



PRIMARY

DIFFERENT NEEDS... YOUR GLOBAL SOLUTION



Bone Referencing
Surgical Technique

Hip

Knee

Spine

Navigation

INTRODUCTION

This brochure describes the surgical technique related to the GMK Primary System.

The technique focuses on knee alignment and in setting tibial and femoral resections based on bony references. Soft tissues are then managed "around" the resections. The technique can be performed in both tibia first and femur first approaches.

The distal femoral resection is referred to the intramedullary canal, while the positioning of the A/P 4in1 speed blocks is based on different anatomic references (posterior condyles, epicondyles or Whiteside line).

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CAUTION

- Federal law (USA) restricts this device to sale by or on the order of physician.
- In the USA for cemented use only.
- Some specific instruments are fixed to the bone by means of dedicated pins. Before using the pins, ensure that they are intact and fully functional. BENT OR DEFECTIVE PINS CAN NOT BE USED AND MUST BE REPLACED BY NEW ONES. Pins extraction must be performed avoiding any bending. This results in axial alignment between the pin and the dedicated extractor.
- It is strongly recommended not to impact or hammer on any instruments unless otherwise specified in the surgical technique.

For detailed instructions contact your local Medacta sales representative.
Please, consider the package inserts for complete product information.

SYMBOLS

Throughout the surgical technique you will find the following symbols:



OPTION

The descriptions in the "Option" boxes are referred alternative way to perform the same procedure.



The descriptions in the "MSS" boxes are referred to instruments purposely designed for Muscle Sparing approaches.



The descriptions in the "PS" boxes are referred to procedures related to the PS version of the GMK Primary Implant.

PLEASE NOTE

In the surgical technique here after described, the resections are performed in the following order:

- Distal femoral resection
- Tibial resection
- A/P femoral resections and chamfers

Nonetheless, the surgeon can change the resections' order, choosing between the following sequences:

- Distal femoral resection
- A/P femoral resections and chamfers
- Tibial resection

or

- Tibial resection
- Distal femoral resection
- A/P femoral resections and chamfers

It is compulsory to perform the distal femoral resection before the A/P resection and chamfers.

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1 INDICATIONS

The GMK - Total Knee System is designed for cemented use in total knee arthroplasty, if there is evidence of sufficient sound bone to seat and support the components.

This knee replacement system is indicated in the following cases:

- Severely painful and/or disabled joint as a result of arthritis, traumatic arthritis, rheumatoid arthritis or polyarthritis.
- Avascular necrosis of femoral condyle.
- Post traumatic loss of joint configuration.
- Primary implantation failure.

Tibial augments are to be attached to the tibial baseplate with both the fixing cylinders and bone cement. If a semi-constrained insert is used, it is mandatory to implant an extension stem both on the tibial and the femoral components.

2 CONTRAINDICATIONS

Total knee replacement is contraindicated in the following cases:

- Progressive local or systemic infection.
- Muscular loss, neuromuscular disease or vascular deficiency of the affected limb, making the operation unjustifiable.
- Severe instability secondary to advanced destruction of condralar structures or loss of integrity of the medial or lateral ligament.

Mental or neuromuscular disorders may create an unacceptable risk to the patient and can be a source of postoperative complications. It is the surgeon's responsibility to ensure that the patient has no known allergy to the materials used.

3 PREOPERATIVE PLANNING

3.1 Radiological planning

This is performed from the scanogram, anterior-posterior, lateral and sunrise knee radiographs.

The goal is to determine the angle formed by the anatomical axis and the mechanical axis of the femur to be treated, to determine the tibial slope, to trace and measure bone resections, to establish the intramedullary guide introduction points, to assess the sizes of the femoral and tibial components, the height of the tibial insert, the thickness of patella to be resected, to study the topography of the operative site (localization of osteophytes and mainly posterior osteophytes).

3.2 Clinical planning

The goal is to assess the range of motion of the joint and patellar centering and to assess whether deformities and ligamentous instability exist or not.

4 SURGICAL APPROACH

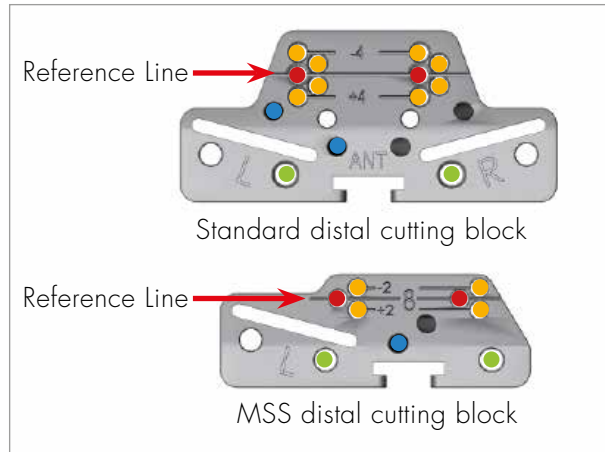
The most commonly used surgical approach is the **medial parapatellar** approach. Other approaches may be used depending on the surgeon's preference. For example, a lateral parapatellar approach is sometimes used in patients with severe valgus deformities.

Other approaches described include the subvastus and midvastus approaches.

Once the arthrotomy has been achieved, it is advisable at this stage to resect any accessible osteophytes, such that they do not interfere with the choice of implant size or with the assessment of joint stability.

5 DISTAL FEMORAL RESECTION

Open the intramedullary canal by means of the 9 mm drill. It is recommended to toggle the drill tip to allow venting of the intramedullary canal. Finally, insert the IM rod.



Distal cutting block holes (left knee)

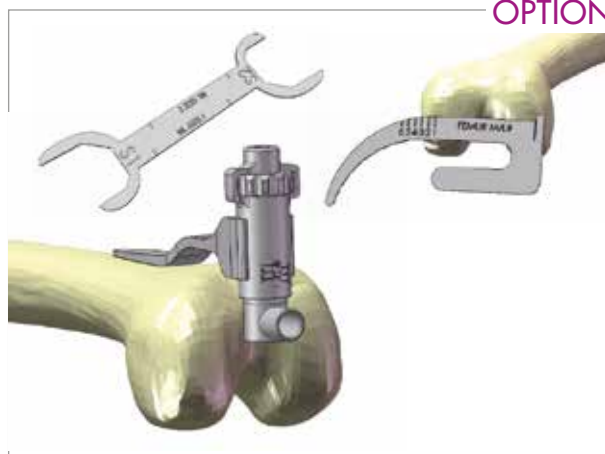
- Parallel positioning holes
- Oblique fixation holes
- Sawblade guide
- Parallel repositioning holes



OPTION

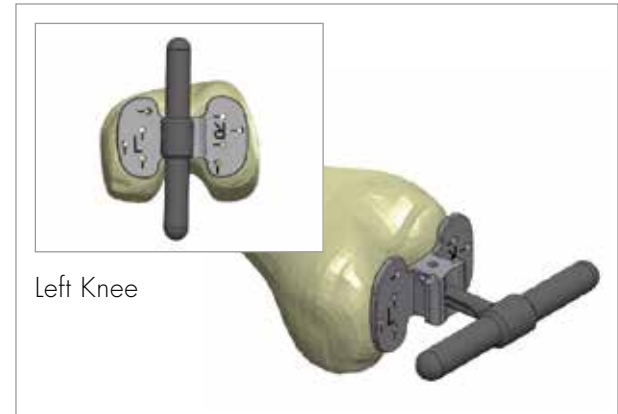
The intramedullary drill bit can be driven by the IM hole gauger.

Assess the femoral size through the dedicated set of femoral template. The medio-lateral width of the femur can be double-checked by means of the sickle finger. Select the femoral size on the femoral intramedullary hole gauger and position this in the middle of the trochlea while in contact with the anterior cortex. This will identify the intramedullary canal accordingly to the femoral size.



OPTION

Assemble the distal cut positioner on the intramedullary guide rod and replace the rod into the canal. The distal cut positioner has 6° correction from the anatomical axis and therefore it must be rotated until the correct operative side can be identified on the block by "R" or "L". Once the 6° distal cut positioner is in place, held by the IM rod, it may be in contact with only one of the distal condyles.

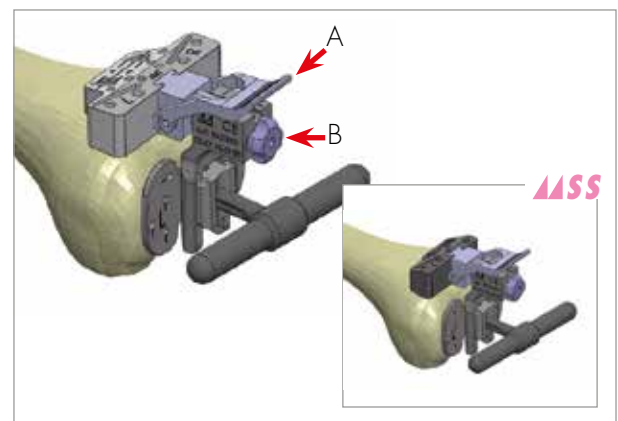


Assemble the distal cut positioner curved rod around the 6° distal cut positioner. Also attach the the distal cutting block. Pulling down the lever (A) firmly attaches the cutting block to the positioner.

SS

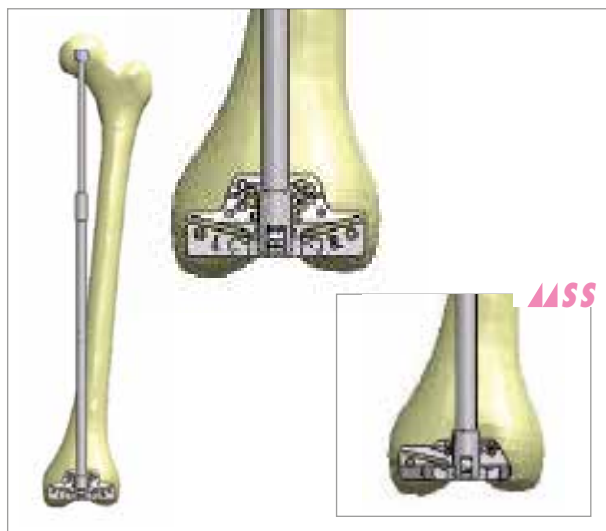
The cutting block is intended for both left and right knees. Be sure to check that the correct side, corresponding to the knee to be operated on, can be read on the anterior face.

The femoral distal resection, routinely planned at 8mm (corresponding to the thickness of the distal and posterior condyles of the femoral component), can be micrometrically adjusted turning the screw (B) in the range from 4mm to 12mm. Fix the block by introducing 2 pins in the holes corresponding to the reference line. If needed the cutting block can be moved distally or proximally in 2mm increments using the repositioning holes.



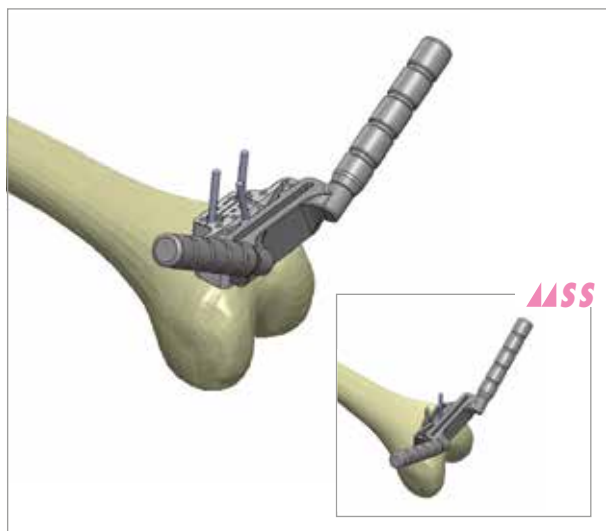
Before performing the resection, check the cutting block position with the sickle finger.

In order to check the correct alignment of the distal cutting block, insert the telescopic alignment rod into the dedicated holes of the cutting block and verify that the rod points in the direction of the center femoral head.



Once the distal cutting block position has been deemed satisfactory, it is recommended to add an additional oblique pin. Disassemble the distal cut positioner by releasing the lever (A). Remove the IM rod assembly to prepare for the distal femoral resection.

Place the saw blade guide and perform the distal resection.

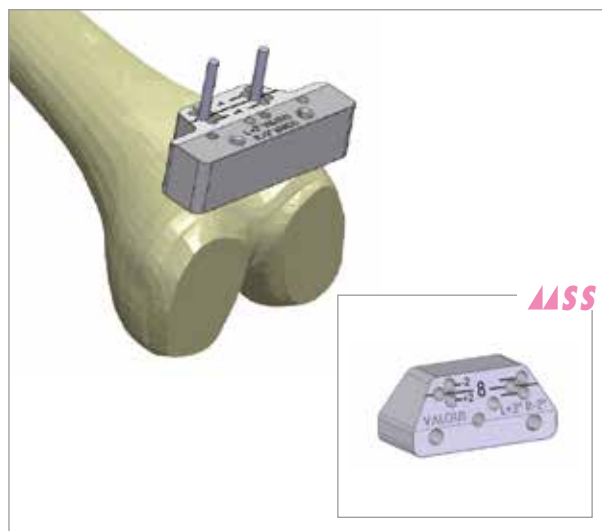


Once the resection is performed, remove the pins and distal cutting block. Should a recut be necessary the pin holes can be located again.



OPTION

An additional cutting block allows the correction of the valgus of the distal resection ($\pm 2^\circ$ valgus). Ensure that the correction cutting blocks are positioned on the same holes row used to perform the distal cut.



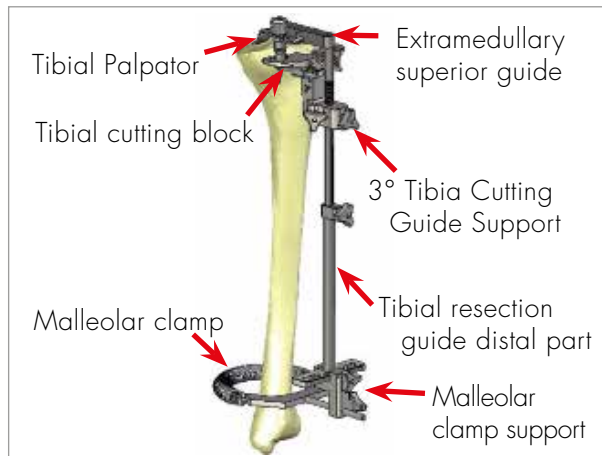
6 TIBIAL RESECTION

The tibial resection can be performed using either extramedullary or intramedullary alignment guides. In case of minimally invasive approach the most suitable guide is the extramedullary one.

6.1 Assembling the tibial guide

Assembling the extramedullary tibial guide

The extramedullary guide consists of:

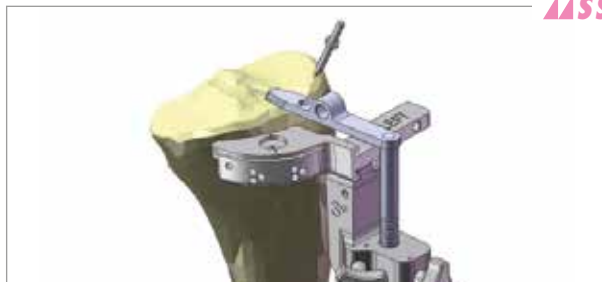


Fix the 3° tibia cutting guide support to the extramedullary superior guide. This support provides 3° posterior slope on the tibial cutting plane, when the stem of the guide is parallel to the tibial crest.

Join the distal stem of the guide to the proximal one, without locking it. Position the malleolar clamp, assembled to its support, at the distal extremity. Slide the tibia cutting guide of the suitable side (left or right) in the 3° support and fix the system by turning the lateral screw of the support. After the resection of ACL (standard PE insert), or of both cruciate ligaments (posterior-stabilized and ultra-congruent inserts), position the assembled guide on the tibia, introducing the longest spike of the extramedullary superior guide in the centre of the tibial intercondylar eminence and fixing the malleolary clamp, taking care that its rotation exactly facing the center of the ankle joint.

MSS

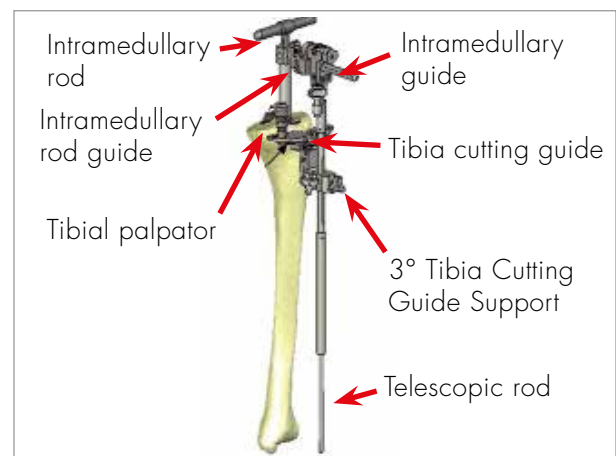
In the case of MSS approach, the superior guide has one stabilization spike and a provisional pin to fix it after all adjustments.



MSS

Assembling the intramedullary tibial guide

The intramedullary guide consists of:



After the resection of ACL (standard PE insert), or of both cruciate ligaments (postero-stabilized and ultra-congruent inserts), open the intramedullary canal with the aid of the 9 mm drill.

CAUTION

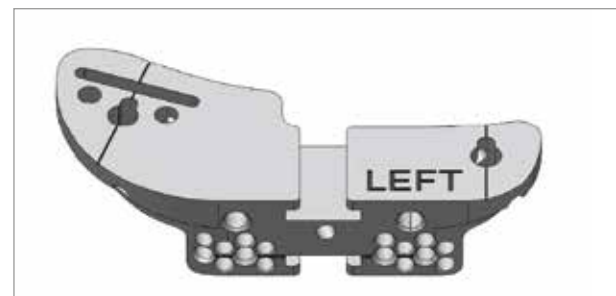
The hole must be drilled anteriorly to the tibial spine to help the alignment with the tibial diaphysis.

Slide the tibia cutting block (standard only) into the 3° tibia cutting guide support and lock the construct by turning the lateral screw.

Insert the intramedullary guide in the 3° support and the telescopic rod in the distal extremity of the intramedullary guide.

Introduce the intramedullary rod equipped with its support as deep as possible in the tibial intramedullary canal.

Build up the intramedullary guide onto the intramedullary rod support in order to position the whole system on the tibia.



6.2 Setting the tibial varus/valgus

To ensure neutral tibial rotation, the centre of the tibial cutting block must be exactly opposite the medial third of the tibial tubercle. The flat anterior border of the cutting block should be parallel to the transverse mediolateral plane of the tibia.



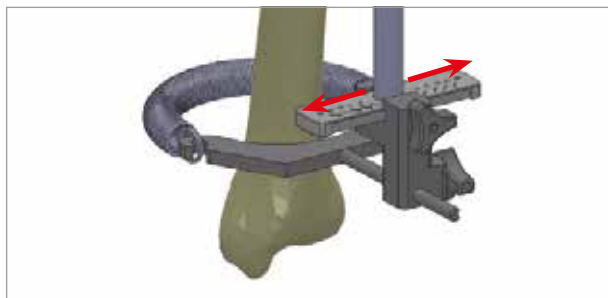
CAUTION

It is important that the cutting guide is carefully centered to prevent any varus or valgus deviation when making the resection.

Setting the tibial varus/valgus - Extramedullary guide

In order to make the tibia cut perpendicular to the mechanical axis, make sure that the malleolar clamp support is on the center of the ankle.

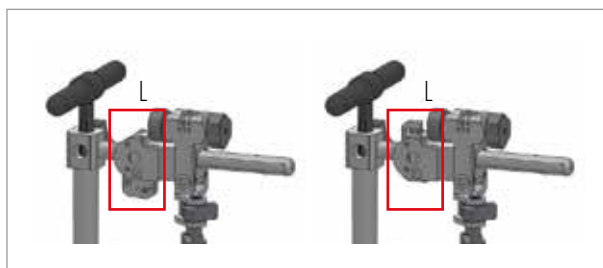
By translating the distal stem on the malleolar clamp support, it is possible to adjust the varus of the tibial resection in the frontal plane (varus or valgus).



Setting the tibial varus/valgus - Intramedullary guide

Adjust the frontal alignment, ensuring that the tip of the telescopic rod is opposite the second metatarsal bone.

With the lever (L) positioned at 90° the tibia cut will be performed perpendicular to the intramedullary reference; if any varus/valgus correction is required, after having unlocked the screw behind the lever, switch the lever in the V/V position and adjust the varus/valgus. Finally, lock the screw behind the lever.

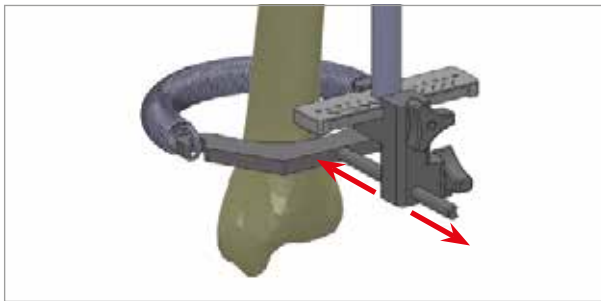


6.3 Setting the tibial slope

It is always recommended to give a posterior slope ranging from 0° to 3°.

Setting the tibial slope - Extramedullary guide

The 3° tibia cutting guide support gives 3° posterior slope, if the extramedullary guide is parallel to the tibial crest. Any further adjustment of the posterior slope can be performed sliding the distal part of the malleolar clamp support along the malleolar clamp rod.



Once the tibial cutting guide rotation, frontal alignment and posterior slope are deemed satisfactory, completely insert in the intercondylar eminence the two spikes of the extramedullary superior guide.

▲▲SS

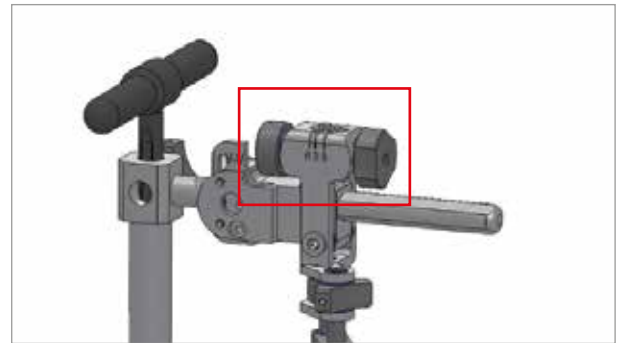
In case of MSS approach, fix the guide, inserting a 2.2mm sword pin in the proximal hole of the superior guide.



▲▲SS

Setting the tibial slope - Intramedullary guide

Adjust the slope of the tibial resection by turning the micrometric screw on the top of the intramedullary guide (possible adjustments from 0° to 8° of posterior slope).



CAUTION

Refer to the slope values marked on the top of the intramedullary guide only. Disregard the 3° marking engraved on the tibial cutting guide support.

6.4 Setting the tibial resection level

Unlock the lateral screw of the 3° support, position the cutting guide few millimetres from the proximal tibia and fix the tibial palpator into the dedicated hole on the cutting guide. Two styli are available, one to make a standard cut, 8 mm from the less worn tibia plateau, and one to make a conservative cut, 2 mm under the most worn plateau.

Setting the tibial resection level - Extramedullary guide

Adjust the cut height using the chosen reference stylus by sliding the 3° support vertically along the extramedullary superior guide (graduation in 2mm increments).

Verify the level of the cut with the help of the sickle finger.



When the adjustment is deemed satisfactory, lock the frontal screw of the 3° support.

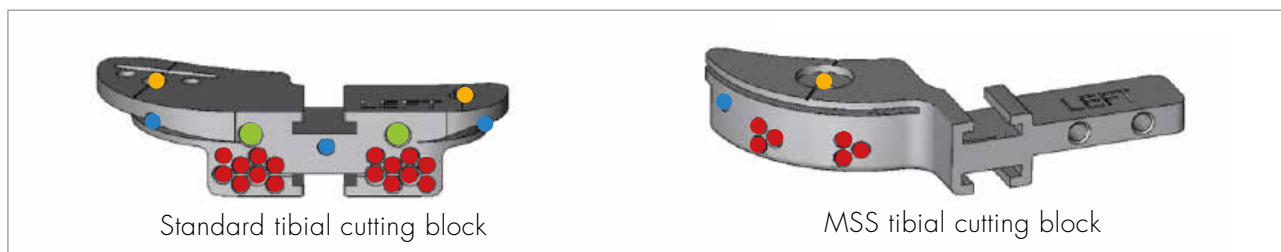
Setting the tibial resection level - Intramedullary guide

Fine-tune the cut height using the chosen reference stylus and adjusting the height screw.



6.5 Fixation of the tibial cutting block

Before fixing the tibial cutting block, it is recommended to check the cut height and the posterior slope with the help of the sickle finger.



Tibial cutting block holes (left knee)

- Parallel positioning holes
- Oblique fixation holes
- Sawblade guide holes
- Palpator holes

After pre-drilling, place two parallel pins in the row of holes marked with a line. This will facilitate additional cut height adjustment should it be necessary.

6.6 Removing the tibial cutting guide

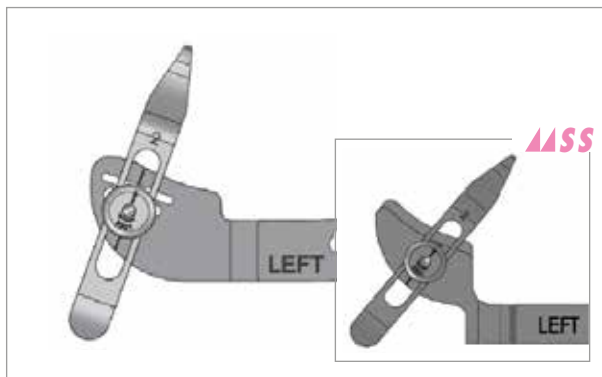
Removing the extramedullary tibial cutting guide

Remove the tibial palpator and unlock the frontal screw of the 3° support guide.
Loosen the extramedullary guide and withdraw the proximal extramedullary rod from the distal stem attached to the malleolar clamp.

Removing the intramedullary tibial cutting guide

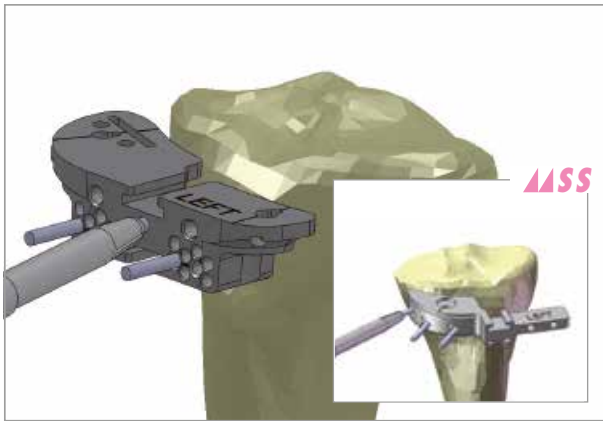
Remove the tibial palpator and the intramedullary guide from the tibial cutting guide. After that, withdraw the intramedullary rod together with its support.

To easily remove the tibial palpator from the tibial cutting block, align the arrow on the palpator to the line marked on the cutting block, as shown in the pictures on the left.
In order to check the frontal alignment of the cutting block, it is possible to assemble to the standard cutting block the telescopic alignment rod and verify if it points to the second metatarsal bone (picture on the right).



6.7 Tibial resection

Bring the tibial cutting guide into contact with the tibia by sliding it along the pins. If needed, in order to increase the stability, a third oblique pin can be introduced through the central hole of the standard tibial cutting block or through the medial hole of the MSS cutting block.



Perform the resection utilizing the sawblade guide (if the standard cutting block is used).



CAUTION

If a standard insert will be used, one or two pins may be fixed in front of the tibial insertion of PCL, in order to protect it during the resection.



CAUTION

As the tibial resection is sloped, ensure rotation and varus/valgus of the tibial cutting guide has not changed during disassembly of the guides before performing the resection.

After having removed the oblique pin and, in case of standard block, the saw blade guide, slide the tibial cutting block over its two parallel pins, which should remain in position in case of any need of tibial recut.



OPTION

If necessary, two additional cutting blocks are available, in order to correct the alignment ($+2^\circ$ varus/valgus) and the posterior slope ($+/- 2^\circ$) of the performed tibial resection. Ensure that the correction cutting blocks are positioned on the same row of holes used to perform the initial tibial resection.

OPTION



In order to protect the tibia after its resection, different cover plates are available, accordingly to the tibial size (1/2, 3/4 and 5/6). The tibial sizing is performed by superimposing the trial tibial baseplates to the resected part of the tibial plateau or directly to the tibia. If needed, a set of tibial templates is available.



CAUTION

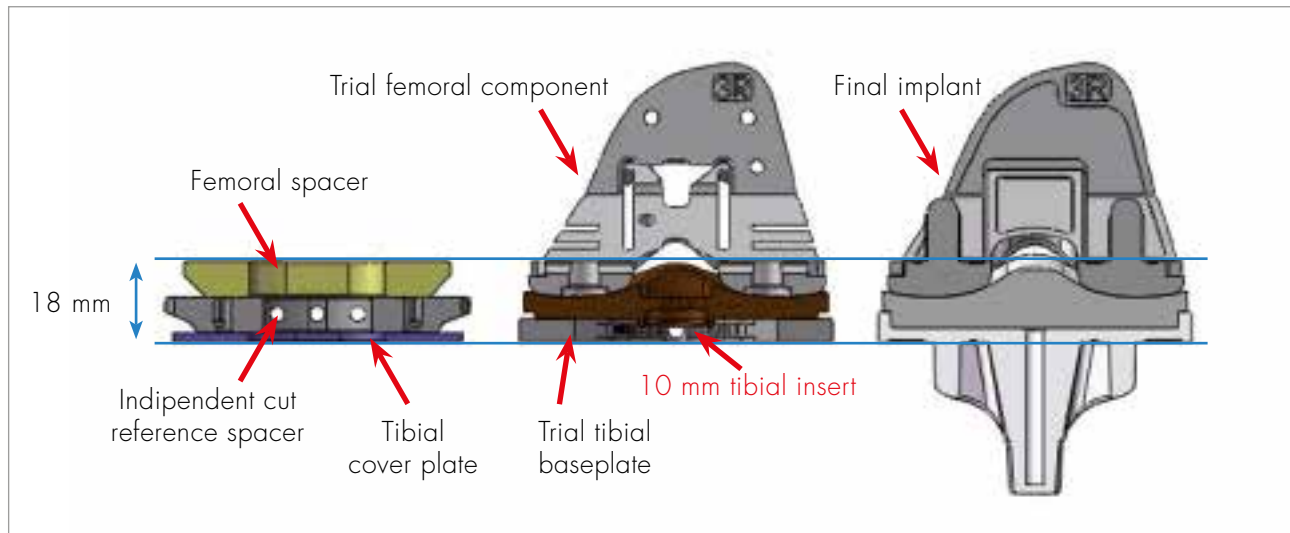
The undersurface of the cover plate is endowed with three cutting spikes. Handle with care.



Full PE

The full PE tibial baseplate is symmetric, use the dedicate set of tibial template to assess the tibial size.

7 EXTENSION GAP CONTROL



In order to check the performed tibial and distal femoral cuts, the independent cut reference spacer assembled with the dedicated femoral spacers will be used.

The femoral spacer simulates the thickness of the femoral component and is available in 2 different widths, suitable for sizes 1-3 and 4-6. Therefore, the thickness of independent cut reference spacer, assembled with the femoral spacer and leaning on the tibial cover plate, corresponds the total prosthesis thickness given by the tibial baseplate, the thinner PE insert and the femoral component.

With the knee in extension, introduce in the joint the independent cut reference spacer endowed with the femoral spacer and assembled with the baseplate handle.

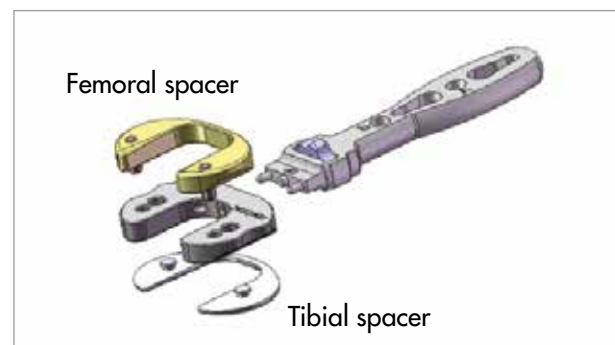
! CAUTION

The femoral spacer has to be fixed to the reference spacer on the side with the "FEMORAL" marking.

In case of laxity, the thickness of the reference spacer can be increased by adding a tibial spacer. Tibial spacers are available in different thicknesses simulating the different tibial inserts (12, 14, 17 and 20 mm).

! CAUTION

The tibial spacers have to be fixed to the reference spacer on the side with the "TIBIAL" marking.



OPTION

If the tibial cover plate are not used, the 10 mm blue tibial spacer must always be added on the tibial side of the reference spacer, in order to simulate the minimum tibial thickness.

In case of laxity, the blue tibial spacers have to be added on the tibial side of the reference spacer, simulating the thicknesses of the different PE inlays (12, 14, 17 and 20 mm).

In contrary, if it is impossible to introduce the reference spacer into the joint, the tibial resection can be changed by re-positioning the tibial cutting block on the two pins left in place. An additional 2mm or 4mm of bone may be resected. If, despite of a posterior release, tests indicate incomplete extension, this would raise the indication for a further 2mm distal femoral cut. In this case, re-position the distal cutting block on the two pins left in place through the holes rows which allow 2mm recuts.

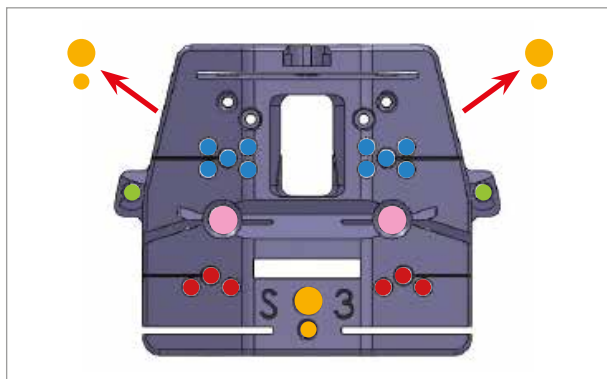
8 ANTERIOR CUT, POSTERIOR CUT AND CHAMFERS

Through the 4 in 1 femoral cutting block the femoral anterior, posterior, and chamfer resections can be performed.



CAUTION

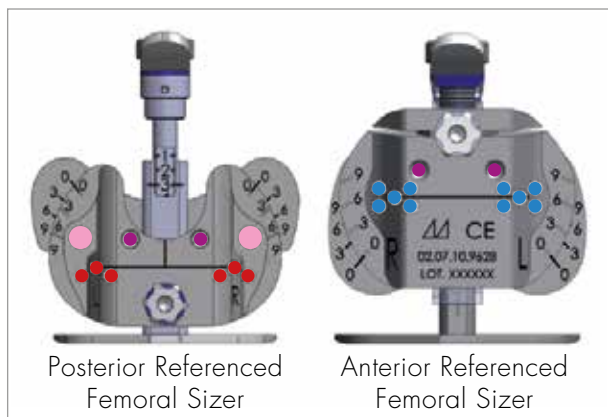
All femoral resections have to be performed by means of a 13mm wide and up to 1.27mm thick sawblade.



4 in 1 cutting block holes

- Parallel positioning holes (Posterior Referencing)
- Parallel positioning holes (Anterior Referencing)
- Oblique fixation holes
- Handle holes
- Cancellous bone screws holes

To position the 4 in 1 cutting block, two different femoral sizers are available:



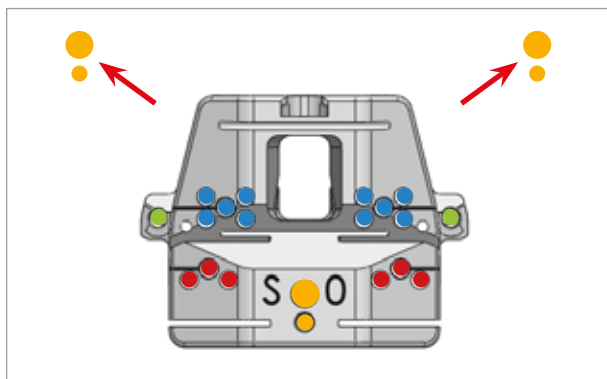
Femoral sizer holes

- Parallel positioning holes (Posterior Referencing)
- Parallel positioning holes (Anterior Referencing)
- 4 in 1 pegs drilling holes
- Epicondylar axis reference holes



CAUTION

For femoral size 0 there is a dedicated 4 in 1 femoral cutting block.

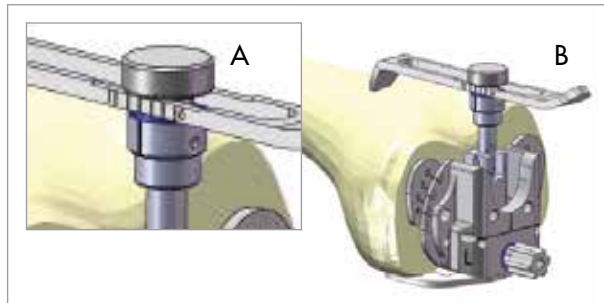


4 in 1 cutting block holes (size 0)

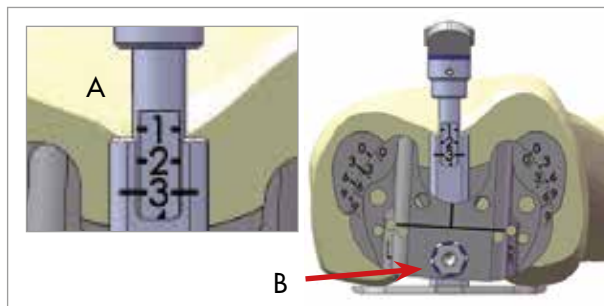
- Parallel positioning holes (Posterior Referencing)
- Parallel positioning holes (Anterior Referencing)
- Oblique fixation holes
- Handle holes

Posterior referencing: femoral sizing and external rotation adjustment

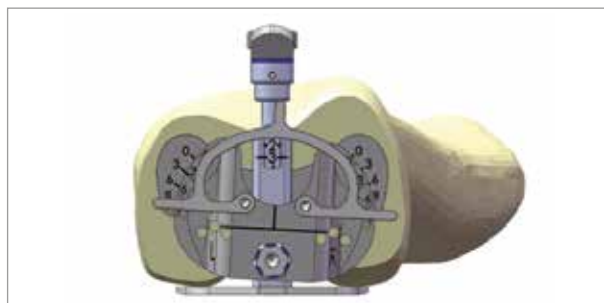
The posterior referencing femoral sizer must be positioned in contact with the distal cut surface, with both the posterior condyles well applied on its base. Refine the positioning of the sizer, by selecting the size of the femur on the anterior palpator (A). Close the sizer till the anterior palpator touches the anterior cortex (B).



The size of the femur can be read on the femoral sizer (A). Set the external rotation (0° , 3° , 6° or 9°) turning the central part of the sizer accordingly to the side to be operated on and lock the system by tightening the central screw of the femoral sizer (B).

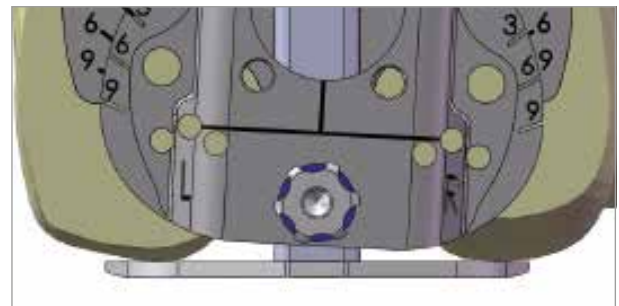


The external rotation can also be checked considering the alignment to the epicondylar axis, using the epicondylar axis reference.

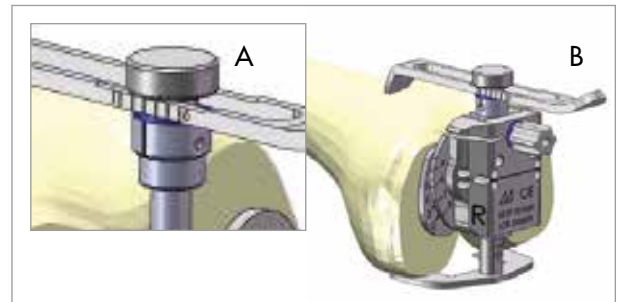


Anterior referencing: femoral sizing and external rotation adjustment

The anterior referencing femoral sizer must be positioned in contact with the distal cut surface. The size of the femur can be read on the femoral sizer.

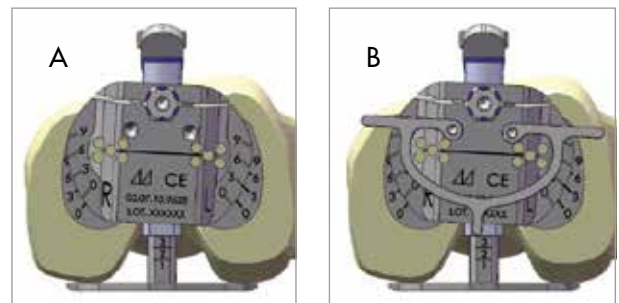


Refine the positioning of the sizer, by selecting the size of the femur on the anterior palpator (A). Place the anterior palpator in contact with the anterior cortex. Close the sizer until its' base touches the posterior condyles (B).



Set the external rotation (0° , 3° , 6° or 9°) turning the central part of the sizer according to the side to be operated on and lock the system tightening the central screw of the femoral sizer (A).

The external rotation can also be checked considering the alignment to the epicondylar axis, using the epicondylar axis reference (B).



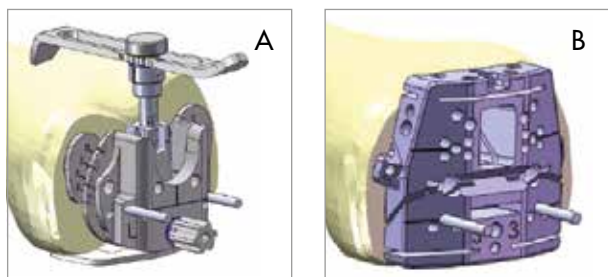
Posterior referencing: 4 in 1 cutting block positioning

Option 1: central pins - Once the position of the sizer is deemed satisfactory, pre-drill and insert 2 pins in the holes identified by a line (A).

CAUTION

While inserting the pins, ensure a continuous contact between the femoral sizer and the distal resection.

Remove the femoral sizer sliding it along the two pins. Select the 4 in 1 cutting block of the selected size and apply it on the distal resection choosing the holes row belonging to the posterior group and marked by a line (B).



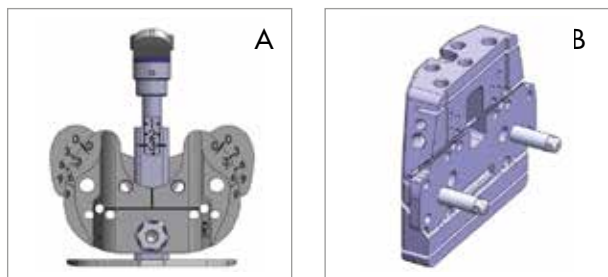
If necessary, the cutting block can be moved 2 mm up, using the holes just below the reference line. Finally, fix the 4 in 1 cutting block using two headed pins inserted in the two lateral oblique fixation holes. Remove the central positioning pins.

Option 2: pegs - Alternatively to the positioning through the central pins, the 4 in 1 cutting block can be positioned through two pegs. Once the adjustment of the femoral sizer is satisfactory, drill the pegs holes through the dedicated holes of the femoral sizer (A).

CAUTION

While drilling, ensure a continuous contact between the femoral sizer and the distal resection.

Finally, remove the femoral sizer, assemble the pegs on the 4 in 1 cutting block of the chosen size and apply it on the distal resection (B).



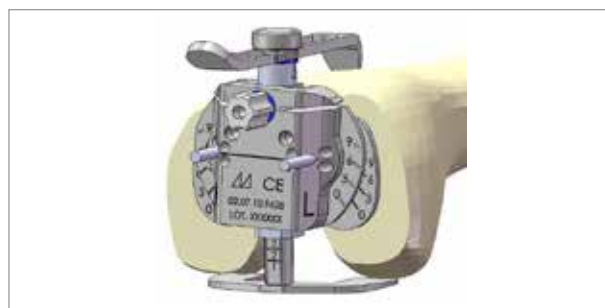
Ensure the complete contact between the 4 in 1 cutting block and the distal resection, using the femoral impactor.

CAUTION

Do not hammer the 4 in 1 cutting block directly, use the femoral impactor. The position of the 4 in 1 pegs DOES NOT CORRESPOND to the position of the pegs of the femoral component. The holes for the final femoral component are performed through the trial femoral component.

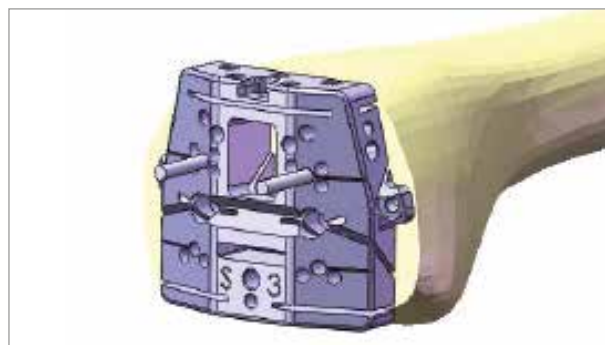
Anterior referencing: 4 in 1 cutting block positioning

Once the position of the sizer is deemed satisfactory, pre-drill and insert 2 pins in the holes identified by a line.

**CAUTION**

While inserting the pins, ensure a continuous contact between the femoral sizer and the distal resection.

Remove the femoral sizer sliding it along the two pins. Select the 4 in 1 cutting block of the selected size and apply it on the distal resection choosing the holes row belonging to the anterior group and marked by a line.



If necessary, the cutting block can be moved 2 mm up or down, using the holes just below or above the reference line.

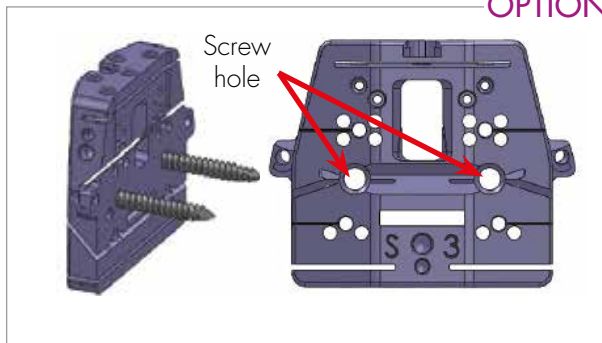
Finally, fix the 4 in 1 cutting block using two headed pins inserted in the two lateral oblique fixation holes. Remove the central positioning pins.



OPTION

Alternatively or together with the fixation by means of the lateral pins, the 4 in 1 cutting block may be fixed to the bone using two cancellous bone screws inserted through the dedicated holes by means of the dedicated screwdriver. This option is not available for femoral size 0.

OPTION



When the 4 in 1 cutting block has been stabilized, perform the femoral resections by means of a 13mm sawblade:

- Anterior femoral resection
- Posterior femoral resection
- Posterior chamfer
- Anterior chamfer



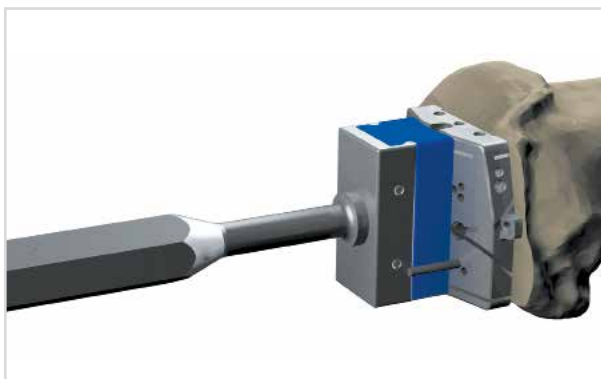
CAUTION

All femoral resections have to be performed by means of a 13mm wide and up to 1.27mm thick sawblade.



CAUTION

It is strongly recommended not to impact or hammer on the 4in1 guide. If the surgeon consider it required, do not impact directly on the guide but rather use the femoral impactor as described in the picture below.

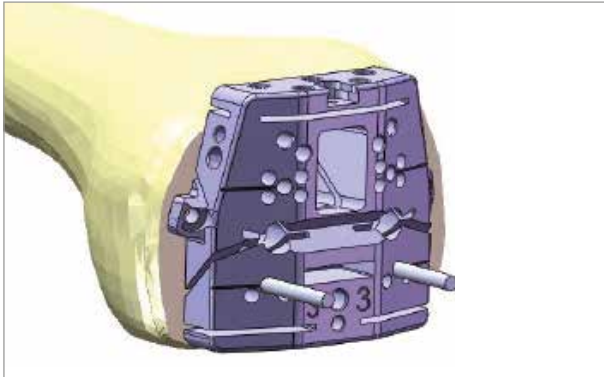


8.1 Femoral upsizing/downsizing

The difference between two successive femoral sizes is 4 mm in both anterior-posterior and mediolateral planes.

Posterior referencing: upsizing/downsizing

Option 1: central pins - If the 4 in 1 cutting block was positioned by means of the the central parallel pins, replace it with the cutting guide of more suitable size using the same row of holes.



CAUTION

In case of downsizing, the anterior resection level is moving 4 mm posteriorly. Make sure that there is no anterior notching and, if necessary, move the guide on the lower pin holes.

Option 2: pegs - If the 4 in 1 cutting block was positioned by means of the pegs, replace it with the cutting guide of the more suitable size using the same pegs' holes.



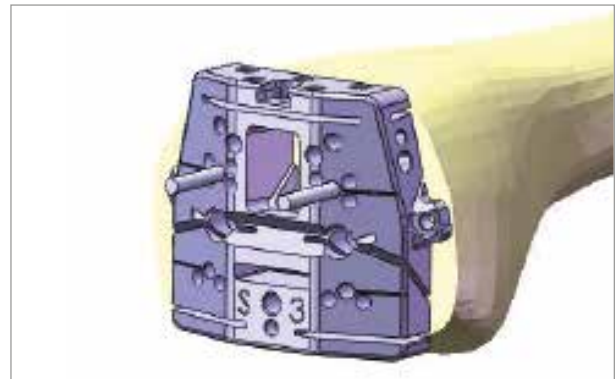
CAUTION

In case of downsizing, the anterior resection level is moving 4 mm posteriorly. Make sure that there is no anterior notching.

If it is necessary to move up the guide, position two central pins on the holes' row marked with a line, remove the cutting block sliding it along the pins, withdraw the two pegs and reposition the pin holes just below the reference line.

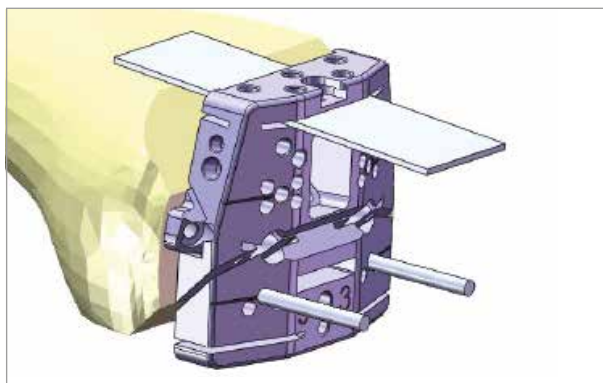
Anterior referencing: upsizing/downsizing

Replace the 4 in 1 cutting block with that of more suitable size using the same row of holes. In case of downsizing, the posterior resection level is moving 4 mm anteriorly. If necessary, the guide can be moved on to the other rows of holes (2 mm modifications).

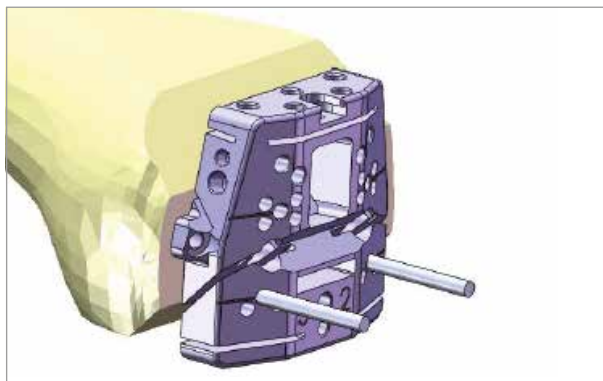


*Posterior referencing:
downsizing after the femoral resections*

If it is necessary to downsize the femoral component after having performed the femoral resections, insert a saw blade in the slot of the anterior resection, apply the 4 in 1 cutting block on the distal cut, ensure that the saw blade is perfectly in contact with the anterior resected surface, and insert two pins in the row of holes belonging to the posterior holes group and marked with a line.



Replace the cutting guide by that of the inferior size. Fix the cutting block following the procedure described in par. 8 (Posterior referencing: 4 in 1 cutting block positioning). Perform the femoral resections.

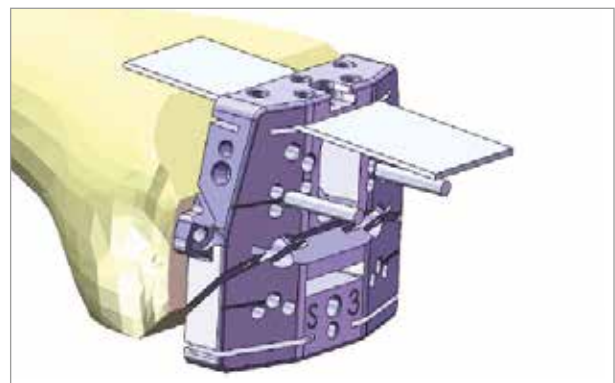


CAUTION

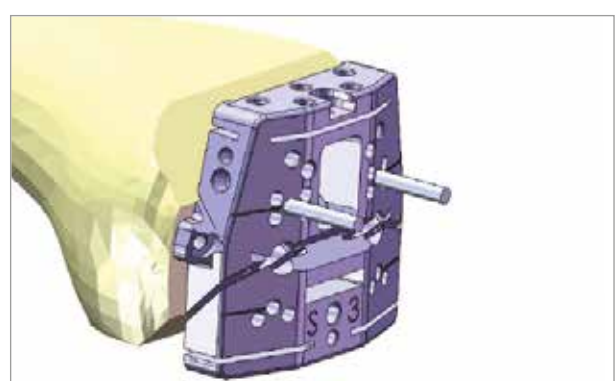
The anterior resection level is moving 4 mm posteriorly. Make sure that there is no anterior notching.

*Anterior referencing:
downsizing after the femoral resections*

If it is necessary to downsize the femoral component after having performed the femoral resections, insert a saw blade into the slot of the anterior resection, apply the 4 in 1 cutting block on the distal cut, ensuring that the saw blade is perfectly in contact with the anterior resected surface, and insert two pins in the row of holes belonging to the anterior holes group and marked with a line.



Replace the cutting guide by that of the inferior size. Fix the cutting block following the procedure described in the page 18 (Anterior referencing: 4 in 1 cutting block positioning).

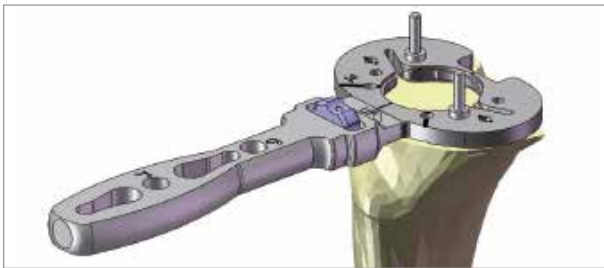


9 TIBIAL FINISHING

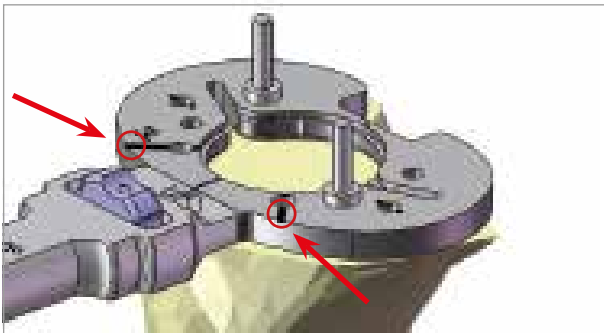
9.1 Tibial baseplate positioning

Fixed

Place the appropriate sized trial tibial baseplate assembled with the trial base handle, on the tibia resection. The tibial baseplate is asymmetrical. Rotate the baseplate until the best coverage of the tibial cortical bone is achieved and fix it by means of two pins. The pins must be always placed in opposite position: one anteriorly and one posteriorly on tibial surface.

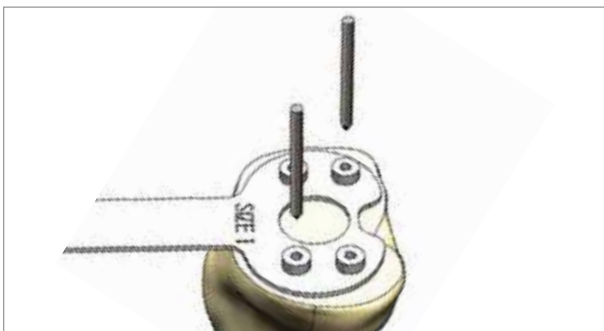


In order to help the identification of the correct positioning of the tibial baseplate two lines are marked on the anterior wall of the tibial implant, corresponding to the alignment lines on the trial tibial baseplate. Once the trial baseplate is fixed, identify the position of these two lines on the tibia by electric diathermy.



Full PE

In case the Full PE Tibial component will be implanted, assess the tibial size and position using the dedicated template. Once the position of the tibial component is adjusted, fix it using two pins.

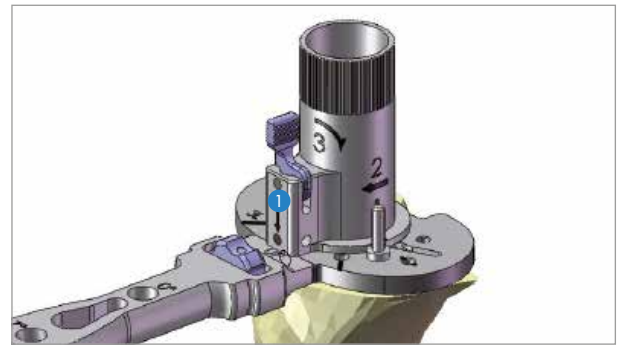


Remove the tibial template and position the trial tibial baseplate on the two pins left in place.

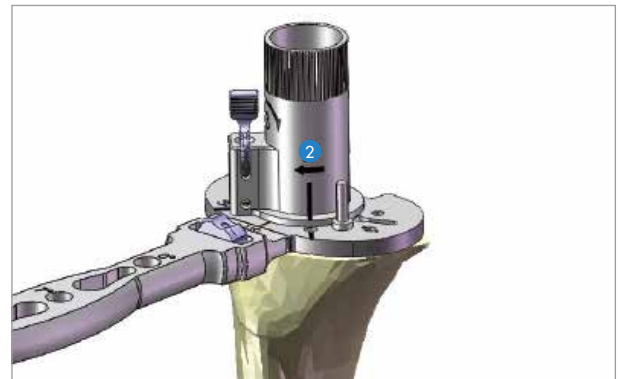
9.2 Tibial finishing

Assemble the reamer guide to the trial tibial baseplate following the marked numbers:

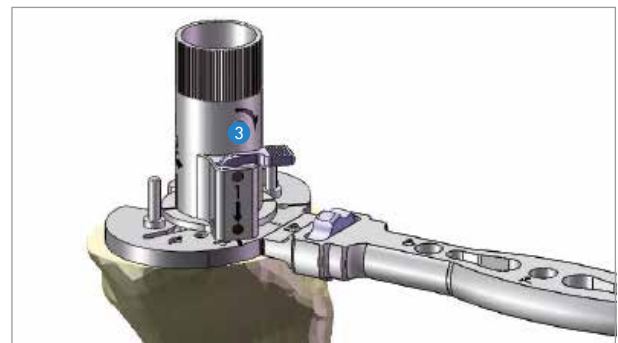
1. Position the reamer guide on the trial tibial baseplate aligning the arrow (1) to the central line of the baseplate.



2. Turn the reamer guide aligning the arrow (2) to one of the two positioning lines of the baseplate.



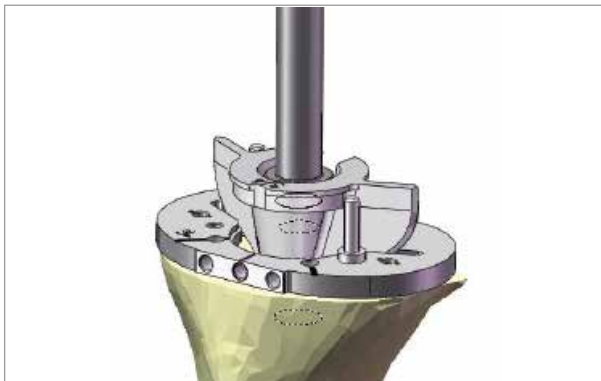
3. Pull down the lever in order to lock the reamer guide.



Insert the dedicated reamer into the guide and prepare the keel hole parallel to the axis of the bone until the depth gauge stopper is reached. To excise the bone drill clockwise, to compact the bone drill counterclockwise (no bone is excised).



Lift up the small lever and remove the reamer guide turning it to the unlocked position. Assemble the trial keel with the handle and impact it through the dedicated hole of the trial baseplate, in order to finish the keel preparation. Remove the trial handle.



9.3 Tibial stem extension

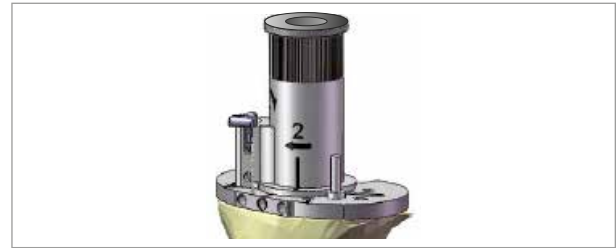
For additional stability a stem extension can be added to the tibial keel.

CAUTION
The tibial stem extension must not be coupled with Full PE tibial component.

CAUTION
In order to avoid the risk of cortical infraction, carefully plan preoperatively the positioning of the stem extension with the help of the X-ray template.

Remove the trial keel from the bone.

Assemble the reamer guide on the trial tibial baseplate and insert the 9mm reduction bush in it. Open the intramedullary canal with the help of the 9mm drill bit, if needed.



Assemble the T-handle with the 9 mm reamer.



Ream the canal until the correct depth is reached.

For 30mm stem option
ream until 65mm mark



For 65mm stem option
ream until 105mm mark



Remove the 9 mm reduction bush and insert the 11 mm reduction bush. Repeat the reaming with the 11 mm reamer, until the same depth previously reached. Insert the reduction bush (\varnothing 15mm) in the reamer guide assembled on the trial baseplate and finish the keel preparation using the 15.5mm reamer.



Remove the reamer guide, assemble the extension stem on the trial keel and impact it through the trial baseplate with the help of the handle.

10 PATELLA

10.1 Resurfacing patella

Lock the patella resection guides into the patellar clamp. After carefully releasing the periphery of the patella, position the resection guides at the appropriate resection level, with the assistance of the patellar stylus assembled in the slot of the resection guide.

CAUTION

Check that at least 13 mm of bone remains after resection.

Firmly lock the clamp with the screwing thumbwheel and perform the patellar resection through the slots of the resection guides.



Select the correct size of the patella implants with the help of the patellar templates.



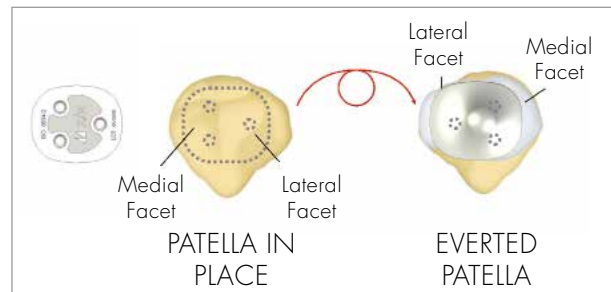
Open the patellar clamp, remove the two resection guides and position the spike jaw and drilling guide.



CAUTION

The surfaces of the drilling guide are endowed with cutting spikes. Handle with care.

To correctly position the patellar component, its single peg has to be positioned on the lateral facet of the patella and the other two pegs on the medial one.



In order to avoid any malpositioning of the patellar component, read the markings carefully on the drilling guide. In case of medial approach (lateral eversion of the patella), the drilling guide has to be assembled to the clamp, so that the side with the EXT marking is facing upwards. In case of lateral approach (medial eversion of the patella), the drilling guide has to be flipped, so that the INT marking can be read.



Apply the drill guide on the resected surface of the patella and drill the three holes using the patellar pegs drill.

After having removed the drilling guide, assemble the patellar impactor on the patellar clamp and impact the appropriate sized trial patella.

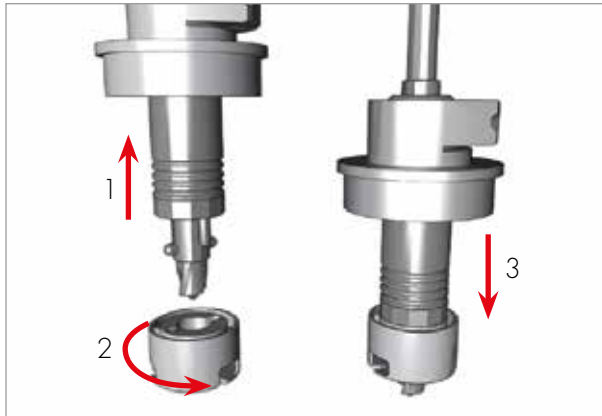
Finally, reduce the patella and test the knee through its full range of motion.

10.2 Inset patella

Choose the size of the patella using the different reamer guides or the dedicated template set, which is available on request.

Assemble the reamer guide of the chosen size and the spike jaw on the patellar clamp.

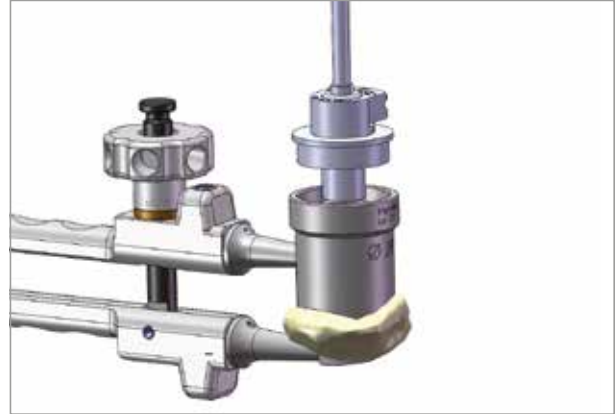
To assemble the reamer of the suitable size to the reamer holder, pull up the locking mechanism of the reamer holder, insert the reamer, turn it 90° and release the locking mechanism, making sure that the reamer is solidly fixed.



Before drilling, check that the depth gauge (A) is in neutral position. If necessary the reaming depth can be modified turning the depth gauge (1 turn = 1 mm).



Insert the reamer into the reamer guide and drill until the depth gauge touches the reamer guide.



! CAUTION

The drill hole should be shallow enough to leave a minimum wall thickness of 13 mm.

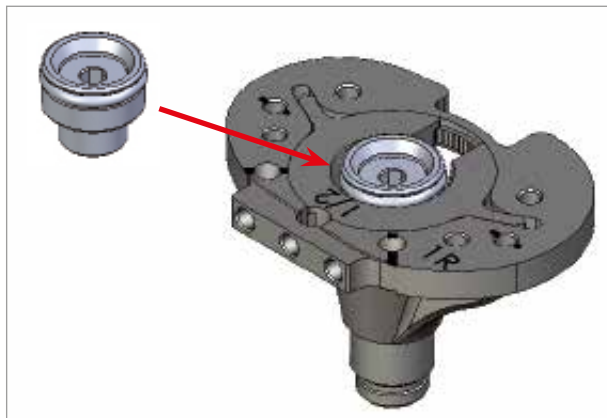
Impact the trial inset patella of the chosen size using of the dedicated impactor assembled to the patellar clamp. Smooth out the bone rim using bone forceps or the oscillating saw. Reduce the patella and test the knee through its full range of motion.



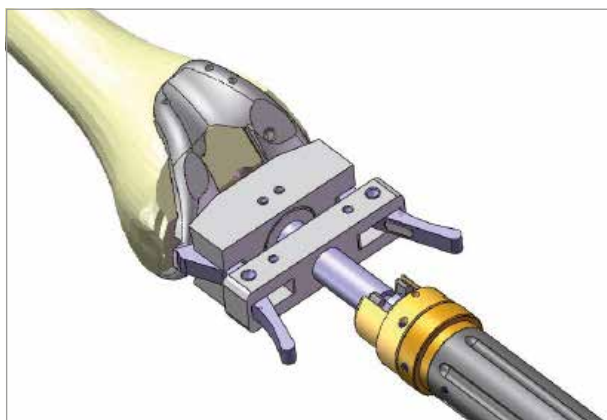
11 TRIALS

Assemble the trial insert on the trial tibial baseplate.

Before positioning the insert, fix in the trial keel the puncher fixing screw with the help of the screwdriver, this allows the fixation of the insert to the baseplate.



Assemble the femoral impactor/extractor on the slide hammer and impact the appropriate sized trial femoral component centering it on the anatomical notch. Ensure overhang medially or laterally is minimized. To ensure the correct positioning of the femoral component, reduce the patella and test the knee in its full range of motion.



CAUTION

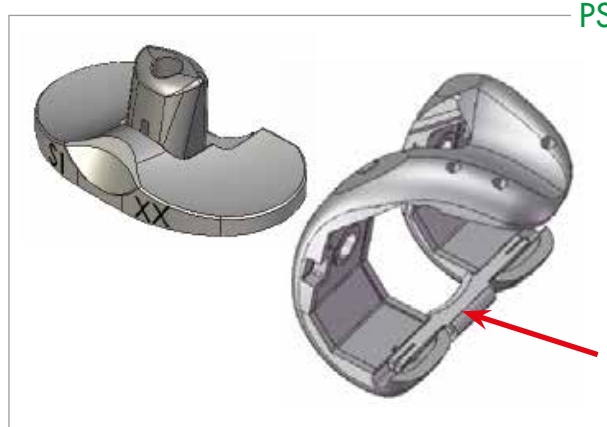
In order to avoid any damaging of the trial trochlea, do not impact the trial femoral component assembled with it.

PS

In case of posterior stabilized implant, the trial has to be performed after the femoral finishing (see § 12 FEMORAL FINISHING).

Assemble the PS trial peg on the fixed tibial insert and the trial PS cam on the trial femur.

In order to not be hindered by the presence of the PS peg, assemble the trial PS Insert after the impaction of the femoral component.



PS

Full PE

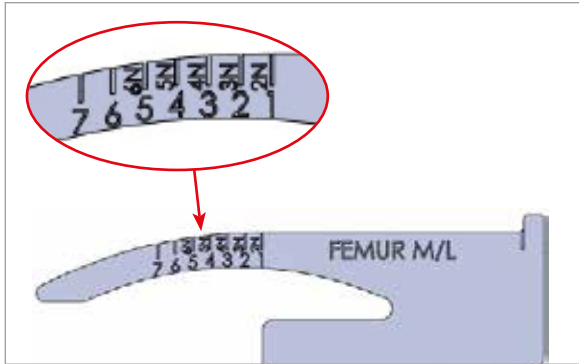
In case a Full PE baseplate will be used, the trials have to be performed using the trial UC or PS insert, according to the Full PE implant type (UC or PS).

12 FEMORAL FINISHING



NARROW

Use the provided marking on the angel wings to double check the M/L dimension of the femoral component.



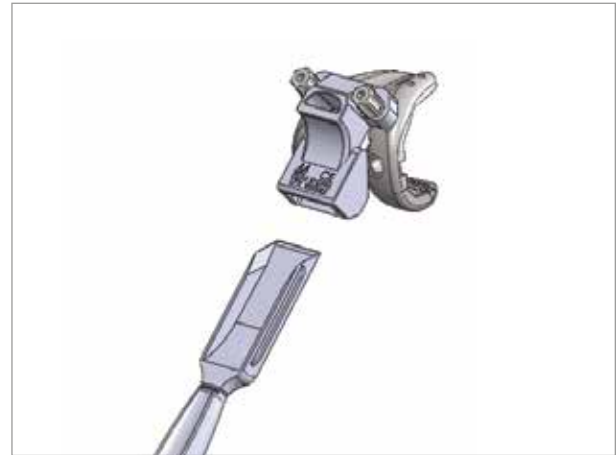
The trial femur for a size X NARROW is the same as for the corresponding size X standard.
The size X standard is 4 mm larger than the X NARROW size.

Once the medio-lateral position of the trial femoral component is deemed satisfying, insert a pin into the anterior holes of the trial femoral component to confer additional stability during the femoral finishing.



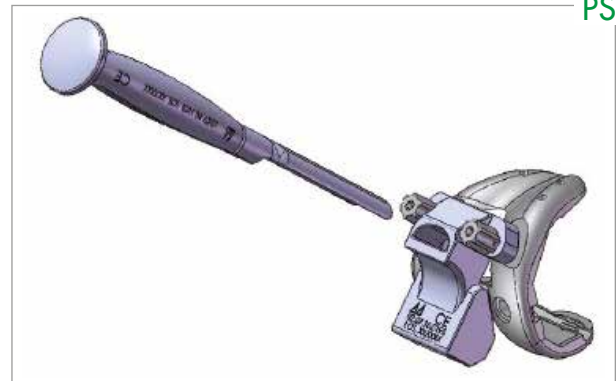
Prepare the holes for the femoral pegs with the dedicated drill.

Assemble the femoral box cutting guide on the trial femoral component and finish the trochlea using the box resection chisel.



PS

In case of posterior stabilized implant, prepare the intercondylar notch using the PS resection chisel through the dedicated holes of the femoral box cutting guide.



PS

Finally, assemble the trial trochlea of the suitable size to the trial femoral component, reduce the patella and test the knee through its full range of motion.



Femoral finishing size 0 (option)

Once the medio-lateral position of the trial femoral component is defined, insert a pin into the anterior holes of the trial femoral component to ensure additional stability during the femoral finishing.



Prepare the holes for the femoral pegs with the dedicated drill.

Remove the trial femoral component and mount the femoral box cutting guide on the femur.

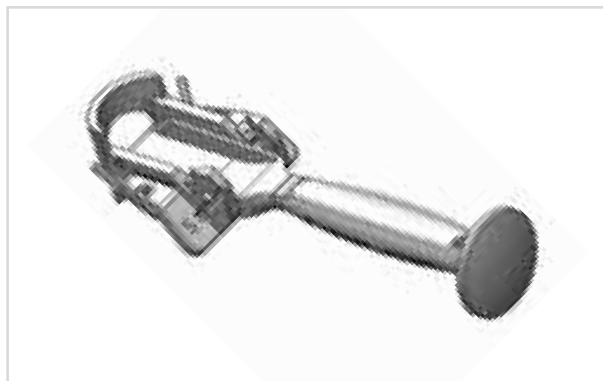
**CAUTION**

For the femoral size 0 the femoral box cutting guide size 1 has to be used. Firmly fix it by means of at least 2 pins.

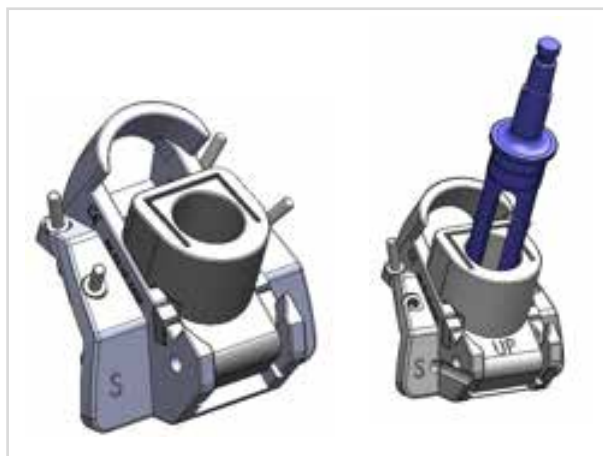
Prepare the throclear finishing with the reamer provided.

**OPTION**

The throclear finishing can be done also by the provided osteotome.

**PS**

The dedicated PS reamer guide has to be clipped on the femoral box cutting guide and the PS finishing can be carried out using the PS reamer.



After the removal of the femoral box cutting guide, the resections have to be checked by means of the box cut verifier.



13 SELECTION OF THE PROSTHETIC COMPONENTS - SIZE MATCHING

13.1 Fixed version

Fixed tibial inserts STD and UC have to be matched with fixed tibial trays from the same size and STD femoral components. STD femoral components size X can be matched with fixed tibial inserts (STD and UC) from size X-1, size X and X+n.

Fixed tibial inserts PS have to be matched with fixed tibial trays from the same size and PS femoral components. PS femoral components size X can be matched with PS fixed tibial inserts from size X-1, size X and X+n. The matching capabilities are shown in tables 1 and 2.

Fixed tibial inserts (STD, PS and UC)							
Fixed tibial trays	Size	1	2	3	4	5	6
	1	✓	✗	✗	✗	✗	✗
	2	✗	✓	✗	✗	✗	✗
	3	✗	✗	✓	✗	✗	✗
	4	✗	✗	✗	✓	✗	✗
	5	✗	✗	✗	✗	✓	✗
	6	✗	✗	✗	✗	✗	✓

Table 1: Matching capabilities for fixed tibial inserts and fixed tibial trays.

Fixed tibial inserts (STD, PS and UC)							
Femoral components	Size	1	2	3	4	5	6
	0	✓	✓	✓	✓	✓	✓
	1 1N	✓	✓	✓	✓	✓	✓
	2 2N	✓	✓	✓	✓	✓	✓
	3 3N	✗	✓	✓	✓	✓	✓
	4 4N	✗	✗	✓	✓	✓	✓
	5 5N	✗	✗	✗	✓	✓	✓
	6 6N	✗	✗	✗	✗	✓	✓
	7 7N	✗	✗	✗	✗	✗	✓

Table 2: Matching capabilities for fixed tibial inserts and femoral components.

13.2 Full PE version

STD femoral components size X can be matched with Full PE UC tibial component from size X-1, size X and X+n.

PS femoral components size X can be matched with Full PE PS tibial component from size X-1, size X and X+n.

Full PE UC or PS tibial components							
Femoral components	Size	1	2	3	4	5	6
	0	✓	✓	✓	✓	✓	✓
	1 1N	✓	✓	✓	✓	✓	✓
	2 2N	✓	✓	✓	✓	✓	✓
	3 3N	✗	✓	✓	✓	✓	✓
	4 4N	✗	✗	✓	✓	✓	✓
	5 5N	✗	✗	✗	✓	✓	✓
	6 6N	✗	✗	✗	✗	✓	✓
	7 7N	✗	✗	✗	✗	✗	✓

Table 3: Matching capabilities for Full PE tibial components and femoral components.

14 FINAL IMPLANTS

14.1 Tibial baseplate

The baseplate should be positioned manually, ensuring that there is no conflict between the posterior edge of the baseplate and the femur, which may result in femoral injury or tibial malrotation.

The final impaction is performed using the baseplate impactor, version suitable for the type of tibial baseplate used. If a stem extension is used, pre-assemble it by removing the plastic plug of the tibial keel, impacting the stem on the keel and, finally, fixing it with a screw inserted through the tibial keel.

CAUTION

To avoid damaging the stem, protect it during impaction. A screwdriver can be inserted in the exagonal hole of the stem and the impaction can be performed hammering on the screwdriver.

CAUTION

The tibial stem extension must not be coupled with Full PE tibial component.

Cemented tibial baseplate

The cemented tibial baseplate is intended to be implanted without cement surrounding the keel. The bone cement must be prepared according to the related instruction for use, provided by the cement manufacturer. Once the cement has the right viscosity, it must be applied on the implant.

CAUTION

For metalback tibial components it is recommended to apply the cement directly on cement pockets but not around the keel.

For Full PE tibial components it is recommended to apply the cement both on the cement pockets and around the keel.

It is recommended not to apply the cement directly to the bone surface, to avoid the risk of having cement around the keel by positioning the implant. Once the tibial baseplate has been fully inserted with the dedicated impactor, the extruded cement is cleared from the tibia, carefully checking that no cement part remains on the articular surface.

14.2 PE insert

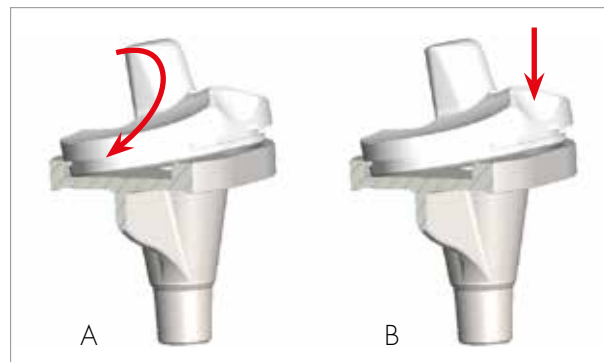
CAUTION

The Full PE tibial component is monoblock, therefore no PE insert have to be clipped on it.

Fixed insert

Place the insert on the tibial baseplate according to the following steps:

1. Make sure that the metallic upper surface of the tibial baseplate is perfectly clean and that no small debris can get interposed between tray and insert during assembly.
2. Engage the posterior lips of the insert in the posterior part of the tibial baseplate.(A)
3. Clip the anterior part of the insert, by exerting pressure on it manually.(B)



OPTION

To perform a final control of the height of the insert, before implanting the definitive PE insert, the trial insert can be positioned on the final baseplate.

PS

The PS insert has to be positioned after the femoral component, in order not to be hindered by the presence of the posterior stabilization peg. Using the screwdriver, fix the PS insert to the tibial tray with the screw packaged with the insert.

CAUTION

The torque limiter screwdriver 3,5 Nm must be used to guarantee that the optimal locking of the screw is achieved.

14.3 Femoral component

Assemble the femoral impactor on the slide hammer. Open the two jaws of the femoral impactor and engage the extremity of the two jaws in the two lateral slots of the femoral component. Lock the femoral component on the impactor by turning the handle firmly.

Position the femoral component, with the help of previously drilled holes for the pegs for correct alignment and finish with hammer impaction.

At the end of impaction, if the operator wishes to change the angle of approach, he may remove the femur impactor, screwing the handle to the maximum to release the runner and therefore remove the presence of the two jaws.

Cemented femoral component

The bone cement must be prepared according to the related instruction for use, provided by the cement manufacturer. Once the cement has the right viscosity, it must be applied to the internal surface of the femoral component into the corresponding cement pockets. The resected surface should be thoroughly cleaned by pulse lavage and the intramedullary canal closed by cancellous bone.

Once the femoral component has been fully inserted with the dedicated impactor, the extruded cement is cleared from the femur, ensuring that no cement remains on the articular surface, on the intercondylar notch and in the joint, in order to avoid excessive UHMWPE wear.

14.4 Patella

Assemble the spike jaw and the pressurizing jaw on the patellar clamp. Place the cement in position. Lock the patella, by firmly screwing the thumbwheel switch of the patellar clamp. The pressurizing jaw has two different sides of use, which observe the same colour significance as that of the two types of patella: blue side for resurfacing patella and yellow side for inset patella. The bone cement must be prepared according to the related instruction of use, provided by the cement manufacturer. Once the cement has the right viscosity, it should be applied to the internal surface of the patellar implant. Hold the implant in the final position and clear the extruded cement from the patella, ensuring that no cement part remains on the articular surface.

15 IMPLANTS NOMENCLATURE

FEMUR STD CEMENTED

Ref. left	Size	Ref. right
02.07.2000L	0	02.07.2000R
02.07.2001L	1	02.07.2001R
02.07.2002L	2	02.07.2002R
02.07.2003L	3	02.07.2003R
02.07.2004L	4	02.07.2004R
02.07.2005L	5	02.07.2005R
02.07.2006L	6	02.07.2006R
02.07.2007L	7	02.07.2007R

FEMUR PS CEMENTED

Ref. left	Size	Ref. right
02.07.2200L	0	02.07.2200R
02.07.2201L	1	02.07.2201R
02.07.2202L	2	02.07.2202R
02.07.2203L	3	02.07.2203R
02.07.2204L	4	02.07.2204R
02.07.2205L	5	02.07.2205R
02.07.2206L	6	02.07.2206R
02.07.2207L	7	02.07.2207R

FEMUR STD CEMENTED - NARROW

Ref. left	Size	Ref. right
02.07.2011L	1N	02.07.2011R
02.07.2012L	2N	02.07.2012R
02.07.2013L	3N	02.07.2013R
02.07.2014L	4N	02.07.2014R
02.07.2015L	5N	02.07.2015R
02.07.2016L	6N	02.07.2016R
02.07.2017L	7N	02.07.2016R

FEMUR PS CEMENTED - NARROW

Ref. left	Size	Ref. right
02.07.2211L	1N	02.07.2211R
02.07.2212L	2N	02.07.2212R
02.07.2213L	3N	02.07.2213R
02.07.2214L	4N	02.07.2214R
02.07.2215L	5N	02.07.2215R
02.07.2216L	6N	02.07.2216R
02.07.2217L	7N	02.07.2217R

TIBIAL COMPONENT FIXED CEMENTED

Ref. left	Size	Ref. right
02.07.1201L	1	02.07.1201R
02.07.1202L	2	02.07.1202R
02.07.1203L	3	02.07.1203R
02.07.1204L	4	02.07.1204R
02.07.1205L	5	02.07.1205R
02.07.1206L	6	02.07.1206R

FULL PE UC TIBIAL COMPONENT*

Ref.	Size	Thickness (mm)
02.07.0110APUC	1	10
02.07.0112APUC		12
02.07.0114APUC		14
02.07.0117APUC		17
02.07.0210APUC	2	10
02.07.0212APUC		12
02.07.0214APUC		14
02.07.0217APUC		17
02.07.0310APUC	3	10
02.07.0312APUC		12
02.07.0314APUC		14
02.07.0317APUC		17

Ref.	Size	Thickness (mm)
02.07.0410APUC	4	10
02.07.0412APUC		12
02.07.0414APUC		14
02.07.0417APUC		17
02.07.0510APUC	5	10
02.07.0512APUC		12
02.07.0514APUC		14
02.07.0517APUC		17
02.07.0610APUC	6	10
02.07.0612APUC		12
02.07.0614APUC		14
02.07.0617APUC		17

FULL PE PS TIBIAL COMPONENT*

Ref.	Size	Thickness (mm)
02.07.0110APPS	1	10
02.07.0112APPS		12
02.07.0114APPS		14
02.07.0117APPS		17
02.07.0210APPS	2	10
02.07.0212APPS		12
02.07.0214APPS		14
02.07.0217APPS		17
02.07.0310APPS	3	10
02.07.0312APPS		12
02.07.0314APPS		14
02.07.0317APPS		17

Ref.	Size	Thickness (mm)
02.07.0410APPS	4	10
02.07.0412APPS		12
02.07.0414APPS		14
02.07.0417APPS		17
02.07.0510APPS	5	10
02.07.0512APPS		12
02.07.0514APPS		14
02.07.0517APPS		17
02.07.0610APPS	6	10
02.07.0612APPS		12
02.07.0614APPS		14
02.07.0617APPS		17

* Full PE PS or UC tibial component must not be coupled with any stem extension.

TIBIAL INSERT STD FIXED

Ref.	Size	Thickness (mm)
02.07.0110SF	1	10
02.07.0112SF		12
02.07.0114SF		14
02.07.0117SF		17
02.07.0120SF		20
02.07.0210SF	2	10
02.07.0212SF		12
02.07.0214SF		14
02.07.0217SF		17
02.07.0220SF		20
02.07.0310SF	3	10
02.07.0312SF		12
02.07.0314SF		14
02.07.0317SF		17
02.07.0320SF		20

Ref.	Size	Thickness (mm)
02.07.0410SF	4	10
02.07.0412SF		12
02.07.0414SF		14
02.07.0417SF		17
02.07.0420SF		20
02.07.0510SF	5	10
02.07.0512SF		12
02.07.0514SF		14
02.07.0517SF		17
02.07.0520SF		20
02.07.0610SF	6	10
02.07.0612SF		12
02.07.0614SF		14
02.07.0617SF		17
02.07.0620SF		20

TIBIAL INSERT UC FIXED

Ref.	Size	Thickness (mm)
02.07.0110FUC	1	10
02.07.0112FUC		12
02.07.0114FUC		14
02.07.0117FUC		17
02.07.0120FUC		20
02.07.0210FUC	2	10
02.07.0212FUC		12
02.07.0214FUC		14
02.07.0217FUC		17
02.07.0220FUC		20
02.07.0310FUC	3	10
02.07.0312FUC		12
02.07.0314FUC		14
02.07.0317FUC		17
02.07.0320FUC		20

Ref.	Size	Thickness (mm)
02.07.0410FUC	4	10
02.07.0412FUC		12
02.07.0414FUC		14
02.07.0417FUC		17
02.07.0420FUC		20
02.07.0510FUC	5	10
02.07.0512FUC		12
02.07.0514FUC		14
02.07.0517FUC		17
02.07.0520FUC		20
02.07.0610FUC	6	10
02.07.0612FUC		12
02.07.0614FUC		14
02.07.0617FUC		17
02.07.0620FUC		20

TIBIAL INSERT PS FIXED

Ref.	Size	Thickness (mm)
02.07.0110PSF	1	10
02.07.0112PSF		12
02.07.0114PSF		14
02.07.0117PSF		17
02.07.0120PSF		20
02.07.0210PSF	2	10
02.07.0212PSF		12
02.07.0214PSF		14
02.07.0217PSF		17
02.07.0220PSF		20
02.07.0310PSF	3	10
02.07.0312PSF		12
02.07.0314PSF		14
02.07.0317PSF		17
02.07.0320PSF		20

Ref.	Size	Thickness (mm)
02.07.0410PSF	4	10
02.07.0412PSF		12
02.07.0414PSF		14
02.07.0417PSF		17
02.07.0420PSF		20
02.07.0510PSF	5	10
02.07.0512PSF		12
02.07.0514PSF		14
02.07.0517PSF		17
02.07.0520PSF		20
02.07.0610PSF	6	10
02.07.0612PSF		12
02.07.0614PSF		14
02.07.0617PSF		17
02.07.0620PSF		20

RESURFACING PATELLA

Size	Ref.
1	02.07.0033RP
2	02.07.0034RP
3	02.07.0035RP
4	02.07.0036RP

INSET PATELLA

Size	Ref.
1	02.07.0041IP
2	02.07.0042IP
3	02.07.0043IP

STEM EXTENSION

Ref.	Ø (mm)	L (mm)
02.07.F11030	11	30
02.07.F11066	11	65

Part numbers subject to change.

NOTE FOR STERILIZATION

The instrumentation is not sterile upon delivery. It must be cleaned before use and sterilized in an autoclave respecting the US regulations, directives where applicable and following the instruction for use of the autoclave manufacturer.

For detailed instructions please refer to the document "Recommendations for cleaning decontamination and sterilization of Medacta International reusable orthopedic devices" available at www.medacta.com



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