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1. INTRODUCTION

This brochure describes the Surgical Technique to implant the GMK Sphere. This technique is designed to be used with arthritic knees that do not have significant bone loss, major contractures or soft tissue laxity. This technique focuses on knee alignment and in setting tibial and femoral resections based on bone references. Soft tissues are then managed “around” the resections. The technique can be used in both tibia first and femur first approaches.

The surgical technique involves extramedullary (EM) alignment for the tibial cut and intramedullary (IM) alignment for the femoral cut. The distal femoral resection is made with respect to the intramedullary canal. The surgeon has the option of making the distal cut with different degrees of valgus relative to the anatomical axis of the femur, in accordance with the patient’s anatomy. The A/P 4in1 cutting block positioning can be based on a choice of anatomical references (posterior condyles, epicondyles or Whitesides line).

CAUTION
Some instruments are fixed to the bone using 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. When extracting pins it is important not to bend them. 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.

1.1 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.

GMK Sphere can be implanted using a kinematic alignment approach. When a kinematic alignment approach is utilized, 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.
- Collagen disorders, and/or avascular necrosis of the femoral condyle.
- Moderate valgus, varus, or flexion deformities.

Tibial wedges cemented are to be attached to the tibial baseplate with both the fixing cylinders and bone cement. The screwed tibial augments are for screwed fixation to the tibial baseplate.

CAUTION
To implant GMK Sphere using the kinematic alignment approach, follow the steps described in the GMK Sphere Calipered Kinematic Alignment surgical technique (ref. 99.26SPHERE.12MIKAUS).

Please note
In the surgical technique described hereafter, the resections are performed in the following order:

A. Distal femoral resection
B. Tibial resection
C. A/P femoral resections and chamfers

Nevertheless, the surgeon can change the order of the resections, choosing the following sequence:

A. A/P femoral resections and chamfers
B. Distal femoral resection
C. Tibial resection

It is compulsory to perform the distal femoral resection before the A/P resection and chamfers.
1.2 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 condylar structures or loss of integrity of the 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.

The Kinematic Alignment Surgical Technique is contraindicated also for patients with greater than 5° valgus deformity with MCL insufficiency.

1.3 PREOPERATIVE PLANNING

Radiological planning

This is performed from the scanogram, anterior-posterior, lateral and sunrise knee radiographs. The goals are to determine the angle formed by the anatomical axis and the mechanical axis, 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 particularly posterior osteophytes).

For implants size matching and nomenclature is mandatory to refer to sections 9 and 11.

Clinical planning

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

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. Additionally both cruciate ligaments are resected 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. DISTAL FEMORAL RESECTION

2.1 PLACING THE INTRAMEDULLARY ROD

Make an entry hole in the distal femur just anterior to the intercondylar notch immediately above the site of attachment of the posterior cruciate ligament. Use the 9 mm drill bit and wobble it slightly to enlarge the entry hole to allow for decompression of the intramedullary canal when inserting the intramedullary rod. This hole should be positioned so that the alignment rod will be placed in the centre of the femoral canal in the AP and medio-lateral plane.

Assemble the distal cut positioner on the intramedullary rod and insert the rod into the canal. The distal cut reference has 6° correction from the anatomical axis: be sure that the “L” or “R” corresponding to the side being operated on is viewed upright.

OPTION
The distal cut reference is available in 0 to 9 degrees with a 1 degree step.

Advance the distal cut reference with the intramedullary rod until it contacts one or both femoral condyles.

OPTION
If needed, the distal plate can be stabilised using pins inserted into the dedicated holes. Pin holes are available either on the medial or lateral side.

2.2 POSITIONING THE DISTAL CUTTING GUIDE

Slide the Micrometric slotted distal cut positioner onto the Distal cut reference. Connect the block on the Micrometric slotted distal cut positioner then secure the connection by pushing the lever (A) down.

OPTION
A Micrometric slotted distal cut positioner is available (ref. 02.07.10.4573).

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

MIS: 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.
2.3 SETTING THE DISTAL FEMORAL RESECTION LEVEL

The femoral distal resection, planned at 9 mm (corresponding to the thickness of the distal condyles of the femoral component), can be adjusted later on by moving the cutting block on the pins. Ensure it is set to the correct distal resection before commencing the osteotomy.

5. **OPTION**

Alternatively, the femoral distal resection, routinely planned at 9 mm (corresponding to the thickness of the distal condyles of the femoral component), can be adjusted by turning the screw (A) on the distal cut positioner in a range of 4 mm to 12 mm.

Fix the distal cutting block by inserting 2 pins in the parallel positioning holes marked in red and one in the oblique hole 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

If needed the cutting block can be moved distally or proximally in 2 mm or 4 mm increments using the repositioning holes. Before performing the resection, check the cutting block position with the angel wing.

6. **OPTION**

Alternatively, the MIS and Standard unslotted distal guide are available.

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

Distal unslotted cutting blocks holes:
- Parallel positioning holes
- Oblique fixation holes
- Saw blade guide holes / alignment rod holes
- Parallel repositioning holes
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 it points to the centre of the femoral head.

Finally, check the resection level using the angel wing and perform the distal cut through the slot built into the guide. Once the resection is performed, remove the pins. Should a re-cut be necessary, the pin holes can be readily located again.

**OPTION**
To correct the distal cut varus/valgus, Standard and MIS recut blocks are available.
CAUTION
The slotted distal cutting guide is compatible only with the Standard unslotted re-cut block but not with the MIS one.
3. TIBIAL RESECTION

The tibia requires only one cut, which is flat. The tibial resection can be performed using the extramedullary alignment guide.

3.1 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)
- Extramedullary superior guide (D)
- Tibial slotted cutting guide (E)
- Tibial stylus (F)

Select the tibial slotted cutting guide for the correct side (left or right as marked on the block) and fix it to the extramedullary superior guide using the 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 extramedullary superior guide (D) into the distal part of the tibial resection guide. Secure the malleolar clamp around the ankle and centre the tibial resection guide over the ankle given by the mid point of the two malleoli. Then position the assembly on the tibia, eyeballing the frontal rotation. Adjust the distance of the rods to the length of the patient’s tibia and fix with the knob provided (black arrow). A stylus (F) is provided to check the tibial resection level.

OPTION

The slotted tibial cutting guide can be mounted on a spiked rod to achieve tibial spine fixation. In this configuration a 3° support is required.

3.2 SETTING THE TIBIAL VARUS/VALGUS WITH THE EXTRAMEDULLARY GUIDE

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 block is centred carefully to prevent any varus or valgus deviation when making the resection.
In order to make the tibial cut perpendicular to the mechanical axis, make sure that the malleolar clamp support is on the centre of the ankle. By translating the distal part of the alignment guide on the malleolar clamp support, it is possible to adjust the varus-valgus of the tibial resection in the frontal plane.

CAUTION
It is recommended to avoid any excessive posterior slope. Whatever the surgeon's preference, it is important that no anterior slope is introduced.

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

CAUTION
When using the 3° support, the support provides 3° of slope on the tibial cut when the tibial extramedullary rod is parallel to the tibial axis.

3.3** SETTING THE TIBIAL SLOPE WITH THE EXTRAMEDULLARY GUIDE**

The posterior slope can be adjusted by sliding the distal part of the malleolar clamp support along the malleolar clamp rod. Moving the support backwards will increase the posterior slope.

When changing the slope it is very important that the cutting guide is centred directly over the anterior aspect of the tibia to avoid unwanted varus or valgus in the tibial cut.

3.4** SETTING THE TIBIAL RESECTION LEVEL WITH THE EXTRAMEDULLARY GUIDE**

The surgeon will be able to evaluate whether the flexion gap is tighter or looser than average. If it seems looser, the surgeon may wish to resect less bone from the tibia. It is obvious that no two tibiae are exactly the same and, therefore, some judgment is necessary at this stage to decide whether any laxity identified is due to loss of bone or stretching of the soft tissue restraints. It is best to err on the conservative side since more bone can always be resected if necessary. Fix the tibial stylus into the dedicated hole on the cutting guide. One side to make a standard cut, 8 mm from the less worn tibia plateau, and the other side to make a conservative cut, 2 mm under the most worn plateau.

Verify the level of the cut using the angel wing. When a satisfactory position has been reached, pin the cutting block using two parallel pins. Use the row marked with a line.
3.5 FIXATION OF THE TIBIAL CUTTING BLOCK

Before fixing the tibial cutting block, it is recommended to check the cut height and the posterior slope using the angel wing.

**OPTION**
The green pin holes are compatible with the unslotted tibial guides.

Tibial cutting block holes (right knee)
- Parallel positioning holes
- Oblique fixation holes
- Tibial stylus holes
- Compatible holes

Once the tibial slotted cutting block is positioned on the tibia, insert a pin into the central slot to stabilise it. Inserting this pin will still allow adjustment of the tibial slope.
After pre-drilling, pin the block to the tibia by using the two parallel positioning holes marked with a line and one oblique fixation hole.

If required the tibial cut can be increased at a later stage by 2 or 4 mm using the pin holes provided.

To check the frontal alignment of the cutting block it is possible to assemble the telescopic alignment rod onto the slotted cutting block to see if it points to the centre of the ankle.

3.6 REMOVING THE EXTRAMEDULLARY GUIDE

Remove the stylus (1) by pulling it upwards and unlock the frontal screw of the eyeballing superior guide (2). Open the malleolar clamp (3) and remove all the construct from the patient (4).
3.7 **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 or through the medial hole of the MIS cutting block.

Finally, perform the tibial proximal resection by cutting through the slot built into the guide.

Slide the tibial cutting block over its two parallel pins and remove it. The parallel pins should remain in position in case a tibial recut is required.

**CAUTION**

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

If necessary, two additional cutting blocks are available, in order to correct the alignment (+2° varus/valgus) and the posterior slope (+/- 2°) 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.

The recut guides are compatible with both slotted standard and MIS tibial cutting blocks.

**OPTION**

The green pin holes are compatible with the unslotted recut guides.
4. EXTENSION GAP CHECK

In order to check the tibial and distal femoral cuts, use the independent cut reference spacer assembled with the dedicated femoral and tibial spacers. The independent cut reference spacer is available in 2 different widths, suitable for sizes 1-3 and 4-6.

The femoral spacer simulates the thickness of the femoral component, while the independent cut reference spacer simulates the minimum thickness of the tibial component. Therefore the thickness of the independent cut reference spacer assembled with the femoral spacer equate to the total prosthesis thickness given by the tibial baseplate, the PE insert and the femoral component. The thickness of the different PE inserts (Flex Insert: 11, 12, 13, 14, 17 and 20 mm; CR Insert: 11, 12, 13 and 14) can be simulated by using different tibial spacers (Flex Insert: 11, 12, 13, 14, 17 and 20 mm; CR Insert: 11, 12, 13 and 14). With the knee in extension, introduce into the joint the independent cut reference spacer complete with the femoral and tibial spacers assembled with the removable handle.

The femoral spacer has to be fixed to the reference spacer on the side marked "FEMORAL". Similarly, the tibial spacer has to be fixed to the reference spacer on the side marked "TIBIAL". In case of laxity, the surgeon can use thicker tibial spacers (Flex Insert: 11, 12, 13, 14, 17 and 20 mm; CR Insert: 11, 12, 13 and 14).

If it is not possible 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 2 mm or 4 mm of bone may be resected. If, despite a posterior release, the tests indicate incomplete extension, this would require a further 2 mm distal femoral cut.
5. ANTerior CUT, POSTerIOr CUT AND CHAMfERS

Once the distal end of the femur has been cut, the size and orientation of the femoral component will be determined by the position of the anterior, posterior condylar and chamfer cuts. The anterior femoral cut is limited in antero-posterior placement by trying to avoid notching the anterior cortex and not wanting too large a gap between flange and anterior cortex. The anterior cortex is most prominent laterally so by increasing the external rotation this will progressively increase the needed AP internal dimension to avoid notching. This means that, for instance, increasing external rotation may require a size 3+ or 4 where a size 3 had initially been measured. The intention is to obtain a flush fit between the anterior flange of the component and the anterior cortex on the lateral side without notching the femur. The medial posterior condylar cut should allow the prosthetic condylar surface to be at roughly the same level as in the non-arthritic knee. In the GMK Sphere the internal anteroposterior dimension varies by 2 mm as the size increases or decreases. If no external rotation of the femoral component is planned the same amount of bone will be resected from both posterior condyles. If external rotation is desired, it can be set using this surgical technique. It should be remembered that in the normal knee there is laxity in the lateral compartment after approximately 20 degrees flexion, which allows the medial pivot action seen in normal knees. Externally rotating the femoral component, while possibly helping with patellar tracking, makes the lateral posterior condyle more prominent than normal and may impede the medial pivot tracking motion seen in the normal knee. A reasonable compromise between these two conflicting requirements is to place the component at about 3 degrees of external rotation. The surgeon has discretion in this matter. Next pins are placed through the appropriate holes in the sizer perpendicular to the cut surface of the distal condyles.

After the pins are placed, the sizer will be removed and the 4in1 cutting block will be placed over the pins. The surgeon must determine if the position of the 4in1 block will result in cuts in the appropriate positions. The guide can be displaced anteriorly or posteriorly by 2 mm using the different sets of holes in the guide. Using the 4in1 femoral cutting block, the femoral anterior, posterior and chamfer resections can be performed.
5.1 POSTERIOR REFERENCING: FEMORAL SIZING AND EXTERNAL ROTATION ADJUSTMENT

Select the right ("R") or left ("L") rotational guide according to the side to be operated on. Select the guide that will provide the desired external femoral rotation (0°, 3° or 5°). Connect the selected rotational guide to the posterior referencing femoral sizer by sliding it onto the driven pins. A ‘click’ will be heard when it is fully engaged.

34.

The posterior referencing femoral sizer is placed flat against the cut edge of the distal femur, with both the posterior condyles secured to its base.

35.

36.
Refine the position of the sizer, by selecting the size of the femur on the anterior stylus.

37.
The external rotation can also be checked taking into account the alignment to the epicondylar axis, using the epicondylar axis reference.

38.

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 size of the femur can be seen on the front of the femoral sizer.
5.2 POSTERIOR REFERENCING: 4IN1 CUTTING BLOCK POSITIONING

Option 1: central pins

39.

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

Once the position of the sizer is satisfactory, pre-drill and insert 1 pin medially and 1 pin laterally in the aligned holes.

CAUTION
Whilst inserting the pins, ensure continuous contact between the femoral sizer and the distal resection.

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

40.

Remove the femoral sizer by sliding it along the two pins

Select the correct size 4in1 cutting block and attach it to the distal resection via the row of holes relating to the parallel positioning holes used in the sizer.
At this stage it is possible to move the 4in1 cutting block anteriorly by 2 mm using the holes just below the reference line. This will increase the flexion gap by 2 mm and decrease the anterior cut level by 2 mm.
The level of the anterior cut must be checked at this stage by placing the angel wing into the slot of the anterior resection.
Once the position is satisfactory, secure the 4in1 block, using two headed pins inserted into the two lateral oblique fixation holes and remove the positioning pins.

Option 2: pegs

41.

As an alternative to positioning through the central pins, the 4in1 cutting block can be positioned using two pegs.
Once the adjustment of the femoral sizer is satisfactory, drill the peg holes through the dedicated holes of the femoral sizer.

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

Finally, remove the femoral sizer, assemble the pegs on the 4in1 cutting block of the chosen size and apply it on the distal resection.
CAUTION
The position of the 4in1 pegs DOES NOT CORRESPOND to the position of the pegs of the femoral component. The holes for the final femoral component are created through the trial femoral component.

5.3 FEMORAL UPSIZING/DOWNSIZING
The difference between successive femoral sizes is 2 mm in both anterior-posterior and mediolateral planes.

Posterior Referencing: upsizing/downsizing
Option 1: central pins
If the 4in1 cutting block was positioned using the central parallel pins, replace it with the cutting guide of the more suitable size using the same row of holes.

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 upwards, position the two central pins on the row of holes marked with a line. Remove the cutting block by sliding it along the pins, withdraw the two pegs and reposition the pin holes just below the reference line.

Option 2: pegs
If the 4in1 cutting block was positioned using the pegs, replace it with the cutting guide with the more suitable size using the same peg holes.

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 upwards, position the two central pins on the row of holes marked with a line. Remove the cutting block by sliding it along the pins, withdraw the two pegs and reposition the pin holes just below the reference line.

5.4 FEMORAL RESECTIONS

OPTION
Alternatively or together with the fixation using the lateral pins, the 4in1 cutting block may be fixed to the bone using two cancellous bone screws inserted through the dedicated holes by means of the dedicated screwdriver.
When the 4in1 cutting block has been stabilised, perform the femoral resections as below:

• Anterior condylar osteotomy
• Posterior 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.

Remove the 4in1 cutting block.

**CAUTION**

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

Replace the cutting guide with the next smaller and fix the cutting block following the procedure described on pages 18 and 19 and perform or repeat the femoral resections.

**CAUTION**

The anterior resection level will move 2 mm posteriorly. Make sure that there is no anterior notching.

**Downsizing after the femoral resections**

If it is necessary to downsize the femoral component after the femoral resections have taken place, insert the saw blade into the slot of the anterior resection, apply the 4in1 cutting block on the distal cut, ensure that the saw blade is in perfect 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.
6. TRIAL REDUCTION

All of the major bone cuts have now been made. The osteotomies described will render the knee stable in flexion and extension when the appropriate components are selected. This must be confirmed. Blocks of varying thickness may be used to evaluate the flexion and extension gaps but misuse could damage the prepared bone surfaces. A better option is to perform a trial reduction. The only change that can be made without altering the bone cuts is the thickness of the tibial component. Therefore tibial trials must be available that are equal in thickness to all the actual components.

In order to perform the trial reduction, position the tibial trial and the femoral trial on the resected bones.

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 tibia resection. The tibial baseplate is asymmetrical. Rotate the baseplate until the best coverage of the tibial cortical bone is achieved.

To change the thickness of the tibial trial insert, pull the lever A and substitute the trial insert. Remove the handle by pressing the button B and reduce the patella. Test the knee with its full range of motion and ensure that the optimal tracking of the components is occurring.

If the knee is stable and well-aligned in flexion and extension, nothing else is required. This outcome should be expected in knees that are initially stable, or unstable but are capable of being placed in normal alignment after a generous medial exposure. Such knees are rarely unstable or lacking full flexion and extension with the correct thickness of tibial trial prosthesis in place.

If the knee is unstable or misaligned, the remedy can be determined, as described here, during the Trial Reduction:

- If the knee is lax in both flexion and extension, a thicker tibial component should be used.
- If the knee is tight in both flexion and extension and if the thinnest tibial trial is being used, more bone must be resected from the tibia.

It is rare that the flexion and extension gaps are noticeably different. Then:

- If it is tight in extension and unacceptably lax in flexion, the option is to cut more bone off the distal femur and revise the chamfer cuts. This creates extra space in the Extension Gap so that a thicker tibial component can be used to stabilise the knee in flexion.
- If the knee is tight in flexion but loose in extension, the option is to use a smaller femoral component. Using a smaller femoral component will require revision of the femoral posterior and chamfer cuts and may involve a loss of flexion because the tibial component may impinge on the femur just proximal to the posterior condyles.

Assemble the femoral impactor/extractor on the slide hammer and impact the appropriate size trial femur centring it on the anatomical notch. Ensure overhanging medially or laterally is minimised.
6.1 TRIAL 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.

<table>
<thead>
<tr>
<th>Tibia bone size</th>
<th>GMK Sphere Femoral Components</th>
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<tbody>
<tr>
<td></td>
<td>GMK Fixed Tibial Trays</td>
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<td>Sizes 1/1+</td>
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<td>Size 6</td>
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</table>

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
7. FINISHING THE FEMUR AND TIBIA

7.1 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.

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.

![Diagram of osteotome](image)

- 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 trochlear-cutting guide (C,D). For enhanced stability, insert two additional pins into the anterior holes of the guide (E,F).

![Instructions for peg holes](image)

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

![Performing cuts](image)

### 7.2 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.

![Checking box cut](image)

**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.
7.3 TIBIAL FINISHING

It is important that the rotation of the tibial component matches the orientation of the femoral component to track the patella. It is a serious error to internally rotate the tibial baseplate. Generally the centre of the baseplate anteriorly will be positioned over the junction of the medial and middle third of the tibial tubercle. The tibial tubercle is itself a slightly laterally positioned structure. Fine adjustment of the position of the tibial baseplate can be made with the femoral and tibial trials in place to obtain the best tracking as the knee is flexed and extended. Use two pins to fix the tibia trial.

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 electrodiathermy.

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.

The pins should always be placed in the opposite position: one anteriorly and one posteriorly on tibial surface. Alternatively, the tibia trial can be fixed using two frontal pins which can be inserted with the trial insert in place.
• Push button (A) to fix the barrel onto the 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.

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

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 9mm 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.

8. **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.

**OPTION**
The patella size can be measured using dedicated templates.

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

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

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

**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. Pressurise the trial resurfacing patella of the appropriate size, reduce the patella and test the knee through its full range of motion.
9. 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.

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Table 1

All GMK Fixed Tibial Trays can be implanted with or without the extension stem. All GMK Resurfacing Patellae can be implanted with all the sizes of GMK Sphere Femoral Components.

* 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

10. 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.

10.1 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.

10.2 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 (ref. 02.07.10.4577) must be used to guarantee that the optimal locking of the screw is achieved.

---

**10.3 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 hammer.

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.

---

**10.4 PATELLA**
Assemble the spike jaw and the pressurising jaw on the patellar clamp. The pressurising 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.
# 11. IMPLANTS NOMENCLATURE

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<td>02.12.0512CRR</td>
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### GMK SPHERE CR TIBIAL INSERT - SIZE6

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<th>REF. LEFT</th>
<th>THICKNESS (mm)</th>
<th>REF. RIGHT</th>
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### RESURFACING PATELLA

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### STEM EXTENSION

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<th>L (mm)</th>
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<tr>
<td>02.07.F11066</td>
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Part numbers subject to change.

NOTE FOR STERILIZATION

The instrumentation is not sterile upon delivery. Instruments must be cleaned before use and sterilized in an autoclave respecting the US regulations, directives where applicable, and following the manufactures instructions for use of the autoclave. For detailed instructions please refer to the document “Recommendations for cleaning decontamination and sterilisation of Medacta International orthopaedic devices” available at www.medacta.com.
12. COMPATIBILITY CHART

GMK Patella

GMK Sphere Femur

GMK Sphere Flex/CR Insert

GMK Tibia

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

<table>
<thead>
<tr>
<th>Size 1</th>
<th>Size 2</th>
<th>Size 3</th>
<th>Size 4</th>
<th>Size 5</th>
<th>Size 6</th>
<th>Size 7</th>
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</thead>
<tbody>
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<td>Size 3+</td>
<td>Size 4+</td>
<td>Size 5+</td>
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</tbody>
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*Tibia size t3-i4 = Tibia size 3 for insert size 4

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