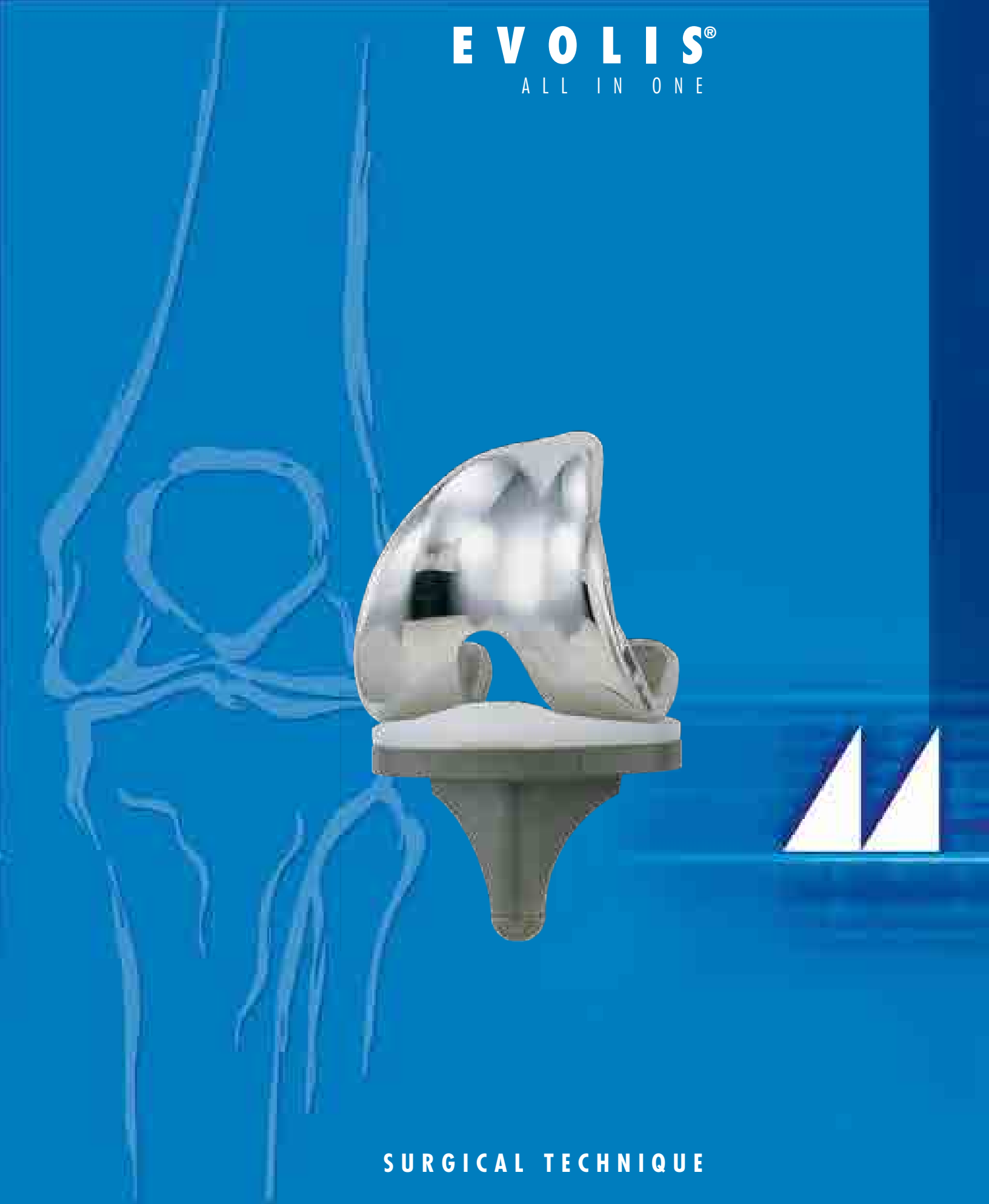
Medacta International

EVOLIS®

ALL IN ONE



SURGICAL TECHNIQUE

INTRODUCTION

This document describes the Surgical Technique for all the three version of Evolis® Total Knee System (Standard, Postero-stabilized and Ultra-congruent). The text will identify which version of prosthesis is discussed by the following symbols:

for Standard version (STD)

for Postero-stabilized version (PS)

for Ultra-Congruent version (UC)

Please, consider the package inserts for complete product information.
Caution: Federal law (USA) restricts this device to sale by or on the order of physician.
In the USA for cemented use only.

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1 INDICATIONS

The Evolis 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 femural 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 ostheocondral structures or loss of integrity of the medial or lateral ligament.

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

3 PREOPERATIVE PLANNING

3.1 RADIOLOGICAL PLANNING

This is performed from the full length standing films, postero-anterior and lateral knee radiographs, the sunrise visio of the patella and from the available templates set.

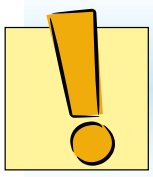
The goal is to determine the angle formed by the anatomical axis and the mechanical axis of the femur to be treated, to determine the tibial slope, to trace and measure bone resections, to establish the intramedullary guide introduction points, to assess the sizes of the femoral and tibial components,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

3.2 CLINICAL PLANNING

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

4 SURGICAL APPROACH

The most commonly used surgical approach is the medial para-patellar approach. The surgeon may, however, use other approaches in certain cases of revision surgery or in the case of severe valgus deformities.

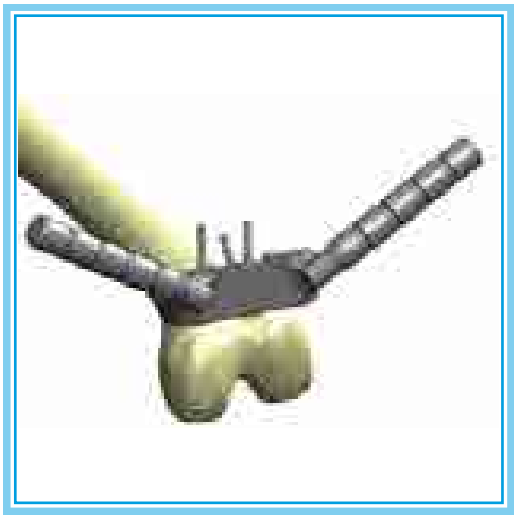


Some specific instruments are fixed to the bone by means of dedicated pins. Before using the pins, ensure that they are intact and fully functional. BENT OR DEFECTIVE PINS CAN NOT BE USED AND MUST BE REPLACED BY NEW ONES.
Pins extraction must be performed avoiding any bending. This results in axial alignment between the pin and the dedicated extractor.
For detailed instructions contact your local Medacta® sales representative.

5 DISTAL FEMORAL CUT

Flex the knee to 90°, then drill, using the 10 mm diameter drill in the axis of the femur, immediately anterior to the femoral insertion of the Posterior Cruciate Ligament. Introduce the intramedullary (IM) rod in the femur to ensure that there is no false rotation.
Place the 6° distal cut positioner on the distal condyles and introduce the IM rod through the orientation hole. The distal cut positioner has 6° of correction from the anatomical axis, it must be rotated till you can read the side corresponding to the knee to be operated on.

NOTE
When the 6° distal cut positioner is in place, it might may possible only contact one of the distal femoral condyles.



Assemble the distal cut positioner rod into the 6° distal cut positioner and the distal cutting block on this. As the cutting block is intended for both left and right knees, check that the correct side, , can be read on the anterior face of the cutting block.
The distal cutting block positioner allows the surgeon to take more or less distal bone, by turning its screw: the cut is planned at 8 mm (corresponding to the final implant thickness) and can be, then, modified by + or - 4 mm. Fix the block by introducing 2 pins in the holes corresponding to the 8 mm marked line. It is then still possible to modify the cut height by 2 mm, by moving the cutting block backward or forward using different holes lines (+ or – 2 mm).

Before performing cut, check the cutting block position with the angel wing. Once the distal cutting block position has been deemed satisfactory, it may be fixed by introducing an oblique pin.
Remove the distal cutting block from the 6° distal cut positioner, then remove the IM rod. Place the saw blade guide and perform the distal resection.

6 TIBIAL STAGE

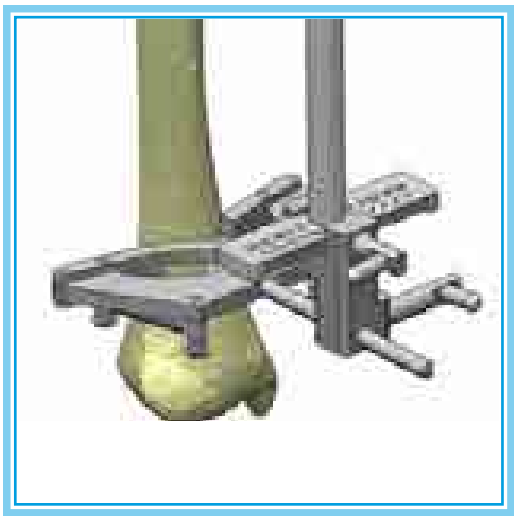
6.1 USE OF EXTRAMEDULLARY ALIGNMENT GUIDE

6.1.1 Assembly of the guide

Fix the frame for the cutting guide to the proximal stem of the tibial guide. This frame already provides 3° of posterior slope on the tibial cutting plane, when the tibial stem is parallel to the tibial crest. Join the distal stem of the guide to the proximal stem, without locking it. Position the malleolar clamp, with its support, at the extremity of the distal stem.
Fix the asymmetrical cutting guide (left or right as a function of the side to be operated on) by turning the locking mechanism on the distal part of its frame.

NOTE
Two types of proximal stems are available, respectively endowed with one or two spikes.

TRICK
In the event of a lateral approach, to limit interference from medially luxated patella, it is advisable to use the tibia cutting guide on the opposite side to that of the knee to be operated on. Fasten the asymmetrical tibial resection guide on the tibial guide at the level of the mark and take care that the side of the guide corresponds to the knee which is to be operated on (right or left knee).



6.1.2 Positioning of the guide

WARNING
Before positioning the guide, it is recommended marking the center of the ankle, usually in line with the second toe with the ankle in dorsi-flexion.

After the resection of ACL (STD version), or of both cruciate ligaments (PS and UC version), position the lower part of the guide taking care that the malleolar clamp is exactly facing the center of the ankle joint.
Position the proximal stem on the tibial plateau by introducing the central spike in the center of the intercondylar eminence and fix it by inserting two provisional pins into the dedicated holes.

OPTION
If the two-spykes proximal stem is used, insert the longest spike in the center of the intercondylar eminence and fix the stem by completely driving in the two spikes.

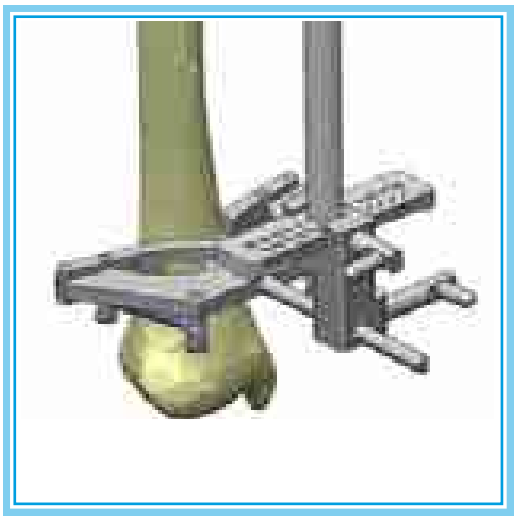
6.1.3 Setting the rotation

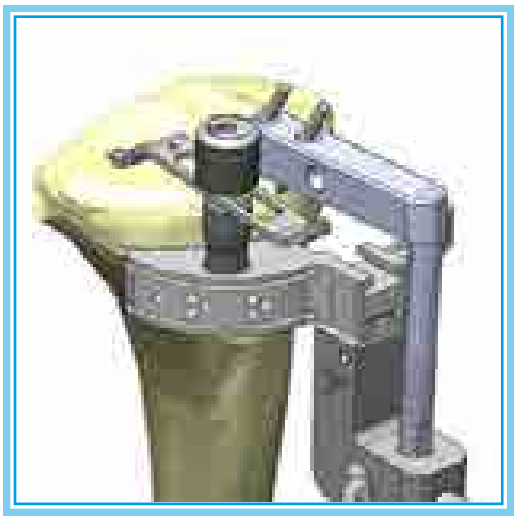
To ensure neutral tibial rotation, set the tibial cutting guide opposite the medial third of the tibial tubercle. The flat anterior border of the cutting guide should be parallel to the transverse mediolateral plane of the tibia.

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

To make the tibial cut perpendicular to the mechanical axis, make sure that the distal stem of the cutting guide is on the center of the ankle.

OPTION
It is possible to adjust the angle of the tibial cut in the frontal plane by translating the distal stem as required.





6.1.4 Setting the posterior tibial slope

Position the tibial stem parallel to the tibial crest. The adjustment of posterior slope is performed through the distal part of the tibial cutting guide.
Once tibia guide rotation, frontal alignment, and posterior slope are satisfactory, definitively fix the tibial guide by driving in the 2 proximal pins. Ensure that the tibial cutting guide is solid by tightening the thumb-screw between the proximal and distal ends.

WARNING

The tibial slope must be set up before setting the level of cut. Until the definitive correct position of the resection guide has been defined the upper and lower part of the tibial guide should remain free to slide into each other.

An excessive slope choice could damage the tibial insertion of the posterior cruciate ligament.

It is recommended not to exceed the 3° of slope given by the frame of the tibial cutting block.

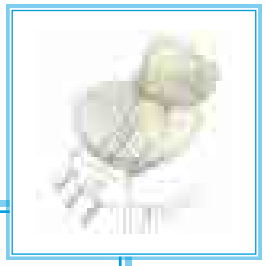
6.1.5 Setting of the level of the cut

Position the cutting guide a few millimeters away from the proximal tibia, and position the tibial stylus on the side that will undergo the deepest resection.

NOTE

Two stylus are available: one makes a 8 mm resection, the other, intended to be applied on the most worn tibia plateau, makes a 2 mm resection.

Adjust the depth of resection using the chosen reference stylus. Ensure the opposite tibial plateau will be adequately resected by using the sickle finger. If necessary the level of the resection can be adjusted by sliding the frame of the cutting guide vertically along the proximal stem (graduation in 2 mm increments). When the adjustment has been deemed satisfactory, lock the screw of the tibial cutting guide frame.



6.1.6 Fixation of the tibial cutting guide

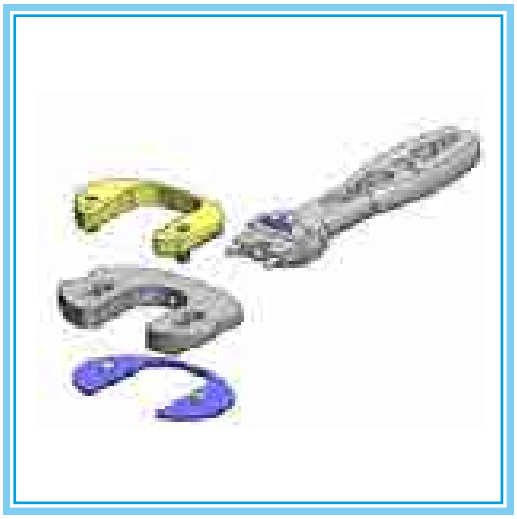
Before fixing the tibial cutting block, it is recommended to check the cut height and the posterior slope with the help of the angel wing. After predrilling, place two parallel pins in the medial row of holes. A third oblique pin must be inserted to ensure the stability, into the most medial hole.

6.1.7 Removing the tibial cutting guide

Remove the stylus and, if necessary, the 2 pins inserted into the proximal stem of the tibial guide.
Separate the proximal part of the guide from the distal part and from the frame of the cutting guide, then withdraw the latter using the extractor mounted on the sliding block.

TRICK

To check varus and valgus prior to making the cut, remove the proximal and the distal parts of the cutting guide and use the T-handle reamer inserted in the frame of the cutting block. Align with the previous mark on the ankle in line with the second toe.



6.2 PERFORMING THE TIBIAL CUT

Perform the tibial resection using the specific blade.

TRICK

To protect the PCL, 1 or 2 x 2.7 mm diameter pins may be fixed in front of the tibial insertion of the PCL.

WARNING

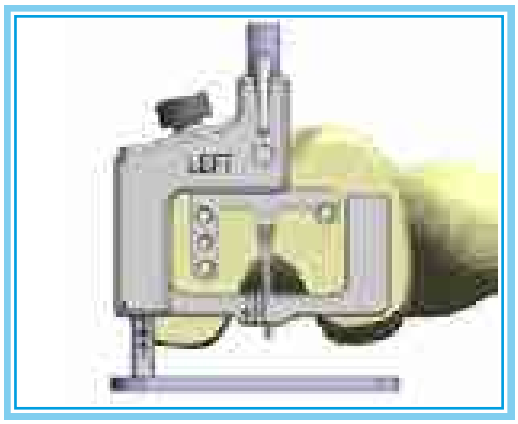
Due to the tibial cut done with slope, ensure that there is no rotation of the tibial resection guide.

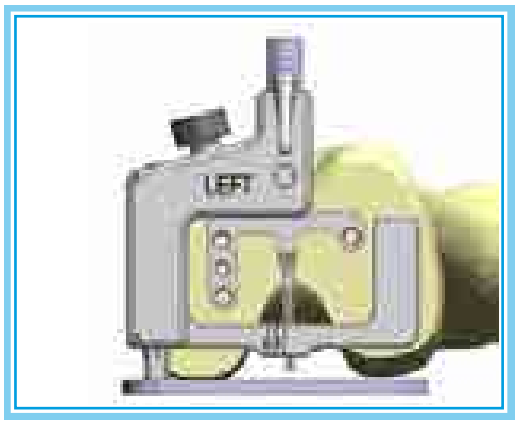
6.3 EXTENSION GAP CONTROL

Remove the convergent pin and the resection guide, sliding it over the two remaining parallel pins. The pins may remain in position in case an additional 2 mm tibial recut is required. Assemble the reference spacer with its handle and the yellow femoral spacer (which represents the distal thickness of the final implant) and a blue tibial spacer (simulating the different tibia side thicknesses, from 9 to 19 mm). In extension insert the assembled spacer and ensure that the knee is stable and correctly balanced. The axis of the limb can be checked by introducing the IM rod in the handle of the spacer. Ensure there is full extension and satisfactory flexion before removing the two pins left in position to retain the ability to make a 2 mm tibial recut. Test, and balance the ligaments in extension.

If, despite a posterior release, tests in extension indicate incomplete extension, this would indicate the need of an additional 2mm or more of distal femoral resection.

If this situation is required, select the distal cut positioner and apply it to the distal resection. Assemble the distal cutting block on the positioner and fixate it using 2 pins in the 8 mm marked line. This will restore the original cutting block position and will allow modification of the distal resection by selecting a more proximal position of the block.





7 ANTERIOR CUT, POSTERIOR CUT AND CHAMFERS

7.1 SETTING THE GUIDE

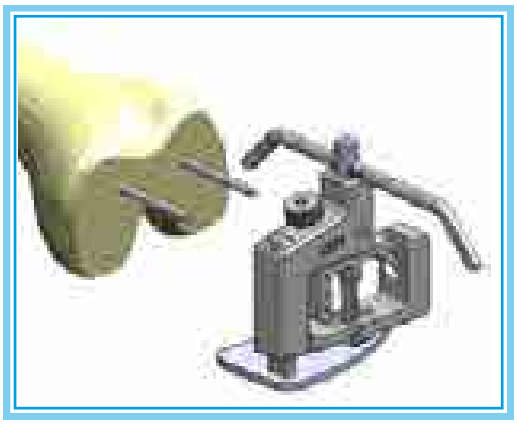
Place the femoral sizer in contact with the distal resection, with the tip of the pointer in contact with the anterior cortex. Check that the side of the knee to be operated on, can be read on the instrument.
Ensure the posterior plate is in contact with the posterior femoral condyles. The selected femoral size can be measured on the posterior plate support.

TRICK
Remove soft tissue on anterior femur to allow the stylus contact with the anterior cortex.

WARNING
In order to optimize the size selection, check the contact point of the anterior pointer, by selecting the size on it and ensuring that it remains vertical on the anterior cortex.

By turning the screw on the top of the sizer, the external rotation can be adjusted, by selecting a value from 0° to 6° of external rotation.

NOTE
For valgus knee typically 3° of external rotation is required to allow for wear of posterior lateral femoral condyle.

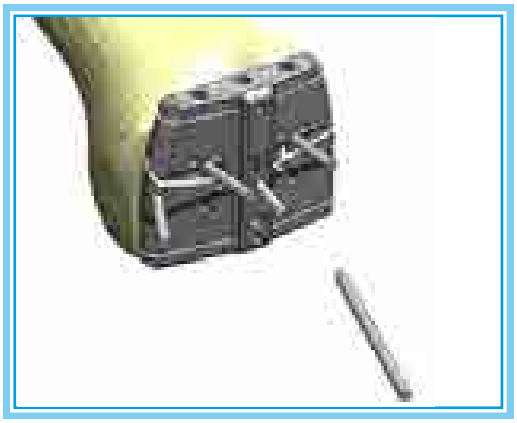


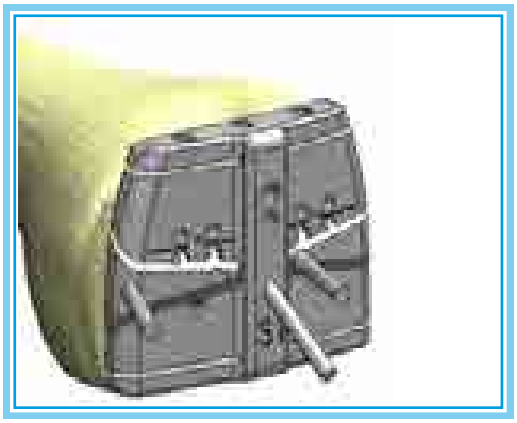
7.2 FIXING THE GUIDE

Once the femoral size has been determined as described, the external rotation adjusted and the position of the femoral sizer has been judged satisfactory, introduce two parallel pins into the dedicated holes, then remove the sizer.

WARNING
While inserting the pins ensure a continuous contact of the sizer with the distal resection.

Select the 4 in 1 femoral cutting block of the corresponding size (as established above) and fix it on the distal resection by selecting the 2 holes, marked by a line.
Before proceeding, check to avoid anterior notching with the help of the angle wing.





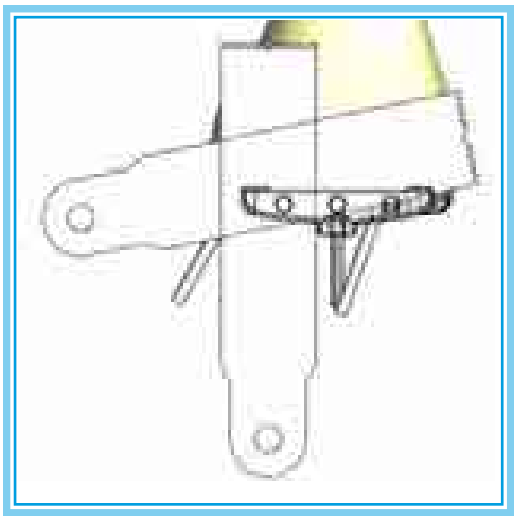
Definitely fix the guide, introducing a first pin in the most medial hole and a second one in the lateral central hole (see picture). A third oblique pin must be introduced in the central hole to ensure the highest stability. Finally, remove the first 2 straight pins, in order to facilitate the cuts to be performed.

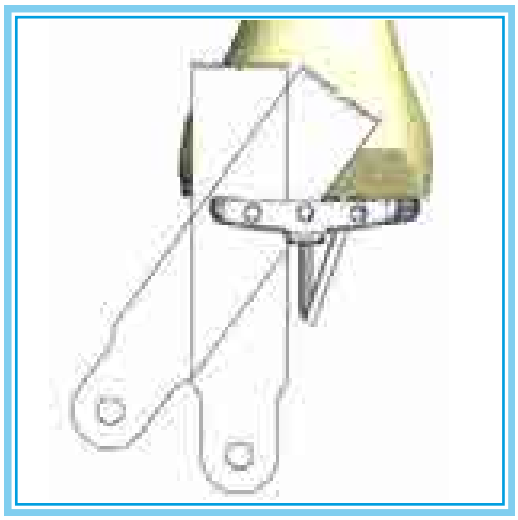
NOTE

The medial and lateral pins lie on the same plane and are oblique compared to the resection plane; the central pin results parallel to the anatomical axis from above and oblique compared to the medial and lateral pins. This positioning increases the stability of the 4 in 1 cutting guide.

TRICK

Headed pins may be used to secure the cutting block providing more secure fixation.



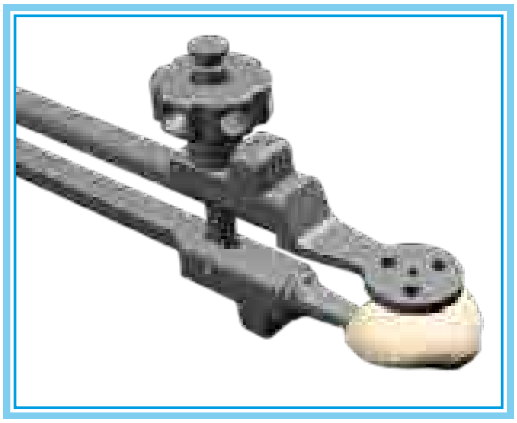


7.3 PERFORMING THE FEMORAL RESECTIONS

Introduce the saw into the guide's slots and perform the femoral resections:

- Anterior cut
- Posterior cut
- Posterior chamfer
- Anterior chamfer

The slots have been shaped in order to maximize the security of the blade, allowing cutting to proceed from the front to the side.

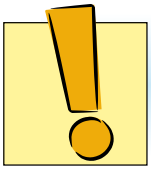


8 PATELLA STAGE

8.1 PATELLA RESURFACING

Lock the patella resection guide into the universal patella clamp.
After carefully releasing the periphery of the patella, position the resection guide at the appropriate resection level, with the assistance of the patellar stylus (possible resection heights from 6 to 14 mm) and firmly lock the clamp with the screwing thumbwheel switch.
Perform the patellar resection through the slots of the resection guides.

TRICK
In order to correctly identify the center of the patellar implant, before performing the resection, drill a 3.2 mm diameter hole in the top of the patella and then after resection, align the central hole of the patella template with this identification drill hole.



WARNING
The thickness of the remaining bone after resection should be at least 13 mm.

Open the patellar clamp, remove the two resection guides, and position the spike jaw and drilling template.
Apply the drilling template on the resected surface of the patella and drill three holes with the 5 mm diameter tapered drill guide.
Remove the drill guide, select the correct size of trial patella and put the guide in place. Four diameters are available (30, 33, 36, 39 mm).
Impact the trial patella, then reduce the patella and test the knee through its full range of motion.

8.2 INSET PATELLA

Choose the size of the patella using the different drill guides (diameters 20, 24, 28 mm).
Click the guide with the corresponding diameter in place on the patella clamp fitted with its toothed jaws.
Ensure that the drill depth gauge is correctly adjusted.

WARNING
Each drill bit is marked at the ideal drill depth for a non-worn patella, i.e. 8 mm. Before drilling, ensure that the drill depth gauge is level with the mark.

Insert the corresponding drill bit into the drill guide and drill until the top of the drill guide touches the depth gauge.
If the drill hole is too shallow, it can be deepened by raising the drill depth gauge (one turn corresponds to one millimeter).

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

Insert the trial patella by grasping it with a clamp whose two teeth are fitted into the specially designed holes.
Smooth out the bone rim using a rongeur or the oscillating saw.
Reduce the patella and test the knee through its full range of motion.

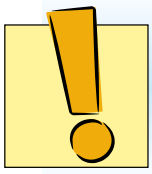
WARNING
The reaming power tool must be operated once the reamer has been completely introduced into the guide. In order to reduce any risk of fracturing the patella, reaming must be performed with caution at low speed, keeping the patellar clamp closed.

TABLE FOR THE SELECTION OF PROSTHETIC COMPONENTS

FEMORAL COMPONENT \ TIBIAL COMPONENT	1	2	3	4	5	6
1	✓	✓	✓	✓	✓	✓
2	✓	✓	✓	✓	✓	✓
3	×	✓	✓	✓	✓	✓
4	×	×	✓	✓	✓	✓
5	×	×	×	✓	✓	✓
6	×	×	×	×	✓	✓

✓ Coupling possible
× Coupling forbidden

9 TESTS



WARNING
The choice of the size of the tibial base-plate and the femoral component are linked. It is mandatory at this point to know the size of the tibial base-plate.

TRICK
In order to pre-select the size of tibial component, the resected part of the tibia may be superimposed on the trial baseplate.

Choose the size of tibial component using the trial baseplates and trial baseplate handle. Once the tibial baseplate size is selected, remove the handle and place the 9mm trial insert. Reattach the baseplate handle and introduce the trial onto the proximal tibia.

Assemble the femur impactor/extractor on the slide hammer and impact the trial femur, centering it on the anatomical notch. Check correct alignment of the lower limb, introducing the intramedullary rod into the trial tibial baseplate handle. Perform varus/valgus stability tests as well assess the flexion of the knee. Adjust the trial insert as indicated. Set the final rotation of the tibial trial component with the patella reduced to ensure acceptable patellar tracking.

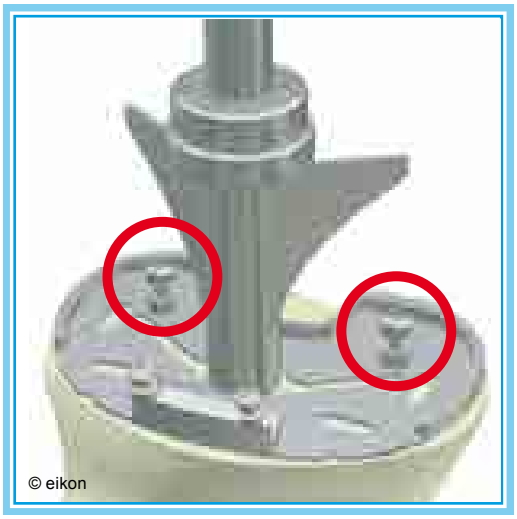
WARNING

The congruence of the insert with the femur requires a perfect positioning of the tibial base-plate in rotation (mandatory use of the trial UC insert). Malposition can be the source of additional stresses on the fixation systems of the femoral and tibial implants and also the cause of an abnormal polyethylene wear. To minimize the risk of possible conflicts in flexion it is strongly suggested to remove posterior osteophytes from femoral condyles.

After setting the rotation of the trial baseplate, the baseplate is fixed to the tibia by two 2.7 mm pins, introduced anteriorly, using the screwdriver as a punch of the pin.
Remove the trial insert.
If the trial baseplate is not centered on the tibial resection, position may be adjusted without affecting rotation by placing two 3.2 mm pins in the medio-lateral adjustment slots and translating the trial baseplate after removing the two 2.7 mm pins. When translation adjustment of the trial baseplate is required, it is recommended that the femoral component is translated the same value.
Overrun of the trial baseplate is generated during flexion-extension movements by medio-lateral positioning of the trial femoral component if the medio-lateral position of the baseplate is modified. The medio-lateral position of the femur must be adjusted equally, in order to allow the baseplate to fall naturally “in front of” the femur. Drill the two holes for the trial femur with the 7 mm diameter tapered drill bit to prepare the holes for the two femoral pegs.

WARNING

Following the contour of the intercondylar notch of the femoral trial implant remove the anatomic notch by the mean of the dedicated gauge. This procedure will prevent any risk of impingement with the post of the insert. Remove femur and tibia trial implants.
Apply the posterior stabilisation shaft on the femoral trial implant. Re-position the femoral trial implant and the tibial trial implant with the posterostabilisation post. Perform flexion/extension movements to verify the absence of impingements.



To strengthen the fit of the tibial trial base-plate and avoid translation movements during the preparation of the keel, put in place two 2.7 mm pins in the holes of the trial tibal base-plate located posteriorly. Make the outline of the tibial stem with the appropriate punch (one size of punch represents 2 sizes of baseplate). Before removing the trial baseplate, identify the position of the two anterior notches by cautery. These should correspond to the position of the two markers on the final baseplate.

OPTION

It is possible to open the canal for the punch using the 10 mm drill and guide. Sometimes following old fractures this is necessary.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10 FINAL IMPLANTS

10.1 STANDARD AND ULTRACONGRUENT VERSIONS

After pulsed lavage, the different implants are placed, in the following order:

- Tibial component.
- Insert.
- Femoral component.
- Patella.

10.1.1 Tibial baseplate

After confirming that the tip of the keel is firmly tightened, the baseplate should be positioned manually, ensuring that there is no impingement 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, assembled with the slide hammer.
In order to increase the primary stability of the baseplate, the operator can, before positioning the baseplate, remove the polyethylene plugs and then after drilling, position 2 or 4 x 6.5 mm diameter self-threading screws (length 20 to 45 mm).

WARNING
Ensure that the connection between screwdriver and screw's head is exactly aligned in vertical direction. An adequate pressure should be applied to ensure that the blade of the screwdriver correctly fits the screw's head. Careful tightening should be applied to the insertion of the bone screws to avoid any risk of damaging the screw, the tibial baseplate and/or the bony hole.
Use the screws with slight central angulation to keep the screws inside the cortex.
In order to avoid any conflict between the screws and the polyethylene insert, ensure that the screws are completely inserted and that the screw's heads don't overhang the tibial baseplate.

10.1.1.1 Cemented Tibial baseplate

The cemented tibia is intended to be implanted without cement surrounding the keel. The bone cement must be prepared according to the related instruction of use, provided by the cement manufacturer. Once the cement has the right viscosity according to its instruction of use, it must be applied only to the undersurface of the tibial baseplate into the corresponding cement pockets and not around the keel. The entire implant site should be accurately cleaned by pulse lavage; once the tibial baseplate has been fully inserted with the dedicated impactor, the extruded cement is cleared from the tibia, carefully checking that all cement is removed from the articular surface.

10.1.2 Insert

The insert must be presented to the baseplate with a posterior tilt to engage the posterior lips of the insert in the baseplate.
Then clip the anterior part of the insert with the assistance of the baseplate impactor.

OPTION

In order to perform a final control of the of the thickness of the insert after having implanted the final femoral and tibial components, it is possible to position the trial insert in the final baseplate. The thickness of the insert can then be confirmed, with the femoral implant in position, provided flexion-extension tests are considered to be satisfactory.

WARNING

In order not to compromise the locking of the insert, ensure before fixing it that nothing is interposed between the baseplate and the insert.

10.1.3 Femoral component

Assemble the femoral impactor on the slide hammer, release the runner as far as it will go, unscrewing the handle of the slide hammer. Open the two jaws of the femoral impactor and engage the two jaws in the two lateral slots of the femoral component. Turn the handle of the slide hammer making sure the plastic runner contacts with the femoral component.

10.1.3.1 Cemented Femoral component

The bone cement must be is prepared according to the related instruction of use, provided by the to the instructions of the cement manufacturer. Once the cement has the right viscosity according to its instruction of use, it must be is applied to the internal surface of the femoral component into the corresponding cement pockets. The entire implant site should be accurately cleaned by pulse lavage and the intramedullary canal sealed by cancellous bone. Once the femoral component has been fully inserted with the dedicated impactor, the extruded cement is cleaned from the femur, carefully checking that all cement is removed from the articular surface and the intercondylar notch, in order to avoid excessive UHMWPE wear.

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

OPTION

After impaction, if the operator wishes to change the angle of approach, he may remove the femur femoral impactor, screwing the handle to the maximum to release the runner and therefore unlock the grasp of the of the two jaws.

TRICK

It is recommended that the surgeon waits until the cement has hardened in full extension.

10.2 POSTERO-STABILIZED VERSION

After cleaning the bone with pulse lavage, the implants are placed, in the following order:

- Tibial component.
- Femoral component.
- Insert.
- Patella.

WARNING
It is essential to position the femoral component before the final insert in order not to be hindered by the presence of the posterior stabilization peg.

10.2.1 Tibial baseplate

After confirming that the tip of the keel is firmly tightened, the baseplate should be positioned manually, ensuring that there is no impingement between the posterior edge of the baseplate and the femur, which may result in femoral injury or tibial malrotation.

10.2.1.1 Cemented Tibial baseplate

The cemented tibia is intended to be implanted without cement surrounding the keel. The bone cement must be prepared according to the related instruction of use, provided by the cement manufacturer. Once the cement has the right viscosity according to its instruction of use, it must be applied only to the undersurface of the tibial baseplate into the corresponding cement pockets and not around the keel. The entire implant site should be accurately cleaned by pulse lavage; once the tibial baseplate has been fully inserted with the dedicated impactor, the extruded cement is cleared from the tibia, carefully checking that all cement is removed from the articular surface.


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The final impaction is performed using the baseplate impactor, assembled with the slide hammer. In order to increase the primary stability of the baseplate, the operator can, before positioning the baseplate, remove the polyethylene plugs and then after drilling, position 2 or 4 x 6,5 mm diameter self-threading screws (length 20 to 45 mm).

WARNING

Ensure that the connection between screwdriver and screw's head is exactly aligned in vertical direction. An adequate pressure should be applied to ensure that the blade of the screwdriver correctly fits the screw's head. Careful tightening should be applied to the insertion of the bone screws to avoid any risk of damaging the screw, the tibial baseplate and/or the bony hole. Use the screws with slight central angulation to keep the screws inside the cortex. In order to avoid any conflict between the screws and the polyethylene insert, ensure that the screws are completely inserted and that the screw's heads don't overhang the tibial baseplate.

10.2.2 Femoral component

Assemble the femoral impactor on the slide hammer, release the runner as far as it will go, unscrewing the handle of the slide hammer. Open the two jaws of the femoral impactor and engage the two jaws in the two lateral slots of the femur. Turn the handle of the slide hammer, making sure that the plastic runner come into contact with the femoral component.

10.2.2.1 Cemented Femoral component

The bone cement must be is prepared according to the related instruction of use, provided by the to the instructions of the cement manufacturer. Once the cement has the right viscosity according to its instruction of use, it must be is applied to the internal surface of the femoral component into the corresponding cement pockets. The entire implant site should be accurately cleaned by pulse lavage and the intramedullary canal sealed by cancellous bone. Once the femoral component has been fully inserted with the dedicated impactor, the extruded cement is cleaned from the femur, carefully checking that all cement is removed from the articular surface and the intercondylar notch, in order to avoid excessive UHMWPE wear.

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

OPTION

After impaction, if the operator wishes to change the angle of approach, he may remove the femoral impactor, screwing the handle to the maximum to release the runner and therefore unlock the grasp of the of the two jaws.

10.2.3 Insert

The insert must be presented to the baseplate with a posterior tilt to engage the posterior lips of the insert in the baseplate. Then engage the anterior part of the insert, using the baseplate impactor and placing the blocking screw provided with the insert using the 3.5 mm screwdriver.

OPTION

In order to perform a final control of the thickness of the insert after having implanted the final femoral and tibial components, is possible to position the trial insert in the final baseplate. The thickness of the insert should then be confirmed, with the femoral implant in position, providing flexion-extension tests are considered to be satisfactory.

TRICK

It is essential to position the femoral component before the final insert in order not to be hindered by the presence of the posterior stabilization peg.

WARNING

In order not to compromise the locking of the insert, ensure before fixing it that nothing is interposed between the baseplate and the insert.

10.3 PATELLAR IMPLANT

Assemble the inferior and superior jaws on the patellar clamp. Place the cemented patella in position. Block the patella, by firmly screwing the thumbscrew of the patellar clamp. The pressurizing jaw has two different sides of use, which observe the same color significance as that of the two types of patella: blue side for resurfacing patella and yellow side for inset patella.

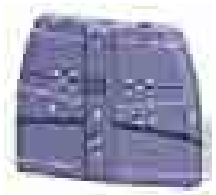
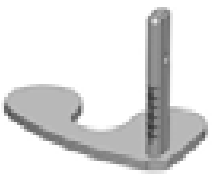
The bone cement must be prepared according to the related instruction of use, provided by the cement manufacturer. Once the cement has reached the right viscosity, according to its instruction of use, it should be applied to the internal surface of the patellar implant. With the patellar clamp, the implant is held in the final position and the extruded cement is cleared from the patella, carefully checking that all cement part is removed from the articular surface.

11 INSTRUMENTATION - NOMENCLATURE

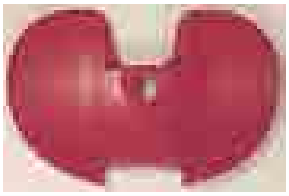
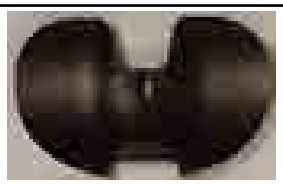
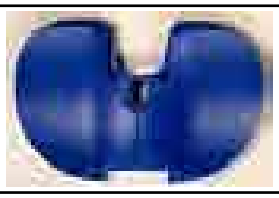
The following are two acceptable combinations to make complete sets of instrument trays:

COMBINATION 1:	**02.07S.802**	**COMBINATION 2:**	**02.07S.801**
	02.07S.803		**02.07S.802**
	02.07S.804		**02.07S.803**
	02.07S.806		**02.07S.805**

TRAY 1 - FEMORAL - REF. 02.07S.801

REF.	Description		Quantity
1.001 1.002 1.003 1.004 1.005 1.006	Trial Femur S 1 R S 2 R S 3 R S 4 R S 5 R S 6 R		6
1.011 1.012 1.013 1.014 1.015 1.016	Trial Femur S 1 L S 2 L S 3 L S 4 L S 5 L S 6 L		6
2.631 2.632 2.633 2.634 2.635 2.636	MIS - Femoral cutting guide 4/1 S 1 S 2 S 3 S 4 S 5 S 6		6
02.07.10.1074	Femur Pegs Drill – Hudson Coupling		1
2.619	MIS Femoral Sizer		1
2.620	MIS Femoral Sizer Right Posterior Condyle Ref.		1
2.621	MIS Femoral Sizer Left Posterior Condyle Ref.		1

*on request

1.030 1.031 1.032 1.033 1.034	STD/PS Trial insert (light blue) S 1/9 mm S 1/11 mm S 1/13 mm S 1/16 mm S 1/19 mm		5
1.040 1.041 1.042 1.043 1.044	STD/PS Trial insert (green) S 2/9 mm S 2/11 mm S 2/13 mm S 2/16 mm S 2/19 mm		5
1.050 1.051 1.052 1.053 1.054	STD/PS Trial insert (red) S 3/9 mm S 3/11 mm S 3/13 mm S 3/16 mm S 3/19 mm		5
1.060 1.061 1.062 1.063 1.064	STD/PS Trial insert (yellow) S 4/9 mm S 4/11 mm S 4/13 mm S 4/16 mm S 4/19 mm		5
1.070 1.071 1.072 1.073 1.074	STD/PS Trial insert (black) S 5/9 mm S 5/11 mm S 5/13 mm S 5/16 mm S 5/19 mm		5
1.080 1.081 1.082 1.083 1.084	STD/PS Trial insert (blue) S 6/9 mm S 6/11 mm S 6/13 mm S 6/16 mm S 6/19 mm		5

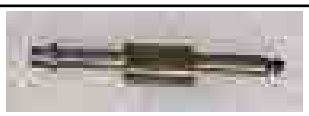
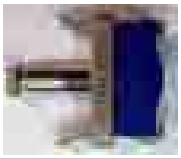
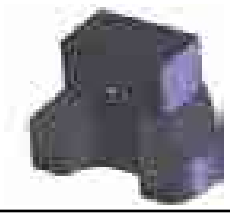
TRAY 2 - TIBIAL GENERAL - REF. 02.07S.802

REF.	Description		Quantity
02.07.10.2143	Tibial cutting guide support 3°		1
02.02.10.0021* or 2.617	Extramedullary superior guide or Extramedullary superior guide (without pins)		1
02.02.10.0020	Tibial resection guide distal part		1
02.02.10.0022	Malleolary clamp support		1
02.07.10.0001*	Telescope Ø 5 mm for extramedullary guide		1
02.02.10.0013	Malleolary clamp		1
2.644 or 02.07.10.2160**	Tibial Palpator 2 mm – MIS or Tibial Palpator 2 mm – Fast Coupling		1
2.645 or 02.07.10.2147**	Tibial Palpator 8 mm – MIS or Tibial Palpator 8 mm – Fast Coupling		1
02.07.10.2166	Distal recut reference		1
2.622 or 02.07.10.2145 + 02.07.10.2146	MIS L/R Tibial Cutting Guide or Right Tibial Cutting Guide + Left Tibial Cutting Guide	 or 	1 or 2
2.618	MIS distal cutting guide		1
2.642	Correction distal MIS cutting guide +2° Varus/ Valgus Unslotted		1
02.07.10.2113	Saw Blade Guide		1
02.07.10.0165	Telescopic alignement set		1

*on request

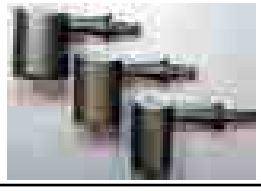
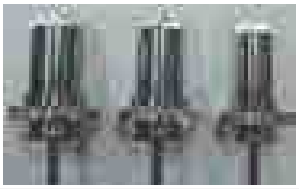
**use with 02.07.10.2145 or 02.07.10.2146 only

TRAY 3 - GENERAL - TIBIAL FINISHING - REF. 02.07S.803

REF.	Description		Quantity
02.02.10.0788	Pins extractor		1
2.170	Slide hammer		1
1.111	Posterior stabilization shaft		1
1.112	Posterior stabilization shaft peg		1
2.162	Femoral extractor		1
02.02.10.0173	Manual rasp		1
02.02.10.0145A	Pins Ø 3.2 mm, L 70 mm		4
02.02.10.0145B	Pins Ø 3.2 mm, L 90 mm		4
02.07.10.2016	GMK Pin ISO5835 Ø 3.2 L 65mm		4
02.07.10.2194	Sword Pin Ø 3.2 L 22 mm		4
02.02.10.0130	Drill bit (Ø 3.2, L 130 mm)		1
2.610 or 1.117	Drill Ø 10 mm – Hudson connection or Drill bit Ø 10 mm		1
1.101	Drill bit Ø 2.7 mm		1
1.106	Pin Ø 2.7 L 30 mm		4
5.011	Baseplate impactor		1

2.616	Distal Cut Positioner – Curved Rod		1
2.614	Distal Cut Positioner – Fixed Block		1
02.07.10.2046	Pin Adaptor - Hudson Coupling		1
1.021 1.022 1.023 1.024 1.025 1.026	Trial baseplate S 1 S 2 S 3 S 4 S 5 S 6		6
2.180 2.181 2.182	Puncher S 1 / S 2 S 3 / S 4 S 5 / S 6		3
1.100	Intramedullary rod Ø 8 mm		1
2.160	Punch handle		1
1.110	Trial base handle		1
2.186	Notching instrument		1
02.07.10.2195	Sickle Finger		1
02.02.10.0146	Pins impactor		2
U40.211.15*	Angled Lexer Osteotome 23 cm 15 mm		1
1.113	Screw driver 3.5 mm		1
2.183	Drill bit guide Ø 10 mm		1

*on request

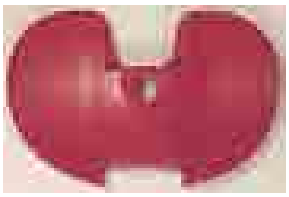
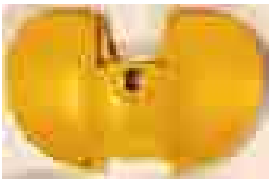
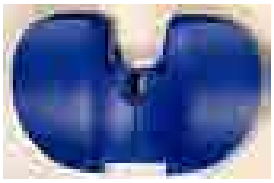
02.07.10.2230	Indipendent Cuts Reference Spacer		1
02.07.10.4730	Femoral spacer S 1-3		2
02.07.10.4731	Femoral spacer S 4-6		
2.600 2.601 2.602 2.603 2.604 2.605 2.606 2.607 2.608 2.609	Tibial spacer S 1-3 9 mm S 1-3 11 mm S 1-3 13 mm S 1-3 16 mm S 1-3 19 mm S 4-6 9 mm S 4-6 11 mm S 4-6 13 mm S 4-6 16 mm S 4-6 19 mm		10
02.07.10.1027	Trial base handle		1
02.02.10.0735*	Patella clamp		1
2.210* 2.214* 2.218*	Barrel Ø 20 mm Ø 24 mm Ø 28 mm		3
2.220* 2.224* 2.228*	Reamer Ø 20 mm Ø 24 mm Ø 28 mm		3
02.02.10.0204*	Patellar palpator		1
2.611* or 1.115*	Patella Drill Ø 5 mm – Hudson Connection or Drill bit Ø 5 mm		1
2.191*	Cut jaws left		2
2.192*	Cut jaws right		
2.193*	Inferior screwing jaws		1
2.194*	Superior screwing jaws		1

*on request

2.195*	Drilling template		1
1.090* 1.091* 1.092* 1.093*	Trial resurfacing patella Ø 30 mm Ø 33 mm Ø 36 mm Ø 39 mm		4
1.095* 1.096* 1.097*	Trial inserted patella Ø 20 mm Ø 24 mm Ø 28 mm		3

*on request

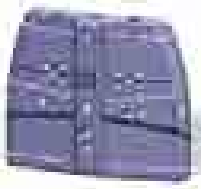
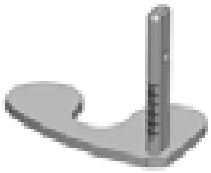
TRAY 4 - STD/PS TIBIAL INSERTS - REF.02.07S.804

REF.	Description		Quantity
1.030 1.031 1.032 1.033 1.034	STD/PS Trial insert (light blue) S 1/9 mm S 1/11 mm S 1/13 mm S 1/16 mm S 1/19 mm		5
1.040 1.041 1.042 1.043 1.044	STD/PS Trial insert (green) S 2/9 mm S 2/11 mm S 2/13 mm S 2/16 mm S 2/19 mm		5
1.050 1.051 1.052 1.053 1.054	STD/PS Trial insert (red) S 3/9 mm S 3/11 mm S 3/13 mm S 3/16 mm S 3/19 mm		5
1.060 1.061 1.062 1.063 1.064	STD/PS Trial insert (yellow) S 4/9 mm S 4/11 mm S 4/13 mm S 4/16 mm S 4/19 mm		5
1.070 1.071 1.072 1.073 1.074	STD/PS Trial insert (black) S 5/9 mm S 5/11 mm S 5/13 mm S 5/16 mm S 5/19 mm		5
1.080 1.081 1.082 1.083 1.084	STD/PS Trial insert (blue) S 6/9 mm S 6/11 mm S 6/13 mm S 6/16 mm S 6/19 mm		5

TRAY 5 - UC TIBIAL INSERTS - REF.02.07S.805

REF.	Description		Quantity
02.01.10.0037 02.01.10.0038 02.01.10.0039 02.01.10.0040 02.01.10.0041	UC Trial insert (light blue) S 1/9 mm S 1/11 mm S 1/13 mm S 1/16 mm S 1/19 mm		5
02.01.10.0042 02.01.10.0043 02.01.10.0044 02.01.10.0045 02.01.10.0046	UC Trial insert (green) S 2/9 mm S 2/11 mm S 2/13 mm S 2/16 mm S 2/19 mm		5
02.01.10.0047 02.01.10.0048 02.01.10.0049 02.01.10.0050 02.01.10.0051	UC Trial insert (red) S 3/9 mm S 3/11 mm S 3/13 mm S 3/16 mm S 3/19 mm		5
02.01.10.0052 02.01.10.0053 02.01.10.0054 02.01.10.0055 02.01.10.0056	UC Trial insert (yellow) S 4/9 mm S 4/11 mm S 4/13 mm S 4/16 mm S 4/19 mm		5
02.01.10.0057 02.01.10.0058 02.01.10.0059 02.01.10.0060 02.01.10.0061	UC Trial insert (black) S 5/9 mm S 5/11 mm S 5/13 mm S 5/16 mm S 5/19 mm		5
02.01.10.0062 02.01.10.0063 02.01.10.0064 02.01.10.0065 02.01.10.0066	UC Trial insert (blue) S 6/9 mm S 6/11 mm S 6/13 mm S 6/16 mm S 6/19 mm		5

TRAY 6 - FEMORAL - REF. 02.07S.806

REF.	Description		Quantity
1.001 1.002 1.003 1.004 1.005 1.006	Trial Femur S 1 R S 2 R S 3 R S 4 R S 5 R S 6 R		6
1.011 1.012 1.013 1.014 1.015 1.016	Trial Femur S 1 L S 2 L S 3 L S 4 L S 5 L S 6 L		6
2.631 2.632 2.633 2.634 2.635 2.636	MIS - Femoral cutting guide 4/1 S 1 S 2 S 3 S 4 S 5 S 6		6
02.07.10.1074	Femur Pegs Drill – Hudson Coupling		1
2.619	MIS Femoral Sizer		1
2.620	MIS Femoral Sizer Right Posterior Condyle Ref.		1
2.621	MIS Femoral Sizer Left Posterior Condyle Ref.		1

02.01.10.0037 02.01.10.0038 02.01.10.0039 02.01.10.0040 02.01.10.0041	UC Trial insert (light blue) S 1/9 mm S 1/11 mm S 1/13 mm S 1/16 mm S 1/19 mm		5
02.01.10.0042 02.01.10.0043 02.01.10.0044 02.01.10.0045 02.01.10.0046	UC Trial insert (green) S 2/9 mm S 2/11 mm S 2/13 mm S 2/16 mm S 2/19 mm		5
02.01.10.0047 02.01.10.0048 02.01.10.0049 02.01.10.0050 02.01.10.0051	UC Trial insert (red) S 3/9 mm S 3/11 mm S 3/13 mm S 3/16 mm S 3/19 mm		5
02.01.10.0052 02.01.10.0053 02.01.10.0054 02.01.10.0055 02.01.10.0056	UC Trial insert (yellow) S 4/9 mm S 4/11 mm S 4/13 mm S 4/16 mm S 4/19 mm		5
02.01.10.0057 02.01.10.0058 02.01.10.0059 02.01.10.0060 02.01.10.0061	UC Trial insert (black) S 5/9 mm S 5/11 mm S 5/13 mm S 5/16 mm S 5/19 mm		5
02.01.10.0062 02.01.10.0063 02.01.10.0064 02.01.10.0065 02.01.10.0066	UC Trial insert (blue) S 6/9 mm S 6/11 mm S 6/13 mm S 6/16 mm S 6/19 mm		5

12 IMPLANTS - NOMENCLATURE

Ti PLASMA SPRAYED STANDARD FEMUR

LEFT	SIZE	RIGHT
3010.001G	1	3010.001D
3010.002G	2	3010.002D
3010.003G	3	3010.003D
3010.004G	4	3010.004D
3010.005G	5	3010.005D
3010.006G	6	3010.006D

CEMENTED STANDARD FEMUR

LEFT	SIZE	RIGHT
3010.201G	1	3010.201D
3010.202G	2	3010.202D
3010.203G	3	3010.203D
3010.204G	4	3010.204D
3010.205G	5	3010.205D
3010.206G	6	3010.206D

Ti PLASMA SPRAYED POSTERO-STABILIZED STANDARD FEMUR

LEFT	SIZE	RIGHT
3012.001G	1	3012.001D
3012.002G	2	3012.002D
3012.003G	3	3012.003D
3012.004G	4	3012.004D
3012.005G	5	3012.005D
3012.006G	6	3012.006D

CEMENTED POSTERO-STABILIZED FEMUR

LEFT	SIZE	RIGHT
3012.201G	1	3012.201D
3012.202G	2	3012.202D
3012.203G	3	3012.203D
3012.204G	4	3012.204D
3012.205G	5	3012.205D
3012.206G	6	3012.206D

Ti-PLASMA SPRAYED TIBIAL BASEPLATE

3031.0001	SIZE 1
3031.0002	SIZE 2
3031.0003	SIZE 3
3031.0004	SIZE 4
3031.0005	SIZE 5
3031.0006	SIZE 6

CEMENTED TIBIAL BASEPLATE

3031.0201	SIZE 1
3031.0202	SIZE 2
3031.0203	SIZE 3
3031.0204	SIZE 4
3031.0205	SIZE 5
3031.0206	SIZE 6

RESURFACING PATELLA

3052.0030	Ø 30
3052.0033	Ø 33
3052.0036	Ø 36
3052.0039	Ø 39

INSET PATELLA

3050.0020	Ø 20
3050.0024	Ø 24
3050.0028	Ø 28

SCREW Ø 6,5 mm

3080.6520	Length 20 mm
3080.6525	Length 25 mm
3080.6530	Length 30 mm
3080.6535	Length 35 mm
3080.6540	Length 40 mm
3080.6545	Length 45 mm

STANDARD INSERT

		THICKNESS
SIZE 1	3040.0109	9
	3040.0111	11
	3040.0113	13
	3040.0116	16
	3040.0119	19

		THICKNESS
SIZE 2	3040.0209	9
	3040.0211	11
	3040.0213	13
	3040.0216	16
	3040.0219	19

		THICKNESS
SIZE 3	3040.0309	9
	3040.0311	11
	3040.0313	13
	3040.0316	16
	3040.0319	19

		THICKNESS
SIZE 4	3040.0409	9
	3040.0411	11
	3040.0413	13
	3040.0416	16
	3040.0419	19

		THICKNESS
SIZE 5	3040.0509	9
	3040.0511	11
	3040.0513	13
	3040.0516	16
	3040.0519	19

		THICKNESS
SIZE 6	3040.0609	9
	3040.0611	11
	3040.0613	13
	3040.0616	16
	3040.0619	19

POSTERO-STABILIZED INSERT

		THICKNESS
SIZE 1	3042.0109	9
	3042.0111	11
	3042.0113	13
	3042.0116	16
	3042.0119	19

		THICKNESS
SIZE 2	3042.0209	9
	3042.0211	11
	3042.0213	13
	3042.0216	16
	3042.0219	19

		THICKNESS
SIZE 3	3042.0309	9
	3042.0311	11
	3042.0313	13
	3042.0316	16
	3042.0319	19

		THICKNESS
SIZE 4	3042.0409	9
	3042.0411	11
	3042.0413	13
	3042.0416	16
	3042.0419	19

		THICKNESS
SIZE 5	3042.0509	9
	3042.0511	11
	3042.0513	13
	3042.0516	16
	3042.0519	19

		THICKNESS
SIZE 6	3042.0609	9
	3042.0611	11
	3042.0613	13
	3042.0616	16
	3042.0619	19

ULTRA-CONGRUENT FLEX INSERT

SIZE 1		THICKNESS
	3046.0109	9
	3046.0111	11
	3046.0113	13
	3046.0116	16
	3046.0119	19

SIZE 2		THICKNESS
	3046.0209	9
	3046.0211	11
	3046.0213	13
	3046.0216	16
	3046.0219	19

SIZE 3		THICKNESS
	3046.0309	9
	3046.0311	11
	3046.0313	13
	3046.0316	16
	3046.0319	19

SIZE 4		THICKNESS
	3046.0409	9
	3046.0411	11
	3046.0413	13
	3046.0416	16
	3046.0419	19

SIZE 5		THICKNESS
	3046.0509	9
	3046.0511	11
	3046.0513	13
	3046.0516	16
	3046.0519	19

SIZE 6		THICKNESS
	3046.0609	9
	3046.0611	11
	3046.0613	13
	3046.0616	16
	3046.0619	19

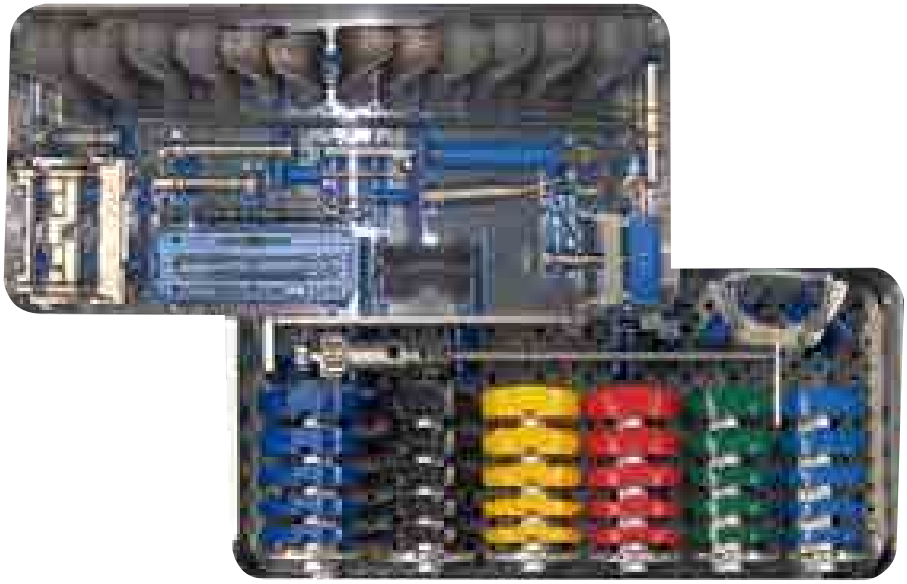
Part numbers subject to change.

Manual instruments supplied non-sterile. Instruments must be cleaned and sterilized prior to use.

Refer to www.medacta.com for instructions on cleaning, decontamination and sterilization of reusable manual instruments.

Medacta International

INSTRUMENTATION



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