contains a double blister with a sterile prefabricated hip spacer. 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. **COPAL® exchange G hip spacer** is sterilized using ethylene oxide.

1.3 Composition

Polymer powder	Polymethyl methacrylate/co-polymer (PMMA)
	Calcium carbonate
	Benzoyl peroxide
	Gentamicin sulphate
	Chlorophyll-copper-complex (E141)
Monomer liquid	Methyl methacrylate
	N,N-Dimethyl-p-toluidine
	Hydroquinone
	Chlorophyll-copper-complex (E141)
	Hydroquinone
Inlay	Surgical Grade Stainless Steel 316 (AISI 316L steel)

It cannot be excluded that **COPAL® exchange G hip spacer** contains traces of histamine.
COPAL® exchange G hip spacer does not contain a radiation source.

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

The data is rounded.

1.4 Supporting equipment
COPAL® exchange G hip spacer will be used with **COPAL® exchange G** hip trial.
For fixation of **COPAL® exchange G hip spacer** to the host bone, **COPAL® exchange G hip spacer** is intended for use with **PALACOS® R** and **COPAL® G+V**. **COPAL® exchange G hip spacer** does not alter the intended use and indications for use of **PALACOS® R** and **COPAL® G+V**.
The instructions for use of the supporting equipment must be followed.

Note: Heraeus Medical GmbH tested the compatibility of **COPAL® exchange G hip spacer** with **PALACOS® R** and **COPAL® G+V**. Heraeus Medical GmbH has not tested the compatibility of **COPAL® exchange G hip spacer** with devices of other manufacturers and does not assume any liability for this. The use of mixing equipment of other manufacturers is done in the sole discretion and responsibility of the user.

1.5 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.

2 Directions for use

2.1 Intended use
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.

2.2 Intended patient population
Adult population, predominantly elderly patients with periprosthetic joint infection.

2.3 Intended user
Healthcare professionals in a clinical context and experienced in the handling of the product.
The surgeon and nurse must be thoroughly familiar with the properties and handling characteristics of **COPAL® exchange G hip spacer**.

2.4 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).
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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.

2.5 Contraindications
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 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 prosthesis 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.

2.6 Adverse events and residual risks

Adverse events

General adverse events

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

Where gentamicin is used, it is possible, in principle, for the antibiotic to trigger typical adverse events:
- 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, in particular, if they also have a history of renal insufficiency:
- having a history of neuromuscular disease
- treated concomitantly with the administration of muscle relaxants

Allergic reactions may occur regardless of the dosage.

Residual risks

Residual risks listed below are procedure related risks which are beyond the control of the manufacturer because they are procedure or user related.

Nervous System
- numbness

Muscoskeletal System
- loosening
- unequal limb length
- loss of range of motion
- ambulation difficulties

Infection
- bacterial infection including cellulitis, and/or osteomyelitis

Generalized Disorders
- heat necrosis
- inflammation
- swelling/edema
- fibrosis

2.7 Warnings

Regarding intended users

Inadequate fixation or unanticipated postoperative events may affect the spacer–bone interface and lead to motion of the spacer against the bone surface. A fibrous tissue layer may develop between the spacer and the bone and loosening of the spacer may occur. Long-term follow-up is advised for all patients on a regularly scheduled basis.

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 fixate the spacer. The instructions for use for **PALACOS®R** and **COPAL®G+V** bone cement used must be consulted beforehand.

Before inserting **COPAL® exchange G hip spacer**, the suitable size should be determined intraoperatively with the help of **COPAL® exchange G trial**. The intended user must adjust to the anticipated situation pre-operatively (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.

Note: COPAL® exchange G hip spacer is a single-use device and must never be re-used! Re-use may result in diminished safety, performance, and compliance with relevant specifications.

Regarding the intended patient population
COPAL® exchange G hip spacer is considered most unlikely to cause gentamicin overdosage.

Monitor patients carefully for any change in blood pressure during and immediately after the insertion of **COPAL® exchange G hip spacer** and fixation with **PALACOS®R** or **COPAL®G+V** bone cements. Hypotensive reactions have occurred shortly after application of bone cement and are usually linked to bone cement pressurization in arthroplasty procedures. Generally, consequences such as cardiac arrest are only reported in very few cases.

After surgical insertion of **COPAL® exchange G hip spacer**, 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 dislocation 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 stabilize 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.

2.8 Precautions
Regarding intended users
Do not use this product after the expiration date printed on the package. This device may not be safe or effective beyond its expiration date.

Follow the handling instructions and Surgical Technique of **COPAL® exchange G hip spacer**.

Before using the **COPAL® exchange G hip spacer**, it should be checked for any damage and completeness.

Fixation with **PALACOS®R** and **COPAL® G+V** bone cements 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 be rinsed with aqueous solution, nor should the pulse lavage touch the spacer or bone cement because any substances present in the spacer or bone cement may be flushed out as a result.

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 prosthesis or another suitable treatment (e.g., arthrodesis of the hip joint) must be carried out.

Regarding the intended patient population
Like all aminoglycosides, gentamicin is potentially nephrotoxic. Independent of the total amount, care should be taken in patients with risk factors for the development of renal failure as well as in patients simultaneously treated with other nephrotoxic drugs, e.g. by periodically monitoring systemic levels of the antibiotic, serum electrolytes and renal function.

The use of **COPAL® exchange G hip spacer** should be limited to patients that are proven to be infected with pathogens sensitive to gentamicin.

When using **COPAL® exchange G hip spacer**, the prepared bone should be carefully cleaned, aspirated, and dried just before **COPAL® exchange G hip spacer** and the bone cement for fixation of **COPAL® exchange G hip spacer** to the host bone is placed.

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.

3 Handling
General information
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, **COPAL® exchange G hip spacer** must not be used and must be disposed of.

Preparation
Before using **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®** or **COPAL®G+V** bone cement is used primarily to stabilize the spacer. Deep penetration of the bone cement into the bone structure is not desir-

able 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 spacer should not be used if the spacer has cracks or broken-off components.

Incompatibilities
Not known according to current knowledge.

Explantation
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.

4 Storage, transport, shelf life, sterilization
Storage
Do not store above 25 °C (77 °F).
COPAL® exchange G hip spacer must be stored in dry conditions and must not be exposed to direct sunlight, ionizing radiation, extremes of temperature, or particulate contamination.

Transport
Care shall be exercised during transport and handling of **COPAL® exchange G hip spacer** to avoid any damage or alteration to the performance characteristics of **COPAL® exchange G hip spacer** and its packaging as received. Do not remove **COPAL® exchange G hip spacer** from the sterile packaging until immediately before use. Do not use if packaging is damaged.

Shelf life
The shelf life of **COPAL® exchange G hip spacer** is printed on the folding box. Do not use **COPAL® exchange G hip spacer** if the date indicated has expired.

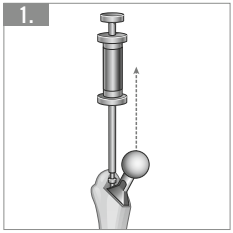
Sterilization
COPAL® exchange G hip spacer has been sterilized using ethylene oxide. The product must not be re-sterilized. Non-sterility may cause an infection in the patient. If the surface of the spacer shows yellow spots, do not use **COPAL® exchange G hip spacer**.

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

6 Disclaimer of liability
Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority.

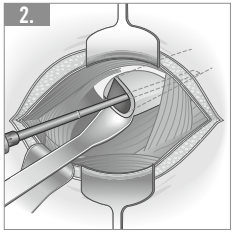
Example of implantation of the spacer

1.



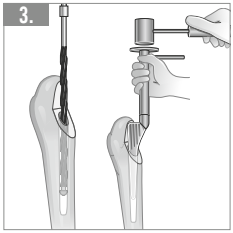
Remove the infected implant and residual cement.

2.



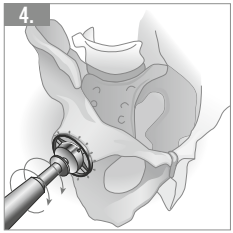
Thoroughly debride and irrigate canal to remove residual cement and tissue.

3.



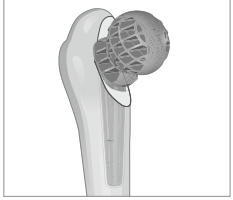
Ream and broach canal to create space for **COPAL® exchange G hip spacer**.

4.



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

TRIAL – DO NOT IMPLANT

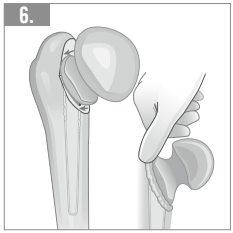


COPAL® exchange G hip trial shall be inserted into the femoral canal to verify stem fit. Once properly seated, the hip joint may be deduced to determine correct fit in the acetabular cavity. After the correct size is identified, **COPAL® exchange G hip trials** must be removed from the cavity as **COPAL®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

5.

After determining the suitable size, coat the upper third of selected stem of **COPAL® exchange G hip spacer** with fresh, doughy cement

6.



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

Symbols


Manufacturer

Country and date of manufacture (DE=Germany)

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


Use-by date

Batch code

Catalogue number

Do not resterilize


Do not use if package is damaged and consult instructions for use

Sterilized using ethylene oxide


Single sterile barrier system with protective packaging inside


Keep away from sunlight


Keep dry

Upper limit of temperature
25 °C (77 ° F)


Do not re-use


Consult instructions for use


Contains a medicinal substance

Medical Device

Unique Device Identifier

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