Heraeus

COPAL® exchange G knee

Preformed PMMA knee spacer containing Gentamicin

Instructions for use

COPAL® exchange G knee

1. Product description
Preformed PMMA knee spacer containing gentamicin.
COPAL® exchange G knee is a temporary knee spacer implant as part of two-stage septic endoprosthesis revision based on bone cement.
COPAL® exchange G knee comprises a tibial component and a femoral component, which together form a bearing and move against one another. They can be used in both the right and the left knee 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 knee contains gentamicin. Gentamicin reduces the risk for bacterial colonisation of the device and is released into the fluid surrounding the joint.
COPAL® exchange G knee is colored with the food colorant E141 (chlorophyll-copper complex) and contains calcium carbonate as X-ray contrast medium.

2. Package contents & composition
COPAL® exchange G knee is available in three different sizes.

Size	Femur (medial-lateral)	Tibia (medial-lateral)
S	54 mm	54 mm
M	64 mm	64 mm
L	74 mm	74 mm

A **COPAL® exchange G knee** package contains a double blister with a sterile prefabricated tibia component and a femur 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 spacers. Both blisters are sealed with Tyvek.

Composition:
Bone cement ingredients: polymethylmethacrylate, calcium carbonate, benzoyl peroxide, N,N-Dimethyl-p-toluidine, hydroquinone, colorant E141, gentamicin (as gentamicin sulfate)

Size		Gentamicin base (in g)
S	Tibia	0.3
	Femur	0.5
M	Tibia	0.6
	Femur	0.9
L	Tibia	0.9
	Femur	1.3

3. Indications
COPAL® exchange G knee (polymethylmethacrylate/gentamicin) is indicated for temporary use (maximum of 180 days) as a total knee replacement (TKR) in skeletally mature patients undergoing a two-stage procedure due to a septic process. **COPAL® exchange G knee** is applied on the femoral condyles and on the tibial plate following removal of the existing implant and radical debridement. The device is intended for use in conjunction with systemic antimicrobial antibiotic therapy (standard treatment approach to an infection).
COPAL® exchange G knee 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.).
Because of the inherent mechanical limitations of the device material polymethylmethacrylate/gentamicin, **COPAL® exchange G knee** 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 knee 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 impairment
- in the case of active local or systemic infection with gentamicin-resistant germs which is active or has not yet been fully treated

COPAL® exchange G knee 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 tibia and/or the distal femur 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 could interfere with the bearing of the tibial and femoral components
- an additional systemic and/or chronic infection is present
- the infected knee endoprosthesis cannot be removed either fully or in part
- there is no total knee 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 knee** 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 knee**:

- Damage to the femur and tibia
- Damage to the surrounding blood vessels and nerves
- Dislocation of the joint or the spacer
- Change to the surrounding tissue
- Difference in leg lengths

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 (see interactions)
- 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 advisable 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 knee**, users should be thoroughly familiar with its properties and use. In addition, users must make themselves familiar with the bone cement used to fix the spacer. The instructions for use for all the products used must be noted beforehand. Before inserting **COPAL® exchange G knee**, the suitable size should be determined intraoperatively with the help of 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 knee contains no instruments.

COPAL® exchange G knee may only be used if it is undamaged. The spacers must not be positioned by striking with a hammer or similar instruments.

The user must ensure that the bone cement used for fixation completely covers the surfaces of the tibial and femoral components intended for fixation. In doing so, prevent the bone cement reaching the bearing surfaces of the tibial and femoral components.

Patient

After surgery, the patient's knee must not be strained. Maximum bending of the knee of 90° is possible. 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. 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 foetus 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 knee** during pregnancy and lactation.

8. Use

General information

COPAL® exchange G knee is intended for single use and must not be re-used or resterilized.

COPAL® exchange G knee 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 knee** must not be used and must be disposed of.

Preparation

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

When using **COPAL® exchange G knee**, the prepared bone should be carefully cleaned and dried just before the spacer is placed.

Fixation with bone cement is used primarily to stabilise 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 cleaning, the spacers should not come into contact with aqueous solution, nor should the pulse lavage touch the spacers because any substances present in the bone cement may be flushed out as a result.

Anomalies
COPAL® exchange G knee should not be used if the spacer has tears or broken-off bone cement parts.

Incompatibilities
Not known according to current knowledge.

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

Explantation
COPAL® exchange G knee 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 knee joint must be provided with an appropriate knee endoprosthesis or another suitable treatment (e.g. arthrodesis of the knee joint) must be carried out.

9. Storage
COPAL® exchange G knee 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.

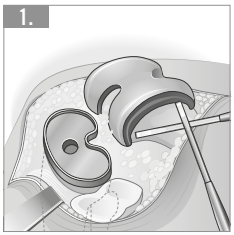
10. Shelf-life
The shelf life is shown on the folding box and on the outer blister. **COPAL® exchange G knee** must not be used after the indicated expiration date.

11. Sterility
COPAL® exchange G knee is sterile and was sterilized with ethylene oxide gas. The contents of unused, opened or damaged packs must not be re-sterilized and must be discarded.
COPAL® exchange G knee is intended for single use and must not be re-used or resterilized.

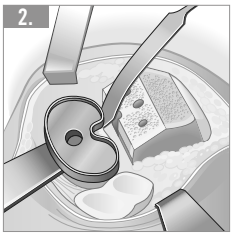
12. Caution
Federal law restricts this device to sale, distribution, and use by or on the order of a physician.

Revision status: 2018-04

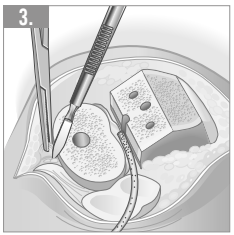
Example of implantation of the spacer



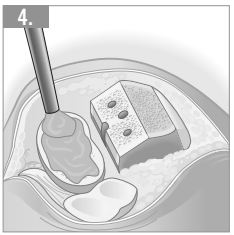
Remove the infected femur (component) and residual bone cement.



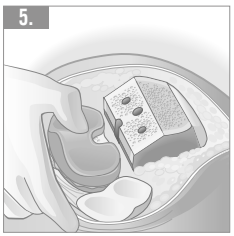
Completely remove the infected endoprosthesis and residual cement.



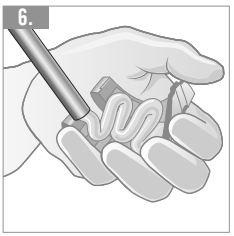
Thoroughly debride the joint space.



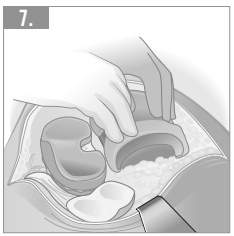
Apply bone cement onto the distal, non-sliding half of the tibial spacer and the proximal bone surface of the tibia.



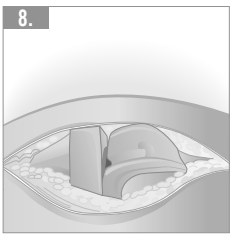
Position the tibial spacer onto the proximal surface of the tibia and carefully remove any excess bone cement residue.



Apply bone cement onto the non-sliding side of the femoral spacer.



Position the femoral spacer onto the distal femur and hold until the bone cement is almost cured.



Before the bone cement has completely set, check that both spacers are correctly seated by repeatedly bending the knee joint.

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 the product sterile barrier system or its packaging is compromised.

Catalogue number

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

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