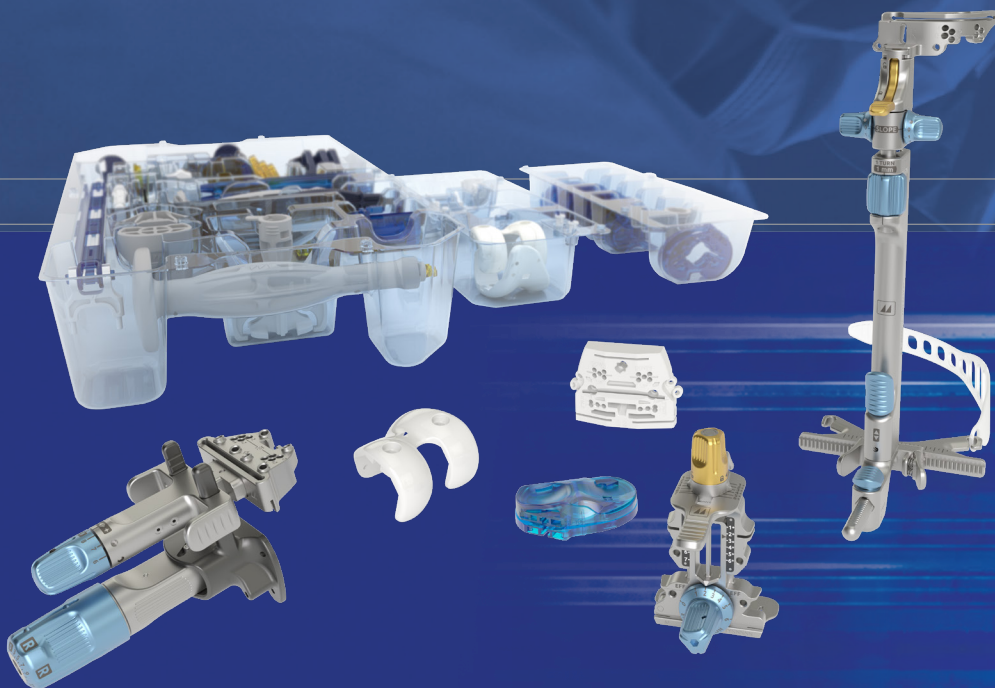


# GAUK® **ULTIMATE** *Efficiency*

KNEE INSTRUMENTS



## Surgical Technique

Joint

Spine

Sports Med

## INDEX

<b>1. INTRODUCTION</b>	<b>4</b>
1.1 Indications	4
1.2 Contraindications	4
<b>2. TIBIAL RESECTION</b>	<b>5</b>
2.1 Extramedullary alignment guide	5
2.2 Tibial cutting block fixation and guide removal	6
2.3 Tibial resection	7
2.4 Tibial resection check	8
<b>3. DISTAL FEMORAL RESECTION</b>	<b>9</b>
3.1 Distal cutting block positioning	9
3.2 Distal cutting block fixation	10
3.3 Distal resection	10
<b>4. EXTENSION GAP CONTROL</b>	<b>11</b>
<b>5. ANTERIOR CUT, POSTERIOR CUT AND CHAMFERS</b>	<b>12</b>
5.1 Femoral sizing	12
5.2 4in1 cutting block positioning - Anterior reference	13
5.3 4in1 cutting block positioning - Posterior reference	14
5.4 4in1 Femoral Resection	15
5.5 Femoral upsizing/downsizing	15
<b>6. TRIALING</b>	<b>16</b>
<b>7. FEMORAL FINISHING</b>	<b>18</b>
<b>8. TIBIAL FINISHING</b>	<b>19</b>
<b>9. OPTION - TIBIAL EXTENSION STEM</b>	<b>20</b>
<b>10. PATELLA RESURFACING</b>	<b>21</b>
10.1 Patella thickness measuring	21
10.2 Patella clamp positioning	22
10.3 Pegs preparation and sizing	23
10.4 Trialling	23
<b>11. SELECTION OF THE PROSTHETIC COMPONENTS - SIZE MATCHING</b>	<b>24</b>

<b>12. FINAL IMPLANTS</b>	<b>25</b>
12.1 Tibial implant	25
12.2 Insert	25
12.3 Femoral component	26
12.4 Patella resurfacing	26
<b>13. ANNEX 1 - MIS CORRECTION CUTTING BLOCK COMPATIBILITY</b>	<b>26</b>
13.1 Proximal tibial recut	26
<b>14. ANNEX 2 - IMPLANT NOMENCLATURE</b>	<b>27</b>
<b>15. ANNEX 3 - INSTRUMENTATION NOMENCLATURE AND CONFIGURATIONS</b>	<b>29</b>
<b>16. ANNEX 4 - METAL SETS</b>	<b>30</b>
<b>17. COMPATIBILITY CHART</b>	<b>32</b>

## 1. INTRODUCTION

This document describes the surgical technique for implanting the GMK Sphere total knee system using GMK UltiMate Efficiency instrumentation.

**PLEASE NOTE:** In the surgical technique described hereafter, the resections are performed as follows:

1. Tibial resection
2. Distal femoral resection
3. A/P femoral resections and chamfers

However, the surgeon can change the order of the resections by choosing between the following sequences:

1. Distal femoral resection
2. Tibial resection
3. A/P femoral resection and chamfers

or

1. Distal femoral resection
2. A/P femoral resection and chamfers
3. Tibial resection

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

### CAUTION

Federal law (USA) restricts this device to sale distribution and use by or on the order of a physician.

GMK UltiMate Efficiency instrumentation are intended to be used as surgical instruments to assist in the positioning of the GMK knee replacement components intra-operatively.

During the surgery:

- Visually inspect the instruments after use to identify any mechanical damage; damage to the instruments may cause the release of particles into the human body.
- Check that the instrumentation set is complete prior to disposal to verify that no pieces have been accidentally left in the human body.

The surgical technique involves the use of reusable metal instruments (GMK UltiMate instruments) and single use instruments (GMK Efficiency). Refer to the section concerning instrumentation nomenclature and configurations, including the list of instruments required to complete the surgical procedure.

### 1.1 INDICATIONS

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

This knee replacement system is indicated in the following cases:

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

Tibial 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. In case a semi-constrained liner is used, an extension stem must be implanted both on the tibial and on the femoral components. In case a GMK Revision tibial tray is used, an extension stem must be implanted.

### CAUTION

Certain specific instruments are fixed to the bone with dedicated pins. Before using the pins, ensure that they are intact and fully functional. **BENT OR DEFECTIVE PINS CANNOT BE USED AND MUST BE REPLACED BY NEW PINS.** When extracting pins it is important to avoid bending as this results in axial misalignment 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.

### CAUTION

A full Efficiency set, including the general tray, the conventional tray and all sizes of femur and tibia, must be available as backup. Alternatively, a full conventional metal instrument set must be available and ready for the surgery as backup.

### 1.2 CONTRAINDICATIONS

GMK Sphere knee replacement is contraindicated in the following cases:

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

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



## 2. TIBIAL RESECTION

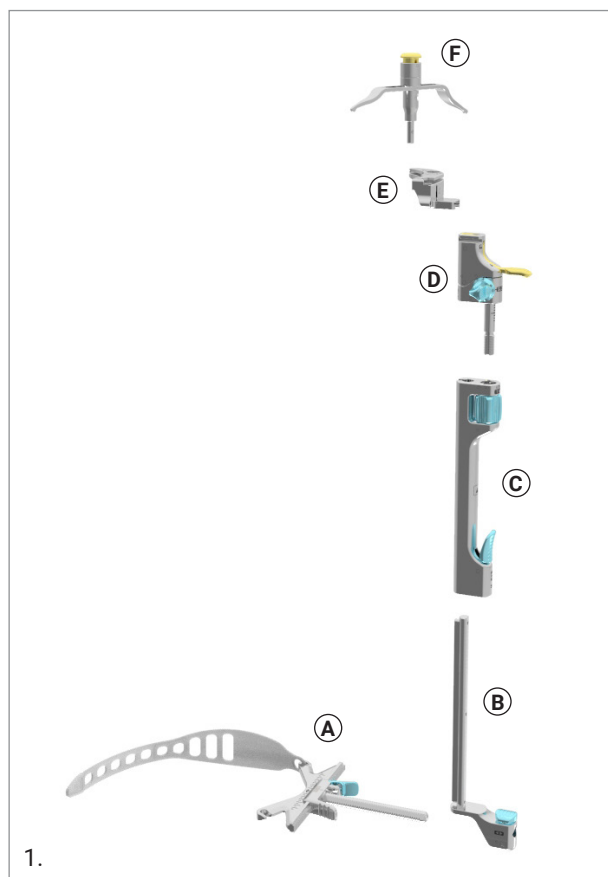
### 2.1 EXTRAMEDULLARY ALIGNMENT GUIDE

The instrument parts have different colors depending on the function:

- Regulation
- Lock-Unlock

The extramedullary guide consists of:

- Malleolar clamp (A)
- Extramedullary guide distal rod (B)
- Extramedullary guide proximal rod (C)
- Tibial cutting block positioner (D)
- Tibial cutting block (E)
- Tibial stylus 2/10 mm (F)

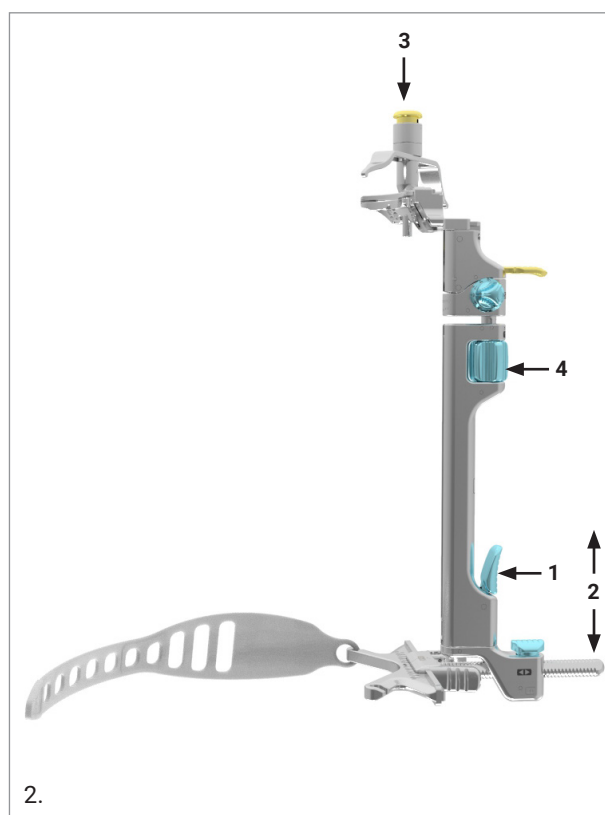


Insert the malleolar clamp (A) into the extramedullary guide distal rod (B) pressing the blue button of the distal rod. Slide the extramedullary guide proximal rod (C) onto the distal rod by pressing the frontal blue button. Insert the tibial cutting block positioner (D) into the distal rod (C). Unlock the frontal yellow lever and slide the tibial cutting block of the correct side (Left or Right) onto the tibial cutting block positioner. Lock the frontal yellow level for the fixation of cutting block. A stylus is provided to check the tibial resection level (F).

### Setting The Tibial Resection Level

Position the assembly on the tibia. Secure the malleolar clamp around the ankle. Press the frontal blue button of the extramedullary guide proximal rod (1), adjust the distance of the rods to the length of the patient's tibia (2) and center the tibial resection block.

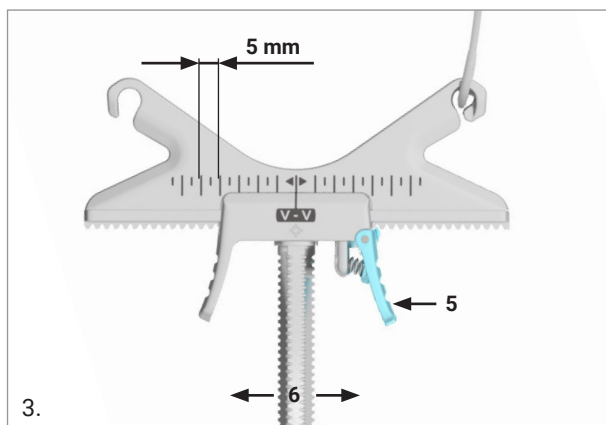
Fix the tibial stylus into the dedicated hole of the cutting block (3). Be careful to completely insert the stylus into the cutting block. One side of the stylus is used to make a standard cut, 10 mm from the less worn tibial plateau, and the other side to make a conservative cut, 2 mm under the most worn plateau. The tibial resection level can be fine-tuned using the frontal blue knob (4). Rotate the frontal blue knob clockwise to increase the tibial resection height and counter clockwise to decrease it. 1 turn corresponds to 1 mm.



### Setting The Tibial Varus and Valgus

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

The varus//valgus alignment of the tibial resection can be adjusted by pressing the blue lever (5) of the malleolar clamp and sliding the assembly in a medial or lateral direction (6).



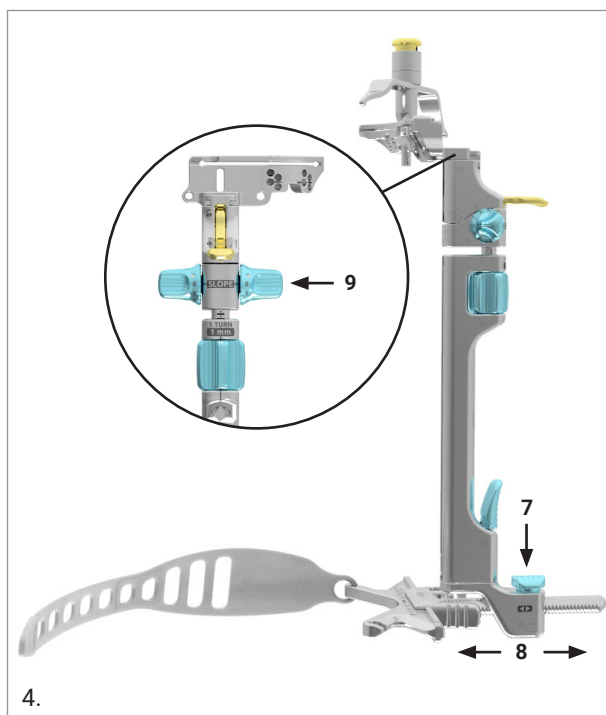
**NOTE:** The distance between two consecutive longer marks is 5 mm.

### Setting The Tibial Slope

Whatever the surgeon's preference, it is important that no anterior slope is introduced.

Press the distal blue button (7) and slide the distal rod of the extramedullary guide along the malleolar clamp (8) in order to align the tibial extramedullary rod to the tibial axis. Moving the distal rod away from the ankle will increase the posterior slope. Tibial slope can be adjusted from 0° to 12° using the frontal posterior slope knob (9). 1 turn corresponds to 1° of slope.

When the extramedullary rods are aligned with the tibial axis in the sagittal plane and the frontal posterior slope knob is set to 0, the cutting guide will be oriented at 90° to the rod in the sagittal plane, thus inducing a posterior slope of 0°.



## 2.2 TIBIAL CUTTING BLOCK FIXATION AND GUIDE REMOVAL

### CAUTION

When the Efficiency pin adapter is used to insert/remove a threaded pin, be sure to clip the pin head in the pin adapter before starting the drill. The pin adapter works properly if a good alignment with the pin is maintained at all times during insertion/removal. For good alignment, please consider approximately an angle of <15° between the holder and pin axes.

### CAUTION

The Efficiency pin extractor should be used with smooth pins. Threaded pins should be removed using the pin adapter. When using the pin extractor, be sure to grab a smooth pin at the section of full-diameter to ensure the best grip.



Tibial cutting block holes

- Oblique fixation holes
- Additional positioning holes
- Central slot
- Parallel positioning holes
- Tibial stylus holes
- Telescopic alignment rod connection

### Extramedullary Alignment Guide Removal

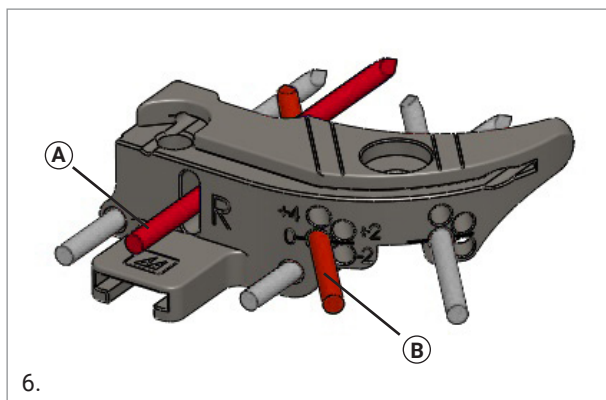
Once the tibial cutting block is positioned on the tibia, insert a pin through the central slot (green hole) of the cutting block to stabilize it. Adjustments can still be made to the tibial slope and the varus/valgus after this pin has been inserted. Remove the stylus by pushing the upper yellow button and pulling the stylus upwards. After pre-drilling the pin holes, insert two parallel pins in the parallel positioning holes (blue holes) marked with the engraved line. If required, the tibial cut can be increased at a later stage by 2 or 4 mm using the additional pin holes. Once the tibial cutting block has been fixed, remove the extramedullary guide assembly leaving the cutting block in place, by opening the malleolar clamp and unlocking the frontal yellow lever for tibial cutting block fixation. Gently remove the assembly by sliding it from the tibial connection.

### OPTION

To further stabilize the tibial cutting block during resection, the extramedullary alignment guide can be left in place.

### CAUTION

During tibial cutting block fixation, impingement between central slot pin (A) and parallel positioning pin (B) may occur. Before fixing pin B, remove central slot pin A.



## 2.3 TIBIAL RESECTION

To check the frontal alignment of the cutting block, attach the telescopic alignment rod to the tibial cutting block. Once the tibial extramedullary rod has been removed, slide the telescopic alignment rod into the tibial cutting block connection (purple slot).

Remove the telescopic rod and bring the tibial cutting guide in contact with the tibia by sliding it along the pins. Insert a third oblique pin into one of the oblique holes of the tibial cutting block (pink holes) to stabilize the guide.

### CAUTION

Before performing the resection, ensure that the resection parameters have not changed while disassembling the guide.

Before performing the resection, check the tibial cutting block position with the angel wing.

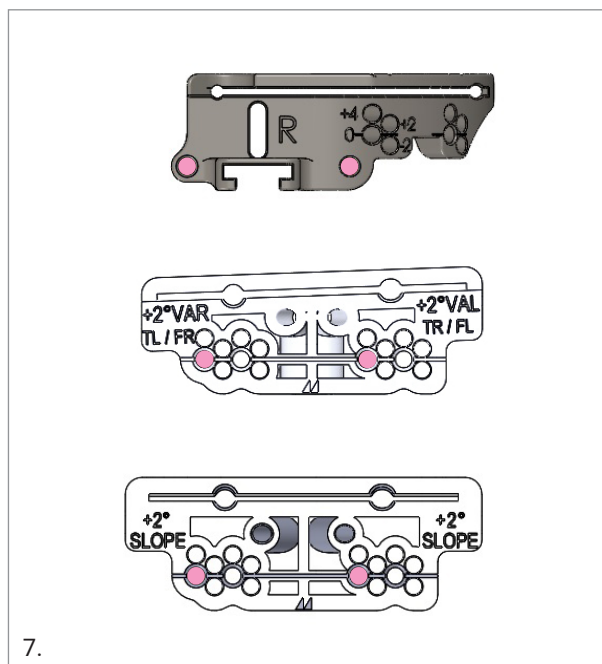
Finally, perform the tibial proximal resection by cutting through the slot built into the guide. Remove the oblique pin, slide the tibial cutting block over the two parallel pins and remove it. The parallel pins should remain in position in case a tibial recut is required.

### CAUTION

Engage the saw blade into the cutting slot before activating the saw. Use physiological solution to cool the cutting block during resection. After resection, rinse the joint before positioning both the trial and final implant.

Should a recut be necessary, reposition the tibial cutting block on a different row of pin holes to modify the tibial resection level.

If necessary, two correction blocks are available, in order to correct the alignment ( $\pm 2^\circ$  varus/valgus) and the posterior slope ( $\pm 2^\circ$ ) of the performed tibial resection.



● Compatible holes

Refer to Annex 1 for MIS correction cutting block compatibility.

### CAUTION

The compatibility between tibial cutting block and correction blocks is provided by the frontal pin holes marked in pink.

## 2.4 TIBIAL RESECTION CHECK

In order to verify the accuracy of the tibial resection and assess the size, lay the tibial sizer on the resected surface of the tibia. Each tibial sizer has two sides, corresponding with two tibial sizes (1-2, 3-4, 5-6).



Insert the tibial spacer into the knee joint in flexion and in extension in order to check the performed tibial resection.



The tibial spacer has two sides, simulating a 10 mm inlay and a 12 mm inlay. If the 10 mm spacer cannot be inserted into the joint, a tibial recut may be necessary (see § 2.3).

Different inlay thicknesses (11, 13 or 14 mm) can be simulated by attaching the corresponding spacers to the 10 mm side of the femoral spacer.

Thicker spacers (17 and 20 mm) are available in the Efficiency extension set (ref. 11.00102 e 11.10102).

In order to verify the varus/valgus and slope of the tibial resection, the telescopic rod can be disassembled from the alignment rod and inserted into the dedicated hole of the tibial spacer.



### 3. DISTAL FEMORAL RESECTION

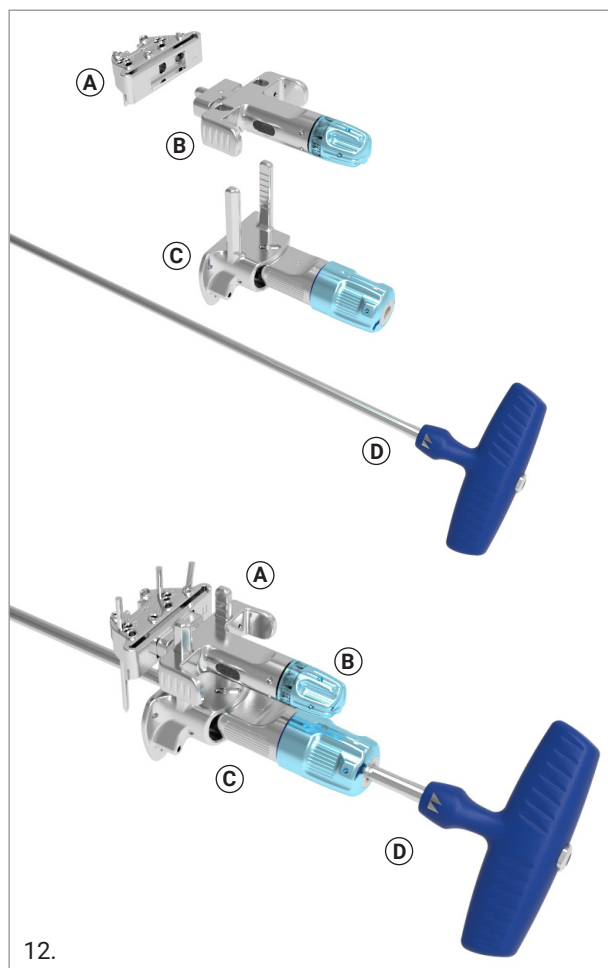
#### 3.1 DISTAL CUTTING BLOCK POSITIONING

Open the intramedullary canal using the 9 mm drill. It is recommended to wiggle the drill tip to allow venting of the intramedullary canal.

Distal resection guide components:

- Distal cutting block (A)
- Distal cut positioner (B)
- Valgus regulation block for distal cut positioner (C)
- IM rod (D)

Assemble the valgus regulation block for the distal cut positioner (C) on the intramedullary rod (D) and insert the rod into the canal.



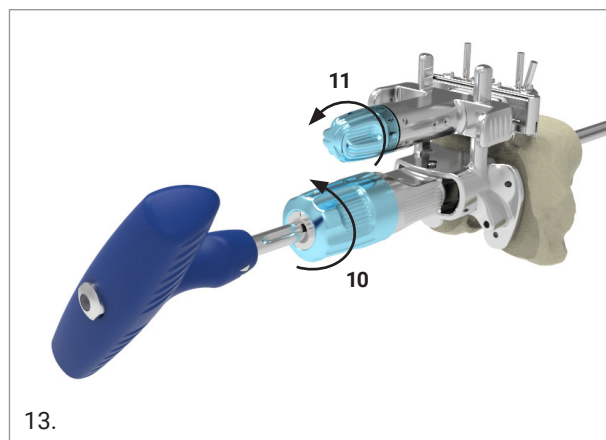
12.

The valgus regulation block for the distal cut positioner allows adjustment of the femoral valgus angle from 0° to 12° using the blue frontal knob (10). 1 step corresponds to 1° of femoral valgus. The right side is indicated by "R" and the left side is indicated by "L".

When the valgus regulation block for the distal cut positioner is secured in place by the IM rod, it may be in contact with only one of the distal condyles.

Assemble the distal cutting block (A) onto the distal cut positioner (B). Then connect the assembly to the valgus regulation block by sliding the distal cut positioner onto the specific tracks.

The femoral distal resection can be adjusted by rotating the anterior blue knob (11). The adjustment range is 6 to 12 mm. 1 step corresponds to 1 mm.



13.

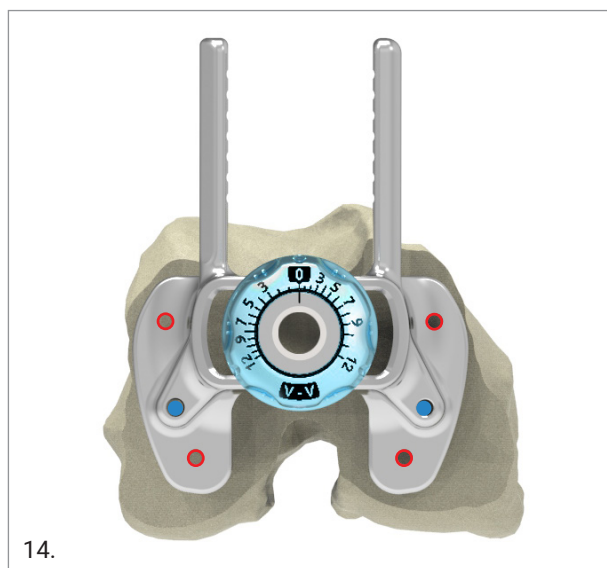
#### OPTION

Fix the valgus regulation block using one or two fixation holes (blue holes in the picture below) on the distal plate of the block.

#### CAUTION

The remaining holes on the distal plate of the block CANNOT be used for the fixation (holes marked with red circles) because the hole diameter is smaller than 3.2 mm. Do not force pin insertion through these holes.





14.

### CAUTION

Headed pins are best used to secure blocks against a flat surface. Smooth pins are recommended for use with cutting blocks against curved surfaces.

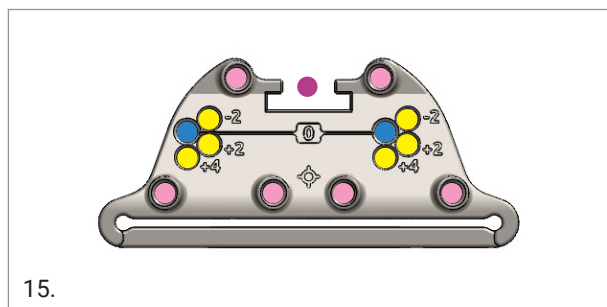
### CAUTION

When the Efficiency pin adapter is used to insert/remove a threaded pin, be sure to clip the pin head in the pin adapter before starting the drill. The pin adapter works properly if a good alignment with the pin is maintained at all times during insertion/removal. For good alignment, please consider approximately an angle of  $<15^\circ$  between the holder and pin axes.

### CAUTION

The Efficiency pin extractor should be used with smooth pins. Threaded pins should be removed using the pin adapter. When using the pin extractor, be sure to grab a smooth pins at the section of full-diameter to ensure the best grip.

## 3.2 DISTAL CUTTING BLOCK FIXATION



15.

Tibial cutting block holes

- Oblique fixation holes
- Additional positioning holes
- Parallel positioning holes
- Telescopic alignment rod connection

Secure the block by introducing 2 pins in the holes corresponding to the engraved reference line (blue holes), then remove the distal cut positioner and the IM rod. If necessary the distal cutting block can be repositioned (yellow holes) to adjust the cutting height distally or proximally in 2 mm increments.

To check the frontal alignment of the distal cutting block, insert the telescopic alignment rod into the dedicated connection of the distal cutting block (purple hole).

When satisfied with the position of the distal cutting block, it is recommended to add an additional pin in the medial or in the lateral oblique fixation hole (pink holes) for stabilization.

## 3.3 DISTAL RESECTION

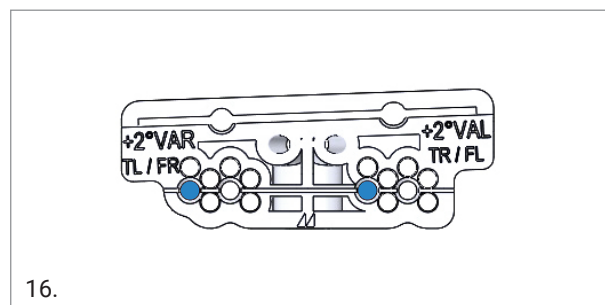
Perform the distal resection using the distal resection slot.

### CAUTION

Engage the saw blade into the cutting slot before activating the saw. Use physiological solution to cool the distal cutting block during resection. After resection, rinse the joint before positioning both the trial and final implant.

Once the resection has been performed, remove the oblique pin and the distal cutting block by sliding it off the parallel pins. It is advisable to leave the parallel pins in place should a recut be necessary.

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



16.

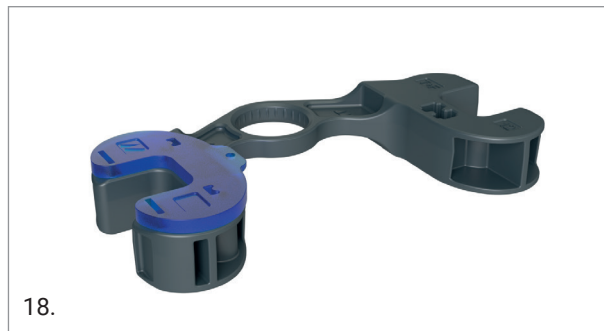
## 4. EXTENSION GAP CONTROL

To check the extension gap, insert the femoral spacer into the knee joint in extension. The femoral spacer simulates the thickness of the final implants (tibia + inlay + femur). One side simulates a final construct with a 10 mm inlay and the other side simulates a final construct with a 12 mm inlay.

In order to verify the alignment, the telescopic rod can be disassembled from the alignment rod and inserted into the dedicated hole of the femoral spacer.



Different inlay thicknesses (11, 13 or 14 mm) can be simulated by attaching the corresponding spacers to the 10 mm side of the femoral spacer. Thicker spacers (17 and 20 mm) are available in the Efficiency extension set (ref. 11.00102 e 11.10102).



If the introduction of the reference spacer into the joint is impossible, the tibial resection can be increased by 2 or 4 mm. Reposition the tibial cutting block distally through the row of holes which will allow a 2 mm recut or a 4 mm recut. If tests indicate incomplete extension, despite a posterior release, an additional 2 mm resection of the distal femur could be performed. In these cases, reposition the distal cutting block on the two pins left in place through the row of pin holes which allows 2 mm recuts.

### CAUTION

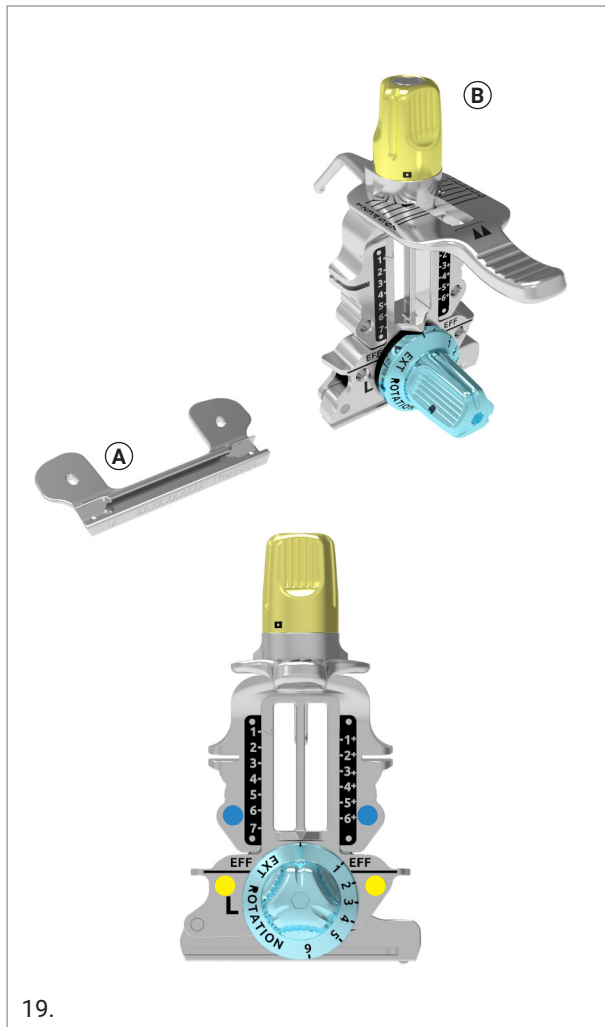
The MIS Efficiency distal correction cutting block (ref. 77.11.0006) is not compatible with the metal distal cutting block (ref.02.12.10.0859).

## 5. ANTERIOR CUT, POSTERIOR CUT AND CHAMFERS

### 5.1 FEMORAL SIZING

Femoral sizer components:

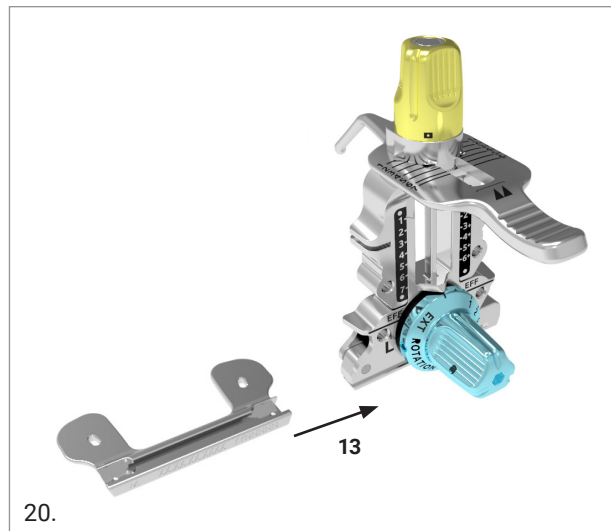
- Condyle support (A)
- Femoral sizer body and stylus (B)



Femoral sizer referencing holes:

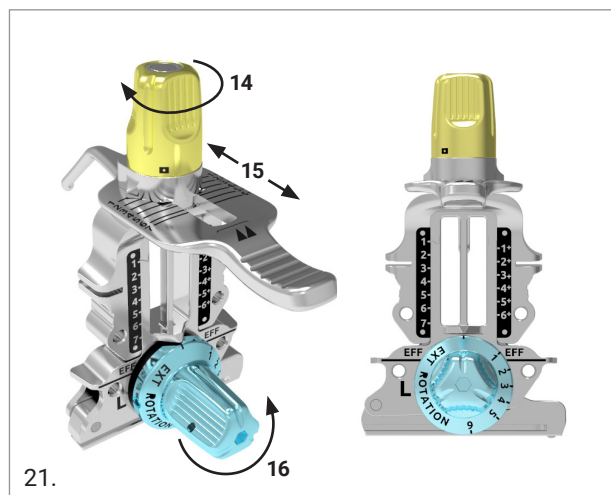
- Posterior referencing holes
- Anterior referencing holes

Choose the femoral sizer according to the side to be operated, as indicated on the femoral sizer body by "R" or "L". 3 sizes of the condyle support are available (Small, Medium and Large). Slide the condyle support of the correct size onto the bottom of the femoral sizer body (13).



The femoral sizer must be positioned in contact with the distal cut surface. The condyle support should be in contact with both posterior condyles. Close the sizer until the stylus touches the anterior cortex. The correct femur size can be read on the femoral sizer body, as showed below.

The femur size can be double-checked by adjusting the position of the stylus. Open the anterior yellow knob of the stylus by turning it clockwise (14) and slide the stylus until the tip of the stylus is in contact with the antero-lateral cortex of the femur (15). Double-check the femoral size by reading the scale on the stylus. Close the anterior yellow knob by turning it counter clockwise.



#### TIP

The anterior resection can be checked by inserting the angel wing into one of the slots of the femoral sizer body.

### CAUTION

The anterior femoral cut is limited in the antero-posterior placement by the need to avoid notching the anterior cortex and creating too large a gap between the flange and anterior cortex. The anterior cortex is most prominent laterally, so increasing the external rotation will progressively increase the minimum AP internal dimension required to avoid notching.

The external rotation can be adjusted from 0° to 6° by pushing and rotating the anterior blue knob (16).

If no external rotation of the femoral component is planned, the same amount of bone will be resected from both posterior condyles.

Once the size of the femur has been chosen, prepare the holes for the 4in1 cutting block fixation using the dedicated drills. Two alternative options are available: anterior referencing holes and posterior referencing holes.

### CAUTION

While drilling, ensure continuous contact between the femoral sizer and the distal resection. Hold the femoral sizer body and stylus in place using one hand.

Remove the femoral sizer.

## 5.2 4IN1 CUTTING BLOCK POSITIONING - ANTERIOR REFERENCE

Open the GMK Efficiency femur set of the chosen femoral size and then take out the 4in1 cutting block. Insert the pins into the anterior reference parallel holes of the 4in1 cutting block of the chosen size. Make sure to use the holes that correspond to the zero reference line (blue holes).

Hold the assembly while positioning the pins in the previously drilled holes. Slide the 4in1 cutting block onto the pins until it is completely flush with the distal resection plane.

### CAUTION

Headed pins are recommended to secure blocks against a flat surface. Smooth pins are recommended for use with cutting blocks against curved surfaces.



22.

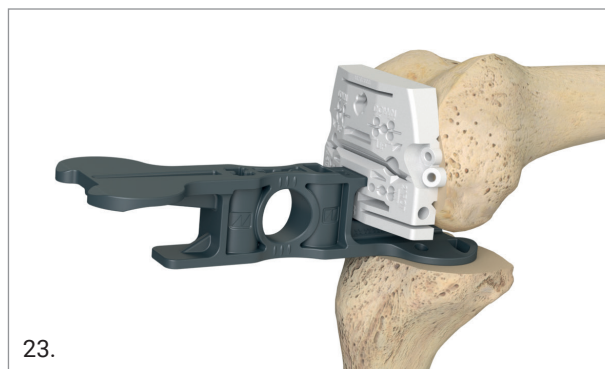
To correct the position of the 4in1 cutting block, move the block onto a different row of parallel pins. To move the 4in1 cutting block 2 mm anteriorly, position the cutting block on the row of pin holes marked "UP". To move the cutting block 2 mm posteriorly, position the 4in1 cutting block on the row of pin holes row marked "DOWN" as shown in figure 22.

Once the 4in1 cutting block has been properly positioned on the femur, visually check the cut height with the angel wing before cutting.

### OPTION

Check the correct femoral external rotation of the 4in1 cutting block by inserting the rotation guide (horseshoe) in the dedicated slot (green in figure 22). The rotation guide simulates the thickness of the final implant (tibia + inlay + femur). It has two sides, simulating a 10 mm inlay and a 12 mm inlay.

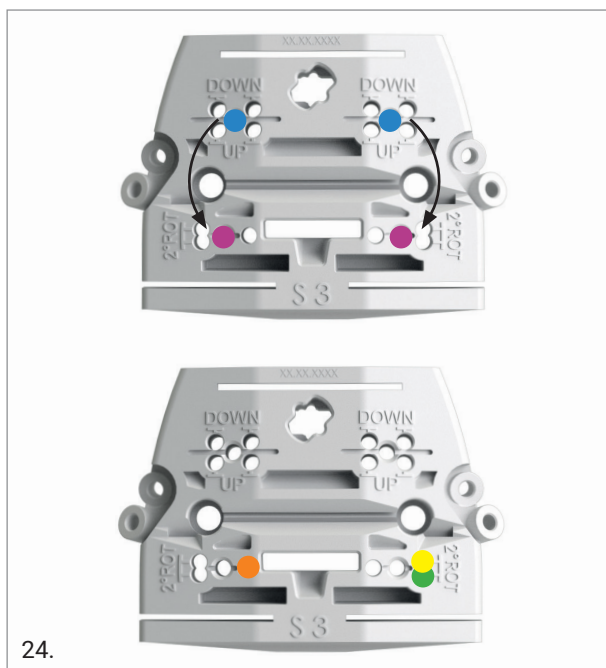
Different inlay thicknesses (11, 13 or 14 mm) can be simulated by attaching the corresponding spacers to the 10 mm side of the rotation guide. Thicker spacers (17 and 20 mm) are available in the Efficiency extension set (ref. 11.00102 and 11.10102).



23.

### External Rotation Modification - Anterior Reference

To correct femoral external rotation, drill the posterior referencing holes and insert two pins (the holes marked with purple circles in figure 24). Then, remove the anterior referencing pins and reposition the 4in1 cutting block on the medial pin hole and on one of the two lateral rotation pins.



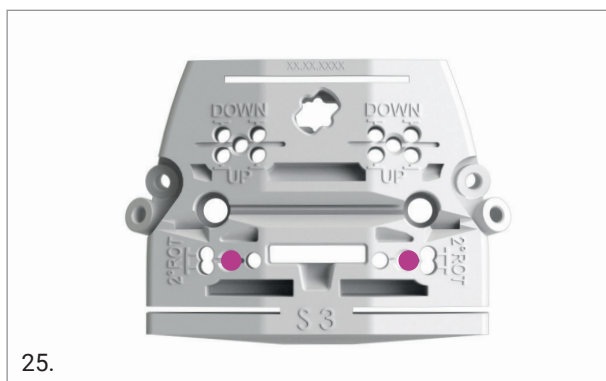
24.

- Medial pin hole
- ● +2 external rotation
- ● -2 external rotation

### 5.3 4IN1 CUTTING BLOCK POSITIONING - POSTERIOR REFERENCE

Insert the pins into the posterior referencing parallel holes of the 4in1 cutting block of the chosen size (purple holes).

Hold the assembly while positioning the pins in the previously drilled holes. Slide the 4in1 cutting block onto the pins until it is in complete contact with the distal resection.



25.

To correct femoral rotation, reposition the 4in1 cutting block on the medial pin hole and on one of the two lateral rotation pins.



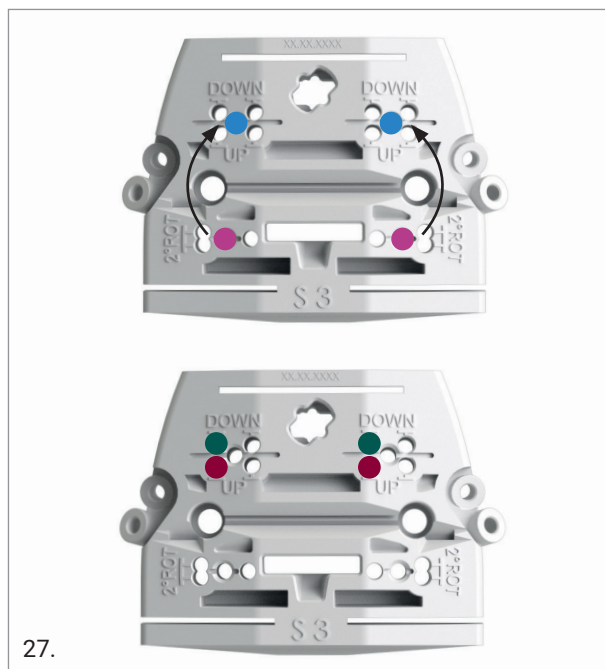
26.

- Medial pin hole
- ● +2 external rotation
- ● -2 external rotation

Once the 4in1 cutting block has been properly positioned on the femur, visually check the cut height using the standard angel wing before cutting.

#### 4in1 Cutting Block Position Modification - Posterior Reference

To correct femoral position, drill the anterior referencing holes and insert two pins. Then, remove the posterior referencing pins and reposition the 4in1 cutting block onto a different row of parallel pins. To move the 4in1 cutting block 2 mm anteriorly, position the cutting block on the row of pin holes marked "UP". To move the cutting block 2 mm posteriorly, position the 4in1 cutting block on the row of pin holes marked "DOWN".



27.

- +2 mm anteriorly
- +2 mm posteriorly



## 5.4 4IN1 FEMORAL RESECTION

Once the 4in1 cutting block position has been properly adjusted, stabilize the block using the options indicated below.



- Oblique fixation holes
- Cancellous bone screw holes

When the 4in1 cutting block has been stabilized, perform the femoral resections:

1. Anterior femoral resection
2. Posterior femoral resection
3. Posterior chamfer
4. Anterior chamfer

### CAUTION

Engage the saw blade into the cutting slot before activating the saw. Use physiological solution to cool the cutting block during resection. After resection, rinse the joint before positioning both the trial and final implant.

Remove the screws and/or the oblique pins. The removal of the 4in1 cutting block can be performed using the end of the trial base handle.



## 5.5 FEMORAL UPSIZING/DOWNSIZING

The difference between two consecutive femoral sizes is 2 mm in both antero-posterior and medio-lateral planes.

### Anterior Referencing: Upsizing/Downsizing

Replace the 4in1 cutting block with one of a more suitable size using the same row of holes.

In case of downsizing, the posterior resection level is moving 2 mm anteriorly. If necessary, the guide can be moved onto the other rows of holes (2 mm modifications).

### Posterior Referencing: Upsizing/Downsizing

Replace the 4in1 cutting block with one of a more suitable size using the same row of holes.

### CAUTION

When downsizing, the anterior resection level is moving 2 mm posteriorly. Make sure that there is no anterior notching and, if necessary, move the guide on to the lower pin holes.

### Anterior Referencing: Downsizing After The Femoral Resections

If it is necessary to downsize the femoral component after having performed the femoral resections, insert a saw blade in the slot of the anterior resection, apply the 4in1 cutting block on the distal cut, ensuring that the saw blade is perfectly flush with the anterior resected surface, and insert two pins in the row of holes belonging to the anterior holes group and marked with a line.

Replace the cutting guide with one of a more suitable size. Fix the cutting block following the procedure described at § 5.2 (4in1 cutting block positioning - Anterior reference).

### Posterior Referencing: Downsizing After The Femoral Resections

If it is necessary to downsize the femoral component after having performed the femoral resections, insert a saw blade into the slot of the anterior resection, apply the 4in1 cutting block on the distal cut, ensure that the saw blade is perfectly in contact with the anterior resected surface, and insert two pins in the row of holes belonging to the posterior holes group and marked with a line.

Replace the cutting guide with one of the inferior sizes. Fix the cutting block following the procedure described at § 5.3 (4in1 cutting block positioning - Posterior reference). Perform the femoral resections.

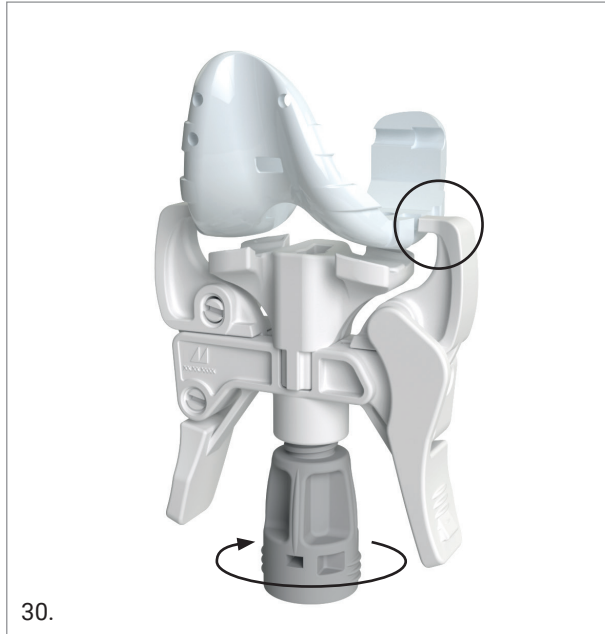
### CAUTION

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

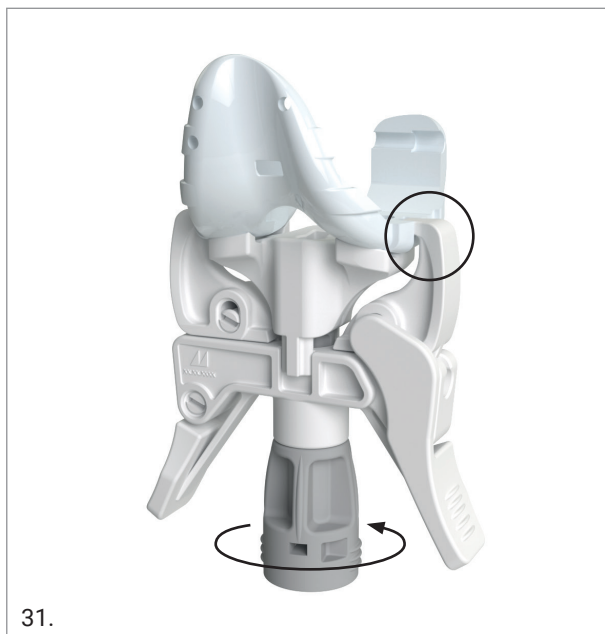
## 6. TRIALING

Assemble the femoral clamp with the multifunctional handle. Take out the appropriate trial femoral component from the GMK Efficiency femur set.

Mount the trial femoral component onto the femoral clamp by unscrewing the mobile part of the clamp and securing the trial femur between the claws of the clamp.



Tighten the clamp to further secure the trial femur by screwing the mobile neck of the clamp.



Position the trial femoral component on the resected femur, centering it medio-laterally.

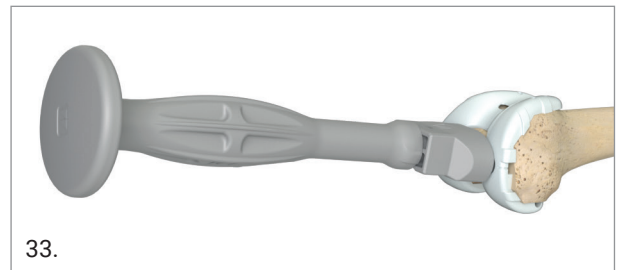
### CAUTION

DO NOT USE the femoral clamp to impact the femoral component onto the femur.



Once the trial femoral component has been positioned, disassemble the femoral clamp from the multifunctional handle.

Assemble the femoral impactor to the multifunctional handle and impact the trial femoral component.



Fix the trial femoral component with one or more pins using the anterior holes. Drill the holes for the femoral pegs using the femoral drill bit, assembled with the dedicated reduction and power equipment.



34.

Open the GMK Efficiency tibial set of the selected tibial size.

### CAUTION

When using a size 3 or 4 tibia, open the insert tray "i3 - t3/4" if the femoral size ranges from 1 to 3+, and the insert tray "i4 - t3/4" if the femoral size ranges from 4 to 7.

Assemble the trial tibial baseplate, of the appropriate size, with the trial base handle. Clip the trial insert, of appropriate thickness, onto the trial baseplate. Reduce the patella and test the knee throughout its range of motion.

**NOTE:** The trial base handle has an offset to allow trialling with the patella left in place.



35.

### OPTION

In the Efficiency tibia set there are 10 mm, 11 mm, 12 mm, 13 mm and 14 mm trial inserts. Should a thicker insert be needed, 17 mm and 20 mm spacers included in the Efficiency extension set can be clipped between the trial baseplate and the 10 mm trial insert.

In order to adjust the rotation of the tibial baseplate, mark the position of the trial baseplate on the bone.



36.

## 7. FEMORAL FINISHING

Assemble the femoral clamp with the multifunctional handle and remove the trial femur. Then, position the femoral box cutting guide on the peg holes. Fix the guide with two pins.

Perform the femoral box resection using the trochlea reamer.



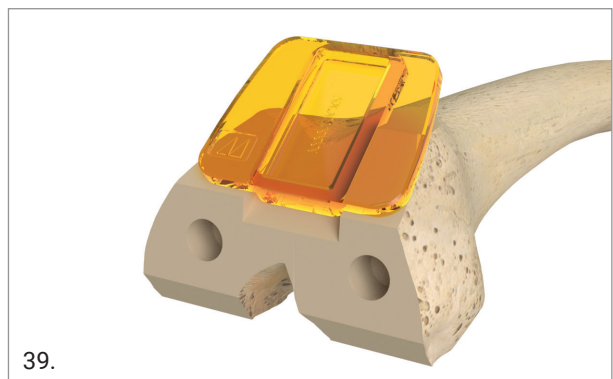
### CAUTION

In order to accurately prepare the femoral box, it is advisable to ream from the anterior aspect of the femur to the posterior aspect.



Remove the femoral box cutting 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.

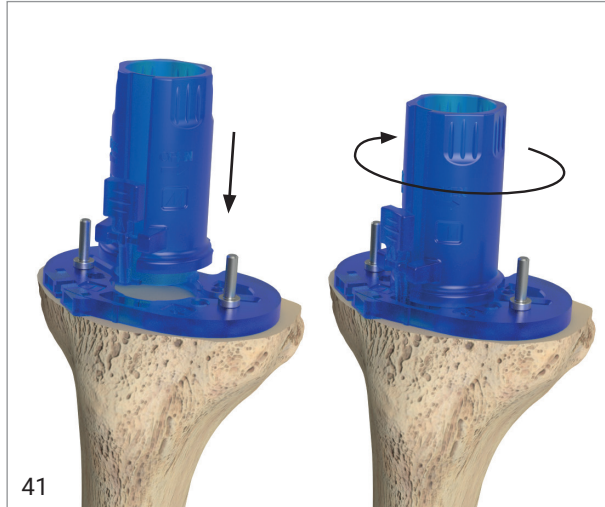


## 8. TIBIAL FINISHING

Position the trial baseplate onto the resected tibia, aligning it to the markings made on the bone during the trialling phase. Check the bone coverage and secure the baseplate with two sword pins.



Assemble the reamer guide to the trial tibial baseplate and rotate it clockwise to lock it into place.



Insert the dedicated reamer into the guide and prepare the keel hole parallel to the axis of the bone until the depth gauge stopper is reached. To excise the bone, ream clockwise.



Once the keel hole has been performed, push the locking lever, turn the reamer guide counter clockwise and remove it.

### CAUTION

In order to avoid damaging the tibia during impaction of the keel, prepare the slots for the keel fins using an oscillating saw.

Assemble the trial keel onto the multifunctional handle and impact it through the dedicated hole of the trial baseplate, thus finishing the keel preparation.



## 9. OPTION - TIBIAL EXTENSION STEM

For additional tibial baseplate stability (if required), an extension stem 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 with the help of the X-ray template.

Remove the trial keel from the bone and re-position the reamer guide.

Open the intramedullary canal using the 9 mm drill bit then insert the 11 mm metal bush into the reamer guide.



Ream the canal until the 30 mm mark on the 11 mm reamer is aligned with the top of the reduction bush.



### OPTION

For the 65 mm stem option, ream until the 65 mm mark on the reamer. The 65 mm trial extension stem is available only in the extension stem complement (§ 16).

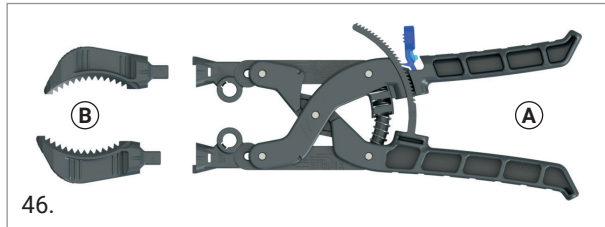
Remove the 11 mm bush and insert the 15.5 mm bush into the reamer guide. Finish the extension stem hole preparation using the 15.5 mm reamer.



Remove the reamer guide and open the dedicated GMK Efficiency extension set. Assemble the trial extension stem (30 mm long) onto the trial keel. Assemble the trial keel+trial extension stem to the multifunctional handle and impact it into the prepared hole.

## 10. PATELLA RESURFACING

Open the GMK Efficiency patella set and take out the patella clamp (A) and the resection jaws (B).



Attach the two resection jaws to the patella clamp. Check that the resection jaws are correctly attached: the markings on the patella clamps and jaws should be aligned.

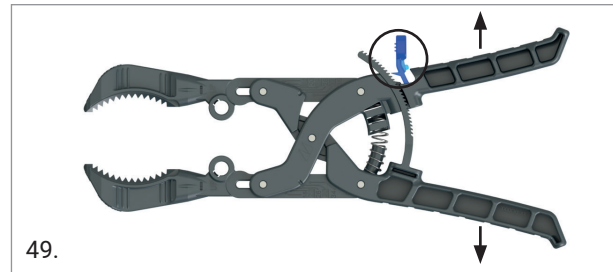
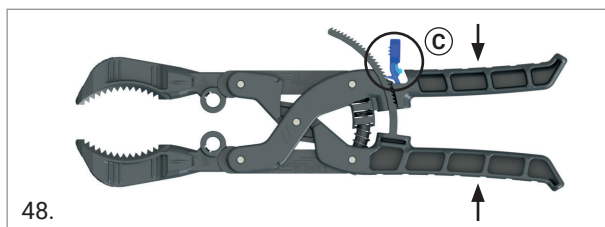


The patella clamp has a locking mechanism that holds the position once the clamp has been closed.

To reset the clamp to the fully-open position, push the locking lever (C) in the "unlocking position" and release the two arms.

### CAUTION

Before pushing the release-lever gently compress the clamp handles, then gently push the lever and release the handles to open the clamp.



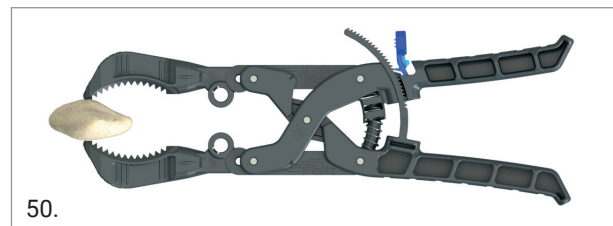
### 10.1 PATELLA THICKNESS MEASURING

The patella clamp assembled with the resection jaws can be used as a calliper to measure the thickness of the patella.

Close the patella clamp until the two tips of the resection jaws touch the most protruding points of the patella.

### CAUTION

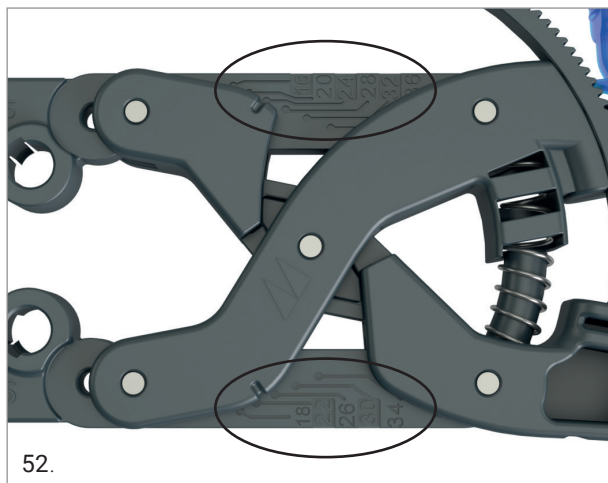
Do not force the patella clamp during this phase as excessive tightening could lead to incorrect measurement.



The thickness is displayed on the scale engraved on the body of patella clamp (24 mm in the example below).

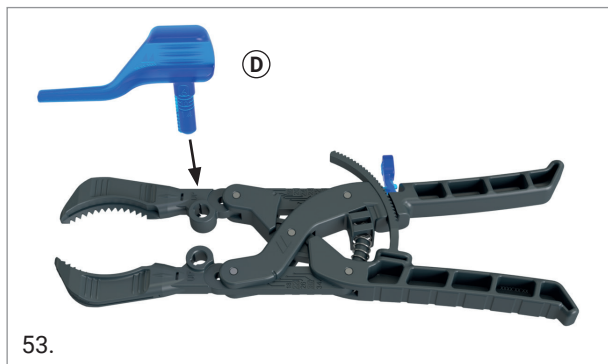


The scale is shown in 2 mm increments, alternated on the two arms of the clamp.

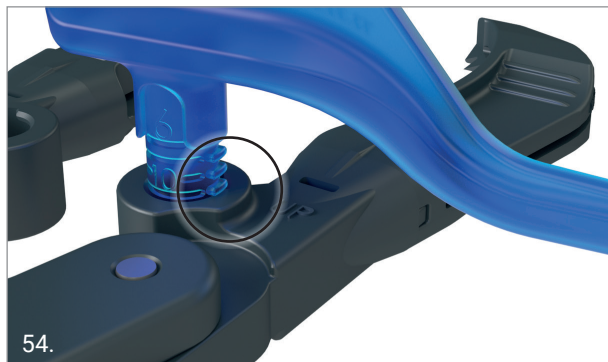


## 10.2 PATELLA CLAMP POSITIONING

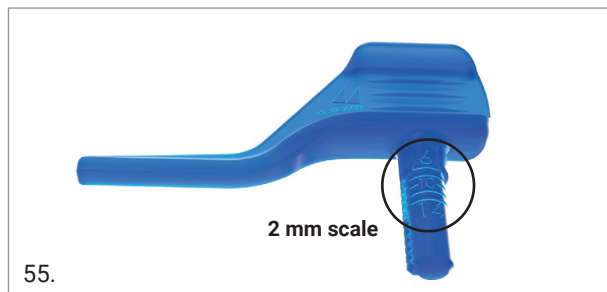
The patella stylus (D) should be positioned in the dedicated slot of the patella clamp, making sure that the “UP” mark is facing upwards.



Only one orientation allows the insertion of the stylus.



A scale is engraved on the stylus, which indicates the thickness of the bone to be resected. Set the resection level referring to this scale.



### CAUTION

Make sure that at least 13 mm of bone remains after resection.

Lock the stylus by turning it towards the center of the patella clamp.

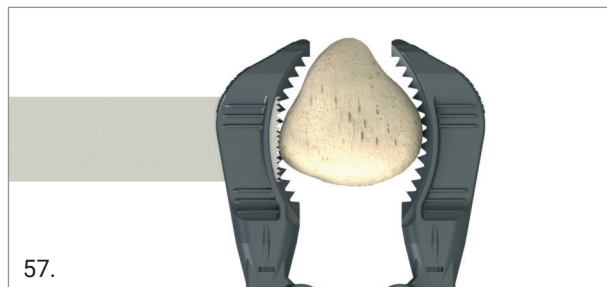
Unlock and open the patella clamp, position the stylus in contact with the highest point of the patella dome and close the jaws to firmly lock the patella rim.



Remove the stylus by turning it into the removal position, then perform the patella resection with an oscillating saw.

### CAUTION

Engage the saw blade into the cutting slot before activating the saw. Use physiological solution to cool the patella cutting guide during resection. After resection, rinse the patella before positioning both the trial and final implant.



Once the cut has been made, unlock the clamp and remove it from the bone.

### 10.3 PEGS PREPARATION AND SIZING

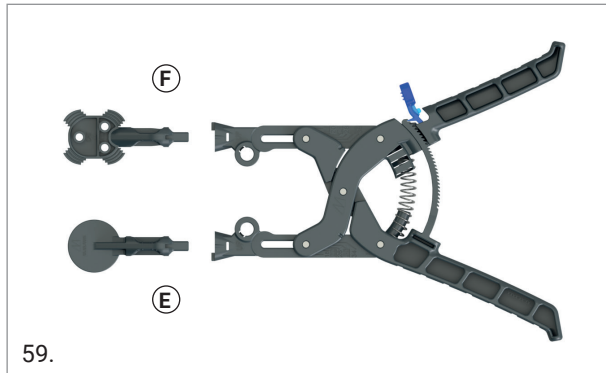
The patella can be sized using the patellar sizers. There are two sizers in the patella set, each one simulating two consecutive sizes (S 1 & 2, S 3 & 4).



Once the size has been selected, assemble the peg holes drilling guide (E) and the base insert (F) to the patella clamp.

#### CAUTION

The patella sizers and the base insert have spikes, **HANDLE WITH CARE.**

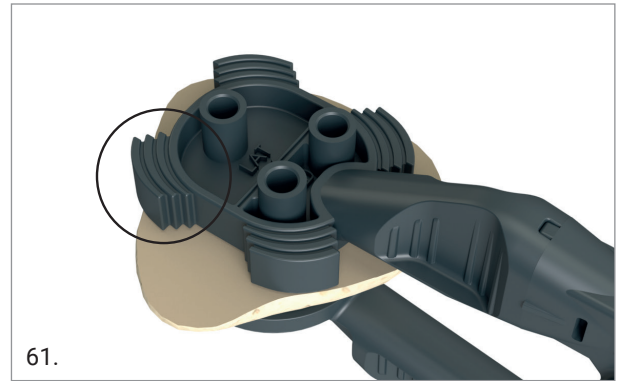


Grab the patella making sure that the MED and LAT marking of the drilling guide are positioned respectively on the medial and lateral sides of patella (the 2 peg holes must be on the medial side of the patella).

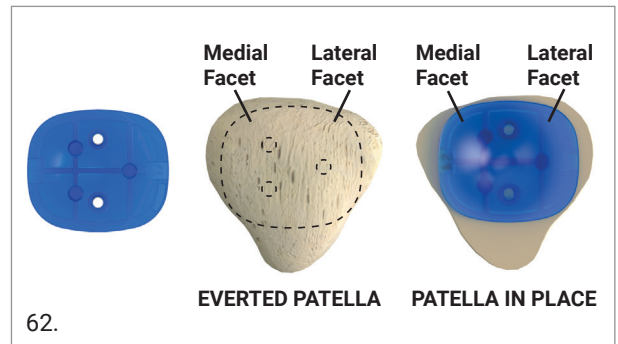


The drilling guide has 4 contours in each corner, corresponding to the profiles of the 4 sizes of the patella implant.

Be sure that the selected contour matches the patella profile on each one of the four angles.

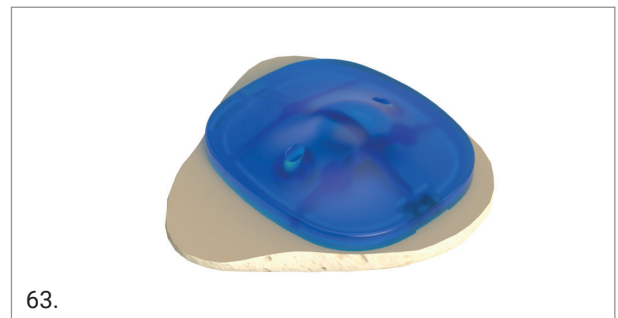


Drill the 3 peg holes using the specific drill bit.



### 10.4 TRIALLING

unlock the clamp and remove it from the patella. Place the trial patella, of the chosen size, on the bone, centering it on the 3 holes.



Assemble the cement cup (G) and the base insert on the patella clamp and pressurise the trial implant on the bone.



Reduce the patella and test the knee throughout its range of motion. When satisfied, remove the trial patella from the bone.

**NOTE:** After completing preparation of the femur, tibia and patella, it is advisable to reduce the patella and test the knee throughout its range of motion, to verify the position of the implants. The trial base handle can be assembled to the trial insert, in order to simplify its insertion into the knee joint. The trial base handle is offset to allow trialling with the patella in place, without removing it.

## 11. SELECTION OF THE PROSTHETIC COMPONENTS - SIZE MATCHING

GMK Fixed Tibial Trays can be matched with GMK Sphere Flex 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**

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 Tibial Insert

\*\* Tibial Trays t3-i4 have the same coverage in AP and ML of a Tibial Tray Size 3 and must be used with a Tibial Insert size 4.

\*\*\* Tibial Trays t4-i3 have the same coverage in AP and ML of a Tibial Tray Size 4 and must be used with a Tibial Insert size 3.



## 12. FINAL IMPLANTS

Having completed all bone preparations and selected the definitive components, the final implants 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 to the under-surface of the tibial implant into the corresponding cement pockets. If cement is applied directly to the bone, please ensure it does not enter the keel hole.

The final impaction is performed using the baseplate impactor, assembled with the multifunctional handle. 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, impact it with the dedicated tibia impactor assembled on the multifunctional handle. The extruded cement must be 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.

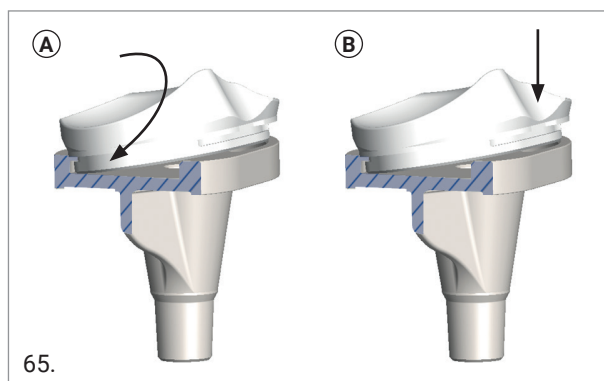
### 12.2 INSERT

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

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

#### 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

The insert 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.

### 12.3 FEMORAL COMPONENT

Assemble the femoral clamp on the multifunctional handle.

Open the femoral clamp jaws and attach them to the femoral component using the two lateral slots. Lock together by turning the handle screw mechanism 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, then assemble the femoral impactor on the multifunctional handle and impact the femoral component.

#### CAUTION

DO NOT USE the femoral clamp to impact the femoral component on the patient's femur bone.

Once the femoral implant has been fully inserted, the extruded cement must be 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 RESURFACING

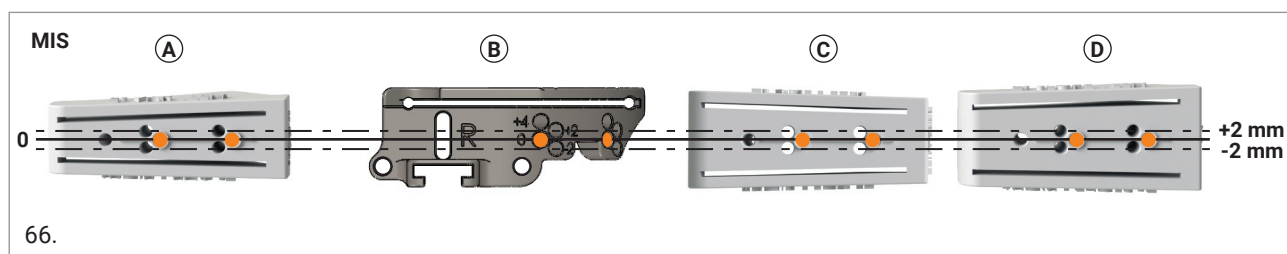
Assemble the spike jaw and the cement cup on the patella clamp.

The bone cement must be prepared as per the manufacturer's "instructions for use". Once the cement reaches the right viscosity, it should be applied to the internal surface of the patellar implant. Lock the patella implant to the patella resected surface by closing the patella 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 - MIS CORRECTION CUTTING BLOCK COMPATIBILITY

### 13.1 PROXIMAL TIBIAL RECUT

In the table below the compatibility between the tibial cutting block and MIS correction cutting blocks is highlighted.



● Compatible holes

(A) +2° varus tibial MIS correction cutting block

(B) tibial cutting block

(C) +2° valgus tibial MIS correction cutting block

(D) +2° slope tibial MIS correction cutting block

## 14. ANNEX 2 - IMPLANT 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 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 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

**RESURFACING PATELLA**

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

**STEM EXTENSION**

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

## 15. ANNEX 3 - INSTRUMENTATION NOMENCLATURE AND CONFIGURATIONS

The tables below shows the GMK UltiMate Efficiency configurations with relative part numbers.

### GMK SPHERE

Reference	Description
02.12S.301NEW	GMK UltiMate Conventional set
02.07S.EFFMETAL	GMK Instrumentation - Metal complement
11.01001 or 11.01002	GMK Efficiency Sphere general set or GMK Efficiency Sphere MIS general set

### GMK SPHERE FEMUR SIZE-SPECIFIC SETS

Reference (carton box)	Reference (no carton box)	Size
11.01011	11.11011	1
11.01111	11.11111	1+
11.01012	11.11012	2
11.01112	11.11112	2+
11.01013	11.11013	3
11.01113	11.11113	3+
11.01014	11.11014	4
11.01114	11.11114	4+
11.01015	11.11015	5
11.01115	11.11115	5+
11.01016	11.11016	6
11.01116	11.11116	6+
11.01017	11.11017	7

### GMK SPHERE – ON DEMAND SETS

Reference	Description
11.00005	GMK Efficiency Resurfacing patella instruments set
11.00006	Sword pin pack
11.00007	Short threaded pins pack
11.00008	Smooth pins pack
11.00009	Threaded pins pack
11.00010	Screws pack
11.00102	Extension instrument set
11.00103	Correction guide instrument set
02.07s.EFFEXT	GMK Instrumentation - Metal complement for primary extension stem

### GMK SPHERE TIBIAL/INSERT SIDE LEFT SETS

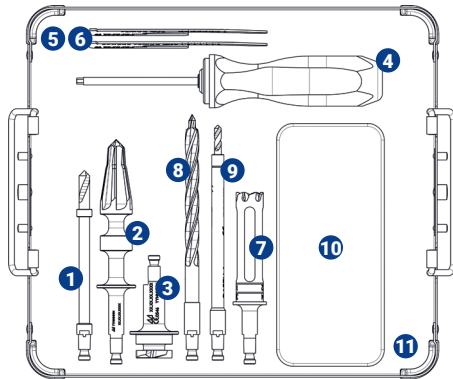
Reference (carton box)	Reference (no carton box)	Size
11.01021	11.11021	1
11.01022	11.11022	2
11.01023	11.11023	3
11.01024	11.11024	4
11.01025	11.11025	5
11.01026	11.11026	6

### GMK SPHERE TIBIAL/INSERT SIDE RIGHT SETS

Reference (carton box)	Reference (no carton box)	Size
11.01031	11.11031	1
11.01032	11.11032	2
11.01033	11.11033	3
11.01034	11.11034	4
11.01035	11.11035	5
11.01036	11.11036	6

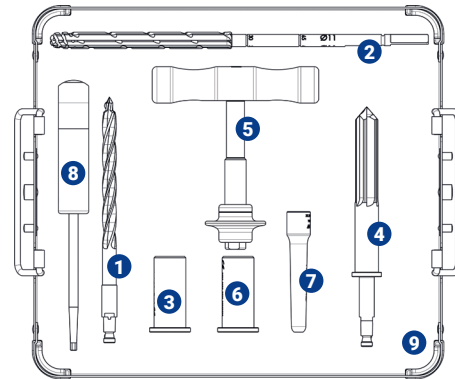
## 16. ANNEX 4 - METAL SETS

### REF. 02.07S.EFFMETAL



N.	Ref.	Description	Q.ty.
1	02.07.10.1074	Drill Ø7 for femoral pegs - Hudson connection	1
2	02.07.10.1071	Reamer for tibial keel - Hudson coupling	1
3	02.07.10.0046	Trochlea finishing reamer	1
4	02.07.10.4577	Torque limiter screwdriver 3.5 N.m	1
5	02.12.10.0142	GMK-SPHERE Multisize Medium Sickle Finger	1
6	02.07.10.0775	Medium Sickle Finger-Narrow	1
7	02.07.10.9795	PS cam resection reamer	1
8	02.02.10.0128	Drill bit (ç 9, L 162 mm) Hudson coupling	1
9	02.02.10.0404	Mobile patella pegs drill (ç4.5,L155) Hudson coupling	1
10	02.08.10.0120	UKM pin Ø 3.2 L=55	2
	02.02.10.0130	Drill Ø3.2 mm L130	1
	02.02.10.0145/A	Pins ç 3.2, L 70 mm	4
	02.02.10.0145/B	Pins ç 3.2, L 90 mm	2
	02.07.10.2294	Pin Ø3.2 L=40 ISO5835-Meche-Head-Triangle	4
	02.07.10.2194	Sword pin Ø3.2 L=22 mm	2
	02.07.10.4741	Threaded pin Ø3.2 L85 longer connection	4
	02.07.10.4650	Screw HA5 - Length 35 - reduced head	3
11	02.07.10.8071	GMK Efficiency Metal Complement tray	1

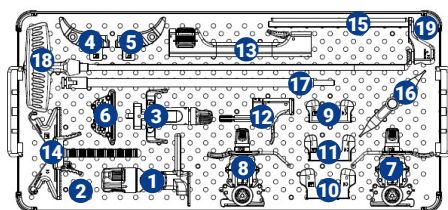
### REF. 02.07S.EFFEXT



N.	Ref.	Description	Q.ty..
1	02.02.10.0128	Drill bit (ç 9, L 162 mm) Hudson coupling	1
2	02.07.10.4590	Primary extension stem reamer D11	1
3	02.07.10.0019	Safe guide reamer reduction bush Ø11	1
4	02.07.10.1072	Drill bit Ø 15.5 mm - Hudson coupling	1
5	02.07.10.2020	Handle for safe Guide reamer	1
6	02.07.10.1052	Primary stem Ø 15.5 mm drill but guide	1
7	02.07.10.1053	Primary cem. trial extension stem/Ø11 mm-L.65 mm	1
8	1.113	Screwdriver 3.5 mm	1
9	02.07.10.8072	GMK Efficiency Extension Stem Complement tray	1



## REF. 02.12S.301NEW



N.	Reference	Description	Q.ty.
1	02.12.10.0854	Valgus Regulation	1
2	02.18.10.0003	Malleolar clamp lace	3
3	02.12.10.0856	Micrometrical Distal	1
4	02.12.10.0857	Slotted Tibia guide - Left	1
5	02.12.10.0858	Slotted Tibia guide - Right	1
6	02.12.10.0859	Distal Slotted Cutting Guide	1
7	02.12.10.1297	Femoral Sizer Left	1
8	02.12.10.1298	Femoral Sizer Right	1
9	02.12.10.0862	Femoral sizer base size 1-2	1
10	02.12.10.0863	Femoral sizer base size 6-7	1
11	02.12.10.0865	Femoral sizer base size 3-4-5	1
12	02.12.10.0950	Micrometric regulation assembly	1
13	02.12.10.0951	Proximal rod assembly	1
14	02.12.10.0952	Ankle clamp assembly	1
15	02.12.10.0955	Distal rod assembly	1
16	02.12.10.0956	Tibia stylus 2/10 mm with button	1
17	02.12.10.0957	Alignment rod	1
18	1.100 or 02.12.10.1103	Femoral Intramedullary rod	1
19	02.12.10.8219	GMK UltiMate Conventional tray	1

## 17. COMPATIBILITY CHART



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

Size 1	Size 2	Size 3	Size 4	Size 5	Size 6	Size 7
Size 1+	Size 2+	Size 3+	Size 4+	Size 5+	Size 6+	
Size 1	Size 2	Size 3	Size 4	Size 5	Size 6	
Size 1	Size 2	Size 3	Size t3-i4*	Size t4-i3**	Size 4	Size 5
Size 1	Size 2	Size 3	Size 4	Size 5	Size 6	
Size 1	Size 2	Size 3	Size 4	Size 5	Size 6	

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

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

## NOTES

Part numbers subject to change.

## NOTE FOR STERILIZATION

GMK Efficiency is delivered sterile. Metal reusable instruments to be used in association with GMK Efficiency must be cleaned before use and sterilized in an autoclave respecting the US regulations, 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 sterilization of Medacta International reusable orthopedic devices" available at [www.medacta.com](http://www.medacta.com).



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IN ORTHOPAEDICS  
AND SPINE SURGERY**

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GMK® UltiMate Efficiency  
Surgical Technique

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