# UNI SCORE®

Unicompartmental Knee System

## Surgical Technique
## Computer-assisted surgery

AMPLITUDE®

## OBJECTIVES

- Correct the wear component of the deformity in a knee where the ligaments are still intact, by:
  - Maintaining the height of the joint space (importance of using the joint space gauge):
    - in the sagittal plane (same tibial slope)
    - in the frontal plane (tibial plateau angle)
  - Keeping a laxity safety margin (under-correction).

**NOTE:** Excess patient weight can be a contraindication for this implant, especially if the tibiofemoral joint is significantly deformed.

**Reminder :** The purpose of this surgical technique description is to provide instructions on how to use the instrumentation properly. The surgeon is fully responsible for the indication, surgical approach, surgical technique and postoperative protocol.

## DESCRIPTION

- The UNI SCORE® Unicompartmental Knee System consists of a cemented or cementless femoral component that is compatible with all the associated tibial baseplates :

Cementless tibial baseplate for fixed insert with peg (optional screw fixation)

Cemented tibial baseplate for fixed insert

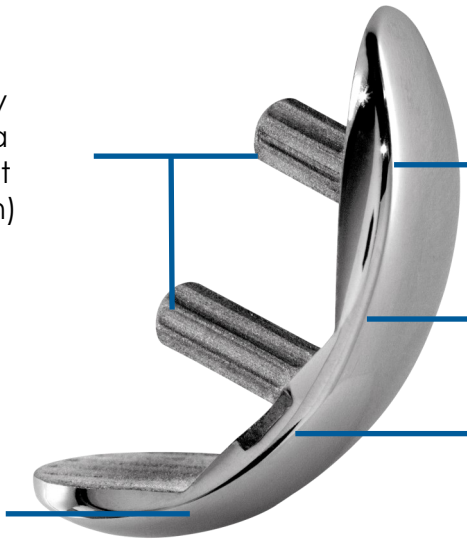
Full-PE (polyethylene) tibial implant



## 1– Femoral component:

Primary stabillity ensured by two parallel pegs forming a 65° angle with the distal cut (prevents implant expulsion)

Made of cobalt-chrome (CoCr) Cementless version has dual coating of 80µm HAP. Cemented version is sandblasted



Symmetrical femoral component with constant radius of curvature throughout the range of motion

Up to 8° camber possible

Minimum femoral component thickness: 6mm

## DESCRIPTION

# 2– Tibial components:

### Tibial baseplates for fixed insert:

Cemented symmetrical tibial baseplate for fixed insert

Made of cobalt-chrome (CoCr)

Cementless asymmetrical tibial baseplate for fixed insert (RM/LL and LM/RL (80 µm plasma-sprayed titanium + 80 µm HAP)

Made of cobalt-chrome (CoCr)

UHMWPE insert

All surfaces that are in contact with the insert have a highly polished finish

Insert locked using double snap-in mechanism

Primary stability of baseplate achieved through sagittal fin

Anteriorly-positioned peg ensures maximum primary fixation

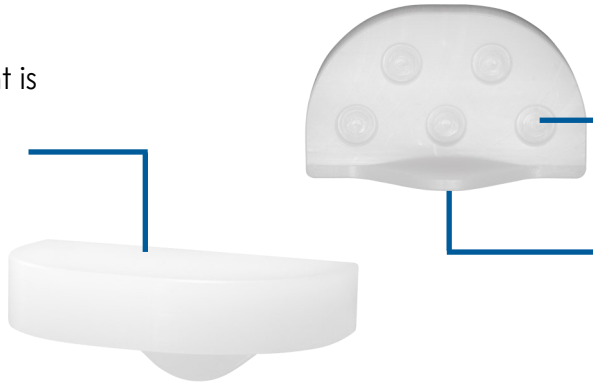
Stability can be improved by adding fixation screw

Screw hole can be blocked with PEEK stopper

### Full-PE tibial implant:

The full-PE tibial implant is symmetrical

Flat bearing surface



Underside of implant has 5 hollowed-out areas or cement, wich ensures primary stability along with sagittal fin

## DESCRIPTION

# 3– Product line:

- **Femoral components:**

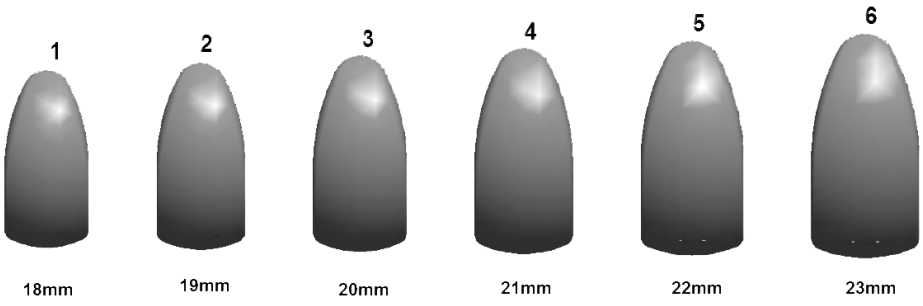
- Cemented: 7 sizes (from 1 to 7)

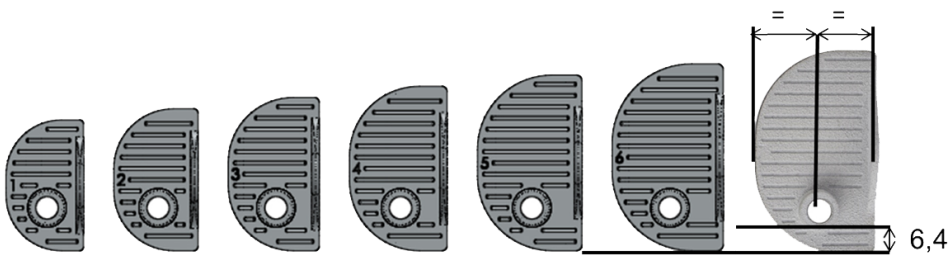
- Cementless: 7 sizes (from 1 to 7)

- **Tibial components:**

| Implants | Tibial baseplates | Inserts |
|---|---|---|
| **Uni SCORE® Tibial baseplate for fixed insert Cementless** | 7 sizes ( 1to 7) RM/LL<br>7 sizes (1 to 7) LM/RL | 7 sizes (1 to 7)<br>4 thicknesses (9 to12mm) |
| **Uni SCORE® Tibial baseplate for fixed insert Cemented** | 7 sizes (1 to 7) | 7 sizes (1 to 7)<br>4 thicknesses (9 to 12mm) |
| **Uni SCORE® Full-PE Tibial Implant** | 7 sizes (1 to 7) | 7 sizes (1 to 7)<br>5 thicknesses (8 to 12mm) |

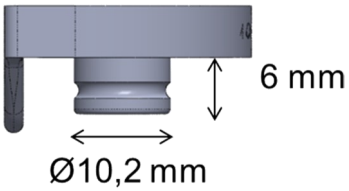
- **All implants available in 1mm increments:**




| | S1 | S2 | S3 | S4 | S5 | S6 | S7 |
|---|---|---|---|---|---|---|---|
| Distance M/L (mm) | 20,8 | 22,6 | 24,4 | 26,2 | 28 | 29,8 | 31,6 |
| Distance A/P (mm) | 35 | 38 | 41 | 44 | 47 | 50 | 53 |

- **Peg dimensions (same for all sizes)**



## 3– Component compatibility

- **Femoral components:**

- Cemented: 7 sizes (from 1 to 7)

- Cementless: 7 sizes (from 1 to 7)

- **Tibial components:**

| | UNI SCORE® Tibial baseplate for fixed insert cementless RM/LL and LM/RL | UNI SCORE® Tibial baseplate for fixed insert cemented |
|---|---|---|
| UNI SCORE® fixed insert | √ | √ |
| Cancellous bone screw ø6,5mm | √ | X |

- **Tibial baseplate for fixed insert and Full-PE tibial implants:**

-The fixed insert can only be used with the tibial baseplate for fixed insert.

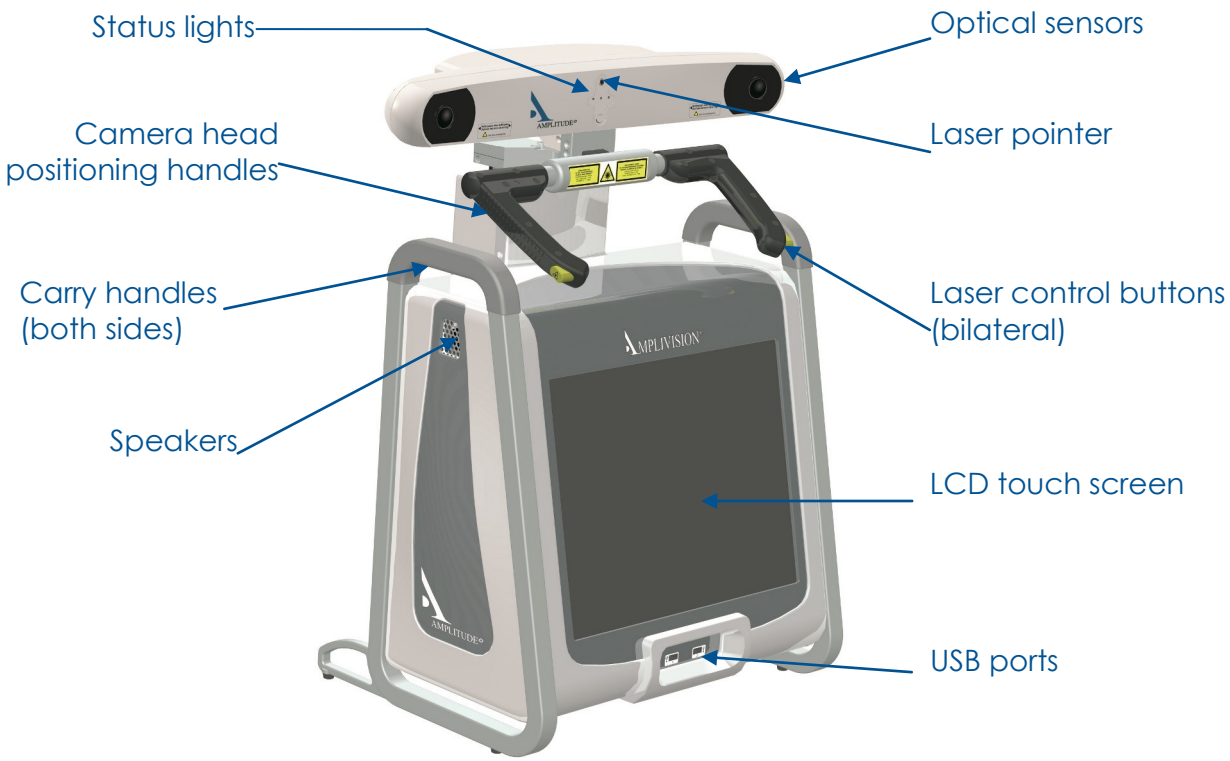
-The fixed insert must be exactly the same size as the tibial baseplate for fixed insert.

-All the femoral component sizes can be combined with any of the tibial baseplates for fixed insert and Full-PE tibial implant sizes.

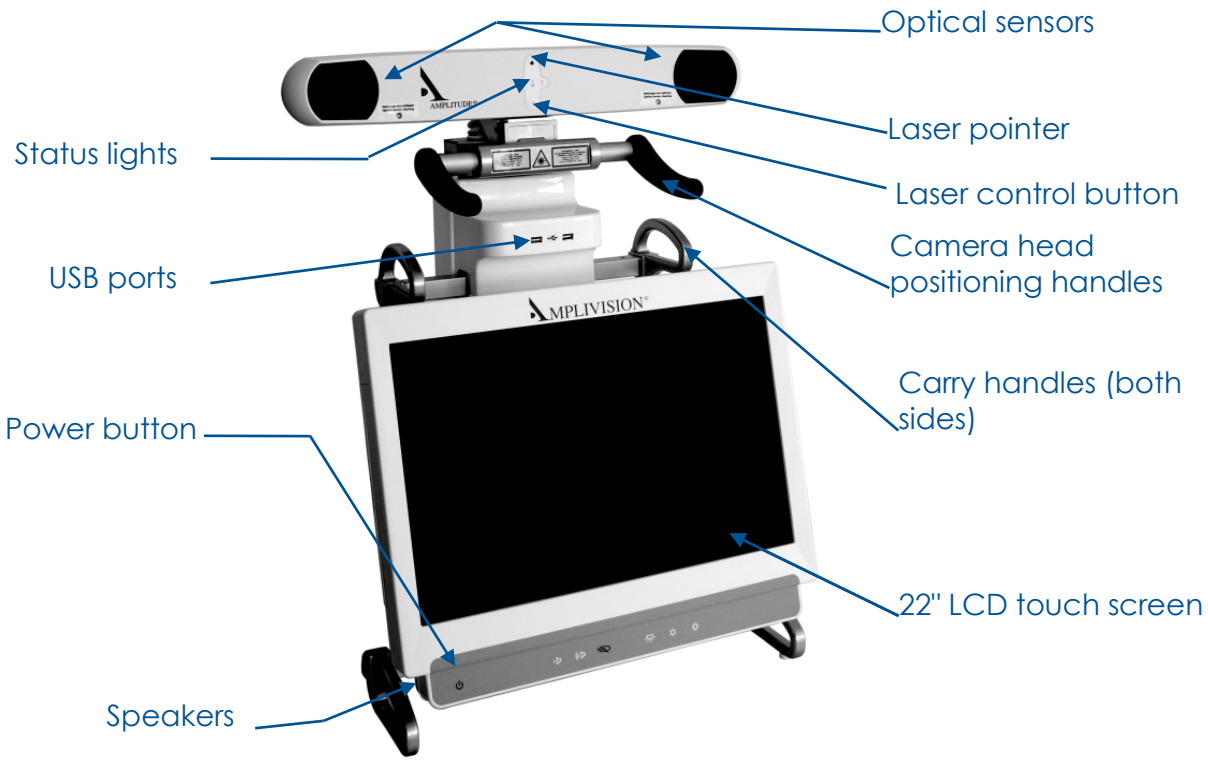
Not all devices presented in this Surgical Technique may be registered in your country. Please contact your Amplitude Sales Representative for availability.

## WORKSTATION COMPONENTS

**FRONT:**




V2 Workstation

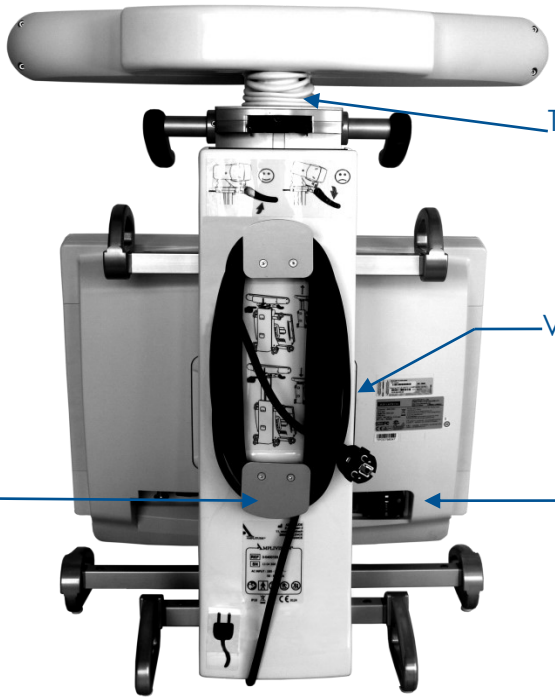



V3 Workstation

## WORKSTATION COMPONENTS

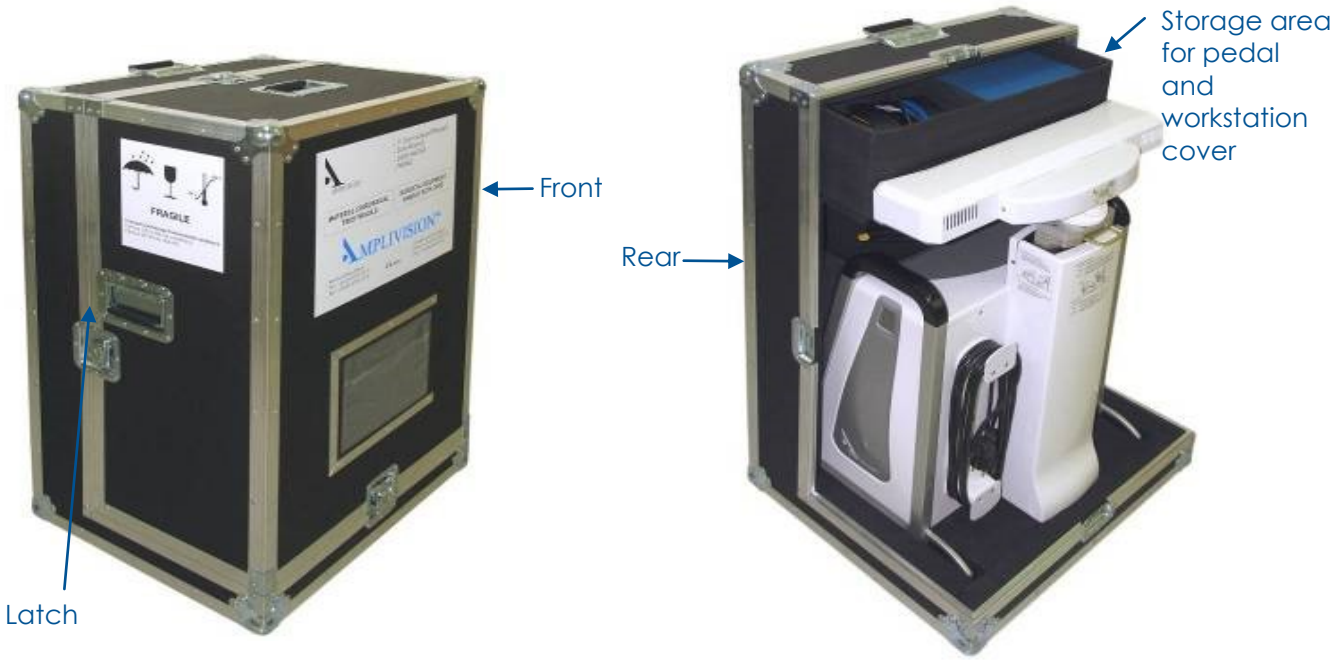
**REAR:**


V2 Workstation

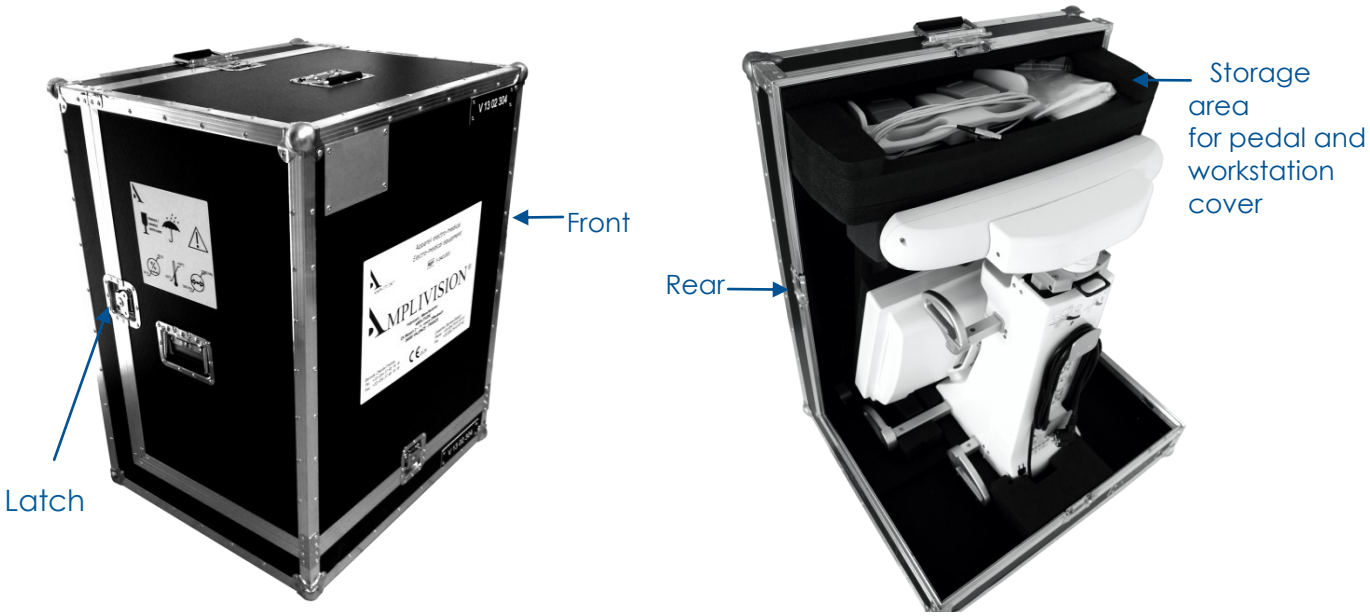



V3 Workstation

## PREPARATION PHASE




Shipping case for V2 Workstation




Shipping trunk for V3 Workstation

Pedals for V2 Workstation

Pedals for V3 Workstation

## PREPARATION PHASE

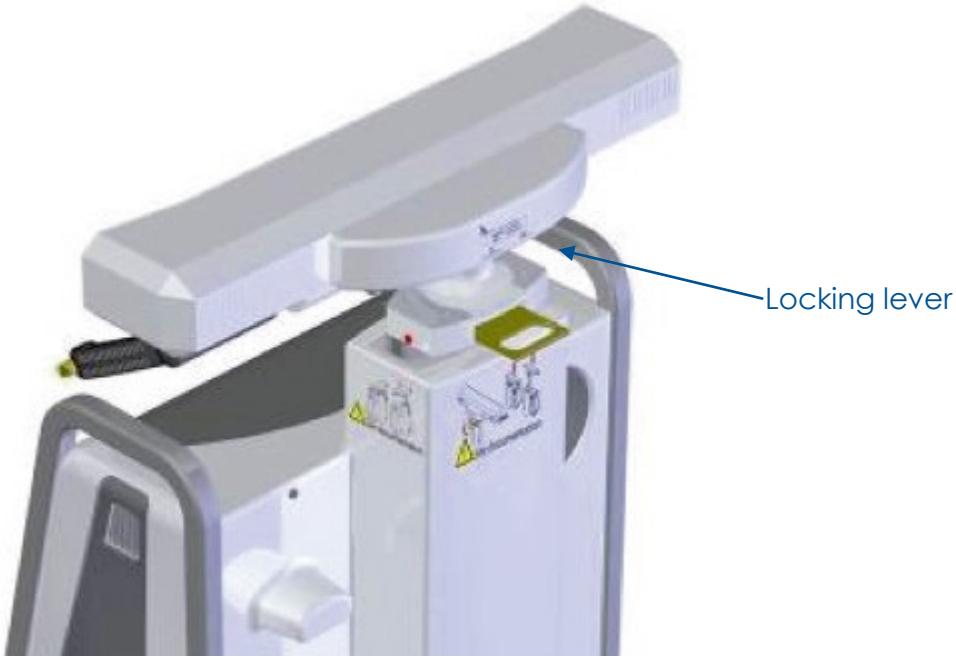
- Unlock the four latches on the shipping trunk.
- Open the front panel and take out the workstation, pedal and pedal cover.
- Place the workstation on a stable table or operating room cart.
- Clean the workstation according to the instructions in the user manual.

**NOTA :** The workstation user manual is found in the shipping trunk.

- Connect the pedal to the back of the V2 Workstation or to the side of the V3 Workstation (refer to photos for location of ports) and slide it into its protective cover (found in the trunk).
- Plug in the workstation's power cord.

## PREPARATION PHASE

### LOCKED POSITION




### UNLOCKED POSITION

## PREPARATION PHASE

- Position the workstation so that it is at least 1.5m from the patient.
- Set the camera head in neutral position (maximum height, no rotation).
- Unlock the adjustable tower: lift the locking lever and let the tower rise freely until it reaches its maximum height.

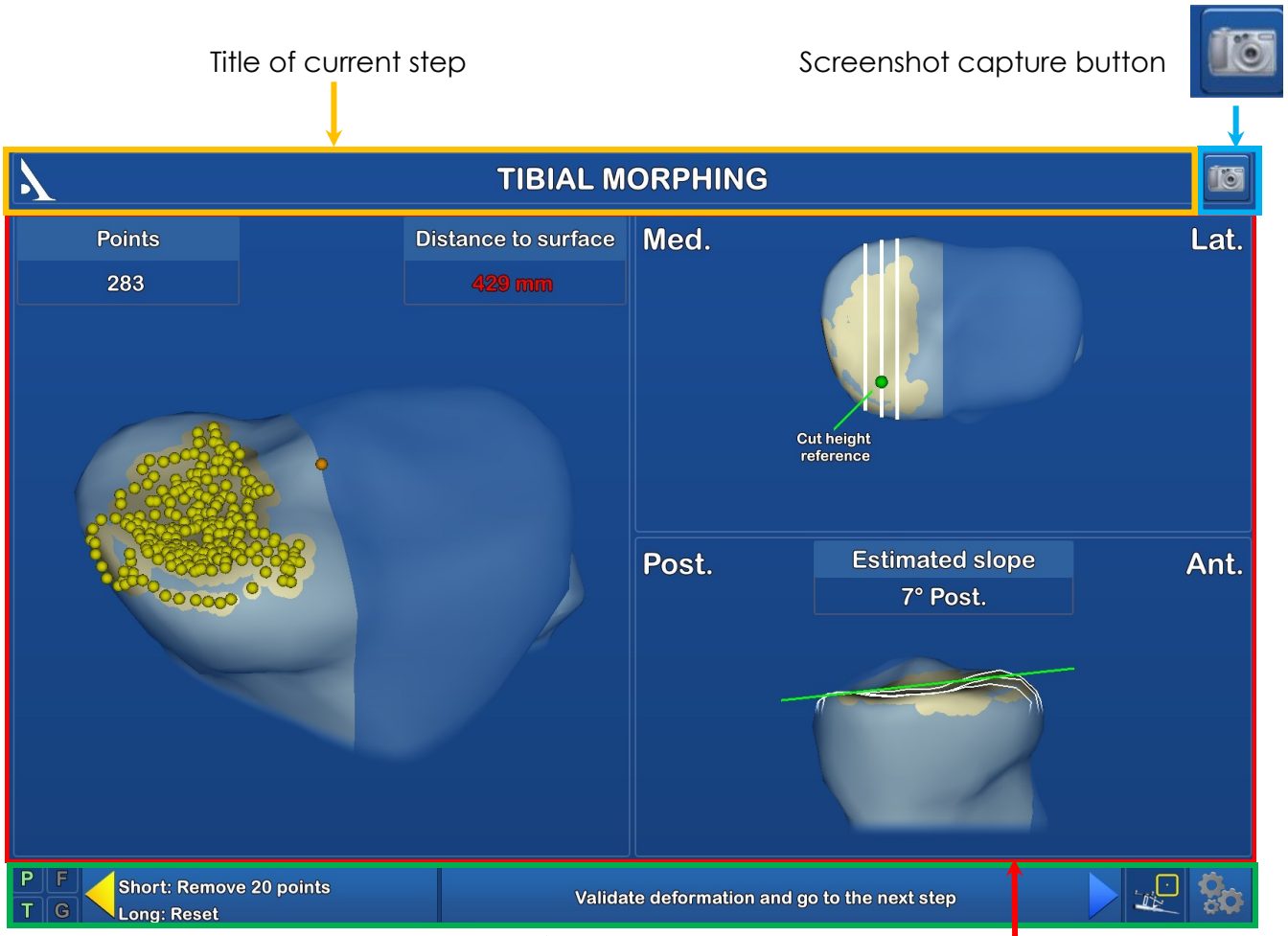
  ⇒ Press the power button:

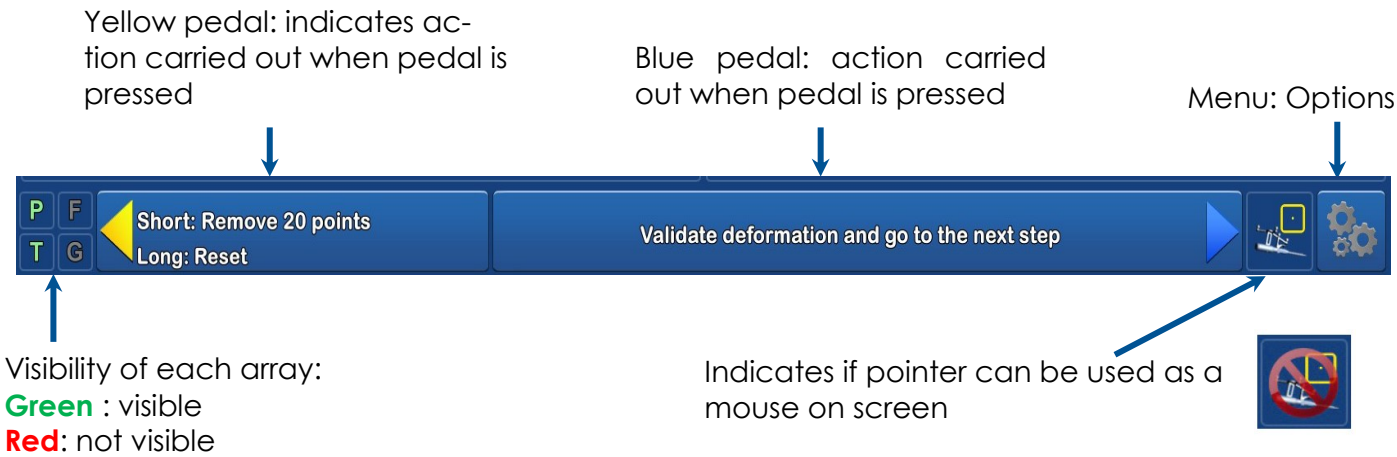
  ⇒ V2 Workstation: move the green button on rear of workstation to «I» position;

  ⇒ V3 Workstation: press the power button at lower right portion of screen . 

  It will turn green when the power is on.

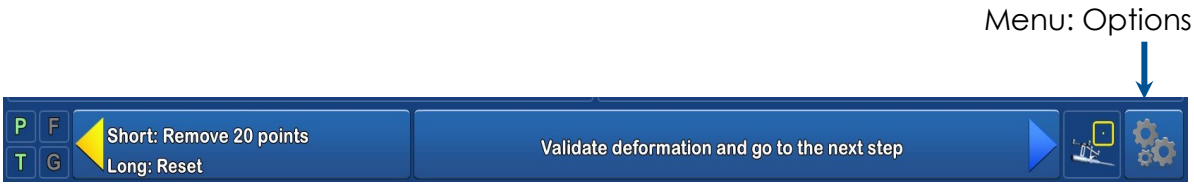
## SCREEN LAYOUT



## OPTIONS MENU DESCRIPTION

**The "Options" menu can be accessed at any point during navigation by clicking the "Options" button in the lower right corner of the screen.**

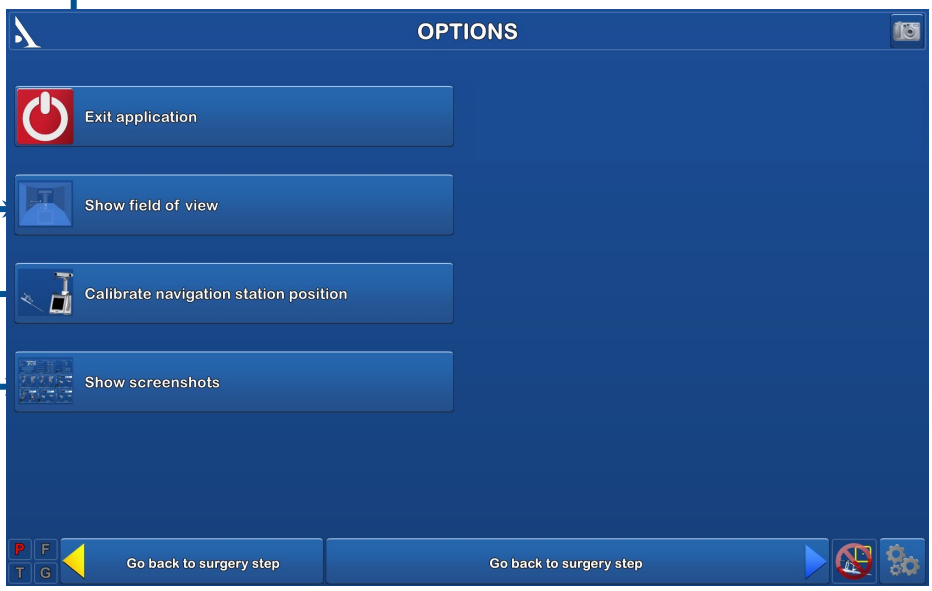



The «Exit Application» button will only be active during the final step.
To exit the application before the final step, go to the «Options» menu to select it.

Show camera field of view to locate arrays

Reset navigation station position relative to surgeon position

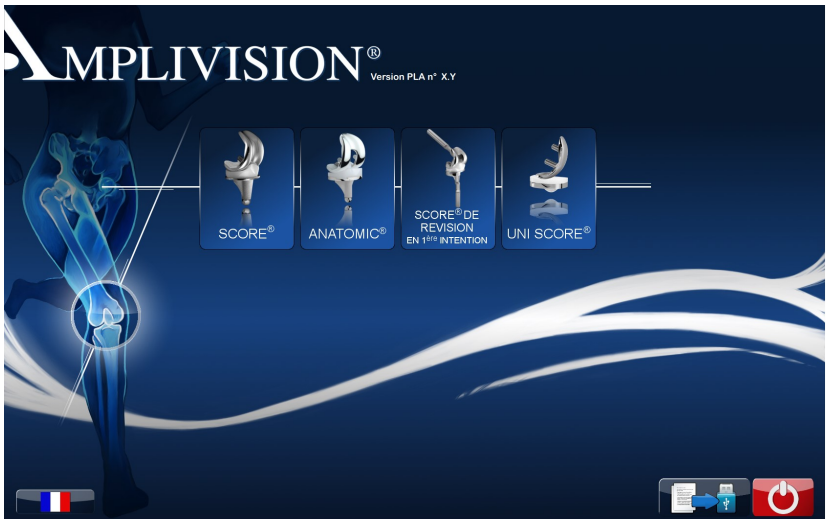
View all the validated steps during the surgery

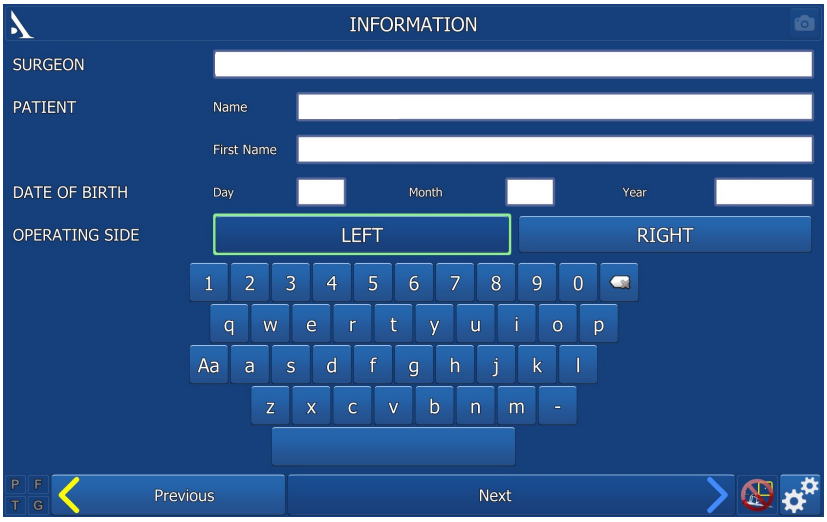


## PREPARATION PHASE

Press the touch screen to select the preferred system language.

Select «Knee», then select the UNI SCORE® implant.




On the «Information» page, input the required information using the virtual keyboard.

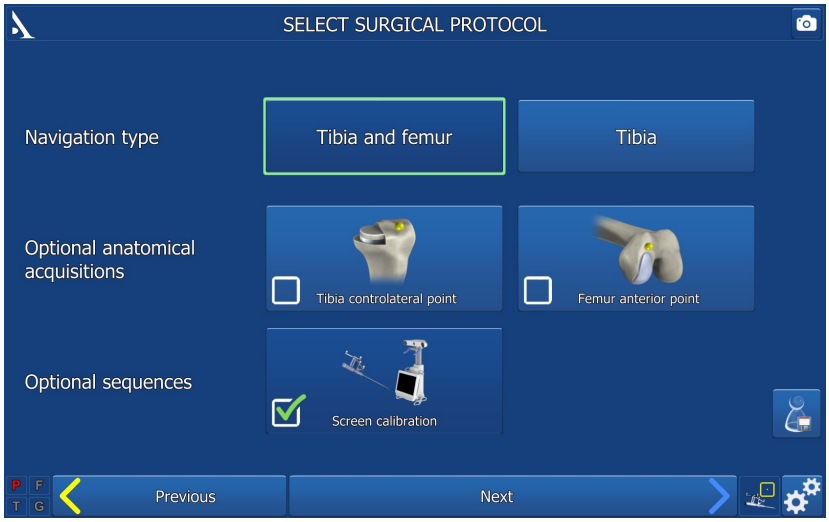
- Surgeon name
- Patient name
- Patient date of birth (optional)
- Operated side (select right or left)

To go to the next step, press the blue pedal or the blue arrow on the screen.

To go to the previous step, press the yellow pedal or yellow arrow on the screen.

## PREPARATION PHASE

Configuring the surgery-related options:




- Navigation can be used with the tibia and femur, or only the tibia. The default is the tibia and femur.
- Whether a contralateral point on the tibia will be acquired. By default, this option is not selected.
- Whether a point will be acquired on the anterior femur. By default, this option is not selected.
- Manual or automatic screen calibration; the default is manual calibration.

**NOTE:** During this step, a user profile can be created (see next page) to save all the selected surgery-related parameters and automatically reuse them during the next surgical navigation with this implant.

To go to the next step, press the blue pedal or the blue arrow on the screen.

# USER PROFILE

## SAVING A USER PROFIL

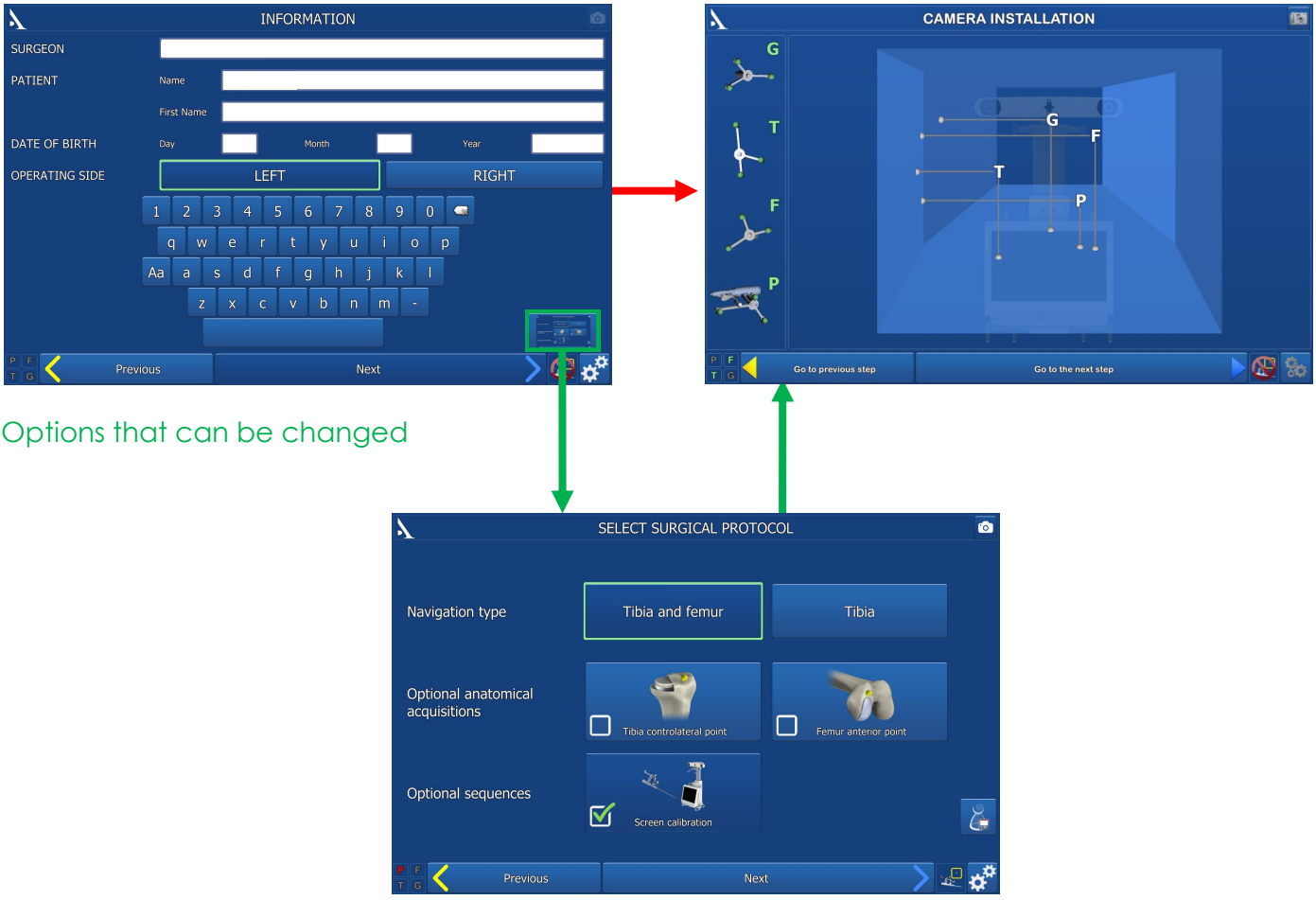
- Once the surgery-related options have been selected, a user profile can be created by pressing the «Save User Profile» button 
- The following information will be saved to a USB drive:
  - ⇒ Surgeon name,
  - ⇒ Surgical option.
  - ⇒ Optional anatomical acquisitions selected
  - ⇒ Optional sequences selected

# USER PROFILE

## WORKING WITH USER PROFILES

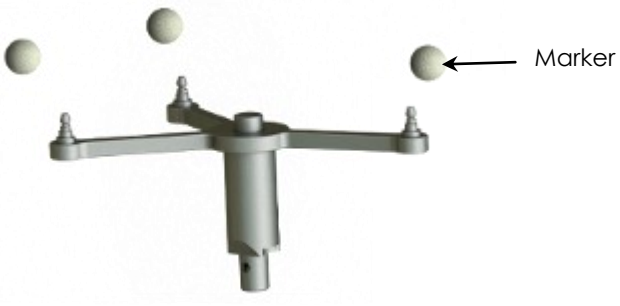
- In future surgical procedures with navigation, plug in the USB drive to automatically load the surgeon's name and preferences.
- At this point, the software will go from the «Information» page to the «Camera Setup» page and will skip the « Select surgical protocol » page.
- To change a saved parameter, press the  button at the lower right corner of the «Information» screen.

Working with user profiles




Options that can be changed

## PREPARATION PHASE

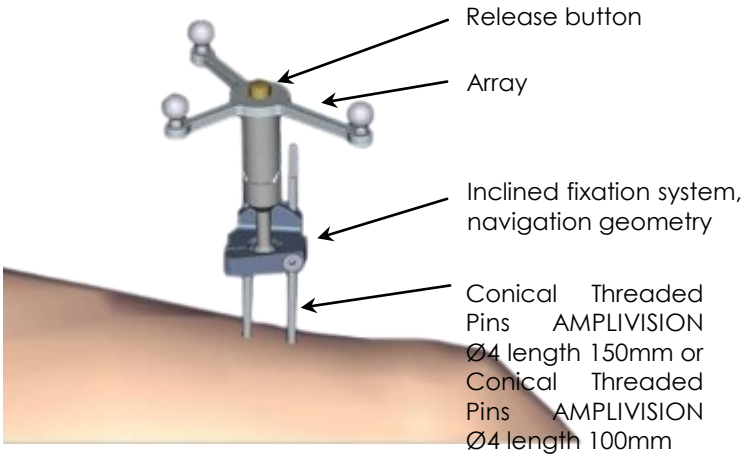



- Clip the AMPLIVISION sterile Markers (packaging per 14) to the arrays:
  - 3 for the T array, tibia navigation
  - 3 for the F array, femur navigation
  - 4 for the Probe, knee navigation
  - 3 for the G array, Instrumentation navigation

- The Conical Threaded Pins AMPLIVISION Ø4 length 150mm or the Conical Threaded Pins AMPLIVISION Ø4 length 100mm must be placed on the anteromedial side of the femur and tibia (when the surgeon stands on the lateral side) and must not interfere with tap placement. They can be inserted either percutaneously or through an incision.

**NOTE**

If the femoral pin is being inserted percutaneously, make sure the knee is flexed to prevent damaging muscle fibres



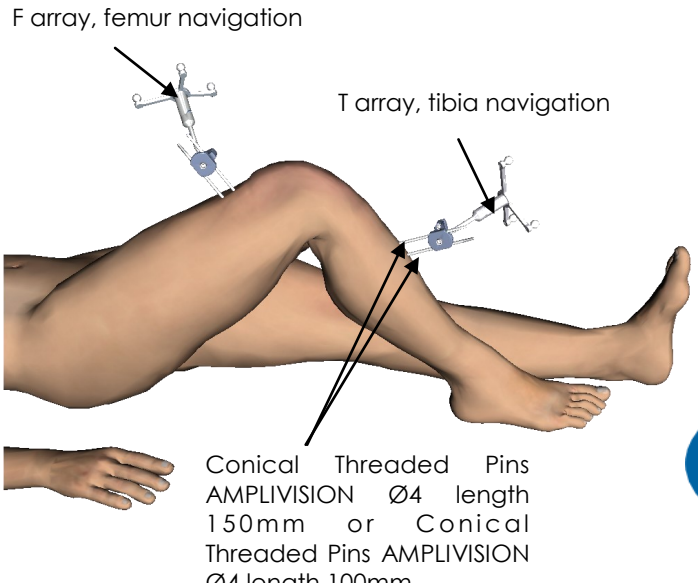

- Insert the first pin: go through the proximal cortex and then into, but not through, the distal cortex.

- Place the Inclined fixation system, navigation geometry, on the first pin to get the proper spacing for the second pin.

- Clip the F array on the moveable part of the support, making sure the arrows are aligned correctly. If the array needs to be removed during the procedure, it can be returned to the same position on the support.

- Orient the array towards the camera head and lock the fixation support.

- Position and secure the arrays so they are always visible to the camera head, whether the knee is flexed or extended.

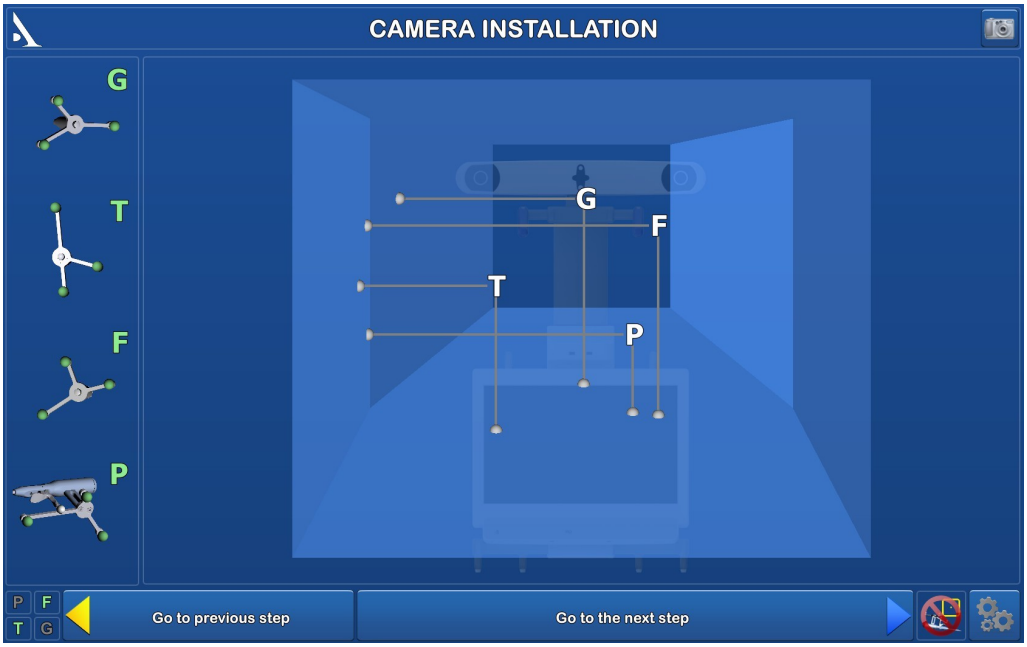



**NOTE**

After approaching the joint and exposing the knee, it is important to remove the osteophytes in order to find the right joint surfaces to be palpated for the digitisation of the joint surfaces (otherwise there is a risk of over- or undersizing the size of the implant).

# WORKSTATION SETUP

## SETTING UP THE CAMERA




Position the camera head so the letters corresponding to the F and T arrays are in the middle of the field of view.

The laser located in the positioning handles on the camera (V2 Workstation) or between the two optical sensors (V3 Workstation) makes this adjustment easier.

Confirm that the P array is visible.

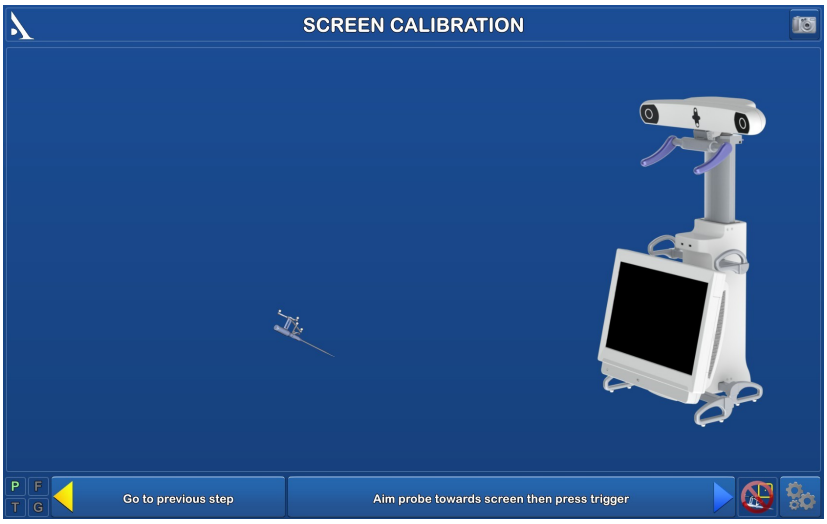
On the left side of the screen, a 3D view of the arrays indicates why a array may not be visible:

- Any marker that is not visible on a array will be red, as will the letter associated with this array.
- The array will be green if it is fully visible.

The array's visibility may be compromised by interfering infrared sources (sunlight, hot lights, dirty markers).

# WORKSTATION SETUP

## CALIBRATION THE USER AND SCREEN




If performing manual calibration: aim the pointer at the centre of the AMPLIVISION® screen and press the trigger to confirm.

From this step on, the AMPLIVISION® system can be controlled with:

- the pointer, by pressing the trigger to confirm,
- the pedal,
- the touchscreen of the AMPLIVISION® workstation.

The system will capture screenshots when

- the user validates a step,
- the user presses the screen capture button at the upper-right corner of the screen.

**NOTE:** If performing automatic calibration, aim the pointer towards the screen and hold it at a slight downward angle. The calibration will be done automatically if the "screen calibration" option was selected when configuring the surgery-related options (see page 19).

**COMMENTS**

The user must make sure the arrays used in this step are fully visible.

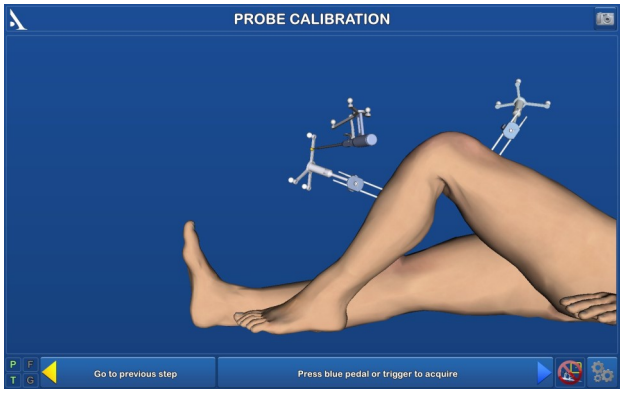
These steps can be saved to a USB drive at the end of the procedure.

The camera position may be recalibrated at any time:

- Press the «Options» button,
- Press the «Calibrate AMPLIVISION® workstation position» button,
- Validate the new position; the system will automatically return to the current surgical step.

# CALIBRATION

## CALIBRATING THE POINTER

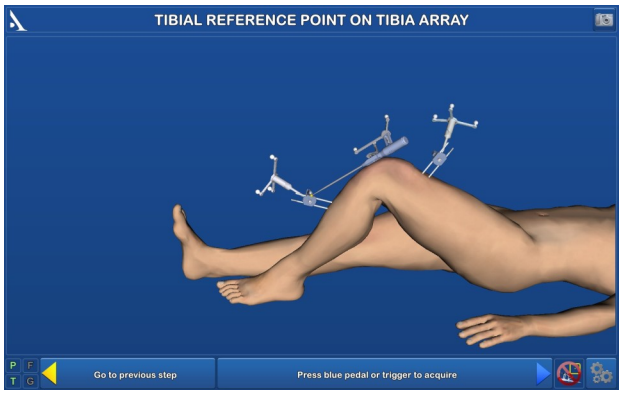



**To define exactly the position of the pointer tip,**

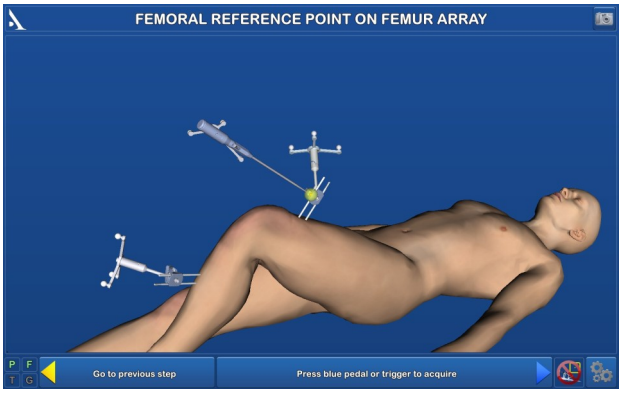
- Calibrate the pointer by placing its tip in the conical calibration mark on one arm of the T array and press trigger to confirm.
- Without lifting the pointer tip, change the pointer's orientation slightly and then confirm again.

## CALIBRATING ARRAYS

**This step validates the final position of the T array on its fixation support. At any point during the procedure, the surgeon can check if the array position has changed by using this reference point.**




**Tibia reference point on array:** Place the pointer tip in one of the two conical calibration marks on the T array support and confirm.



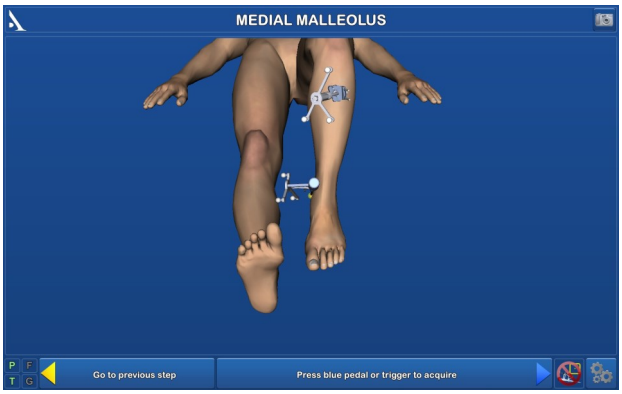

**Femur reference point on array:** Repeat these same steps with the F array support.

At any time during the procedure, place the pointer tip on the previously acquired tibia and/or femur reference point. The words «Femur OK» and/or «Tibia OK» will appear in the lower right corner of the screen if the array has not moved relative to its support.

If the array has moved, the surgeon can continue the procedure without navigation or go back to the reference point step.

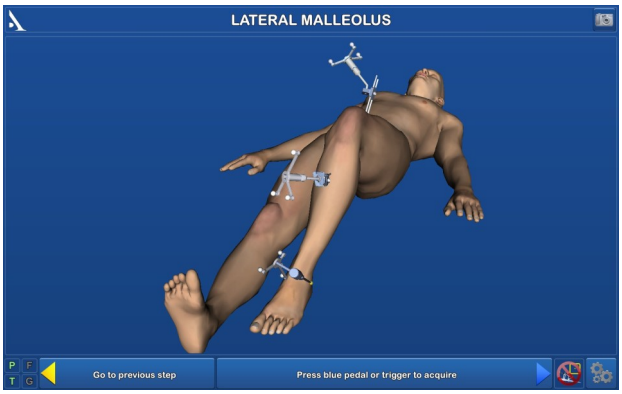
**However, there is no way to check if the array–fixation support system has moved. If in doubt, continue the procedure without navigation.**

## ANKLE CENTRE ACQUISITION




**Medial malleolus:** Place the pointer tip on the most medial point of the medial malleolus.

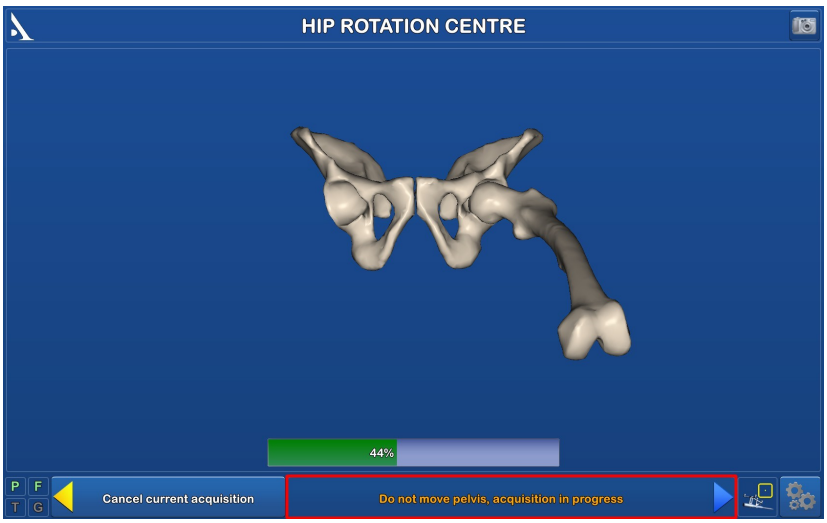
Press the trigger on the pointer to confirm.




**Lateral malleolus:** Place the pointer tip on the most lateral point of the lateral malleolus.

Press the trigger to confirm.

## HIP CENTRE ACQUISITION



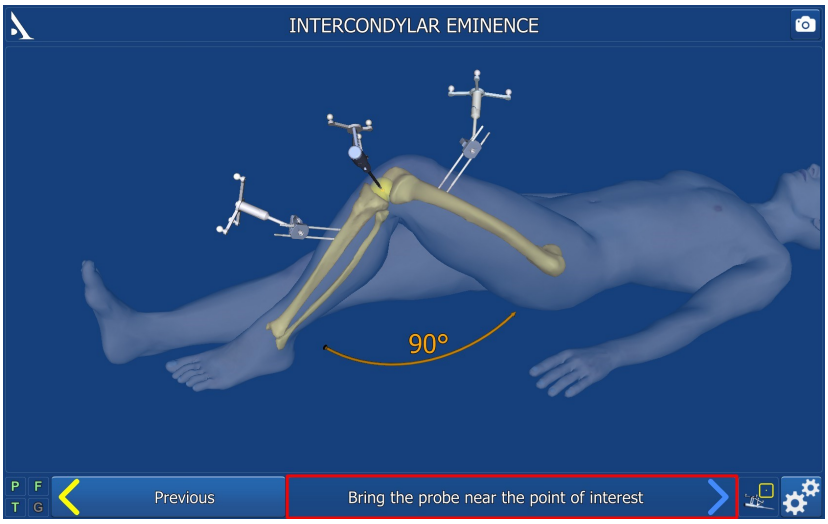

Extend the patient's leg and grasp his/her ankle.

Press the blue arrow (or blue pedal) or move the leg in a small circle to start acquiring the hip centre.

Move the leg in a small circle (15 cm knee displacement) until the system has acquired 100% of the points it needs.

Once the acquisition is finished, the system will calculate the hip centre. If the result is acceptable, the system automatically goes to the next step. If it is not acceptable, the system will prompt the user to restart the acquisition. During this step, the system will beep once when the acquisition starts and once when it ends. A status bar shows the progress being made during the acquisition.

## TIBIAL ACQUISITION




### Centre of tibia:

Flex the knee

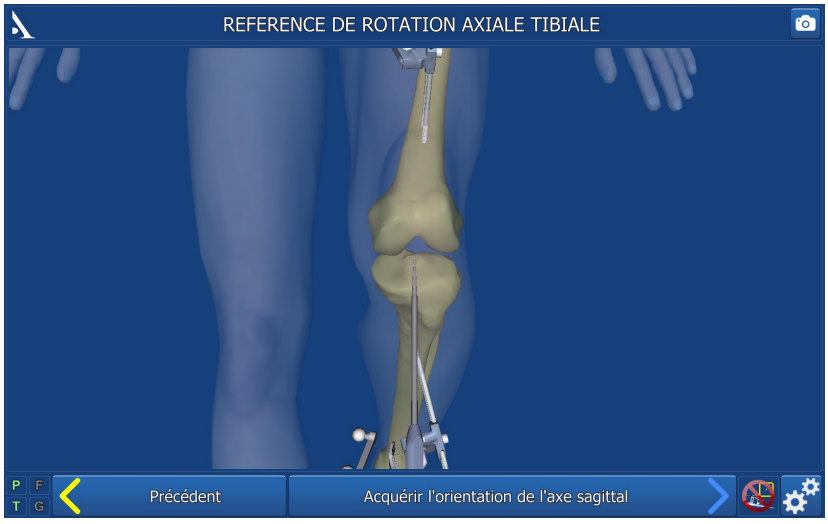
Place the pointer tip on the middle of the intercondylar eminence on the axis of the tibial shaft.

Press the trigger to confirm.

### Acquisition of tibial sagittal axis as rotational reference:

After the middle of the intercondylar eminence has been acquired, place the pointer tip on the intercondylar eminence and turn the body of the pointer.

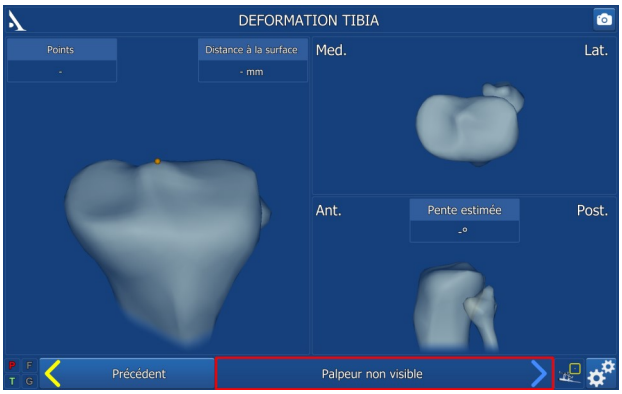
Once it corresponds to the desired sagittal plane orientation, confirm its position.



# TIBIAL ACQUISITION

## DIGITISATION OF ARTICULAR SURFACE

**The goal of this step is to digitize the damaged tibial joint surface and to acquire a reference point for the resection height.**





The acquisition process is initiated by pressing the trigger on the probe and it ends when the trigger is released. The system will beep to indicate the start and end of the acquisition.

Place the probe tip on the joint surface being acquired. Press and hold the trigger, then move the tip over the surface. The system will continuously acquire points and draw a contour map of the joint surface in real time. A counter in the upper-left corner shows how many points have been acquired.

Once at least 20 points have been acquired, the following information will be displayed:

- three white lines (that will be used to estimate posterior slope) and one green point on the anterior side of the tibia (will define reference point for the resection height) in the upper right corner
- the estimated slope (corresponding to the joint model on the screen) in the lower right corner
- the estimated anatomical slope is shown as a green line on the sagittal view. The three planes used in the calculation are also shown.

To verify the accuracy of the acquired points, move the probe tip over the joint surface without pressing the trigger. The system will show the accuracy of the contours in the 3D model:

- the probe will be green when the distance between the calculated and actual value is less than 1 mm
- the probe will be red when the distance between the calculated and actual value is more than 1 mm

If the contour accuracy is satisfactory, confirm this step and go to the next step.

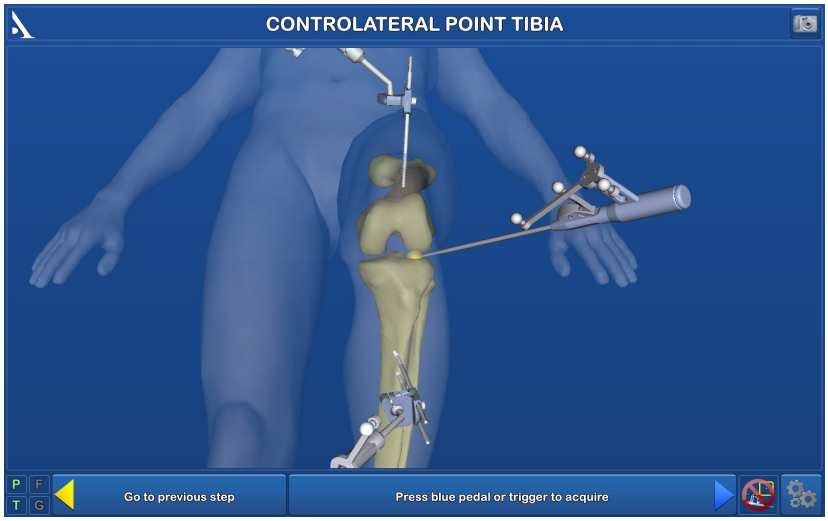
If the acquisition is not satisfactory, you can either:

- tap the yellow pedal to erase the last 20 acquired points
- press and hold the yellow pedal to erase all the points

## TIBIAL ACQUISITION: OPTIONAL-CONTRALATERAL POINT

### ACQUIRING A REFERENCE POINT ON THE HEALTHY SIDE (CONTRALATERAL POINT):

**This step is only needed if you chose to acquire a tibial reference point on the healthy side in the surgery-related options (see page 19).**

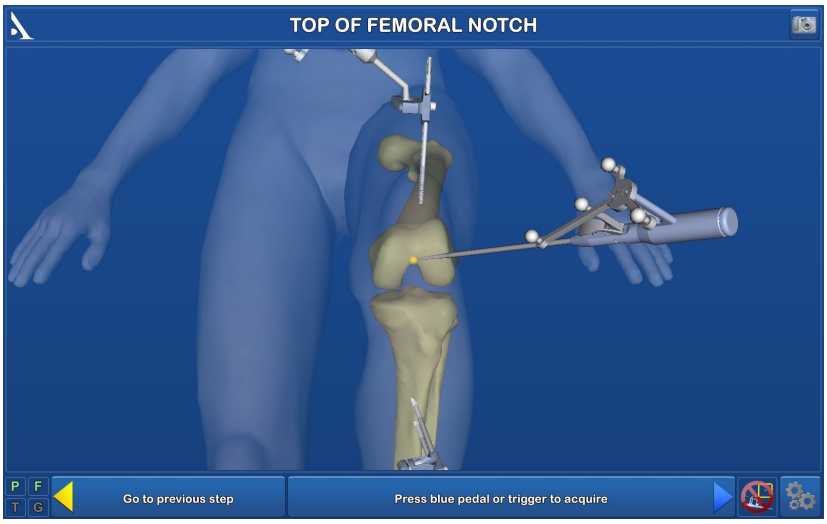



Place the probe on the chosen reference point on the healthy side and press the trigger or pedal.

This point will be displayed in the planning sequence (see page 35).

# FEMORAL ACQUISITION

## ACQUIRING A REFRENCE POINT ON THE TOP OF FEMORAL NOTCH

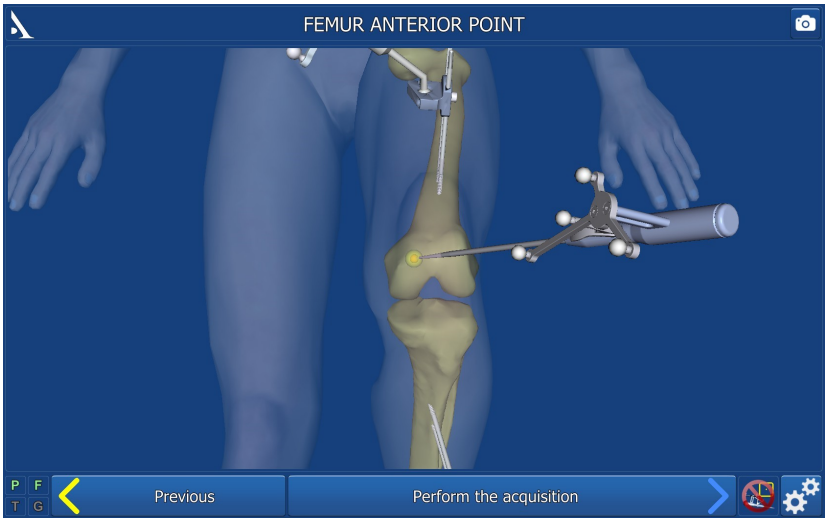



Place the pointer tip at the top of the femur's intercondylar notch and along the femoral shaft axis, then confirm.

## OPTIONAL: POINT ON ANTERIOR FEMUR (TIBIA AND FEMUR VERSION):

This acquisition is only performed if you chose to acquire a reference point on the femur's anterior cortex in the surgery preferences (see page 19).

Place the pointer on the chosen reference point and press the trigger or pedal.

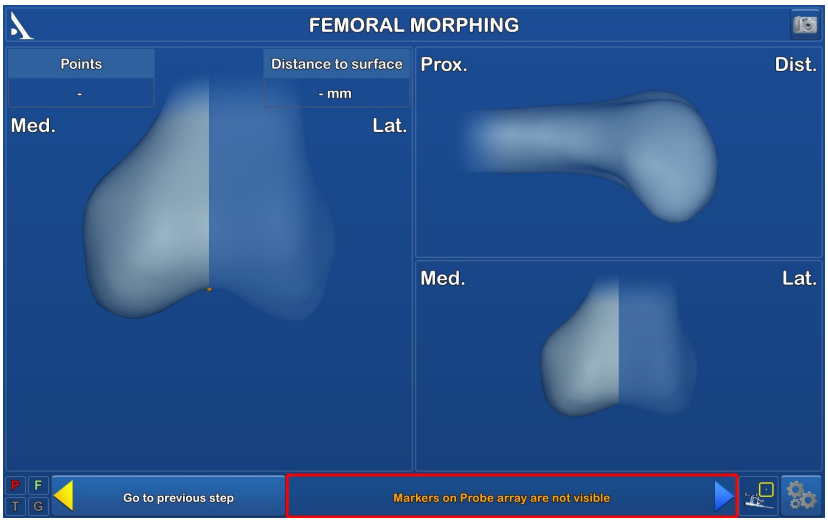



This point will be shown during navigation of the posterior femur cut (see page 45) and can be used to determine the size of the femoral component.

# FEMORAL ACQUISITION

## DIGITISATION OF FEMORAL ARTICULAR SURFACE

**The goals of this step are to acquire the femoral bone surface and verify its accuracy.**

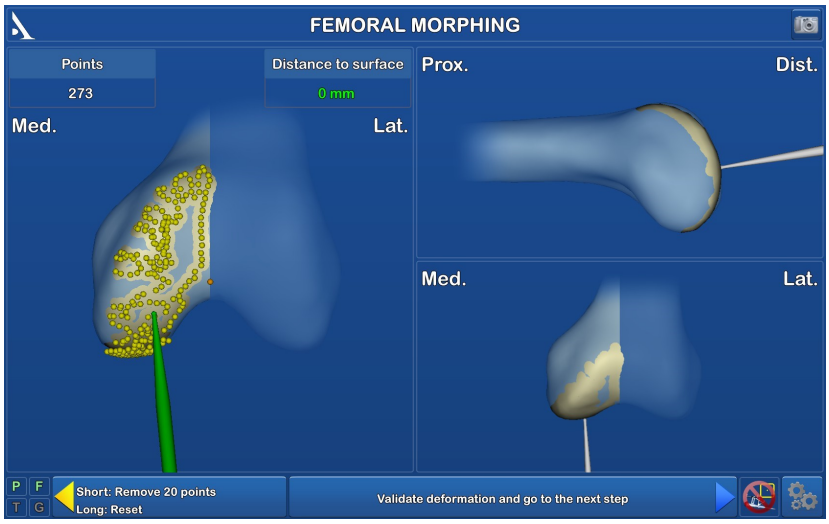



You will need to acquire points distally, on the anterior and posterior portions, on the epicondyle of the operated compartment and in the notch, if possible.

Place the probe tip on the bone surface. Press and hold the trigger then move the tip along the joint surface being acquired.

During the acquisition, the system will draw a contour map of the surface in real time. The number of points acquired is shown in the upper left corner.

To verify the accuracy of the acquired points, move the probe tip over the joint surface without pressing on the trigger.




The system will show the accuracy of the contours in the 3D model:

- the probe is green when the distance between the calculated and actual value is less than 1mm
- the probe will be red when the distance between the calculated and actual value is more than 1mm

If the contour accuracy is satisfactory, confirm this step and go to the next step.

If the acquisition is not satisfactory, you can either:

- tap the yellow pedal to erase the last 20 acquired points
- press and hold the yellow pedal to erase all the points

# HKA ACQUISITION

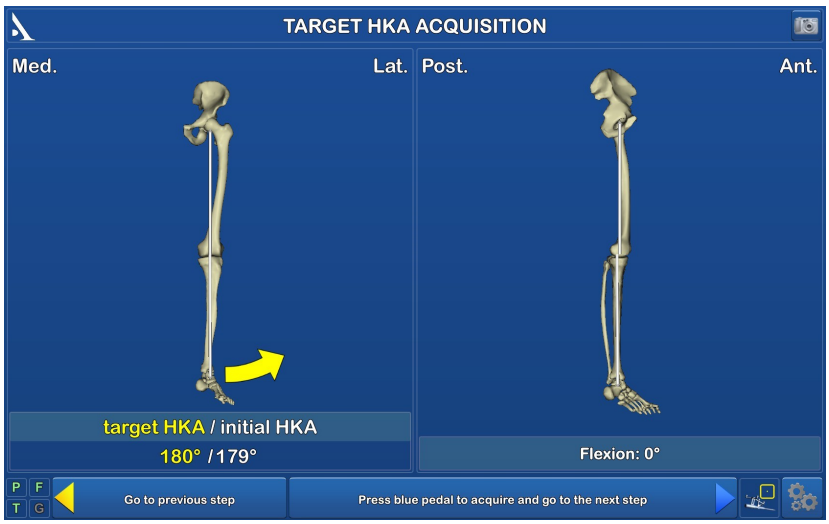
**The objective of these two steps is to acquire the initial (preoperative) HKA angle and the target HKA angle. The latter will be used to initialise the value of the tibial resection height in the "Planning" sequence.**

## ACQUISITION OF INITIAL HKA ANGLE

Extend the leg so that there is no load on it.

Press the blue pedal with the knee extended.


## ACQUISITION OF TARGET HKA ANGLE



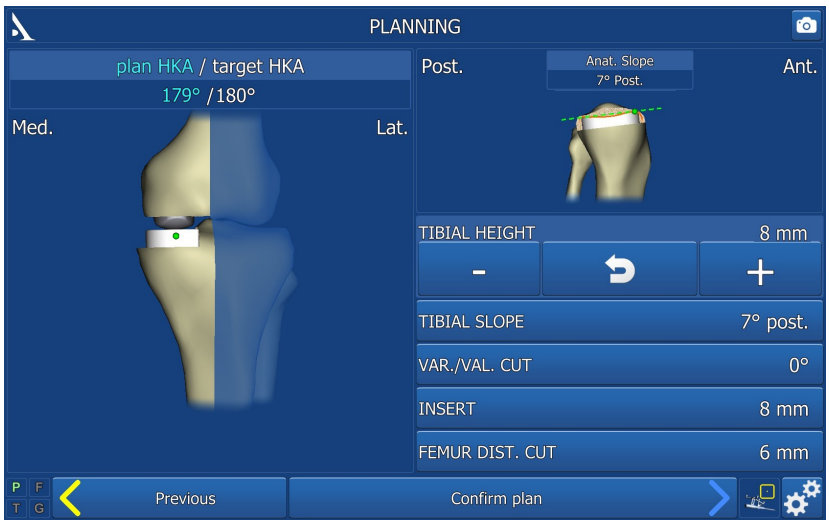

Extend the leg and apply a load to it until the target HKA angle is achieved.

Once the target angle is achieved, press the blue pedal with the knee extended.

## PLANNING

Before performing the tibial cut, the system displays the suggested tibial implant orientation and position, along with the distal femoral cut thickness.

These parameters can be adjusted using the +/- keys on the right side of the touch screen.



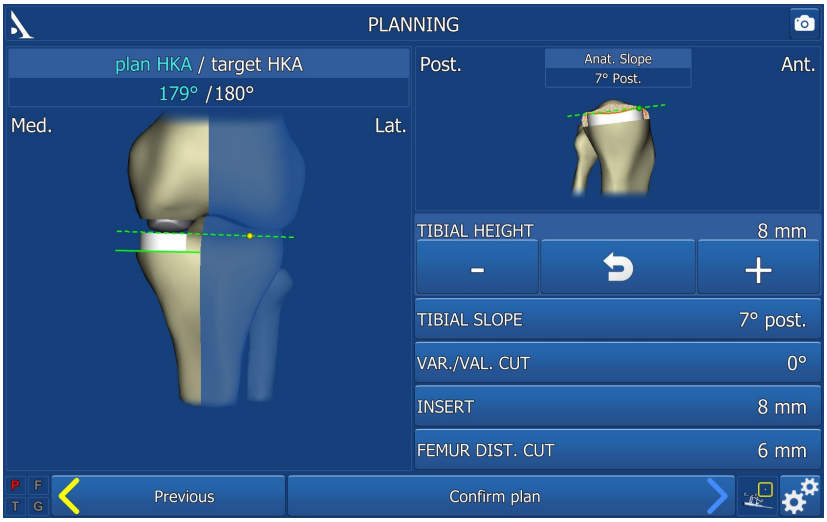

The following adjustments can be made:

- height of tibial cut (default value is the one needed to achieve the target HKA angle)
- posterior tibial slope (default value is the anatomical slope)
- varus/valgus of the tibial component (default value is (180 – target HKA angle)/2)
- thickness of tibial insert (default value is 8mm)
- thickness of distal femoral cut (default value is 6mm)

To return to the default value, press the middle key (white arrow). 

Validate the plan once the desired changes (if any) have been made

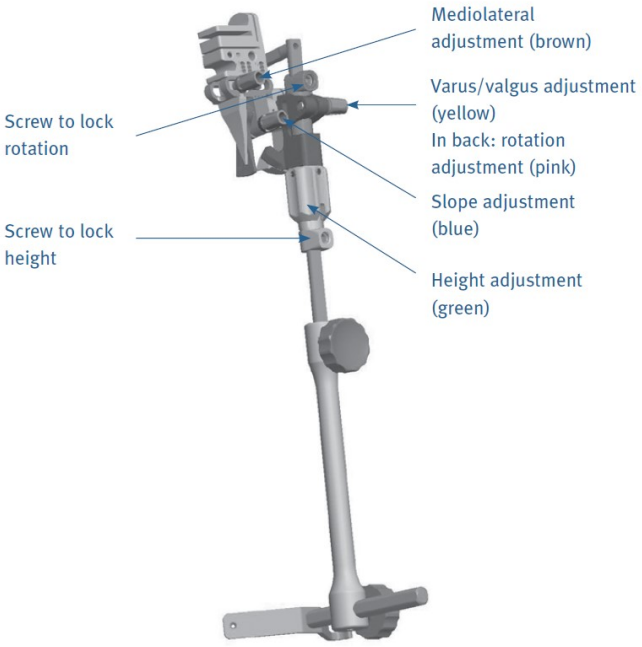
### PLANNING : OPTIONAL CONTROLATÉRAL POINT




**If the option for a reference point on the healthy side was selected, a green dotted line will be visible between the reference point on the healthy side (yellow) and the upper portion of the insert.**
**This is used to verify the resection height relative to the healthy side.**

# EXTRAMEDULLARY TIBIAL AIMING

## PREPARATION




Flex the knee at 90°.

Remove any medial osteophytes.

Put two retractors into place: one on the medial side of tibia and the other on the lateral side near the ACL insertion.

See pages 45 for assembly on back table.

Place the Array support for unicompartmental tibial aimer on the tibial resection guide and secure it with the H5 Screwdriver.

Assemble the extramedullary slider bar with the resection guide (right or left) and the aiming column.

Assemble the malleolar clamp on the aiming column.

Assemble the malleolar clamp on the aiming column.

**NOTE :** Pre-lock all locking and adjustment screws to ensure stability of the aim when positionning.

## PLACEMENT AND ADJUSTMENTS

Position the aiming frame.

Loosen the mediolateral screw of the tibial resection guide (brown knob).

Loosen the rotation adjustment screw (pink knob).

Set the mediolateral position (brown knob) and rotation (pink knob) of the sagittal cut; use the resection gauge as needed to pin point the location.

Lock the mediolateral and rotation adjustment screws.

Place the drill bush of the Extramedullary slide bar 0.5cm below the anterior edge of the tibia and centered over the intercondylar eminence (medial side of tibial tuberosity).

Secure the assembly using the collared Ø4 and 100mm K-wire and universal AO quick-connect adaptor.

**NOTE :** The position of the collared K-wire must be enough external (medial UKA) or internal (lateral UKA).

## TIBIAL CUT

**The goal of this step is to use the alignment device to position the navigated cut onto the planned cut.**


The colours on the screen adjustments correspond to the ones on the UNI SCORE® tibial resection guide; they identify which part of the resection guide must be adjusted (see page 56 for more details)

The following information is displayed below the dynamic views: Green: height, Yellow: varus/valgus and Blue: slope

The planned value is in blue on the screen. It will turn green when the value is within ± 1mm or ± 1° of the planned value.

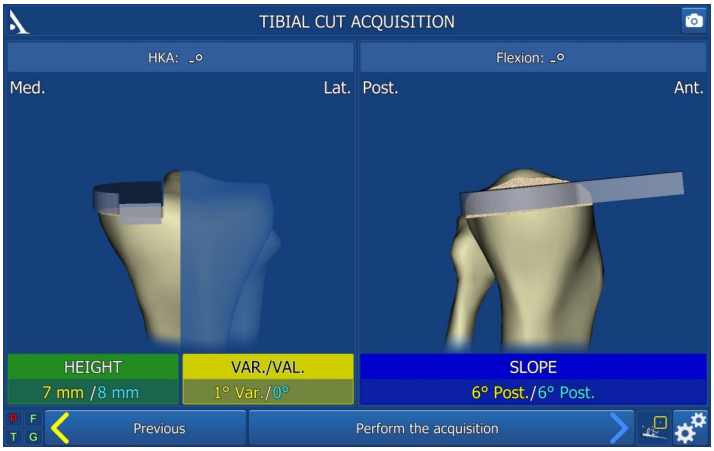
When the navigated values correspond to the planned values, secure the resection guide by placing the collared pin above the extramedullary slider bar. Next, insert two headless pins into the holes marked "0". The resection guide can be further stabilised with a headed pin (oblique axis).

Confirm the position (blue pedal, probe or touch screen).

Make the tibial cut using the narrow saw blade.


**NOTE:** The step can be confirmed even if the navigated values are ± 1mm or ± 1° of the planned value. A message will appear asking you to confirm that you want to go to the next step.

### ACQUISITION OF TIBIAL RESECTION PLANE




Place the G array on the Measuring Plate for Unicompartmental Tibial Resection.

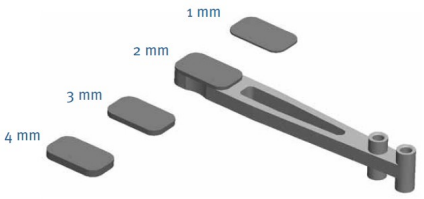
Position the plate on the tibial cut and confirm its position.

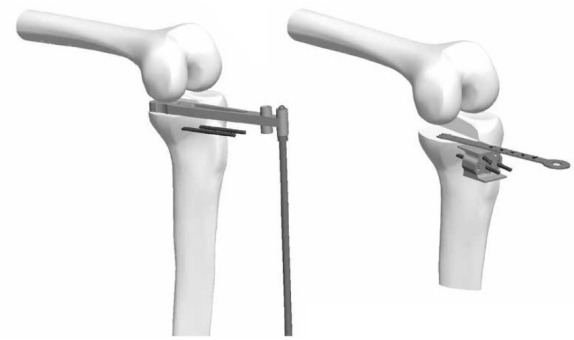
For each tibial parameter, the planned value is shown in blue and the actual value in yellow.

To go to the next step, press the blue pedal or the blue arrow at the bottom of the screen.

# VERIFICATION OF FLEXION AND EXTENSION GAPS

## VERIFICATION OF FLEXION GAPS



Flex the knee.

Check the gaps using the 8mm spacer that can be connected with the extramedullary alignment rods.

Add to the 8mm spacer wedges (thicknesses 1, 2, 3 or 4mm) to more precisely set the ligament tension and determine the height of the tibial insert.

If the anterior side of the baseplate lifts off during joint testing (insufficient slope), the tibial cut can be redone while increasing the tibial slope by 2° or 4° with the specific resection guide.

**NOTE:**

To increase the tibial slope by 2°, place the tibial recutting block on the K-wires at '0' (the 'slope 2°' marking must be visible). If the resection height also needs to be increased, set the recutting block on the K-wires at +2 or +4mm. Make the cut by pushing the blade in the upper side of the guide until it stops. To increase the tibial slope by 4°: place the tibial recutting block so the 'slope 4°' marking is visible.

## VERIFICATION OF EXTENSION GAPS

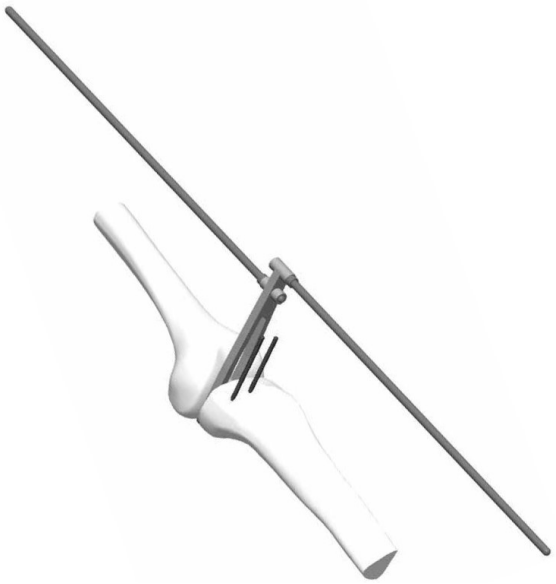
Extend the knee.

Use an electrocautery pen to mark the femur where the anterior edge of the tibial plateau is located when the knee is extended.

Insert the same spacer and the wedge used when the knee was flexed.

If the femoral condyle is significantly worn, 1 or 3mm wedge can be used to fill the distal condylar defect; the wedge is placed between the condyle and spacer.

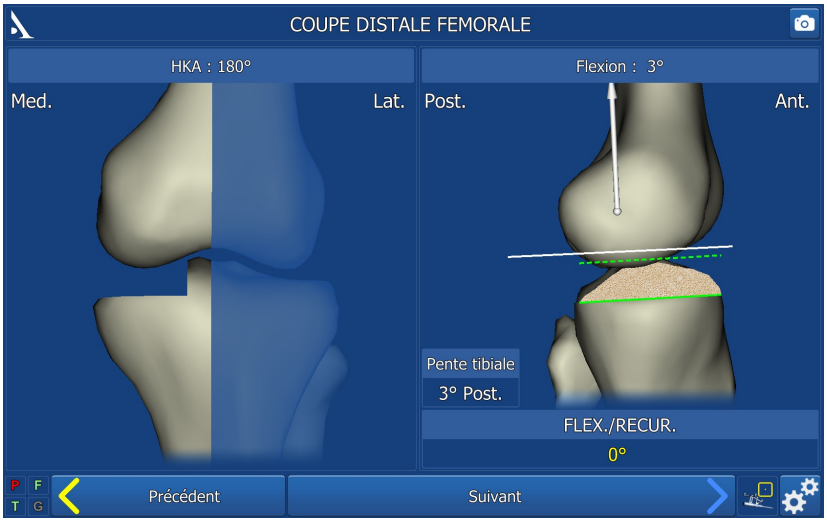
Once the extension and flexion gaps are satisfactorily balanced, remove the two headless pins.



# TIBIA ONLY PROTOCOL

## ACQUISITION OF DISTAL FEMORAL CUT

**The goal of this step is to see how much flexum/recurvatum is induced when the distal resection guide is placed on the tibial cut.**




The white line corresponds to the planned distal femoral cut.

The green dotted line is parallel to the tibial cut (green line).

To make sure the flexum/recurvatum are 0°, flex the leg until the white line and green dotted line overlap.

**NOTE:**

You can skip this step by tapping the blue pedal or clicking "Next".

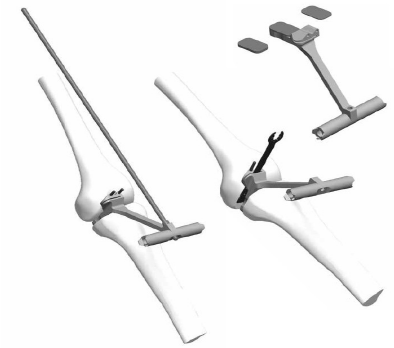
## DISTAL FEMORAL CUT IN EXTENSION

Extend the knee.

Place the distal resection guide (MED.L/LAT.R or MED.R/LAT.L) against the distal condyle and tibial cut.

Check the guide position with the extramedullary alignment rod.

Check the guide position relative to the mark on the anterior edge of the tibial plateau with the knee extended.



Insert two headless pins using a surgical motorised hand-piece and universal or AO quickconnect adapter.

Make the distal femoral cut.

Remove the two headless pins and the distal resection guide.

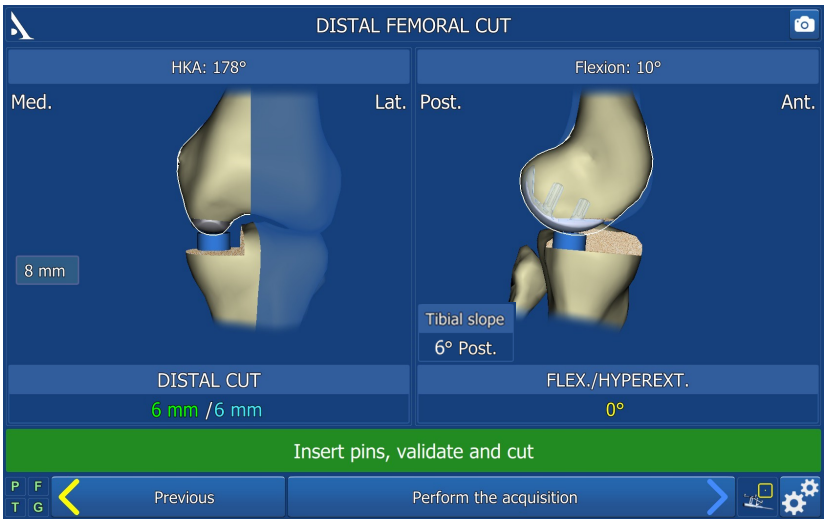
**NOTE:**

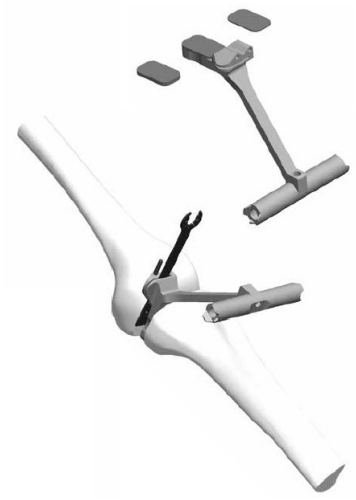
If a wedge was used during the verification of flexion and extension gaps, place it between the distal resection guide and the tibial cut to more precisely set the ligament tension, place it between the distal resection guide and the distal condyle to fill the distal condylar defect.

## TIBIA AND FEMUR PROTOCOL

### ACQUISITION OF DISTAL FEMORAL CUT

**The goal of this step is the use navigation to set the position of the distal resection guide.**



Extend the knee.

Place the distal resection guide (MED.L/LAT.R or MED.R/LAT.L) so it rests against the distal condyle and tibial cut.

**NOTE:**

If a wedge was used during the verification of flexion and extension gaps, place it between the distal resection guide and the tibial cut to more precisely set the ligament tension, place it between the distal resection guide and the distal condyle to fill the distal condylar defect.

Adjust the position of the distal resection guide based on the desired flexum/recurvatum.
When all the navigated values correspond to the planned values, insert two headless pins using a surgical motorised hand-piece and universal or AO quickconnect adapter.
Confirm the acquisition.

**NOTE:**

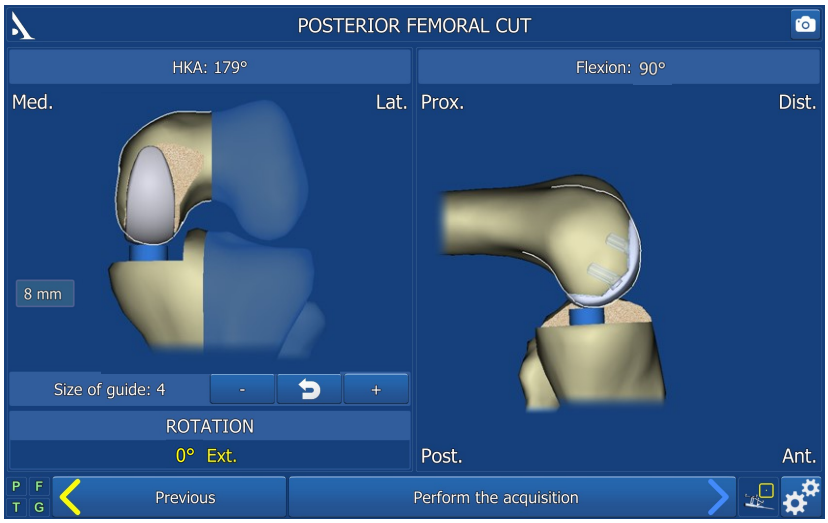
The step can be confirmed even if the navigated values are ± 1mm or ± 1° of the planned value. A message will appear asking you if you really want to go to the next step.

Make the distal femoral cut.
Remove the two headless pins and the distal resection guide.

## TIBIA AND FEMUR PROTOCOL

### POSTERIOR FEMORAL CUTS

**The goal of this step is to use navigation to set the position of the posterior femoral resection guide and the chamfer cut.**




Flex the knee to 90°.

Select the posterior femoral resection guide that matches the operated side (MED.L/LAT.R or MED.R/LAT.L). Use the H5 screwdriver to place it on the femoral resection guide clamp.

The rotation of the femoral component and the intra-articular space (for the operated compartment) are shown on the screen.

Determine the best femoral component size using the 7 resection guide templates and the following criteria:

- Make sure there is no anterior overhang by setting the camber; the component must not project beyond the mark that represents the tibia's anterior edge, otherwise the patella could be impinged,
- Make sure there is good mediolateral coverage and the component is as centred as possible,
- Ensure the component fully rests on the distal cut and the posterior condyle.

**NOTE:**
If you change the size of the femoral resection guide, this new size must be selected on the screen as it is not automatically detected by the workstation.

Insert the headless pins using a surgical motorised hand-piece and universal or AO quick-connect adapter.

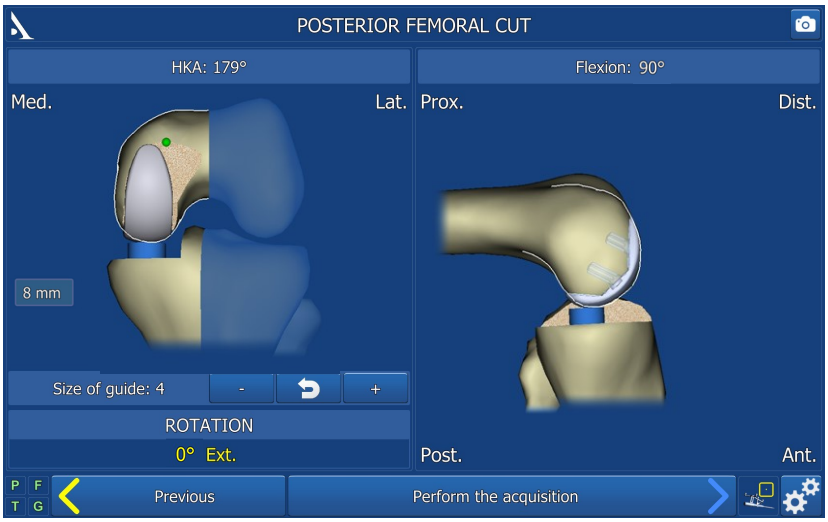
Make the posterior condylar cut (6 mm maximum) and then the chamfer cut.

## TIBIA AND FEMUR PROTOCOL

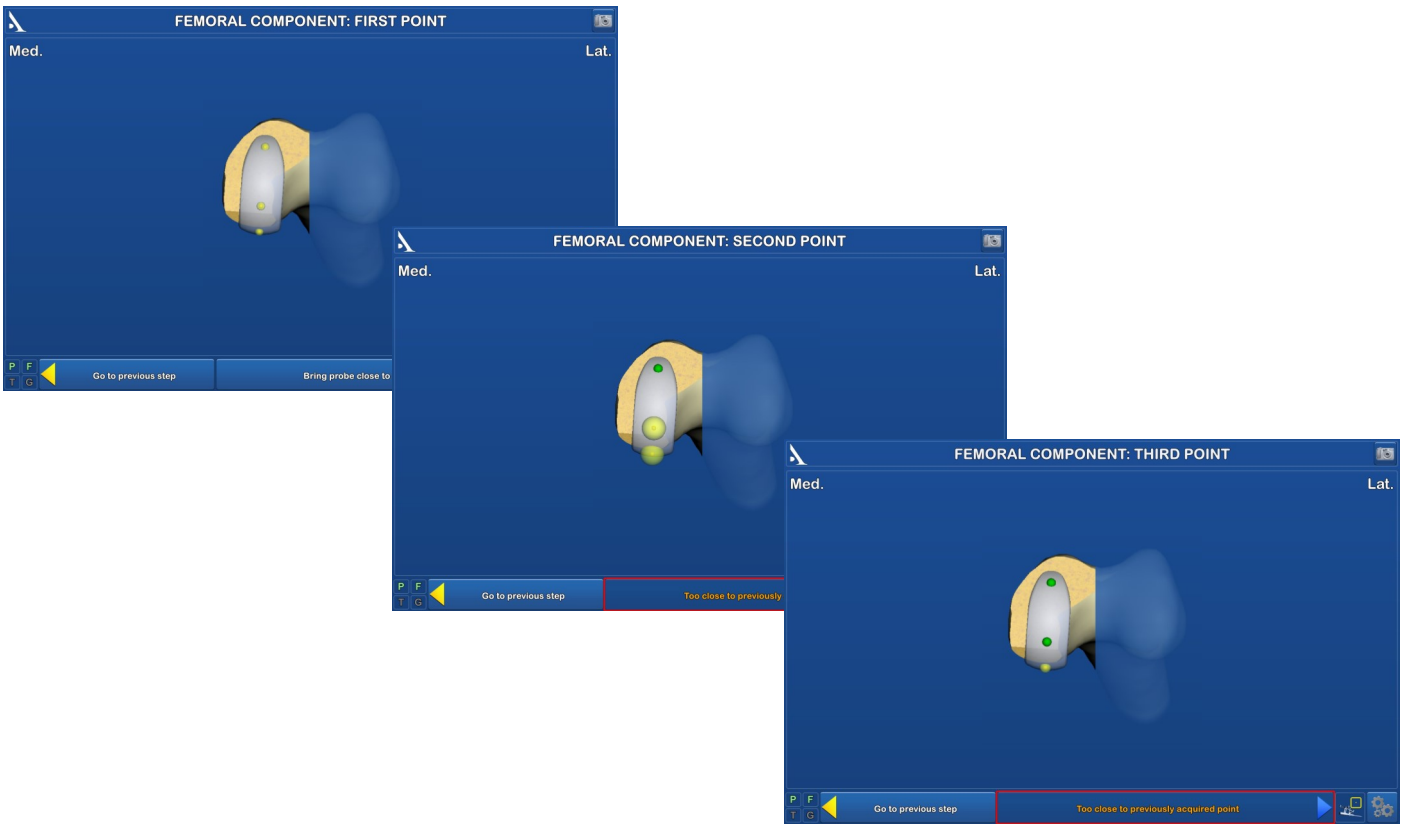
### ANTERIOR FEMORAL CORTEX OPTION:

**If the option to acquire a point on the anterior femoral cortex was selected, the point acquire is displayed in green during this step.**

**This will help you choose the size of the posterior femoral resection guide and chamfer cut.**



## ACQUISITION OF THE TRIAL FEMORAL COMPONENT




Use the femoral component holder to put the trial femoral component into place.

Place the probe tip in each of the three conical holes and confirm the position of each by pressing the blue pedal or trigger.

Make the peg holes using the femoral peg drill guide.

**NOTE:**

You can go to the next step (Surgery summary) without acquiring the trial femoral component. A message will appear asking you to confirm that you want to go to the next step. In this case, only the HKA value will be shown; the gaps will not.

## SURGERY SUMMARY

### FINAL POSITION OF TRIAL INSERT

Select the trial insert of the thickness shown on the screen.

On the tibial cut, place the trial FIXED insert for a FIXED baseplate (full-PE or metal tray).


Move the knee through a flexion/ extension cycle to assess its range of motion and stability.

The laxity in real time is shown on the screen, along with the HKA angle obtained with the selected insert thickness.

If the HKA angle need to be altered, place a trial insert of a different thickness on the tibial baseplate. Repeat the trials until the desired range of motion and stability have been achieved.

All navigation steps have been completed.

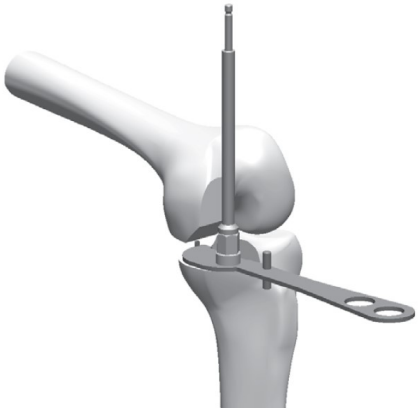
**REMINDER:**

Minimum thickness of the full-PE tibial implant: 8mm

Minimum thickness of fixed-bearing insert: 9mm

# PLACEMENT OF CEMENTLESS TIBIAL BASEPLATE FOR FIXED INSERT

## PRÉPARATION DU PLOT



Screw the drilling barrel onto the tibial positioning plate and tighten it using the drilling barrel wrench.

Place the entire assembly back on the tibial cut; hyperflexing the knee and externally rotating the tibia will make insertion easier.

Prepare the peg hole by drilling with the Ø 10mm drill bit until it stops.

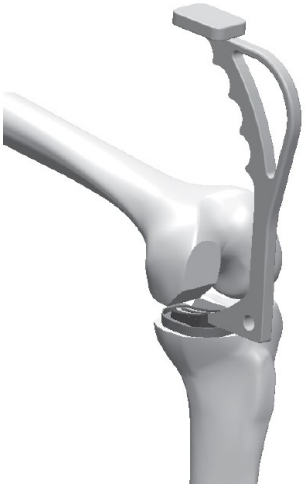
**NOTE:**

If it is difficult to tighten and loosen the drilling barrel on the plate, use the wrench for extension stem available in the instrumentation set.

## WITHOUT FIXATION SCREW

If no fixation screw is needed when using the cementless tibial baseplate for fixed insert.

- Impact the baseplate (without the insert) using the tibial baseplate impactor.
- Put the PEEK stopper into the hole on the top of the baseplate.
- Based on the thickness validated during the testing phase, select an insert of the same size as the baseplate.
- Slide in the posterior edge of the insert, making sure the attachment notches are completely clear.
- Impact the anterior edge of the insert with the tibial impactor.



**NOTE:**

The PEEK stopper is packed with the cementless tibial baseplate for fixed insert; it can be used with or without a fixation screw.

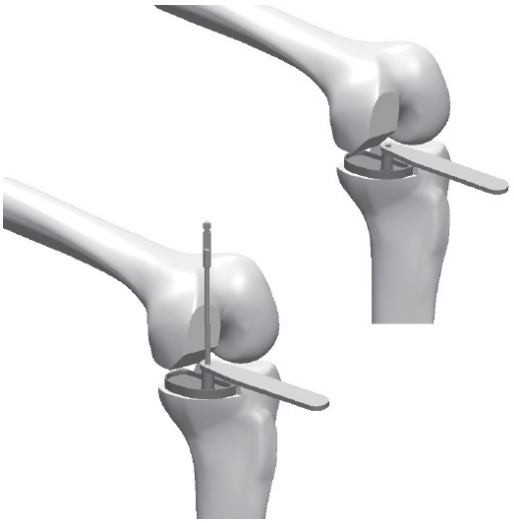
**NOTE:**

The stopper, insert and tibial baseplate can be assembled on the back table.

## PLACEMENT OF CEMENTLESS TIBIAL BASEPLATE FOR FIXED INSERT

### WITH FIXATION SCREW

If fixation screw is needed with the cementless tibial baseplate for fixed insert:

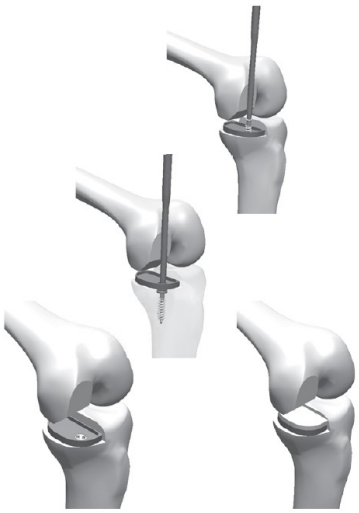


Put the drill guide for Ø3.2mm drill bit into place; the screw can be angled up to 18°.

Drill a hole using the 145mm long, Ø3.2mm drill bit.

Select a Ø6.5mm fixation screw that matches the hole's depth; screws are available in lengths of 16mm, 20mm and up to 55mm in 5-mm increments.

Use the screw holder to hold the screw and put it through the peg hole.
Tighten the screw with the H3.5 screwdriver until the bottom of the screw head touches the tibial baseplate.



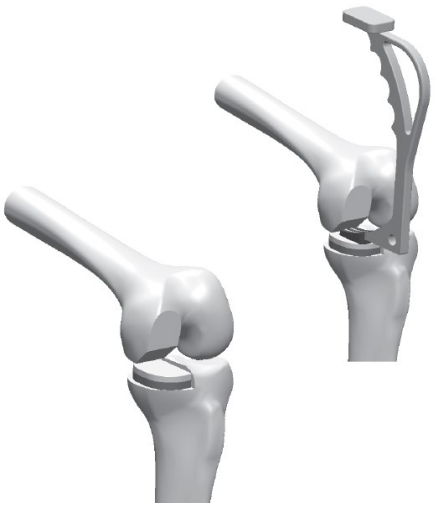
Put the PEEK stopper into the hole on the top of the baseplate.

Based on the thickness validated during the testing phase, select the insert of the same size as the baseplate. Slide in the posterior edge of the insert, making sure the attachment notches are completely clear.
Impact the anterior edge of the insert with the tibial impactor.

**NOTE:**

The PEEK stopper is packed with the cementless tibial baseplate for fixed insert; it can be used whether a screw is present or not.

## PLACEMENT OF CEMENTED TIBIAL BASEPLATE FOR FIXED INSERT



Impact the baseplate using the tibial baseplate impactor.

Based on the thickness validated during the testing phase, select an insert of the same size as the baseplate. Slide in the posterior edge of the insert, making sure the attachment notches are completely clear.

Impact the anterior edge of the insert with the tibial impactor.

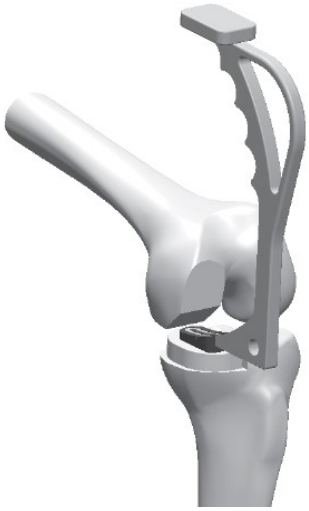
The insert and baseplate can either be assembled on the back table, or after the baseplate has been cemented in place; make sure the cement is dry and the attachment area is completely clear.

**NOTE:**

Follow the instructions provided with the surgical cement.

## PLACEMENT OF FULL-PE TIBIAL IMPLANT

Impact the full-PE tibial implant of the same size and thickness as that validated during the testing phase.



**NOTE:**

Follow the instructions provided with the surgical cement.

## PLACEMENT OF FINAL FEMORAL COMPONENT

Put the femoral component (cemented or cementless) in its holder.

Flex the knee 90° and impact the component.

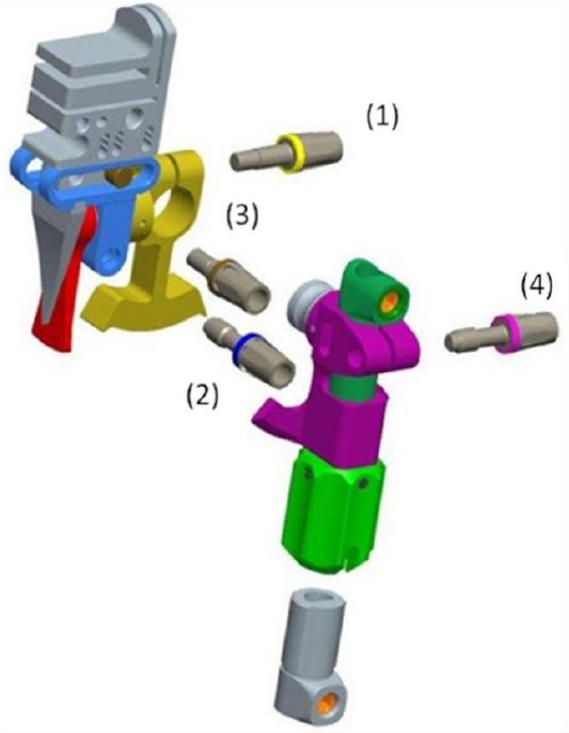
Finish impacting with the femoral component impactor.

**NOTE:**

Follow the instructions provided with the surgical cement.

## ASSEMBLY OF TIBIAL RESECTION GUIDE

### MEDIAL LEFT / LATERAL RIGHT




Fully loosen the yellow screw (1).

Remove the tibial resection guide from its support.

Flip the tibial resection guide 180° and secure it to its support (on the right), then put the yellow screw back into place (1).

Loosen the blue screw (2) and put it back on the anterior side of the guide (accessible to surgeon).

Loosen the brown screw (3) and put it back on the anterior side of the guide (accessible to surgeon).

Loosen the pink screw (4) and put it back on the same side as the yellow screw (1).

### MEDIAL RIGHT / LATERAL LEFT

Fully loosen the yellow screw (1).

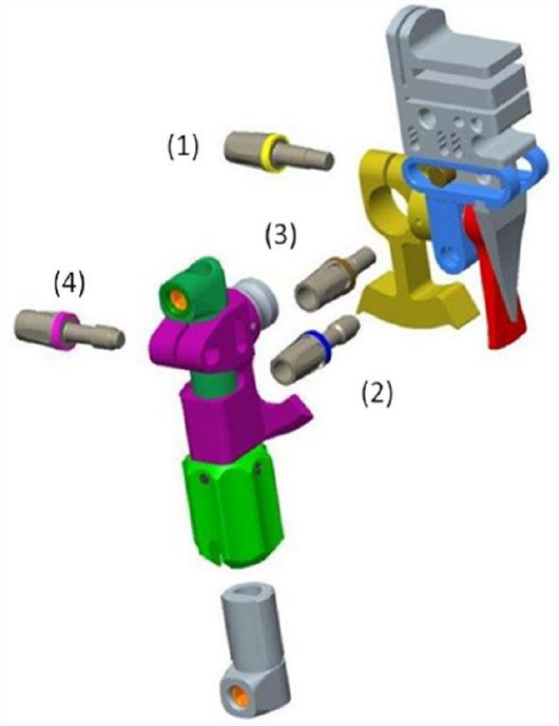
Remove the tibial resection guide from its support.

Flip the tibial resection guide 180° and secure it to its support (on the left), then put the yellow screw back into place (1).

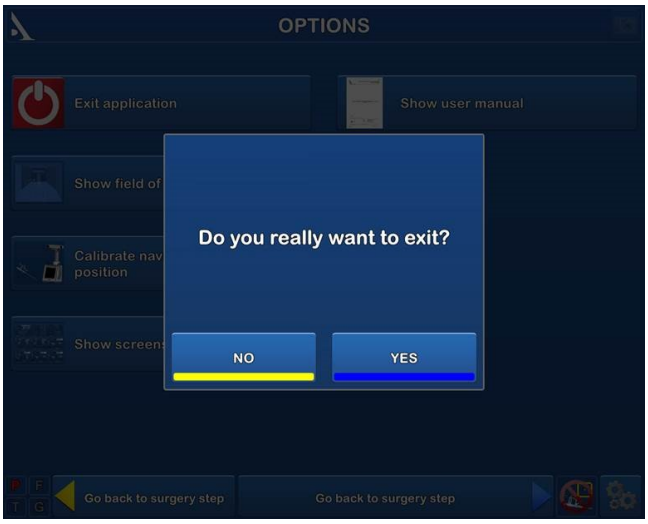
Loosen the blue screw (2) and put it back on the anterior side of the guide (accessible to surgeon).

Loosen the brown screw (3) and put it back on the anterior side of the guide (accessible to surgeon).

Loosen the pink screw (4) and put it back on the same side as the yellow screw (1).



## SAVING THE SURGERY REPORT




Press the button to exit the application:

- It is available immediately after the last step of the «Post-operative alignment» procedure or
- it can be found on the «Options» page at any point during the procedure.

The message «Do you really want to exit?» will appear. Press «Yes» to confi rm.

The message «Copy report to USB drive?» will appear.

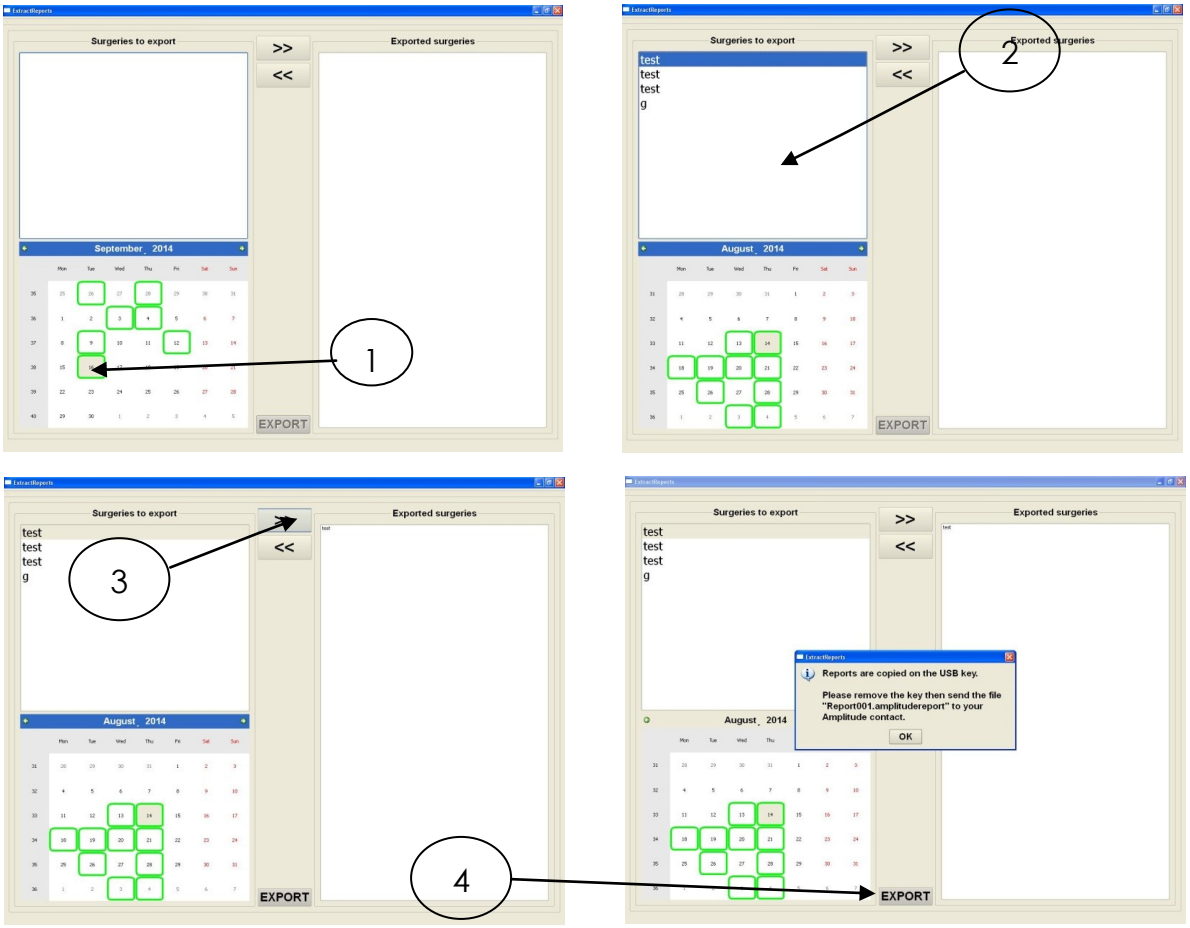
Indicate whether you want to create a backup copy of the surgery report by pressing the «Yes» or «No» button.

A message will appear asking you to insert a USB drive. Insert the USB drive in the slot on the screen (see V2 and V3 workstation descriptions for slot locations) and confirm that you would like to backup the report.


In the surgery report, a file named «report.html» contains the following elements:

- Patient name and surgeon name
- Bone contour maps
- Implant planning pages
- Bone resection navigation pages
- Postoperative validation pages

## OPENING A SAVED SURGERY REPORT




If a saved surgery report is not transferred to a USB drive, it can still be retrieved at a later date.

- Turn on the AMPLIVISION® workstation.
- When the AMPLIVISION® welcome screen appears, press the  button on the lower right of the screen.
- The message «Do you want to extract patient data?» will appear. Press «OK».
- A calendar will appear. The dates on which surgery reports were saved will be highlighted in green. Select the dates corresponding to the procedure(s). For each date, AMPLIVISION® lists available reports in the «Surgeries to export» window.
- Use the touch screen to select the reports to be exported and then press the button to move them to the «Exported surgeries» window.
- Insert the USB drive and press the button to copy these reports to it. A message will appear when the operation is complete.

To ensure confidentiality, the exported reports are saved in an encrypted file format, «Report001.amplitudereport» on the USB drive. Contact AMPLITUDE to obtain access to the desired report.

## STORING THE WORKSTATION

Press the button  at the lower right corner of the screen.

Confirm that you want to shut down the system.

The system will shut down.

Disconnect the power cord and wind it around the power cord holder located on the back of the workstation.

Disconnect the pedal.

Set the camera head in neutral position (maximum height, no rotation).

Clean the workstation and pedal according to the instructions in the user manual.

Lock the adjustable tower: lower the locking handle and fi rmly push down on it to completely lower the tower.

Put the workstation back into the shipping trunk.

Place the pedal and covers in the shipping trunk.

Lock the four latches on the shipping trunk.

## INSTRUMENTATION SET

In addition to the UNI SCORE® instrumentation, the following are required:

- AMPLIVISION® Navigation Station,
- Sterile, single-use markers (14 per pack),
- The **AMPLIVISION® Navigation Set** (ref. : 2-0299923).

### Stérile markers (ref. 3-0400902) :

The arrays must be equipped with markers to be visible to the camera. These markers are attached through the nipples on the array (3 for the F, T and G arrays and 4 for the pointer P).

### Single-use AMPLIVISION® Conical Pins (ref. 2-0252200) :

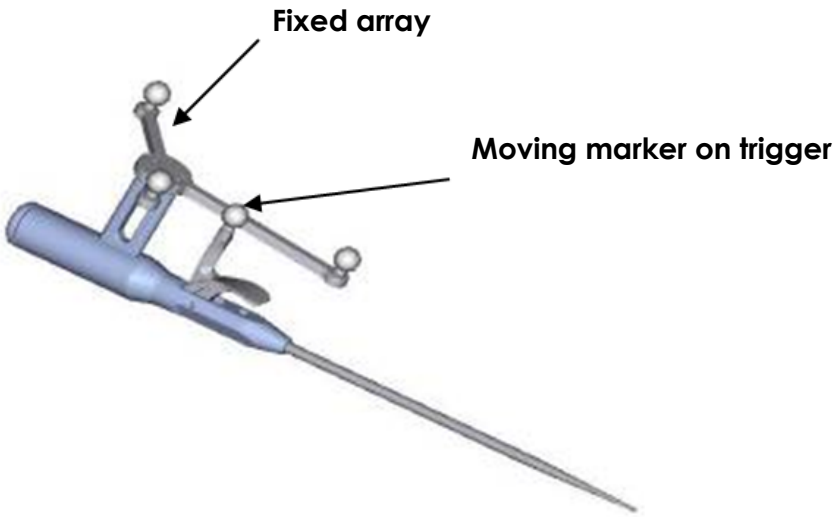
Single-use, Ø4 diameter, 150-mm long Conical Pins are available in packs of 4. These Conical Pins will be inserted into the femur and tibia; the array supports will be mounted on the inserted Conical Pins.

## INSTRUMENTATION SET

### INSTRUMENTS

**Probe knee navigation:**

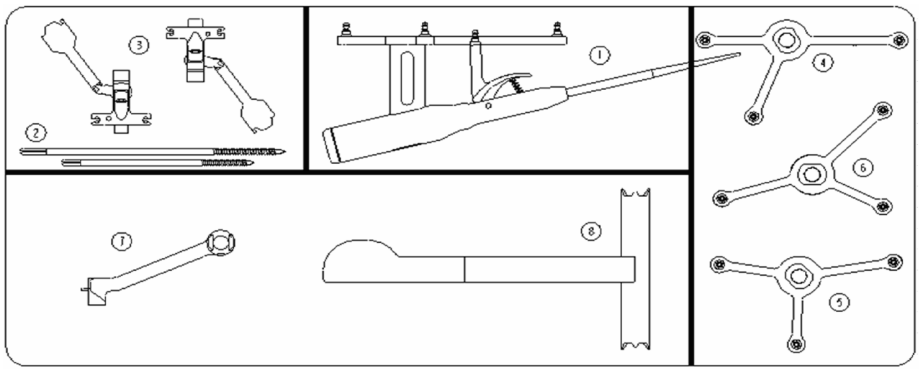
This instrument is used to acquire specific points and areas on the patient's anatomical structures. It is also used to remotely control certain active elements on the screen. The pointer must be fitted with four markers, one of them being on the trigger.




**Measuring Plate for Unicompartmental Tibial Resection:**

The measuring plate for unicompartmental tibial cut have 2 connection ports for the G-array (one of each side). The array can only be clipped into an instrument's connection port in a single position and orientation.

## AMPLIVISION® NAVIGATION SET 2-0299923



| Item | Name | Product No | Qty |
|---|---|---|---|
| **1** | Probe knee navigation | 2-0215700 | 1 |
| **2** | Conical Threaded Pins AMPLIVISION Ø4 length 150mm | 2-0235500 | 4 |
| **2** | Conical Threaded Pins AMPLIVISION Ø4 length 100mm | 2-0235900 | 4 |
| **3** | Inclined fixation system, navigation geometry | 2-0117200 | 2 |
| **4** | T array, tibia navigation | 2-0215800 | 1 |
| **5** | F array, femur navigation | 2-0117400 | 1 |
| **6** | G array, Instrumentation navigation | 2-0117500 | 1 |
| **7** | Array support for unicompartmental tibial aimer | 2-0220800 | 1 |
| **8** | Measuring Plate for Unicompartmental Tibial Resection | 2-0220900 | 1 |

# NOTES

# NOTES

# NOTES

# NOTES

Reference : TO.G.GB.031/2.1

AMPLITUDE

**Service Clients-France :**
Porte du Grand Lyon,
01700 Neyron, France
Tel. : +33 (0)4 37 85 19 19
Fax : +33 (0)4 37 85 19 18
E-mail : amplitude@amplitude-ortho.com

**Customer Service-Export :**
11, cours Jacques Offenbach. ZA Mozart 2,
26000 Valence, France
Tel. : +33 (0)4 75 41 87 41
Fax : +33 (0)4 75 41 87 42
E-mail : amplitude@amplitude-ortho.com

**Internet : www.amplitude-ortho.com**