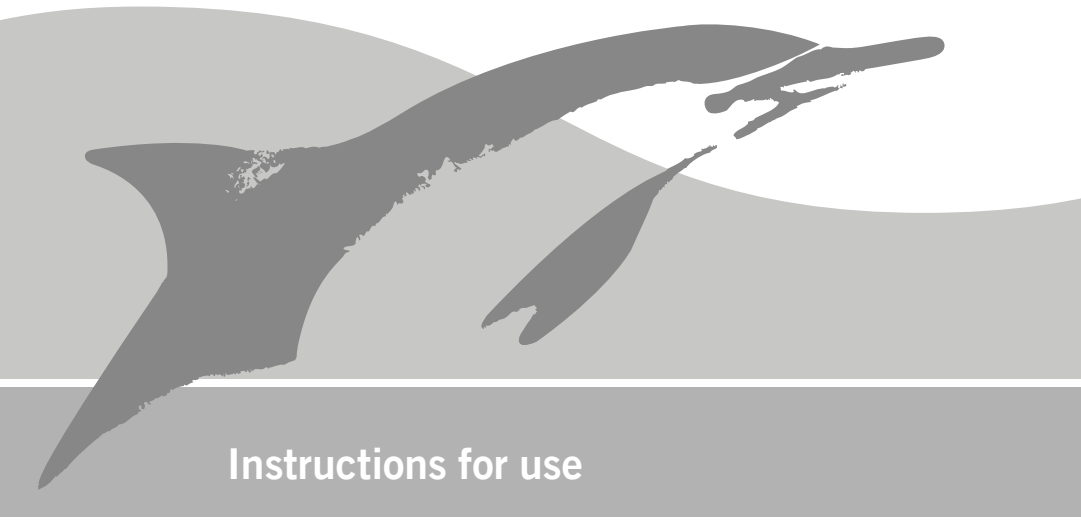
Heraeus

Medical

COPAL® knee mould Trials

Trials for knee spacer made from COPAL® knee moulds



Instructions for use

℞ Only

DESCRIPTION OF HANDLING STEPS STARTING ON PAGE 5

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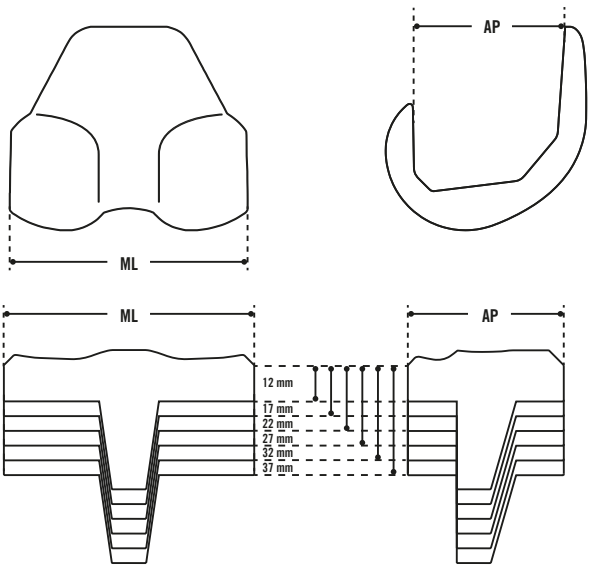
COPAL® knee mould Trials

1 General information

1.1 Device Description

COPAL® knee mould Trials are an accessory device for intra-operative determination of the correct size of spacer made from **COPAL® knee moulds** (Size S: 5159868, Size M: 5159869, Size L: 5159870). **COPAL® knee mould Trials** are used for a very short period of time (few minutes) during the first stage of a two-stage exchange revision procedure due to a septic process after thorough debridement and are intended for single use. **COPAL® knee mould Trials** resemble the spacer made from **COPAL® knee moulds** in size, shape, and geometry. **COPAL® knee mould Trials** are easily distinguishable from **COPAL® knee mould spacers** due to their prominent blue color and the stamping "Do not implant".

		Femur trial		Tibia trial	
Size	REF	Media Lateral (ML)	Anterior Posterior (AP)	Media Lateral (ML)	Anterior Posterior (AP)
S	5159874	60 mm	43 mm	65 mm	45 mm
M	5165923	70 mm	48 mm	75 mm	49 mm
L	5165924	80 mm	52 mm	85 mm	53 mm
Tibia heights					
12 mm					
17 mm					
22 mm					
27 mm					
32 mm					
37 mm					



1.2 Device sizes and packaging

Device sizes

COPAL® knee mould Trials consist of a tibia and femur trial and are available in three different sizes: S, M and L.
The tibia trial can be customized to 6 different heights.

Package content of one size

See pictogramm 1 on page 2:
- 1 set of product stickers for documentation (2)
- 1 instruction for use (2)

See pictogramm 2 on page 2:
- 1 Femur Trial (1)
- 1 Tibia front plate (2 c)
- 1 Tibia back plate with stem (2 b)
- 1 Tibia back plate without stem (2 a)

See pictogramm 3 on page 2:
- 5 middle plates

Packaging design

The **COPAL® knee mould Trials** of one size are double packaged: In the first inner pouch the femur trial and the tibia trials are located. In the second inner pouch, there are five middle plates.
The **COPAL® knee mould Trials** of one size are packed in two inner pouches and the protective outer pouch. The inner pouches are sterilized with ethylene oxide for usage in sterile area.
The protective outer pouch is non-sterile on the outside and sterile on the inside.

1.3 Composition

Composition
Polypropylene (United States Pharmacopeia USP class 6 conform): YUNGSOX-PP-5090T
Color: Pantone Blue 2935C Masterbatch: MEVOPURE-BLUE PP5M415780-ZN

1.4 Supporting equipment

The **COPAL® knee mould Trials** can be used with the following products from Heraeus Medical GmbH only:

COPAL® knee moulds

The instructions for use of the **COPAL® knee moulds** must be followed.

2 Directions for use

2.1 Intended use

COPAL® knee mould Trials are intended to be inserted into the patient's cavity of the femur and tibia during a two-stage exchange revision surgery to determine the correct size of spacers to be made from **COPAL® knee moulds**.
COPAL® knee mould Trials are inserted only for a very short period of time (few minutes) and no implantation is needed.
COPAL® knee mould Trials can be used in both, the right and the left knee joint.

2.2 Intended patient population

The intended patient population are skeletally mature patients.

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® knee mould Trials**. As the **COPAL® knee mould Trials** need to be assembled prior to use an assembling test should be performed to ensure the familiarity with it.

2.4 Indications

COPAL® knee mould Trials are indicated to determine the correct size of spacers to be made from **COPAL® knee moulds** during a two-stage revision surgery.

2.5 Contraindications

COPAL® knee mould Trials must not be used in the following cases:
- suspected or proven hypersensitivity to components of the trial material

2.6 Adverse events and residual risks

The assessment of adverse events is based on the following frequencies:

Frequent:	> 1: 1,000
Probable:	1: 10,000 to 1:1,000
Occasional:	1: 100,000 to 1:10,000
Remote:	1:1,000,000 to 1:100,000
Improbable:	< 1:1,000,000

Adverse events

There are no adverse events.

Residual risks

Residual risks listed below are procedure related risks which are beyond the control of the manufacturer.

Musculoskeletal System
Improbable damage to while insertion: – Tibia – Femur

Vascular System, Heart, Respiratory System, Blood and Lymphatic System, Nervous System
Improbable damage to while insertion: – surrounding tissue, blood vessels and nerves

Procedural Complications
– Fracture of the spacer – Dislocation of the spacer

2.7 Warnings

Regarding intended users

Avoid over pressuring of the trial inside the patients joint because it may damage bones, tendons, or surrounding tissue.

Regarding the intended patient population

There are no limitations for the patients due to the very short insertion time of **COPAL® knee mould Trials** during surgery.

2.8 Precautions

Regarding intended users

Do not use **COPAL® knee mould Trials** after the expiration date printed on the product label that is applied to the outer pouch. This device may not be safe or effective beyond its expiration date. This device is for single use and must not be re-used or resterilized. Follow the handlings instruction to avoid wrong assembling of the **COPAL® knee mould Trials**. Do not use this device if another spacer than the spacer made from **COPAL® knee mould Trials** is to be implanted during the interim period of a two-stage exchange surgery. Do not implant the **COPAL® knee mould Trials**.
COPAL® knee mould Trials must not be positioned by striking with a hammer or similar instruments. When using **COPAL® knee mould Trials**, the prepared bone should be carefully cleaned, aspirated, and dried just before the trial is placed.

Regarding the intended patient population

Do not use **COPAL® knee mould Trials** in patients with suspected or proven hypersensitivity and/or allergy to components of the trial material.

Pregnancy and lactation

There are no limitations for pregnant or lactating women.

3 Handling

A numbered visualization of the handling is depicted on the first page of these instructions for use. Use
COPAL® knee mould Trials under sterile conditions.
Prior to using **COPAL® knee mould Trials**, consult the instructions for use of the **COPAL® knee mould Trials**. Make sure that the handling steps of the **COPAL® knee moulds** are followed adequately (see 1.4 Supporting equipment).
COPAL® knee mould Trials contains the following non sterile/sterile packaging components:

Packaging component	Condition
Femur and tibia trial	
Small IFU bag (glued on outer pouch)	outside: non-sterile inside: non-sterile
Outer pouch (1)	outside: non-sterile inside: sterile
Inner pouch (3)	outside: sterile inside: sterile
Inner pouch (4)	outside: sterile inside: sterile

1	The outer pouch (1) is unsterile and contains two inner pouches which are sterile (3/4). A small IFU bag (2) is glued on the outside of the outer pouch.
2	The first inner pouch is mandatory and contains one femur trial (1) and a tibia trial (2) which consists of a back plate without stem (a), a back plate with stem (b) and a front plate (c).
3	The second inner pouch belongs to the tibia trial and contains 5 middle plates which can be used optional to customize the height of the tibia trial.

3.1 Non-sterile preparation steps

Non-sterile user

- Prepare the small IFU bag and outer pouch, the instructions for use and product stickers.
- Open the outer pouch.
- Present the sterile inner pouch to the sterile user for sterile removal.

3.2 Sterile preparation steps

Sterile user

- Lift out one of the inner pouches at the free part of the outer pouch under sterile conditions.
- Repeat the same with the second inner pouch.
- Open the first pouch and place the trial parts on a sterile, flat surface.
- Repeat the same with the second pouch.

3.3 Assembling

Sterile User: Pictograms 4–11
A numbered visualization of the handling is depicted on the first page of these instructions for use.

4	The femur trial is ready to be used.
5	The tibia trial is ready to be used with the smallest height of 12 mm and back plate with stem (c). **Note:** The height of 12 mm is only achieved when front (c) and back plate (with or without stem) are assembled.
6	To use it without a stem the tibia trial needs to be assembled before usage. The front plate (c) can be detached from back plate (b) so the front plate (c) and the back plate (a) can be clipped together to receive the smallest tibia height of 12 mm.
7	Tibia trial is completed only, when back plate (a or b) is mounted on front plate (c) and no gap is visible between the two plates.
8	Optionally, the height of the tibia can be adjusted using different amounts of middle plates in between the tibia back plate (a or b) and front plate (c).

9	Back plate (a or b) mounted with front plate (c) show the smallest height of 12 mm. Five more middle plates can be added which have 5 mm each: Plus 1 middle plate: 17 mm Plus 2 middle plates: 22 mm Plus 3 middle plates: 27 mm Plus 4 middle plates: 32 mm Plus 5 middle plates: 37 mm *Example: Front plate (7 mm) + 3 middle plates (3x5 mm) + back plate (5 mm) = 27 mm total height.*
10	A finished result of the tibia could be option 1 with a front plate (c) optionally selected middle plates and back plate with stem (b). Or as a second option with back plate without stem (a). Tibia trial is completed Only when back plate (a or b) is mounted and no gap is visible between the two plates.
11	During the use of the trials, the middle plates can always be remounted between a back plate (a or b) and front plate (c) to achieve the correct tibia height. The easiest way to do this is to open the middle plates sideways to remove middle plates. **Note:** After using **COPAL® knee mould Trials** the presence of all parts noted on the counting chart should be checked.

3.4 Surgical procedure

Sterile User: Pictograms 12–15
The surgical approach to the knee joint may be chosen in accordance with pre-existing approaches or the surgeon's personal preferences.
A numbered visualization of the handling is depicted on the first page of these instructions for use.

12/ 13	All infected prosthetic components and residual bone cement must be removed from the femur, tibia, and patella, as shown in Image 9 and 10.
14	Complete debridement of the bone bed and of necrotic tissue should also be performed prior to the insertion of **COPAL® knee mould Trials**.
15	**COPAL® knee mould Trials** shall be used to determine the suitable size of the PMMA knee Spacer intraoperatively made from **COPAL® knee moulds**. **COPAL® knee mould Trials** resemble the spacer in the same size, shape, and geometry. **COPAL® knee mould Trials** shall be positioned into the joint space. This procedure is repeated until the correct size is found. For assembling the tibia for different heights see chapter 3.4. **Note:** Tibia and Femur trial must be from one size. The height of the tibia can be changed by adding or removing middle plates of the same size. **Note:** The knee must not be too tight as it will tighten further upon cement fixation of the **COPAL® knee moulds** femoral component. Tightness may be relieved by downsizing and/or recontouring the femoral bone to achieve a satisfactory fit. **Note:** After the correct size is identified, **COPAL® knee mould Trials** must be removed from the knee. Implantation is prohibited.

4 Storage, transport, shelf life, sterilization

Storage
Storage between 4°C (39°F) and 25°C (77°F).
COPAL® knee mould Trials 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® knee mould Trials** to avoid any damage or alteration to the performance characteristics of the **COPAL® knee mould Trials** and their packaging as received. Do not remove **COPAL® knee mould Trials** from the sterile packaging until immediately before use. Do not use if packaging is damaged.

Shelf life
The shelf life of **COPAL® knee mould Trials** is printed on the product label that is applied to the outer pouch. Do not use **COPAL® knee mould Trials** if the date indicated has expired.

Sterilization
COPAL® knee mould Trials have been sterilized using ethylene oxide. The product must not be re-sterilized. Non-sterility may cause an infection in the patient.

5 Disposal

Single components of **COPAL® knee mould Trials**, set solid material as well as packaging material must be disposed of as clinical waste in compliance with local 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.

Symbols


Manufacturer


Date of manufacture


Use by date

Batch code

Catalogue number

Sterilized using ethylene oxide


Single sterile barrier system with protective packaging inside

Do not resterilize


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


Keep away from sunlight


Keep dry

Temperature limit between 4°C (39°F) and 25°C (77°F)


Do not re-use


Consult instructions for use

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

Heraeus

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