

GAAK SPHERE

MEDIALY STABILIZED KNEE

STABILITY FOR LIFE



Surgical Technique

Joint

Spine

Sports Med

CALIPERED KINEMATIC ALIGNMENT

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1. INTRODUCTION

1.1 KINEMATIC ALIGNMENT APPROACH

The three goals of Kinematically Aligned Total Knee Arthroplasty are:

1. Restore the native tibial-femoral articular surfaces
2. Restore the native knee and limb alignments
3. Restore the native laxities of the knee.

This document describes the Calipered Kinematic Alignment technique main steps to kinematically align the femoral and tibial components to the native tibial-femoral articular surface.

Through a series of caliper measurements, adjustments are made until the thickness of the femoral and tibial resections match the thickness of the femoral and tibial components within ± 0.5 mm, after compensating for worn cartilage (~ 2 mm) and the kerf of the saw blade (~ 1 mm).

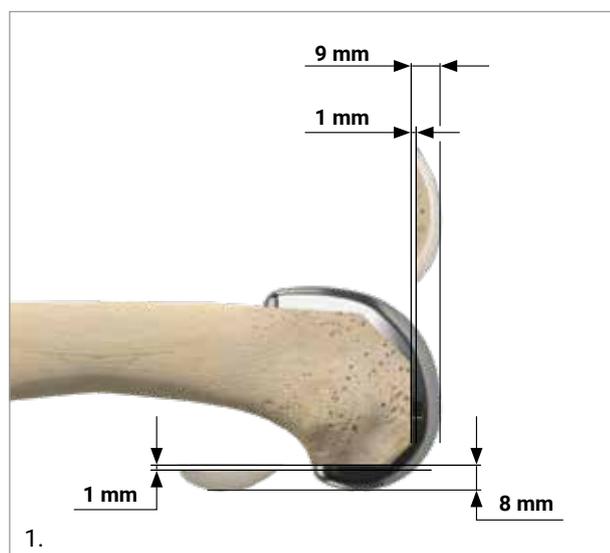
Hence, target caliper measurement = Implant Thickness - Cartilage Wear - Saw Blade Thickness

This restores the native joint lines and co-aligns the axes of the components with the three kinematic axes of the knee without ligament release.

EXAMPLE: In a varus knee there is typically cartilage wear on the medial distal condyle, whereas the lateral distal condyle and the posterior condyles exhibit minimal wear. Consequently:

Example target caliper measurements:

- Unworn Posterior Femoral Condyles
= 8 mm - 0 mm - 1 mm = 7 mm
- Worn Distal Femoral Condyles
= 9 mm - 2 mm - 1 mm = 6 mm
- Unworn Distal Femoral Condyle
= 9 mm - 0 mm - 1 mm = 8 mm



The technique described in this document is applicable only to cases where the anatomical landmarks required through the procedure can be identified. If these landmarks are not identifiable, alternative tools like patient matched technology are required to kinematically align the femoral and/or tibial components, provided enough information on the patient's native anatomy is available to plan implant positioning.

CAUTION

Should it not be possible to identify any of the anatomical landmarks described in this surgical technique, follow the steps described in the standard GMK Sphere surgical technique (ref. 99.26SPHERE.12 & 99.26I.12).

Complex cases should be carefully analyzed in order to determine whether an alternative alignment approach or additional corrections should be considered. For example, extra-articular deformity might be best corrected with realignment osteotomy.

1.2 INDICATIONS

The GMK Sphere 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.

1.3 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 osteochondral 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.

1.4 SURGICAL APPROACH

The most common surgical approach is the vertical midline skin incision and a medial parapatellar approach. Other approaches may be used depending on the surgeon's preferences. After exposing the joint via elevation of the medial retinaculum, flex the knee. Prior to any bone resection define the normal bony architecture by removing the osteophytes (including those at the intercondylar notch) as collectively these contribute to the maintenance of any malalignment and conceal the true bone size.

Resect the anterior cruciate ligament. If you are using a GMK Sphere CS insert, resect also the posterior cruciate

ligament which also aids exposure by permitting easier subluxation of the tibia for its subsequent osteotomy.

CAUTION

If a cruciate retaining insert (CR Insert) is used, the posterior cruciate ligament must be preserved.

During all procedures it is the intention to replace the bone and cartilage, that has been lost secondary to the arthritic process and resected as part of the arthroplasty, with a similar thickness of polyethylene and metal provided by the prosthetic components.

2. TIBIO-FEMORAL OFFSET MEASUREMENT

When using a GMK Sphere CR insert, the measurement of the tibio-femoral offset can be a reference to check the slope once the trial implants are in place. Flex the knee to 90°. Expose the knee using a medial approach. Position the arms of the offset caliper against the distal medial femoral condyle and anterior tibia. Orientate the longer arm parallel to the patella tendon. Measure the distance. When cartilage on the medial femoral condyle is worn to the bone subtract 2 mm from the offset measurement.



CAUTION

This measurement is not reliable in case of deficient ACL with postero-medial wear of the tibia.

To evaluate the slope in such cases please refer to the table GMK Sphere decision tree - CR insert in chapter 8.1.

3. DISTAL FEMORAL RESECTION

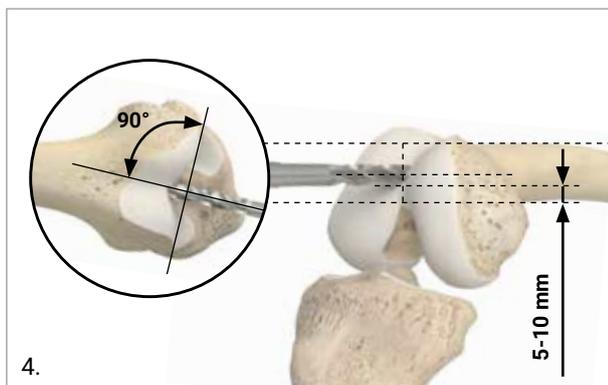
Calipered kinematic alignment sets the femoral component coincident to the distal articular surface of the native femur. Restoring the native distal femoral line requires compensations of ~2 mm for worn cartilage when present on the distal femoral condyles. When measuring the cut, ~1 mm of saw blade kerf should be accounted for. Compensation for bone wear is rarely required at the 0° of flexion position on the osteoarthritic femoral condyle with end-stage varus or valgus deformity.

3.1 PLACING THE INTRAMEDULLARY ROD

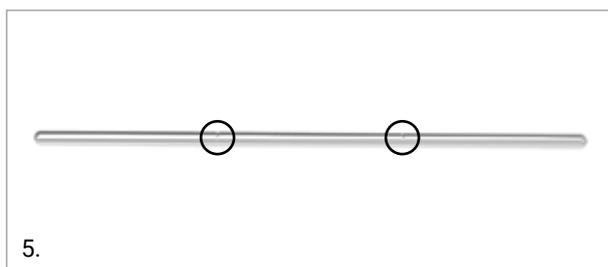
First, set the flexion-extension position of the femoral component. Drill a hole midway between the top of the intercondylar notch and the anterior cortex, depending on the anterior-posterior size of the femur. Keep a 5-10 mm bridge of bone between the posterior rim of the drill hole and the top of the intercondylar notch. Orient the drill parallel to the anterior surface and perpendicular to the distal articular surface of the distal femur.

CAUTION

Excessive flexion of the femoral component could lead to patellar instability. Orienting the drill hole parallel to the anterior surface of the distal femoral shaft minimizes flexion of the femoral component.



Insert the rod 8-10 cm into the femur using the marks engraved on the shaft as a reference.



Determine the extent of cartilage wear on each distal femoral condyle. Use a ring curette to remove any partially worn cartilage on the bone.

Set the varus-valgus angle and proximal-distal level of the femoral component. This is done using a distal cut referencing guide. The guide can compensate for 2 mm of cartilage wear on the worn condyle(s).

4 distal referencing guides are available:

- 1x UNWORN/UNWORN: This is for cases with no cartilage wear on either distal femoral condyle
- 1x UNWORN/WORN: This is for cases with cartilage wear on the right medial or left lateral condyle
- 1x WORN/UNWORN: This is for cases with cartilage wear on the left medial or right lateral condyle
- 1x WORN/WORN: This is for cases with wear on both distal femoral condyles



Select the appropriate guide depending on the operative side and the pattern of cartilage wear.

Place it onto the intramedullary rod and advance it until it contacts both femoral condyles. Stabilize the distal cut reference guide by means of two threaded pins into the distal holes.

3.2 POSITIONING THE DISTAL CUTTING GUIDE

Slide the fixed slotted distal cut positioner onto the distal cut reference guide.

Connect the distal cutting block to the fixed slotted distal cut positioner then secure the connection by pushing the lever down.

CAUTION

The slotted distal cutting guide is NOT compatible with the Micrometric Distal Cut Positioner unslotted version (ref.02.07.10.0185).

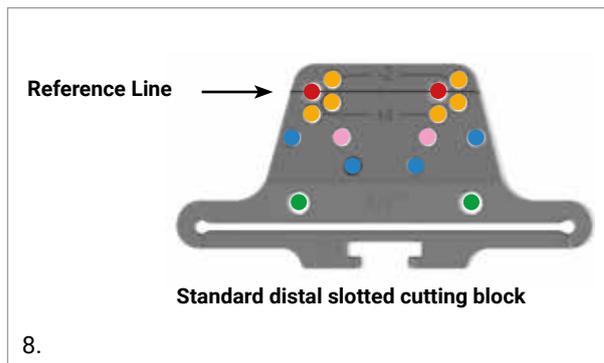


The femoral distal resection is set at 9 mm, corresponding to the thickness of the distal condyles of the femoral component.

OPTION

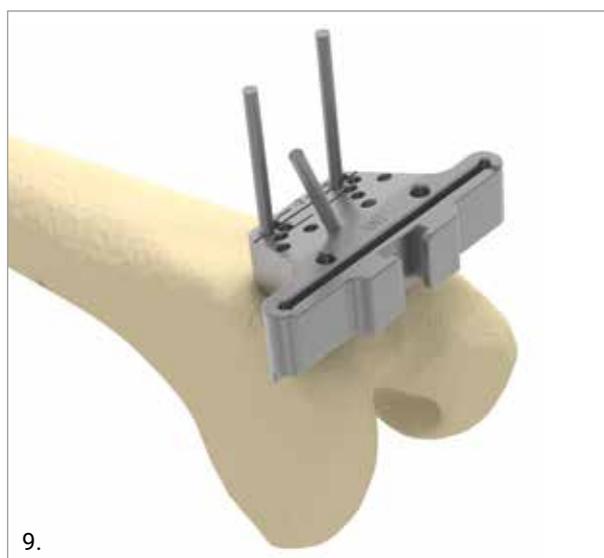
Alternatively, a micrometric distal cut positioner is available. The distal resection level can be adjusted by turning the screw on the distal cut positioner. Make sure to set a 9 mm distal resection.

Stabilize the distal cutting block by inserting two pins in the parallel positioning holes (marked in red in the figure below) and one pin in the oblique hole (marked in blue in the figure below) and then remove everything except the distal cutting block by releasing the lever.



Distal cutting block holes (right knee)

- Parallel positioning holes
- Oblique fixation holes
- Alignment rod holes
- Parallel repositioning holes
- Additional fixation holes



Check the distal femoral resection level using the angel wing. Perform the distal cut with a 1.27 mm thickness saw blade through the slot built into the guide. Once the resection is performed, remove the pins.

VERIFICATION CHECK

Using the dedicated caliper, check the thickness of the resected medial and lateral distal femoral bone and cartilage (if present) resection. Measurement on the unworn condyles should read 8.0 ± 0.5 mm. Worn condyles should measure 6.0 ± 0.5 mm. These values equal the 9 mm thickness of the distal condyles of the GMK Sphere femoral component after compensating for the ~ 1 mm kerf of the saw blade and 2 mm of worn cartilage when present.

In cases of a 1 mm under-resection, refine the cut through the slot of the distal cutting block.

Should a recut be necessary, use the repositioning holes to move the distal cutting block proximally in 2 mm increments. Before performing the recut, check the distal cutting block position with an angel wing.

If one or both condyles have been over-resected by 1 or 2 mm, the correct joint line level is restored using dedicated washers, as described in the next section.

TIP

Mark the number of millimeters of over-resection on each distal femoral condyle with a pen as a reference for selecting the correct washer.

4. ANTERIOR CUT, POSTERIOR CUT AND CHAMFER

Calipered kinematic alignment sets the femoral component coincident to the posterior articular surface of the native femur. Restoring the native posterior femoral line requires compensation for cartilage wear when present. Compensation for bone wear at 90° of flexion position is rarely required on the osteoarthritic femoral condyle with end-stage varus or valgus deformity.

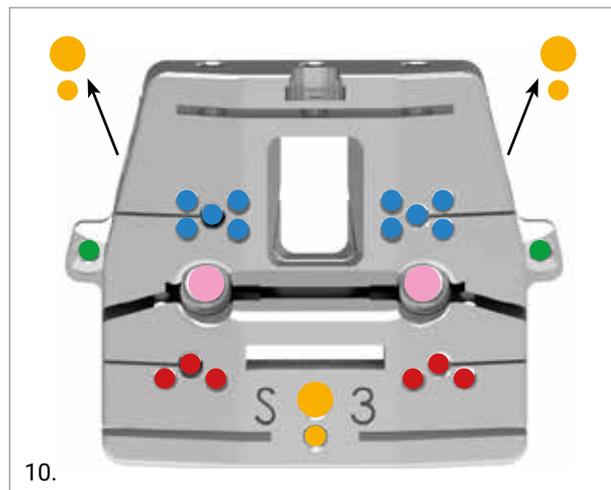
Set the anterior-posterior translation and internal-external rotation of the femoral component by placing the 0° posterior referencing guide in contact with the posterior femoral condyles.

Use the 4in1 cutting block to perform the anterior, posterior, and chamfer resections of the femur. All femoral resections must be performed using a sawblade 13 mm wide with a maximum thickness of 1.27 mm.

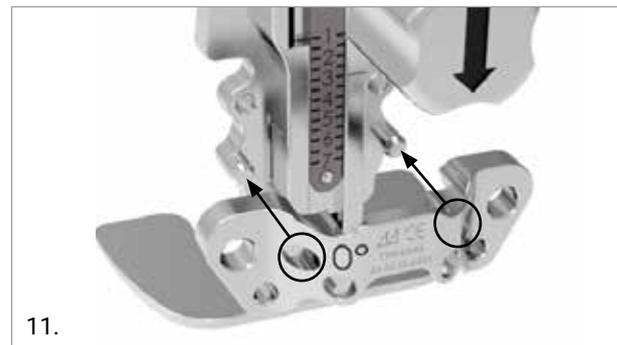
4.1 FEMORAL SIZING

A modular femoral sizer is available to position the 4in1 cutting block.

Select the 0° rotational guide. Slide the rotational guide onto the driven pins to connect the rotational guide to the posterior referencing femoral sizer. A 'click' will be heard when it is fully engaged.



- 4in1 cutting block holes
- Parallel positioning holes (Posterior Referencing)
- Parallel positioning holes (Anterior Referencing)
- Handle holes
- Oblique fixation holes
- Cancellous bone screw holes



The posterior referencing femoral sizer must be flush against the cut edge of the distal femur. Both the posterior condyles should be in contact to its base. The position of the posterior referencing guide rarely requires correction because it is uncommon for the posterior femoral condyles to experience complete cartilage loss.

TIP

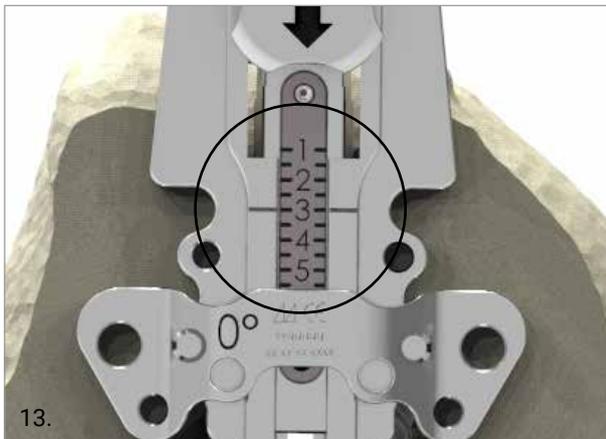
Insert an angel wing between the foot of the Posterior Referencing Femoral Sizer posterior to the worn femoral condyle when compensating for worn cartilage.



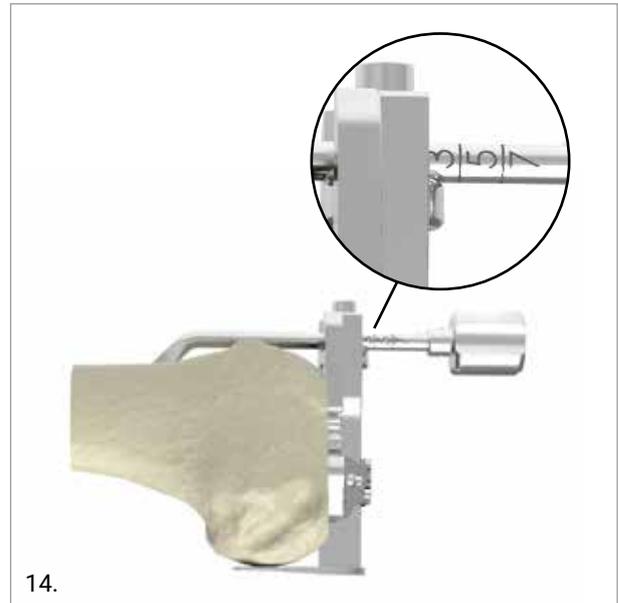
To measure the size of the femur:

1. The stylus should contact the anterior ridge of the lateral femoral cortex.
2. The posterior plates should be in contact with both the medial and lateral posterior femoral condyles.

The size can be read on the front of femoral sizer.



The position of the sizer can be refined by selecting the size of the femur using the anterior stylus.



4.2 4IN1 CUTTING BLOCK POSITIONING

Option 1: Posterior Pegs

Once the size has been established, drill through the dedicated peg holes, indicated in blue on the picture below, on the femoral sizer to prepare for the posterior pegs on the 4in1 block.



Femoral sizer holes

- Parallel positioning holes (Posterior Referencing)
- 4in1 peg drilling holes (Posterior Referencing)
- Epicondylar axis reference holes
- Fixation holes

CAUTION

While drilling, ensure that contact between the femoral sizer and the distal resection remains flush and intact.

OPTION

To achieve further stabilization, insert two pins into the fixation holes.

Remove the femoral sizer from the bone. Select the 4in1 block which corresponds to the size previously determined. Prepare the 4in1 cut block by assembling the pegs to the back of the cutting block. Apply the 4in1 block onto the distal femoral resection.

Check the level of the anterior cut by placing the angel wing into the slot of the anterior resection.



CAUTION

The position of the 4in1 cutting block pegs DOES NOT CORRESPOND to the position of the final femoral component lugs. Preparation for the lugs of the final femoral component is in a later step.

If one or both distal condyles were over-resected, move the position of the 4in1 block distally using the dedicated 1 and 2 mm washers.



To apply the washer, slide it over the posterior peg of the 4in1 block until it contacts the flat surface of the back of the 4in1 block. Secure the washer by inserting the short fixation peg on the washer into the cancellous bone screw hole. Confirm the washer lies flush.



NOTE: The position of the cancellous bone screw holes relative to the posterior fixation pegs changes from size to size.

Secure the 4in1 block by inserting two headed pins into the lateral oblique fixation holes.

Option 2: Posterior Referencing Pins

CAUTION

If a correction washer is required, the posterior referencing pins cannot be used.

Once the size has been established, pre-drill the medial and lateral posterior referencing pin holes through the femoral sizer. Then insert one pin in the medial hole and one pin in the lateral hole.

CAUTION

While drilling, ensure that contact between the femoral sizer and the distal resection is maintained.

Remove the femoral sizer by sliding it off the medial and lateral pins inserted.



Select the 4in1 block which corresponds to the size previously determined. Slide the 4in1 block over the pins through the corresponding row of parallel positioning holes until it contacts the distal resection.

Check the level of the anterior cut by placing the angel wing into the slot of the anterior resection.

Once the position of the 4in1 block is satisfactory, secure the cutting block by inserting two headed pins into the two lateral oblique fixation holes. Remove the positioning pins.

OPTION

If no correction washers were used, cancellous bone screws can be used alternatively or together with the lateral pins to stabilize the 4in1 guide. Insert the cancellous bone screws through the dedicated holes using the dedicated screwdriver.

CAUTION

It is strongly recommended not to impact or hammer the 4in1 guide with a mallet. If the surgeon considers such action necessary, do not impact directly on the 4in1 guide. Use the femoral impactor as shown in the picture below.



4.3 POSTERIOR CUT, ANTERIOR CUT AND CHAMFERS

When the 4in1 cutting block has been stabilized via either the posterior referencing pegs or posterior referencing pins, perform the posterior condylar cut.

VERIFICATION CHECK

Using the dedicated caliper, check the thickness of the resected medial and lateral posterior femoral bone and cartilage (if present) resections. Measurement on the unworn condyles should read 7.0 ± 0.5 mm. Worn condyles should measure 5.0 ± 0.5 mm. These values equal the 8 mm thickness of the posterior condyles of the GMK Sphere femoral component after compensating for the ~1 mm kerf of the saw blade and 2 mm of cartilage wear when present.

If needed, refine the cut through the slot of the 4in1 block.

In the rare event a 2 mm recut is necessary, reposition the block using the posterior referencing pins.

If the posterior referencing pegs were used, position the two central pins on the row of holes marked with a line. Remove the cutting block, withdraw the two pegs and reposition the pin holes just below the reference line.

If a 1 or 2 mm washer was used, place an angel wing between the 4in1 block and the bone on the over-resected condyle.

Perform the remaining femoral resections as follows:

- Anterior cut
- Posterior chamfer
- Anterior chamfer

CAUTION

All femoral resections must be performed using a saw blade 13 mm wide with a maximum thickness of 1.27 mm.

Remove the fixation pins, pegs and/or screws and then remove the 4in1 block.

4.4 FEMORAL UPSIZING/DOWNSIZING

The difference between successive femoral sizes is 2 mm in both anterior-posterior and medio-lateral dimensions.

Option 1: Posterior Pegs

Replace the 4in1 block with a more suitable size using the posterior peg holes.

CAUTION

In the event downsizing is necessary, the anterior resection level will move 2 mm posteriorly. Use an angel wing to check this adjustment and ensure the downsized 4in1 block cuts will not result in anterior notching of the femur.

Option 2: Posterior Referencing Pins

If the 4in1 cutting block was positioned using the central parallel pins, replace the cutting guide with the more suitable size using the same row of pin holes.

CAUTION

In the event downsizing is necessary, the anterior resection level will move 2 mm posteriorly. Use an angel wing to check this adjustment and ensure the downsized 4in1 block anterior cut will not result in anterior notching of the femur.

5. TIBIAL RESECTION

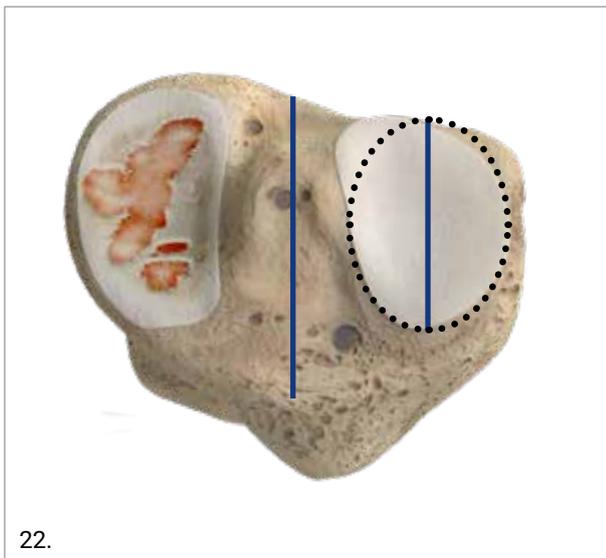
Calipered kinematic alignment sets the tibial component parallel to the flexion-extension axis of the native knee and coincident with the plane of the native tibia, which means restoring the varus-valgus and the slope, after compensating for cartilage and bone wear.

5.1 MARK THE A/P AXIS ON THE TIBIA

On the lateral tibial condyle, mark the anterior-posterior axis (blue line) of the almost elliptically-shaped boundary of the articular surface (black dots).

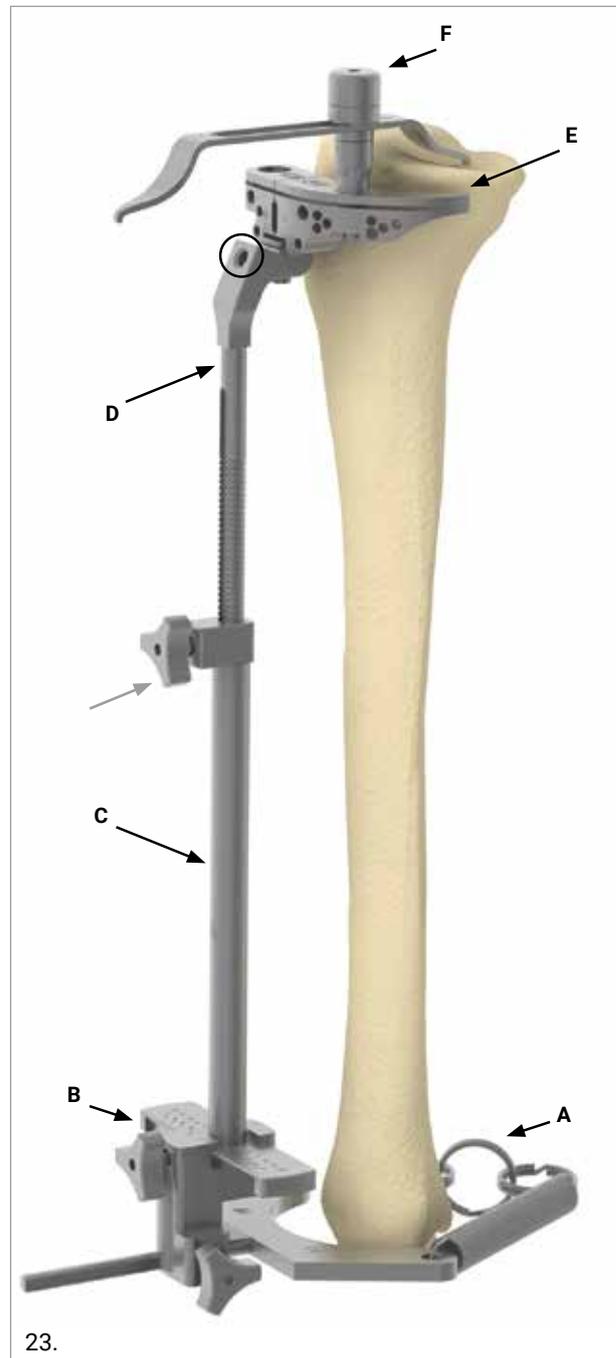
Mark also the anterior-posterior axis that passes through the center of the tibia and parallel to the A/P axis of the lateral compartment.

This will be the reference to adjust the rotation of the tibial cutting block.



5.2 ASSEMBLING THE EXTRAMEDULLARY GUIDE

The extramedullary guide consists of the following components:



- Malleolar clamp (A)
- Malleolar clamp support (B)
- Tibial resection guide distal part (C)
- Eyeballing extramedullary superior guide (D)
- Tibial slotted cutting guide (E)
- Tibial stylus (F)

Select the tibial slotted cutting guide which corresponds to the operative side (left or right). Fix the slotted tibial cutting guide to the extramedullary eyeballing superior guide using the set screw provided (black circle). Insert the malleolar clamp (A) into the malleolar clamp support (B). Slide the distal part of the tibial resection guide (C) into the malleolar clamp support. Then slide the eyeballing extramedullary superior guide (D) into the distal part of the tibial resection guide.

Secure the malleolar clamp around the ankle.

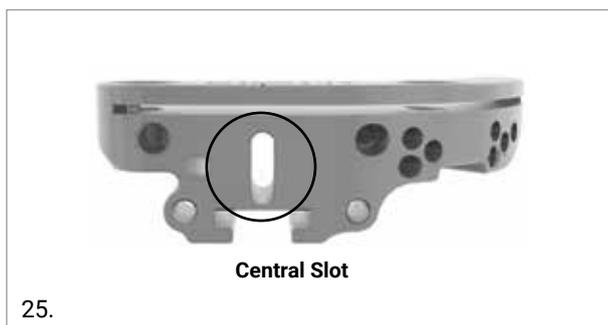
Position the assembly on the tibia and adjust the frontal rotation. The mark engraved on the top of the tibial slotted cutting guide should be aligned to anterior-posterior axis of the lateral tibial condyle previously marked.



Adjust the distance of the rods to the length of the patient's tibia and fix with the knob provided (grey arrow). A stylus (F) is provided to check the tibial resection level.

OPTION

Once the tibial slotted cutting block is positioned on the tibia, insert a pin into the central slot to fix the rotation. Inserting this pin will still allow adjustment of the tibial slope and varus/valgus.



CAUTION

The cutting block does not have a built-in slope, i.e. when the extramedullary jigs are aligned with the tibial axis, the system provides a slope of 0°.

5.3 SETTING THE TIBIAL VARUS/VALGUS WITH THE EXTRAMEDULLARY GUIDE

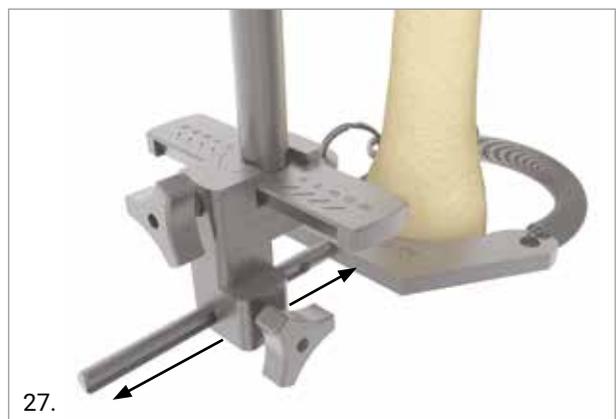
TIP

Set the varus-valgus orientation of the tibial resection parallel to the articular surface of the native tibia compensating for cartilage and bone wear. Translating the malleolar clamp support 15 mm lateral sets the guide to ~ 3° varus to the tibial mechanical axis. Visually fine-tune the varus/valgus setting of the tibial cutting guide looking at the tibia articular surface.



5.4 SETTING THE TIBIAL SLOPE WITH THE EXTRAMEDULLARY GUIDE

Place an angel wing in the saw slot of the slotted tibial cutting guide. Set the tibial slope by sliding the distal part of the malleolar clamp support along the malleolar clamp rod until the angel wing is parallel to the slope of the medial joint line after compensating for cartilage and bone wear.



It is recommended to avoid any excessive posterior slope, and it is important to check that no anterior slope is introduced.

5.5 SETTING THE TIBIAL RESECTION LEVEL WITH THE EXTRAMEDULLARY GUIDE

Fix the tibial stylus into the dedicated hole on the cutting guide. One side of the stylus allows to make a 8 mm cut from the less worn tibia plateau, and the other side to make a 2 mm from the most worn plateau.

Set the proximal-distal translation of the tibial component by adjusting the level of the saw slot until the 8 mm side of the tibial stylus contacts the center of the less worn tibial condyle.

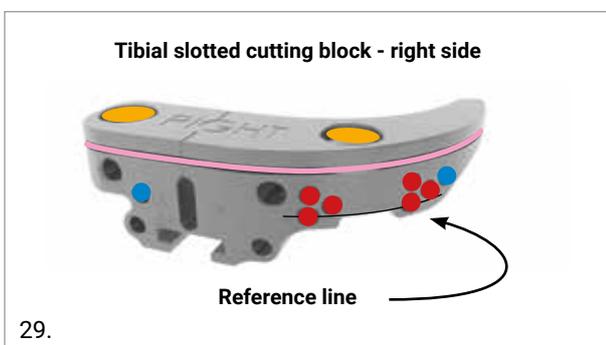


The goal is to perform a conservative resection that allows for any corrections or recuts that might be necessary to re-establish soft tissue balance.

5.6 STABILIZATION OF THE TIBIAL CUTTING BLOCK

Check the cut height and posterior slope using the angel wing before fixing the tibial cutting block.

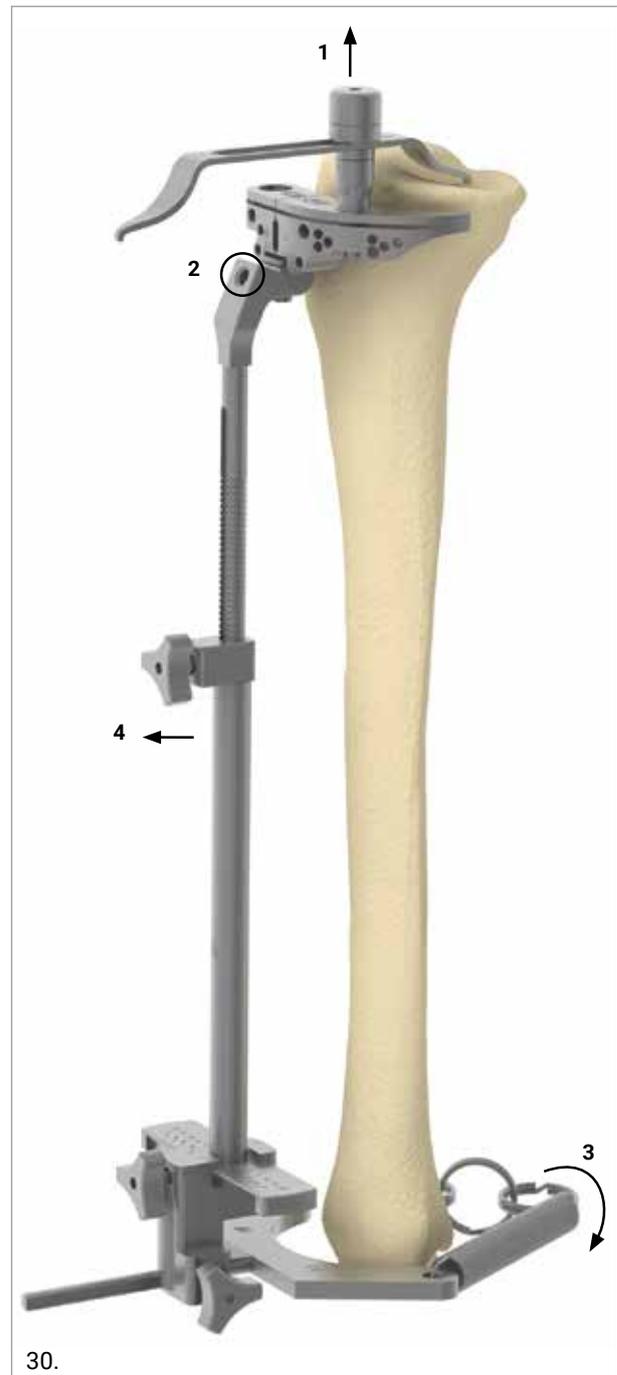
Pin the block to the tibia by using the two parallel positioning holes marked with a line and one oblique fixation hole.



- Parallel positioning holes
- Oblique fixation holes
- Tibial stylus holes
- Sawblade slot

5.7 REMOVING THE EXTRAMEDULLARY GUIDE

Remove the stylus by pulling it upwards (1). Unlock the frontal screw of the extramedullary guide body (2). Open the malleolar clamp (3) and remove the construct from the patient (4).



5.8 TIBIAL RESECTION

Bring the tibial cutting guide into contact with the tibia by sliding it along the pins. If an increase in stability is required, a third oblique pin can be introduced through the oblique hole of the tibial slotted cutting block.



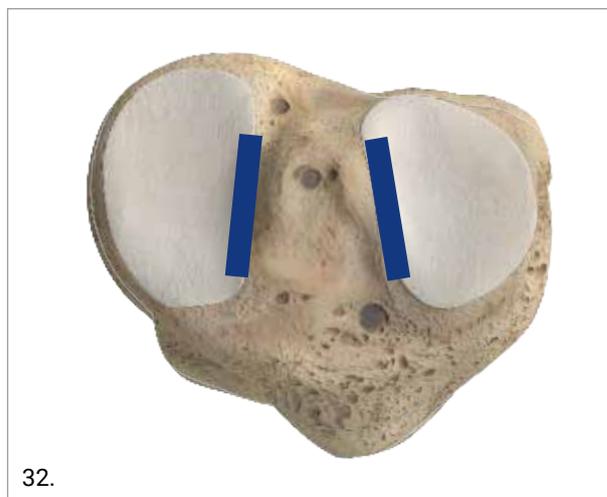
CAUTION

Check that the rotation and varus/valgus of the tibial cutting guide has not changed during disassembly of the guides before performing the resection.

Finally, perform the tibial proximal resection by cutting with a 1.27 mm thickness saw blade through the slot built into the guide. Slide the tibial cutting block over its two parallel pins and remove it.

VERIFICATION CHECK

Measure the thickness of the resected medial and lateral tibial condyles at the base of the tibial spines. This two measurements should be equal ± 0.5 mm. When one tibial condyle is thinner than the other by 1 mm or more, expect tightness in that compartment and/or slackness in the other when assessing varus-valgus laxity with the knee in full extension. Confirm the slope of the medial tibial resection is parallel to the native slope after compensating for wear. Any adjustment is performed only after checking the flexion/extension gap, as described in the following sections.



6. FLEXION GAP CHECK

Test the flexion gap using the flexion-extension spacers (available thicknesses: 10, 11, 12, 13, 14 mm). Use the side marked as "FLEX".

At 90° of flexion lateral laxity should be higher than medial laxity, which matches the native laxities of the knee.



VERIFICATION CHECK

Assess the relative tightness between the medial and lateral compartments by internally and externally rotating the spacer. The spacer should fit tight and pivot about the medial compartment and fit loose in the lateral compartment. This tighter medial/looser lateral fit indicates a trapezoid shaped flexion space like the native knee.

7. EXTENSION GAP CHECK

Test the extension gap with the flexion-extension spacer (available thicknesses: 10, 11, 12, 13, 14 mm). Use the side marked as "EXT".



Retract the medial and lateral soft-tissues and view the interfaces between the femoral resection, spacer, and tibial resection. Manually apply a varus-valgus stress with the knee in full extension.

Confirm that laxity is negligible.

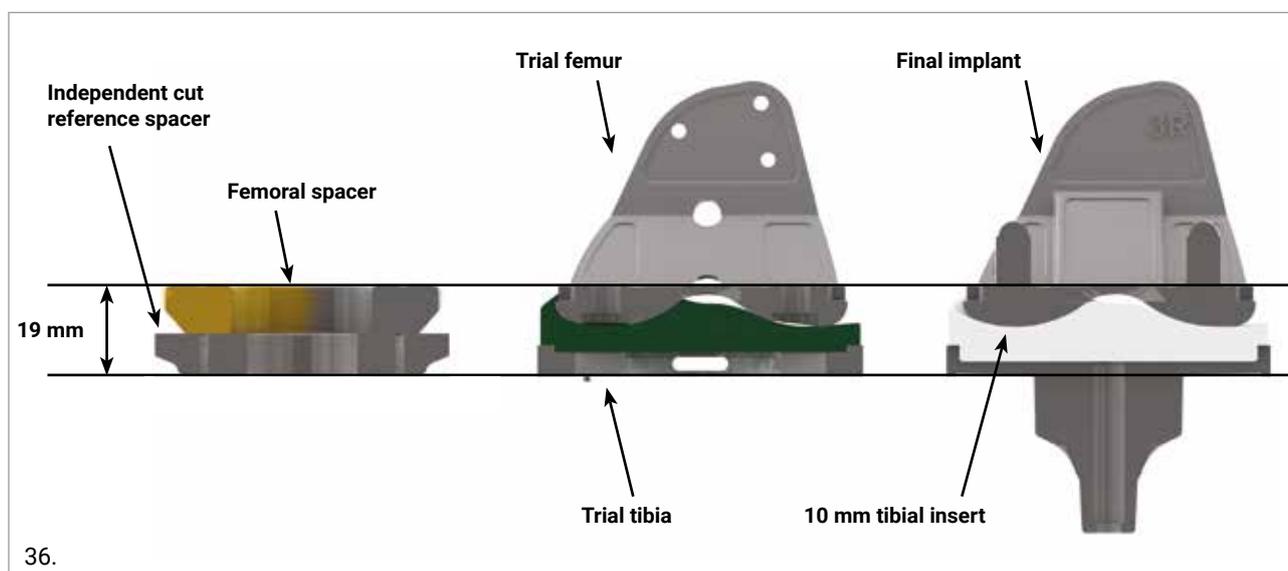
OPTION

As an alternative, modular spacers can be used in order to check the extension gap. The femoral spacer simulates the thickness of the femoral component, while the independent cut reference spacer simulates the thickness of the tibial component plus the minimum 10 mm insert. Assemble the independent cut reference spacer with the femoral spacer and the removable handle and introduce it into the joint space.



In case of laxity, the thickness of the different PE inserts (11, 12, 13, 14, 17 and 20 mm) can be simulated by using different tibial spacers (11, 12, 13, 14, 17 and 20 mm).

The femoral spacer must be fixed to the reference spacer on the side marked "FEMORAL". Similarly, the tibial spacer must be fixed to the reference spacer on the side marked "TIBIAL".



VERIFICATION CHECK

At 0° of flexion varus/valgus laxity should be minimized and native knee and limb alignments should be restored. The medial and lateral gaps should be equally stable when applying the varus-valgus stress, which restores both a tight rectangular extension gap and the compartment forces like the native knee.

CAUTION

If 1 or 2 mm washers were used in combination with the 4in1 block, an equivalent laxity should be allowed when evaluating the thickness of the tibial insert.

If necessary, a 2 mm recut can be performed through the dedicated block. Position the block on the cut surface and stabilize it inserting two pins in the fixation holes before cutting.



If a correction is needed to restore a tight rectangular gap, follow the steps below.

TIGHT MEDIAL & LOOSE LATERAL IN EXTENSION	TIGHT LATERAL & LOOSE IN MEDIAL EXTENSION
Remove medial osteophytes.	Remove lateral osteophytes.
Reassess.	Reassess.
Recut tibia in 1° - 2° more varus.	Recut tibia in 1° - 2° more valgus.
Insert 1 mm thicker spacer.	Insert 1mm thicker spacer.

Varus and valgus adjustments of 2° can be performed through the dedicated blocks. Position the appropriate block on the cut surface and stabilize it inserting two pins in the fixation holes before cutting.



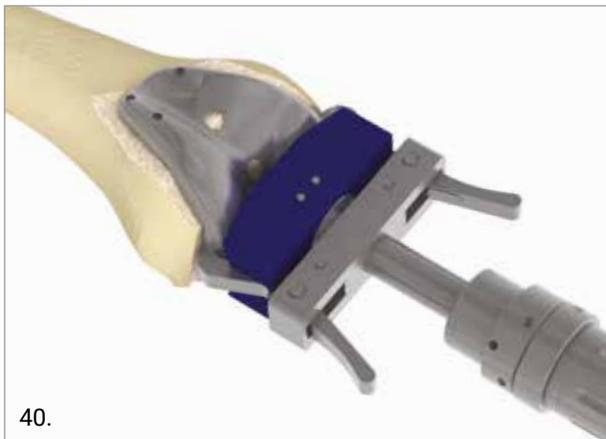
8. TRIAL REDUCTION

To position the tibial trial, attach the tibial trial insert of the correct thickness on the appropriately sized tibial trial.

Connect the removable handle and place the tibial trial on the tibial cut plane. The tibial baseplate is asymmetrical. Rotate the baseplate until the best coverage of the tibial cortical bone is achieved.

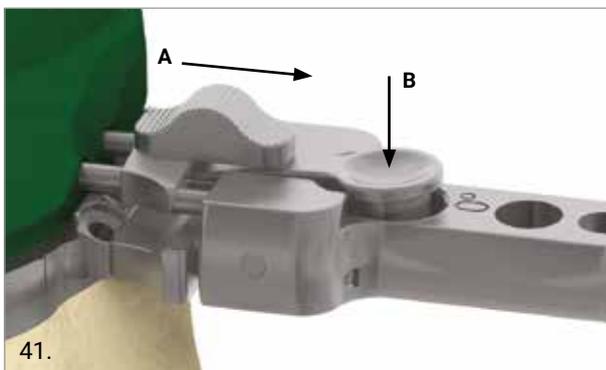


Assemble the femoral impactor/extractor on the slide hammer and impact the appropriate size trial femur centering it on the anatomical notch. Ensure medial or lateral overhang is minimized.



To change the thickness of the tibial trial insert, pull the lever (A) and substitute with a more appropriate trial insert.

Remove the handle by pressing the button (B) and reduce the patella. Test the knee by moving it through its full range of motion to ensure optimal tracking of the components.



CAUTION

During trialing, remove the trial femur before changing the trial insert. Changing the trial insert with the trial femur in place could be difficult due to the conformity of the medial compartment.

8.1 BALANCE THE TKA WITH TRIAL COMPONENTS

If corrections are needed, a stepwise alignment algorithm determines the actions to achieve kinematic alignment. The underlying principle of this algorithm is that the corrections requiring a recut of bone are performed by fine-tuning the varus/valgus, slope, and proximal-distal positions of the tibial resection, and not by recutting the femur.

Balance the knee in full extension, 15-20° of flexion, and 90° of flexion referring to the steps in the GMK Sphere CS and Sphere CR Decision-Trees below.

Balance the TKA in Full Extension and 15-20° of Flexion

Place the knee in full extension. Confirm the knee fully extends without a flexion contracture.

Retract the medial and lateral soft-tissues and examine the interface between the femoral component and insert. Manually apply a varus-valgus stress. Confirm the laxity is negligible and increase insert thickness if needed.

Flex the knee 15-20°. Confirm the lateral compartment opens ~2 mm more than the medial compartment.

Balance the TKA in 90° of Flexion

Place the knee in 90° of flexion. Manually distract the tibia from the femur, apply a posterior drawer test. Confirm the knee is stable. If corrections are needed, refer to the steps in the GMK Sphere - Flex Insert and GMK Sphere - CR Insert decision trees below.

CAUTION

When using GMK Sphere Flex insert, confirm complete resection of the posterior cruciate ligament.

VERIFICATION CHECK

When using the GMK Sphere CR insert, confirm the A-P offset matches the offset measured at the time of exposure. When the A-P offset is greater than at exposure and the knee is tight in flexion and well-balanced in extension, recheck the tibial slope and insert thickness. Refer to the steps in point 4 in the GMK Sphere - CR Insert decision trees below.

When the A-P offset is less than at exposure and the knee is well-balanced in extension and loose in flexion, recheck the integrity of the posterior cruciate ligament, the tibial slope, and the insert thickness. Refer to the steps in point 6 in the GMK Sphere - CR Insert decision trees below.

It is possible to adjust the posterior slope (+/- 2°) using the dedicated recut block. Ensure that the correction cutting blocks are positioned on the same row of holes used to perform the initial tibial resection.



After any correction is applied, check again the extension and flexion gaps.

GMK SPHERE DECISION-TREE - FLEX INSERT

		FLEXION		
		Tight	Ok	Loose
EXTENSION	Tight	1	2	3
	OK	4	5	6

1. If the joint is tight both in extension and flexion recut tibia and remove 1-2 mm more bone (or if possible decrease the thickness of the articular surface)
2. If the joint is tight in extension and well balanced in flexion:
 - Remove posterior femoral osteophytes.
 - Strip posterior capsule.
 - Insert trial component and gently manipulate knee into extension.
 - Reassess.
 - Resect additional proximal tibial bone with decreased posterior slope and increase the thickness of the articular surface.
3. If the joint is tight in extension and loose in flexion:
 - Remove posterior osteophytes.
 - Strip posterior capsule.
 - Insert trial component and gently manipulate knee into extension.
 - Reassess.
 - Resect an additional 2 mm from the distal femur and use a 2-mm thicker liner. *
4. If the joint is well balanced in extension and tight in flexion:
 - Confirm complete resection of the PCL.
 - Increase posterior slope.
5. If the joint is well balanced both in extension and flexion no further modifications are necessary.
6. If the articulation is well balanced in extension and loose in flexion:
 - If still loose in flexion reduce slope or resect 1 - 2 mm bone from distal femur and add thicker Sphere CS insert.
 - Add thicker spacer and recheck knee extends fully.
 - Remove posterior osteophytes.
 - Strip posterior capsule.
 - Insert trial component and gently manipulate knee into extension.
 - Reassess.
 - Resect additional proximal tibial bone with decreased posterior slope and increase the thickness of the articular surface.

* This approach requires the surgeon to accept that raising the femoral joint line by 2 mm violates the kinematic alignment goal of restoring the native tibial-femoral articular surfaces

GMK SPHERE DECISION-TREE - CR INSERT

		FLEXION		
		Tight	Ok	Loose
EXTENSION	Tight	1	2	3
	OK	4	5	6

1. If the joint is tight both in extension and flexion recut tibia and remove 1-2 mm more bone (or if possible decrease the thickness of the articular surface)
2. If the joint is tight in extension and well balanced in flexion:
 - Remove posterior osteophytes.
 - Strip posterior capsule.
 - Insert trial component and gently manipulate knee into extension.
 - Reassess.
 - Resect additional proximal tibial bone with decreased posterior slope and increase the thickness of the articular surface.
3. If the joint is tight in extension and loose in flexion:
 - Remove posterior osteophytes.
 - Strip posterior capsule.
 - Insert trial component and gently manipulate knee into extension.
 - Reassess.
 - Resect an additional 2 mm from the distal femur and use a 2-mm thicker liner. *
4. If the joint is well balanced in extension and tight in flexion, increase posterior slope until native A-P offset is restored at 90° of flexion.
5. If the joint is well balanced both in extension and flexion no further modifications are necessary.
6. If the articulation is well balanced in extension and loose in flexion:
 - When knee does not fully extend check PCL tension.
 - When PCL is incompetent use Sphere Flex insert.
 - Add thicker spacer and recheck knee extends fully.
 - Remove posterior osteophytes.
 - Strip posterior capsule.
 - Insert trial component and gently manipulate knee into extension.
 - Reassess
 - Resect additional proximal tibial bone with decreased posterior slope and increase the thickness of the articular surface.

* This approach requires the surgeon to accept that raising the femoral joint line by 2 mm violates the kinematic alignment goal of restoring the native tibial-femoral articular surfaces

8.2 TIBIAL BRIDGE TRAY

In some cases, if different femur and tibia sizes are required, the surgeon should use the trial bridge tray.

The trial bridge tray is a baseplate which allows the use of an insert with a different size to the tibia.

Two main cases are considered:

Case A: femur size 3 and tibia size 4.



Because the size 3 femoral implant is compatible with size 3 insert, it is not possible to use a size 4 tibial implant (compatible only with size 4 insert). In this case the surgeon should use t4-i3 trial bridge tray, which has the same coverage in AP and ML of a size 4 tibial implant and must be used with a size 3 insert.

CAUTION

If a size 4 tibial implant is going to be implanted with a femur of a smaller size (3+, 3, 2+, 2, 1+, 1) a bridge tibial tray t4-i3 must be used.

Case B: femur size 4 and tibia size 3.



Because the size 4 femoral implant is compatible with size 4 insert, it is not possible to use a size 3 tibial implant (compatible only with size 3 insert). In this case the surgeon should use t3-i4 Trial bridge Tray, which has the same coverage in AP and ML of a size 3 tibial implant and must be used with a size 4 insert.

CAUTION

If a size 3 tibial implant is going to be implanted with a femur of a larger size (4, 4+, 5, 5+, 6, 6+ or 7) a bridge tibial tray t3-i4 must be used.

For compatibility chart refer to chapter 11.

9. FINISHING THE FEMUR AND TIBIA

9.1 FEMORAL FINISHING

Once trial reduction has been deemed satisfactory, secure the femoral trial by inserting two pins into the anterior holes. Drill the holes for the femoral pegs through the holes in the distal condyles of the femoral trial.



CAUTION

Clear the posterior condyles from any osteophytes and any overhanging bone that could impinge during flexion, especially in the medial compartment.

Remove the pins and the femoral trial. Prepare the femoral trochlear-milling guide: the size of the femoral implant can be selected turning the screw inside the blue circle. Sizes 1, 3 and 5 are shown on the right scale, while sizes 2, 4 and 6 can be selected on the left scale.

When implanting a size 7 femoral implant, size 6 must be selected on the femoral trochlear-cutting guide, as peg position does not change between the two sizes. Please note that peg position does not change between size 1 and 1+, 2 and 2+, and so on.

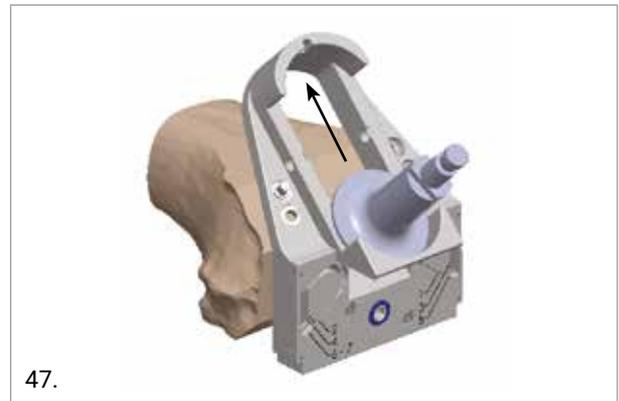


● Fixation holes

Position the trochlear-milling guide on the distal resection plane using the built-in pegs and insert two pins into the fixation holes. For enhanced stability, it is recommended to use a different row of pin holes on the medial and lateral side of the guide. Position the reamer at the lower end of the reaming guide and ream the femoral box by sliding the reamer upwards onto the guide.

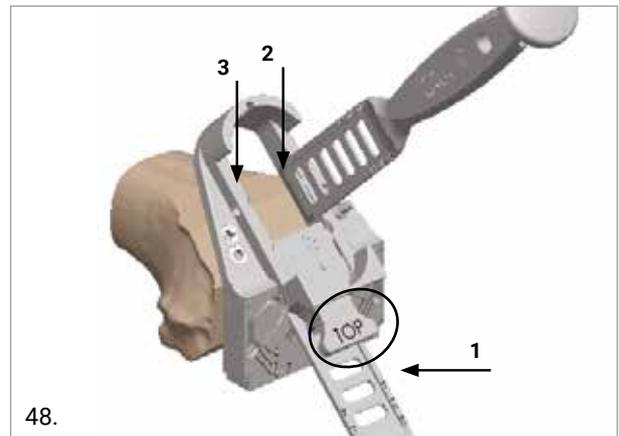
CAUTION

The reaming guide might overhang the anterior cut, depending on femoral size. Reaming should be stopped when bone contact is lost, even though the upper end of the guide has not been reached. Make sure to stop reaming before coming in contact with the anterior femoral soft tissues to avoid damaging them.



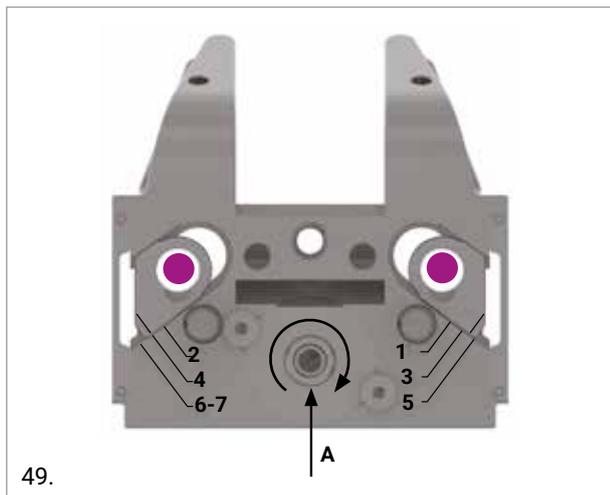
OPTION

The femoral trochlear-milling guide can be used also with the osteotome. Assemble the adapter ensuring the "TOP" mark is facing up. Perform the cuts following the sequence shown in the figure to finish the trochlea.



Option : osteotome

Femoral finishing can be performed with the osteotome by using the femoral trochlear-cutting guide.

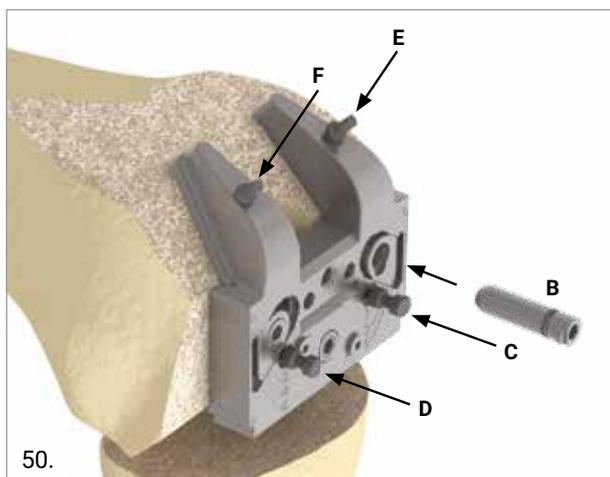


49.

● Femoral peg holes

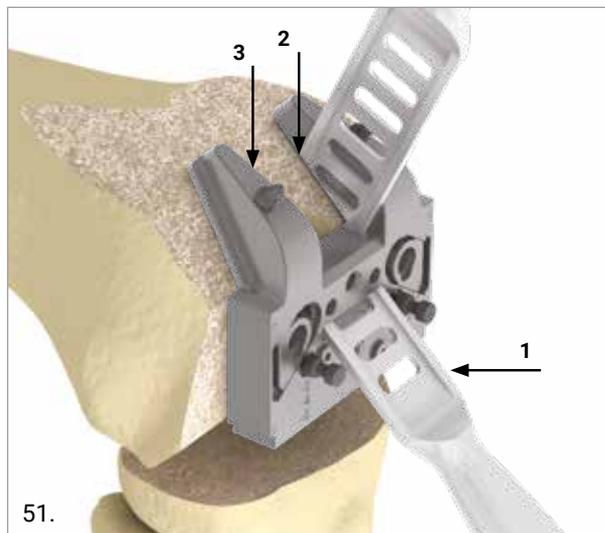
Remove the femoral trial, and prepare the femoral trochlear cutting guide by turning the screw (A) and selecting the size of the femoral implant. Sizes 1, 3 and 5 can be selected on the right scale, while sizes 2, 4 and 6 can be selected on the left scale. When implanting a size 7 femoral implant, size 6 must be selected on the femoral trochlear-cutting guide, as peg position does not change between the two sizes. Please note that peg position does not change between size 1 and 1+, 2 and 2+ and so on.

Place the femoral trochlear-cutting guide on the resected femur and insert two pegs into the previously drilled holes (B). Use the built-in pins to stabilize the femoral trochlearcutting guide (C,D). For enhanced stability, insert two additional pins into the anterior holes of the guide (E,F).



50.

Perform the cuts following the sequence shown in the figure to finish the trochlea.



51.

9.2 FEMORAL FINISHING CHECK

Remove the femoral trochlear milling guide and check the performed femoral box cut by superimposing the box cut verifier on the trochlea. The femoral box cut is correct if the medial and lateral flanges of the box cut verifier are flush with the femoral bone. If a correction is needed, refine the cut using the manual rasp.



52.

OPTION

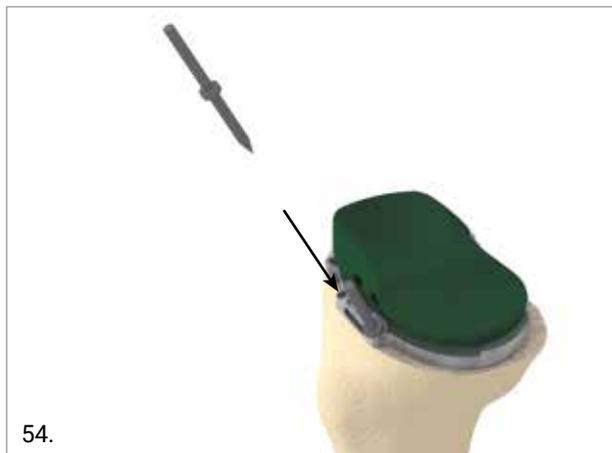
The femoral box cut can be checked using the manual rasp (ref. 02.02.10.0173). Remove the femoral trochlear milling guide and lay the rasp on the base of the femoral box. The cut is correct if the upper surface of the manual rasp and the femoral bone are flush. If a correction is needed, refine the cut using the manual rasp.

9.3 TIBIAL FINISHING



53. The pins should always be placed in the opposite position: one anteriorly and one posteriorly on tibial surface.

Alternatively, the tibial trial can be fixed using two frontal pins which can be inserted with the trial insert in place.



CAUTION

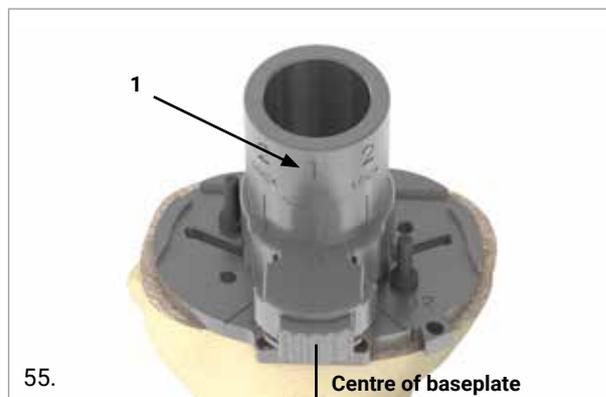
During trials, remove the trial femur before changing the trial insert. Changing the trial insert with the trial femur in place could be difficult due to the shape of the medial compartment.

It is fundamental to perform the trial reduction and find the correct position of the tibial trial in order to centre the spherical medial femoral compartment on the spherical medial tibial plateau.

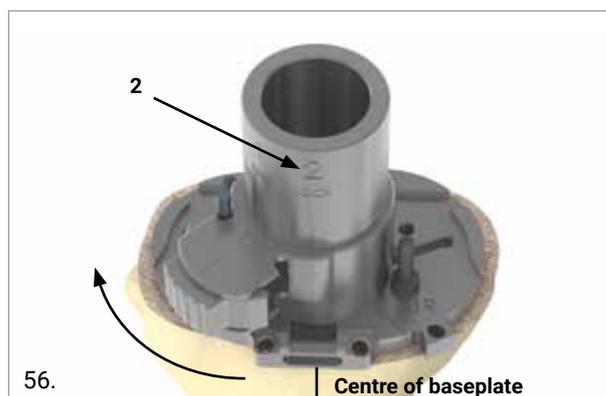
In order to help identify the correct position of the tibial baseplate two lines are marked on the anterior wall of the tibial implant, corresponding to the alignment lines on the trial tibial baseplate. Once the trial baseplate is fixed, identify the position of these two lines on the tibia by electrocautery.

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

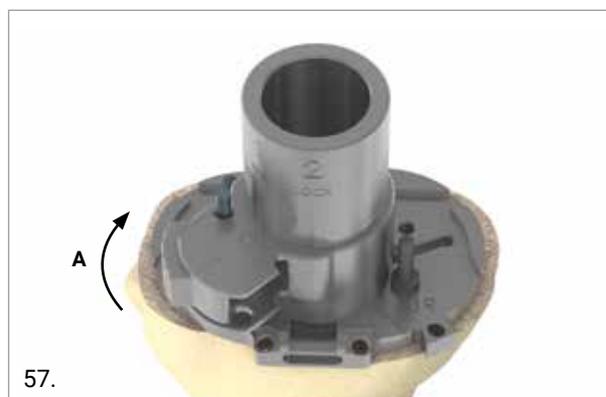
- Position the reamer guide on the trial tibial baseplate aligning mark (1) to the centre of the baseplate.



- Turn the reamer guide aligning mark (2) to the centre of the baseplate.



- Push button (A) to fix the barrel onto the anterior pin.



Once the barrel is firmly locked to the pin, proceed to the tibial reaming using the conical reamer provided. Insert the dedicated reamer into the guide and prepare the keel hole parallel to the axis of the bone until the depth stop is reached. To remove bone use the reamer clockwise, to compact bone use the reamer counter clockwise (no bone is excised).



Remove the reamer guide by 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.



9.4 TIBIAL STEM EXTENSION

For additional tibial baseplate stability (if required) a stem extension can be added to the tibial keel.

Two stem length options are available for primary TKA with GMK Sphere: 30 mm and 65 mm.

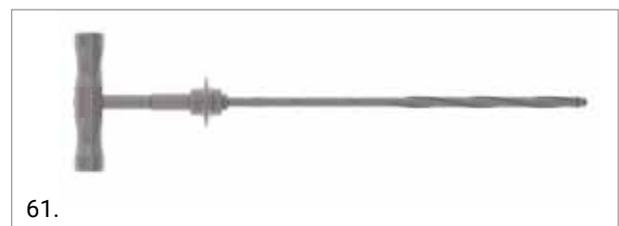
CAUTION

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.

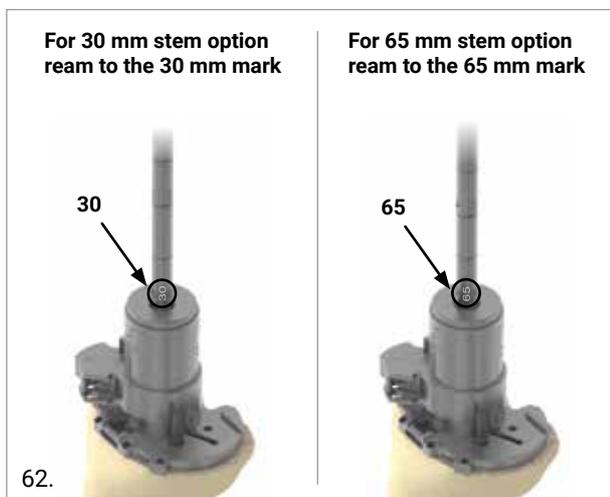
Remove the trial keel from the bone. Assemble the reamer guide on the trial tibial baseplate and insert the 11 mm reduction bush in it. Open the intramedullary canal with the help of the 9 mm drill bit, if needed.



Assemble the T-handle with the 11 mm reamer.



Ream the canal until the correct depth is reached.



Remove the 11 mm reduction bush and insert the 15.5 mm reduction bush in the reamer guide assembled on the trial baseplate and finish the keel preparation using the 15.5 mm 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.

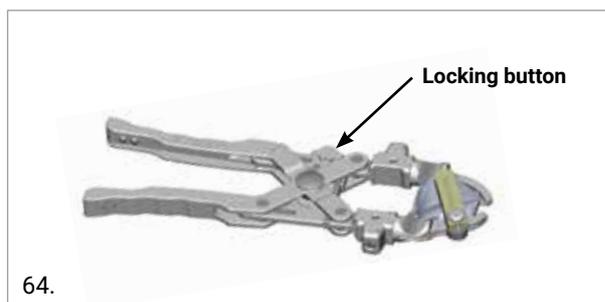
10. PATELLA

There are two options when dealing with the patella. The patella can be either resurfaced or denervated. Both techniques appear to give good results. The disadvantage of resurfacing the patella is that the patella is weakened because of the amount of bone that is necessarily removed to accommodate an implant. This results in a patella that is more prone to fracture than a non-resurfaced patella and repairing such fractures can be difficult. However, whether or not the surgeon resurfaces the patella it is essential that the patella tracks correctly in the trochlear groove of the femoral component. There are occasions when the loss of patellar bone is such that correct tracking of the patella can only be obtained when the patella is resurfaced. However the surgeon must understand that if patellar maltracking is present it is more likely to be due to tightness of the lateral patellar retinaculum which should be corrected by an appropriate release. To treat the patella two alternative options are available: resurfacing or inset patella.

Option 1: Resurfacing Patella

Insert the patella resection guides into the patella 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 one slot of the resection guide. The stylus should be in contact with the top of the patella dome allowing for a 10 mm fixed cut.

Then close the clamp handle until contact between the resection guides and the patella bone is made and lock the clamp with the button provided.



CAUTION

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

Perform the patellar resection through the slots of the resection guides.

OPTION

The patella size can be assessed using dedicated templates.

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



CAUTION

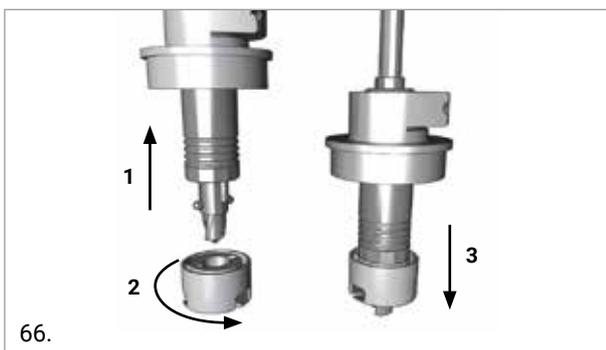
To correctly position the patellar component, its single peg has to be positioned on the lateral facet of the patella and the other two pegs on the medial facet once the patella is in place i.e. not luxated.

Apply the drilling guide on the resected surface of the patella and drill the three holes using the patellar pegs drill. Pressurize the trial resurfacing patella of the appropriate size, reduce the patella and test the knee through its full range of motion.

Option 2: Inset patella

Choose the size of the patella using the different reamer guides or the dedicated template set. 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, make the reamer is firmly fixed.



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



CAUTION

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

Pressurize the trial inset patella of the appropriate size, reduce the patella and test the knee through its full range of motion.

Finally, cement the patella implant using the clamp and the provided squeezer.



11. SELECTION OF THE PROSTHETIC COMPONENTS - SIZE MATCHING

GMK Fixed Tibial Trays can be matched with GMK Sphere Flex/CR Tibial Inserts and GMK Sphere Femoral Components according to Table 1.

Tibia bone size	GMK Fixed Tibial Trays	GMK Sphere Femoral Components						
		Sizes 1/ 1+	Sizes 2/2+	Sizes 3/3+	Sizes 4/4+	Sizes 5/5+	Sizes 6/6+	Size 7
1	Size 1	Insert* size 1	Insert* size 1	Insert* size 1				
2	Size 2	Insert* size 2	Insert* size 2	Insert* size 2				
3	Size 3	Insert* size 3	Insert* size 3	Insert* size 3				
	Size t3-i4**				Insert* size 4	Insert* size 4	Insert* size 4	Insert* size 4
4	Size t4-i3***	Insert* size 3	Insert* size 3	Insert* size 3				
	Size 4				Insert* size 4	Insert* size 4	Insert* size 4	Insert* size 4
5	Size 5				Insert* size 5	Insert* size 5	Insert* size 5	Insert* size 5
6	Size 6				Insert* size 6	Insert* size 6	Insert* size 6	Insert* size 6

Table 1

* GMK Sphere Flex/CR Tibial Insert

** Tibia size t3-i4 = Tibia size 3 for insert size 4

*** Tibia size t4-i3 = Tibia size 4 for insert size 3

All GMK Fixed Tibial Trays can be implanted with or without the extension stem.

All GMK Patellae can be implanted with all the sizes of GMK Sphere Femoral Components.

12. FINAL IMPLANT

Having completed all bone preparations and selected the definitive components these are opened in an aseptic manner and implanted with bone cement. It is generally easier to implant the tibial component first.

12.1 TIBIAL IMPLANT

The tibial implant 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 bone cement must be prepared according to the related instructions for use, provided by the cement manufacturer. Once the cement reaches the right viscosity, it must be applied only to the undersurface of the tibial implant into the corresponding cement pockets. If cement is applied directly to the bone please make sure it does not enter the keel hole. The final impaction is performed using the baseplate impactor, assembled with the slide hammer. 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. Once the tibial implant has been fully inserted using the dedicated impactor, the extruded cement is cleared from the tibia, carefully checking that no cement remains in the joint.

CAUTION

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

CAUTION

The tibial extension stem must not be coupled with TiNbN coated fixed tibial baseplates

12.2 INSERT

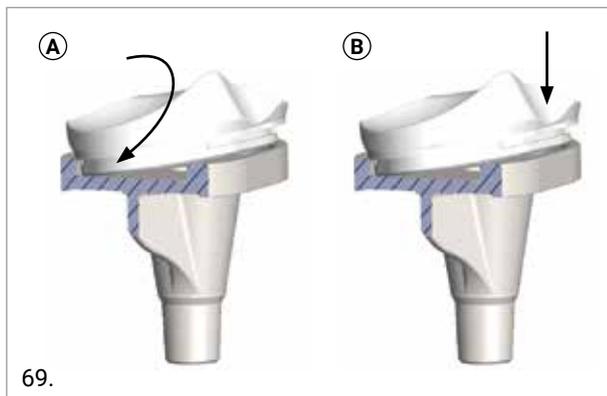
To verify the final height of the insert, prior to implanting the definitive tibial insert, the trial insert can be positioned on the final baseplate.

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)

CAUTION

Once the posterior lips of the insert are fully engaged into the posterior part of the tibial baseplate, apply downward pressure to clip it firmly in position. If difficulty is experienced whilst trying to clip the insert in place, remove and reposition it. A 'click' will be heard or felt when the insert is correctly connected.



WARNING

When using a GMK Sphere Flex insert, it can be further secured through an optional screw packaged together with it. If the screw option is chosen, the torque limiter screwdriver 3.5 N·m must be used to guarantee that the optimal locking of the screw is achieved.

12.3 FEMORAL IMPLANT

Attach the femoral impactor to the slide hammer. Open the femoral impactor jaw and attach it to the femoral component using the two lateral slots. Lock together by turning the handle firmly.

The bone cement must be prepared according to the cement manufacturer's instructions. Once the cement reaches the right viscosity, it must be applied to the internal surface of the femoral implant into the corresponding cement pockets. The resected bone surface should be thoroughly cleaned by pulse lavage and the intramedullary canal closed by cancellous bone. Position the femoral implant using the previously drilled peg holes for correct alignment and finish by impacting with the dedicated femoral impactor. Once the femoral implant 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.

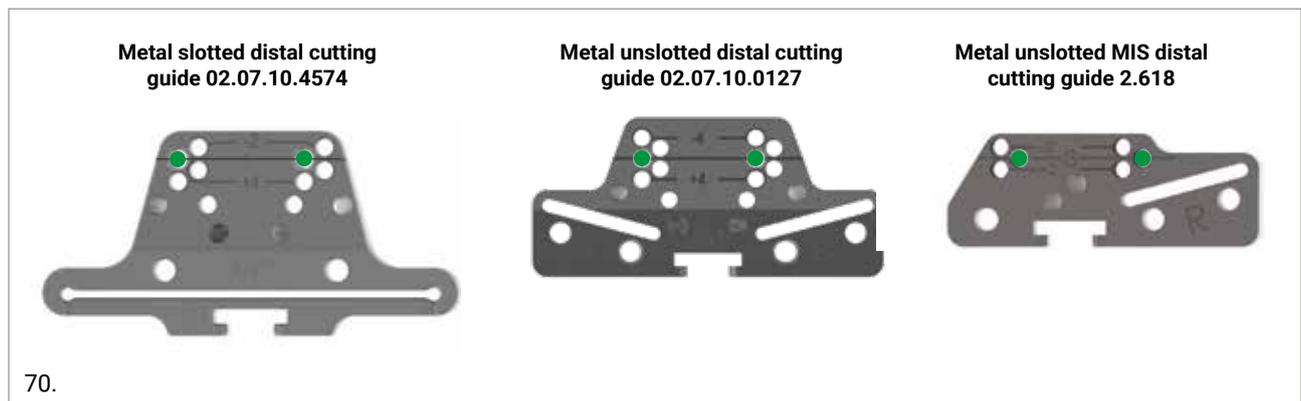
12.4 PATELLA

Assemble the spike jaw and the pressurizing jaw on the patellar clamp. The pressurizing jaw has the blue side specifically designed for the resurfacing patella. The bone cement must be prepared according to the cement manufacturer's instructions. Once the cement reaches the right viscosity, it should be applied to the internal surface of the patellar implant. Lock the patella, by firmly screwing the thumbwheel switch of the patellar clamp. Hold the implant in the final position and clear the extruded cement from the patella, ensuring that no cement remains on the articular surface.

13. ANNEX 1 UNSLOTTED GUIDE COMPATIBILITY

13.1 DISTAL FEMORAL RESECTION

In the table below is highlighted the compatibility between the metal slotted distal cutting guides and the metal unslotted distal cutting guides.

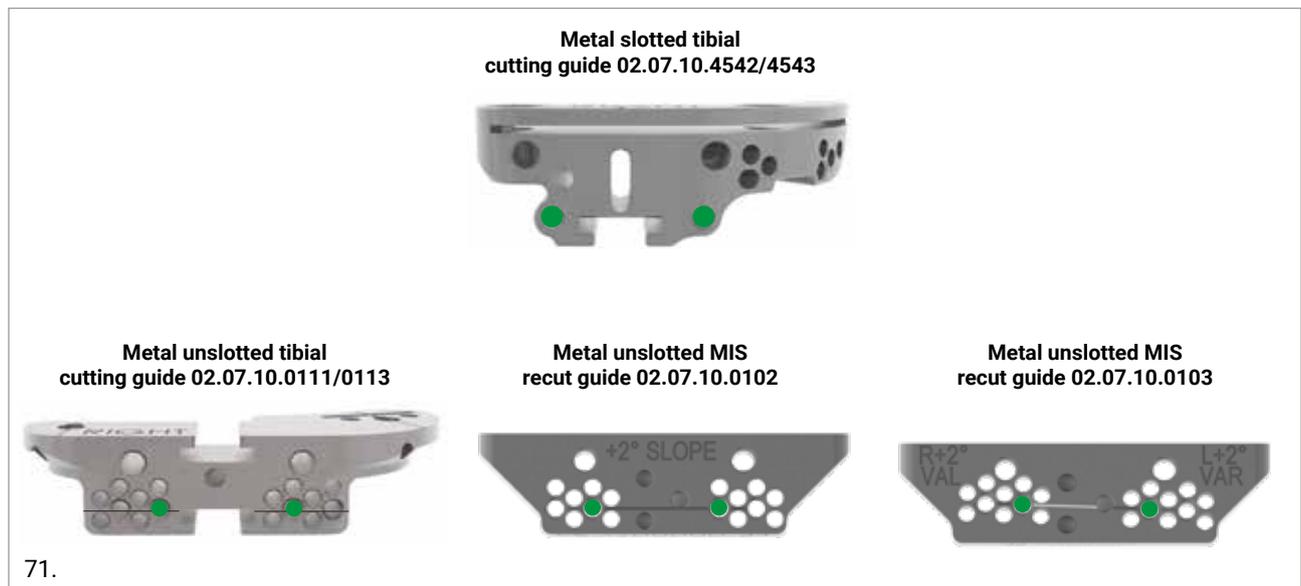


● Compatible holes

The unslotted cutting guide is compatible only with the unslotted distal cut positioner (ref. 02.07.10.0185).

13.2 PROXIMAL TIBIAL RESECTION

The compatibility between the unslotted metal distal cutting guides is highlighted in the table below.

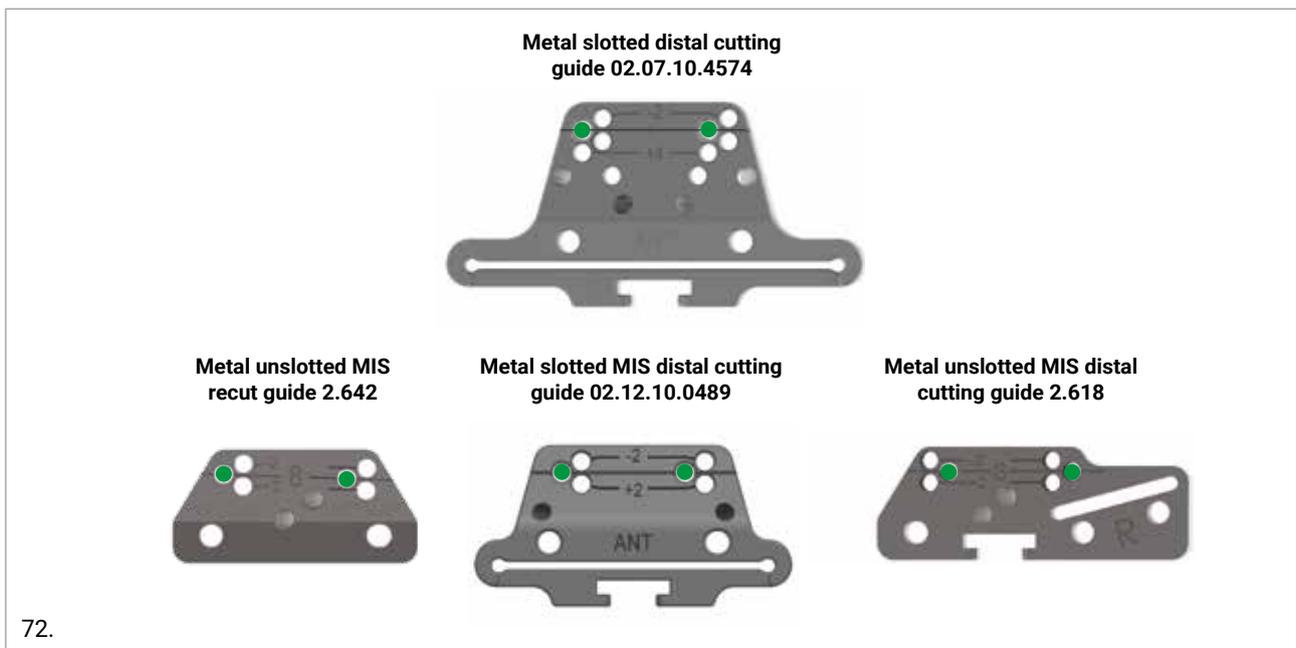


● Compatible holes

14. ANNEX 2 MIS GUIDE COMPATIBILITY

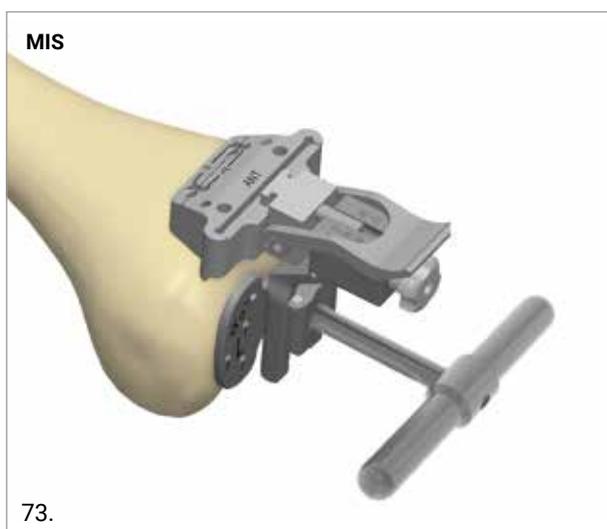
14.1 DISTAL FEMORAL RESECTION

The compatibility between the metal slotted distal cutting guides and the MIS metal distal cutting guide is highlighted in the table below.



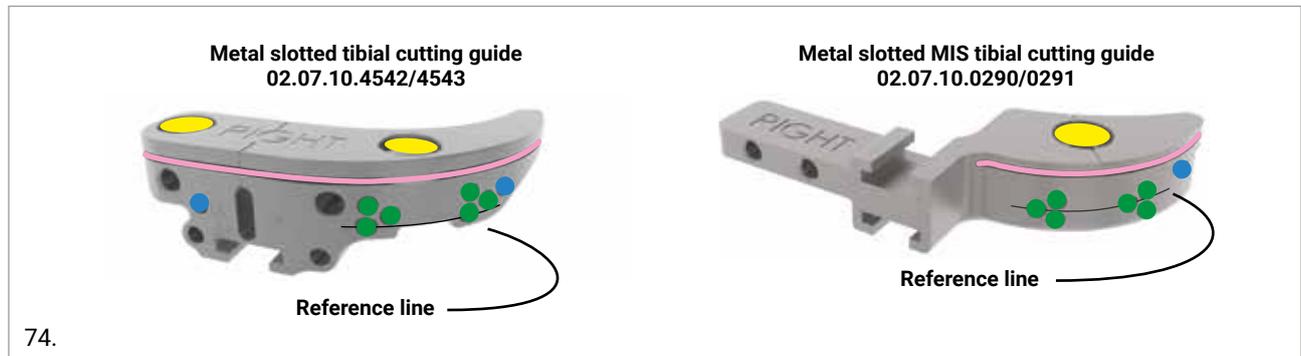
● Compatible holes

The MIS distal cutting block is intended for both left and right knees. Check that the correct side corresponding to the knee to be operated on, can be read on the anterior surface.



14.2 PROXIMAL TIBIAL RESECTION

The compatibility between the the metal slotted tibial cutting and the MIS metal distal cutting guide is highlighted in the table below.

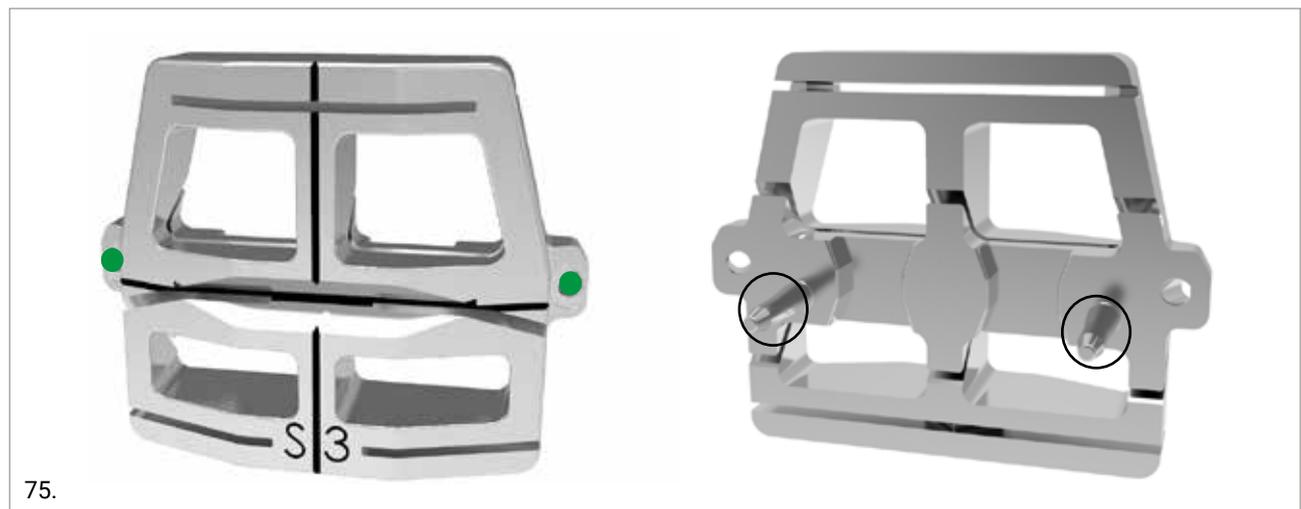


Tibial cutting block holes (right knee)

- Parallel positioning holes
- Oblique fixation holes
- Tibial styli holes
- Sawblade slot

15. ANNEX 3 4IN1 CUTTING BLOCK COMPATIBILITY

It is also possible to use 4in1 built-in pins to perform anterior cut, posterior cut and chamfers.

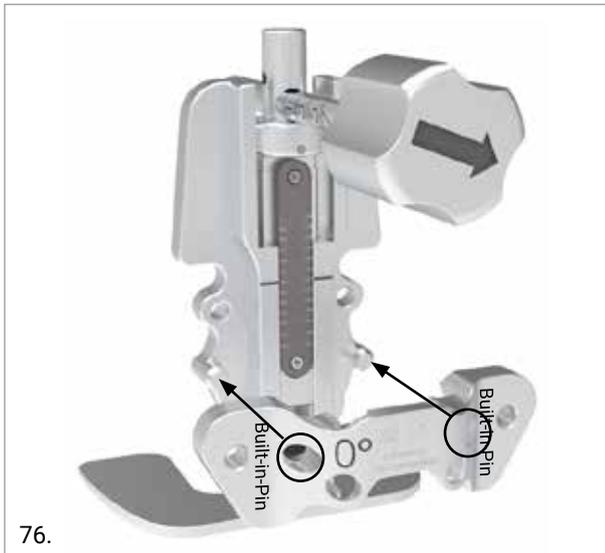


- Oblique fixation pins
- Built-in pins

A modular femoral sizer is available to position the 4in1 cutting block.

15.1 POSTERIOR REFERENCING: FEMORAL SIZING AND EXTERNAL ROTATION ADJUSTMENT

Connect the 0° rotational guide to the Posterior Referenced Multisize Femoral Sizer by sliding it onto the driven pins. A 'click' will be heard when it is fully engaged.



The posterior referencing femoral sizer is placed flat against the distal cut surface, with both the posterior condyles in contact to its base.



Close the sizer until the stylus is brought into contact with the anterior surface ridge of the lateral femoral cortex and the posterior plates are in contact with the medial and lateral posterior condyles.

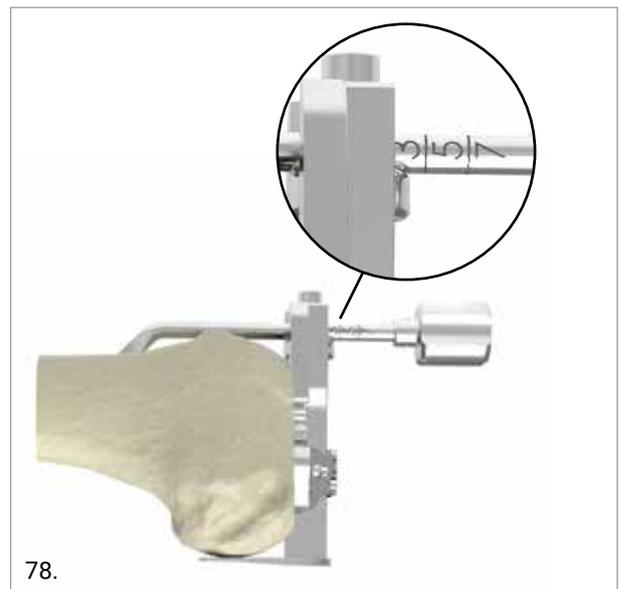
The position of the posterior referencing guide rarely requires correction because it is uncommon for the posterior femoral condyles to experience complete cartilage loss.

TIP

Insert an angel wing between the foot of the Posterior Referencing Femoral Sizer posterior to the worn femoral condyle when compensating for worn cartilage

The size of the femur can be seen on the front of the femoral sizer.

Refine the position of the sizer, by selecting the size of the femur on the anterior stylus.



15.2 POSTERIOR REFERENCING: 4IN1 CUTTING BLOCK POSITIONING



Femoral sizer holes:

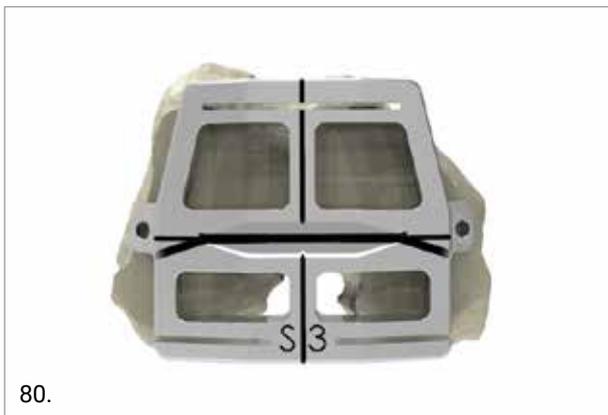
- Fixation holes
- Epicondylar axis reference holes
- 4in1 built-in pins drilling holes

Once the position of the sizer is satisfactory, drill the built-in pins holes through the dedicated holes of the femoral sizer (blue circles).

CAUTION

While drilling, ensure that contact between the femoral sizer and the distal resection is maintained.

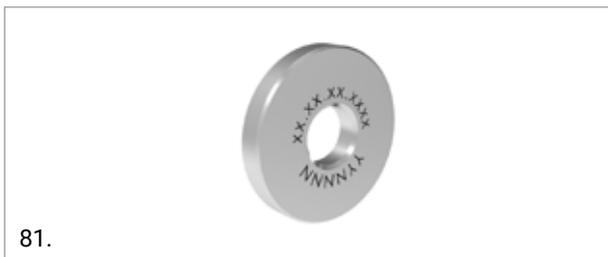
Finally, remove the femoral sizer and position the 4in1 cutting block of the correct size on the distal resection.



CAUTION

The position of the 4in1 built-in pins DOES NOT CORRESPOND to the position of the lugs of the femoral component. The holes for the final femoral component lugs are created through the trial femoral component.

If one or both distal condyles were over-resected, correct the position of the 4in1 block using the dedicated 1 and 2 mm washers.



To apply the washer, slide it over the posterior peg of the 4in1 block until it contacts the flat surface of the back of the 4in1 block. Confirm the washer lies flush.



Check the anterior and posterior resection level using the angel wing. Whether a femoral upsizing/downsizing or a 4in1 block repositioning is required, see the paragraph below.

15.3 FEMORAL UPSIZING/DOWNSIZING

The difference between successive femoral sizes is 2 mm in both anterior-posterior and mediolateral planes.

Posterior Referencing: upsizing/downsizing

Replace the cutting guide with the more suitable size. With posterior referenced guides, the level of the anterior resection will change. On the contrary, the posterior resection will be fixed.

CAUTION

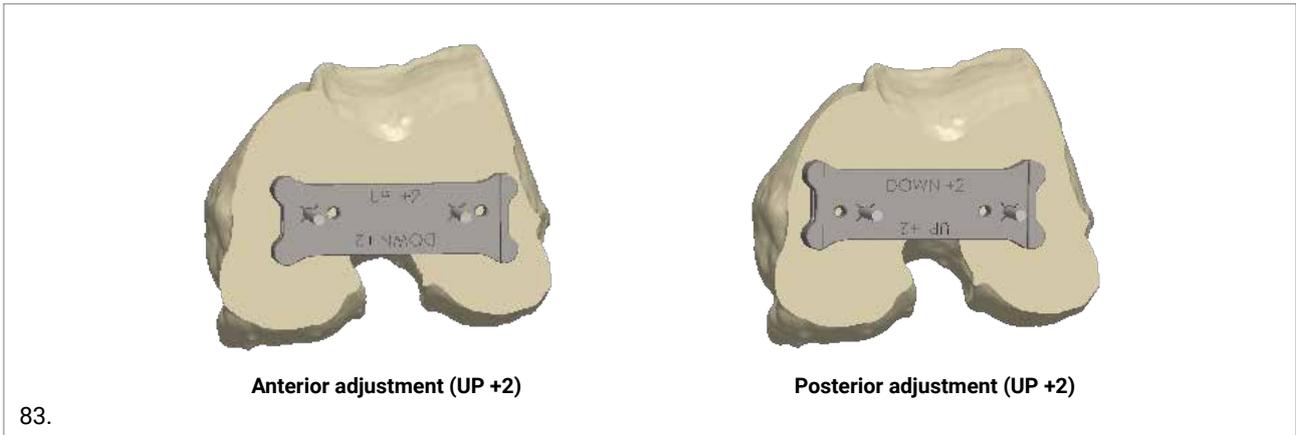
In the event of downsizing, the anterior resection level will move 2 mm posteriorly. Make sure that there is no anterior notching.

If it is necessary to move the guide of the chosen size in the anterior-posterior direction, use the repositioning plate (ref. 02.07.10.3965) for a 2 mm displacement of the guide.

CAUTION

The upward/downward movement of the 4in1 cutting block will affect the flexion gap.

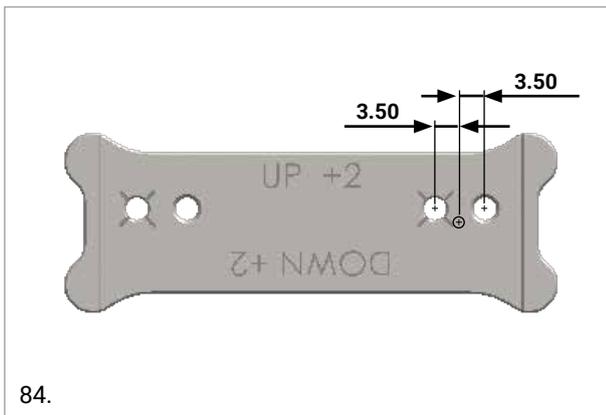
Remove the 4in1 cutting guide and place the repositioning plate on the distal resection using the same pin holes. For the upward/downward movement of the cutting block, place the repositioning plate as shown in the picture below:



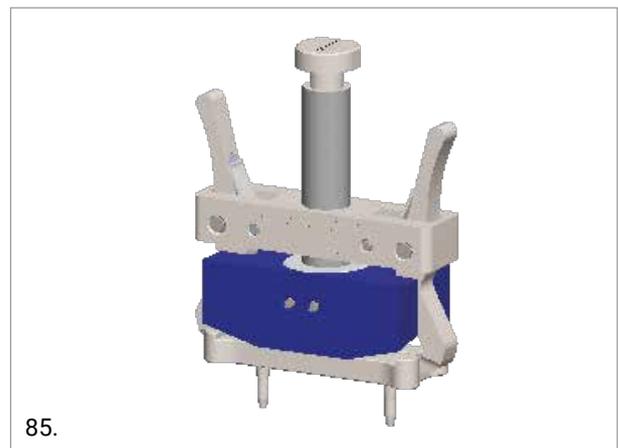
CAUTION

Use the pair of holes marked in the same manner (☒ ☒ or ○ ○) for a correct repositioning of the 4in1 cutting block built-in pins.

When using the repositioning plate the position of the 4in1 cutting block will be shifted 3.5 mm in mediolateral direction.



Drill the new holes and remove the repositioning plate. In order to facilitate the removal of the plate, the femoral impactor/extractor (ref. 02.02.10.0174) can be used. Assemble the femoral impactor to the slider hammer, grab the lateral grooves of the plate and pull it out.



Position the 4in1 cutting block on the distal resection using the new pair of holes.

Check the resection levels using the angel wing.

If the position is satisfactory, secure the 4in1 block using two headed pins inserted in the two oblique fixation holes and perform the femoral resection as below:

- Posterior condylar osteotomy
- Anterior condylar osteotomy
- Posterior chamfer
- Anterior chamfer

CAUTION

All femoral resections must be performed using a sawblade 13 mm wide and up to 1.27 mm thick.

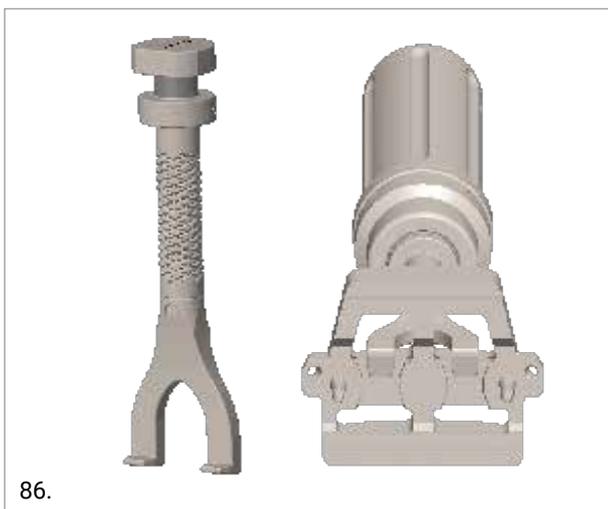
CAUTION

It is strongly recommended not to impact or hammer directly on the 4in1 guide. If the surgeon considers such action required, do not impact directly on the guide, use the impactor 02.07.10.2187.

Once the resections are complete, remove the 4in1 cutting block.

OPTION

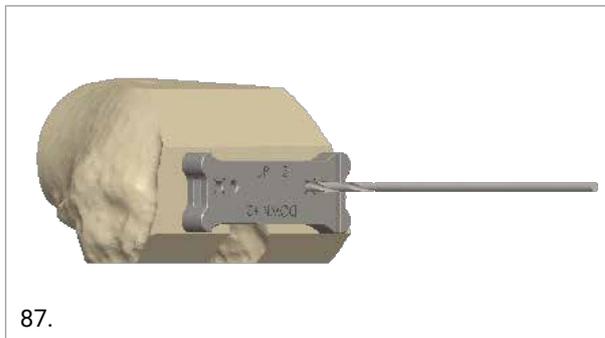
To facilitate the removal of the 4in1 cutting guide, a dedicated extractor (ref. 02.12.10.0187) is available. Assemble the extractor to the slide hammer, grab the 4in1 cutting block as shown in the picture below and pull it out.



Downsizing after femoral resections

If, despite soft tissue release, the flexion gap is still tight, a femoral downsizing may be needed.

Using the existing holes, place on the distal resection the repositioning plate (UP +2), drill a new pair of holes, remove the repositioning plate and position the next smaller 4in1 cutting block using the new holes.



The posterior resection will move 2 mm anteriorly. On the contrary, the level of the anterior resection is not changed.

Check the resection levels using the angel wing. If the cutting block position is satisfactory, fix the cutting block and perform the femoral resections as explained in the § 15.2.

16. IMPLANTS NOMENCLATURE

GMK SPHERE FEMUR CEMENTED

REF. LEFT	SIZE	REF. RIGHT
02.12.0001L	1	02.12.0001R
02.12.0021L	1+	02.12.0021R
02.12.0002L	2	02.12.0002R
02.12.0022L	2+	02.12.0022R
02.12.0003L	3	02.12.0003R
02.12.0023L	3+	02.12.0023R
02.12.0004L	4	02.12.0004R
02.12.0024L	4+	02.12.0024R
02.12.0005L	5	02.12.0005R
02.12.0025L	5+	02.12.0025R
02.12.0006L	6	02.12.0006R
02.12.0026L	6+	02.12.0026R
02.12.0007L	7	02.12.0007R

GMK SPHERE FEMUR CEMENTED TiNbN

REF. LEFT	SIZE	REF. RIGHT
02.12.0701L	1	02.12.0701R
02.12.0721L	1+	02.12.0721R
02.12.0702L	2	02.12.0702R
02.12.0722L	2+	02.12.0722R
02.12.0703L	3	02.12.0703R
02.12.0723L	3+	02.12.0723R
02.12.0704L	4	02.12.0704R
02.12.0724L	4+	02.12.0724R
02.12.0705L	5	02.12.0705R
02.12.0725L	5+	02.12.0725R
02.12.0706L	6	02.12.0706R
02.12.0726L	6+	02.12.0726R
02.12.0707L	7	02.12.0707R

GMK FIXED TIBIAL TRAY 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
02.12.T3i4L	t3-i4	02.12.T3i4R
02.12.T4i3L	t4-i3	02.12.T4i3R
02.07.1204L	4	02.07.1204R
02.07.1205L	5	02.07.1205R
02.07.1206L	6	02.07.1206R

GMK SPHERE TIBIAL TRAY CEMENTED TiNbN*

REF. LEFT	SIZE	REF. RIGHT
02.07.2801L	1	02.07.2801R
02.07.2802L	2	02.07.2802R
02.07.2803L	3	02.07.2803R
02.12.28T3i4L	t3-i4	02.12.28T3i4R
02.12.28T4i3L	t4-i3	02.12.28T4i3R
02.07.2804L	4	02.07.2804R
02.07.2805L	5	02.07.2805R
02.07.2806L	6	02.07.2806R

* TiNbN coated fixed tibial component must not be coupled with any stem extension.

GMK SPHERE FLEX TIBIAL INSERT - SIZE1

REF. LEFT	THICKNESS (mm)	REF. RIGHT
02.12.0110FL	10	02.12.0110FR
02.12.0111FL	11	02.12.0111FR
02.12.0112FL	12	02.12.0112FR
02.12.0113FL	13	02.12.0113FR
02.12.0114FL	14	02.12.0114FR
02.12.0117FL	17	02.12.0117FR
02.12.0120FL	20	02.12.0120FR

GMK SPHERE FLEX TIBIAL INSERT - SIZE2

REF. LEFT	THICKNESS (mm)	REF. RIGHT
02.12.0210FL	10	02.12.0210FR
02.12.0211FL	11	02.12.0211FR
02.12.0212FL	12	02.12.0212FR
02.12.0213FL	13	02.12.0213FR
02.12.0214FL	14	02.12.0214FR
02.12.0217FL	17	02.12.0217FR
02.12.0220FL	20	02.12.0220FR

GMK SPHERE FLEX TIBIAL INSERT - SIZE3

REF. LEFT	THICKNESS (mm)	REF. RIGHT
02.12.0310FL	10	02.12.0310FR
02.12.0311FL	11	02.12.0311FR
02.12.0312FL	12	02.12.0312FR
02.12.0313FL	13	02.12.0313FR
02.12.0314FL	14	02.12.0314FR
02.12.0317FL	17	02.12.0317FR
02.12.0320FL	20	02.12.0320FR

GMK SPHERE FLEX TIBIAL INSERT - SIZE4

REF. LEFT	THICKNESS (mm)	REF. RIGHT
02.12.0410FL	10	02.12.0410FR
02.12.0411FL	11	02.12.0411FR
02.12.0412FL	12	02.12.0412FR
02.12.0413FL	13	02.12.0413FR
02.12.0414FL	14	02.12.0414FR
02.12.0417FL	17	02.12.0417FR
02.12.0420FL	20	02.12.0420FR

GMK SPHERE FLEX TIBIAL INSERT - SIZE5

REF. LEFT	THICKNESS (mm)	REF. RIGHT
02.12.0510FL	10	02.12.0510FR
02.12.0511FL	11	02.12.0511FR
02.12.0512FL	12	02.12.0512FR
02.12.0513FL	13	02.12.0513FR
02.12.0514FL	14	02.12.0514FR
02.12.0517FL	17	02.12.0517FR
02.12.0520FL	20	02.12.0520FR

GMK SPHERE FLEX TIBIAL INSERT - SIZE6

REF. LEFT	THICKNESS (mm)	REF. RIGHT
02.12.0610FL	10	02.12.0610FR
02.12.0611FL	11	02.12.0611FR
02.12.0612FL	12	02.12.0612FR
02.12.0613FL	13	02.12.0613FR
02.12.0614FL	14	02.12.0614FR
02.12.0617FL	17	02.12.0617FR
02.12.0620FL	20	02.12.0620FR

GMK SPHERE CR TIBIAL INSERT - SIZE1

REF. LEFT	THICKNESS (mm)	REF. RIGHT
02.12.0110CRL	10	02.12.0110CRR
02.12.0111CRL	11	02.12.0111CRR
02.12.0112CRL	12	02.12.0112CRR
02.12.0113CRL	13	02.12.0113CRR
02.12.0114CRL	14	02.12.0114CRR

GMK SPHERE CR TIBIAL INSERT - SIZE2

REF. LEFT	THICKNESS (mm)	REF. RIGHT
02.12.0210CRL	10	02.12.0210CRR
02.12.0211CRL	11	02.12.0211CRR
02.12.0212CRL	12	02.12.0212CRR
02.12.0213CRL	13	02.12.0213CRR
02.12.0214CRL	14	02.12.0214CRR

GMK SPHERE CR TIBIAL INSERT - SIZE3

REF. LEFT	THICKNESS (mm)	REF. RIGHT
02.12.0310CRL	10	02.12.0310CRR
02.12.0311CRL	11	02.12.0311CRR
02.12.0312CRL	12	02.12.0312CRR
02.12.0313CRL	13	02.12.0313CRR
02.12.0314CRL	14	02.12.0314CRR

GMK SPHERE CR TIBIAL INSERT - SIZE4

REF. LEFT	THICKNESS (mm)	REF. RIGHT
02.12.0410CRL	10	02.12.0410CRR
02.12.0411CRL	11	02.12.0411CRR
02.12.0412CRL	12	02.12.0412CRR
02.12.0413CRL	13	02.12.0413CRR
02.12.0414CRL	14	02.12.0414CRR

GMK SPHERE CR TIBIAL INSERT - SIZE5

REF. LEFT	THICKNESS (mm)	REF. RIGHT
02.12.0510CRL	10	02.12.0510CRR
02.12.0511CRL	11	02.12.0511CRR
02.12.0512CRL	12	02.12.0512CRR
02.12.0513CRL	13	02.12.0513CRR
02.12.0514CRL	14	02.12.0514CRR

GMK SPHERE CR TIBIAL INSERT - SIZE6

REF. LEFT	THICKNESS (mm)	REF. RIGHT
02.12.0610CRL	10	02.12.0610CRR
02.12.0611CRL	11	02.12.0611CRR
02.12.0612CRL	12	02.12.0612CRR
02.12.0613CRL	13	02.12.0613CRR
02.12.0614CRL	14	02.12.0614CRR

RESURFACING PATELLA

SIZE	REF
1	02.07.0033RP
2	02.07.0034RP
3	02.07.0035RP
4	02.07.0036RP

INSET PATELLA

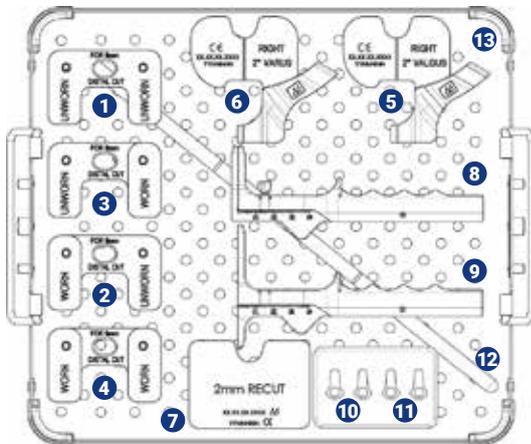
SIZE	REF
1	02.07.0040IP
2	02.07.0041IP
3	02.07.0042IP
4	02.07.0043IP

STEM EXTENSION*

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

* Stem extension must not be coupled with TiNbn coated fixed tibial baseplates.

17. KA INSTRUMENT COMPLEMENT

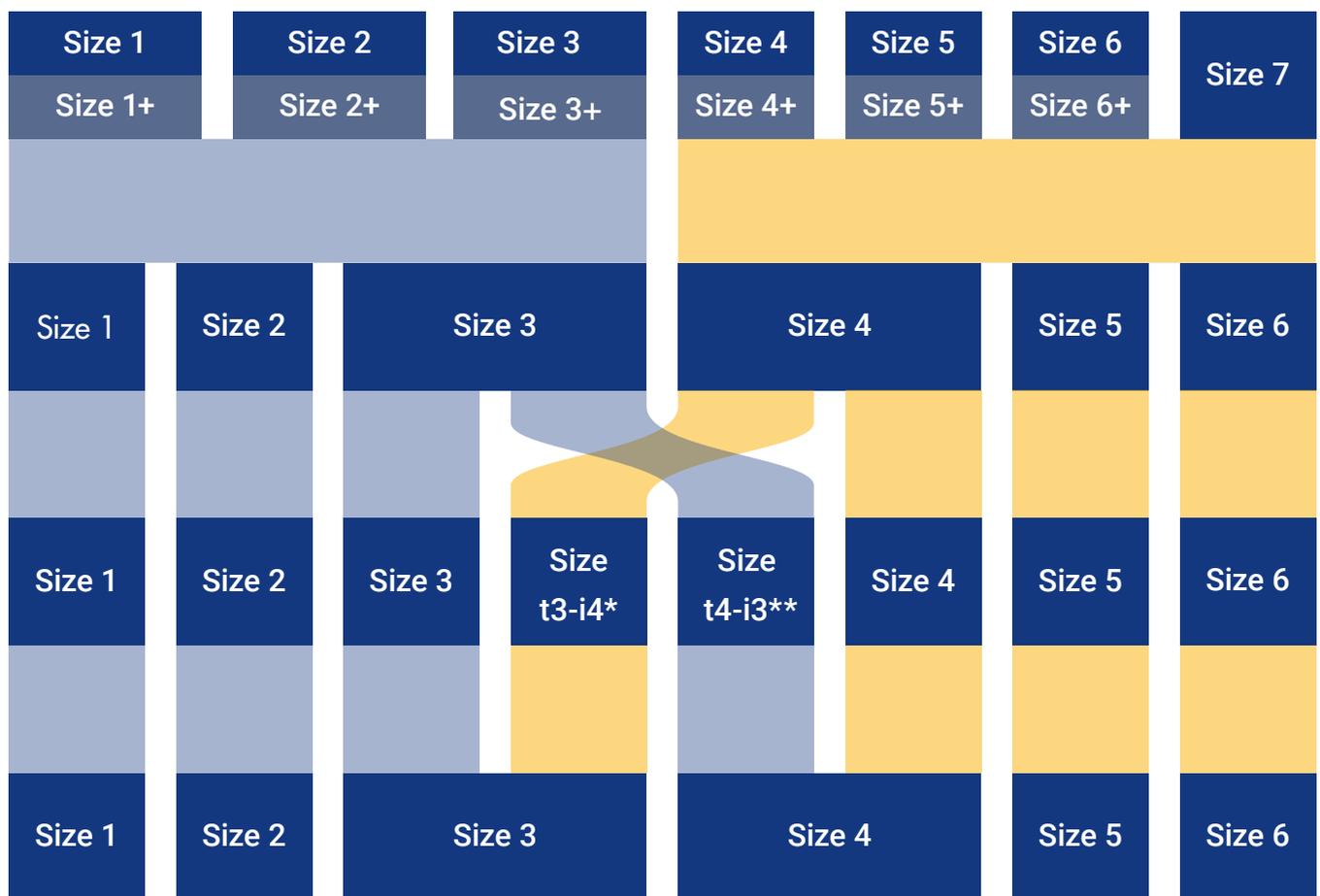


N.	Reference	Description	Q.ty
1	02.12.10.0721	Distal Cut Reference Block Unworn-Unworn	1
2	02.12.10.0722	Distal Cut Reference Block Worn-Unworn	1
3	02.12.10.0723	Distal Cut Reference Block Unworn-Worn	1
4	02.12.10.0724	Distal Cut Reference Block Worn-Worn	1
5	02.12.10.0725	2° Valgus correction cutting guide	1
6	02.12.10.0726	2° Varus correction cutting guide	1
7	02.12.10.0727	+2mm correction cutting guide	1
8	02.12.10.0728	Bone resection caliper	1
9	02.12.10.0729	Tibia-femur offset caliper	on demand
10	02.12.10.0730	+1mm Washer for 4in1	on demand
11	02.12.10.0731	+2mm Washer for 4in1	2
12	02.12.10.0732	IM Rod	1
13	02.12.10.8214	GMK Sphere Kinematic Alignment - Tray	1

18. COMPATIBILITY CHART



All GMK Patellae can be implanted with all the sizes of GMK Sphere femurs



*Tibia size t3-i4 = Tibia size 3 for insert size 4

**Tibia size t4-i3 = Tibia size 4 for insert size 3

Part numbers subject to change.

NOTE FOR STERILISATION

The instrumentation is not sterile upon delivery. It must be cleaned before use and sterilised in an autoclave in accordance with the regulations of the country, EU directives where applicable and following the instructions for use of the autoclave manufacturer. For detailed instructions please refer to the document "Recommendations for cleaning decontamination and sterilisation of Medacta International orthopaedic devices" available at www.medacta.com.



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GMK Sphere Calipered
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Surgical Technique

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rev. 00

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