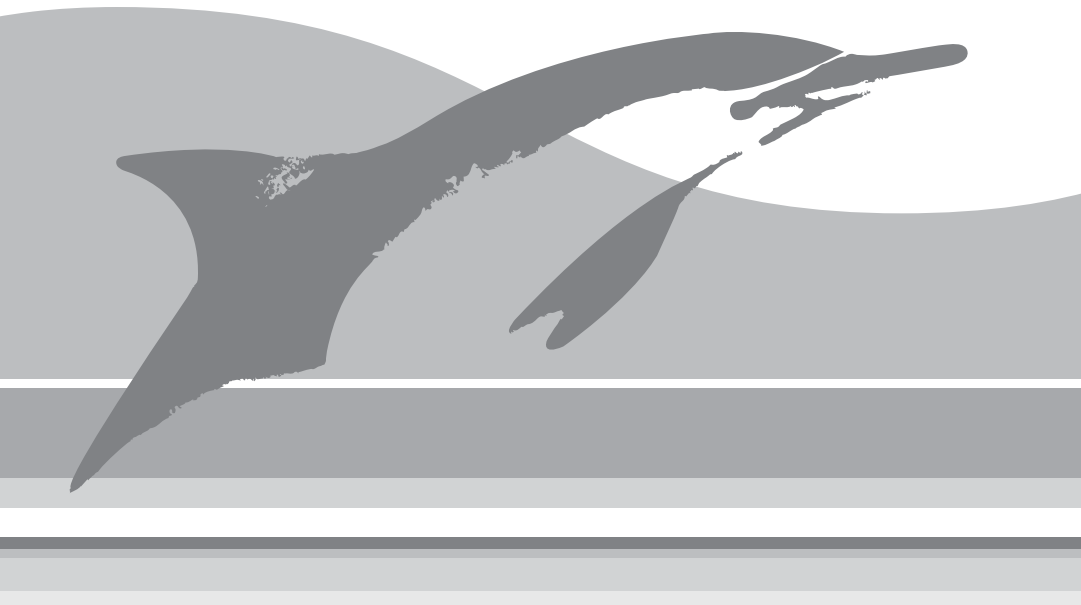
Heraeus

COPAL® knee moulds

Moulds for temporary knee spacer



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COPAL® knee moulds

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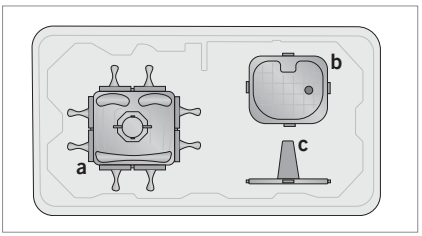
Product description
COPAL® knee moulds are sterile single-use moulds used for the preparation of spacers that are intended as temporary knee replacement after thorough debridement as part of two-stage septic joint prosthesis revision.
COPAL® knee moulds comprise a tibial component and a femoral component, which together creates an articulating bearing surface. They can be used in both the right and the left knee joint.
The spacer function provides that after removal of the prosthesis the existing joint space is retained and contraction of the musculature and the surrounding tissues is prevented.
COPAL® knee moulds are intended for single use and must not be re-used or resterilized.

Package contents
COPAL® knee moulds are available in 3 different sizes.

Size	Femur (medial-lateral)	Tibia (medial-lateral)
S	60 mm	65 mm
M	70 mm	75 mm
L	80 mm	85 mm

The height of all 3 tibia sizes (size S, M, L) can be adjusted from 12mm to 37mm.



One set of **COPAL® knee moulds** includes:
1 mould to prepare the femoral component (a)
1 mould to prepare the tibial component (b) and tibia cap without stem (b)
1 tibia cap with stem (c)

COPAL® knee moulds are double packaged. The outer blister is non-sterile on the outside and sterile on the inside. Inside of the outer blister is a sterile inner blister that contains the set. Both blisters are sealed with Tyvek.

Composition
All components of the **COPAL® knee moulds** are made of medical-grade plastic and are latex-free and PVC-free.

Indications for Use
COPAL® knee moulds are designed to prepare spacers by filling the moulds with bone cement. **COPAL® knee moulds** are disposable cement spacer molds indicated for use to mold a temporary total knee replacement (TKR) for skeletally mature patients undergoing a two-stage procedure due to a septic process. The molded temporary knee spacer is indicated for an implantation period of 180 days or less. Because of inherent mechanical limitations of the device material (**PALACOS® R+G bone cement**), the molded temporary spacer is only indicated for patients who will consistently use traditional mobility assist devices (e.g. crutches, walkers) throughout the implant period.

Contraindications
The spacers prepared with **COPAL® knee moulds** must not be implanted in patients in whom:
- their health precludes two-stage prosthesis 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 may interfere with the bearing of the tibial and femoral components.
- an additional systemic and/or chronic infection is present.
- the infected knee joint prosthesis 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.

Adverse Reactions
The following adverse effects are possible when using spacers prepared with **COPAL® knee moulds**:
- Damage to the femur and tibia
- Damage to the surrounding blood vessels and nerves
- Dislocation of the joint or the spacer
- Changes to the surrounding tissue
- Difference in leg lengths

Warnings and precautions
User
Before using **COPAL® knee moulds** the user should be well acquainted with their properties, handling and application. We recommend that users practice the complete procedure before using it for the first time. It is also essential that users are familiar with the bone cement application system used to fill the **COPAL® knee moulds**. Two mixing and application systems with **PALACOS® bone cement** and the bone cement application systems **PALAMIX®** are required for the filling process. For further information, please read carefully the Instructions for Use of **PALACOS® R+G** and **PALAMIX®.** The femoral component can only be filled using an application system with an application nozzle having a maximum diameter of 15 mm. We recommend filling the **COPAL® knee moulds** with a **PALAMIX®** mixing system.
The stability of the spacer is reduced if there are air pockets and cracks in the cement; these can be prevented by slowly filling the moulds and using vacuum mixing for the bone cement.

COPAL® knee moulds may only be used if they are undamaged. The spacers prepared with **COPAL® knee moulds** must not be positioned under force or 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. After using **COPAL® knee moulds** the presence of all parts noted on the counting chart should be checked.

After surgery
After surgery the patient may only stand up, walk and sit down with the help of walking aids with partial weight bearing and maximum bending of the knee of 90°.
The patient must be informed of this beforehand and warned that there is a high risk of the spacer breaking 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.

Handling
Preparation
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. The **COPAL® knee moulds** set does not include any instruments. The user must also be familiar with **PALACOS® R+G bone cement** and the mixing and application system **PALAMIX®** that will be used to fill the **COPAL® knee moulds**. For intraoperative determination of the correct size of the spacer to be made from **COPAL® knee moulds**, **COPAL® knee mould Trials** (REF: Size S: 5159874, Size M: 5165923, Size L: 5165924) can be used. The instructions for use for all the products used must be noted beforehand.

Before using the **COPAL® knee moulds** set, it should be checked for any damage and completeness. 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® knee moulds** set must not be used and must be disposed of.

The femoral component is made up of two pre-assembled halves that are held together by sliding closures. There is a filling port for the bone cement in the centre of the back of the mould. Integrated into the port is an eject mechanism that enables the prepared spacer to be released from the mould after the bone cement has cured by screwing it out of the mould in a clockwise direction.
The tibial component is made up of a height-adjustable mould in which the height of the tibial spacer can be set in 5-mm increments (from 12 mm to 37 mm). The tibia cap can be optionally selected with or without a stem.

The following quantities of **PALACOS® R+G bone cement** are needed to fill the **COPAL® knee moulds**: (Measured using the **PALAMIX®** vacuum mixing system and Heraeus bone cement).

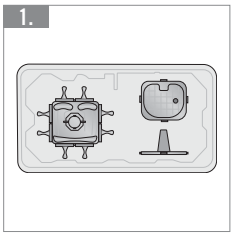
Filling volume for the femoral component

Size	Recommended number of packages of bone cement (1×40)
S	1
M	2
L	2

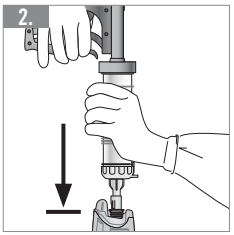
Filling volume for the tibial component

Size	Height	Recommended number of packages of bone cement (1×40)
S	Up to 32 mm	2
S	From 37 mm	3
M	Up to 27 mm	2
M	From 32 mm	3
L	Up to 22 mm	2
L	From 27 mm	3

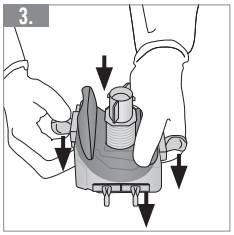
Preparation of the spacer
Femoral component



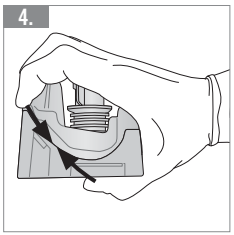
Check the contents of the **COPAL® knee moulds** for completeness.
Prepare the mixing system and the bone cement.



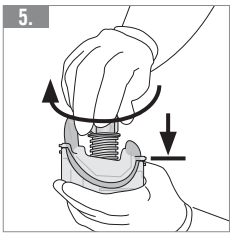
Mix the bone cement in the mixing system and attach the shortest possible application nozzle. When the cement reaches the application phase*, slowly and evenly fill the mould. The nozzle must completely touch ground of the valve with a little force throughout the entire filling process. The mould is completely filled when small amounts of cement exit the vents.



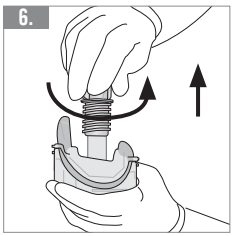
When the cement has completely cured*, remove or break off the sliding clips.



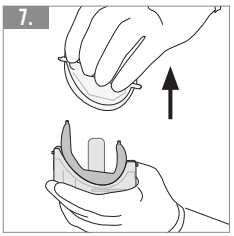
Compress the mould between your hands to release the spacer from the surfaces. A cracking sound indicates that it has detached.



Turn the screw clockwise with pressure until it stops (thread is no longer visible).

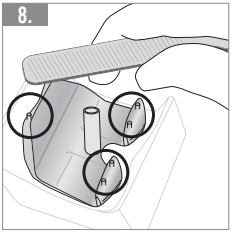


Screw the spacer off in a counterclockwise direction and remove the screw.

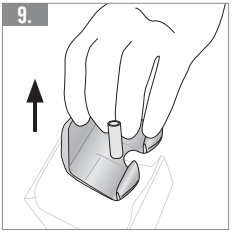


Remove the transparent top shelf of the mould.

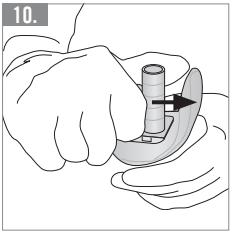
* For the exact processing times, refer to the instructions for use of the bone cement.



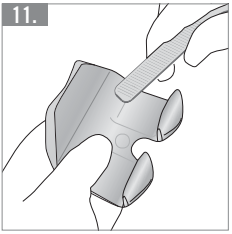
If necessary, remove any burrs or unevenness.



Take the spacer out of the remaining green mould half.

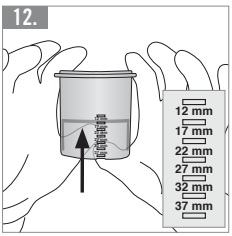


Break the application vent off the spacer.



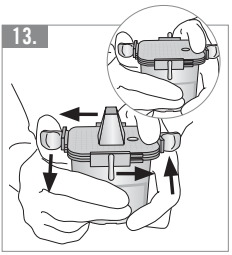
If necessary, remove any burrs or unevenness.

Tibia component

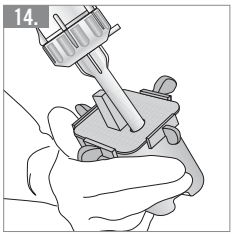


Adjust the distance for the height of the tibial spacer by pushing up the base plate according to the scale. Prepare the mixing system and the bone cement.

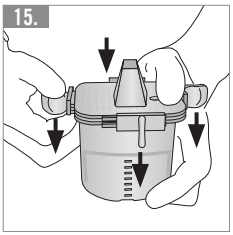
If necessary (base plate pushed up too far), correct the height: Push the base plate all the way up and remove it. Insert the base plate again, with the bearing surface facing upwards.



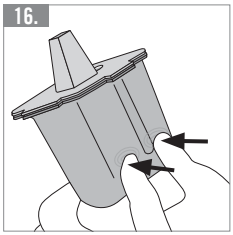
Attach a tibia cap (with or without a stem) and slide on all 4 corresponding clips to close the mould.



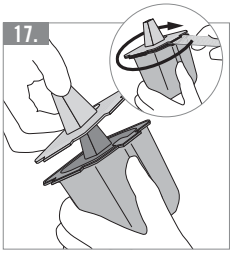
Mix the bone cement in the mixing system and attach the shortest possible application nozzle. As soon as the cement reaches the application phase*, slowly and evenly fill the mould. The nozzle must completely touch ground of the valve throughout the entire filling process.



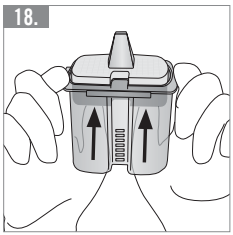
When the cement has completely cured*, remove or break off the sliding clips.



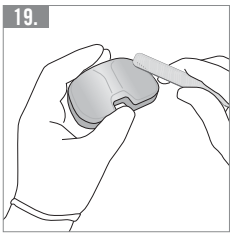
Compress the mould between your hands (at the bottom of the green part) to release the spacer from the surfaces. A cracking sound indicates that it has detached.



Loosen the tibia cap all around with the help of a flat instrument to remove it afterwards.



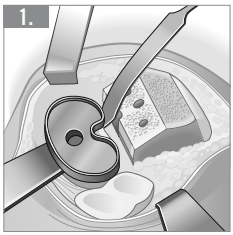
Mechanically release the cover plate and remove it. Press the spacer out from below. Be sure that your index finger dont block the spacer.



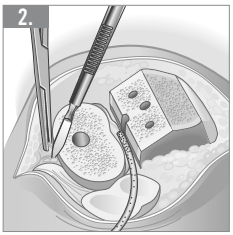
If necessary, remove any burrs or unevenness. After using **COPAL® knee moulds** the presence of all parts noted on the counting chart should be checked.

* For the exact processing times, refer to the instructions for use of the bone cement.

Use in patients
Implantation

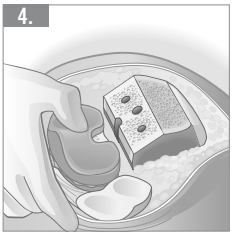


Completely remove the infected prosthesis and residual cement.

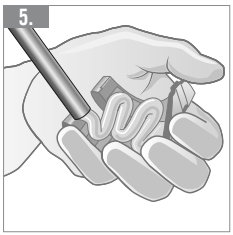


Thoroughly debride and irrigate the joint space to remove residual cement and tissue.

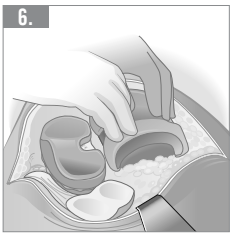
Apply doughy cement (end of application phase) onto the backside of the tibial spacer and the proximal cut surface of the tibia.



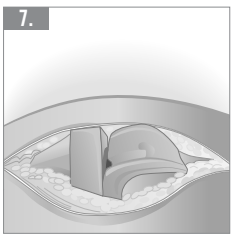
Position the tibial spacer onto the proximal tibia and carefully remove any excess cement along the edges.



Apply doughy cement (end of application phase) onto the backside of the femoral spacer and the distal cut surfaces of the femur.
Ensure that distal and anterior gaps are filled between spacer and femur cuts.



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 seated and interacting properly by taking the knee through multiple range of motion.

Fixation with 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 cured, the joint space must be cleaned of any bone cement particles. During the cleaning, the remaining spacers must not come into contact with aqueous solution nor should the pulse lavage touch the spacer to avoid premature dissolution of the antibiotics contained in the cement.

Explantation
The spacers prepared with **COPAL® knee moulds** may remain in the patient for a maximum of 180 days and must then be explanted. After the explantation, the knee joint must be provided with an appropriate knee joint prosthesis or another suitable treatment (e.g. arthrodesis of the knee joint) must be carried out.

Storage
COPAL® knee moulds must be stored unopened in a dry and clean location in the original packaging.

Shelf-life
The expiration date is shown on the outer blister.
COPAL® knee moulds must not be used after the expiry date.

Sterility
COPAL® knee moulds are sterile. Ethylene oxide gas is used for sterilization. They are intended for single use and must not be re-used or resterilized. The contents of an opened set or damaged packages must be disposed of.

Disposal
COPAL® knee moulds and the outer packaging can be disposed of in normal hospital waste. Please comply with local environmental legislation and waste disposal regulations.

MRI Safety Information
COPAL® knee moulds have not been evaluated for safety in the MR environment.
Regarding the safety of the spacer molded from **COPAL® knee moulds** in MR environment consult the Instruction for Use of the respective bone cement.

SYMBOLS

Manufacturer

Sterilized using ethylene oxide

Consult instructions for use

Keep dry

Do not re-use

Do not resterilize

Do not use if the product sterile barrier system or its packaging is compromised

Use by date

Batch code

Catalogue number

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

Heraeus

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