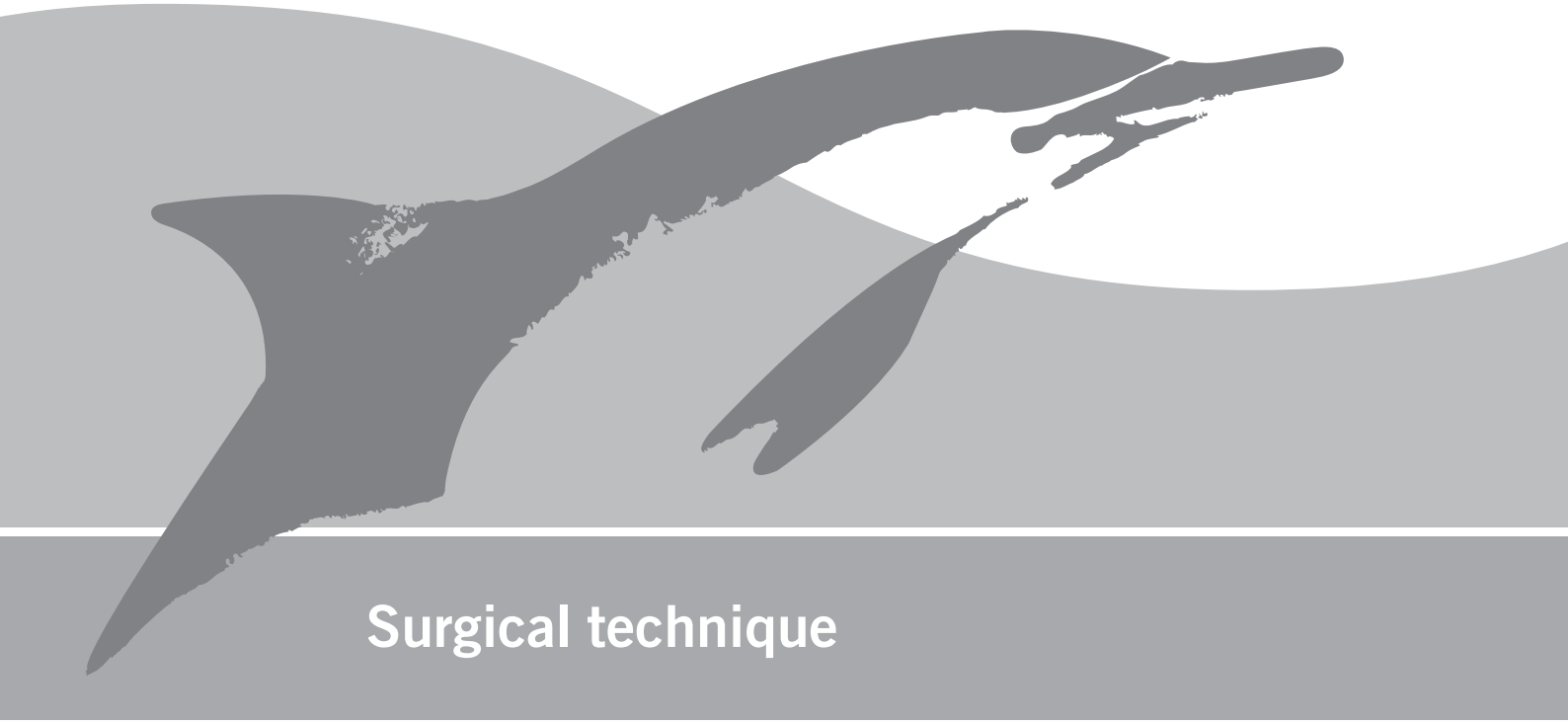
Heraeus

Medical

COPAL® exchange G hip
COPAL® exchange G knee



Surgical technique

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EN Surgical Technique

1 General information

Infection is one of the major complications of total hip arthroplasty (THA) and total knee arthroplasty (TKA). Estimates of the incidence of infection following primary THA vary between 1 % and 3 % [1]. The incidence of infection after TKA has been reported to be 1 % with an increase to 5 % in patients with revision TKA [2, 3]. The gold standard for treatment of chronic periprosthetic joint infection (PJI) has been two-stage procedure [4]. Cement spacers assist to provide antibiotic release into the joint space surrounding the implant.

1.1 Device Description

COPAL® exchange G hip and **knee spacers** provide a temporary joint prosthesis with a natural range of motion for patients undergoing a two-stage revision procedure for an infected total joint.
COPAL® exchange G hip and **knee spacers** are prefabricated spacers and are made out of bone cement loaded with Gentamicin antibiotic. They contain 1.0 g Gentamicin base (as Gentamicin sulphate) per 40 g of plain cement. Gentamicin reduces the risk for bacterial colonization of the device and is released into the fluid and tissue surrounding the joint.
COPAL® exchange G hip and **knee spacers** are placed into the joint to maintain joint mobility and stability, reducing soft-tissue contracture and hence to facilitate the subsequent reimplantation of a prosthesis. **COPAL® exchange G hip** and **knee spacers** provide limited patient mobility while the infection is being treated.
COPAL® exchange G hip and **knee spacers** are single-use devices and are made of fully formed polymethylmethacrylate (radiopaque PMMA with gentamicin). The possibility of partial weight bearing after implantation into the patient is supported by fatigue and compression tests.

COPAL® exchange G hip spacer
COPAL® exchange G hip spacer is designed as a hemi-hip prosthesis and contains an inner stainless steel core (of grade AISI 316L) serving as a reinforcing structure.

COPAL® exchange G knee spacer
COPAL® exchange G knee spacer comprises a tibia and femur component to form one and the same knee spacer usable for the left and the right knee.

COPAL® exchange G trials
A set of trials are available for both,
COPAL® exchange G hip spacers and
COPAL® exchange G knee spacers to determine the suitable size intra-operatively.

Sterilization
COPAL® exchange G hip and **knee spacers** are supplied in a double-sterile, blister-in-blister package. The spacers are sterilized using ethylene oxide.

1.2 Device sizes

COPAL® exchange G hip spacer
COPAL® exchange G hip spacer comes in the following 8 sizes:

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

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.

COPAL® exchange G knee spacer
The **COPAL® exchange G knee spacer** comes in the following three size versions:

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

2 Directions for use

Indication for use

COPAL® exchange G hip spacer

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.

COPAL® exchange G knee spacer

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.).
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.

3 Handling

COPAL® exchange G hip spacer maintains joint space and allows limited mobility with partial weight bearing*.
COPAL® exchange G hip and **knee spacers** are only indicated for patients who will consistently use traditional mobility assist devices (e.g. crutches, walkers, canes) throughout the implantation period.

*) 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 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.

Preoperative Planning information

No specific instrumentation is required to successfully implant **COPAL® exchange G hip** and **knee spacers.**

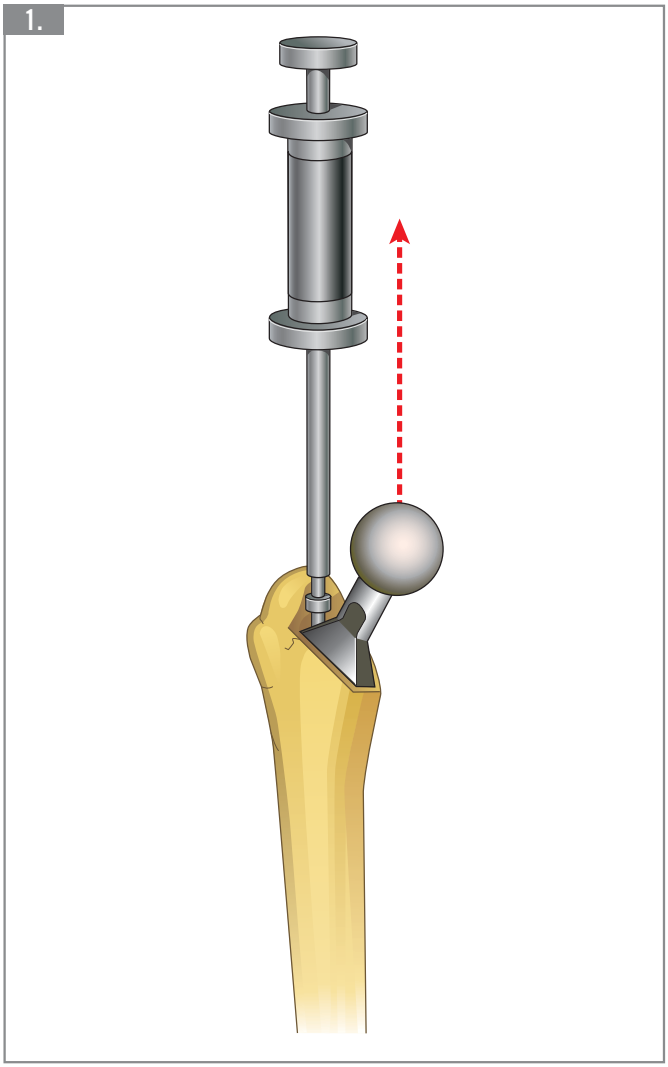
Moreover, it is recommended that the following instruments and accessories are available for the procedure, depending on whether it is a hip or knee procedure:
- **COPAL® exchange G hip trials** and **COPAL® exchange G knee trials**
- Extraction instrument
- Long straight gouge osteotome or long notched osteotome
- Flat, narrow flexible osteotome
- Straight femoral canal reamer and/or flexible canal reamer
- Acetabular and finishing reamer
- Polytipped femoral head impactor
- Oscillating sawblade for femoral component
- Femoral extractor
- **PALACOS® R** bone cement
- **COPAL® G+V** bone cement (only applicable with **COPAL® exchange G hip spacer**)

The size selection for **COPAL® exchange G hip** and **knee spacers** is based upon, e.g.:
- Dimensions of the removed implants
- Remaining bone stock
- State of ligamentous apparatus
- Flexion and extension spaces
- **COPAL® exchange G trials** resemble the spacer in the same size, shape and geometry

EN Surgical Technique for COPAL® exchange G hip spacer

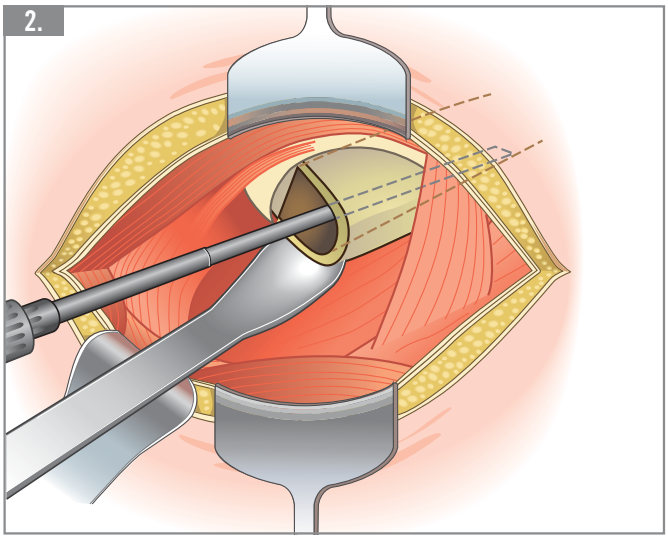
The surgical approach to the hip joint may be chosen in accordance with pre-existing approaches or the surgeon's personal preferences.
Prior to the insertion of **COPAL® exchange G hip trials** and the implantation of **COPAL® exchange G hip spacers** all infected prosthetic components and residual bone cement (in case of a cemented prosthesis) must be removed from the femoral canal prior to implantation of **COPAL® exchange G hip spacer.**
In the first step, disrupt the cement between bone and the femoral component adequately, so that it can be extracted using an extraction instrument, as shown in image 1.
Complete debridement of necrotic tissue should also be performed prior to implantation.

1.



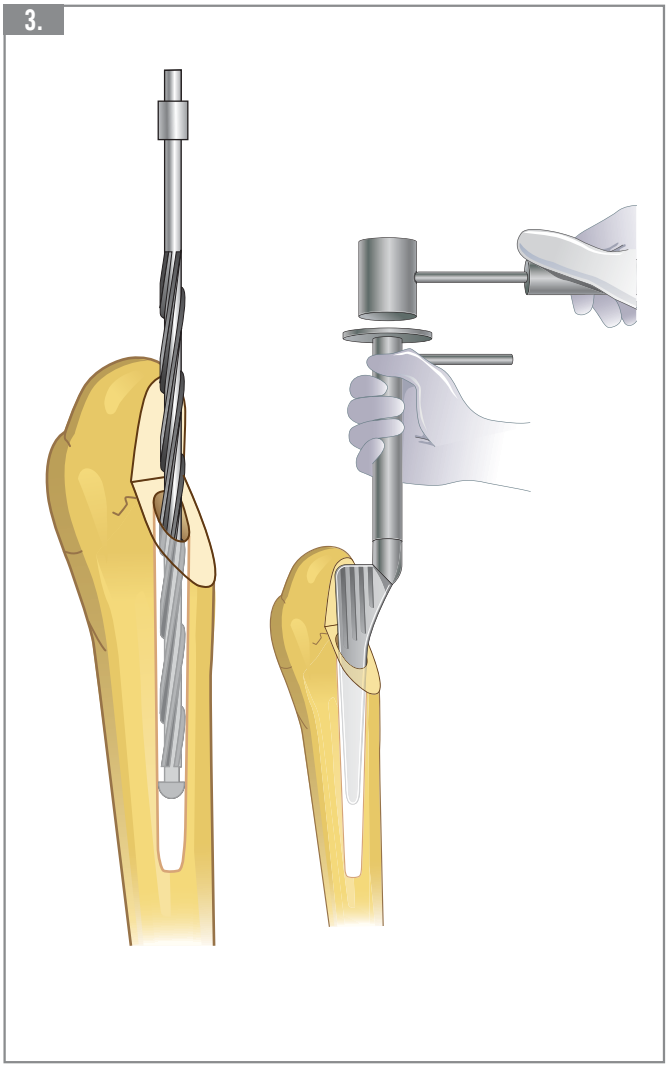
Suitable osteotomes may be used to remove the cemented or cementless femoral stem. As shown in image 2, a long straight gouge can be used for cement removal from the distal stem level.
Deploying a long notched osteotome might be an alternative.
For the cementless femoral stem a flat, narrow flexible osteotome might be appropriate for the femoral stem removal.

2.



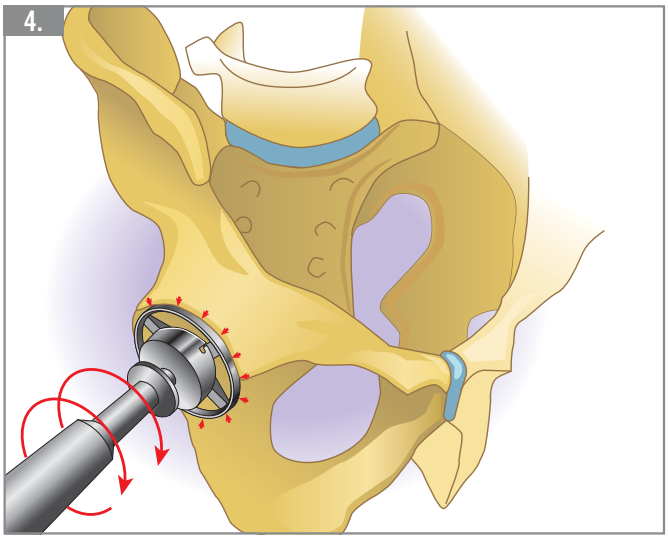
It may be necessary to ream the femoral canal in order to obtain an optimal fit of **COPAL® exchange G hip spacer**, offering a short, medium and a long stem version. The final preparation of the femoral canal can be conducted with a straight femoral canal reamer, as shown in image 3.
As depicted in image 3, flexible canal reamers may be used alternatively to prepare the femoral canal prior the insertion of **COPAL® exchange G hip trials** and the implantation of **COPAL® exchange G hip spacers.**
It is recommended to leave a tolerance for the insertion of **COPAL® exchange G hip spacer**, owing to the partial cementation (see image 5).

3.



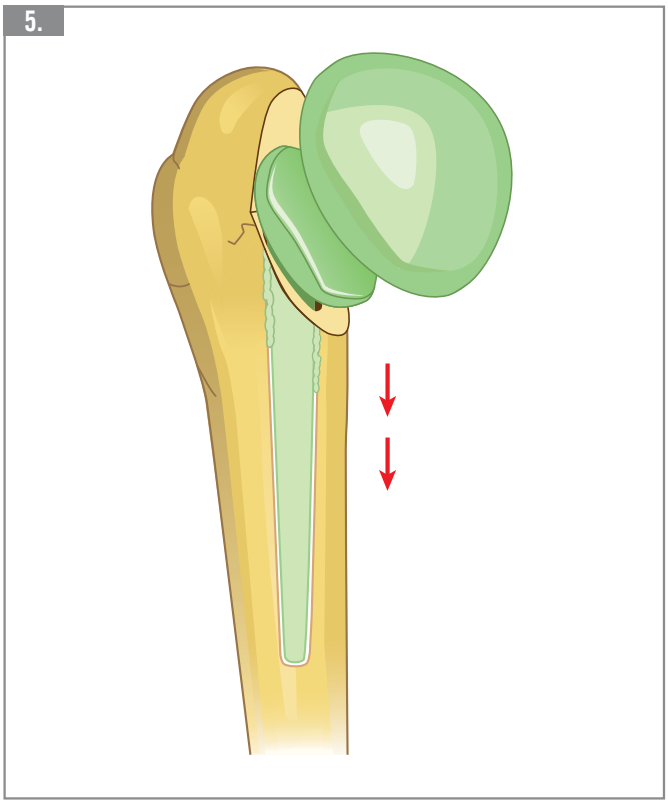
A good circumferential exposure of the acetabulum is an indispensable premise before starting with the bone preparation.
It may be necessary to ream the acetabulum in order to debride the bone surface and match the head of **COPAL® exchange G hip spacer**, as shown in image 4. Different options of head diameters are presented in the Instruction for Use of **COPAL® exchange G spacer** and the Surgical Technique of **COPAL® exchange G spacer** and on the product labelling of **COPAL® exchange G spacer**. As shown in the next image, for determining the suitable size of the Spacer different sets of **COPAL® exchange G trials** shall be used intraoperatively. Appropriate care must be taken to maintain as much healthy bone stock as possible. Any standard acetabular reamer may be used for this purpose.

4.



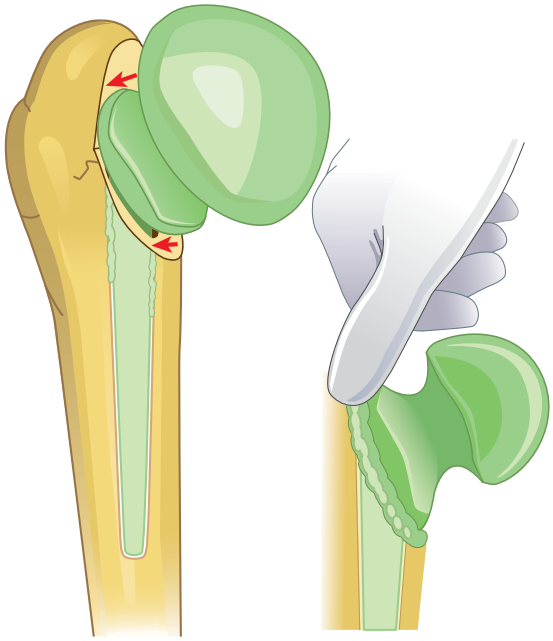
After removal of all infected prosthetic components and residual bone cement as well as after complete debridement, **COPAL® exchange G hip trials** shall be used in order to determine the suitable size of the PMMA hip spacer intraoperatively.
COPAL® exchange G hip trials resemble the spacer in the same size, shape and geometry.
COPAL® exchange G hip trials 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. An adequate fit of **COPAL® exchange G hip trials** head into the acetabular cavity will assist in reducing the incidence of dislocation.
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 during the interim phase of a 2-stage revision surgery or even permanently.
For easy distinction, **COPAL® exchange G hip trials** comprise of a hollow body and conspicuous color.

Based on the suitable combination of **COPAL® exchange G hip trial** head and stem, the corresponding **COPAL® exchange G hip spacer** shall be chosen.
A polytipped head impactor can be used to properly place **COPAL® exchange G hip spacer**, as shown in image 5.
For the achievement of an axial and rotational stability of **COPAL® exchange G hip spacer** in the femoral canal and reduction of any mechanical complications (spacer dislocations, fractures) during the interim period, a partial cementation of **COPAL® exchange G hip spacer** onto the proximal femur third by use of doughy **PALACOS® R** or **COPAL® G+V** bone cement is recommended.
Avoid full cementation of **COPAL® exchange G hip spacer** into the femur because this might complicate the later prosthesis reimplantation procedure.



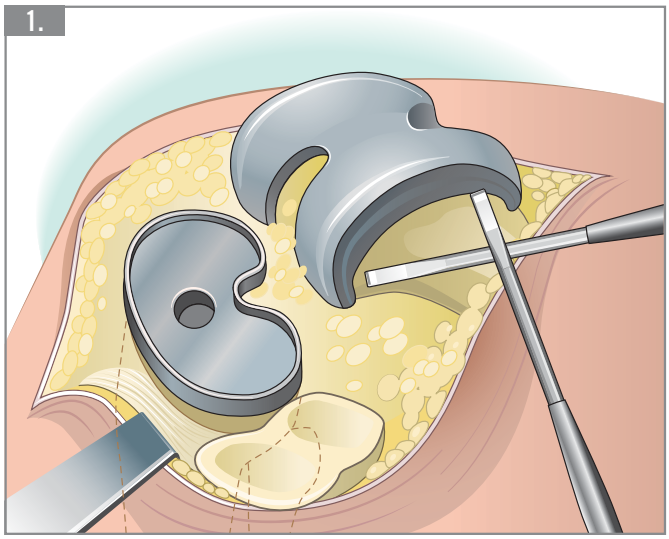
Optionally, doughy **PALACOS® R** or **COPAL® G+V** bone cement can be used at the collar of **COPAL® exchange G hip spacer** to further strengthen the implant-bone interface, as shown in image 6.

6.

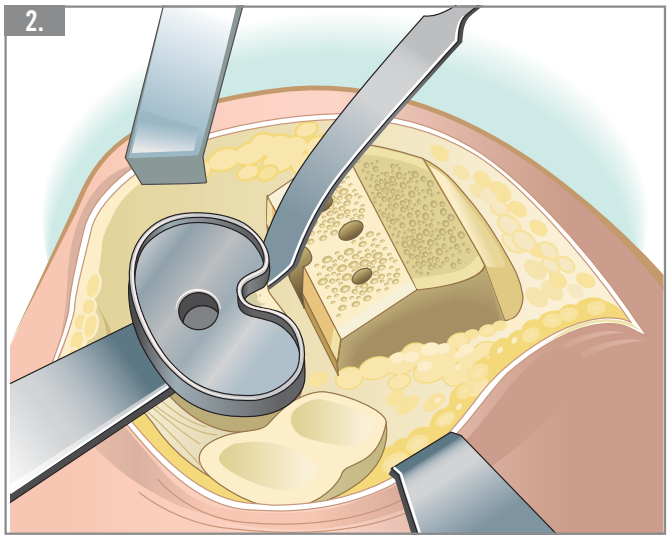


EN Surgical Technique for COPAL® exchange G knee spacer

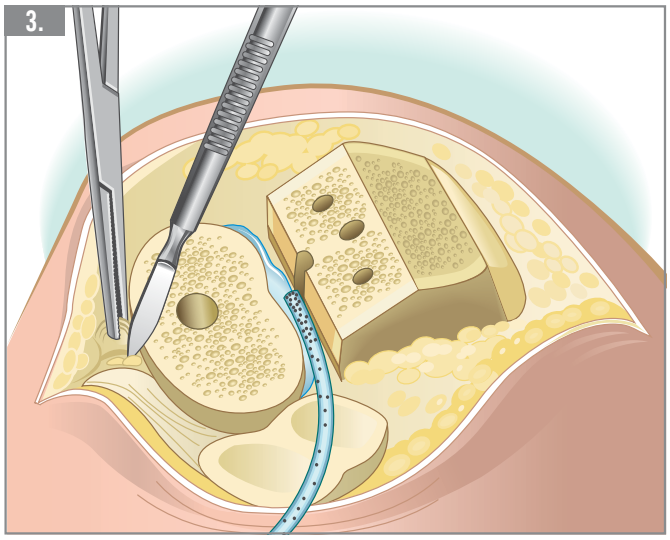
The surgical approach to the knee joint may be chosen in accordance with pre-existing approaches or the surgeon's personal preferences.
All infected prosthetic components and residual bone cement must be removed from the femur, tibia and patella, as shown in Image 1 and 2.
Complete debridement of necrotic tissue should also be performed prior to implantation.



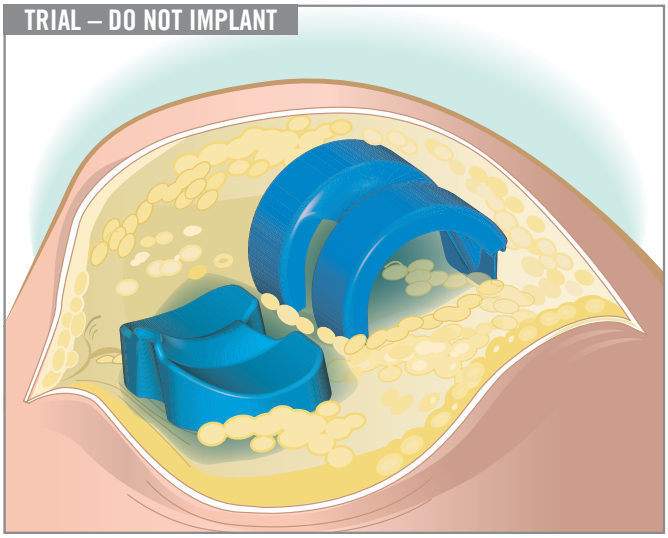
After removal of the polyethylene insert – which reduces the capsular tension and enhances the working space – Flat, Narrow Flexible Osteotomes and/or an oscillating Sawblade may be used to transect the femoral component.
Note that the oscillating saw should not be used for the posterior condyles due to the risk of iatrogenic lesion of the collateral ligaments and surrounding soft tissue (see Image 1). The femoral component may be extracted by use of direct blows onto the anterior flange. Alternatively, a femoral extractor may be used.
Flat, Narrow Flexible Osteotomes and/or an oscillating Sawblade may be used to transect the tibial plateau portion of the prosthesis, as shown in Image 2.



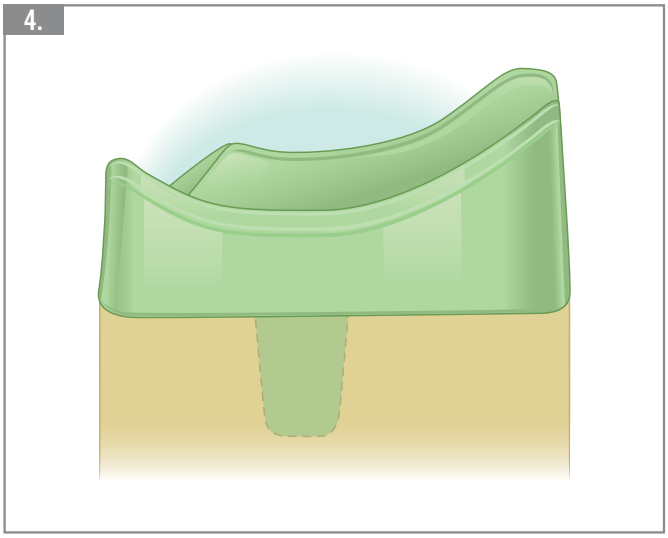
Complete debridement of necrotic tissue should also be performed prior to size determination of spacers by using trials and the spacer implantation, as shown in Image 3. This step is the most important process for successfully eradicating the infection.



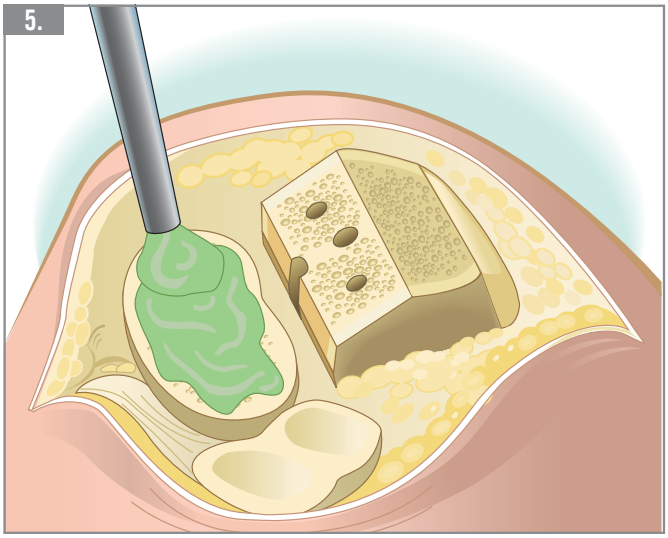
After removal of all infected prosthetic components and residual bone cement as well as after complete debridement, **COPAL® exchange G knee trials** shall be used in order to determine the suitable size of the PMMA knee spacer intra-operatively.
COPAL® exchange G knee trials resemble the spacer in the same size, shape and geometry. A set with 3 different knee Trials consisting of femoral and tibial component is offered.
COPAL® exchange G knee trials shall be positioned into the joint space and the knee shall be reduced (Figure 2). The knee should not be too tight as it will tighten further upon cement fixation of the femoral component.
Tightness may be relieved by downsizing and/or recontouring the femoral bone to achieve a satisfactory fit.
After the correct size is identified,
COPAL® exchange G knee trials must be removed from the knee as Trials must not be implanted during the interim phase of a 2-stage revision surgery or even permanently.
For easy distinction, Trials comprise of a hollow body and conspicuous color.



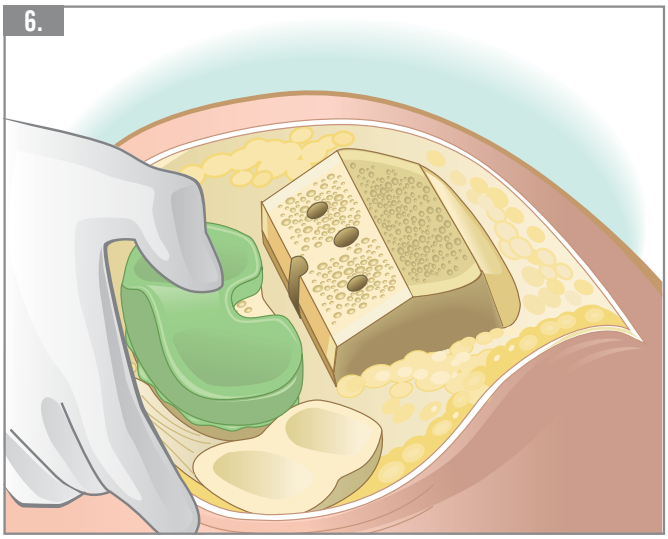
The non-articulating side of the tibial component of the **COPAL® exchange G knee** has a short cement stem, approximately 12 mm long. The purpose of the stem is to increase the stability of the tibial component, as shown in Image 4.



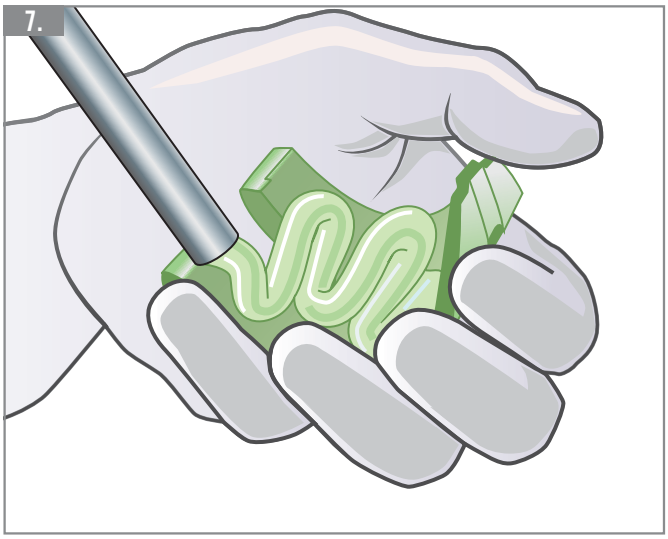
Prepare a fresh batch of **PALACOS®** bone cement. Once it reaches a doughy state, apply a generous amount to the proximal surface of the tibia, as shown in Image 5.



There is the option to also use doughy **PALACOS®** bone cement on the non-articulating surface of the tibial component. Manually position the tibial component of the **COPAL® exchange G knee spacer** on the proximal tibia, taking care to remove all extruding bone cement. Pay specific attention to the tibial rotation in order to secure a normal articulation to the femoral component.

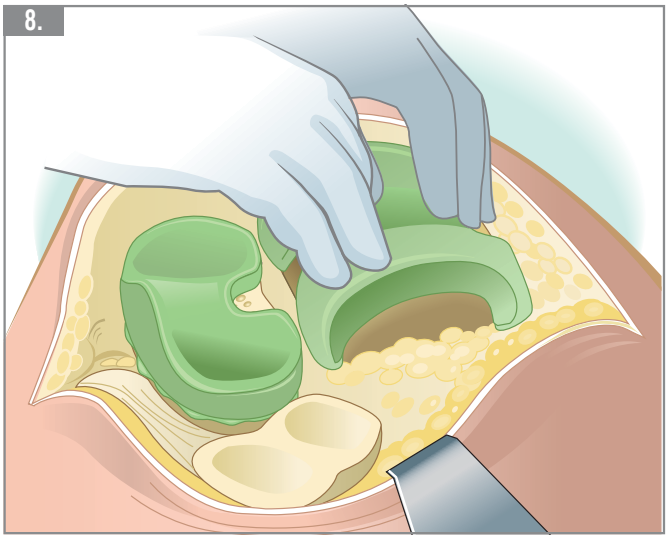


Apply a layer of doughy **PALACOS®** bone cement to the non-articulating surface of the femoral component, as shown in Image 7.



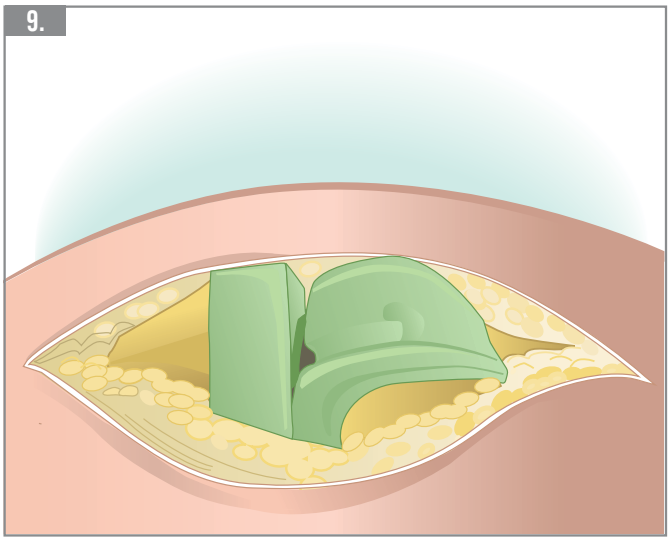
Manually place the femoral component onto the distal femur, as shown in Image 8. Due to the incongruence between the remaining femoral bone and the interior geometry of the **COPAL® exchange G knee spacer**, the femoral component may not rest "flush" on the distal femur. Take care not to force the component into position as this could result in fracturing the prosthesis itself. DO NOT use an impactor and mallet to seat the prosthesis as this can fracture the implant. Remove all extruded bone cement, maintaining femoral component position until the cement fully cures.

8.



Care must be taken to ensure that no uncured bone cement remains on the articulating surfaces that could fuse the joint and/or accelerate the wear process.
Reduce the knee, move into extension and gently flex-extend the knee a couple of times in order to ensure a proper tracking of the **COPAL® exchange G knee spacer**, before the cement has fully hardened. Final curing of the cement should be accomplished with the knee in extension, see Image 9.

9.



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3. Willis-Owen CA, Konyves A, Martin DK. Factors affecting the incidence of infection in hip and knee replacement: an analysis of 5277 cases. J Bone Joint Surg Br. 2010; 92: 1128–33.
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