NEXTAR™

AUGMENTED REALITY SURGICAL PLATFORM

NextAR™ Knee | Surgical Technique

Medacta International | JOINT

Proprietary Augmented Reality surgical platform

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1. INTRODUCTION

1.1 INDICATIONS

The NextAR TKA Platform is intended to be used to support the surgeon during total knee replacement procedures by providing information on bone resections, ligaments behavior, instrument and implant positioning.

The NextAR™ TKA Platform is intended to be used in combination with NextAR™ stereotaxic instruments and general surgical instruments to implant the GMK Sphere Total knee system and perform ligament balancing. As an optional display, the smart glasses can be used auxiliary to the NextAR Platform to view the same 2D stereotaxic information as presented by the NextAR Platform.

The smart glasses should not be relied upon solely and should always be used in conjunction with the primary computer display.

The MyKnee NextAR cutting guides include a camera/target holder and a PSI MyKnee cutting guide both for tibia and femur. The MyKnee cutting guides must be used as anatomical cutting blocks specific for a single patient anatomy, to assist in the positioning of total knee replacement components intraoperatively and in guiding the marking of bone before cutting. The use of MyKnee NextAR™ cutting guides are applicable only for the "PSI-based" approach. MyKnee NextAR TKA cutting guides are for single use only.

The NextAR stereotaxic instruments are intended to be used to support the surgeon during specific orthopedic surgical procedures by providing information on bone resections, ligaments behavior, instrument and implant positioning. The NextAR stereotaxic instruments, when registered with the MyKnee NextAR TKA cutting guides, provide reference to a patient's rigid anatomical structures, such as the femur and tibia, that can be identified relative to pre-operative CT based planning.

1.

1.2 GENERAL

This document describes the surgical technique for implanting the GMK Sphere total knee system, using NextAR TKA platform. This technique applies only to surgical cases planned with the MyKnee platform. MyKnee NextAR Efficiency cutting blocks can be used in association only with GMK Efficiency Single Use Instruments. The part numbers for these blocks are listed in the NextAR MyKnee cutting blocks tables 15.2.

CAUTION
Use the NextAR TKA platform (table 15.5) exclusively in association with specifically designed metal instrument listed in table 15.1, GMK Efficiency (15.3), single use sensors (15.4) and MyKnee NextAR cutting blocks listed in the 'MyKnee NextAR Femoral Distal cutting blocks Efficiency' (15.2), 'MyKnee NextAR Tibial cutting blocks' tables (15.2). MyKnee standard and MIS femoral and tibial cutting blocks that are not listed, are NOT COMPATIBLE with NextAR TKA platform. The compatibility of the MyKnee NextAR cutting blocks is indicated on the labels of these blocks. Always check that the description on the cutting blocks' label states "MyKnee NextAR Femoral distal cutting block Efficiency" or "MyKnee NextAR Tibial cutting block".

CAUTION
The NextAR system does not provide information of a diagnostic nature This manual illustrates the software NextAR Knee v.1.1.4 and hardware operating modes and provides the necessary instructions for their proper and safe use.

CAUTION
The system shall be used exclusively by suitably trained personnel. Reading this manual is an integral part of the training process. Should any part of the manual not be clear, refer to the specialized Medacta staff for help.

CAUTION
Like all electrical devices, then NextAR platform may be subject to malfunction due to improper use or technical reasons. It is always possible to complete the surgery with the aid of the standard equipment. MyKnee NextAR cutting blocks are custom-made devices intended to be used as anatomical cutting blocks, specifically designed for single patient anatomy, to assist in the positioning of GMK Sphere total knee replacement components and NextAR instruments intraoperatively. MyKnee NextAR cutting blocks are intended for use only with Medacta GMK Sphere, when the clinical evaluation of the patient complies with the indications for use. MyKnee NextAR cutting blocks are intended for single use only. The MyKnee NextAR cutting blocks are supplied in two different boxes: the femoral cutting block and the 3D femur model are packed in one box, while the tibial cutting block and the 3D tibia model are packed in another one.

CAUTION
The MyKnee NextAR cutting blocks can be supplied sterile or non-sterile. If they are supplied non-sterile, it is the healthcare institution's responsibility to clean and sterilize the blocks before use. Please read the "Note for sterilisation" included at the end of this surgical technique.

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

CAUTION
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 CANNOT BE USED AND MUST BE REPLACED BY NEW ONES. When extracting pins it is important to avoid any bending. It is strongly recommended not to impact or hammer on any instruments unless otherwise specified in the surgical technique. For detailed instructions contact your local Medacta sales representative.

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

1.3 CONTRAINDICATIONS

Contraindications in using NextAR Platform are the same as the situations when a total knee replacement is contraindicated. It is the surgeon's responsibility to verify that the patient is not allergic to the material of which the MyKnee NextAR cutting blocks are made (Polyamide PA12).

1.4 PREOPERATIVE PLANNING

The pre-operative planning is managed through the website myknee.medacta.com in cooperation between the surgeon and Medacta International.

Please contact Medacta International to gain access to the website.

The goal of the preoperative planning is to assess the surgical parameters regarding femoral and tibial implantation in order to manufacture dedicated, patient specific cutting blocks.

Parameters are to be planned by the surgeon and include:

- Femoral implant size
- Tibial implant size
- Femoral resections:
- Posterior cut height, on both condyles (medial and lateral)
- Distal cut height, on both condyles (medial and lateral)
- Femoral angles
  Varus / valgus
  Flexion / Extension
- Femoral rotation
- Internal / external rotation vs posterior condyles line and vs epicondylar axis
- Tibial resection
- Proximal cut height related to both plateaux (medial and lateral)
- Tibial angles
  Varus / valgus
  Posterior slope

CT imaging is used to create a tri-dimensional bone model of the patient's knee anatomy and to detect collateral ligaments' origins and insertions. This bone modelling is the basis for the anatomical cutting blocks, that can fit the patient's knee morphology, without using any alignment jigs to position them.

NOTE: Please refer to the official CT protocols available on the website https://myknee.medacta.com. Scans taken with different protocols may lead to unusable images.

NOTE: Before using MyKnee NextAR procedures, every Radiological Center must be registered. Please contact Medacta International to register your Radiological Center.

CAUTION

Different MyKnee NextAR cutting blocks are available depending on the scanning technology used. The surgeon will receive a MyKnee Surgical Planning Report (ref.M08.59) that indicates the surgical parameters, according to his default profile which is previously set by the surgeon on the MyKnee website. It is the surgeon's responsibility to validate the preliminary planning or set different parameters according to his/her assessment. Both validation and changes in the planning must be communicated via the MyKnee website. After the planning is confirmed by the surgeon, the MyKnee blocks are manufactured and delivered to the agent responsible.

CAUTION

Please note that the NextAR software available in the O.R. is an offline system. So, it is the surgeon's responsibility to download the planning from the MyKnee website on a USB key, and upload on it on the NextAR platform before starting the surgery following the instruction in the O.R. setup paragraph §2.

1.5 SURGICAL APPROACH

The most commonly used surgical approach is the medial parapatellar approach.

CAUTION

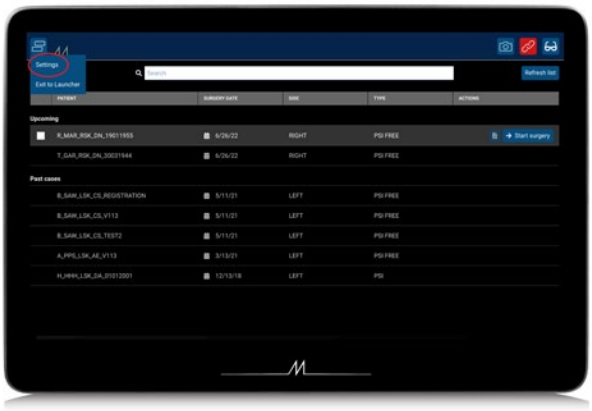
DO NOT remove any osteophytes from the tibia or femur in order not to alter the bony references of the MyKnee NextAR anatomical cutting blocks.

2. O.R. SETUP

The display is not intended to be sterilized, so before using it, cover it with a transparent sterile drape.

Then starting the platform by pressing the On/Off button located in the anterior part of the screen.

Once the launcher is initialized select the NextAR application v.1.1.4.

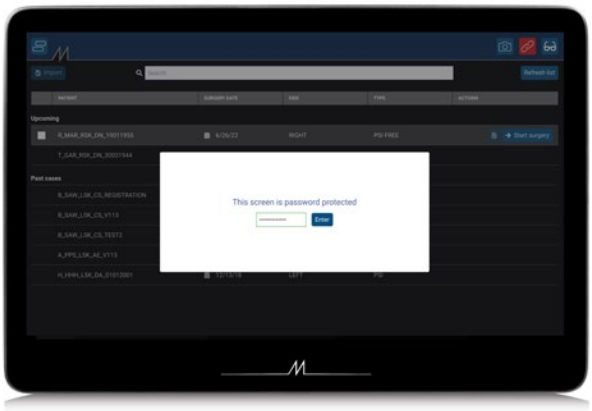


2.

Before starting the surgery, click on the top left menu in the main page and tap on Settings. Then insert the correct password and click on Workflow:

- Select “METAL” if you want to use Ref. 02.23.10.0044
- Select “EFFICIENCY” if you want to use Ref. 02.23.10.0037

4.



3.

5.

Connect the USB-key, with one or more cases already validated, to the PC by one of the anterior USB ports.

Go to the Patients list and click import, the system automatically updates the new cases, listing them by date.

To turn ON/OFF the Smart glasses the user needs to hold the power button for 3 seconds.

LIGHT-WEIGHT DESIGN

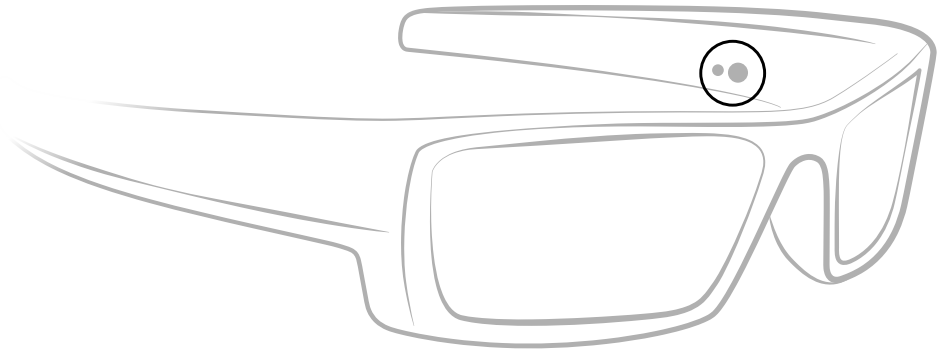
PRESCRIPTION LENSES

WIRELESS SOLUTION

INTEGRATED CAMERA

USB CONNECTION

3 SEC. Power ON/OFF



6.

CAUTION

The device is not intended to be sterilized. The device must not be touch by a user in sterile apparel. The touched pad is disabled, glasses are controlled completely via PC.

The AR glasses are configured to be discoverable via Bluetooth connection and will automatically launch the NextAR TKA app when turned on. The NextAR PC will scan for Bluetooth devices, and the user must select the glasses from a list of device names.

The AR Glasses stream some information and data from the NextAR PC, enabling visualization of some surgery steps directly on the sterile field.

CAUTION

They must be used always in conjunction with the PC. They are not intended to run the NextAR TKA application independently.

Select the case from the patient list and click on “start surgery” button to begin the surgery.

If a case, that is not scheduled for the current day is selected, a warning will be visualized on the screen.

Firstly, turn on the Camera. Once it has connected to the platform, a check will be shows on the screen, then turn on the tracker. Once the tracking system is connected, the icon on the right upper corner of the screen will become white and it will be possible to visualize the tracker moving on the screen.

3. CAMERA AND SENSOR PLACEMENT – PSI OPTION

The positioning of camera and sensor is undertaken by the MyKnee NextAR cutting blocks or the MyKnee PPS NextAR pin positioner blocks.

MyKnee NextAR cutting blocks.

Both femoral and tibial block are composed of:

- MyKnee cutting block
- Camera/Sensor holders
- Screw, used to fix the connection between the cutting guide and the sensor holder

Each block is shipped assembled.

MyKnee PPS NextAR pin positioner blocks.

Both femoral and tibial block are composed of:

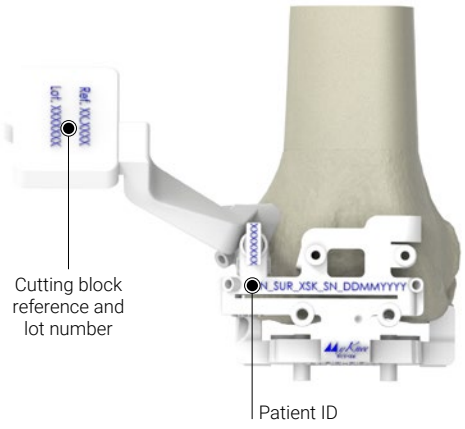
- Modular MyKnee PPS Pin positioner block

Each block is shipped assembled.

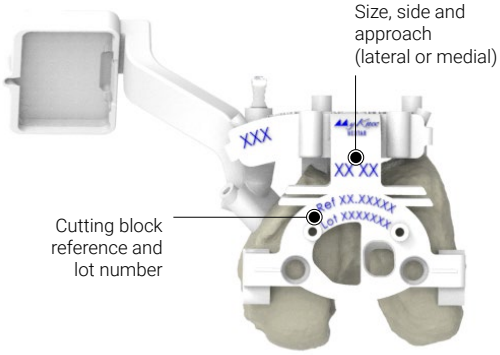
3.1 DISTAL BLOCK POSITIONING

3.1.1 MyKnee NextAR Cutting Blocks

Each MyKnee NextAR femoral cutting block shows the following information



7.



8.

Before starting the surgery, please check the MyKnee data accurately matches the patient details. An example of patient ID is shown below:

N_SUR_XXK_SN_DDMMYYYY

- **N** = first letter of patient's given name
- **SUR** = first three letters of patient's last name
- **XSK (GMK Sphere)** = side operated, left (LSK) or right (RSK)
- **SN** = surgeon's first and last name initials
- **DDMMYYYY** = patient's birth date (DD=day, M=month, YYYY=year)

CAUTION

If the cutting block reference number does not clearly correspond with the patient details, it MUST NOT be used for surgery. In this situation please contact Medacta staff immediately.

CAUTION

Do not use MyKnee NextAR cutting blocks on a patient for whom the pre-operative planning has not been carried out. A MyKnee cutting block used on a different patient will lead to unpredictable total knee replacement outcomes.

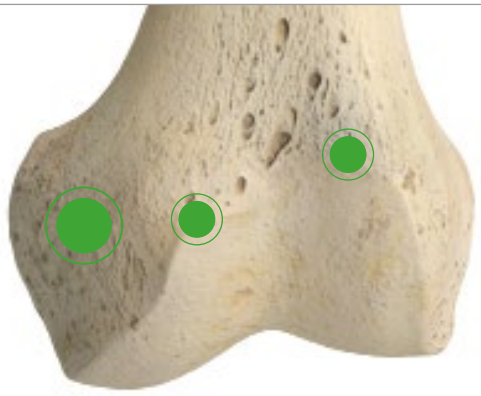
CAUTION

Do not remove any osteophytes from the femur bone.

A plastic 3D model of the patient's femoral bone is provided to simulate the correct positioning of the MyKnee NextAR distal cutting block. This plastic model can be supplied sterile or non-sterile. When supplied non-sterile, it must be sterilised by the healthcare institution (Please read the "Note for sterilisation" included at the end of this surgical technique). Check the correct fit between the bone model and the distal cutting block and, by using the angel wing, both distal and anterior cut depth. The planned distal and posterior resection levels are marked on the bone model.

The block has to be positioned manually on the distal femur. Considering the anatomical shape of the block, only one orientation is possible. The correct placement corresponds to the position of maximum stability of the block.

To ensure maximum stability, verify that the points of contact between the MyKnee NextAR distal cutting block and the femur are respected.



Cutting blocks contact area

CT-based cutting blocks contact area

9.

CAUTION

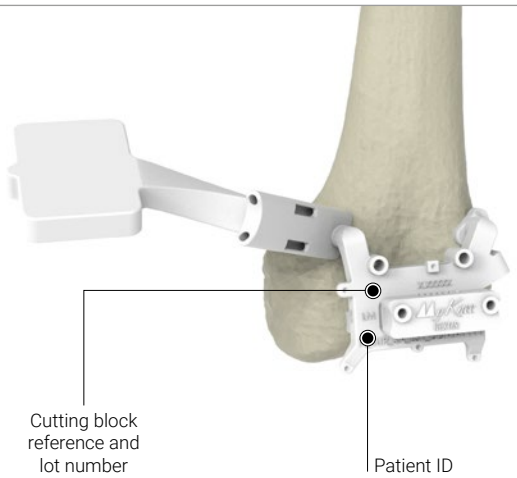
When using CT-based MyKnee NextAR femoral cutting block, cartilage and soft tissue covering the cutting block contact areas must be removed from the bone, using an electric cutter(see figure above) to obtain the most stable position for the cutting block.

CAUTION

Inaccurate positioning may lead to cut parameters not in line with the planning.

3.1.2 MyKnee PPS NextAR Pin Positioner Blocks

Each MyKnee PPS NextAR femoral block shows the following information:



10.

Before starting the surgery, please check that the MyKnee data accurately match the patient details. An example of patient ID is shown below:

N_SUR_XXK_SN_DDMMYYYY

- **N** = first letter of patient's first name
- **SUR** = first three letters of patient's last name
- **XSK (GMK Sphere)** = side operated, left (LSK) or right (RSK)
- **SN** = surgeon's first and last name initials
- **DDMMYYYY** = patient's birth date (DD=day, M=month, YYYY=year)

CAUTION
If the pin positioner block reference number does not match the patient details, it MUST NOT be used for surgery. In this situation, please contact Medacta staff immediately.

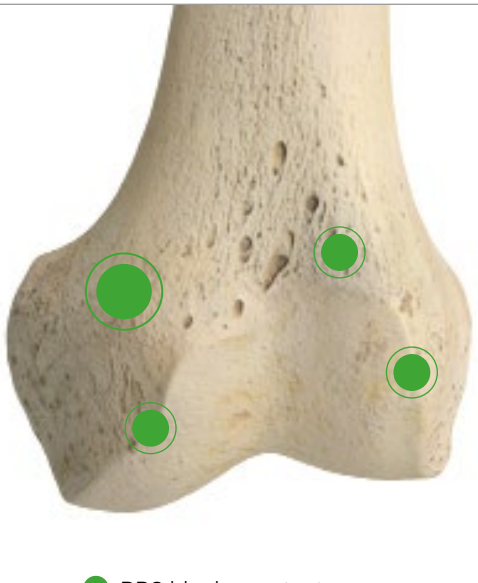
CAUTION
Do not use the MyKnee PPS NextAR blocks on a patient for whom the pre-operative planning has not been carried out. Using a MyKnee PPS block on a different patient will lead to unpredictable total knee replacement outcomes.

CAUTION
Do not remove any osteophytes from the femur bone.

A plastic 3D model of the patient's femoral bone is provided to simulate the correct positioning of the MyKnee PPS NextAR distal block. This plastic model can be supplied sterile or non-sterile. When supplied non-sterile, it must be sterilised by the healthcare institution (Please read the "Note for sterilisation" included at the end of this surgical technique). Check the correct fit between the bone model and the distal cutting block and, by using the angel wing, verify both the distal and anterior cut depth. The planned distal and posterior resection levels are marked on the bone model.

The block must be positioned manually on the distal femur. Due to the anatomical shape of the block, only one orientation is possible. The correct placement corresponds to the position of maximum stability of the block.

To ensure maximum stability, verify that the points of contact between the MyKnee PPS NextAR distal block and the femur are respected.



11.

CAUTION
When using the CT-based MyKnee PPS NextAR femoral block, remove any cartilage and soft tissue (if present) covering the cutting block contact areas from the bone using an electric cutter (see figure above) in order to obtain the most stable position for the cutting block.

CAUTION
An inaccurate positioning may lead to cut parameters not in line with the planning.

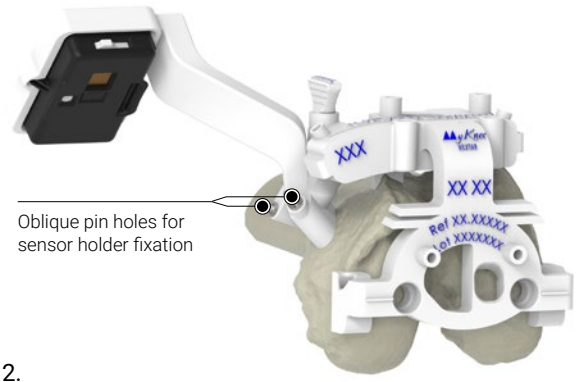
3.2 FIXING THE DISTAL BLOCK AND CAMERA HOLDER

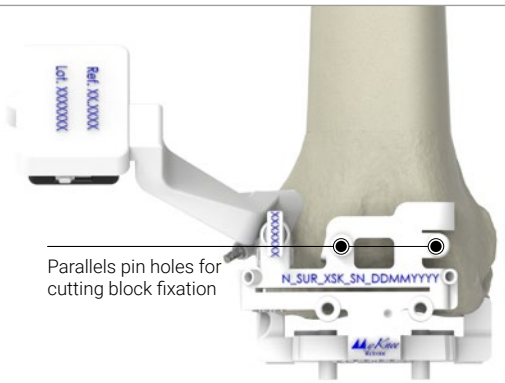
3.2.1 MyKnee NextAR Cutting Blocks

When satisfied with the position of the distal cutting block, it can be fixed on the femur using standard 3.2 mm diameter pins as shown in the picture below.

To guarantee a stable fixation two parallel pins plus an oblique one must be used.

Use two threaded pins to fix the camera holder.





12.

CAUTION
Do not alter the cutting block position while drilling pin holes, to avoid any guide and sensor misalignment. Use the triangular screwdriver to tighten the fixation pins of the sensor holder.

Once the cutting guide has been correctly arranged on the femur, cut parameters are automatically set for the knee undergoing surgery according to the pre-operative planning.

3.2.2 MyKnee PPS NextAR Pin Positioner Blocks

When satisfied with the position of the PPS distal block, you can fix it on the femur using the standard 3.2 mm diameter pins, as shown in the picture below.

A **B** **C**

13.

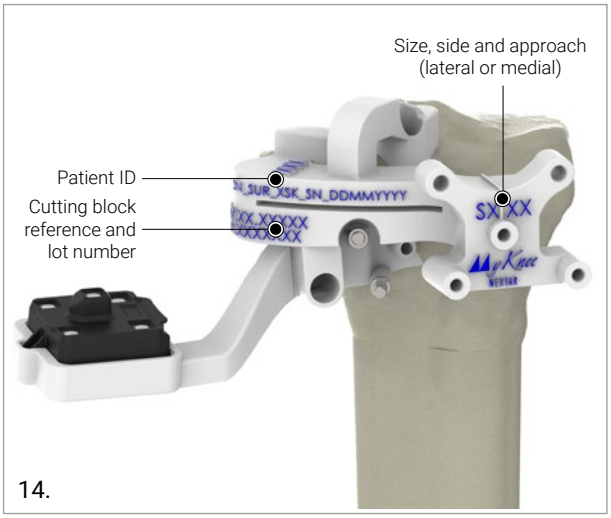
CAUTION
Do not alter the PPS block position while drilling the pin holes, in order to avoid any guide and sensor misalignment.

Once the PPS guide has been correctly fixed on the femur, the cut parameters are automatically set for the knee undergoing surgery according to the pre-operative planning.

3.3 TIBIAL BLOCK POSITIONING

3.3.1 MyKnee NextAR Cutting Blocks

Each MyKnee NextAR tibial cutting block shows the following information:



14.

Before starting the surgery, please check that the Myknee data accurately match the patient details. An example of patient ID is shown below:

N_SUR_XXK_ SN_DDMMYYYY

- **N** = first letter of patient's given name
- **SUR** = first three letters of patient's last name
- **XSK (GMK Sphere)** = side operated, left (LSK) or right (RSK)
- **SN** = surgeon's first and last name initials
- **DDMMYYYY** = patient's birth date (DD=day, M=month, YYYY=year)

CAUTION

If the cutting block reference number does not clearly correspond with the patient details, it MUST NOT be used for surgery. In this situation please contact Medacta staff immediately.

CAUTION

Do not use MyKnee NextAR cutting blocks on a patient for whom the pre-operative planning has not been carried out. A MyKnee cutting block used on a different patient will lead to unpredictable total knee replacement outcomes.

CAUTION

Do not remove any osteophytes from the tibia bone.

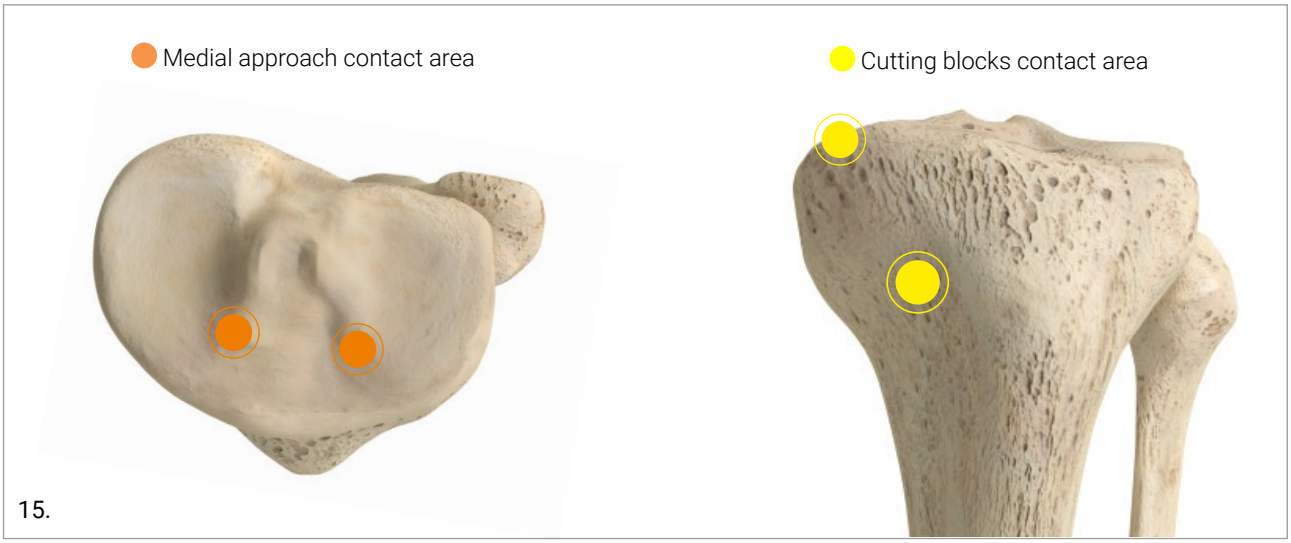
A plastic 3D model of the patient's tibia bone is provided to simulate the correct positioning of the MyKnee NextAR tibia cutting block on the patient's anatomy. This plastic model can be supplied sterile When supplied non-sterile, it must be sterilised by the healthcare institution (Please read the "Note for sterilisation" included at the end of this surgical technique).

Check to make sure there is a correct fit between the bone model and also check the planned tibia resection level marked on the bone model.

The block has to be positioned manually on the tibia plateau.

Considering the anatomical shape of the block, only one orientation is possible. The correct placement corresponds to the position of maximum stability of the block.

To ensure maximum stability, verify, by using the 3D plastic model, that the points of contact between the MyKnee NextAR tibia cutting block and the tibial bone are respected



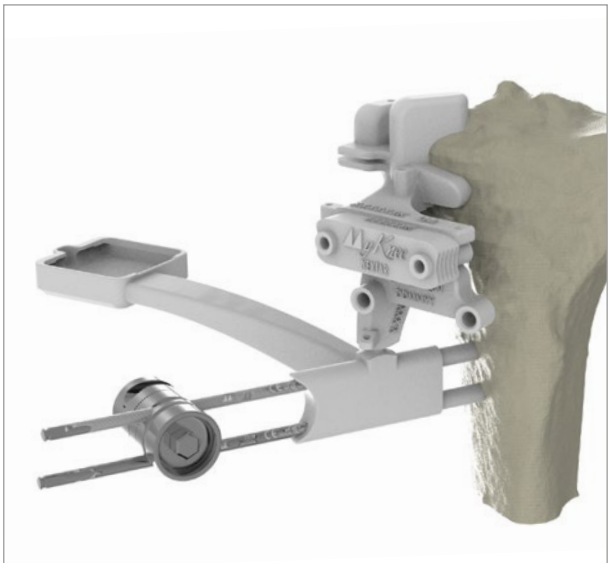
15.

CAUTION
When using the CT-based MyKnee NextAR tibial cutting block, cartilage and soft tissue covering the cutting block contact areas must be removed from the bone, using an electric cutter(see figure above) to obtain the most stable position for the cutting block.

CAUTION
Inaccurate positioning may lead to cut parameters not in line with the planning.

3.3.2 MyKnee PPS NextAR Pin Positioner Blocks

Each MyKnee NextAR tibial cutting block shows the following information:



16.

Before starting the surgery, please check that the Myknee data accurately match the patient details. An example of patient ID is shown below:

N_SUR_XXK_SN_DDMMYYYY

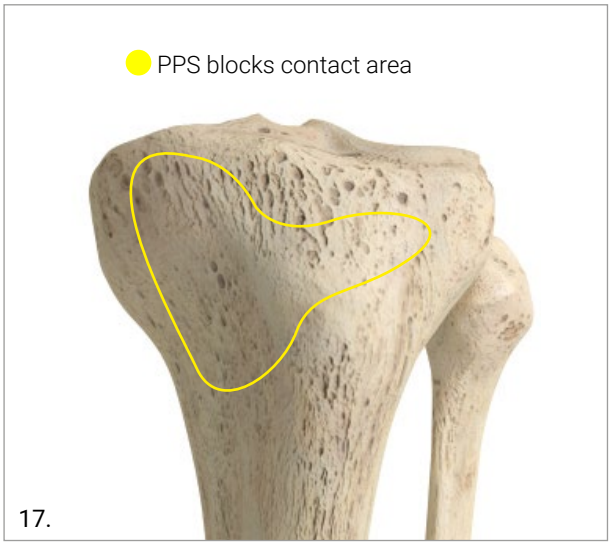
- **N** = first letter of patient's given name
- **SUR** = first three letters of patient's last name
- **XSK (GMK Sphere)** = side operated, left (LSK) or right (RSK)
- **SN** = surgeon's first and last name initials
- **DDMMYYYY** = patient's birth date (DD=day, M=month, YYYY=year)

CAUTION
If the PPS block reference number does not match the patient details, it MUST NOT be used for surgery. In this situation please contact Medacta staff immediately.

CAUTION
Do not use MyKnee NextAR PPS blocks on a patient for whom the pre-operative planning has not been carried out. A MyKnee PPS block used on a different patient will lead to unpredictable total knee replacement outcomes.

CAUTION
Do not remove any osteophytes from the tibia bone.

A plastic 3D model of the patient's tibia bone is provided to simulate the correct positioning of the MyKnee NextAR PPS tibia Pin positioner block on the patient's anatomy. This plastic model can be supplied sterile. When supplied non-sterile, it must be sterilised by the healthcare institution (Please read the "Note for sterilisation" included at the end of this surgical technique).
Make sure there is a correct fit with the bone model and check the planned tibia resection level marked on the bone model.
The block must be positioned manually on the tibia plateau. Due to the anatomical shape of the block, only one orientation is possible. The correct placement corresponds to the position of maximum stability of the block.
To ensure maximum stability verify, by using the 3D plastic model, that the points of contact between the MyKnee NextAR PPS tibia block and the tibial bone are respected.



17.

CAUTION
When using the CT-based MyKnee NextAR PPS tibial block, remove from the bone any cartilage and soft tissue covering the cutting block contact areas using an electric cutter (see figure above), in order to obtain the most stable position for the cutting block.

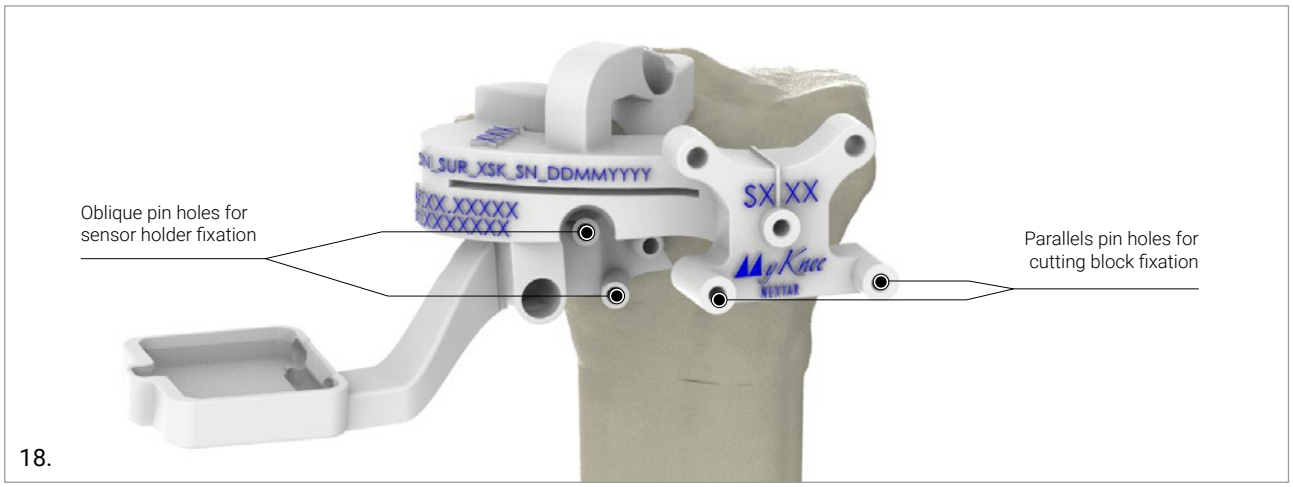
CAUTION
An inaccurate positioning may lead to cut parameters not in line with the planning.

3.4 FIXING THE TIBIAL BLOCK AND SENSOR HOLDER

3.4.1 MyKnee NextAR Cutting Blocks

When satisfied with the position of the tibial cutting block, it can be fixed on the tibia using standard 3.2 mm diameter pins in the parallel pin holes, as shown in the picture below.

Then fix the sensor holder with the threaded pin, using the divergent pin holes on the pad, as shown in the picture below.



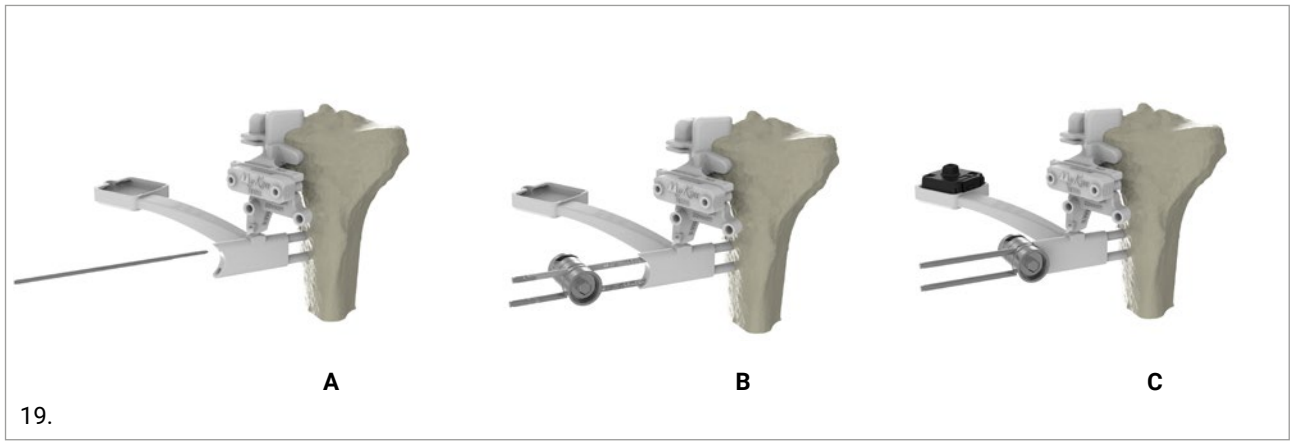
18.

CAUTION
Do not alter the cutting block position while drilling the pin holes, to avoid any guide and sensor misalignment. Use the triangular screwdriver to tighten the fixation pins of the sensor holder.

Once the cutting guide has been correctly arranged on the tibia, cut parameters are automatically set for the knee undergoing surgery according to the pre-operative planning

3.4.2 MyKnee PPS NextAR Pin Positioner Blocks

When satisfied with the position of the PPS tibial block, you can fix it on the tibia using the standard 3.2 mm diameter pins in the parallel pin holes, as shown in the picture below.

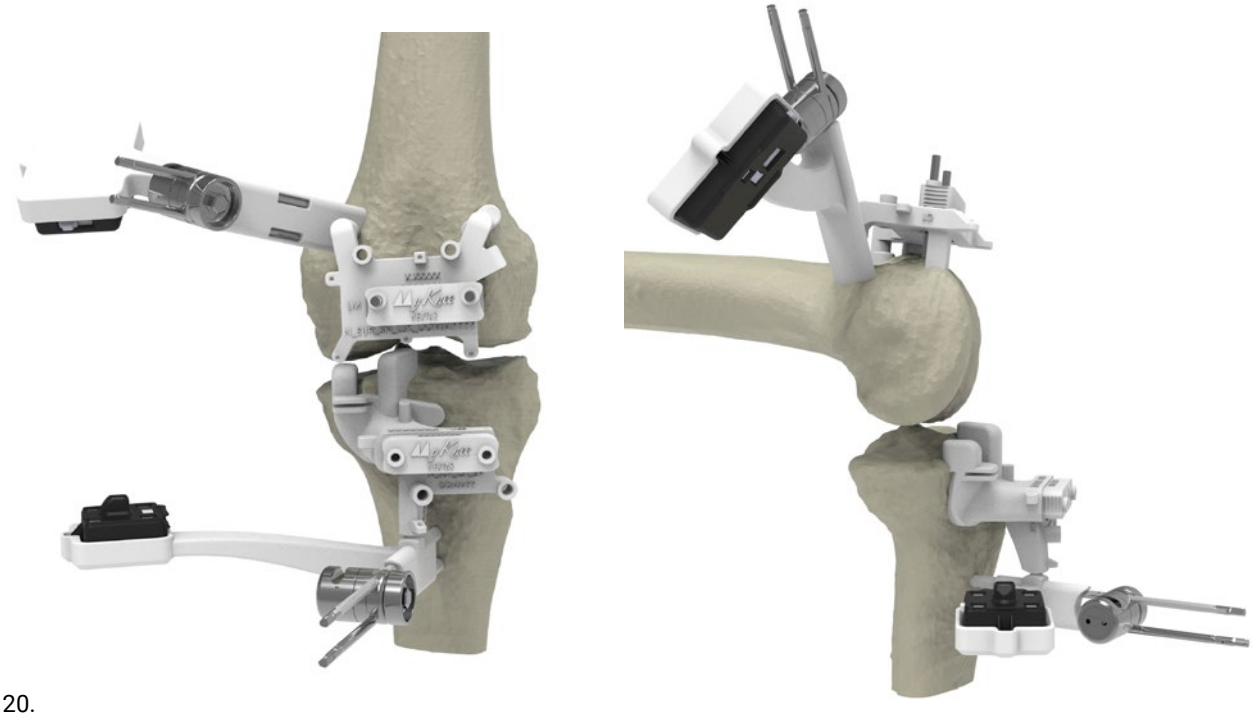


19.

CAUTION
Do not alter the PPS block position while drilling the pin holes, in order to avoid any guide and sensor misalignment.

Once the cutting guide has been correctly fixed on the tibia, the cut parameters are automatically set for the knee undergoing surgery according to the pre-operative planning.

The final set up of both femoral and tibial PPS block and sensor holders is the following:



20.

4. CAMERA AND TARGET PLACEMENT – PSI-FREE OPTION

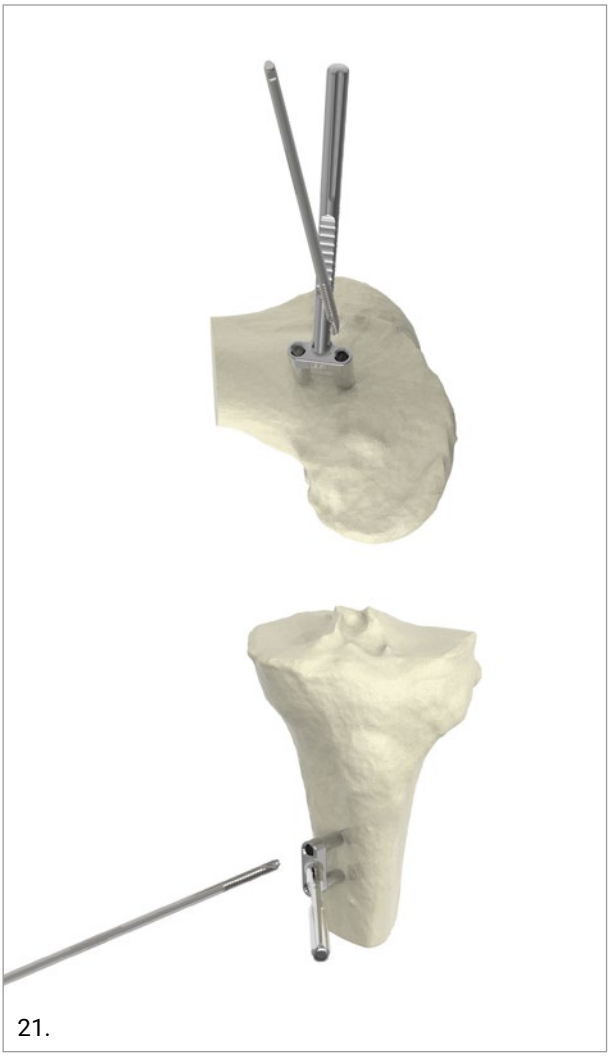
4.1 CAMERA AND SENSOR HOLDER POSITIONING

Easy-clip option

For proper positioning of the camera and target respectively on the femur and the tibia of the patient, follow the instructions below.

The pins holding the sensors can be positioned either percutaneously or inside the incision according to the specific requirements and the different surgical techniques. They must be inserted into the anterior aspect of the bone, longitudinally to the bony axes.

Use the pin placement guide to identify the proper location of the pins as shown in the picture 17. After selecting the appropriate location, insert the pins into the bone.

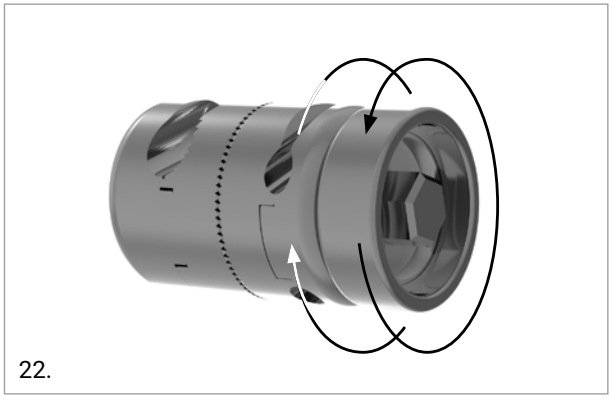


21.

CAUTION

Secure the pins medially with the anatomical axis of the tibia or femur in order to prevent any conflicts with the alignment rod that can be used to control the tibial or femoral cutting guide positioning.

Unscrew the Easy-Clip hinge to open it.

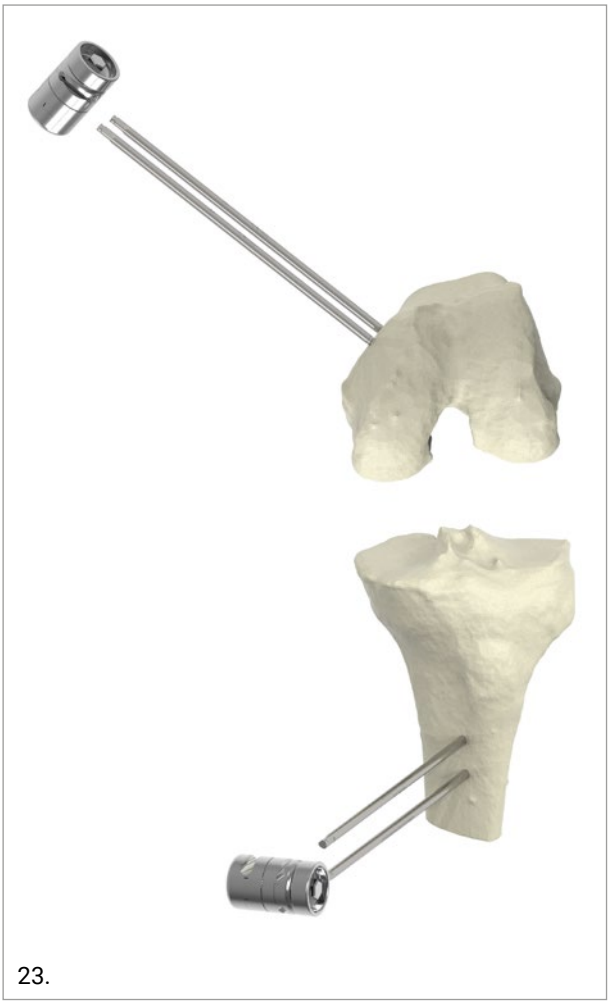


22.

CAUTION

Carefully unscrew the Easy-CLIP hinge without forcing it beyond its limit.

Fit the Easy-CLIP on the pins, then position the hinge so that the locking knob is facing opposite to the camera.



23.

Insert the arm holder into the dedicated hole and rotate it around the axis to fix the orientation of the sensors. With the knee in extension, the tibial sensor should be approximately perpendicular to the ground, while the femoral sensor should be positioned at about 45° to the ground. The two sensors must be positioned medially and on the same axis in the frontal plane.

24.

Using the special Allen wrench, tighten the Easy-CLIP to lock the entire assembly.

25.

CAUTION

Make sure that the mechanical assembly has been sufficiently tightened and that none of its parts are loose. Any change of position of the reference arrays during surgery will invalidate the exactness of the data and will make it necessary to abort navigation or to repeat the acquisition procedure from the beginning.

4.2 ACQUISITION

The acquisitions are extremely important for the proper functioning of the navigation process. The quality of the information provided by the NextAR TKA to the surgeon is, infact, strictly related to the accuracy of the acquisitions performed using the pointers or sensors fixed to bone.

The pointer adopted for NextAR TKA uses the single-point acquisition approach. The surgeon must place the pointer on the appropriate anatomical reference point for a few seconds and the system will automatically register it.

Each of the femur and tibia bone registration patterns consists of 26 points.

CAUTION

Using the MyKnee cutting blocks, it may not be needed to take all 26 points if you get the green check after the first 6 points taken. If you do not get the green check, you must continue to acquire the remaining 20 points.

The patient-specific model is derived from a CT scan, so only the bony anatomy is segmented. Therefore, the bone registration points must be collected on the bone; for this reason, make sure to penetrate the cartilage and stop at the bone surface with the tip's pointer.

4.2.1 Femur registration

Assemble the straight pointer with the sensor holder and clip the square sensor into the seat.

26.

Collect all the bone femur registration points following the instructions displayed and try to place the tip of the pointer in the same location displayed on the screen. However, it is not mandatory to follow the pattern shown on the screen. An acoustic signal advises the surgeon that the point has been captured.

4.2.2 Tibia registration

Assemble the curved pointer with the sensor holder and clip the rectangular sensor into the seat.

Collect all the bone tibia registration points following the instructions displayed and try to place the tip of the pointer in the same location displayed on the screen. However, it is not mandatory to follow the pattern shown on the screen. An acoustic signal advises the surgeon that the point is captured.

27.

5. SOFT TISSUE ASSESSMENT

5.1 ACQUISITION OF L0

Once the planned position is confirmed it is possible to start acquiring information about the ligament's elongation.

MyKnee NextAR
Unlock the key of the MyKnee NextAR femoral and tibia cutting block to slide off the cutting guide.

MyKnee PPS NextAR
Pull the modular central part of the MyKnee PPS Block out. The first step is the registration of the collateral ligaments refrence length, L0.

Following the instructions on the screen, hold the knee between 0° and 10° of flexion until the software has registered the data. A progress bar shows the progression of the acquisition.

OPTION
It is possible to use a dedicated set of spacers, available in 1,2,3,4 mm of thickness (ref.02.12.10.1366 /1367 /1368 /1369), to compensate the damaged cartilage and replicate the pre-arthritic joint anatomy.

CAUTION
In case of joint contraction requiring any kind of release, it should be performed before the registration of the L0, to avoid inaccurate value of the collaterals length.

OPTION
If there is a flexion contraction and the leg cannot be extended, the registration at any flexion angle can be activated by clicking on the purple button (see image below). The L0 will not represent the length in extension but will be limited to the length of the ligaments at the degrees of flexion at the moment of the acquisition.

28.

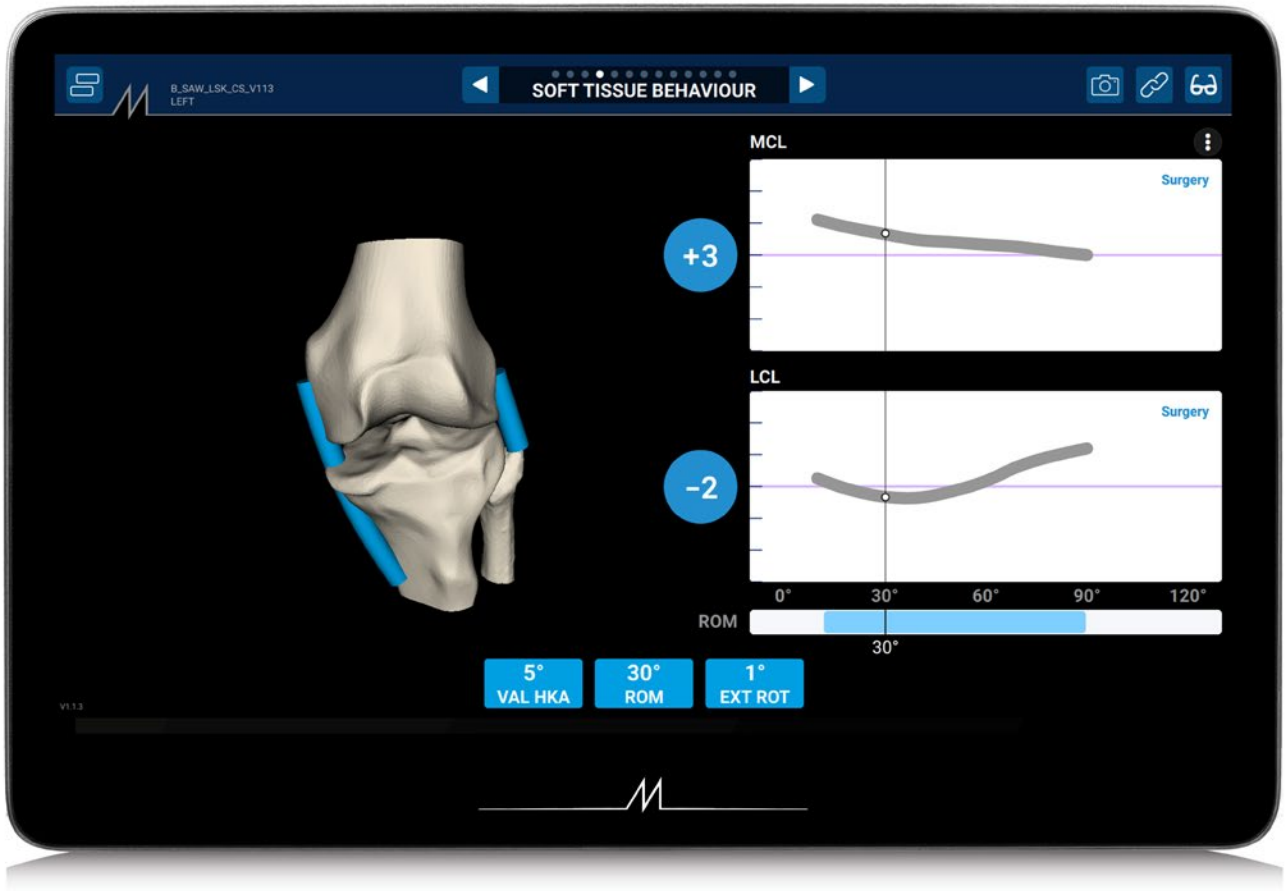
5.2 REAL-TIME 3D LIGAMENTS TRACKING

When L0 is defined, the software shows the graphs of the collateral ligaments' length variation.

Two graphs are shown on the right of the 3D patient model anatomy:

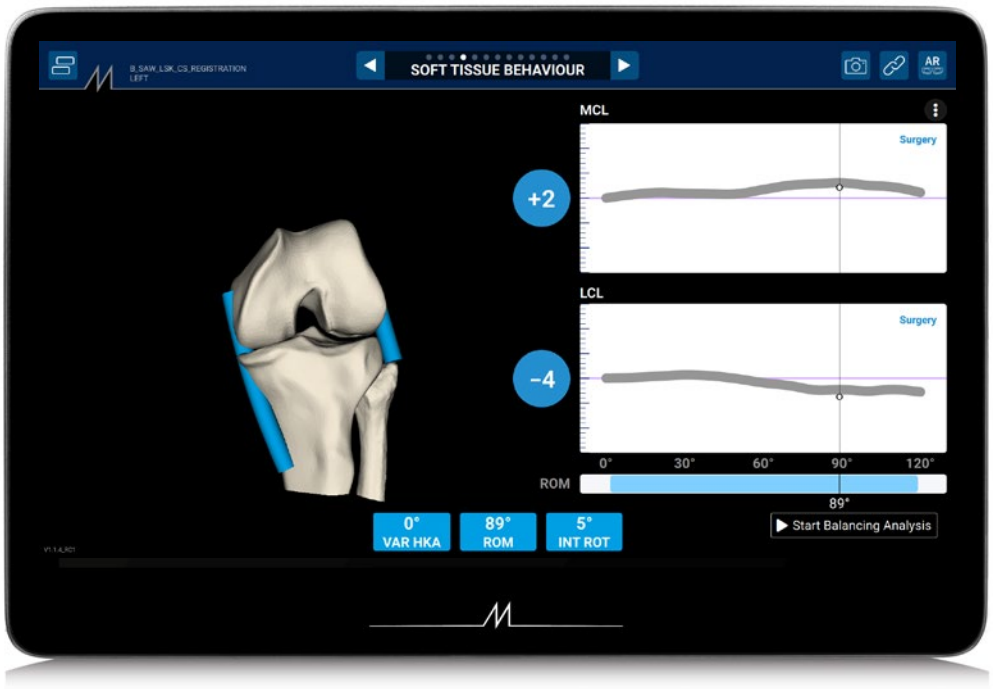
- The medial collateral ligament plot, labelled with MCL, is displayed on the right-upper section
- The lateral collateral ligament graph (LCL) is plotted on the right-lower section.
- Each graph displays:
  - A purple straight line which indicates L0;
  - On the y-axis a graduated scale with 1 mm of accuracy;
  - The value in a light-blue circle indicates the difference in mm between the L0 and the registered ligament length at the current degree of flexion.

During this step, the surgeon can assess the ligament length variation throughout the range of motion, a progress bar under the two graphs shows the progression of flexion. The design of the system enables an intraoperative evaluation with the patella in place.



29.

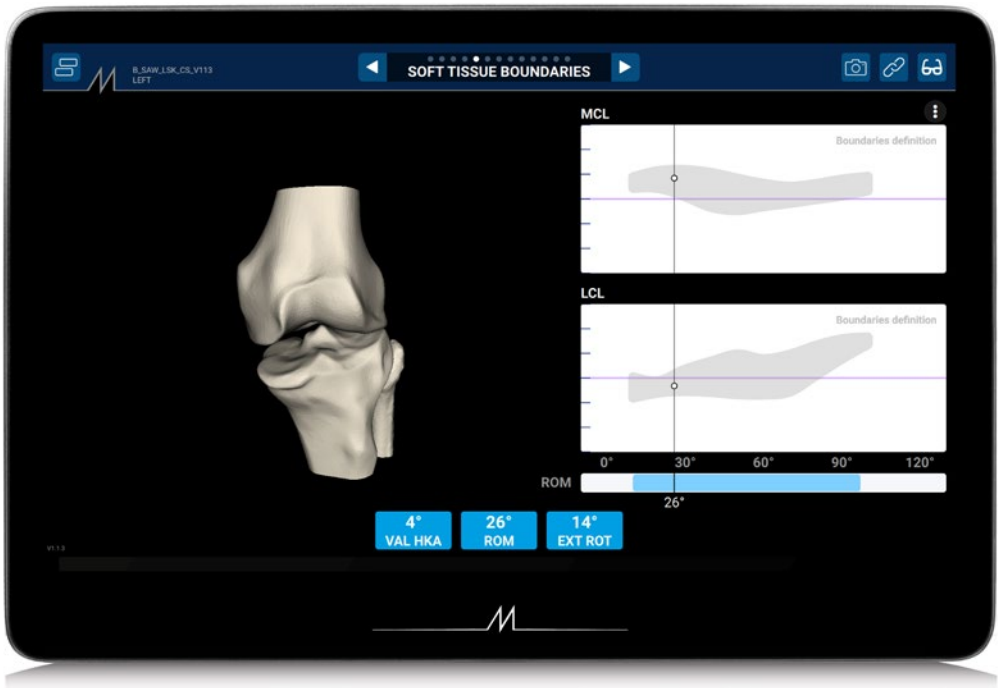
OPTION
Click of "Start Analysis" to see the Soft Tissue Behaviour.



30.

5.3 BOUNDARIES DEFINITION

At this stage it is possible define the limits of maximum elongation and shortening of the collateral ligaments throughout the entire range of motion.



31.

Starting from full extension, apply a varus or valgus stress to the leg and, continuing to stress, flex the knee until the maximum angle of flexion. Then repeat the procedure forcing the knee in the opposite way.

The software displays MCL and LCL graphs in the right-hand side of screen, which displays a plot of two grey boundary areas.

6. INTRAOPERATIVE PLANNING

At this point, after having collected data about the soft tissue, it is possible to adjust the pre-operative plan. Pre-operative data and post-operative values are showed in the column on the left side of the screen. The surgeon can modify these values selecting the editable box and clicking on plus or minus symbols. Values can be also updated by touching the green box beside the 3D model on the right hand side, and using plus and minus buttons. Click on the burger menu beside the label FEMUR or TIBIA (see image below) to view the desired 3D model and open the list of parameters which can be modified.

Different views are available both for femur and tibia:

- **BONE:** this selection allows to visualize the projected cuts on the bone
- **CUT:** this view shows the bone cut according to the plan
- **IMPLANT:** this section provides a visualization of the position of the implant in accordance with plan
- **CT SCAN:** the surgeon can evaluate the position of the implant directly on the CT-Scan

32.

The software adjusts the 3D model in real time after any changes in the plan have been made by the surgeon.

33.

OPTION

The highlighted box shows the distance of the origins and insertions of the collateral ligaments or gaps in accordance with the planning. The software adjusts the graphs of the gaps and ligaments in real time as any changes in the plan are made by the surgeon. To enlarge the graph click the expand button . Click on “LIGAMENTS” or “GAPS” to switch the views.

34.


PLANNING
Medial
Lateral
-10 mm
-8 mm
-6 mm
-4 mm
-2 mm
0 mm
2 mm
4 mm
6 mm
8 mm
0°
90°
TIGHT
LOOSE
0°
30°
60°
90°
120°
Play
LIGAMENTS
GAPS
IMPLANTS
Femur
3+
Tibia
3
Insert
10
FEMUR
Varus
1.0°
Shift d/p
0.0
Ext. Rot.
3.0°
Shift a/p
0.0
TIBIA
Varus
0.0°
Post Slope
1.0°
Reset to original Planning

35.

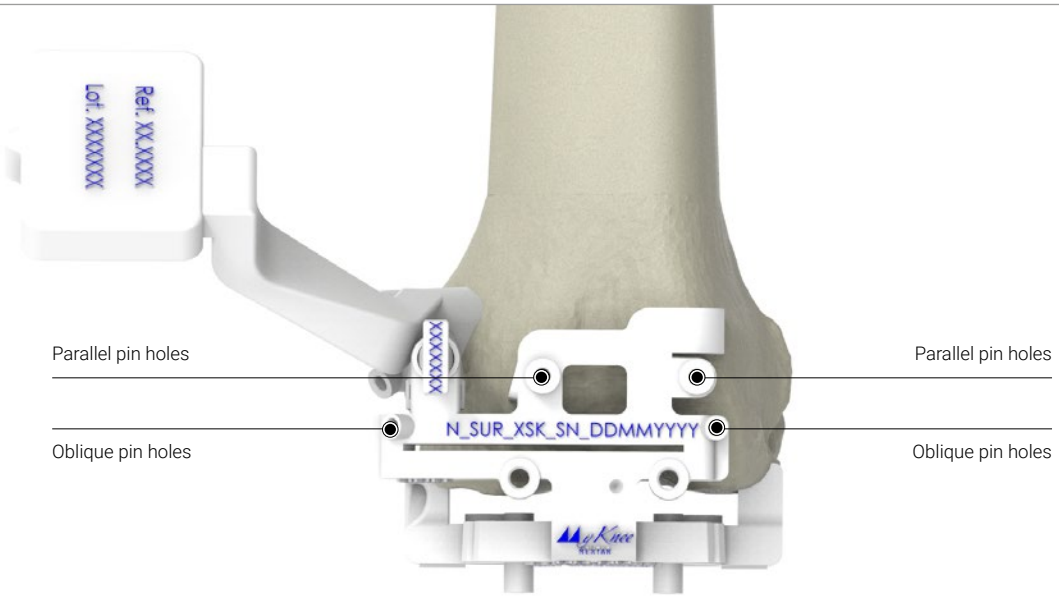

PLANNING
MCL
LCL
0°
90°
0°
90°
0°
30°
60°
90°
120°
Play
LIGAMENTS
GAPS
IMPLANTS
Femur
3+
Tibia
3
Insert
10
FEMUR
Varus
1.0°
Shift d/p
0.0
Ext. Rot.
3.0°
Shift a/p
0.0
TIBIA
Varus
0.0°
Post Slope
1.0°
Reset to original Planning

7. DISTAL RESECTION

The distal cut can be performed both using the MyKnee NextAR cutting block or the dedicated micrometric guide.

7.1 MYKNEE FEMORAL RESECTION

If the preoperative planning has not been modified, the distal cut can be performed by means of the femoral MyKnee NextAR block. Slide the cutting block onto the parallel pins, left in place during the femur check in the previous step. Fix the block on the femur using at least one of the oblique pin holes as shown in the picture below.



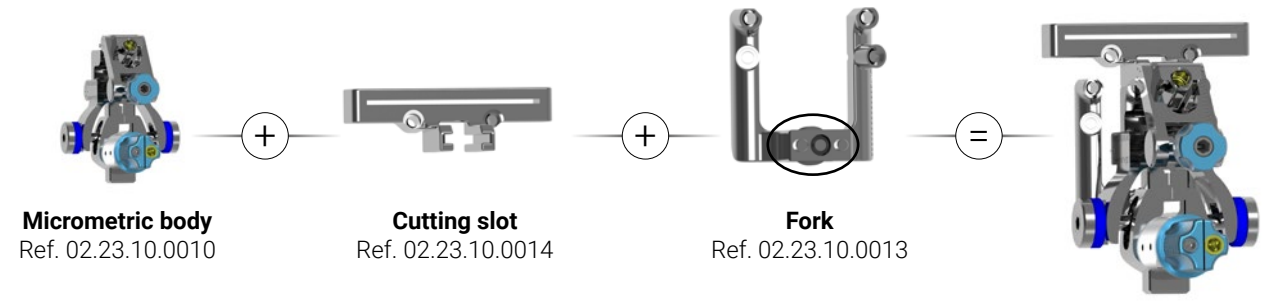
36.

7.2 MICROMETRIC FEMORAL RESECTION

7.2.1 PSI-based approach: option 1

This option is only compatible with MyKnee NextAR cutting guides. In case the preoperative planning has been modified or any correction cut is needed, the micrometric cutting block can be used to perform the distal cut.

Assemble the micrometric cutting guide with the following parts:



Micrometric body
Ref. 02.23.10.0010

Cutting slot
Ref. 02.23.10.0014

Fork
Ref. 02.23.10.0013

37.

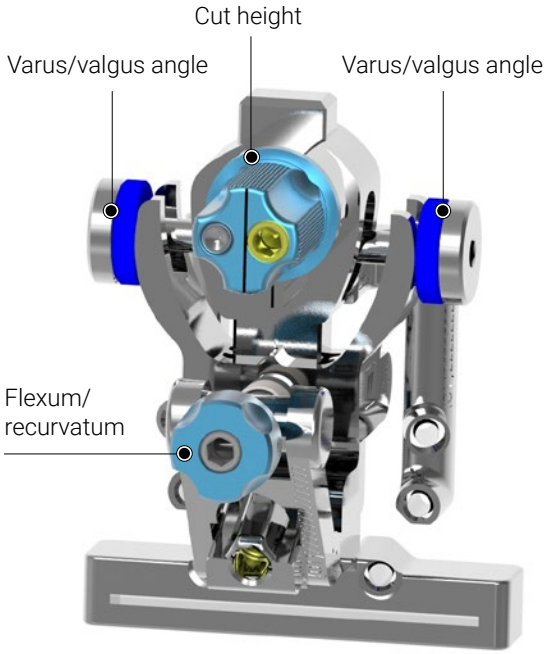
Connect the fork with the micrometric body by means of the connection highlighted in the red circle, then tighten the screw to lock the assembly.
Next, slide the micrometric cutting block on the parallel pins (see chapter §6.4 to see compatibility holes among the instrumentation), then assemble the cut checker with the handle, and clip the square sensor into the seat.

38.

CAUTION
Make sure that the marking FEM is facing upward once the instrument has been assembled.

Insert the cut checker inside the slot of the cutting guide, it works as reference to properly adjust, by means of the micrometric guide, the orientation and height of the cut according to the planning data shown on the screen.

Turn the knob with the screwdriver to regulate:



39.

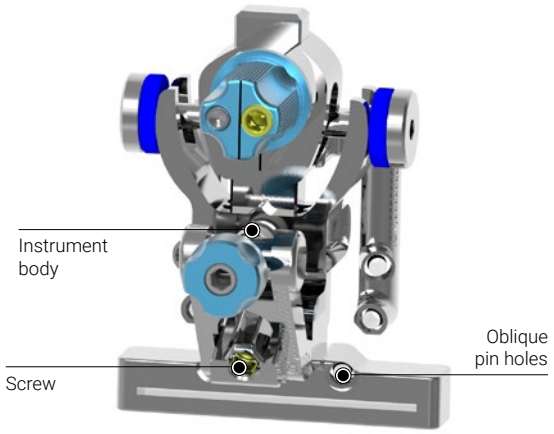
When the blue line overlaps with the green one, fix the guide using at least one of the oblique pin holes in order to guarantee a stable fixation as shown in the picture.

Extract the cut checker from the slot, visually double-check the cut height using the standard angel wing prior to cutting. Then perform the distal resection using a blade up to 1.27 mm thick.

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

OPTION

Once the cutting guide is properly fixed, the micrometric body can be removed by unlocking the screw with the screwdriver and by sliding it off. The oblique pin below the cutting guide must be inserted. See the image below:

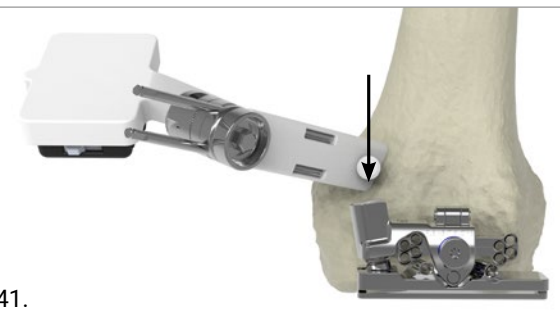


40.

7.2.2 PSI-based approach: option 2

This option is compatible with MyKnee NextAR cutting guides and MyKnee PPS NextAR.

Slide the micrometric cutting block on the parallel pins (see chapter §7.4 to see compatibility holes among the instrumentation).



41.

The marking “MED”, indicated by the black arrow, must be always positioned in the medial part of the bone.

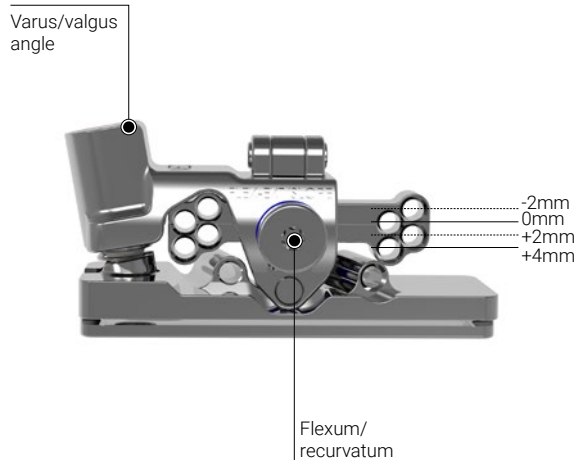
Then assemble the cut checker with the handle and clip the square sensor into the seat.

CAUTION

Make sure that the marking FEM is facing upward once the instrument has been assembled.

Insert the cut checker inside the slot of the cutting guide, it works as a reference to properly adjust, by means of the micrometric guide, the orientation and height of the cut according to the planning data shown on the screen.

Turn the knob with the screwdriver to regulate:



42.

When the blue line overlaps with the green one, fix the guide using at least one of the oblique pin holes in order to guarantee a stable fixation as shown in the picture.

Extract the cut checker from the slot, visually double-check the cut height using the standard angel wing prior to cutting. Then perform the distal resection using a blade up to 1.27 mm thick.

CAUTION

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

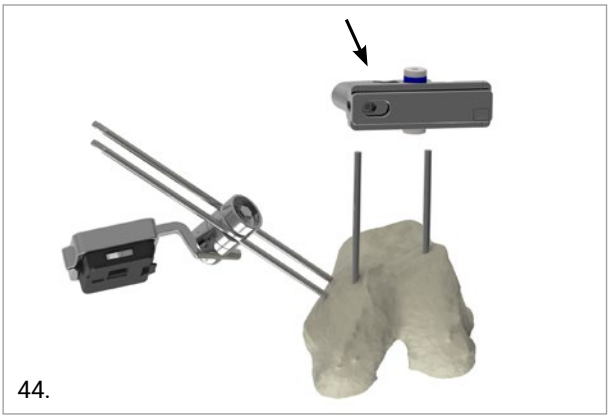
7.2.3 PSI-free approach: option 1

Use the specific instruments to make holes for the micrometric pins. Assemble the sleeve with the handle and clip the rectangular sensor into the seat, it works as a reference to properly adjust the orientation and height of the cut according to the planning data shown on the screen.

43.

When the blue line overlaps with the green one, fix the two parallel pins onto the bone

Slide the micrometric cutting block on the parallel pins (see chapter §7.4 to see compatibility holes among the instrumentation).



44.

The marking "MED", indicated by the black arrow, must be always positioned in the medial part of the bone.

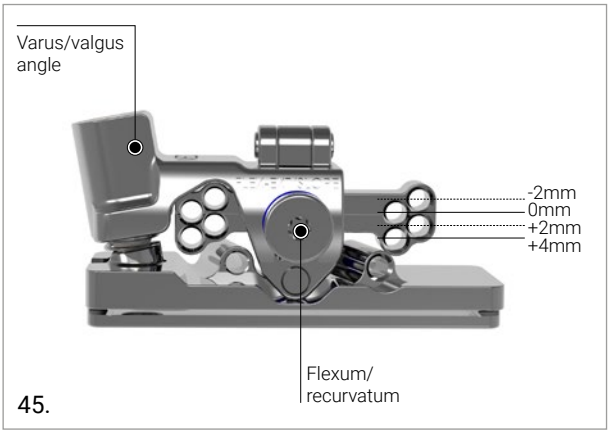
To fine tune the resection level, assemble the cut checker with the handle and clip the square sensor into the seat.

CAUTION

Make sure that the marking FEM is facing upward once the instrument has been assembled.

Insert the cut checker inside the slot of the cutting guide, it works as a reference to properly adjust, by means of the micrometric guide, the orientation and height of the cut according to the planning data shown on the screen.

Turn the knob with the screwdriver to regulate:



45.

When the blue line overlaps with the green one, fix the guide using at least one of the oblique pin holes in order to guarantee a stable fixation as shown in the picture.

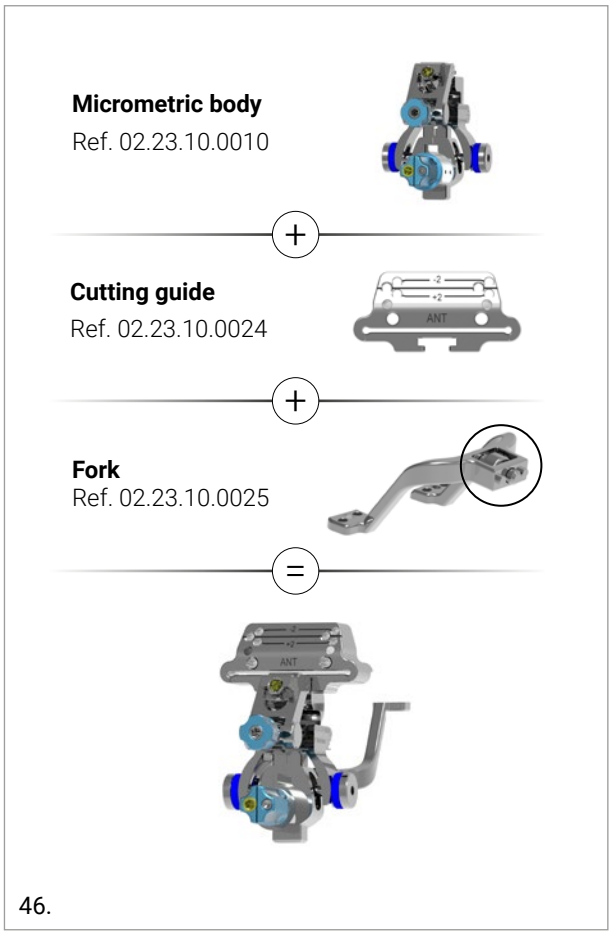
Extract the cut checker from the slot, visually double-check the cut height using the standard angel wing prior to cutting. Then perform the distal resection using a blade up to 1.27 mm thick.

CAUTION

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

7.2.4 PSI-free approach: option 2

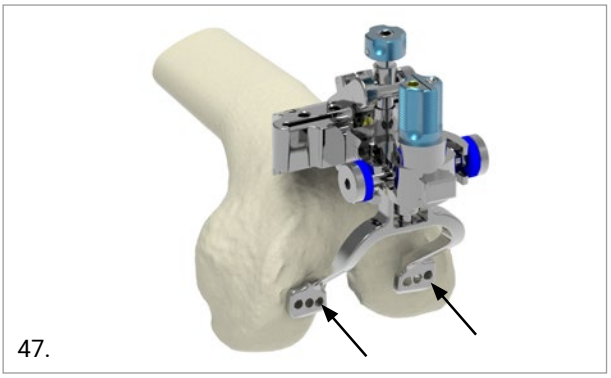
In this scenario, assemble the micrometric cutting guide with the following parts (see images below):



46.

Connect the fork with the micrometric body by means of the connection highlighted in the red circle, then tighten the screw to lock the assembly.

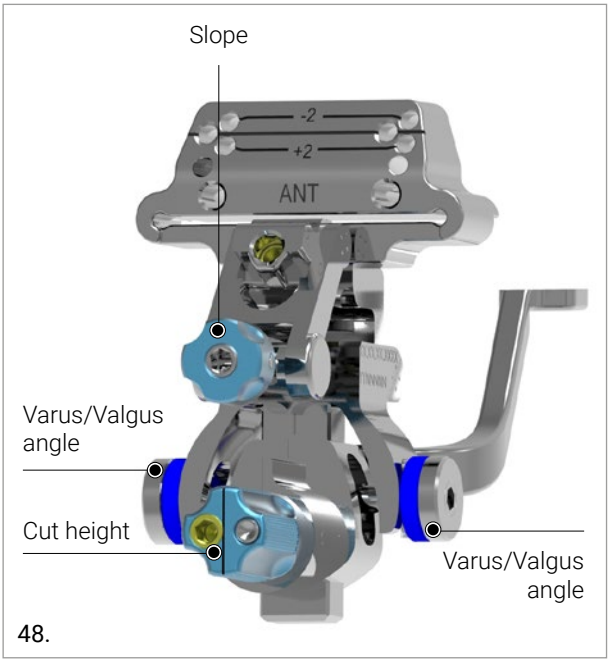
Next, place the crotch in contact with the distal condyles as shown in the picture below, using two pins (black arrows in the picture) to fix the construct to the bone


47.

Then assemble the cut checker with the handle and clip the rectangular sensor into the seat.

CAUTION
Make sure that the marking FEM is facing upward once the instrument is assembled.

Insert the cut checker inside the slot of the cutting guide, it works as reference to properly adjust, by means of the micrometric guide, the orientation and height of the cut according to the planning data shown on the screen.

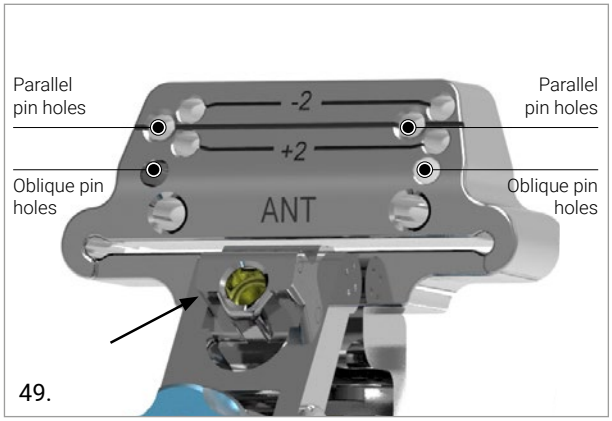


48.

When the blue line overlaps with the green one, fix the cutting block with two parallel pins and at least one oblique pin, as shown in the pictures below.

Once the distal cutting block has been properly fixed to the femur, extract the cut checker from the slot and visually double-check the cut height using the standard angel wing before cutting.

Remove the pins from the distal condyle, unlock the screw (black arrow in the picture below) and slide out the micrometric body in order to leave only the cutting guide fixed to the bone.



49.

Then carry out the distal resection, using a blade of up to 1.27 mm thickness.

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

7.3 DISTAL CUT CHECKING

After the cut has been performed, it must be checked by means of the specific instrument. Assemble the cut verifier with the handle and clip the square sensor into the seat.


50.

CAUTION
Make sure that the marking FEM is facing upward once the instrument is assembled.

Remove the MyKnee NextAR cutting block, by unlocking the key, or the micrometric cutting guide, and then place the cut checker surface onto the resected bone as shown in the image below and hold the instrument in position. NextAR will automatically register the level of resection when it matches the planned value. Varus/valgus angle, medial and lateral cut height are shown on the 3D bone model; real-time values are shown in light-blue, while the planned values are displayed in green.

51.

OPTION

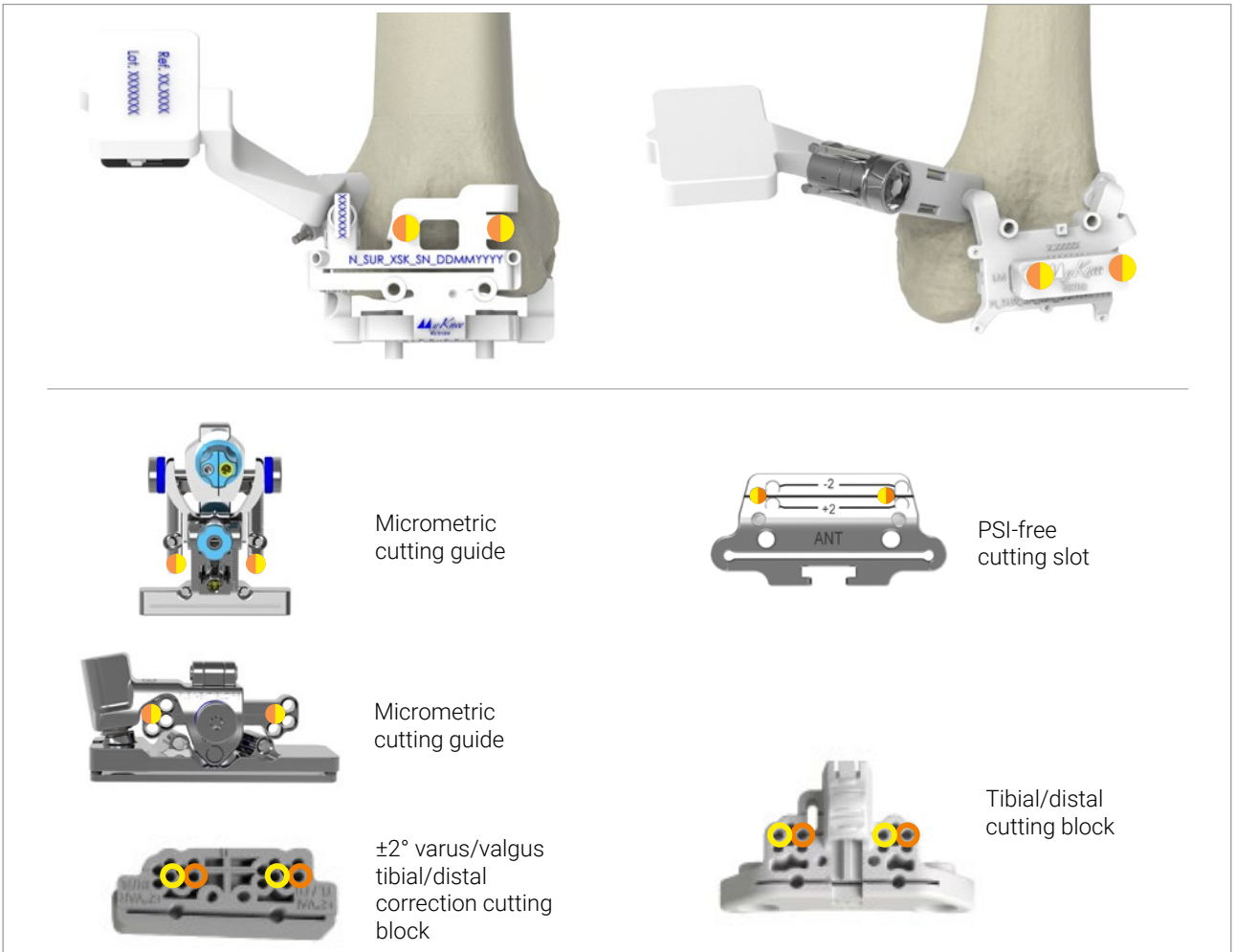
Micrometric correction

In the case that a recut is required, a micrometric cutting guide (see the chapter §7.2) or the standard GMK Efficiency may be used (see the chapter §7.4)

7.4 COMPATIBILITY WITH STANDARD INSTRUMENTATION

The picture below shows the correspondence between the MyKnee NextAR femoral cutting block pins holes and the Efficiency femoral and micrometric cutting block pins row.

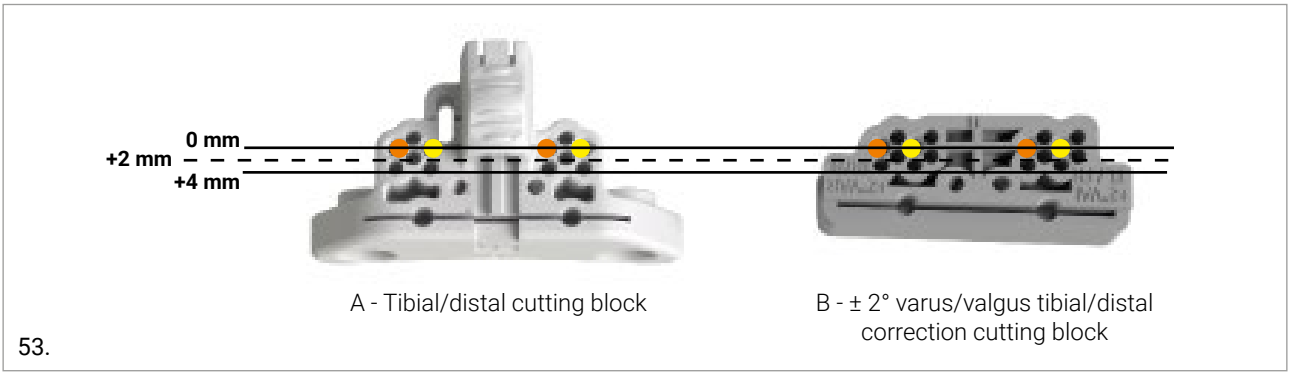
If needed, position the corresponding Efficiency femoral cutting block onto the parallel pins using the two most lateral parallel pin holes or the two most medial ones.



52.

NOTE: Cutting guides A-B-C shown in the picture above are the same used in performing the tibia cut turned by 180° as shown. Please see chapter §8.4

The femoral resection level can be modified by moving the tibial/distal cutting block to a different row of pin holes.



53.

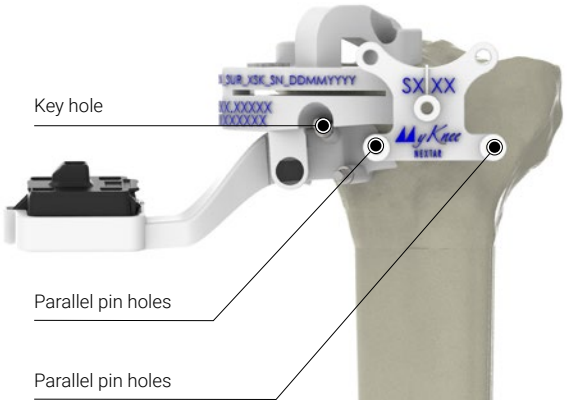
8. TIBIA RESECTION

The proximal cut can be performed both using the MyKnee NextAR cutting block or the micrometric guide.

8.1 MYKNEE TIBIA RESECTION

If the preoperative planning has not been modified, the proximal cut can be performed by means of the tibia MyKnee NextAR block.

Slide the cutting block onto the parallel pins and secure the block to the sensor holder locking the key as shown in the picture below



54.

Once the tibial cutting block has been properly fixed to the tibia, visually double check the cut height using the standard angel wing before cutting. Then carry out the tibial resection using a blade up to 1.27 mm thick.

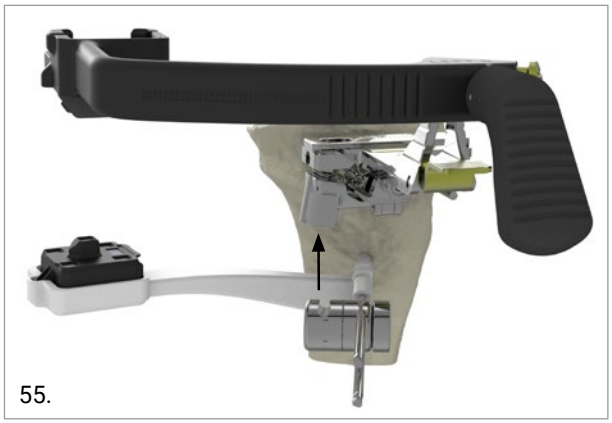
CAUTION
Engage the saw blade into the cutting slot before activating the saw. Use a physiological solution to cool the cutting block during resection. After resection, rinse the joint before positioning both the trial and final implant.

8.2 MICROMETRIC PROXIMAL RESECTION

8.2.1 PSI-based approach: option 1

This option is compatible with MyKnee NextAR cutting guide and MyKnee PPS NextAR

Slide the micrometric cutting block on the parallel pins (see chapter §8.4 to see compatibility holes among the instrumentation).



55.

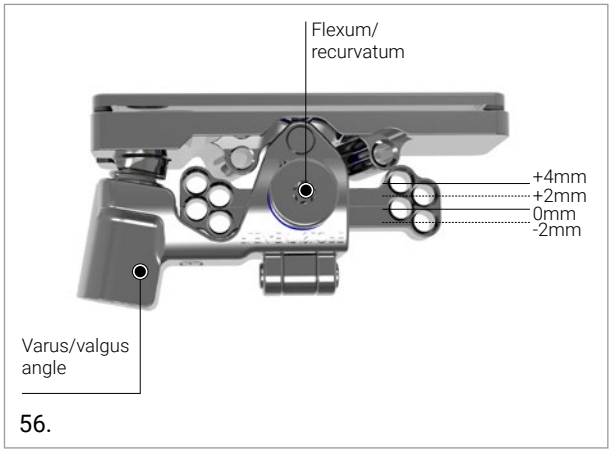
The marking “MED”, indicated by the black arrow, must be always positioned in the medial part of the bone.

Then assemble the cut checker with the handle and clip the square sensor into the seat.

CAUTION
Make sure that the marking FEM is facing upward once the instrument has been assembled.

Insert the cut checker inside the slot of the cutting guide, it works as a reference to properly adjust, by means of the micrometric guide, the orientation and height of the cut according to the planning data shown on the screen.

Turn the knob with the screwdriver to regulate:



56.

When the blue line overlaps with the green one, fix the guide using at least one of the oblique pin holes in order to guarantee a stable fixation as shown in the picture.

Real-time values Planned values

57.

Extract the cut checker from the slot, visually double-check the cut height using the standard angel wing prior to cutting. Then perform the distal resection using a blade up to 1.27 mm thick.

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

8.2.2 PSI-based approach: option 2

This option is only compatible with MyKnee NextAR cutting guides. If the preoperative planning has been modified or any correction cut is needed, the micrometric cutting block can be used to perform the proximal cut.

Assemble the micrometric cutting guide with the following parts:

Micrometric body
Ref. 02.23.10.0010

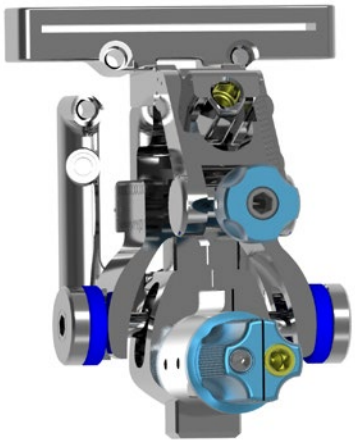
+

Cutting slot
Ref. 02.23.10.0014

+

Fork
Ref. 02.23.10.0013

=



58.

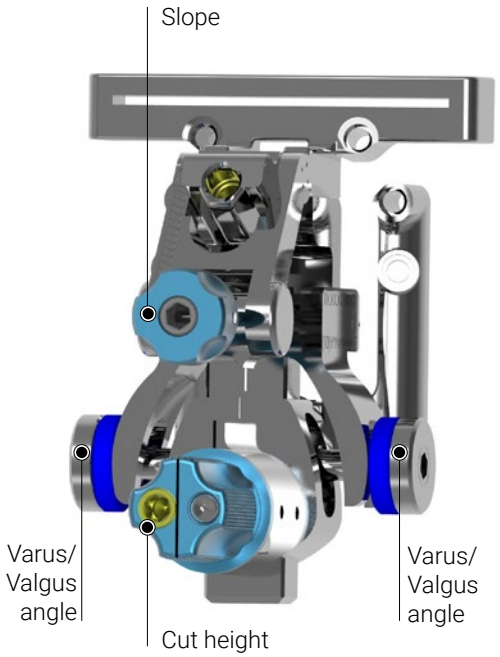
Next, slide the micrometric cutting block onto the parallel pins (see chapter §8.5 for compatibility holes in the instrumentation), then assemble the cut checker with the handle and clip the rectangular sensor into the seat.

59.

CAUTION
Make sure that the marking TIB is facing upward once the instrument is assembled.

Insert the cut checker inside the slot of the cutting guide, it works as reference to properly adjust, by means of the micrometric guide, the orientation and height of the cut according to the planning data shown on the screen.

Turn the knob with the screwdriver to regulate:



60.

Then fix the cutting block with at least one oblique pin when the blue line overlaps with the green one.

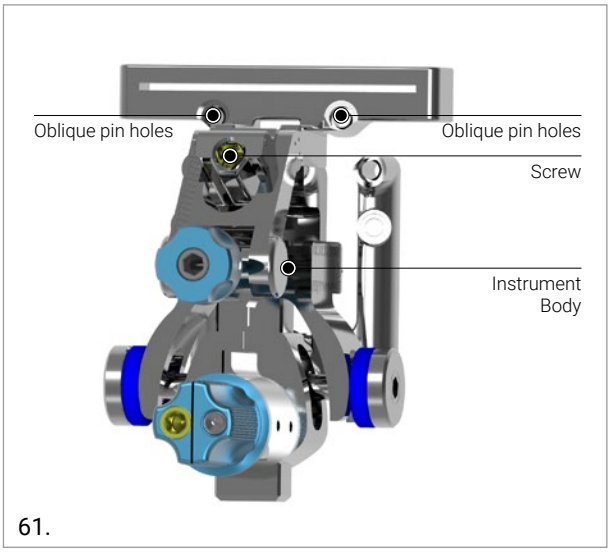
Once the tibial cutting block has been properly fixed to the tibia, extract the cut checker from the slot and visually double-check the cut height using the standard angel wing before cutting. Then carry out the tibial resection using a blade up to 1.27 mm thick.

CAUTION

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

OPTION

Once the cutting guide is properly fixed, the micrometric body can be removed unlocking the screw with the screwdriver and sliding it off. The oblique pin below the cutting guide must be inserted. See the image below



61.

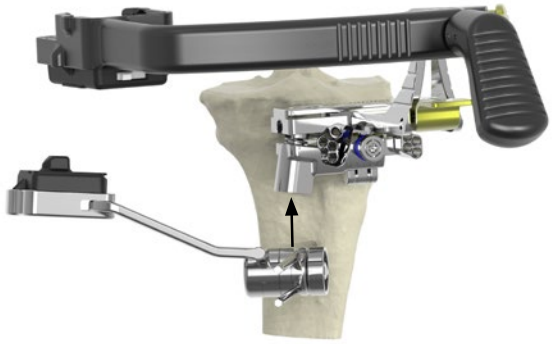
8.2.3 PSI-free approach: OPTION 1

Use the specific instruments to make holes for the micrometric pins. Assemble the sleeve with the handle and clip the rectangular sensor into the seat, it works as a reference to properly adjust the orientation and height of the cut according to the planning data shown on the screen.

Real-time values Planned values

62.

When the blue line overlaps with the green one, fix the two parallel pins onto the bone. Slide the micrometric cutting block on the parallel pins (see chapter §7.4 to see compatibility holes among the instrumentation).



63.

The marking “MED”, indicated by the black arrow, must be always positioned in the medial part of the bone.

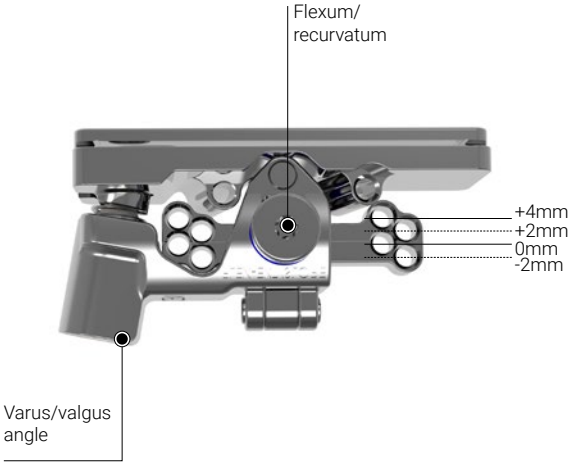
Then assemble the cut checker with the handle and clip the square sensor into the seat.

CAUTION

Make sure that the marking FEM is facing upward once the instrument has been assembled.

Insert the cut checker inside the slot of the cutting guide, it works as a reference to properly adjust, by means of the micrometric guide, the orientation and height of the cut according to the planning data shown on the screen.

Turn the knob with the screwdriver to regulate:



64.

When the blue line overlaps with the green one, fix the guide using at least one of the oblique pin holes in order to guarantee a stable fixation as shown in the picture.

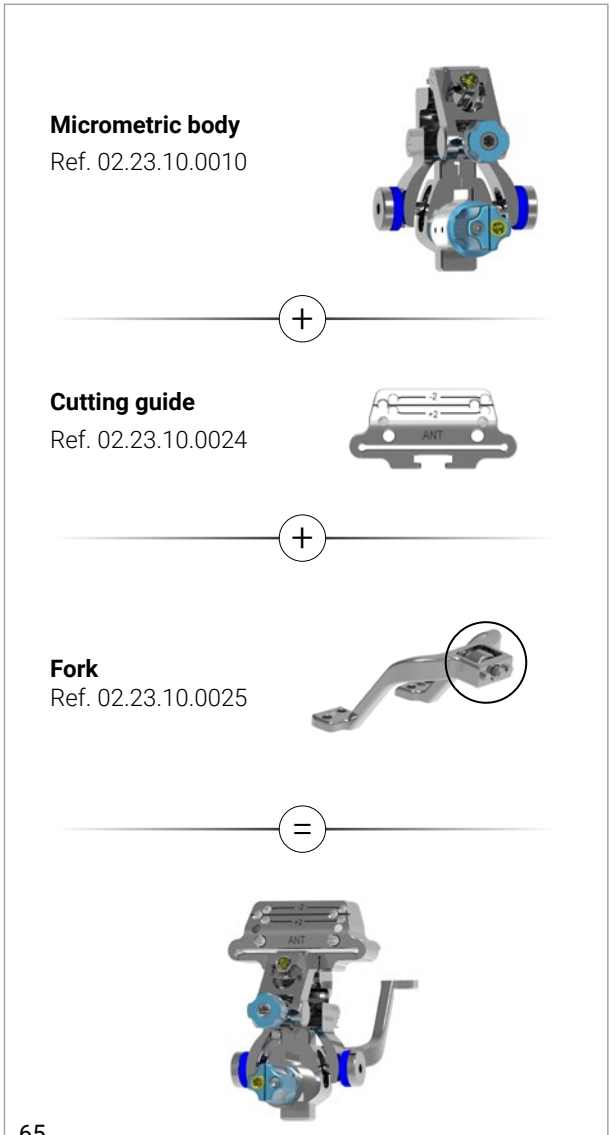
Extract the cut checker from the slot, visually double-check the cut height using the standard angel wing prior to cutting. Then perform the distal resection using a blade up to 1.27 mm thick.

CAUTION

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

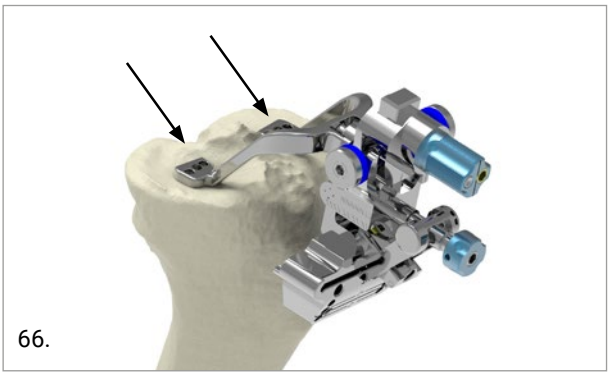
8.2.4 PSI-free approach: OPTION 2

In this scenario, assemble the micrometric cutting guide with the following parts (see images below):



65.

Next, place the crotch in contact with the tibial plateau as shown in the picture below, and use two pins to fix the construct to the bone.

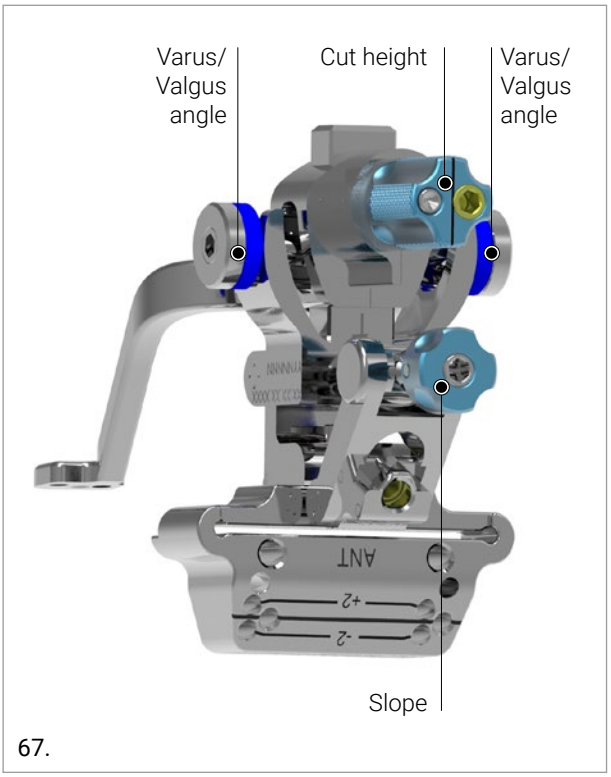


66.

Then assemble the cut checker with the handle and clip the rectangular sensor into the seat.

CAUTION
Make sure that the marking TIB is facing upward once the instrument is assembled.

Insert the cut checker inside the slot of the cutting guide, it works as reference to properly adjust, by means of the micrometric guide, the orientation and height of the cut according to the planning data shown on the screen.
Turn the knob with the screwdriver to regulate.

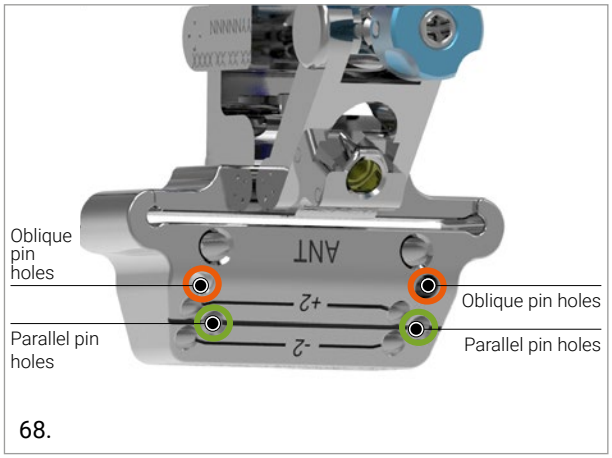


67.

Then fix the cutting block with two parallel pins and at least one oblique pin when the blue line overlaps with the green one, as shown in the pictures below.

Once the tibial cutting block has been properly fixed to the tibia, extract the cut checker from the slot and visually double-check the cut height using the standard angel wing before cutting.

Remove the pins from the plateau, unlock the screw (black arrow in the picture) and slide out the micrometric body in order to leave only the cutting guide fixed to the bone.



68.

Then carry out the tibial resection using a blade of up to 1.27 mm thickness.

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

8.3 PROXIMAL CUT CHECKING

After the cut has been performed, it must be checked by means of the specific instrument. Assemble the cut verifier with the handle and clip the rectangular sensor into the seat.

69.

CAUTION

Make sure that the marking TIB is facing upward once the instrument is assembled.

Remove the MyKnee NextAR cutting block, by unlocking the key, or the micrometric cutting guide, then place the cut checker surface onto the resected bone as shown in the image below. Hold the instrument in position. The NextAR will automatically register the level of resection when it matches the planned value. Varus/valgus angle, medial and lateral cut height are shown on the 3D bone model; real-time values are shown in light-blue, while the planned values are displayed in green.

70.

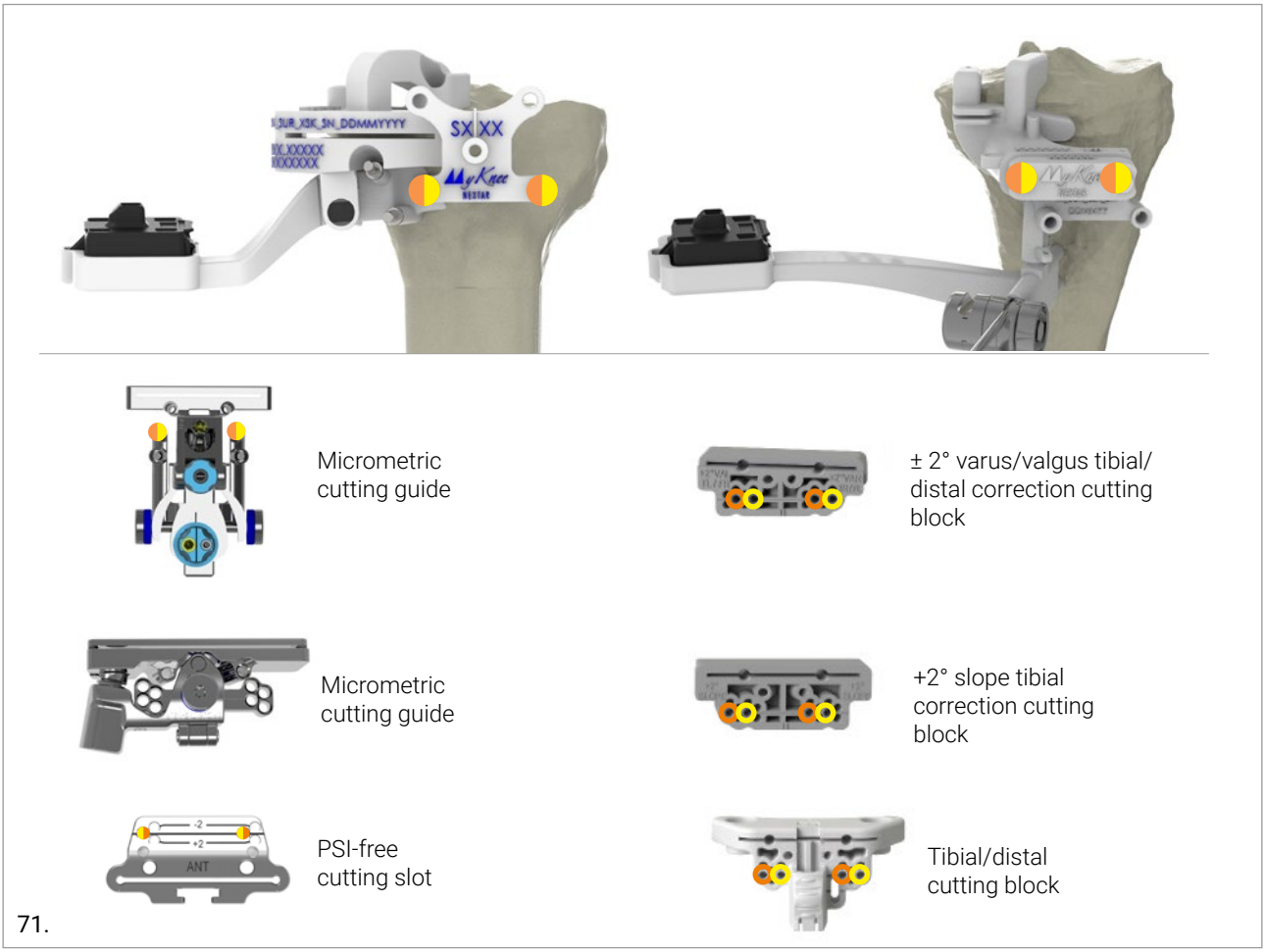
OPTION

Micrometric correction

In the case that a recut is required, a micrometric cutting guide (see the chapter §8.2) or the standard GMK Efficiency may be used (see the chapter $8.4)

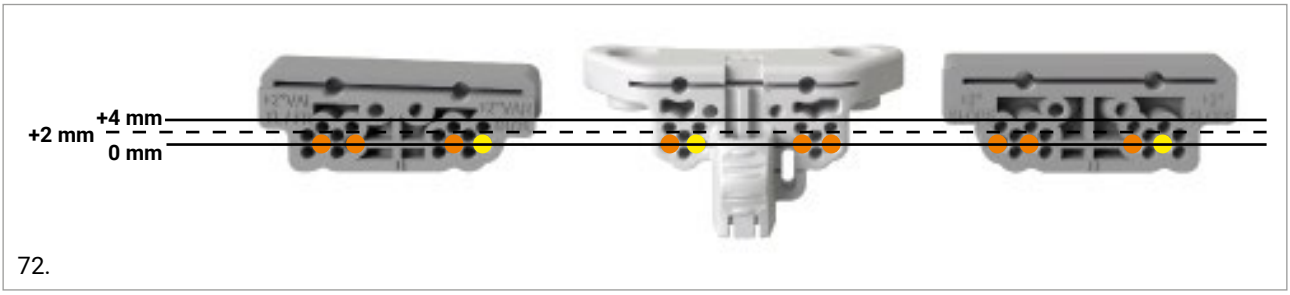
8.4 COMPATIBILITY WITH STANDARD INSTRUMENTATION

The picture below shows the correspondence between the MyKnee NextAR tibial cutting block pins holes and the Efficiency tibial and micrometric cutting blocks pins row. If needed, position the corresponding Efficiency tibial cutting block onto the parallel pins using the two most lateral parallel pin holes or the two most medial ones.



71.

NOTE. Cutting guides A-B-C-E shown in the picture above are the same used in performing the tibia cut turned by 180° as shown. Please see chapter §7.4



72.

The tibial resection level can be modified by moving the tibial/distal cutting block onto a different row of pin holes.

- A. ± 2° varus/valgus tibial/distal correction cutting block
- B. Tibial/distal cutting block
- C. +2° slope tibial correction cutting block

8.5 TIBIA ROTATION

During this step it is possible to evaluate the tibial tray position to achieve the optimal bone coverage and implant rotation.

Assemble the specific instrument with the trial baseplate, insert the trial handle into the arm holder and clip the rectangular camera into the seat.

- Ref 02.23.10.0038 is compatible only with the GMK Efficiency trial baseplates

73

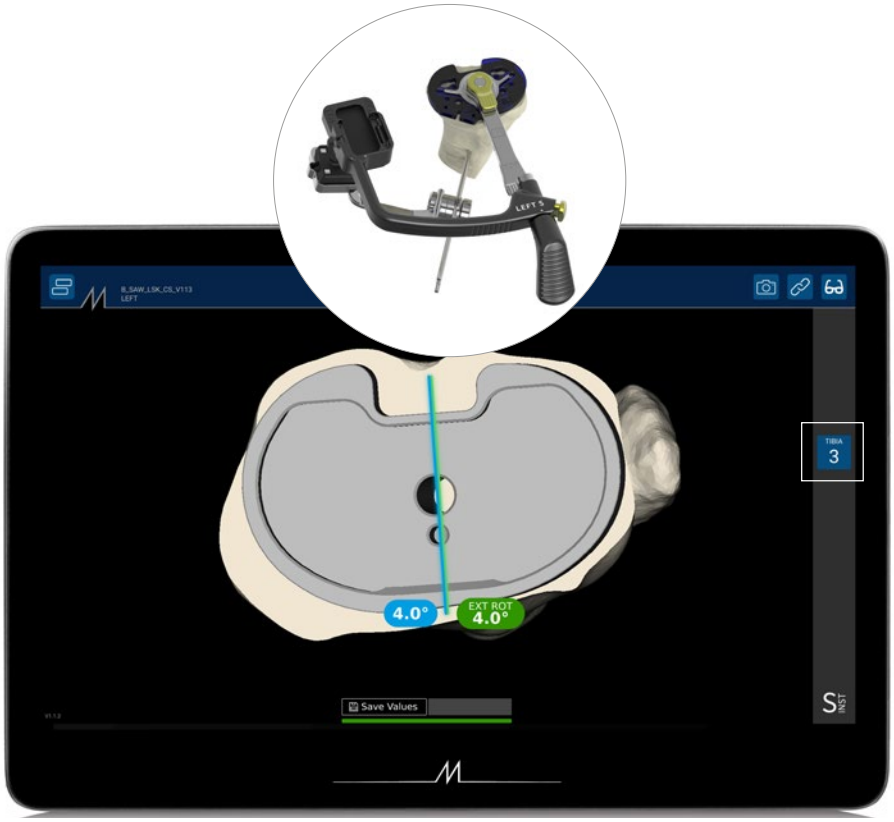
- Ref 02.23.10.0045 is compatible only with the metal trial baseplate

74.

Place the trial tibial baseplate onto the resected bone surface. Use the NextAR guides to position the baseplate in order to match the planned rotation and the optimal bone coverage.

CAUTION

Make sure that the trial baseplate size being used matches the planned implant size (see the white square in the image below) in order to avoid incorrect implant alignment.



75.

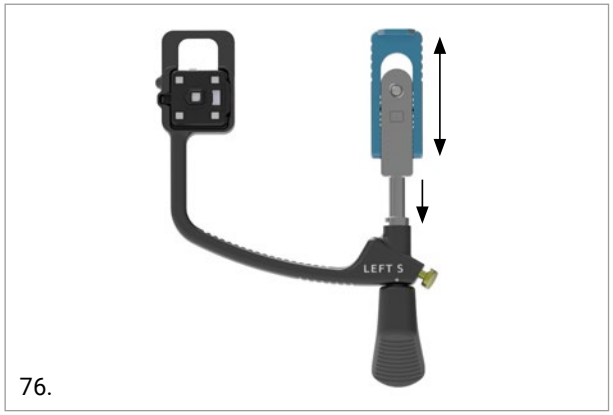
The blue line overlapping the green one corresponds to the planned position, and marks the position of the trial baseplate on the bone in correspondence of the reference line.

9. ANTERIOR CUT, POSTERIOR CUT AND CHAMFERS

Two different options are available to perform the 4-in-1 resections:

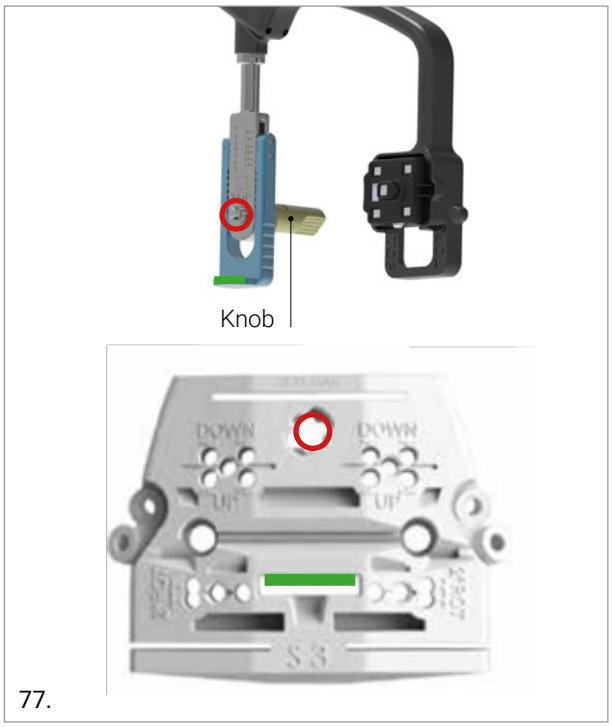
- Ref 02.23.10.0037, compatible only with 4-in-1 Efficiency
- Ref 02.23.10.0044, compatible only with 4-in-1 Efficiency and Metal

02.23.10.0037
Connect the 4-in-1 holder to the holder arm (black arrow in the image below), select the planned size of the cutting block by sliding the moving part up or down on the instrument (black arrow in the image below) and clip the square sensor into the seat.



76.

Then assemble the 4-in-1 cutting block with the NextAR 4-in-1 holder, inserting it in the dedicated holes, then fix the assembly by pressing and turning the central knob clockwise.



77.

02.23.10.0044
Assemble the 4-in-1 cutting block with the NextARTM 4-in-1 holder by inserting it in the anterior cut slot as shown in the figure below:


78.

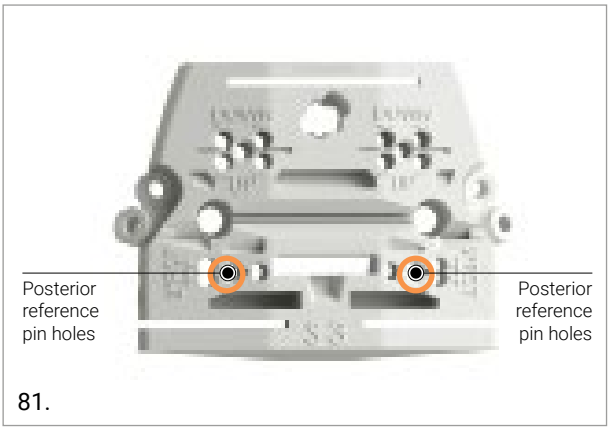
CAUTION
Be sure that the size of the 4-in-1 cutting block that is being used matches with the planned implant size (see red square in the image below) in order to avoid incorrect implant alignment.

WARNING
The appropriate instrument must be setted before starting the surgery. Please refer to §2 on how to select the correct instrumentation

79.

Put the assembly in contact with the bone and position the cutting guide by free-hand following the instruction on the screen. Once the blue line overlaps the green one, the 4-in-1 block is in position in accordance with the plan.

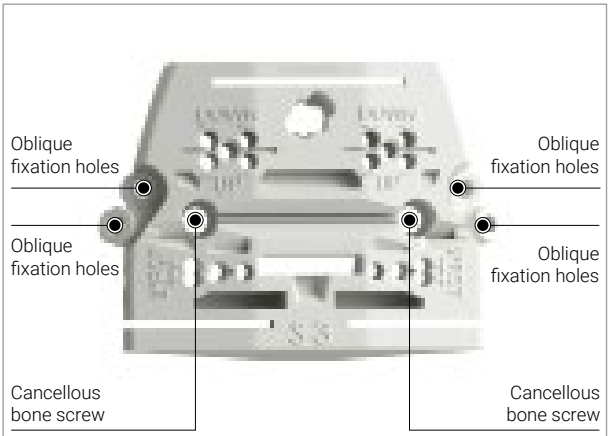
80.



81.

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

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



82.

9.1 4 IN 1 FEMORAL RESECTION

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

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

CAUTION

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

Remove the screws and/or the oblique pins.

The removal of the 4in1 cutting block can be performed using the end of the trial base handle.

83.

10. TIBIA FINISHING

Follow the same procedure as described in the dedicated GMK Efficiency Sphere conventional surgical technique

11. FEMUR FINISHING

Follow the same procedure as described in the dedicated GMK Efficiency Sphere conventional surgical technique

12. PATELLA

Follow the same procedure as described in the dedicated GMK Efficiency Sphere conventional surgical technique

13. TRIALS

Follow the same procedure as described in the dedicated GMK Efficiency Sphere conventional surgical technique

13.1 POST-OP LIGAMENTS EVALUAITON

Once the trials are properly positioned the post- op balancing can be performed.

The first step is the acquisition of the post-operative soft tissue boundaries, as performed in the preoperative phase. This means the definition of the maximum stretch and shortening of the collateral ligaments throughout the entire range of motion with trials in place.

Starting from full extension, apply a varus or valgus stress to the leg and, continuing to stress, flex the knee until the maximum angle of flexion. Then repeat the procedure forcing the knee in the opposite way.

In the following section, the NextAR displays both preoperative and postoperative boundaries overlapped. Thus, a collateral ligament and joint stability evaluation can be performed assessing the ligament length variation throughout the range of motion with the patella reduced.

The trial insert thickness can be changed in case the planned one does not guarantee the proper joint stability.

CAUTION

Be sure that the thickness of the insert selected on the screen matches the trial that is being used (see red square in the image below).

84.

14. FINAL IMPLANTS

Follow the same procedure as described in the dedicated GMK Efficiency Sphere conventional surgical technique

15. INSTRUMENTS OVERVIEW

Table 15.1 Metal instruments

REF. NO.	DESCRIPTION	QTY
02.23.10.0026	NextAR Micrometric guide small	1
02.23.10.0027	NextAR small camera holder right	1
02.23.10.0028	NextAR small target holder right	1
02.23.10.0029	NextAR small camera holder left	1
02.23.10.0030	NextAR small target holder left	1
02.23.10.0031	NextAR Straight stylus conical connection	1
02.23.10.0032	NextAR curved stylus conical connection	1
02.23.10.0033	NextAR small handle conical connection left	1
02.23.10.0034	NextAR small handle conical connection right	1
02.23.10.0035	NextAR large handle conical connection left	1
02.23.10.0036	NextAR large handle conical connection right	1
02.23.10.0037	NextAR GMK Eff 4in1 holder conical conn	1
02.23.10.0038	NextAR GMK Eff trial baseplate holder conical conn	1
02.23.10.0039	NextAR Slot checker conical connection	1
02.23.10.0040	NextAR Cut checker conical connection	1
02.23.10.0041	NextAR sleeve for micrometric cutting guide	1
02.23.10.0042	NextAR drilling guide for sensor holders	1
02.23.10.0043	Screwdriver Torx T15	1
02.23.10.0044	NextAR GMK 4in1 slot holder conical conn	1
02.23.10.0045	NextAR GMK Metal trial basepl holder conical conn	1
04.01.10.0582	Slim EasyClip	2
33.25.0012	Double 6mm hexagonal hole key	1
02.07.10.4040	Triangle headed screwdriver	1
02.18.10.0267	Pin Ø3.2 L=55mm HA3.5 Meche Head Triangle	5
02.07.10.2294	Pin Ø3.2 L=40 ISO5835-Meche-Head-Triangle	7
02.07.10.2299	Pin Ø3.2 L=100 ISO5835-L=25-Meche-Triangle	4
02.07.10.2303	Pin Ø3.2 L=150 ISO5835-L=25-Meche-Triangle	4
02.08.10.0120	UKM Pin Ø 3.2 L=55	2
02.02.10.0130	Drill Ø3.2mm L130	1
02.02.10.0145/A	Pins ç 3.2, L 70 mm	4
02.02.10.0145/B	Pins ç 3.2, L 90 mm	2
02.07.10.2194	Sword Pin Ø3.2 L=22mm	2
02.07.10.4741	Threaded Pin Ø3.2 L85 longer connection	4
02.07.10.4650	Screw HA5 – Length 35 - reduced head	3
02.12.10.1366	Spoon Like Spacer Short- 1mm	1
02.12.10.1367	Spoon Like Spacer Short- 2mm	1
02.12.10.1368	Spoon Like Spacer Short- 3mm	1
02.12.10.1369	Spoon Like Spacer Short- 4mm	1
02.23.10.8202	NextAR 2.0 instruments tray	1

Table 15.2 MyKnee NextAR

MYKNEE NEXTAR TIBIAL CUTTING GUIDE

Size	SIDE	Imaging	Non sterile reference	Sterile reference
1	Left	CT	15.1231	15.1231S
2	Left	CT	15.1232	15.1232S
3	Left	CT	15.1233	15.1233S
4	Left	CT	15.1234	15.1234S
5	Left	CT	15.1235	15.1235S
6	Left	CT	15.1236	15.1236S
1	Right	CT	15.1241	15.1241S
2	Right	CT	15.1242	15.1242S
3	Right	CT	15.1243	15.1243S
4	Right	CT	15.1244	15.1244S
5	Right	CT	15.1245	15.1245S
6	Right	CT	15.1246	15.1246S

MYKNEE NEXTAR FEMORAL CUTTING GUIDE

Size	SIDE	Imaging	Non sterile reference	Sterile reference
1	Left	CT	16.1011	16.1011S
2	Left	CT	16.1012	16.1012S
3	Left	CT	16.1013	16.1013S
4	Left	CT	16.1014	16.1014S
5	Left	CT	16.1015	16.1015S
6	Left	CT	16.1016	16.1016S
7	Left	CT	16.1017	16.1017S
1	Right	CT	16.1021	16.1021S
2	Right	CT	16.1022	16.1022S
3	Right	CT	16.1023	16.1023S
4	Right	CT	16.1024	16.1024S
5	Right	CT	16.1025	16.1025S
6	Right	CT	16.1026	16.1026S
7	Right	CT	16.1027	16.1027S

MYKNEE NEXTAR FEMORAL CUTTING GUIDE SIZE+

Size	SIDE	Imaging	Non sterile reference	Sterile reference
1+	Left	CT	16.1011M	16.1011SM
2+	Left	CT	16.1012M	16.1012SM
3+	Left	CT	16.1013M	16.1013SM
4+	Left	CT	16.1014M	16.1014SM
5+	Left	CT	16.1015M	16.1015SM
6+	Left	CT	16.1016M	16.1016SM
1+	Right	CT	16.1021M	16.1021SM
2+	Right	CT	16.1022M	16.1022SM
3+	Right	CT	16.1023M	16.1023SM
4+	Right	CT	16.1024M	16.1024SM
5+	Right	CT	16.1025M	16.1025SM
6+	Right	CT	16.1026M	16.1026SM

MYKNEE NEXTAR PPS BLOCK

Side	Imaging	Non sterile reference	Sterile reference
Left	CT	15.8010	15.8010S
Left	CT	16.8010	16.8010S
Right	CT	15.8020	15.8020S
Right	CT	16.8020	16.8020S

Table 15.3 Efficiency

SPHERE GENERAL SET

REFERENCE (carton box)	REFERENCE (no carton box)	DESCRIPTION
11.01001	11.11001	General Sphere Instrument set

SPHERE GENERAL SET

REFERENCE (carton box)	REFERENCE (no carton box)	DESCRIPTION
11.01011	11.10011	1
11.01012	11.10012	2
11.01013	11.10013	3
11.01014	11.10014	4
11.01015	11.10015	5
11.01016	11.10016	6
11.01017	11.10017	7
11.01111	11.10111	1+
11.01112	11.10112	2+
11.01113	11.10113	3+
11.01114	11.10114	4+
11.01115	11.10115	5+
11.01116	11.10116	6+

GMK SPHERE TIBIAL/INSERT SIDE LEFT SETS

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

GMK SPHERE TIBIAL/INSERT SIDE RIGHT SETS

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

OPTIONAL SETS

REF. LEFT	THICKNESS (mm)	REF. RIGHT
11.00005	11.10005	Resurfacing patella instrument set
11.00102	11.10102	Extension instrument set
11.00103	N/A	MIS Correction guide instrument set
11.00006	11.10006	Sword pins pack
11.00007	11.10007	Short threaded pins pack
11.00008	11.10008	Smooth pins pack
11.00009	11.10009	Threaded pins pack
11.0001	11.1001	Screw pack
11.00027	11.10027	Drills and Reamers Sphere Instr Set

Table 15.4 Sensors

REF. NO.	DESCRIPTION	PICTURE
02.23.10.0011	NextAR infrared camera	
02.23.10.0012	NextAR active infrared tracker small	
09.23.10.NXDESK	NextAR PC desk	

Table 15.5 Platform

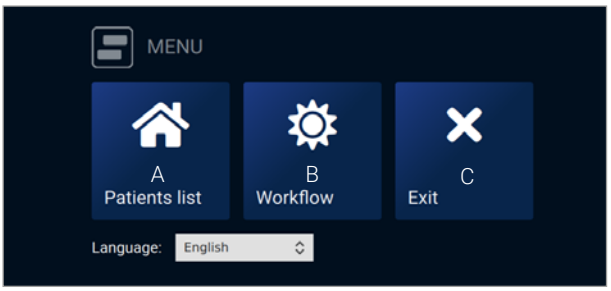
REF. NO.	DESCRIPTION	PICTURE
09.23.10.ARGLASSES	NextAR AR glasses	
75.76.102	Trolley	
75.76.103	Table Support	
75.76.104	Flightcase Trolley	
09.23.10.C-	NextAR power cable	
09.23.10.C-GROUND	Ground table	

16. APPENDIX A: USER MANUAL

In this section, a brief guide about the use of the software is given. Please read the Instructions for use for any technical information about the components of the platform. The initial screen is the following:

85.

1. Menu button: Click on it and then on settings, to open the following section:



Which provides the following options::
- Return to Patients list (A);
- Open workflow options (B), this section is accessible only by Medacta staff;
- Exit the software (C).

2. Search bar, provides a rapid search facility to find a case within the list.
3. Software version: v 1.1.3
4. Screenshot button: Takes a screenshot at any point in the surgery;
5. Tracking system icon: gives feedback about the connection of the tracking system. If it is white the sensors are connected, while if it is red they are disconnected. It is possible to access the information about the tracking system, such as a serial number and battery, by clicking on it.
6. AR Glasses icon: gives feedback about the glasses connection status. By tapping on, it is possible to manage the connection of the glasses.
7. Import button: allows an import new cases from a USB key when it is connect to the terminal.
8. Report, if available produces a Report of the surgery in a PDF format.
9. Start surgery, by tapping on it the surgery will begin.

The patient list is organized by date and it is divided into three different sections:

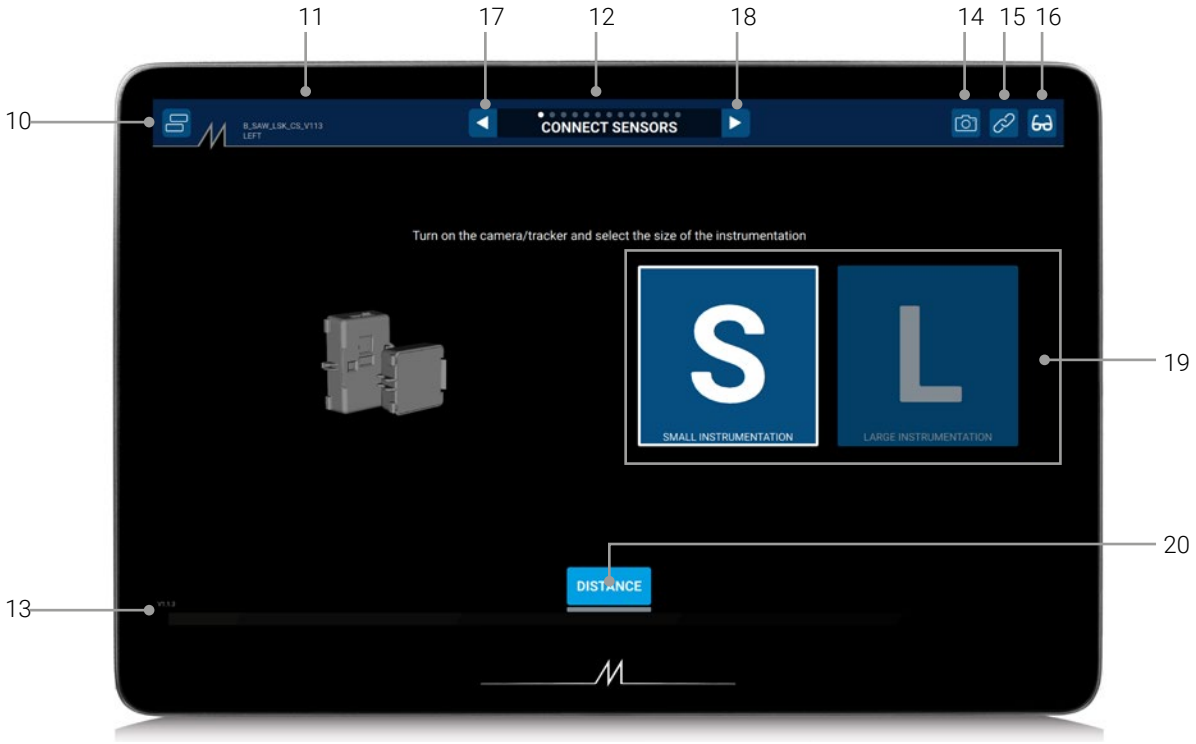
- past surgery already performed
- Today surgery, case scheduled for the current day
- Upcoming surgery, surgery scheduled for the next days.

The list shows the following information:

- Patient's case code
- Surgery date
- Side to be operated
- Action, which can be done on this case

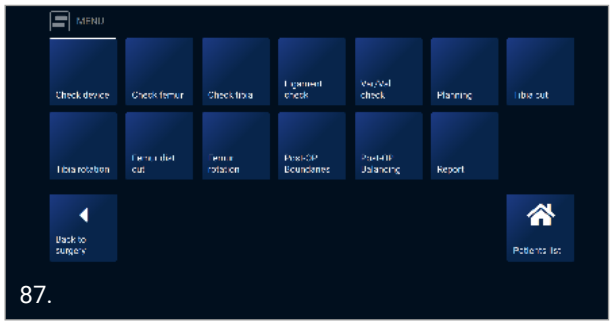
16.1 SURGERY STEP:

Connect sensor



86.

10. Menu button. Click on it and then on settings, to open the following section:



87.

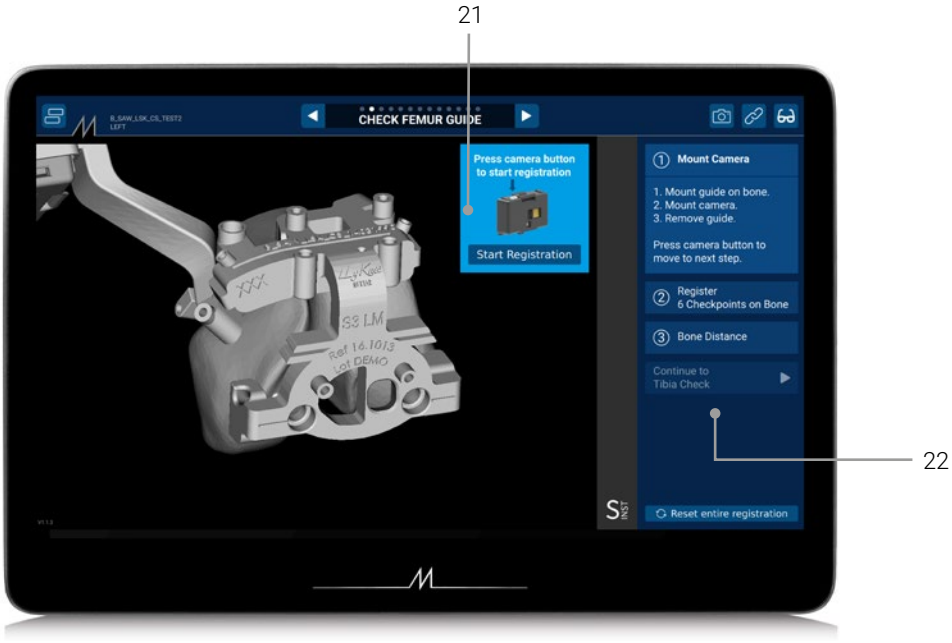
It is possible to rapidly change the surgical step, go back to the current surgery or go to Patient list.

11. Information about the surgery:
    - Case code;
    - Date of the surgery;
    - Side to be operated.
12. Surgical step
13. Software version
14. Screenshot, it is possible to save a picture of the screen at any point of the surgery
15. Sensors icon, it gives information about sensors status. If it is white they are connected to the platform, if not it is red. By touching it, it is possible to access to technical information about sensors, such as battery status, serial number.
16. AR glasses icon, opens a dialogue window to check the connection status. If there is a green light beside the name of the glasses it means that they are connected.Icons from 1 to 9 are always present during any surgical step, only the number 3 changes in accordance with the surgical step.
17. Backward button
18. Forward button
19. Action that has to be done in this step:
    - Turn on camera
    - Then, once the camera is connected (√) turn on the sensor and follow the instruction
    - select the correct size of the NextAR handle
20. Distance between sensor

Glasses view:
It shows the distance between the sensors.

88.

16.2 PSI OPTION - CHECK FEMUR GUIDE



89.

90.

21. Information on how to start the registration
22. Information regarding the registration process
23. Numbers of points to be acquired. The line under the box is always present during this step and has the following meaning:
    - Green line: sensors are correctly measuring
    - Grey line: sensors are unable to detect signal (in the limit region to detect signal (a warning "target out of range" will be displayed)

Glasses view:
It shows the distance between virtual model and real model.

91.

16.3 CHECK TIBIA GUIDE :

92.

93.

24. Information on how to start the registration
25. Surgery step instructions
26. Numbers of points to be acquired. The line under the box is always present during this step and has the following meaning:
    - Green line: sensors are correctly measuring
    - Grey line: sensors are unable to detect signal (in the limit region to detect signal (a warning “target out of range” will be displayed)

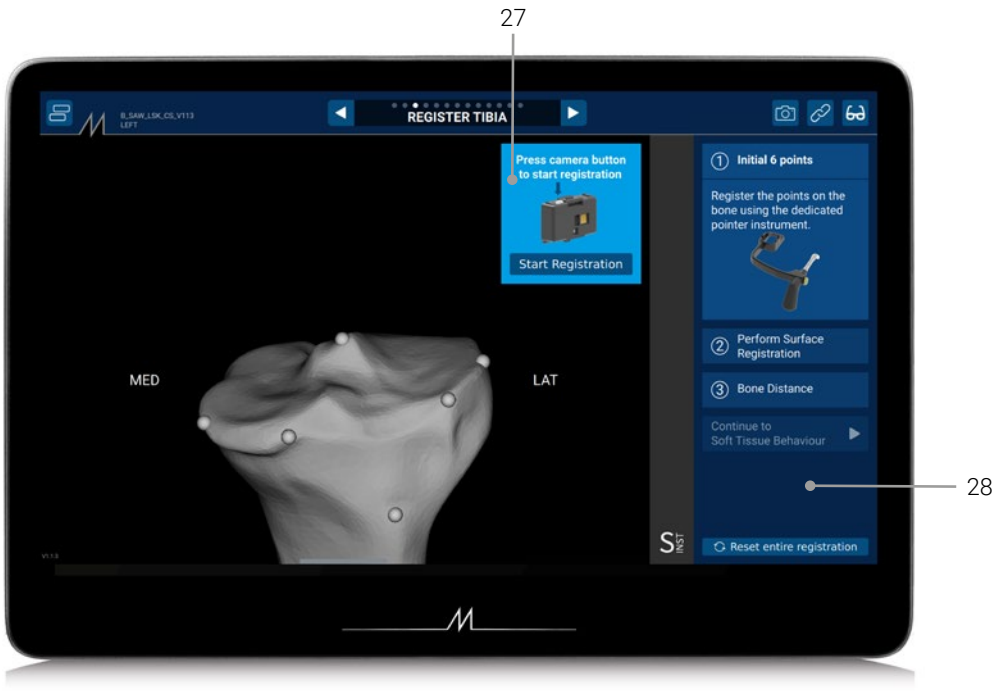
Glasses view:
It shows the distance between virtual model and real model.

94.

16.4 PSI-FREE OPTION - BONE REGISTRATION:

95.

96.

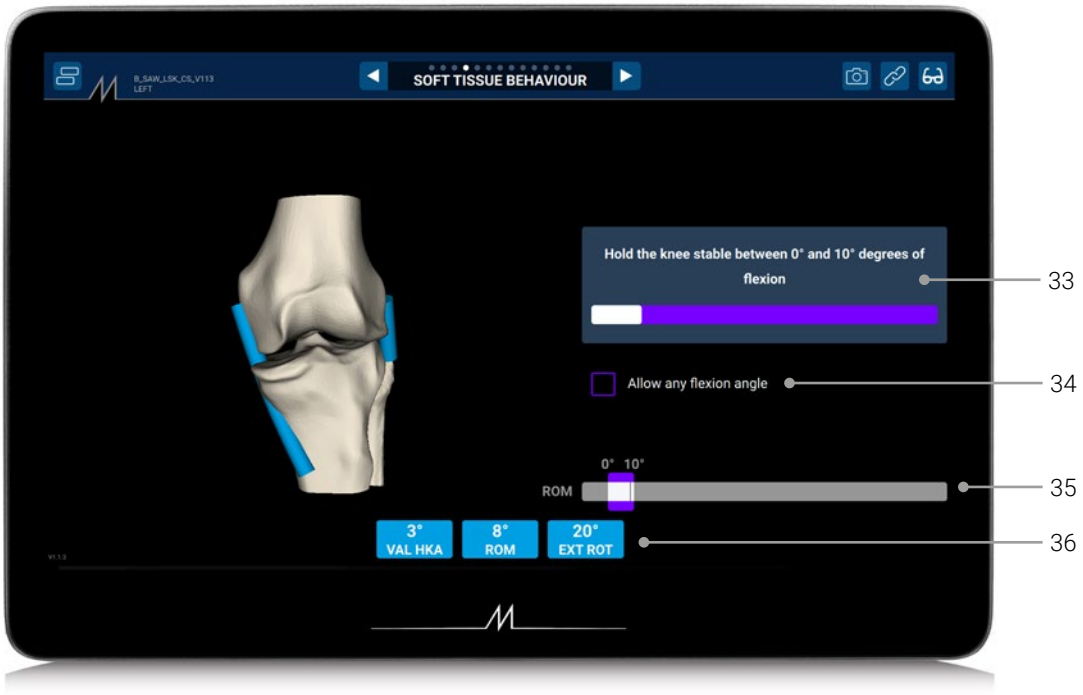


97.

98.

27. Information on how to start the registration
28. Surgery step instructions
29. Click on this button to repeat the acquisition of the last point point during registration or to redo all surface registration
30. Click on this button to reset the entire registration
31. Real-time counter of registered points
32. This box shows the points to be selected. The software guides the selection of the points, dividing them into groups of 3 - 4 points at a time according to the different areas of the bone taken into consideration.

16.5 SOFT TISSUE BEHAVIOUR (L0 ACQUISITION):



99.

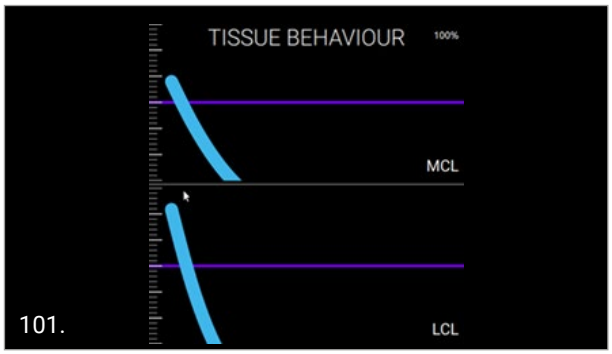
33. Progress bar: it shows the progress of the acquisition phase
34. Touch this icon to allow any flexion angle acquisition
35. Progress bar that shows the flexion angle
36. Real-time data:
    - HKA angle
    - Flexion angle
    - Tibia rotation

16.6 SOFT TISSUE BEHAVIOUR

100.

37. Elongation graph, they show the length variation of collateral ligament. MCL stands for Medial Collateral Ligament graph, while LCL stands for Lateral Collateral Ligament graph.
38. Difference, in millimetres, between the L0 length (purple line) and the ligament length at the current degree of flexion
39. Progress bar shows the real-time flexion
40. Real time data:
    - HKA angle
    - Flexion angle
    - Tibia rotation

Glasses view:
It shows the graphs of ligament elongation.



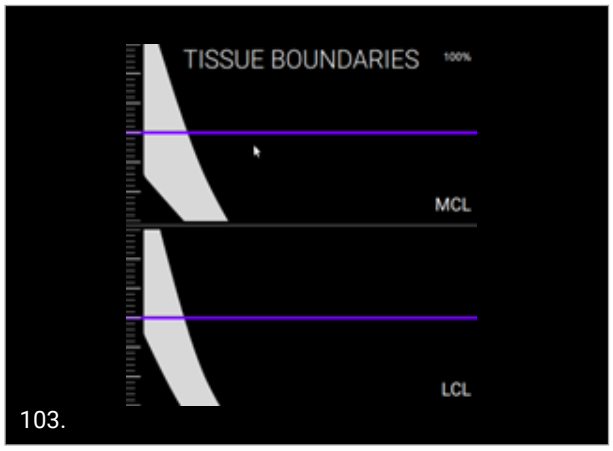
101.

16.7 SOFT TISSUE BOUNDARIES

102.

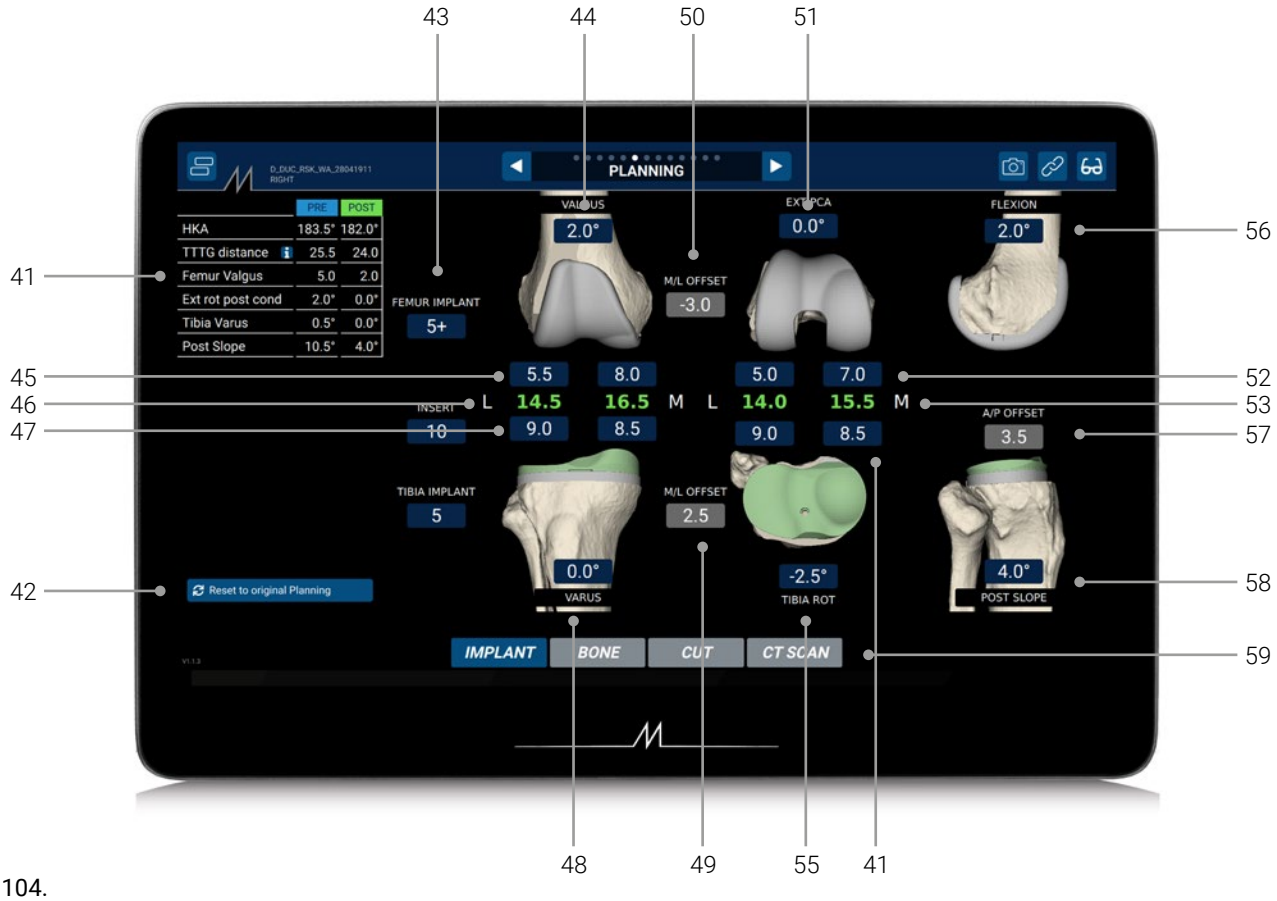
Only one difference with respect to the previous screen, it shows the grey area of the soft tissue boundaries.

Glasses view:



103.

16.8 PLANNING



104.

41. Pre-op data displayed in blue and Post-op data displayed in green
42. Reset button: it deletes any modifications done during the session. The data are reset to the originally planned ones.
43. Implants sizes
44. Femoral Varus/Valgus cut angles
45. Femoral medial and lateral cut height (according to side to be operated)
46. Measured resection in extension
47. Tibial medial and lateral cut height (according to side to be operated)
48. Femoral Varus/Valgus cut angles
49. Medio-Lateral offset of the tibial implant
50. Medio-Lateral offset of the femoral implant
51. External rotation
52. Medial and Lateral femur posterior cut (according to side to be operated)
53. Measured resection at 90° degrees
54. Tibial medial and lateral cut height (according to side to be operated)
55. 15. Tibial implant rotation
56. 16. Flexion cut angle
57. Tibial implant antero-posterior shift
58. Tibial posterior slope cut angle
59. Different planning view (see §6)

Parameters from 43 to 58 can be modified by touching the icon and using plus minus buttons.

Other views:


PLANNING
PRE
POST
HKA 183.5° 182.0°
TTTG distance 25.5 24.0
Femur Valgus 5.0 2.0
Ext rot post cond 2.0° 0.0°
Tibia Varus 0.5° 0.0°
Post Slope 10.5° 4.0°
VALGUS
2.0°
EXT PCA
0.0°
FLEXION
2.0°
FEMUR IMPLANT
5+
M/L OFFSET
-3.0
5.5
8.0
5.0
7.0
INSERT
10
L 14.5 16.5 M
L 14.0 15.5 M
9.0
8.5
9.0
8.5
A/P OFFSET
3.5
TIBIA IMPLANT
5
M/L OFFSET
2.5
0.0°
VARUS
-2.5°
TIBIA ROT
4.0°
POST SLOPE
Reset to original Planning
IMPLANT
BONE
CUT
CT SCAN

105.

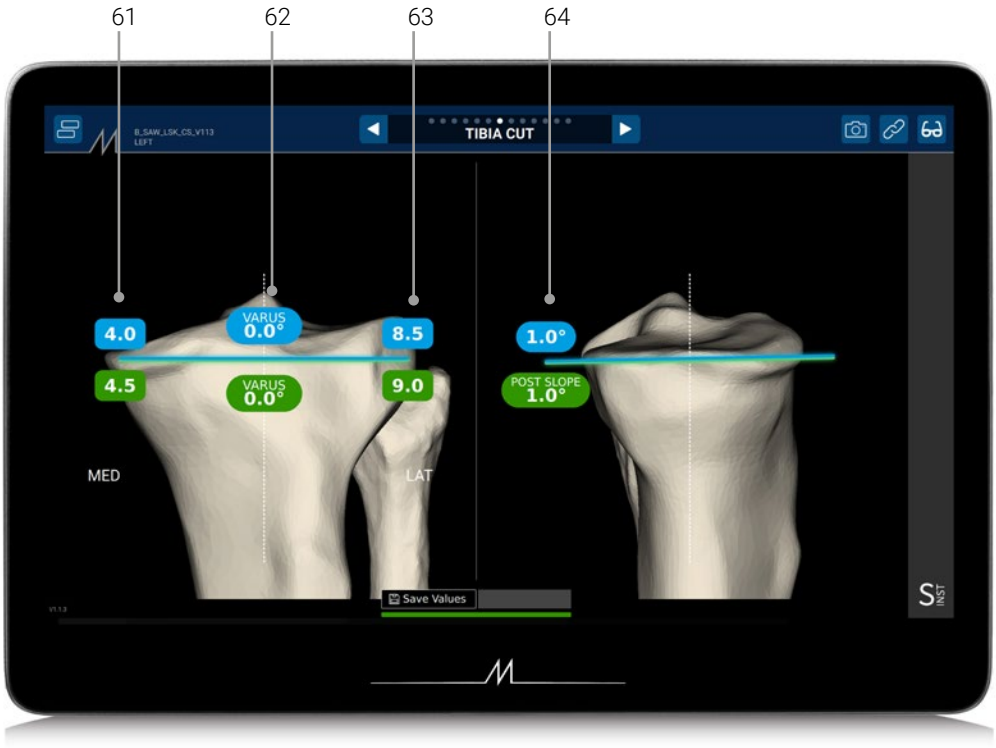

PLANNING
PRE
POST
HKA 183.5° 182.0°
TTTG distance 25.5 24.0
Femur Valgus 5.0 2.0
Ext rot post cond 2.0° 0.0°
Tibia Varus 0.5° 0.0°
Post Slope 10.5° 4.0°
VALGUS
2.0°
EXT PCA
0.0°
FLEXION
2.0°
FEMUR IMPLANT
5+
M/L OFFSET
-3.0
5.5
8.0
5.0
7.0
INSERT
10
L 14.5 16.5 M
L 14.0 15.5 M
9.0
8.5
9.0
8.5
A/P OFFSET
3.5
TIBIA IMPLANT
5
M/L OFFSET
2.5
0.0°
VARUS
-2.5°
TIBIA ROT
4.0°
POST SLOPE
Reset to original Planning
IMPLANT
BONE
CUT
CT SCAN

106.

107.

60. Scroll-bar to navigate the CT-Scan. The images are shown with the contour of the planned implant in place.

16.9 TIBIA CUT

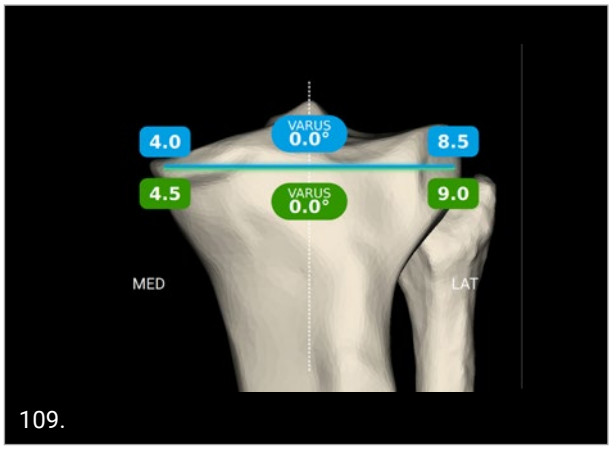


108.

61. Medial plateau cut height (according to side to be operated)
62. Varus/Valgus cut angles: positive number means varus angle, negative numbers stand for valgus.
63. Lateral plateau cut height (according to side to be operated)
64. Posterior slope cut angle

Planned data are shown in green, while in blue are shown the real-time ones

Glasses view:
It shows a single view of the bone, planned section line and real-time resection line. Values are real-time ones.



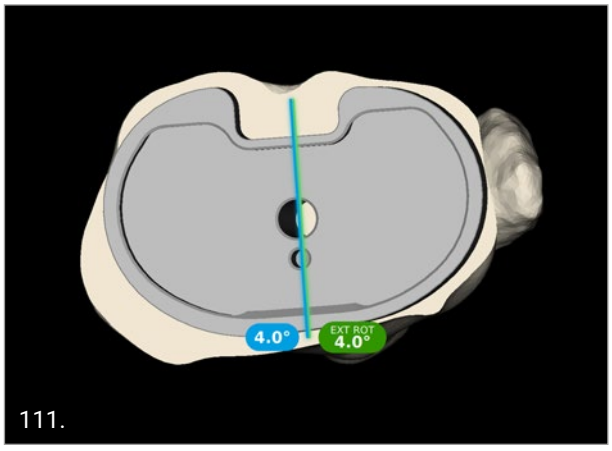
109.

16.10 TIBIA ROTATION

110.

65. Implant rotation
66. Implant size. Can be modified by tapping on it and using plus/minus button

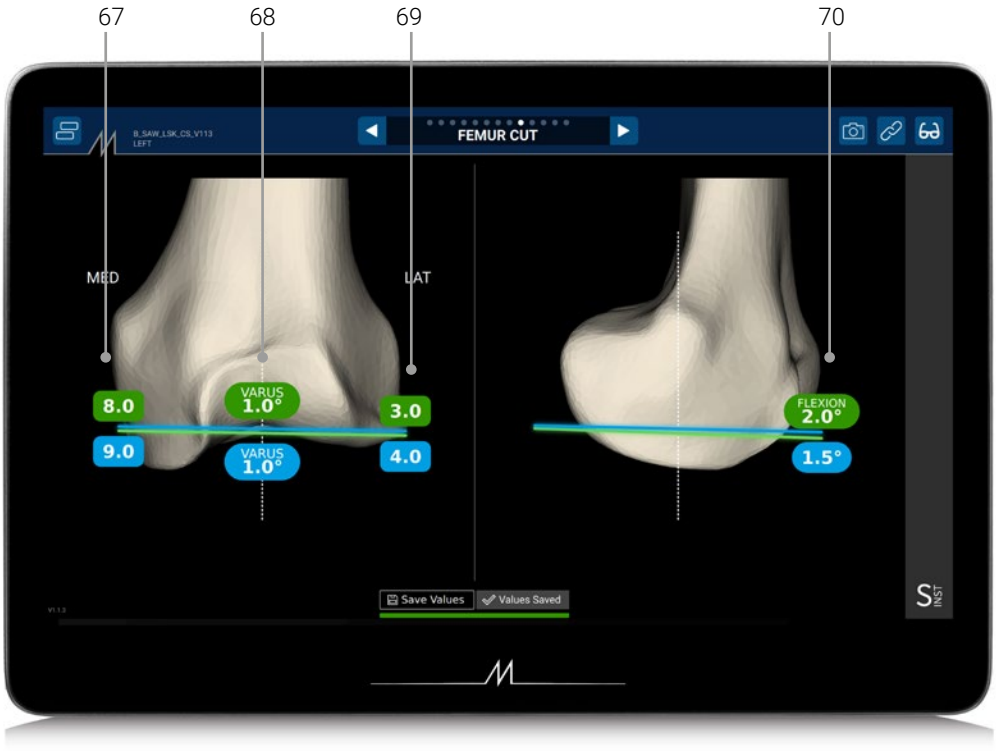
Glasses view:
It shows a single view of the bone, planned rotational reference. Values are real-time ones.



111.

16.11 DISTAL CUT

Platform view:

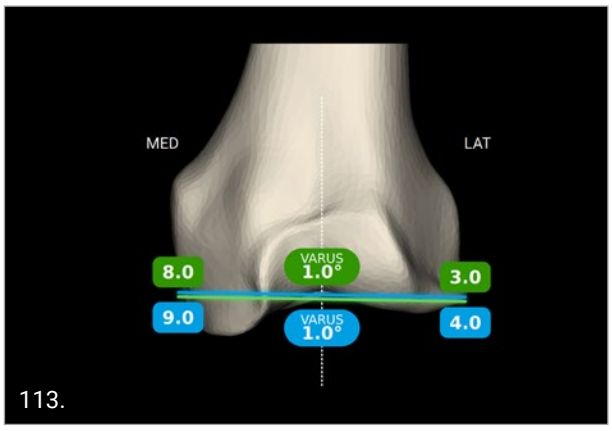


112.

67. Medial distal cut height (according to side to be operated)
68. Varus/Valgus cut angles: positive number means varus angle, negative numbers stand for valgus.
69. Lateral distal cut height (according to side to be operated)
70. Flexion cut angle

Planned data are shown in green, while in blue are shown the real-time ones

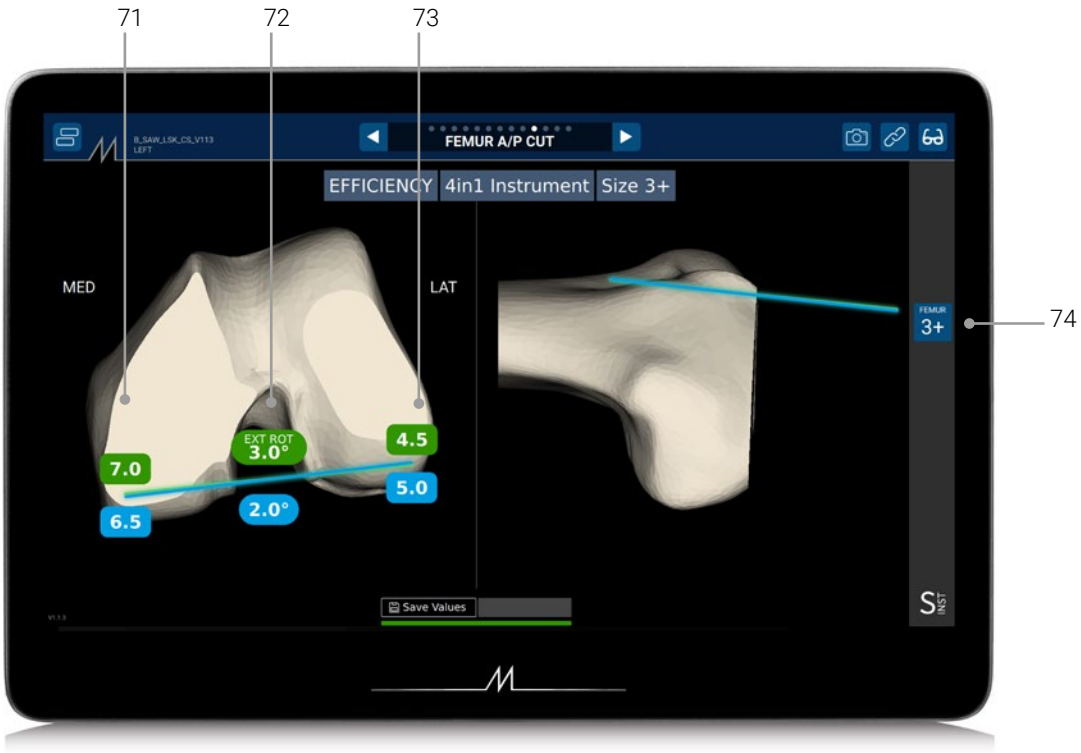
Glasses view:
It shows a single view of the bone, planned section line and real-time resection line. Values are real-time ones.



113.

16.12 FEMUR A/P CUT

Platform view:

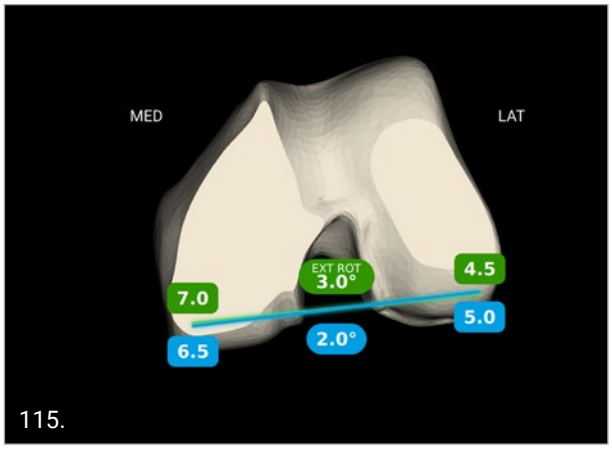


114.

71. Medial posterior cut height (according to side to be operated)
72. External rotation cut angles:
73. Lateral posterior cut height (according to side to be operated)
74. Femur implant size. Implant size can be modified by tapping on it and using plus/minus button

Planned data are shown in green, while in blue are shown the real-time ones

Glasses view:
It shows a single view of the bone, planned section line and real-time resection line. Values are real-time ones.



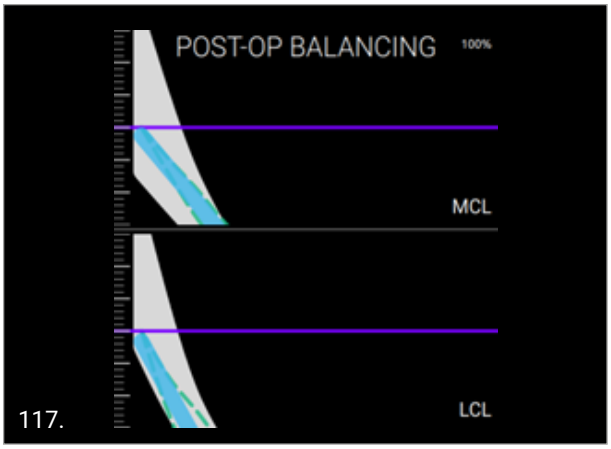
115.

16.13 POST-OP BALANCING

116.

75. Ligament length variation graph throughout the range of motion, it is specific for each comparent, medial and lateral. It shows:
    - Blue line: real-time length ligament variation
    - Purple line: L0 length
    - Grey area: pre-op soft tissue boundaries
    - Green dashed line: post-op soft tissue boundaries
76. Insert implant thickness. Can be modified pressing plus/minus buttons
77. Real-time HKA angle
78. Real-time degree of flexion
79. Real-time external rotation
80. Pre-op external rotation

Glasses view:
It shows the graphs of ligament elongation with pre-op and post-op soft tissue boundaries



117.

NOTES

Part numbers subject to change.

NOTE FOR STERILISATION

In case the instrumentation is not sterile upon delivery, it must be cleaned before use and sterilized in an autoclave respecting the regulation of the country, US directives where applicable and following the instructions for use of the autoclave manufacturer.
For detailed instructions please refer to the document “Recommendations for cleaning decontamination and sterilization of Medacta International reusable orthopedic devices” available at www.medacta.com.

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Surgical Technique

ref: 99.26NEXTAR.12US
rev. 07

Last update: October 2022