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#### INTRODUCTION

The GMK® Primary can be implanted following different Surgical Techniques, according to the surgeon's preferences and habits:

- · Bone Referencing Muscle Sparing and Conventional Surgical Technique
- AllinOne Surgical Technique
- iMNS™ Navigated Surgical Technique
- · LBS Surgical Technique
- · Ligament Tensor Surgical Technique.

In this brochure a soft tissues referencing Surgical Technique is described, the LBS Surgical Technique.

This surgical technique ensures an accurate soft tissue balancing thanks to the specially designed LBS (Ligament Balancing System) representing a virtual distal femoral resection.

The LBS is used in extension to position the distal cutting block and to simulate:

- · Leg axis and the extension gap
- · Distal femoral resection.

Through the Rotation Guide the position of the A/P 4-in-1 speed block is automatically adjusted, with respect to the ligament tensioning and the flexion and extension gaps.

# Medacta® International gratefully thanks

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GAAK° PRIMARY



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# **SYMBOLS**

Throughout the surgical technique you will find the following symbols:

Option

The descriptions in the "Option" boxes refer to an alternative way to perform the same procedure.

MSS

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

PS

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



#### CAUTION

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

Please, consider the package inserts for complete product information.





LBS SURGICAL TECHNIQUE

#### 1 INDICATIONS

The GMK<sup>®</sup>- 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.

#### 2 CONTRAINDICATIONS

Total knee replacement is contraindicated in the following cases:

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

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

## 3 PRE-OPERATIVE PLANNING

# 3.1 Radiological Planning

This is performed from the scanogram, anteriorposterior, lateral and sunrise knee radiographs.

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

# 3.2 Clinical Planning

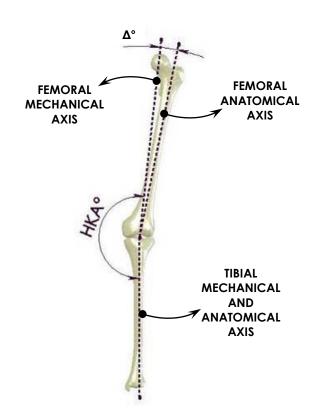
The goal is to assess the range of motion of the joint and patellar centring and to assess whether deformities and ligamentous instability exist or not.

# 4 SURGICAL APPROACH

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

Other approaches described include the subvastus and midvastus approach.

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





#### 5 TIBIAL RESECTION

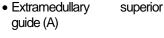
The tibial resection can be performed using either extramedullary or intramedullary alignment guides. For a muscle sparing approach the most suitable guide is the extramedullary one.

# 5.1 Assembling the Tibial Guide

#### Assembling the Extramedullary Tibial Guide

The extramedullary guide consists of the following





- 3° Tibia Cutting Guide Support (B)
- Tibial resection quide distal part (C)
- Malleolar clamp support (D)
- Malleolar clamp (E)
- Tibial Palpator (F)
- Tibial cutting block (G)

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

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

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



## Assembling the Intramedullary Tibial Guide

The intramedullary guide consists of the following components:

- Intramedullary guide (A)
- Intramedullary rod guide (B)
- Intramedullary rod (C)
- 3° Tibia Cutting Guide Support (D)
- Telescopic rod (E)
- Tibial Palpator (F)
- Tibial cutting block (G)

After the resection of ACL (standard PE insert), or of both cruciate ligaments (posterostabilized and ultracongruent inserts), open the intramedullary canal with the aid of the 9 mm

The hole must be drilled anteriorly to the tibial

drill.

spine to help the alignment with the tibial diaphysis.

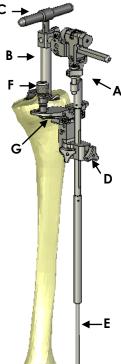
Slide the tibia cutting block (standard only) into the 3° tibia cutting guide support and lock the system by turning the lateral screw.

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

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

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







#### LBS SURGICAL TECHNIQUE



# 5.2 Setting the tibial varus/valgus

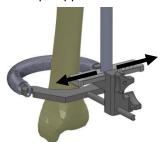
To ensure neutral tibial rotation, the centre of the tibial cutting block must be exactly opposite the medial third of the tibial tubercle. The flat anterior border of the cutting block should be parallel to the transverse mediolateral plane of the tibia.



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

# Setting the tibial varus/valgus Extramedullary Guide

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



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

# Setting the tibial varus/valgus - Intramedullary Guide

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

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



# 5.3 Setting the tibial slope

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

# Setting the tibial slope - Extramedullary Guide



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

of the malleolar clamp malleolar clamp rod.

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

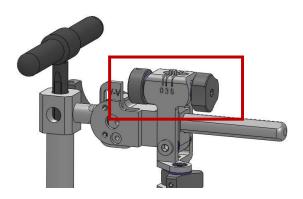
MSS

For a muscle sparing approach, fix the guide, inserting a 2.2mm sword pin in the proximal hole of the superior guide.



#### Setting the tibial slope - Intramedullary Guide

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





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







# 5.4 Setting the tibial resection level

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

## Setting the tibial resection level - Extramedullary Guide



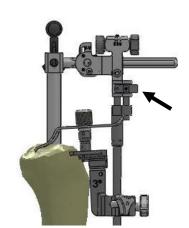
Adjust the cut height the chosen using reference stylus by sliding the 3° support vertically along the extramedullary superior guide (graduation in 2mm increments).

Verify the level of the cut with the help of the

sickle finger.

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

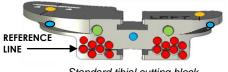
## Setting the tibial resection level - Intramedullary Guide



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

# 5.5 Fixation of the tibial cutting block

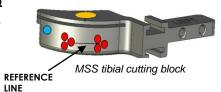
Before fixing the tibial cutting block, it is recommended to check the cut height and the posterior slope with the help of the sickle finger.



# Standard tibial cutting block

#### Tibial Cutting block holes (left knee)

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



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

# 5.6 Removing the tibial cutting guide

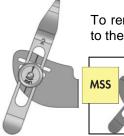
#### Removing the Extramedullary tibial cutting guide

Remove the tibial palpator and unlock the frontal screw of the 3° support guide.

Loosen the extramedullary guide and withdraw the proximal extramedullary rod from the distal stem attached to the malleolar clamp.

#### Removing the Intramedullary tibial cutting guide

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



To remove the tibial palpator from the tibial cutting block, align the arrow on the palpator to the line marked on the cutting block, as shown in the pictures on the left.



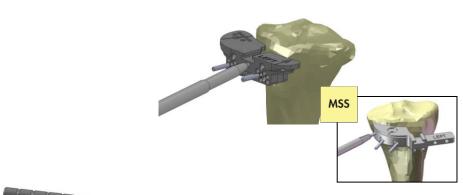




In order to check the frontal alignment of the cutting block, it is possible to assemble to the standard cutting block the telescopic alignment rod and verify if it points to the second metatarsal bone.

# 5.7 Tibial resection

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





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



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



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





LBS SURGICAL TECHNIQUE

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

# Option

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.





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







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

# Full PE

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

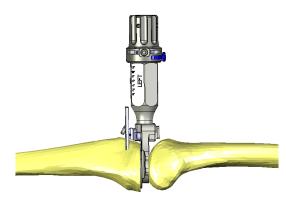




#### LBS SURGICAL TECHNIQUE

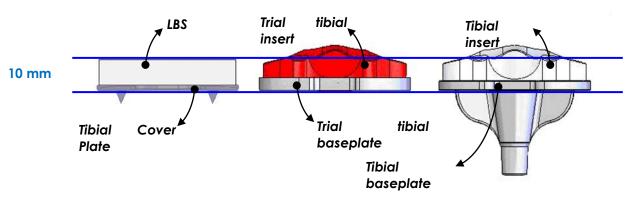
GAAK° PRIMARY

#### **TIBIAL RESECTION CHECK** 6

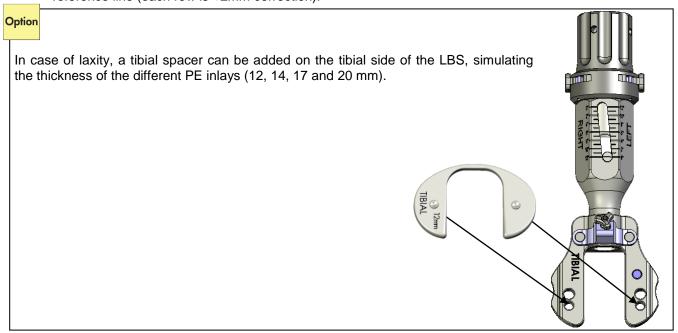


To check the performed tibia resection, put the knee in extension and insert the LBS in the joint, so that the "TIBIAL" marking is facing the tibial cover plate.

The LBS and the tibial cover plate simulate the minimum tibial thickness (10 mm), that is the thickness of the tibial baseplate and the corresponding PE insert.



If it is not possible to insert the LBS in the joint, the height of the tibial resection can be changed by dropping the tibial cutting block to the two tibial pins left in place for this purpose, using the rows of holes above the reference line (each row is +2mm correction).

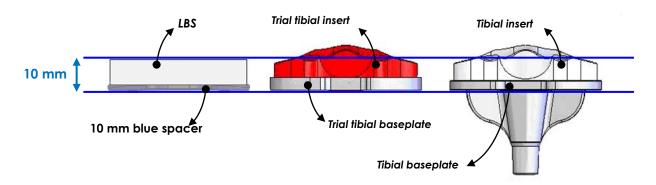






If the tibial cover plate is not used, the <u>10 mm blue tibial spacer must always be added</u> on the tibial side of the LBS, in order to simulate the minimum tibial thickness.

In case of laxity, the <u>blue tibial spacers</u> have to be added on the tibial side of the LBS, simulating the thickness of the different PE inlays (12, 14, 17 and 20 mm).







#### 7 LIGAMENT BALANCING SYSTEM

Open the intramedullary canal by means of the 9mm drill. It is recommended to toggle the drill tip to allow venting of the intramedullary canal.



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

The medio-lateral width of the femur can be double-checked by means of the sickle finger.

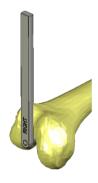
Select the femoral size on the femoral intramedullary

hole gauger and position this in the middle of the trochlea while in contact with the anterior cortex. This will identify the intramedullary canal according to the femoral size.

Put the knee in flexion and insert the LBS IM rod in the intramedullary canal.



The LBS IM rod is available in two versions, left and right. Please ensure that the correct one is inserted according to the side being operated on.



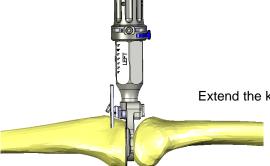
To improve the accuracy of the alignment, it is suggested to add to the proximal part of the IM rod an extension stem of 100 mm. In case of short femur a 50 mm extension stem is also available.

Please note that the insertion of the IM rod without any extension stem can lead to wrong alignment.

Keeping the knee in flexion (90°), insert the LBS on the LBS IM rod, without pushing it all the way.



If a tibial spacer was used to check the tibial resection (§6 - TIBIAL RESECTION CHECK), make sure that the spacer is still assembled to the LBS.

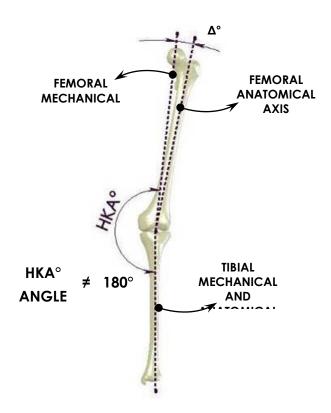


Extend the knee and insert the LBS completely in the joint.







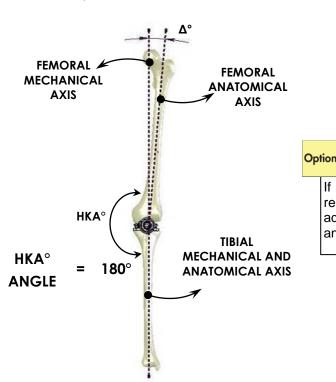


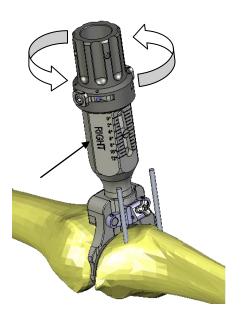
As the tibial cut has been performed perpendicular to the tibial mechanical axis, the residual deformity (if given) should be checked and corrected acting on the distal resection and the ligament balancing.

The value of the  $\Delta^{\circ}$  angle between the femoral anatomical and mechanical axis, has to be estimated by pre-operative X – Rays planning.

The  $\Delta^\circ$  angle must then be set on the LBS, by turning the upper washer according to the marked scale relating to the side to be operated on.

By means of this adjustment, the LBS allows to reduce the joint and to simulate the planned HKA.





If pre-operative X-Rays are not available, it is recommended to pre-set the value at 6° and then to adjust it according to the ligament balance in extension and the HKA alignment rod.







It is always recommended to check the limb alignment using the HKA alignment rod. The rod is assembled on the top of the LBS: the proximal tip of the latter should point to the centre of the hip, while the distal tip should point to the second metatarsal bone.

With the LBS in place it is possible to check the ligament balance. If there is any instability, add a thicker tibial spacer to the LBS, simulating a thicker PE insert.

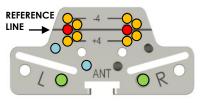
If the joint is constrained, it is possible to reduce the thickness of the tibial spacer, which simulates a higher tibia resection or a release.

These choices depend on the patient's anatomy, on the surgery and on the surgeon's judgement.

Once the knee joint has been considered well balanced and the mechanical axis is deemed satisfactory, proceed with the distal resection.



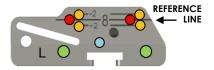
# 8 FEMORAL DISTAL RESECTION



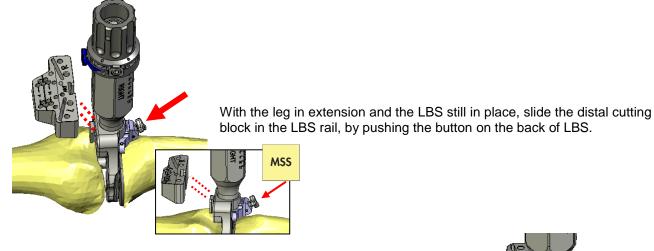
Standard distal cutting block

#### **Distal Cutting block holes**

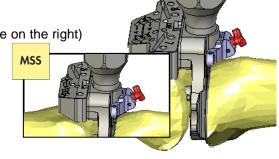
- Parallel positioning holes
- Oblique fixation holes
- Sawblade guide/alignment rod holes
- Parallel repositioning holes

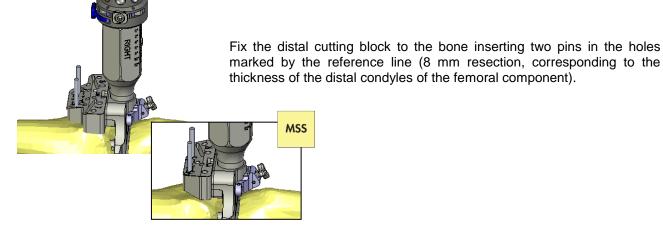


MSS distal cutting block



Firmly tighten the LBS screw (red highlighted in the picture on the right) in order to secure the cutting block to the LBS.



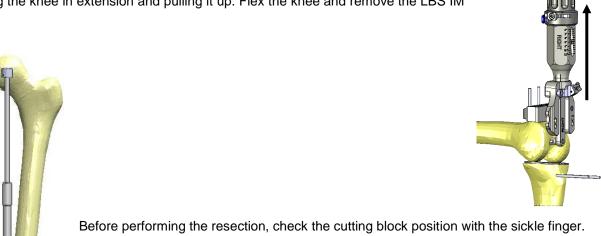




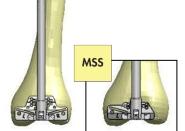


#### LBS SURGICAL TECHNIQUE

Once the guide has been fixed, release the LBS from the cutting block, unscrewing the locking screw and pushing the button on the back, and remove it from the IM rod holding the knee in extension and pulling it up. Flex the knee and remove the LBS IM Rod.

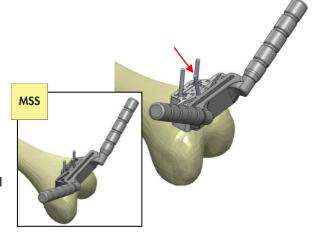


Before performing the resection, check the cutting block position with the sickle finger. In order to double-check the correct alignment of the distal cutting block the telescopic alignment rod can be inserted into the dedicated holes of the cutting block. Verify that it points in the direction of the centre of the femoral head.



Once the distal cutting block position is adjusted, it is recommended to add an additional oblique pin in the dedicated hole, to stabilize the guide.

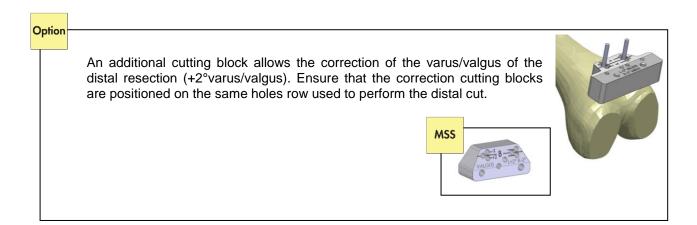
Place the saw blade guide and perform the distal resection.







Once the resection is performed, remove the oblique pin and the distal cutting block. The parallel pin should be left in place in case distal recut is required.



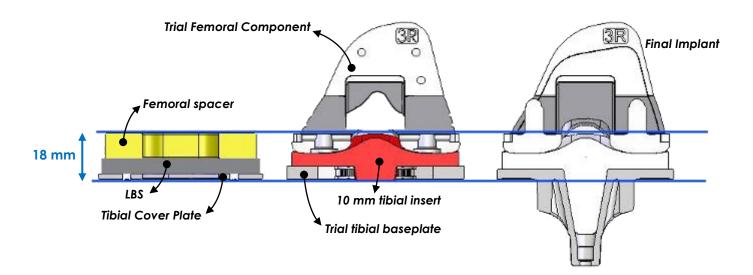


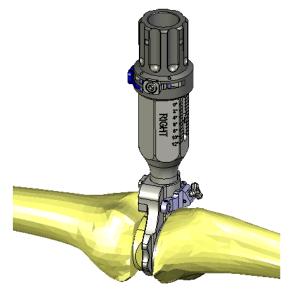


#### 9 EXTENSION GAP CONTROL

In order to check the performed femoral distal resection, the LBS assembled with the femoral spacer will be used.

The femoral spacer simulates the thickness of the femoral component (8 mm) and is available in 2 different widths, suitable for sizes 1-3 and 4-6. Therefore, the thickness of the LBS, assembled with the femoral spacer (and, if necessary, with a tibial spacer) and leaning on the tibial cover plate, corresponds to the total prosthesis thickness given by the tibial baseplate, the PE insert and the femoral component.





With the knee in extension, insert into the joint the LBS endowed with the femoral spacer and, if required, with the tibial spacer used during the distal cutting block positioning (§7 - LIGAMENT BALANCING SYSTEM).

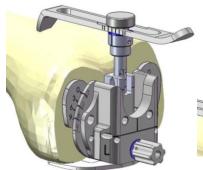
Verify that the knee is stable and correctly balanced in extension.

Once the extension gap has been checked and considered satisfactory, it is possible to remove the parallel pins of the distal cutting block, left in place in case any distal recut is required.



# 10 ANTERIOR CUT, POSTERIOR CUT AND CHAMFERS

#### 10.1 Femoral size evaluation

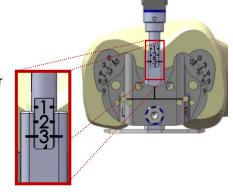


To assess the size of the femur, the femoral sizer must be positioned flush to the distal resection, with both posterior condyles well applied on its base.



Fine-tune the positioning of the sizer, by selecting the size of the femur on the graduated scale on the anterior palpator.

Close the sizer until its anterior palpator touches the femoral anterior cortex; the size of the femur can be read on the femoral sizer.



# 10.2 4in1 femoral cutting block positioning

The femoral anterior, posterior and chamfers resections are performed with the 4 in 1 femoral cutting block.



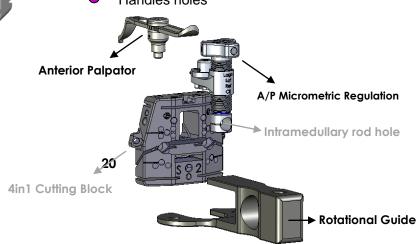
All femoral resections have to be performed by means of a 13mm wide and up to 1.27mm thick sawblade.



#### 4in1cutting block holes

- A/P Micrometric Regulation holes
- Anterior Palpator holes
- Oblique fixation holes
- Cancellous bone screws holes
- Parallel positioning holes (Posterior Referencing)
- Parallel positoning holes (Anterior Referencing)
- Handles holes

The 4in1 cutting block must be assembled with the following components:





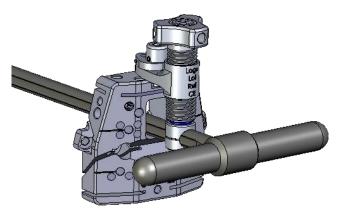
- · Anterior palpator
- A/P micrometric regulation
- · Rotational guide

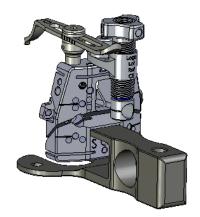


Assemble the A/P micrometric regulation on the 4in1 cutting block and fix it by turning its fixation screw, so that the two laser-marked lines are perpendicular.

Adjust the position of the A/P micrometric regulation as far down as possible turning the upper screw, this will simplify the positioning of the 4in1 cutting block to the bone.

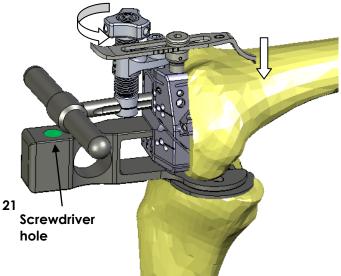
Ensure that the intramedullary rod can be inserted through the holes of both the A/P micrometric regulation and the 4in1 cutting block.





Insert the rotational guide in the dedicated slot and screw the anterior palpator on the 4in1 cutting block.

Flex the knee and position the cutting block flush to the distal cut, whilst introducing the intramedullary







rod through the A/P micrometric regulation into intramedullary canal.

With the knee at 90°, position the rotation guide on the tibial cover plate.



Should the positioning of the rotation guide be hindered by the dimension of the posterior condyles, a pre-cut of the posterior condyles is suggested.



Remember to assemble to the rotation guide the same tibial spacer used during the evaluation of the extension gap.

Turn the A/P micrometrical regulation until the anterior palpator touches the femoral anterior cortex.



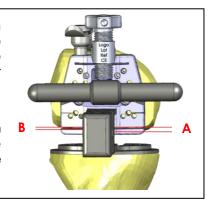
In order to better adjust the femoral rotation it is possible to introduce a screwdriver in the hole (green highlighted in the picture above) of the rotational guide to force it.



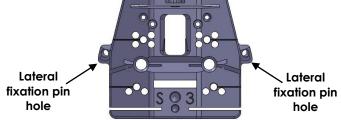
It is advisable to compare the automatic adjustment of the rotation of the cutting block given by the rotation guide with the conventional anatomical references (Whiteside's line and the epicondylar axis) or with the cutting plane created by the posterior condyles

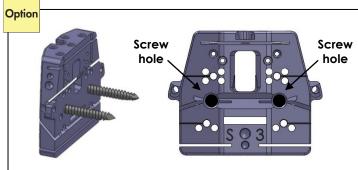
# External rotation = medial cut (A) > lateral cut (B)

Avoid any internal rotation and excessive external rotation. An excessive external rotation (A>>B) may be caused by inadequate medial ligament release or by a wrong rotational placement of the cutting block.



Once the positioning of the 4in1 cutting block has been adjusted, fix the block to the bone inserting two pins in the lateral holes of the 4in1 cutting block.





Alternatively or twith the fixation by means of the lateral pins, the 4 in 1 cutting block may be fixed to the bone using two cancellous bone screws inserted through the central holes by means of the dedicated screwdriver.



Once the 4in1 cutting block has been fixed, remove the intramedullary rod, the anterior palpator and the rotational guide from the cutting block. Turn the fixation screw of the A/P micrometric regulation, so that the two reference lines are aligned, and remove it from the cutting block.

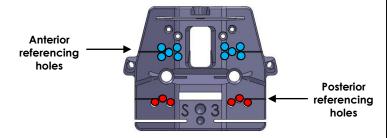




The previous fixation methods don't allow any re-positioning of the guide after the adjustment of the femoral rotation. In case of any need for fine-tuning the position of the 4in1 cutting block, the fixation by means of pins inserted in the parallel holes marked with a line should be considered.

On the 4in1 cutting block there are two different groups of parallel holes, anterior or posterior referenced.

Once the 4in1 cutting block has been fixed, remove the intramedullary rod, the anterior palpator and the rotational guide



from the cutting block. Turn the fixation screw of the A/P micrometric regulation and remove it from the cutting block.

If necessary, the cutting block can be moved 2 mm anteriorly or posteriorly, using the holes belonging to the same group (anterior or posterior referencing).

Once the positioning of the 4in1 cutting block has been finally adjusted, fix the block to the bone inserting two pins in the lateral holes of the 4in1 cutting block and/or using the cancellous bone screws. Remove the parallel pins.

The femoral resections have to be performed in the following order:

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



All femoral resections have to be performed by means of a13mm and up to 1.27mm thick wide sawblade.



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







#### 10.3 Femoral Upsizing/Downsizing

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

#### Posterior Referencing: Upsizing/Downsizing

Insert two pins in the posterior referencing parallel holes marked with a line and remove the lateral pins and/or the screws used to fix the 4in1 cutting block during the resections.



Replace the 4in1 cutting block with that of more suitable size using the same row of holes and, after having fixed the block with lateral pins, perform the femoral cuts.



In case of downsizing, the anterior resection level is moving 4 mm posteriorly. Make sure that there is no anterior notching and, if necessary, move the guide on the lower pin holes (2mm correction).

# Downsizing after the femoral resections

If it is necessary to downsize the femoral component after having performed the femoral resections, insert a saw blade in the slot of the anterior resection, apply the 4 in 1 cutting block on the distal cut,



ensure that the saw blade is flush to 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 that of inferior size. Fix the cutting block with the lateral pins and perform the femoral resections.



The anterior resection level is moving 4 mm posteriorly. Make sure that there is no anterior notching and, if necessary, move the guide on the lower pin holes (2mm correction).

#### Anterior Referencing: Upsizing/Downsizing

Insert two pins in the anterior referencing parallel

holes marked with a line and remove the lateral pins and/or the screws used to fix the 4in1 cutting block during the resections.



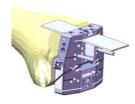
Replace the 4 in 1 cutting block with that of more suitable size using the same row of holes and, after having fixed the block with lateral pins, perform the femoral cuts.



In case of downsizing, the posterior resection level is moving 4 mm anteriorly. If necessary, the guide can be moved on the other rows of holes (2 mm correction).

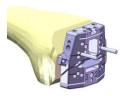
#### Downsizing after the femoral resections

If it is necessary to downsize the femoral component after having performed the femoral resections, insert a saw blade in the slot of the anterior resection, apply the



4 in 1 cutting block on the distal cut, ensuring that the saw blade is perfectly in contact with the anterior resected surface, and insert two pins in the row of holes belonging to the anterior holes group and marked with a line.

Replace the cutting guide with that of inferior size. Fix the cutting block with the lateral pins and perform the femoral resections.





The posterior resection level is moving 4 mm anteriorly. If necessary, the guide can be moved on to the other rows of holes (2 mm correction).

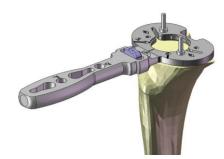




# 11 TIBIAL FINISHING

# 11.1 Tibial baseplate positioning

#### **Fixed**



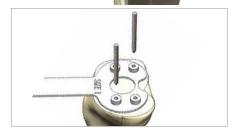
Place the appropriate sized trial tibial baseplate assembled with the trial base handle, on the tibia resection. The tibial baseplate is asymmetrical. Rotate the baseplate until the best coverage of the tibial cortical bone is achieved and fix it by means of two pins. The pins must always be placed in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

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

#### **Full PE**

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

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



# 11.2 Tibial finishing

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

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



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







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





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

To excise the bone drill clockwise, to compact the bone drill counterclockwise (no bone is excised).

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







#### 11.3 Tibial Stem Extension

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



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



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

Remove the trial keel from the bone.



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

Assemble the T-handle with the 9mm reamer.



Ream the canal until the correct depth is reached.

Remove the 9mm reduction bush and insert the 11mm reduction bush. Repeat the reaming with the 11mm reamer, until the same depth previously reached.

Insert the reduction bush ( $\emptyset$ 15mm) 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.





#### 12 PATELLA

# 12.1 Resurfacing patella

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



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

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



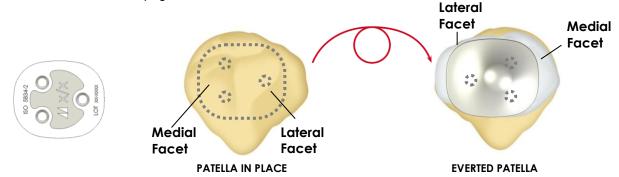


Select the correct size of the patella implants with the help of the patellar templates.

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



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



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







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

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

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

## 12.2 Inset patella

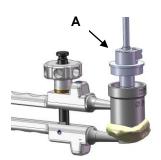
Choose the size of the patella using the different reamer guides or the dedicated template set available. Assemble the reamer guide of the chosen size and the spike jaw on the patellar clamp.

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





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









DEEPER HOLE

MORE SHALLOW HOLE

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



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

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





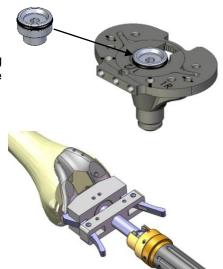


#### 13 TRIALS

Assemble the trial insert on the trial tibial baseplate.

<u>For a fixed implant</u>, before positioning the insert fix the puncher fixing screw in the trial keel with the help of the screwdriver, this allows the fixation of the insert to the baseplate.

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

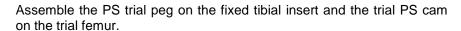


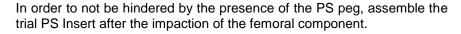


In order to avoid any damaging of the trial trochlea, don't impact the trial femoral component assembled with it.

PS

For a posterior stabilized implant, the trial has to be performed after the femoral finishing (see §14 FEMORAL FINISHING).









#### Full PE

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





# 14 FEMORAL FINISHING

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



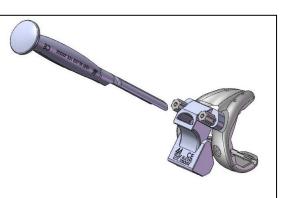
Prepare the holes for the femoral pegs with the dedicated drill.



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

PS

For a posterior stabilized implant, prepare the intercondylar notch using the PS resection chisel through the dedicated hole of the femoral box cutting guide.





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





# 15 SELECTION OF THE PROSTHETIC COMPONENTS - SIZE MATCHING

#### 15.1 Fixed version

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

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

**Table 1 -** Matching capabilities for fixed tibial trays and fixed tibial inserts.

	Fixed tibial inserts (STD, PS and UC)									
	Size	1	2	3	4	5	6			
	1	✓	X	X	X	X	X			
l tray	2	X	✓	X	X	X	X			
tibia	3	X	X	✓	X	X	X			
Fixed tibial tray	4	X	X	X	✓	X	X			
	5	X	X	X	X	✓	X			
	6	X	X	X	X	X	✓			

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

	Fixed tibial inserts (STD, PS and UC)								
	Size	1	2	3	4	5	6		
	1	✓	✓	✓	✓	✓	✓		
nts	2 2N	✓	<b>√</b>	✓	<b>√</b>	<b>√</b>	<b>√</b>		
Femoral components	3 3N	X	✓	✓	<b>✓</b>	<b>√</b>	<b>✓</b>		
ral cor	4 4N	X	Х	<b>√</b>	<b>√</b>	<b>√</b>	<b>√</b>		
Femo	5 5N	X	Х	X	<b>√</b>	<b>√</b>	<b>√</b>		
	6 6N	X	Х	Х	X	✓	<b>✓</b>		
	7	X	X	X	X	X	✓		





# 15.2 Full PE version

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

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

	Full PE UC or PS tibial components									
	Size	1	2	3	4	5	6			
	1	✓	✓	✓	✓	✓	✓			
ints	2 2N	✓	✓	✓	✓	✓	✓			
Femoral components	3 3N	X	✓	<b>√</b>	<b>√</b>	<b>√</b>	✓			
oral co	4 4N	X	X	✓	<b>√</b>	✓	✓			
Fem	5 5N	X	X	X	<b>✓</b>	✓	✓			
	6 6N	X	X	X	X	✓	✓			
	7	X	X	X	X	X	<b>√</b>			

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





#### 16 FINAL IMPLANTS

# 16.1 Tibial baseplate

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

The final impaction is performed using the baseplate impactor, version suitable for the type of tibial baseplate used. If a stem extension is used, preassemble 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.



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



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

#### Cemented tibial baseplate

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



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

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

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

#### 16.2 PE Insert

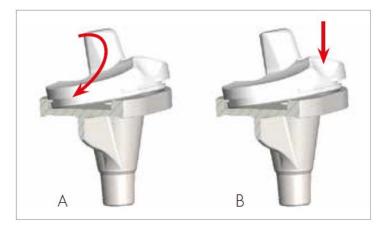


The Full PE tibial component is monoblock, therefore no PE insert have to be clipped on it.

#### Fixed insert

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

- 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.
- 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)









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

PS

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



The torque limiter screwdriver 3.5 Nm must be used to guarantee that the optimal locking of the screw is achieved.

#### 16.3 Femoral component

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

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

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

#### Cemented femoral component

The bone cement must be prepared according to the related instructions for use, provided by the cement manufacturer. Once the cement has the right viscosity, it must be applied to the internal surface of the femoral component into the corresponding cement pockets. The resected bone surface should be thoroughly cleaned by pulse lavage and the intramedullary canal closed by cancellous bone. Once the femoral component has been fully inserted with the dedicated impactor, the extruded cement is cleared from the femur, ensuring that no cement remains on the articular surface, on the intercondylar notch and in the joint, in order to avoid excessive UHMWPE wear.

#### 16.4 Patella

Assemble the spike jaw and the pressurizing jaw on the patellar clamp. The pressurizing jaw has two different sides of use, which observe the same colour significance as that of the two types of patella: blue side for resurfacing patella and yellow side for inset patella. The bone cement must be prepared according to the related instructions for use, provided by the cement manufacturer. Once the cement has the right viscosity, it should be applied to the internal surface of the patellar implant. 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.





# 17 IMPLANTS NOMENCLATURE

#### **FEMUR STD CEMENTED**

Ref. Left	Size	Ref. Right						
02.07.2001L	1	02.07.2001R						
02.07.2002L	2	02.07.2002R						
02.07.2003L	3	02.07.2003R						
02.07.2004L	4	02.07.2004R						
02.07.2005L	5	02.07.2005R						
02.07.2006L	6	02.07.2006R						
02.07.2007L	7	02.07.2007R						

#### FEMUR STD CEMENTED- NARROW

Ref. Left	Size	Ref. Right
02.07.2012L	2N	02.07.2012R
02.07.2013L	3N	02.07.2013R
02.07.2014L	4N	02.07.2014R
02.07.2015L	5N	02.07.2015R
02.07.2016L	6N	02.07.2016R

#### **FEMUR PS CEMENTED**

Ref. Left	Size	Ref. Right
02.07.2201L	1	02.07.2201R
02.07.2202L	2	02.07.2202R
02.07.2203L	3	02.07.2203R
02.07.2204L	4	02.07.2204R
02.07.2205L	5	02.07.2205R
02.07.2206L	6	02.07.2206R
02.07.2207L	7	02.07.2207R

#### FEMUR PS CEMENTED- NARROW

Ref. Left	Size	Ref. Right
02.07.2212L	2N	02.07.2212R
02.07.2213L	3N	02.07.2213R
02.07.2214L	4N	02.07.2214R
02.07.2215L	5N	02.07.2215R
02.07.2216L	6N	02.07.2216R

# **TIBIAL TRAY FIXED CEMENTED**

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

# **FULL PE UC TIBIAL COMPONENT \***

Ref.	Size	Thickness [mm]	Ref.	Size	Thickness [mm]
02.07.0110APUC		10	02.07.0210APUC		10
02.07.0112APUC	1	12	02.07.0212APUC	2	12
02.07.0114APUC	1	14	02.07.0214APUC		14
02.07.0117APUC		17	02.07.0217APUC		17
Ref.	Size	Thickness [mm]	Ref.	Size	Thickness [mm]
02.07.0310 APUC		10	02.07.0410APUC		10
02.07.0312 APUC	3	12	02.07.0412APUC	4	12
02.07.0314 APUC	3	14	02.07.0414APUC	4	14
02.07.0317 APUC		17	02.07.0417APUC		17





Ref.	Size	Thickness [mm]	Ref.	Size	Thickness [mm]
02.07.0510 APUC	5 -	10	02.07.0610APUC		10
02.07.0512 APUC		12	02.07.0612APUC	6	12
02.07.0514 APUC		14	02.07.0614APUC	6	14
02.07.0517 APUC		17	02.07.0617APUC		17

# **FULL PE PS TIBIAL COMPONENT \***

Ref.	Size	Thickness [mm]	Ref.	Size	Thickness [mm]
02.07.0110 APPS		10	02.07.0210 APPS		10
02.07.0112 APPS	1	12	02.07.0212 APPS	2	12
02.07.0114 APPS	ı	14	02.07.0214 APPS	2	14
02.07.0117 APPS		17	02.07.0217 APPS		17
Ref.	Size	Thickness [mm]	Ref.	Size	Thickness [mm]
02.07.0310 APPS		10	02.07.0410 APPS	4	10
02.07.0312 APPS	3	12	02.07.0412 APPS		12
02.07.0314 APPS	3	14	02.07.0414 APPS		14
02.07.0317 APPS		17	02.07.0417 APPS		17
Ref.	Size	Thickness [mm]	Ref.	Size	Thickness [mm]
02.07.0510 APPS		10	02.07.0610 APPS		10
02.07.0512 APPS	5	12	02.07.0612 APPS	6	12
02.07.0514 APPS	3	14	02.07.0614 APPS	6	14
02.07.0517 APPS		17	02.07.0617 APPS		17

<sup>\*</sup>Full PE PS or UC tibial component must not be coupled with any stem extension

## **TIBIAL INSERT STD FIXED**

Ref.	Size	Thickness [mm]	Ref.	Size	Thickness [mm]
02.07.0110SF		10	02.07.0210SF		10
02.07.0112SF		12	02.07.0212SF		12
02.07.0114SF	1	14	02.07.0214SF	2	14
02.07.0117SF		17	02.07.0217SF		17
02.07.0120SF		20	02.07.0220SF		20
Ref.	Size	Thickness [mm]	Ref.	Size	Thickness [mm]
02.07.0310SF		10	02.07.0410SF		10
02.07.0312SF		12	02.07.0412SF		12
02.07.0314SF	3	14	02.07.0414SF	4	14
02.07.0317SF		17	02.07.0417SF		17
02.07.0320SF		20	02.07.0420SF		20
Ref.	Size	Thickness [mm]	Ref.	Size	Thickness [mm]
02.07.0510SF		10	02.07.0610SF		10
02.07.0512SF		12	02.07.0612SF		12
02.07.0514SF	5	14	02.07.0614SF	6	14
02.07.0517SF		17	02.07.0617SF		17
02.07.0520SF		20	02.07.0620SF		20





# TIBIAL INSERT UC FIXED

Ref.	Size	Thickness [mm]	Ref.	Size	Thickness [mm]
02.07.0110FUC		10	02.07.0210FUC		10
02.07.0112FUC		12	02.07.0212FUC		12
02.07.0114FUC	1	14	02.07.0214FUC	2	14
02.07.0117FUC		17	02.07.0217FUC		17
02.07.0120FUC		20	02.07.0220FUC		20
Ref.	Size	Thickness [mm]	Ref.	Size	Thickness [mm]
02.07.0310FUC		10	02.07.0410FUC		10
02.07.0312FUC		12	02.07.0412FUC		12
02.07.0314FUC	3	14	02.07.0414FUC	4	14
02.07.0317FUC		17	02.07.0417FUC		17
02.07.0320FUC		20	02.07.0420FUC		20
Ref.	Size	Thickness [mm]	Ref.	Size	Thickness [mm]
02.07.0510FUC		10	02.07.0610FUC		10
02.07.0512FUC		12	02.07.0612FUC		12
02.07.0514FUC	5	14	02.07.0614FUC	6	14
02.07.0517FUC		17	02.07.0617FUC		17
02.07.0520FUC		20	02.07.0620FUC		20

# **TIBIAL INSERT PS FIXED**

Ref.	Size	Thickness [mm]	Ref.	Size	Thickness [mm]
02.07.0110PSF		10	02.07.0210PSF		10
02.07.0112PSF		12	02.07.0212PSF		12
02.07.0114PSF	1	14	02.07.0214PSF	2	14
02.07.0117PSF		17	02.07.0217PSF		17
02.07.0120PSF		20	02.07.0220PSF		20
Ref.	Size	Thickness [mm]	Ref.	Size	Thickness [mm]
02.07.0310PSF		10	02.07.0410PSF		10
02.07.0312PSF		12	02.07.0412PSF		12
02.07.0314PSF	3	14	02.07.0414PSF	4	14
02.07.0317PSF		17	02.07.0417PSF		17
02.07.0320PSF		20	02.07.0420PSF		20
Ref.	Size	Thickness [mm]	Ref.	Size	Thickness [mm]
02.07.0510PSF		10	02.07.0610PSF		10
02.07.0512PSF		12	02.07.0612PSF		12
02.07.0514PSF	5	14	02.07.0614PSF	6	14
02.07.0517PSF		17	02.07.0617PSF		17
02.07.0520PSF		20	02.07.0620PSF		20





# **RESURFACING PATELLA**

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

# **INSET PATELLA**

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

# **EXTENSION STEM**

Ref.	Ø [mm]	L [mm]
02.07.F11030	11	30
02.07.F11066	11	65

Part numbers subject to change.
<b>Note for sterilization</b> : the instrumentation is not sterile upon delivery. It must be cleaned before use and sterilized in an autoclave respecting the US regulations, directives where applicable and following the instruction for use of the autoclave manufacturer.  For detailed instructions please refer to the document "Recommendations for cleaning decontamination and sterilization of Medacta <sup>®</sup> International reusable orthopedic devices" available at <a href="www.medacta.com">www.medacta.com</a> .
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