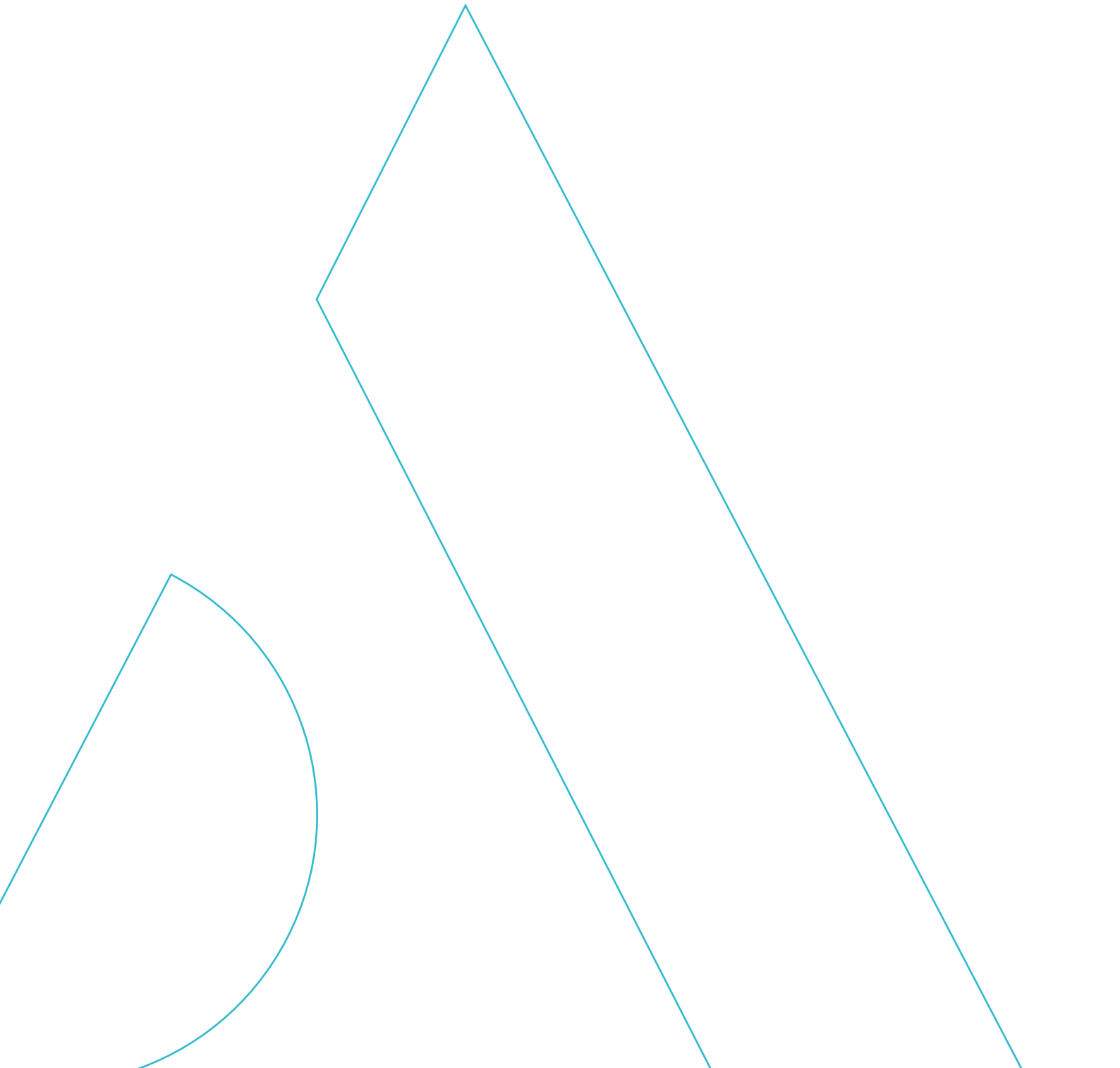
andy

amplitude


# Surgical Technique

## Total knee replacement surgical technique with andy robotic system



# Summary

# Introduction

- This Surgical Technique Supplement describes the use of the andy robotic system for implanting Amplitude's total knee arthroplasty (TKA) systems.

- The andy - surgical robot is a system used to perform tibial resection, distal femoral resection and 4-in-1 femoral resections with a robotic saw.
  Each of the femoral cuts can be performed with an automated mode during which the robot's blade will follow a defined resection path under surgeon supervision.
  The tibial and any other cut can be performed by using the joystick of the robotic arm.

- This surgical technique replaces the following paragraphs from conventional surgical techniques:

- For SCORE TKA with conventional 4-in-1 instrumentation: **TO.G.009**
  > The paragraphs on the distal femoral cut
  > Paragraphs on the tibial alignment
  > The paragraphs on the tibial cut
  > The paragraphs on the 4-in-1 Femoral Resection
  > The paragraphs on the extension & flexion gap measurement, the femoral sizing, the trials.

- For the SCORE II TKA with conventional 4-in-1 instrumentation: **TO.G.012** and **TO.G.013 and TO.G052**
  > The paragraphs on the distal femoral cut
  > The paragraphs on tibial alignment
  > The paragraphs on the tibial cut
  > The paragraphs on the 4-in-1 Femoral Resection
  > The paragraphs on the extension & flexion gap measurement, the femoral sizing, the trials.

- For ANATOMIC TKA with conventional 4-in-1 instrumentation: **TO.G.002**
  > The paragraphs on the distal femoral cut
  > The paragraphs on the tibial alignment
  > The paragraphs on the tibial cut
  > The paragraphs on the 4-in-1 Femoral Resection
  > The paragraphs on the extension & flexion gap measurement, the femoral sizing, the trials.

- For TRAX CR TKA with conventional 4-in-1 instrumentation: **TO.G.041**
  > The paragraphs on the distal femoral resection
  > The paragraphs on the tibial sytem
  > The paragraphs on the tibial resection
  > The paragraphs on the 4-in-1 Femoral Resection
  > The paragraphs on the extension & flexion gap measurement, the femoral sizing, the trials.

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

# System description

## andy - surgical robot


The robotic system is composed of:

- The robotic arm: andy - surgical robot
- The navigation unit: amplivision V4
- The robotic navigation software: AKN V4
- The dedicated and standard andy instrumentation: including the robotic oscillating saw attachment
- Accessories: navigation and robotic footswitchs

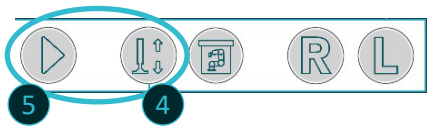
andy is composed of a cart placed on wheels and a 7-axis active arm.
The navigation unit and software work in a duo with the robotic arm. The latter is rolled next to the operated leg, facing the amplivision V4's camera during the bone resection steps. The robotic arm is covered with a sterile drape. A sterile reusable robotic oscillating saw attachment is assembled to the arm.

# Set up summary

## Robot initialization and set-up

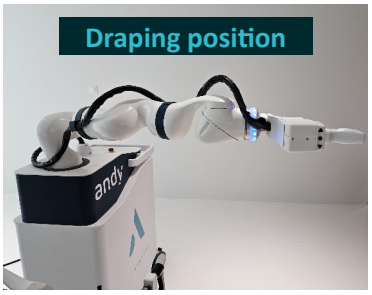
### 1. System Start-up and initialization

1. Plug-in and start Amplivision
2. Plug-in andy and connect it to Amplivision
3. Place key in vertical position and start robot (button «ON»)
4. Put the stabilizers on
5. Launch robot initialization by pressing «Play» on the cart until reaching draping position




### 2. Drape positionning

The robot draping position is obtained at the end of the start-up procedure.




### 3. Robot Left/Right Position

Press the Left or Right button (accordingly to the operated leg) until robotic arm position is final.

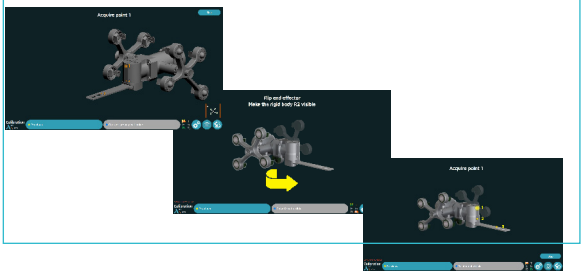

### 4. Saw attachment assembly

At this step, the sterile drape is placed. Assemble the saw attachment on the robotic arm.

### 5. Saw blade calibration

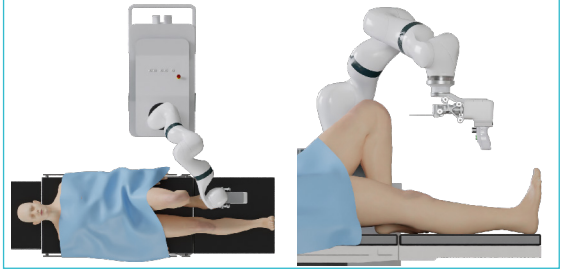
Make sure the saw attachment arrays are visible by the camera and proceed with saw blade calibration.

1. With the pointer register the 3 interest points visible on screen
2. With the hand guiding button, turn the saw attachment around until the second array is visible by the Amplivision
3. Register the 3 interest points



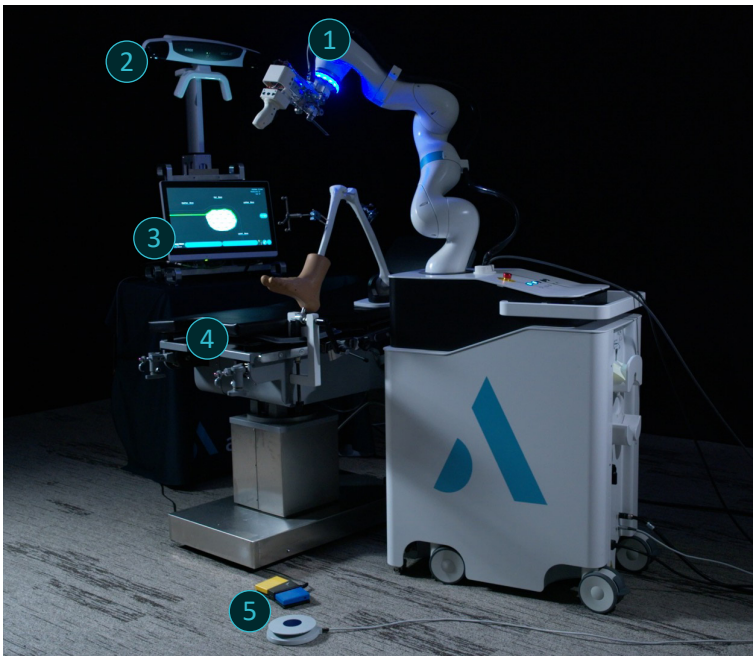
### 6. System Position for resection steps

- Once again, press the Left or Right button (accordingly to the operated leg) until robotic arm position is final.
- Position the robot next to the operated leg (as indicated on screen).
- Put the robot's stabilizers to avoid any movement of the cart during resections.



# System overview

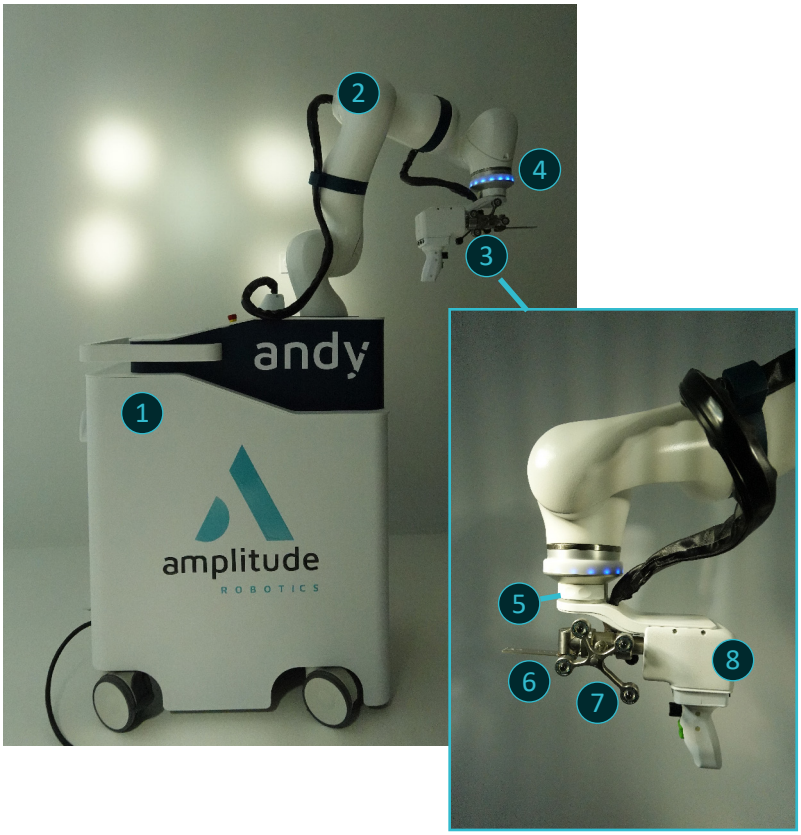
## Main components and set up




| General settings | |
|---|---|
| 1 | **andy - surgical robot** |
| 2 | **Amplivision**<br>*Navigation Unit* |
| 3 | **Robotic navigation software**<br>*AKN V4 must be installed for robot use* |
| 4 | **Operating table:**<br>*Robot next to operated leg* |
| 5 | **andy footswitch**<br>*Navigation and robot* |

**NOTE**

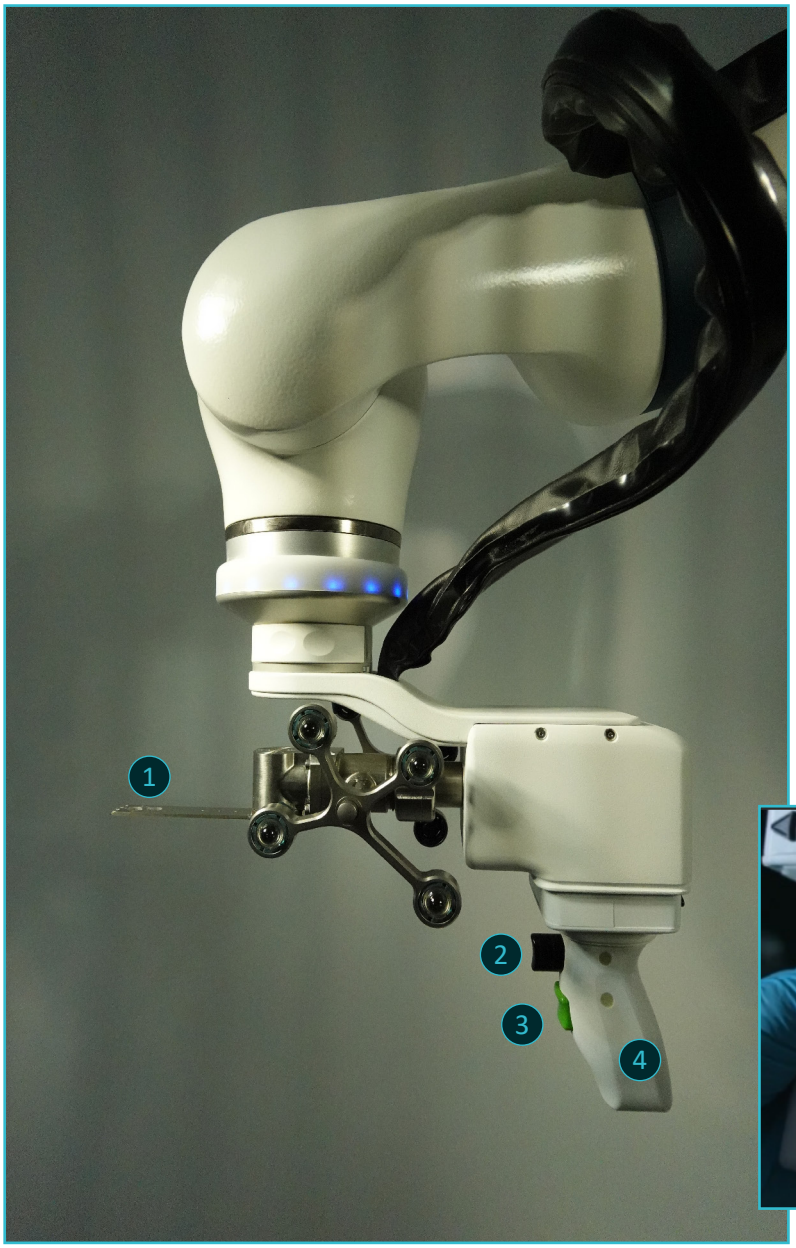
The robotic arm system is designed to be used on its own. It cannot be only be connected to Amplitude approved devices.

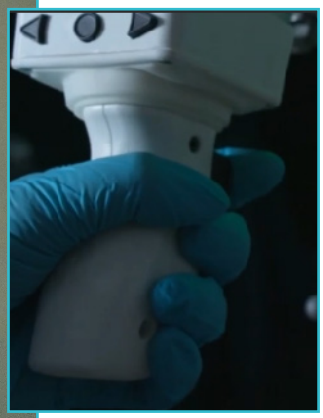



| andy - robotic arm | |
|---|---|
| 1 | **Robotic cart**<br>*movable - on wheels* |
| 2 | **Active robotic arm**<br>*7 axis* |
| 3 | **Oscillating saw attachment**<br>*Sterile and reusable - Thick sawblade* |
| 4 | **LED indicator** |
| 5 | **Handguiding button**<br>*Robotic arm displacement at any step of the procedure* |
| 6 | **Sawblade**<br>*Thickness 2mm* |
| 7 | **Motor array**<br>*Projections resistant position markers* |
| 8 | **Joystick**<br>*Motor control and displacement during resections* |

# System overview

## Main components and set up



**Joystick and saw attachment**

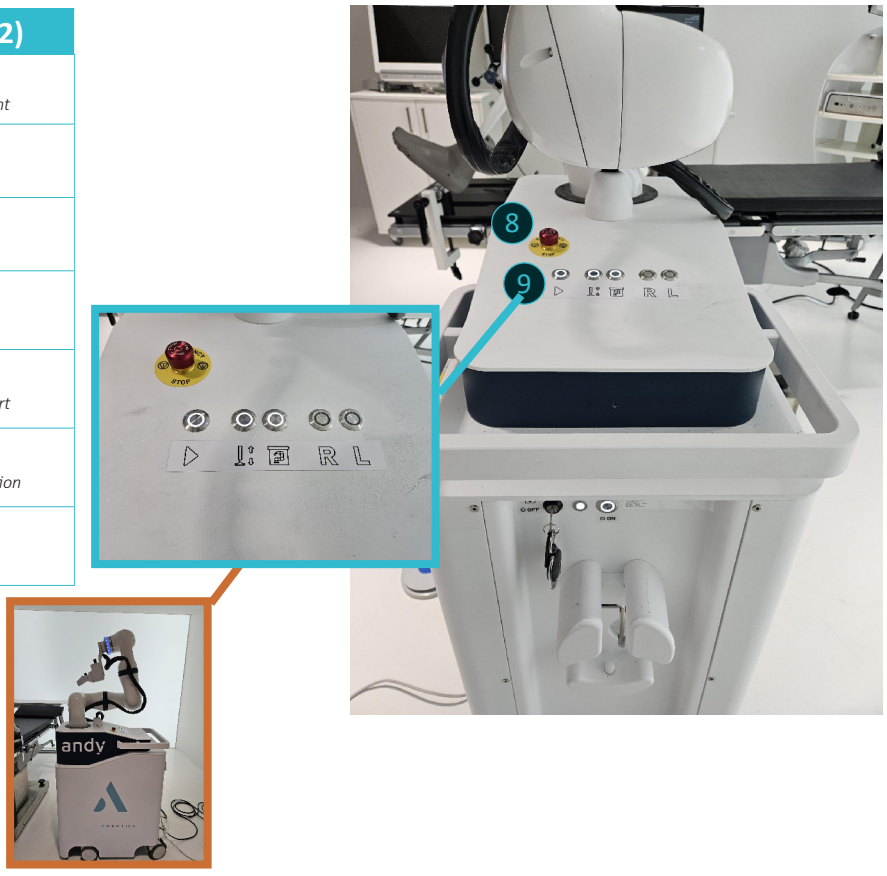
1. **Oscillating sawblade**
   *Thickness 2mm*
2. **Sawblade activating trigger**
   *Progressive trigger active when plane alignement is completed*
3. **Alignment button**
   *Keep pressed for sawblade alignment on plane*
4. **Handle**
   *Active when plane alignement is completed*
5. **Boundaries buttons**
   *Cutting boundaries modification*

# System overview

## Robotic cart

| andy - robotic cart (1/2) | |
|---|---|
| 1 | **Start-up**<br>*Two sub-elements* |
| 2 | **Key-switch**<br>*«ON» Position* |
| 3 | **Power indicator**<br>*Press «ON» once key is on «ON» position* |
| 4 | **Connexion system** |
| 5 | **Amplivision connexion plug**<br>*Connect it once the Amplivision is started* |
| 6 | **Power cable plug**<br>*Plug and play easy start-up* |
| 7 | **Footswitch cable plug**<br>*Alignement and automated resection footswitch* |


| andy - robotic cart (2/2) | |
|---|---|
| 8 | **Emergency button**<br>*Stops robot immediatly at any moment* |
| 9 | **Control pannel**<br>*Accessible to practitionner nurse* |
| 10 | **Initialization button**<br>*Calibration and draping position* |
| 11 | **Stabilizers**<br>*Place or remove stabilizers* |
| 12 | **Storage position button**<br>*Mandatory position for robot transport* |
| 13 | **Operated leg side**<br>*Left leg or Right leg robotic arm's position* |
| 14 | **Robot storage position**<br>*Storage and transport position* |

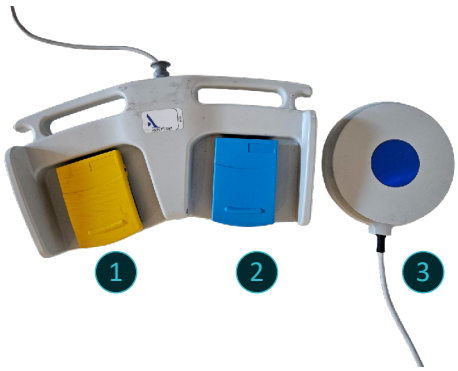


# System overview

## Navigation unit: Amplivision

| Amplivision navigation unit | |
|---|---|
| 1 | **HD Camera**<br>*Position tracking* |
| 2 | **Touch screen** |
| 3 | **Storage position** |
| 4 | **Power cable**<br>*Plug & play system: easy start-up* |
| 5 | **Robot connexion plug**<br>*Connexion cable between andy and amplivision* |
| 6 | **Amplivision footswitch plug**<br>*Connexion cable between for amplivision amplivision footswit-ch* |


## Accessories



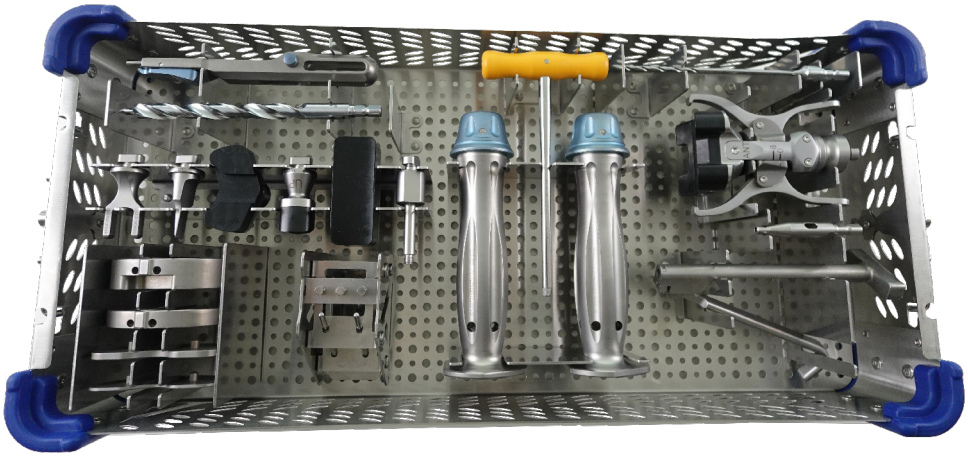

| andy - accessories | |
|---|---|
| 1 | **Amplivision amplivision footswitch**<br>*Previous step* |
| 2 | **Amplivision amplivision footswitch**<br>*Next step* |
| 3 | **andy** footswitch<br>Blade resection plane alignement<br>*Automatic femoral resections* |

# System overview

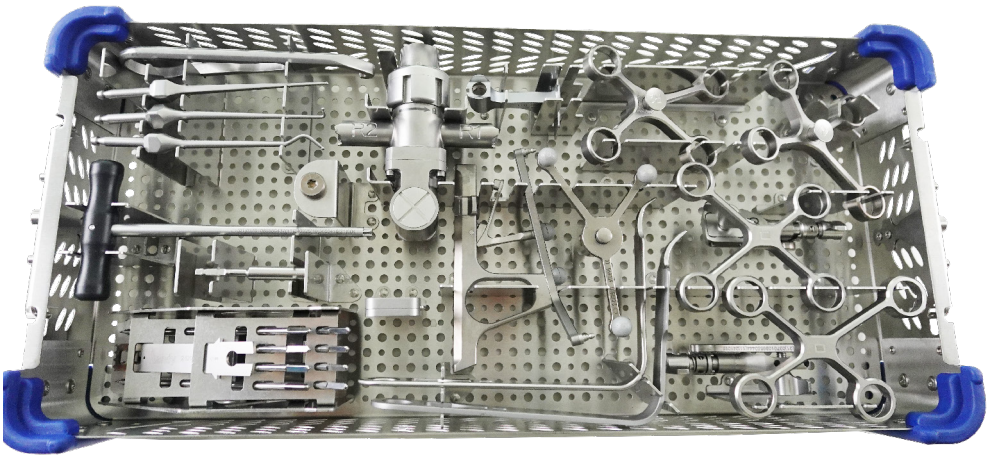
## Specific robotic instrument trays

Andy - Surgical robot is provided with two specific reusable instrument trays:

- andy universal: 2-02999161



- andy dedicated: 2-02999162



## Oscillating sawblade

- **Standard non-sterile sawblade for robot - 2-1202001**

  The sawblade is 2 mm thick.

# System overview

## Disposables

### Projection Resistant Sterile Markers - 2-0301000

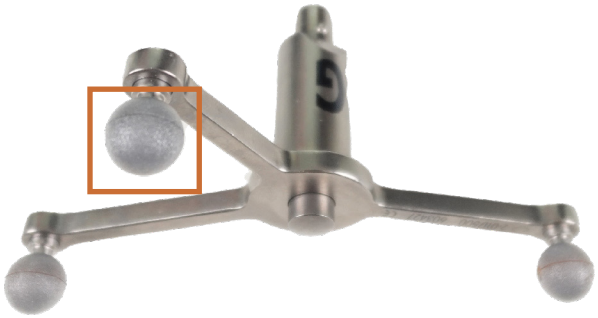
- 1 pack per surgery (16 markers)

### Sterile drape

- 1 per surgery


### Passive sphere

- 1 pack per surgery (9 markers)

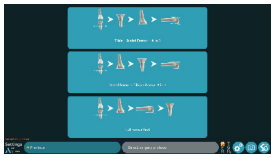


# Workflow overview

## Robotic total knee arthoplasty

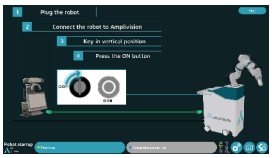
### 1. Home Page

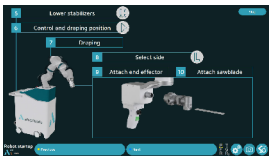
Choose the resection order



### Set-up

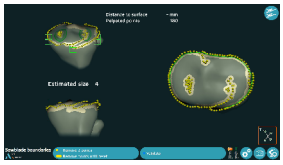
Robot initialization, sterile drape set up and saw attachment assembly

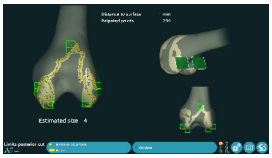



### 3. Surgical Plan

Anatomical registrations

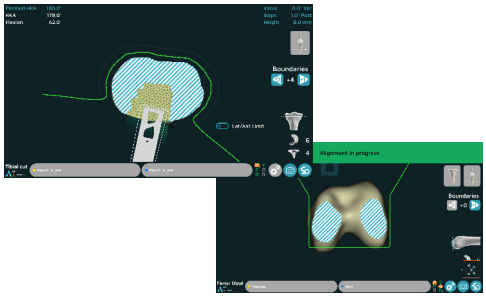



Surgical Planning

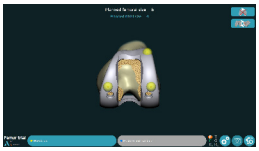
### 4. Resections

Robotic manual or automatic resections

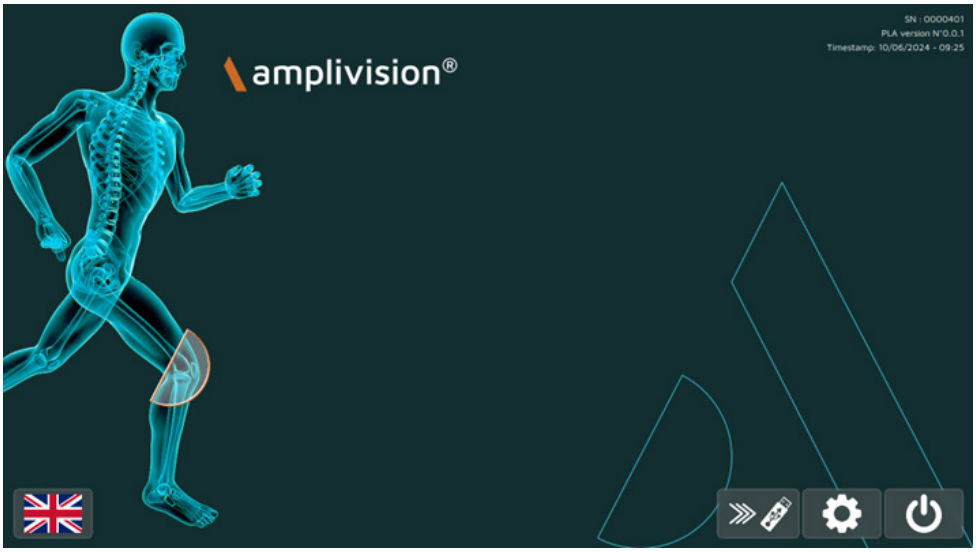



### 5. Implantation

Trial and definitive implants

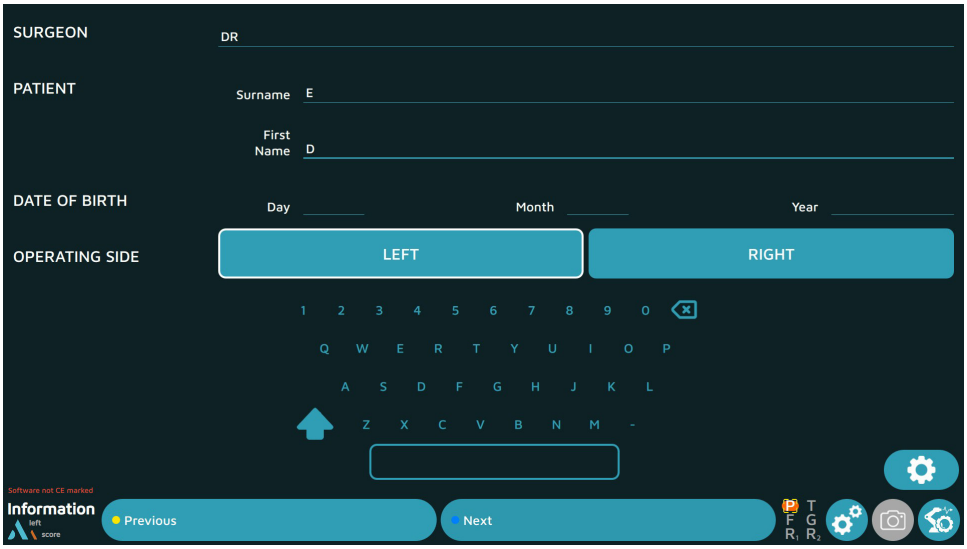


# Starting the software




On the touch screen

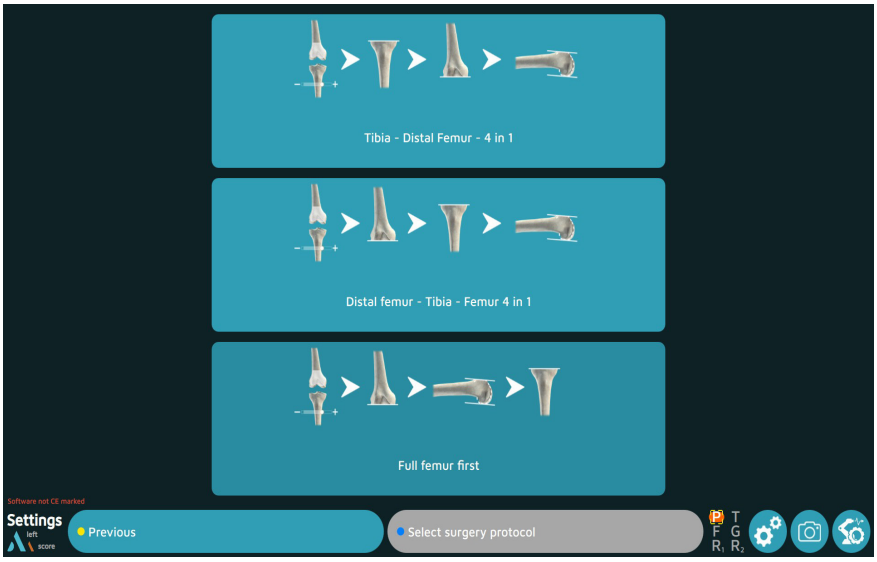
- Select the language.
- Select the knee.
- Select the implant.




- On the « Information » page, input the required information using the virtual keyboard.
  - Surgeon name
  - Patient name and Surname
  - Patient date of birth (optional)
  - Operated side (select right or left)
- To go to the next step, press the blue amplivision footswitch or Next on the screen.
- To go to the previous step, press the yellow amplivision footswitch or Previous on the screen.

# User settings

## Order of the resections



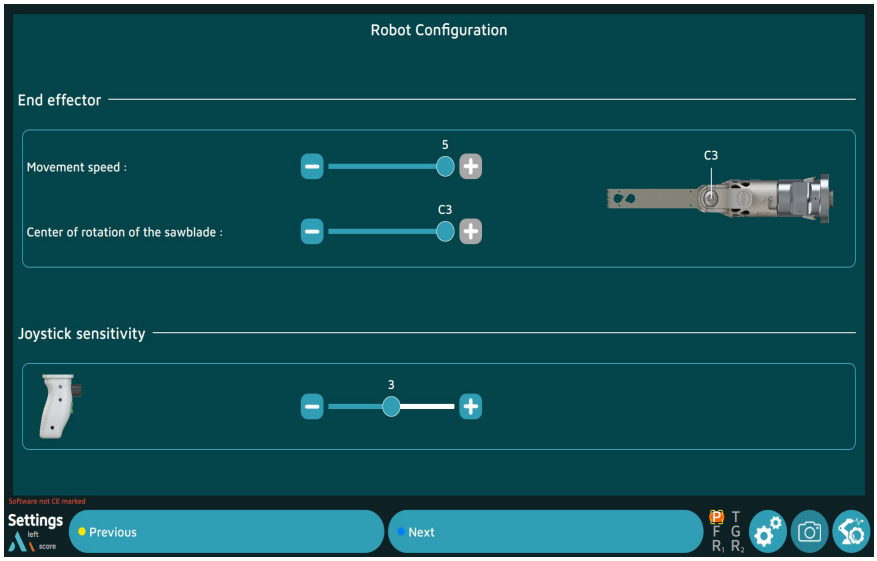

Select the order of the resections:

**Distal femoral cut first then tibial cut then 4-in-1 femoral cuts**
**Tibial cut first then Distal femoral cut then 4-in-1 femoral cuts**
**Femoral cuts first then tibial cut**

- Press the blue amplivision footswitch to continue to the next step

# User settings

## Robot Configuration




### Oscillating saw attachment (end effector)

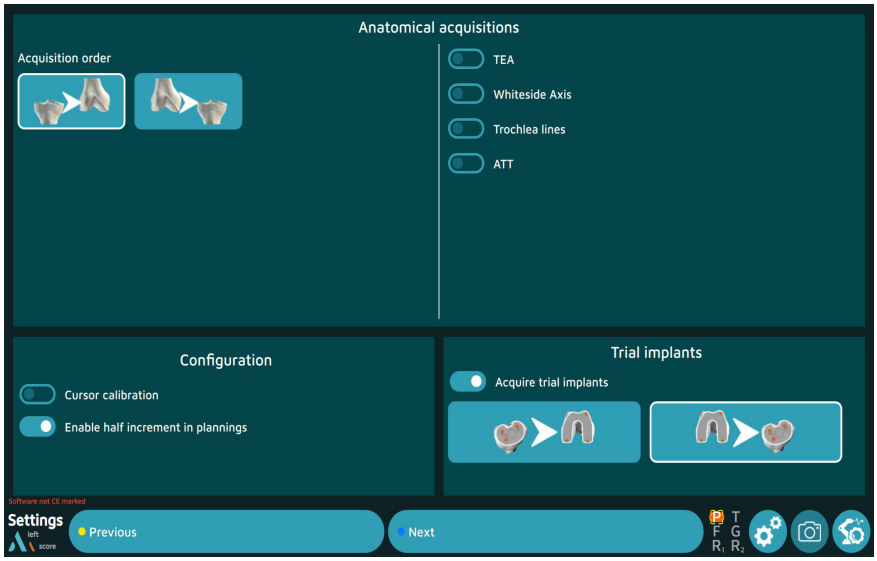
**Movement speed:** choice of the displacement speed when using the joystick.
**Center of rotation of the sawblade:** position of the center of rotation when using the joystick.

### Joystick sensitivity

**Set joystick sensitivity level:** at maximum level (5), the response time for displacement is minimal (and vice versa).

# User settings

## Anatomical registration options




**Registration**
Tibial registration first or femoral registration first

**TEA Biepicondylar axis**
Registration of the medial epicondyle and lateral epicondyle to calculate the Biepicondylar axis
**Whiteside line**
Registration of the Whiteside line using the probe
**Trochlear line**
Registration of a serie of points on the anatomical trochlear to calculate its orientation
**ATT (Anterior Tibial Tuberosity)**
Registration of the Anterior Tibial Tuberosity

**Probe calibration**
Select this option to calibrate the probe position relative to the screen manually. If the option has not been ticked, the calibration will be done automatically.
**Enable half increment**
Select this option to enable planification of implant positioning by half millimeter increments.

**Trial registration**
Assessment of the implant trials positionning

- Press the blue amplivision footswitch to continue to the next step.

# User settings

## Planning options


### Preferences

The preferences allows to pre-positionned the implants reagrding surgeons user settings, during the planning those values can be changed

**For the tibia,** it is possible to pre-register the posterior slope, the tibial resection thickness, the tibial insert thickness

**For the femur,** it is possible to pre-register the flexion, the femoral rotation, the distal resection thickness.

### Limits for the planning

**If the stop to the limits is activated**, the software will not go beyond this values for each of the parameters chosen by the surgeon, for the tibial varus/valgus, the femoral varus/valgus, the femoral external rotation an the femoral internal rotation.

This stop to the limits is valid for the kinematic alignment (KA) which will switch to the restricted Kinematic Alignment (rKA), and for the Functionnal Alignment.

During the planning all the values can be changed.

### Femoral resection reference

Choice between the Anterior reference and the Posterior reference.

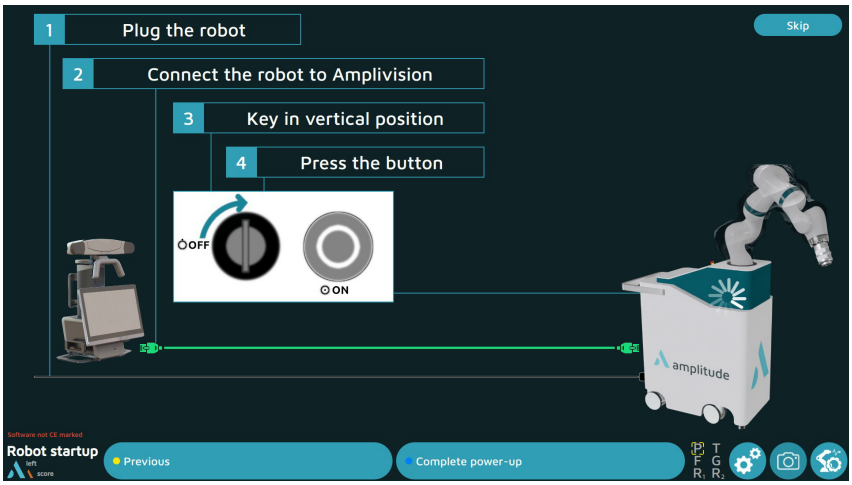
- Press the blue amplivision footswitch to continue to the next step.

**NOTE**

At this step (end of option selection), a User Profile can be created to save all the choices made, and to reuse them automatically for the next interventions.

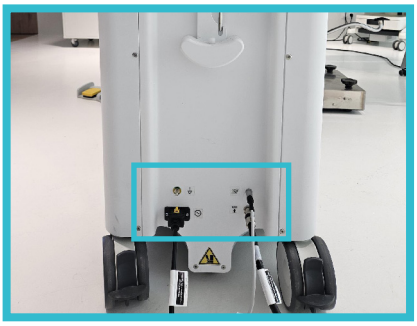
# Set up

## Robot start-up




### 1 Plug the robot

Plug the power cable.



### 2 Connect the robot to Amplivision

Connect the Amplivision cable.

**NOTE**

The Amplivision must be **turned on** before connecting the robot.

### 3 Turn the key in the vertical position

This unlocks the power security.


### 4 Press the button «on»

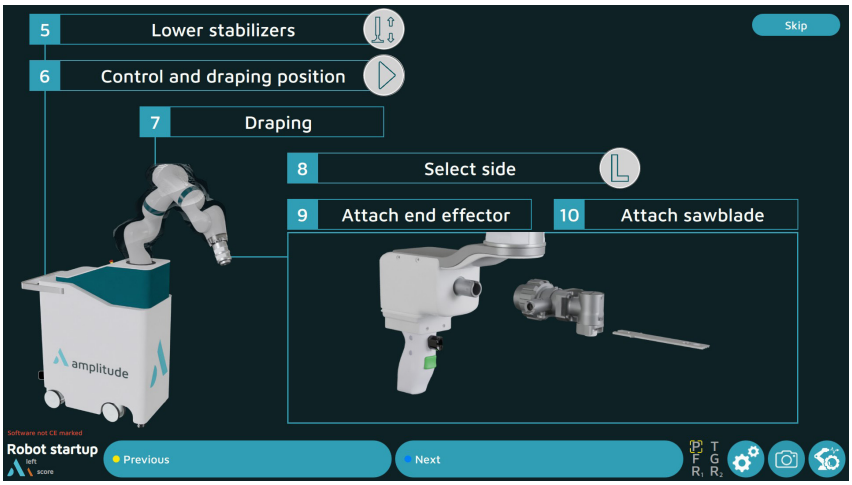
The robot will start.

**NOTE**

The steps 1 to 4 can be done either at the start of the intervention or can be skipped and realized later in the surgical flow.

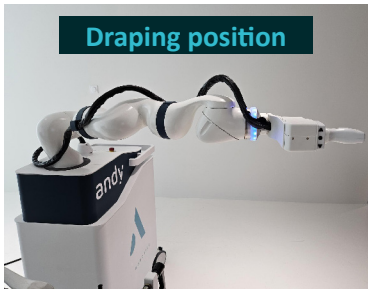
# Set up

## Robot set up




### 5 Lower stabilizers

Press the stabilizer button on the control pannel until they are fully in place. Take care not to crush any object while doing so. Button might be released during lowering, and stabilizers will go up immediatly.

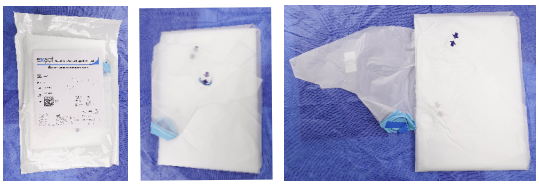



### 6 Control and draping position

Press the Start button to carry out calibration, until draping position is reached. User must be aware of robot's motion at this step to avoid any conflict with the environment.

### 7 Draping (Beware that the drape is single tyvek packaged)

- Unfold the first part of the drape:



- Place your hands where indicated on the sterile drape

- Carefully unfold the drape around the robotic arm and cart.

# Set up

## Saw attachment assembly

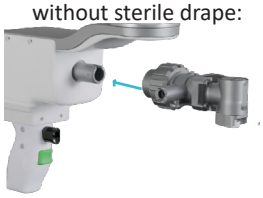
### 8 Select operated leg side

- For a right operated leg (or left) press the R (or L) button on the control pannel until final position is reached by the robotic arm.

### 9 Attach Robotic oscillating saw attachment

1. Remove the strip on the sterile drape
2. Insert the saw attachment through the drape
3. Slide the saw attachment on the male part of the robotic arm until you reach abutment
4. Screw the saw attachment with the Robotic tightening wrench

For information, view without sterile drape:







**NOTE**

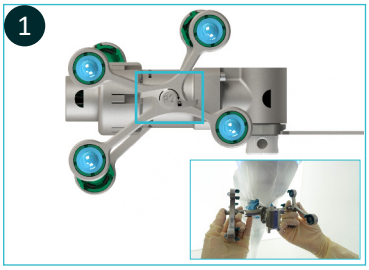
A change of sterile gloves must be done at this point. Be aware to avoid any breach of sterile barrier at this step.

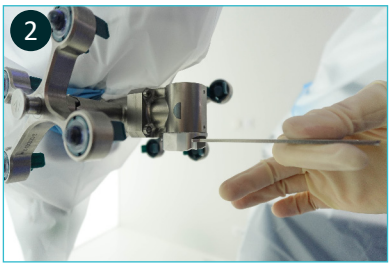
### 10 Attach sawblade on the saw attachment

1. Screw the two motor arrays R1 & R2 on the saw attachement
2. Insert the saw blade onto the saw attachment
3. Place the screw on the sawblade
4. Screw the sawblade with T30 screwdriver

**NOTE :**

Make sure to screw the R1 and R2 arrays the correct way, as indicated on the securing wing-nut.





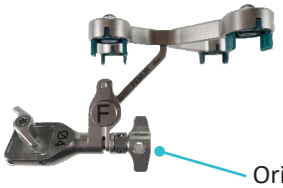
# Set up

## Setting up of the arrays

- The patient's leg should be positionned leaning against a standard thigh support:

- Clip the Projection Resistant Sterile Markers to the arrays:
  - 4 markers for the tibial array (T)
  - 4 markers for the femoral array (F)
  - 4 for each of the motor arrays (R1, R2)

**Array**



Orientation adjustment screw

Conical Threaded Pins AMPLIVISION Ø4 length 150mm

Projection Resistant Sterile Marker

- Clip Passive Sphere on:
  - the G array, 3 Spheres
  - the Probe, 4 Spheres

# Set up

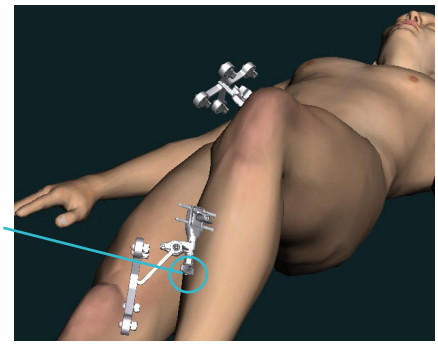
## Setting up of the arrays

- **The Conical Threaded Pins** AMPLIVISION Ø4 length 150mm must be placed:
  - On the anteromedial side of the femur, in the incision. They must not interfere with the sawblade during anterior resection particularly.
  - On the anteromedial side of the tibia. They can be inserted either percutaneously or through an incision. The must not interfere with the robot's joystick during resections.

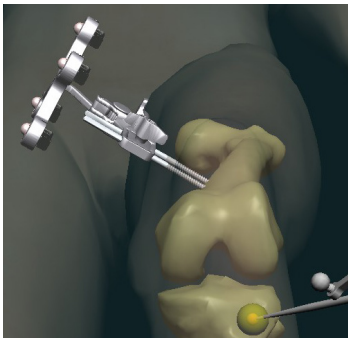
**NOTE**

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

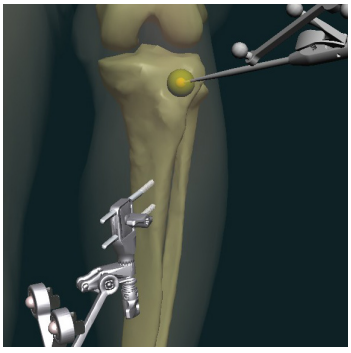
- **Array positionning:**
  - Insert the first conical threaded pin AMPLIVISION Ø4 length 150mm: go through the proximal cortex and then into, but not through, the distal cortex.
  - Place the array on the first pin to get the proper spacing for the second pin.
  - Use the different axis to position the array towards the camera head and lock the fixation support. A T30 screwdriver can be used to secure locking.
  - Position and secure the arrays so they are always visible to the camera head, whether the knee is flexed or extended.
  - Position the tibial array on the anteromedial side, about 2cm away below the ATT. The array must not interfere with robot's joystick during resection. Pins can be inserted either percutaneously or through an incision.
  - Using the same pins, position the femoral array medially within the incision



Femoral array position



Tibial array position

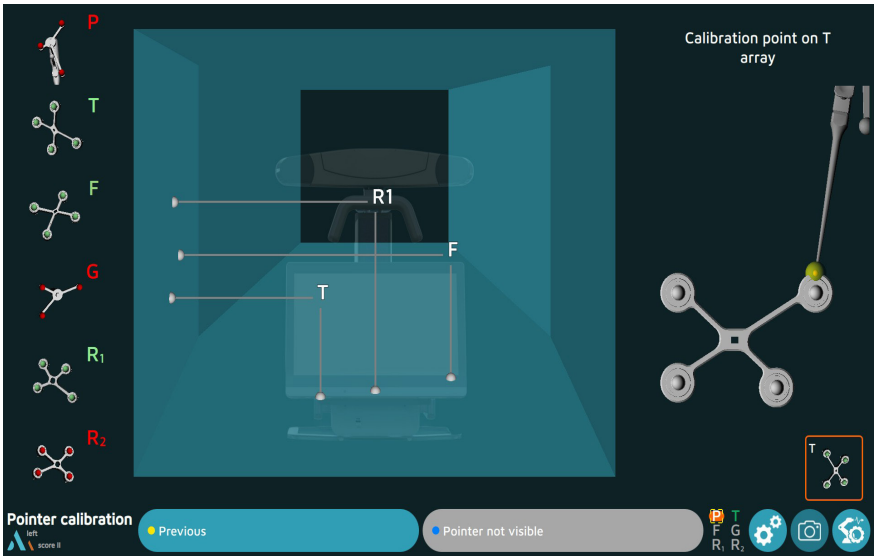


**NOTE**

After approaching the joint and exposing the knee, it is important to remove the osteophytes in order to find the appropriate 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).

# Set up

## Setting up of 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 between the two optical sensors of the AMPLIVISION V4 workstation makes this adjustment easier.

- Confirm that the Probe knee navigation P array is visible.
- On the left side of the screen, a 3D view of the arrays indicates why an array may not be visible:

  - Any passive sphere that is not visible on an 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 passive spheres).

## Probe calibration

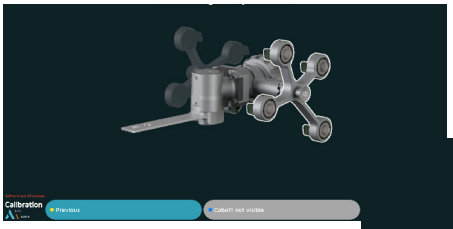
To define exactly the position of the probe tip,

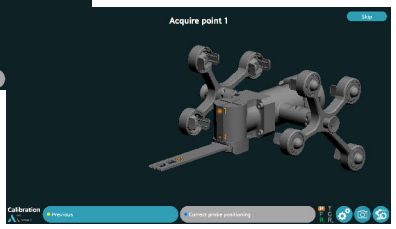
- Calibrate the probe by placing its tip in the calibration mark on the T array
- Press trigger to confirm
- Without lifting the probe tip, change the probe's orientation slightly
- Press the trigger to confirm

# Set up

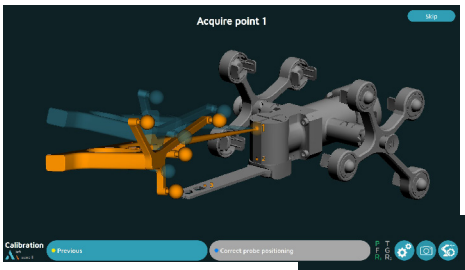
## Saw attachment calibration

To define exactly the position of the sawblade,

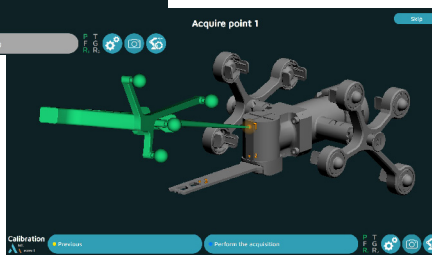


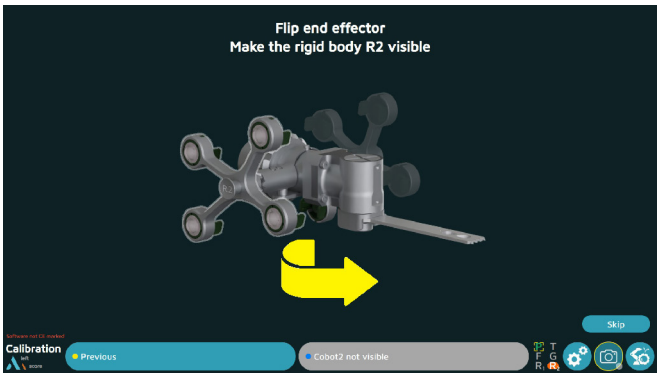




- Registrer the points 1, 2 and 3 as indicated on the screen in that order.

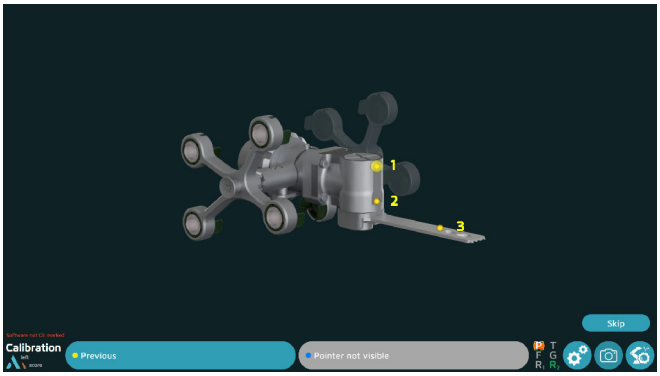



- Make sure the pointer is in the correct orientation.




- Flip the robotic arm using the hand guiding button until the second motor array is visible from camera.




- Register the points 1, 2 and 3 as indicated on the screen, in that order.
- Press L (or R) on the control pannel to recover the initial arm position.

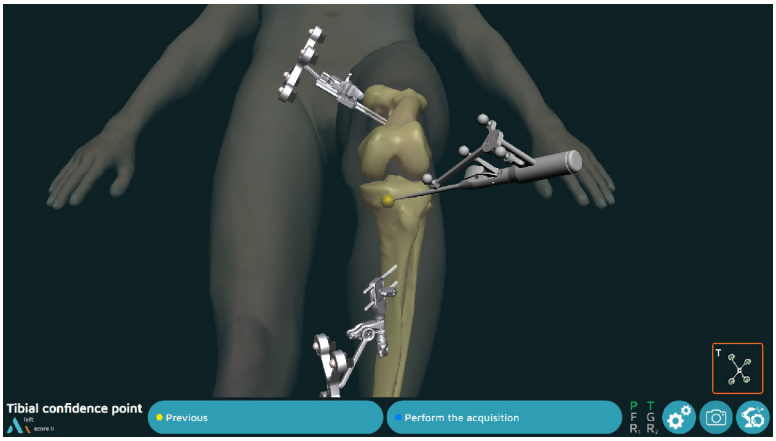
**NOTE**

These steps can be skipped and performed after the planing step, before the resections.

# Confidence points

## Tibial confidence point

- Place a landmark using on the tibial bone ensuring that the it is placed in hard bone and located approximately 10 mm away from the tibial cut.
- Register the point.




## Femoral confidence point

The confidence point is used to verify the va

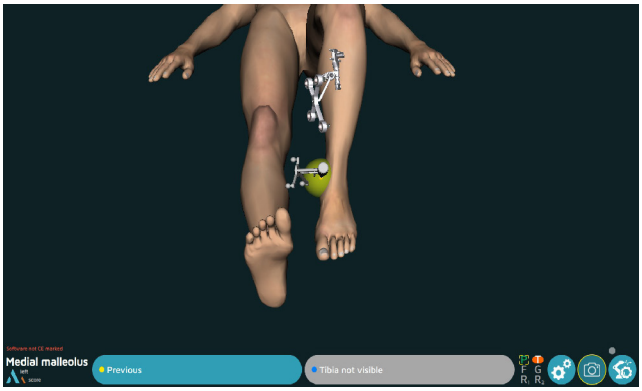
- Place a landmark using on the femoral bone ensuring that the it is placed in hard bone and located approximately 10 mm away from the nearest femur cut..
- Register the point.

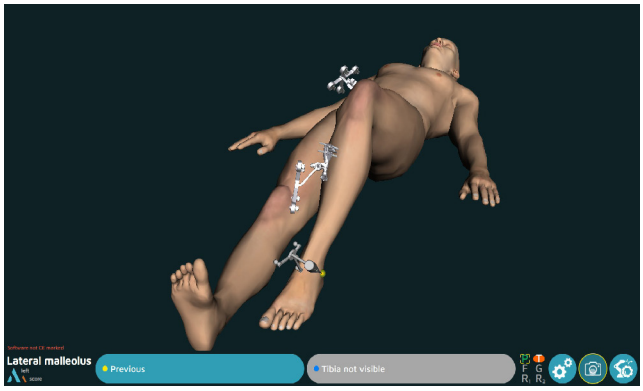

**NOTE**

Place confidence points as far as reasonably possible from the resection planes to avoid inadvertent resection.

# Tibial registrations

## Ankle center registration




Case where the order of anatomical acquisitions is the **tibia first**.

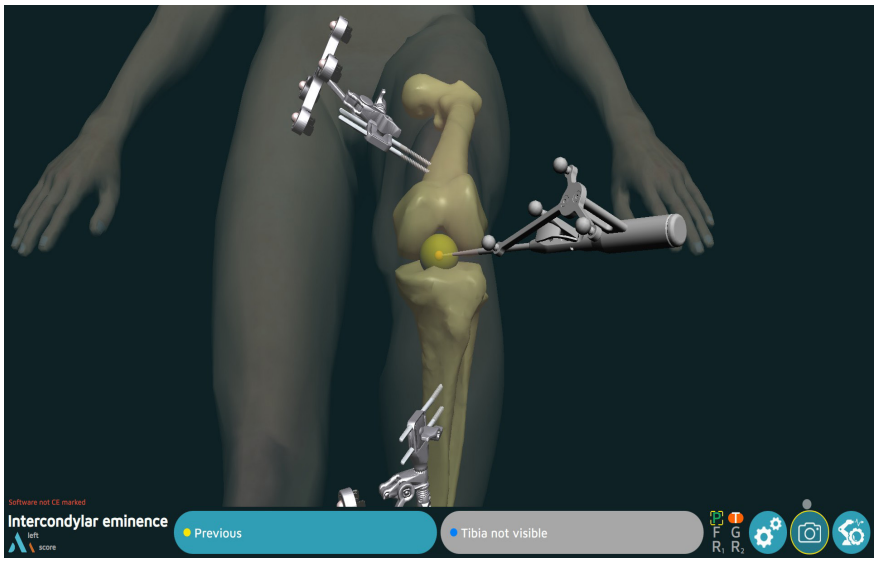
### Medial malleolus

- Place the probe tip on the most medial point of the medial malleolus.
- Press the trigger on the probe to confirm.

### Lateral malleolus

- Place the probe tip on the most lateral point of the lateral malleolus.
- Press the trigger to confirm.

## Tibial center registration

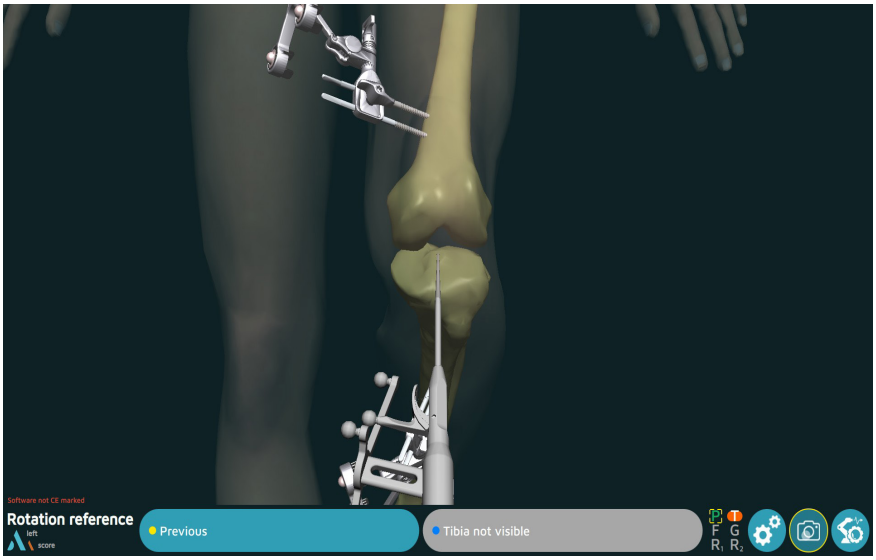



- Place the probe tip on the middle of the intercondylar eminence on the axis of the tibial shaft.
- Press the trigger to confirm.

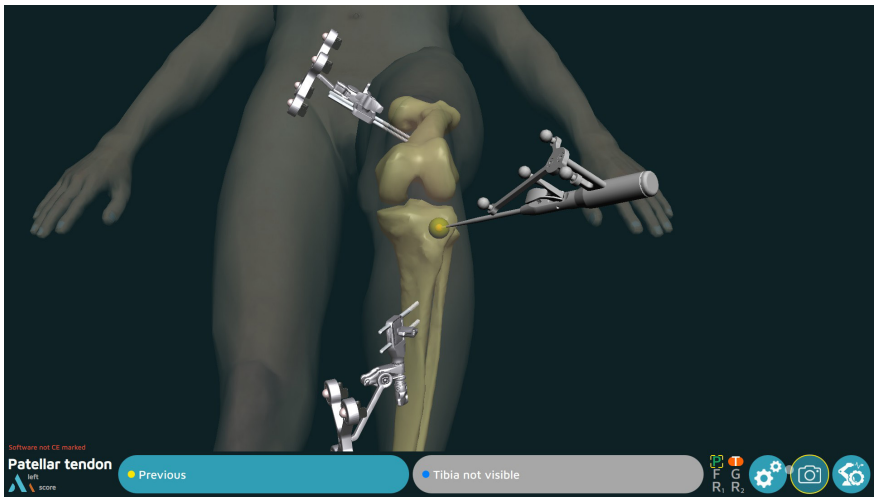
# Tibial registrations

## Tibial reference rotation

- Place the probe tip on the intercondylar eminence and turn the body of the probe.
- Once it corresponds to the desired sagittal plane orientation, confirm its position.



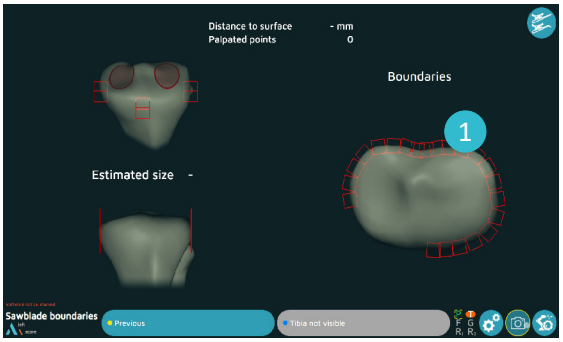

## Patellar tendon

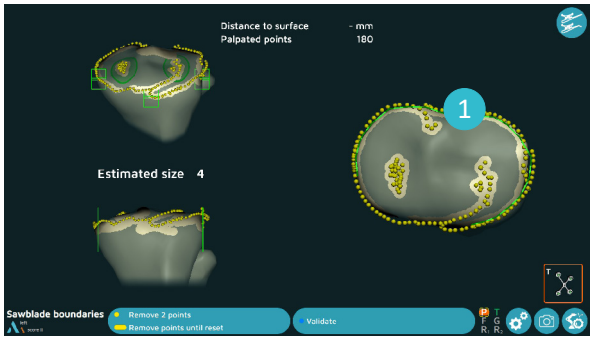



- Place the probe tip on the patellar tendon attachment.
- Press the trigger to confirm the probe.

# Tibial registrations

## Tibial bone surface and resection boundary registration




**The goal of this step is to register the tibial bone surface and the tibial resection boundary. The boundary is a frontier beyond which the robot's blade will not go. It allows soft tissues protection during resection step.**

Two probe tips are available for this step in order to help access specific parts of the tibia (posterior wall for example):

**NOTE**

Once the tip is locked on the probe, **make sure to calibrate** it by placing the tip on the calibration mark of the tibial array. The software will automatically switch to the calibration screen.

Once probe tip has been chosen and calibrated:

- Place the probe tip on the bone surface
- Press the trigger on the probe: the system will beep to indicate the start and end of the acquisition.
- Hold down the trigger while moving the tip along the surfaces that need to be acquired:
  - Medial and lateral articular surfaces used to determine height of cut
  - Contour of tibial plateau at the articular surface, as well as at the level of the planned tibial cut
  - Resection boundary registration (1)
- Release the trigger to stop the registration

*At any time, the surgeon may release the trigger, move the probe tip to another location and then press the trigger again to continue the registration.*

*The system will continuously register points and draw a contour map of the surface in real time. A counter at the top of the screen shows how many points have been registred.*

*The software will not proceed to the next step until the anterior part and one of the two lateral parts are green and the boundary line is complete.*

NOTE

Make sure the probe tip is always in contact with the tibial bone surface when the trigger is pressed, especially for the tibial posterior wall.

# Tibial registrations

## Tibial bone surface and resection boundary registration

### Verification of the contours

Release the trigger and place the probe tip on the registred bone surface. The DISTANCE TO SURFACE value is shown: this distance is the error between the palpated point and the same point on the digitised 3D model (accuracy of contours). The number will be green if this distance is equal to or less than 1 mm, and white if it is not.

### Removal of acquired points

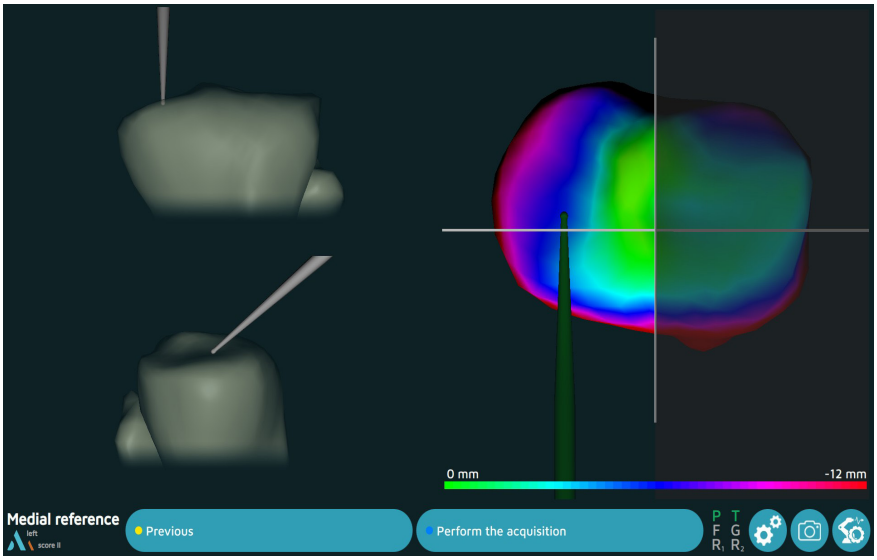
The last 2 acquired points can be deleted by pressing the yellow amplivision footswitch.

Press and hold down the yellow amplivision footswitch (for at least 2 seconds) to erase all the acquired points.

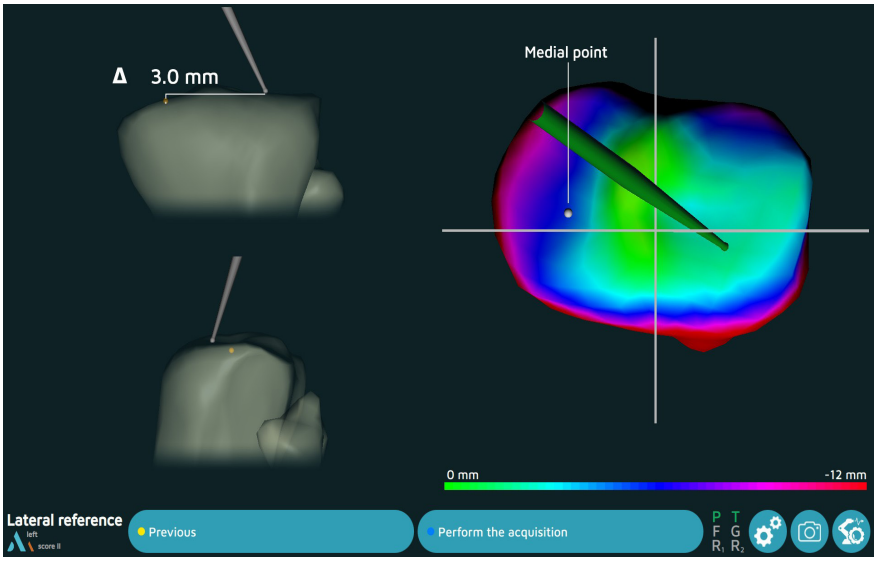
If the contour accuracy is satisfactory, confirm this step and go to the next step.

# Tibial registrations

## Reference points




- Place the probe tip on the medial tibial bone surface
- Confirm



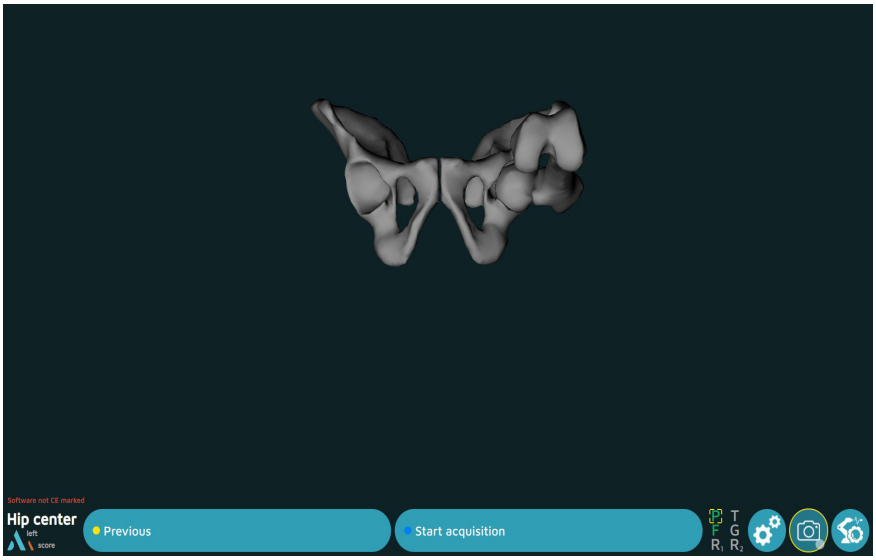

- Place the probe tip on the lateral tibial bone surface
- Confirm

**NOTE**

Those two points will be used as references to calculate the thickness of the tibial resection

# Femoral registrations

## Hip center registration

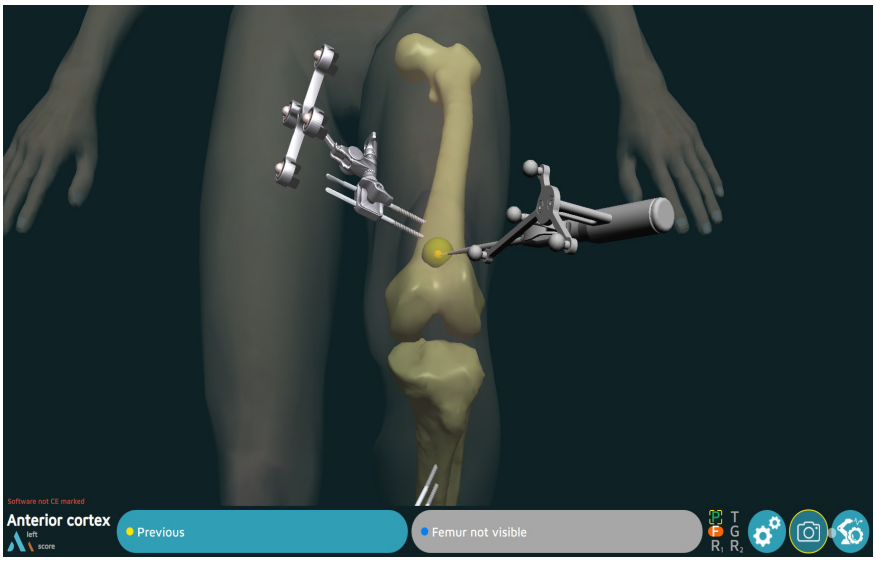



- Extend the patient's leg
- Grasp the ankle
- Move the leg in a small circle (15 cm knee displacement), the registration will automatically start
- Continue the movement until the system has acquired 100% of the points it needs.

*If the result is acceptable, the system automatically goes to the next step.If not, the system will prompt the user to restart the acquisition.*

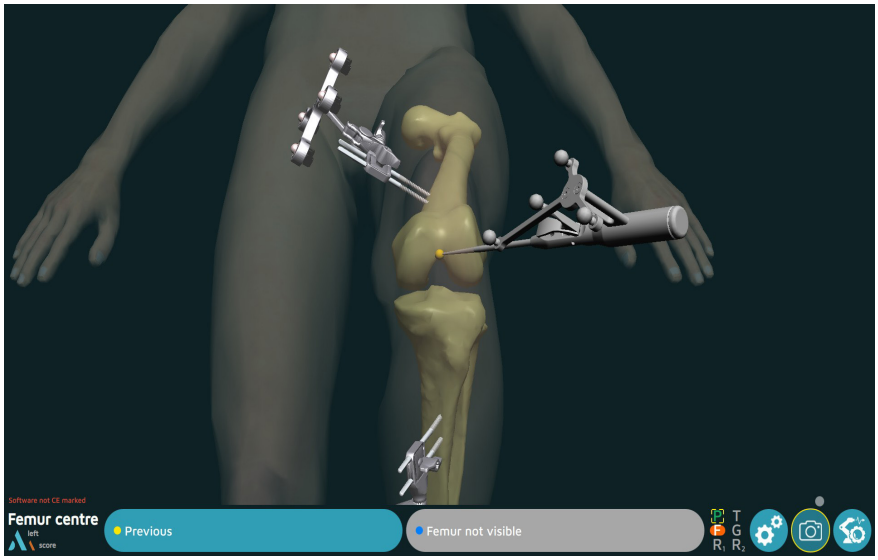
## Femoral anterior cortex registration

- Place the probe tip on the anterior femoral cortex
- Confirm



# Femoral registrations

## Top of the intercondylar notch registration



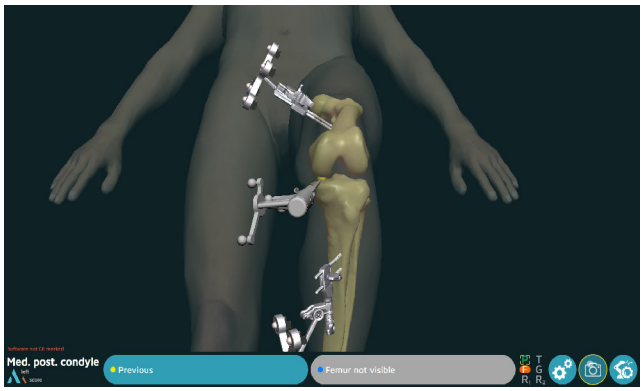

- Place the probe tip at the top of the femur's inter-condylar notch and along the femoral shaft axis
- Confirm

**NOTE**

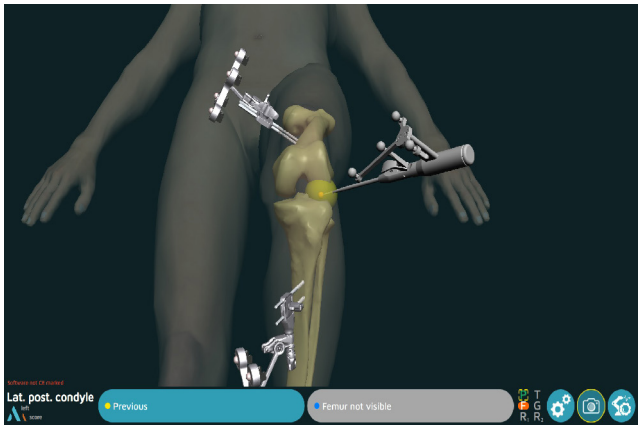
The femoral mechanical axis is calculated using the hip centre and the top of the intercondylar notch.

## Posterior condyles registration

- Place the probe tip on the medial posterior condyle
- Confirm




- Place the probe tip on the lateral posterior condyle
- Confirm




**NOTE**

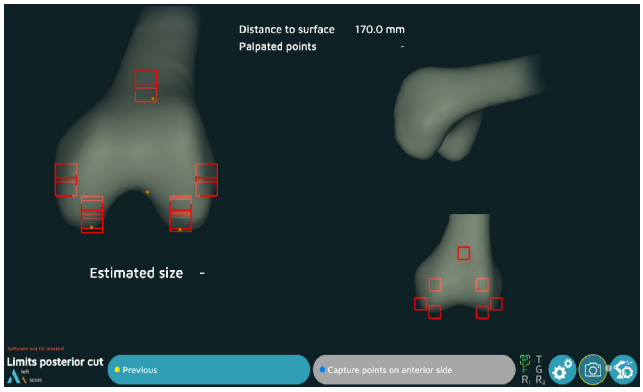
Using the femur's mechanical axis and the posterior condylar axis, the AMPLIVISION system calculates the frontal femoral plane and estimates the sagittal and transverse planes

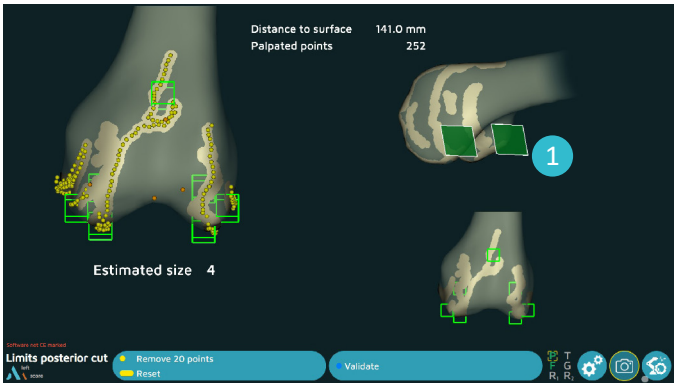
**NOTE**

The points at the top of the posterior condyles are re-calculated during the condyle digitalisation. The planes are then recalculated to make them more accurate

# Femoral registrations

## Femoral registration




**The goals of this step are to acquire the femoral bone surface and the posterior boundary for resection**.

The same two probe tips presented for tibial surface registration can be used at this step.

Once probe tip has been chosen and calibrated:

- Place the probe tip on the bone surface.
- Press the trigger : the system will beep to indicate the start and end of the acquisition
- It is best to draw the contour of the femur carefully.
- The posterior planes represent the posterior boundaries for the femoral posterior cut. They will turn green when the most posterior point is registered on each side (1)

*At any time, the surgeon may release the trigger, move the probe tip to another location and then press the trigger again to continue the registration.*

*The system will continuously register points and draw a contour map of the surface in real time. A counter in the upper-left corner shows how many points have been registred.*

*The software will not proceed to the next step until the all boxes are registered (in green)*

*The system will continuously acquire points and draw a contour map of the surface in real time and the matching femoral component size is shown in the lower left part of the screen.*

**NOTE**

Make sure the probe tip is always in contact with the tibial bone surface when the trigger is pressed

## Verification of the contours

Release the trigger and place the probe tip on the registred bone surface. The DISTANCE TO SURFACE value is shown: this distance is the error between the palpated point and the same point on the digitised 3D model (accuracy of contours). The number will be green if this distance is equal to or less than 1 mm, and white if it is not.

## Removal of acquired points

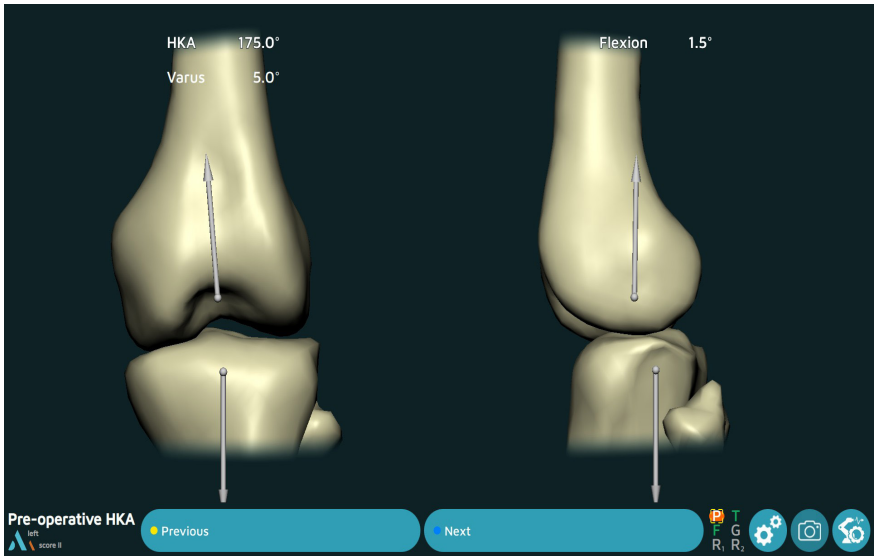
The last 20 acquired points can be deleted by pressing the yellow amplivision footswitch.

Press and hold down the yellow amplivision footswitch (for at least 2 seconds) to erase all the acquired points.

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

# Femoral registrations

## Pre-operative alignment




- The software allows to visualize the pre-operative HKA (Hip Knee Ankle)

# Planning

## AKN Planning software

The software **Global Planning** proposes 3 surgical alignments to position the implants :

The **Mechanical Alignment** (MECA):

This alignment is proposed by default.

From the users settings of the surgeon, orientations et height of the resections are calculated to obtain a mechnical axis of 180°: **HKA plan = 180°.**

The curves representing the gaps are the result of those femoral and tibial positionning.

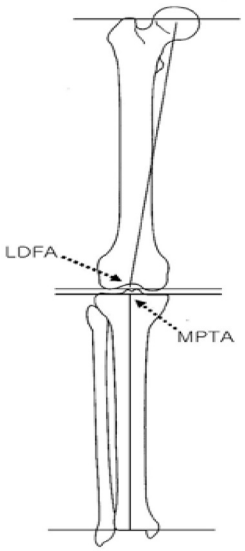
At any time the surgeon can change the values of the height and of the orientation to customize the planning.

The **Kinematic Alignement** (KA or rKA):

This alignment requires a voluntary action by clicking on the KA button (or rKA if the stops at the limits is activated).

The software proposes to fill in the level of cartilage wear on the distal femoral and proximal tibial compartments. This values of wear allow to calculate the LDFA (Lateral Distal Femoral Angle) and the MPTA (Medial Proximal Tibial Angle).

From this data, the resections height and orientation are calculated to perform a femoral and a tibial resurfacing. The femoral and tibial varus/valgus angles proposed will correspond respectively to the LDFA and MPTA and the thicknesses of the resections will correspond to the thicknesses of the implants : 8 mm for the distal femoral resection and femoral posterior resection, and 10 mm for the tibial resection.




The curves representing the gaps are the result of those femoral and tibial positionning.

At any time the surgeon can change the values of the height and of the orientation to customize the planning.

The **Functionnal Alignment** (GAPS):

This alignment requires a voluntary action by clicking on the GAPS button.

The software starts to perform a tibial resurfacing (tibial resection is oriented according to the MPTA and height is 10mm), next it is calculating the height and orientation of the femoral resection in order to balance the gaps at X mm (X corresponding to the thickness of the chosen insert or 10 mm by default) all along the rang of motion.

At any time the surgeon can change the values of the height and of the orientation to customize the planning.

**NOTE**

For more details please refer to AKN V3 operating technique

# Planning

## Planning screen

HKA Plan = HKA planned
HKA = HKA live
Flexion = angle of flexion of the leg

MECA = button for mechanical alignement
KA (or rKA) = button for kinematic alignment or restricted kinematic alignment
GAPS = button for functionnal alignment
*A button is circled with a white line when the selected software is active without any modification. It is circled in gray when a value is modified.*

Ligament gaps curves in mm with specific values at 0°, 30° and 90°

Reset button for gaps registration

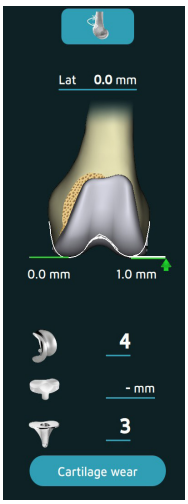
LDFA value in degree

Whiteside line or transepicondylar line orientation (option)

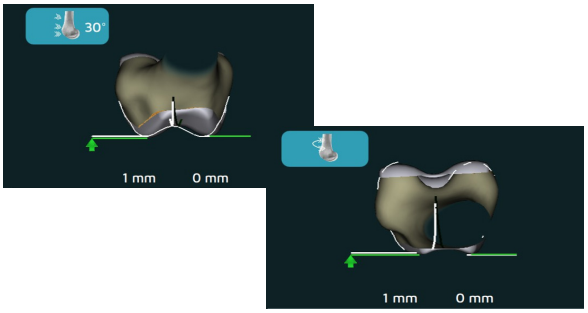
Notching value en mm


Current step
Operated side
Implant name

MPTA value in degree



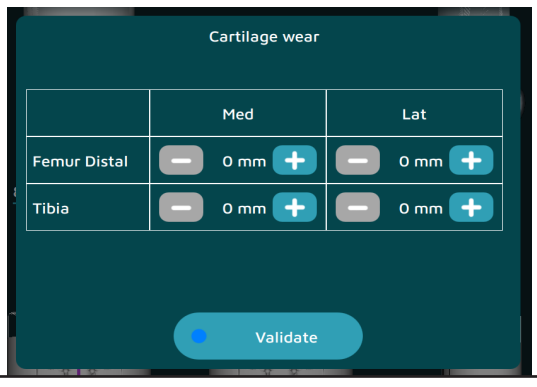

Trochlear view modification:
- Free mode associated with leg flexion
- 30° or 60° or 80° mode




Overhang values of the anatomical flanges versus prosthetic flanges at the different selected angle

Adjustment of the size of the femoral implant
Adjustment of the tibial implant thickness

Adjustment of the thickness of the cartilage wear



# Planning

## Registration of the gaps


The software allows to assess the ligament gaps all along the rom of extension (ROM).

The registration of this gaps is ready to start upon arrival in the planning screen.

- Start with the knee in extension, forced the varus until full flexion and forced the valgus to come back to the extension
- The maximum gaps values obtained during the extension/flexion cycle will be represented on the graph


The button **Stop** located under the curve or pressing the blue amplivision footswitch allows you to stop the registration


The button **Reset** allows to restart an registration of the curves

# Planning

## Mechanical alignment (MECA)


By default the software proposes orientations of the resections according to the Mechanical Alignment to reach an HKA at 180° ==> **HKA Plan = 180°**.

The button MECA is circled with a white line to show that this mode is active.

The parameters that are underlined in blue can be modified using the probe.

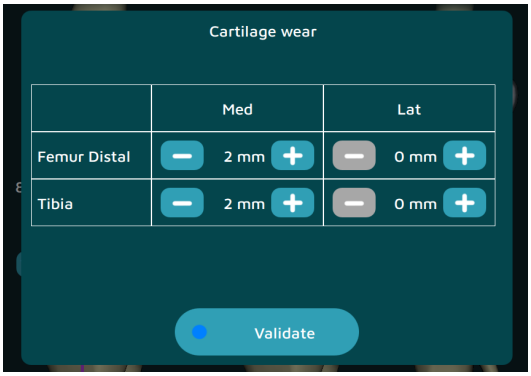
- Target the probe on the screen
- Move the cursor on the value to be changed, the blue squares appear on both side of the value
- Click on the symbol to change the value
- Check all the parameters and the gaps
- Click on next to perform the resections

# Planning

## Kinematic Alignment (KA or rKA)


- Click on the button **KA**. The button is circled with a white line.

A pop-up automatically opens and allows to fill in the wear of the cartilage.




- Target the probe on the screen
- Fill in the wear of the cartilage on the different compartments with the button located on both side of the values.
- Confirm

The values of LDFA and MPTA are then recalculated according to these wears and the software modifies the orientations according to these new values : tibial resurfacing (tibial cut height at 10 mm - cartilage wear) et femoral resurfacing (distal and posterior femoral cut heights at 8 mm - cartilage wear). The gaps values are also updated.

The parameters that are underlined in blue can be modified using the probe.

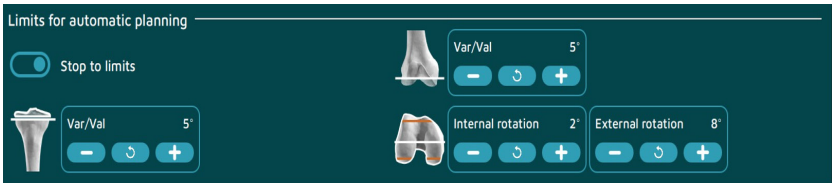
- Target the probe on the screen
- Move the cursor on the value to be changed, the blue squares appear on both side of the value
- Click on the symbol to change the value
- Check all the parameters and the gaps

*If a value exceeds a limit previously recorded, it flashes and is displayed in orange.*

- Click on next to perform the resections

*The button indicates rKA in case the limit stops are active in the user settings*

*The software takes these values into account when calculating the positioning of the tibia (maximum varus/ valgus) and the femur (maximum varus/ valgus; maximum internal and external rotation).*



# Planning

## Inverse Kinematic Alignment (GAPS)


- Click on the **GAPS** button. The button is circled in white.

A pop-up automatically opens and allows to fill in the wear of the cartilage.

Based on a tibial resurfacing (resection oriented on the MPTA and tibial cut height at 10 mm - cartilage wear), the software calculates the femoral cut heights and orientations in order to balance the spaces throughout all the range of motion.

The parameters underlined with a blue line can be modified using the probe.

- Target the probe on the screen
- Move the cursor on the value to be changed, the blue squares appear on both side of the value
- Click on the symbol to chnage the value
- Check all the parameters and the gaps

*If a value exceeds a limit previously recorded, it flashes and is displayed in orange.*

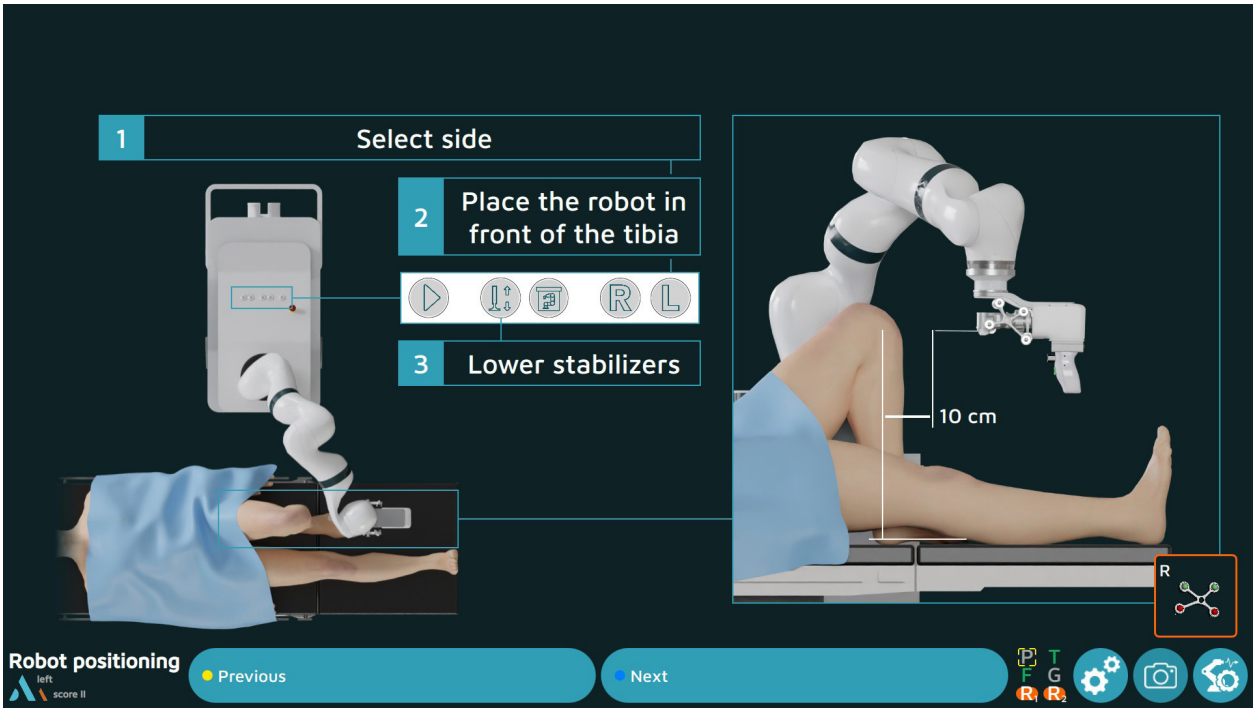
- Click on next to perform the resections

**NOTE**

The GAPS button is grayed out until all ligament spaces are filled in.

# Robot positioning

## Robotic bone resection




Robot is positioned next to the operated leg to prepare for resections:

1. Select the side of the operated leg on the cart's control pannel by pressing the R/L button until final position is reached.
2. Place the robot in front of the tibia of the operated leg as described on the screen.
3. Once position is conform, lower stabilizers to avoid any movement of the cart during resection.

**NOTE**

It will not be possible to activate the sawblade until stabilizers are in place.

**NOTE**

The patient's leg must lie against a leg holder to avoid abrupt leg motion during resection.

# Tibial resections

## Joystick handling: manual resection mode

Tibial resection must be performed using the robot's joystick by going through the following points:

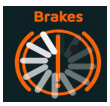
### Joystick mode of operation

1. Make sure the motor's array (R1 or R2) is visible by the navigation camera.
2. Press the robot's footswitch (or the green button on the joystick) to obtain sawblade alignment on the resection plane.
3. Once robot's LEDs are fixed green, joystick functions will be activated: motion and blade activation.

**If alignment fails, make sure that R1 (or R2) is visible by the camera, or consult «Appendix I» of this document for more information.**

*User handling is helped with several functions:*

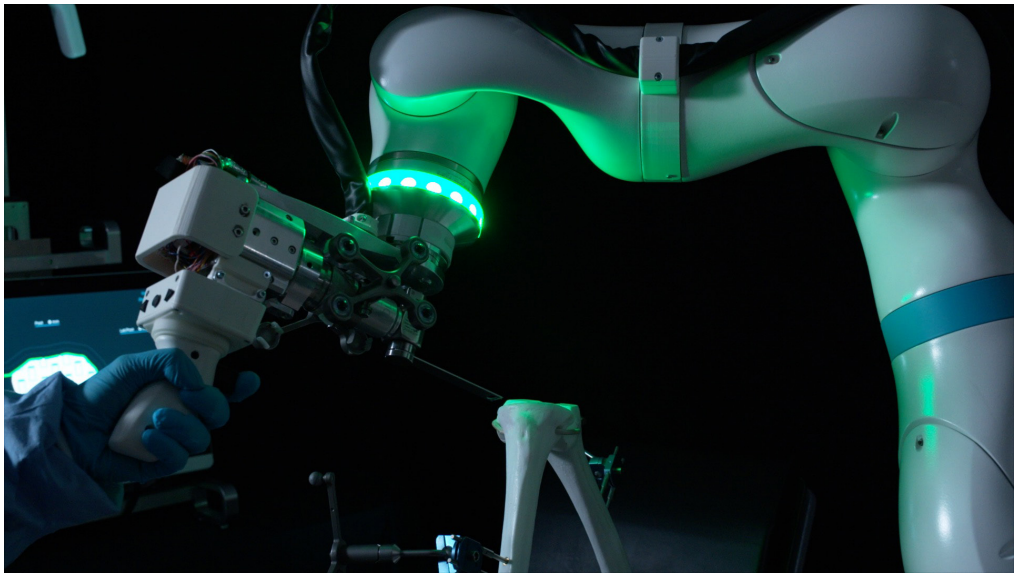
- *Robot will not go beyond defined boundaries during registration, for soft tissue safety.*
- *Motion will be stopped if the robot reaches uncut bone without blade activation.*
- *Any motion will be stopped if uncut zones of the sawblade reach uncut bone to avoid any bone fracture.*
- *Robot will move along the boundaries when reaching them to help trajectory.*
- *Maximum displacement speed will decrease depending on bone's hardness to ensure resection quality.*
- *If extreme resistance or unexpected sudden movement is detected, robot will go into security mode, activating security breaks: immediate stop to protect all surroung tissues. It will take a couple of seconds (until the icon on the navigation screen disapears) to be able to realign the blade (using the footswitch or green button) and use the joystick in order to assess the situation.*




*In case of blade blockage, use the hand-guiding button to release the robotic arm. Then use the robot footswitch (or green button) to align the blade on the resection plane.*

**NOTE**

As andy is an active robot, motion is performed by the robotic arm. Joystick handling does not necessitate any use of force: on the contrary, light touch is advised.

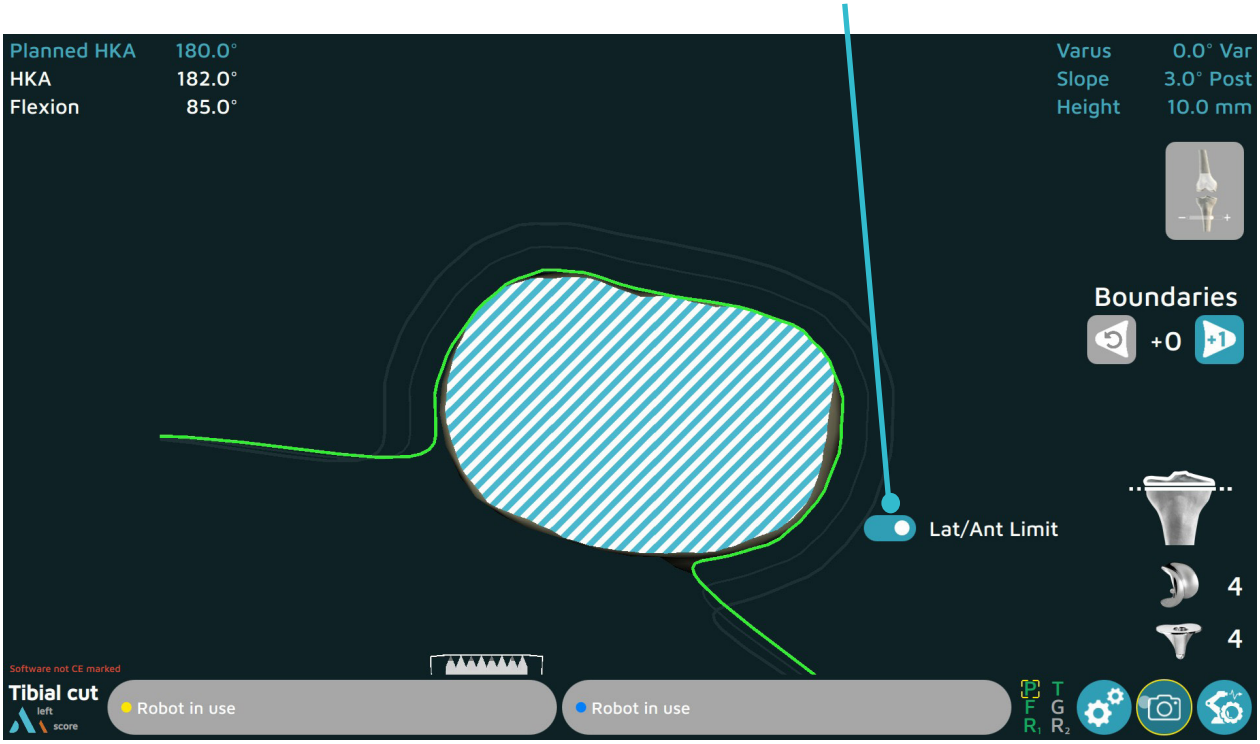


# Tibial resections

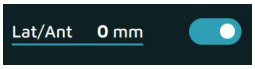
## Tibial boundaries

### Boundaries modes of operation

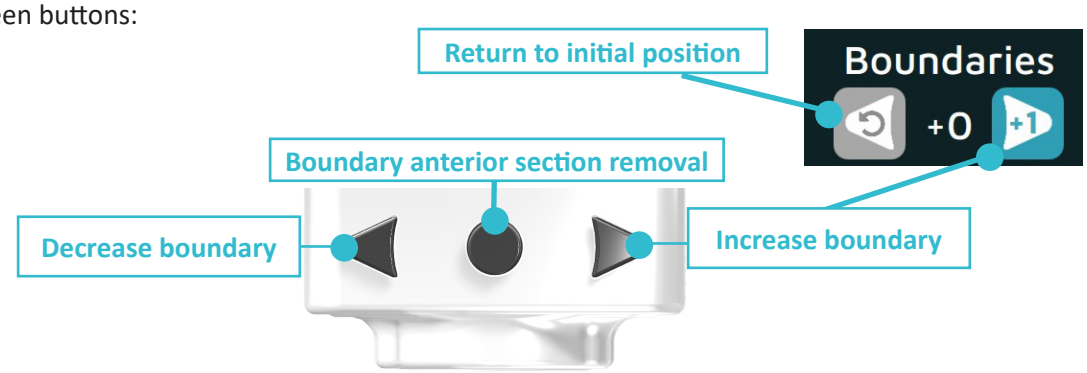
A tibial lateral anterior boundary can be implemented (patellar tendon).




The lateral anterior section of the boundary can be removed with the dedicated button on the screen or on the joystick:




The boundary can be pushed back or brought to initial position at any moment using the following joystick or screen buttons:



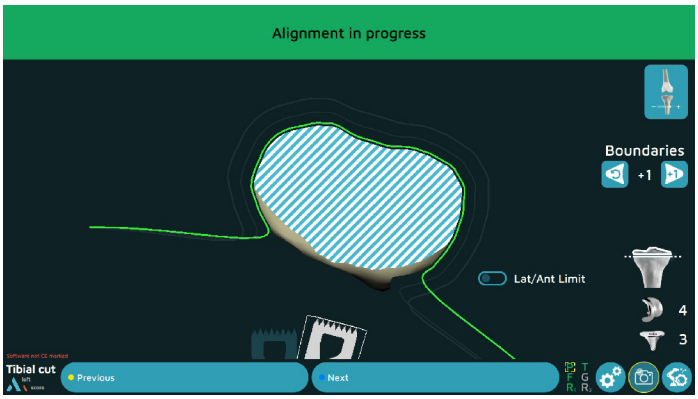

**NOTE**

During femoral cuts, boundaries can be modified in this manner as well.

# Tibial resections

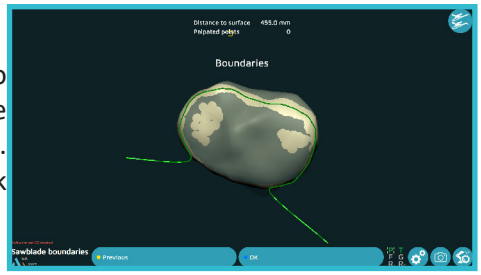
## Tibial resection

1. Place appropriate retractors to protect soft tissues.
2. Align the sawblade on the tibial resection plane by pressing on the robot's footswitch or green button of the joystick:




3. Once alignment is obtained (green LEDs) keep footswitch/button pressed and use the joystick to perform resection.


**Boundary additional registration:** At this step, it is possible to complement boundary registration if need be. For this, place the probe next to the tibial surface and click to switch to boudary registration. Once finished, validate with the blue amplivision footswitch to go back to resection screen and finish tibial cut.




**Planning modification:** Planning modification and re-cut is available with the dedicated button on screen: 

### Resection registration:

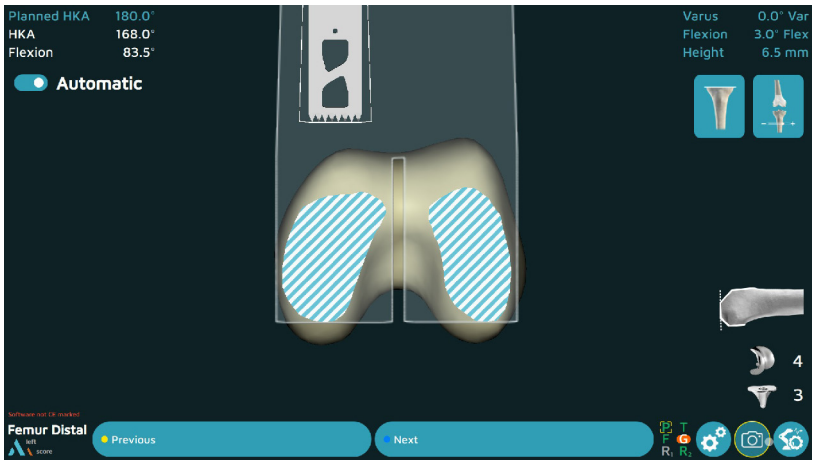
It is possible to verify the resection surface placing the Reversible Plate on the cut. Once verification is valid, press the blue amplivision footswitch to continue to the next step of the procedure.

# Femoral resections

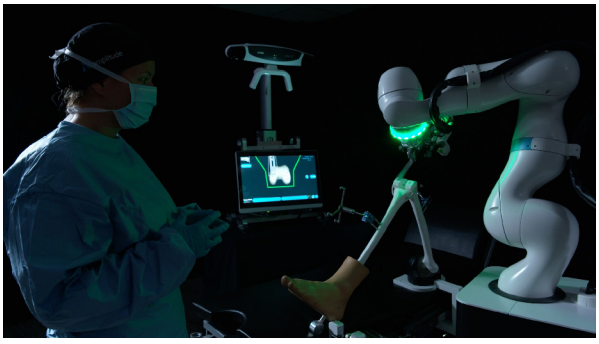
## Automated resection mode: Distal resection

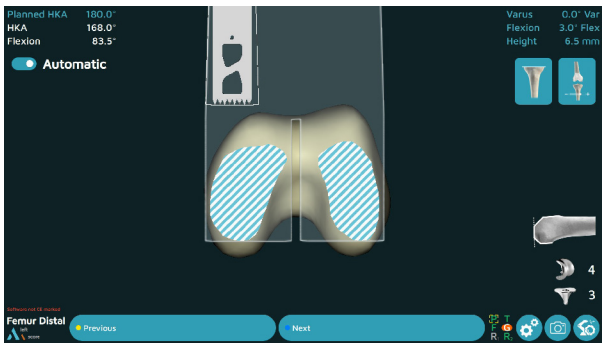
Femoral resections can each be performed with the robotic automatic feature, according to the following steps (distal resection example):

1. Place appropriate retractors to protect soft tissues.
2. Align the sawblade on the resection plane by pressing on the robot's footswitch:



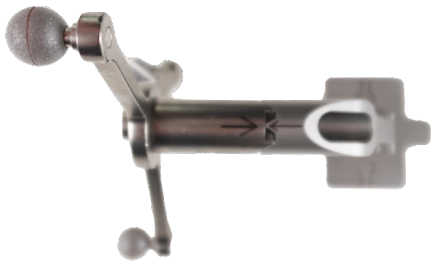

3. Once alignment is obtained (green LEDs) keep andy footswitch pressed, robot will mark a stop. A bipping sound will indicated sawblade activation: Make sure to remove your hands away from the blade.
4. Resection will be performed automatically while the robot follows its resection path. At any moment, surgeon can stop pressing the footswitch: robot movement and sawblade activation will stop immediatly.






### Resection registration:

It is possible to verify the resection surface by placing the Reversible Plate on the cut. Once verification is valid, press the blue amplivision footswitch to continue to the next step of the procedure.

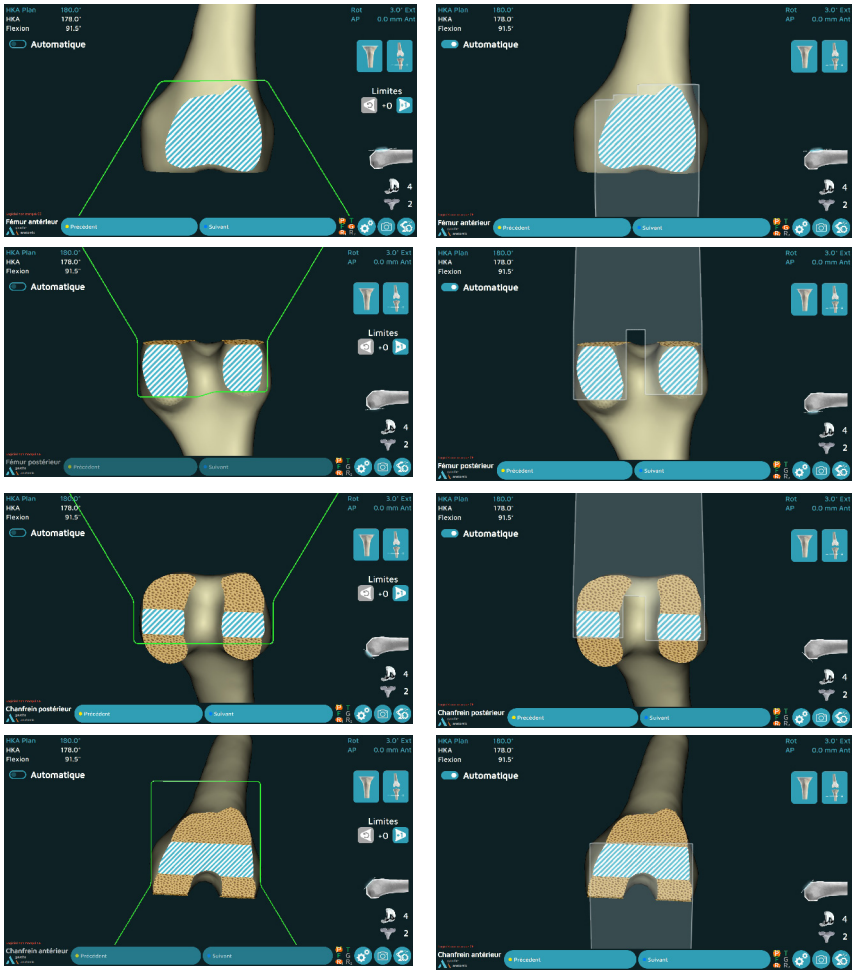


# Femoral resections

## 4-in-1 resections

Each 4-in-1 resections can be performed using manual or automatic resection modes. The order of cuts is the following: Anterior, Posterior, Posterior chamfer, Anterior chamfer.

**Robotic manual mode** **Robotic automated mode**




**Boundary handling** is done the same way as during tibial resections.


As for tibial resection, it is possible to re-register the posterior cut's boundary if necessary. For this, place the probe next to the bone's surface and click once to go to boundary registration screen.

**Planning modification** and re-cut is available with the dedicated button on screen:  . Tibial and femoral cuts can be modified at this step.

### Resection registration:

- If distal resection has been verified, it is possible to verify the anterior resection by placing the Reversible Plate on the cut.
- Once verification is valid, press the blue amplivision footswitch to continue to the next step of the procedure.
- All distal and anterior resections can be verified with the Reversible Plate.

# Femoral navigation

## Femoral preparation guide placement

This step only applies to the ANATOMIC TKA.


### For ANATOMIC Knee:

- Choose the same size of Femoral preparation guide as the 4-in-1 resection guide used previously (the planned size is shown on the screen).
- Place the universal handle on the oval clip by simultaneously pushing and turning the handle one-quarter turn.
- Place the probe tip on the conical mark located on the front of the femoral preparation guide. The mediolateral distance between the planned position (blue value) and true guide position will be shown (yellow value).
- Once the guide has been centred in the mediolateral direction, remove the universal handle and secure it with three Headed pins length 30 mm.
- Prepare the femoral trochlea (described in the Conventional Surgical Technique TO.G.002 for ANATOMIC knee).

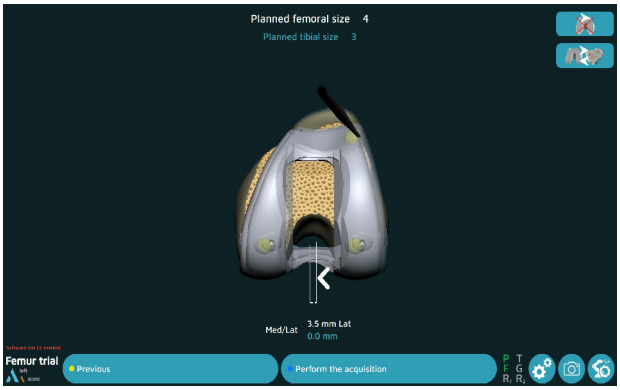
**NOTE**

This step is optional. If centring the guide without navigation assistance, skip this step by pressing the blue amplivision footswitch, probe or blue button.

## Placement of the trial femoral component

### For SCORE, SCORE II, ANATOMIC and TRAX CR Knees:

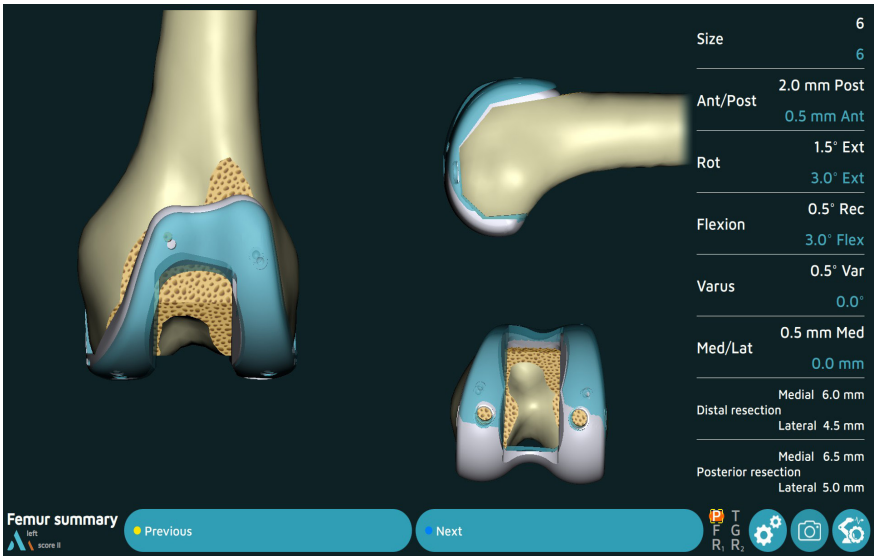
- Select the trial femoral component of the same size as the 4-in-1 resection guide used in the previous steps (the planned size is shown on the screen) and of the same operated side.
- For SCORE, SCORE II and TRAX CR TKAs: Place the probe tip on the conical mark located on the front of the trial femoral component. The mediolateral distance between the planned position (blue value) and true guide position will be shown (yellow value).
- Impact the trial component using the femoral component impactor until being in contact with the distal resection.
- Mark the entry point for the two pegs with the Drill for peg holes. Insert the 2 Trial pegs for trial femoral component.




- Repeat the validation with the trigger by positioning the probe tip in the other two conical marks (any order).
- For ANATOMIC TKA, do the validation of the 3 conical marks (any order).

# Femoral navigation

## Femoral summary




- The trial implant's position (grey) is superimposed over the planned implant position (blue).
- The size and final position of the trial femoral component are shown in white; the planned values are in blue.
- Press the blue amplivision footswitch to confirm and continue to the next step.

# Trials navigation

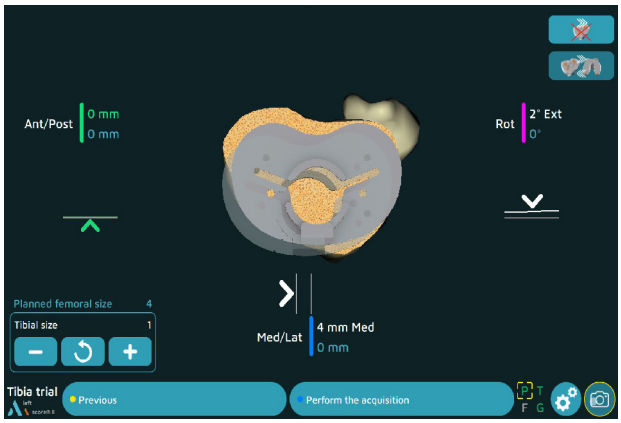
## Placement of the trial tibial baseplate

### For the SCORE and SCORE II TKAs: 2 options


**Acquisition of trial baseplate position using conical calibration marks:**

- Select the appropriate tibial baseplate (the estimated size is shown on the screen) and secure it to the universal handle.
- Position and secure the trial baseplate with two, 30-mm long headed pins.
- Using the probe, acquire the position of the three calibration marks located on the baseplate to identify its position on the tibia.

Detection of the G array by the camera


**Navigation of trial baseplate position with universal handle:**

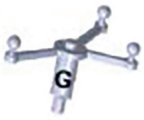
- Secure the G array support to the universal handle.
- Select the appropriate tibial baseplate (the estimated size is shown on the screen) and secure it to the universal handle.
- Place the trial tibial baseplate on the tibial cut and compare its medio-lateral, anteroposterior and rotational position values. The values will be displayed in green if they are beyond ± 1 mm or ± 1° from the target values (in blue).
- Use the arrows to adjust the baseplate position to match the planned position.
- Once the trial baseplate's position has been determined, secure the trial baseplate with two Headed pins length 30 mm.
- Confirm its position by pressing the blue ampli-vision footswitch.

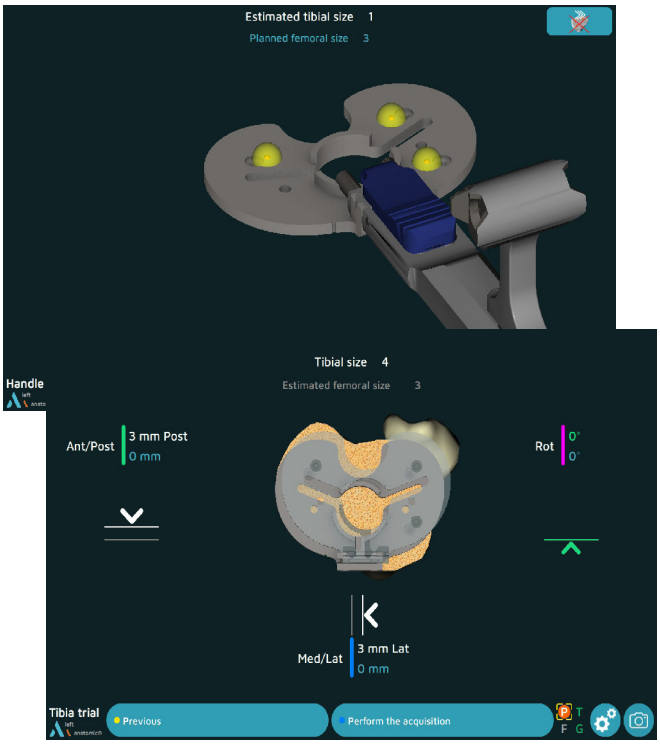
# Trials navigation

## Placement of the trial tibial baseplate

### For the ANATOMIC and TRAX CR TKAs: 2 options


Detection of the G array by the camera




**Acquisition of trial baseplate position using conical calibration marks:**

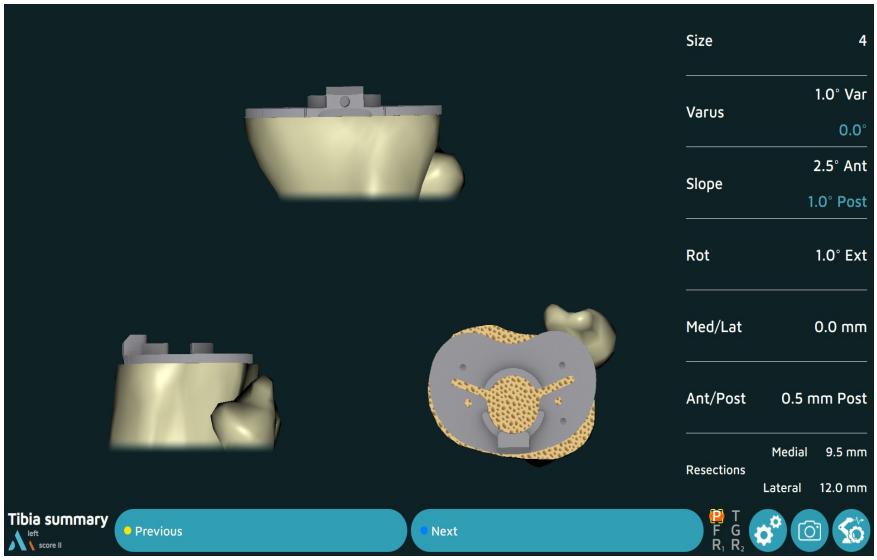
- Select the appropriate tibial baseplate (the estimated size is shown on the screen) and secure it to the baseplate handle.
- Position and secure the trial baseplate with two Headed pins length 30 mm.
- Using the probe, acquire the position of the three calibration marks located on the baseplate to identify its position on the tibia.

**Navigation of trial baseplate position with baseplate handle:**

- Secure the array support to the baseplate handle, and then attach the G array.
- Select the appropriate tibial baseplate (the estimated size is shown on the screen) and secure it to the baseplate handle.
- Calibrate the handle's position by placing the probe on each of the three calibration marks on the baseplate.
- Place the trial tibial baseplate on the tibial cut and compare its mediolateral, anteroposterior and rotational position values. The values will be displayed in green if they are beyond ± 1 mm or ± 1° from the target values (in blue).
- Use the arrows to adjust the baseplate position to match the planned position.
- Once the trial baseplate's position has been determined, secure the trial baseplate with two Headed pins length 30 mm.
- Confirm its position by pressing the blue amplivision footswitch.

# Trials navigation

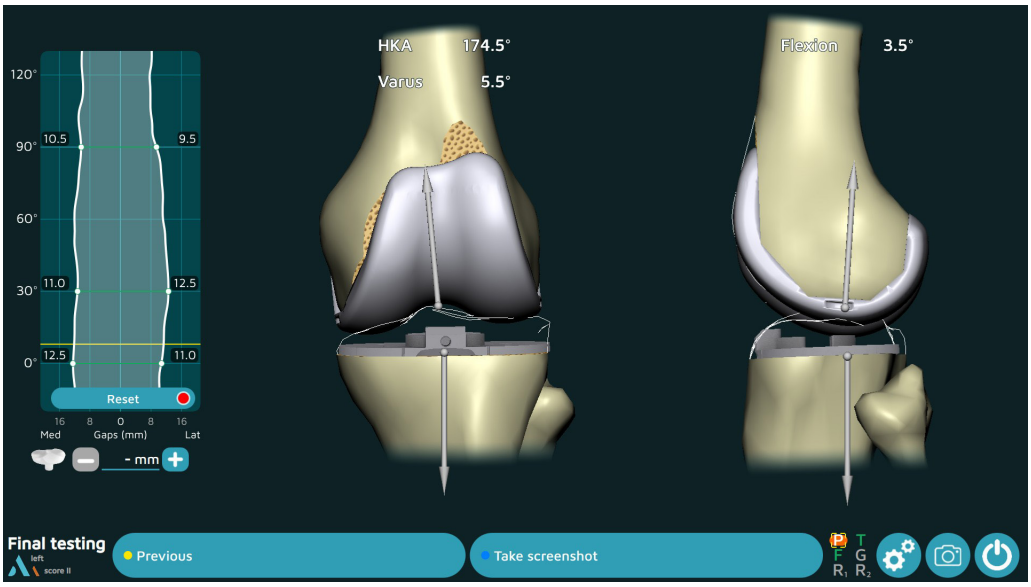
## Tibial summary




- The trial implant's position (grey) is superimposed over the planned implant position (blue).
- The size and final position of the implant are shown in white; the planned values are in blue.
- Press the blue amplivision footswitch to confirm and continue to the next step.

# Final test

## Post-operative alignment



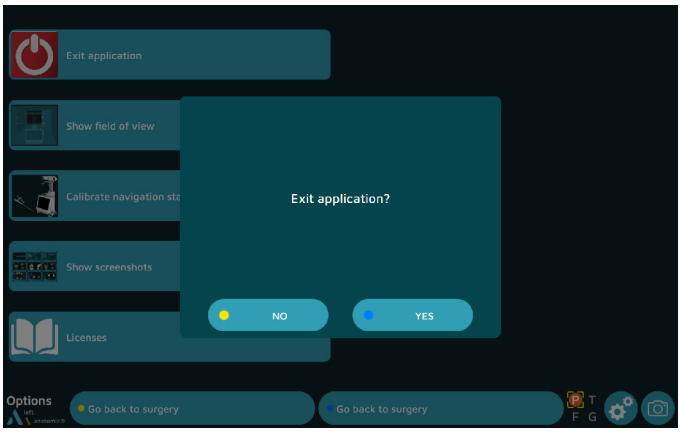

- At this step, the software allows the final HKA and varus to be visualized in real time.
- If the acquisition of the trial implants has been performed, the gaps will be displayed.
- In this step, it is possible to record the information that appears on the screen (regardless of the degree of flexion) using the blue amplivision footswitch (or the blue button).

**All navigation steps have been completed.**

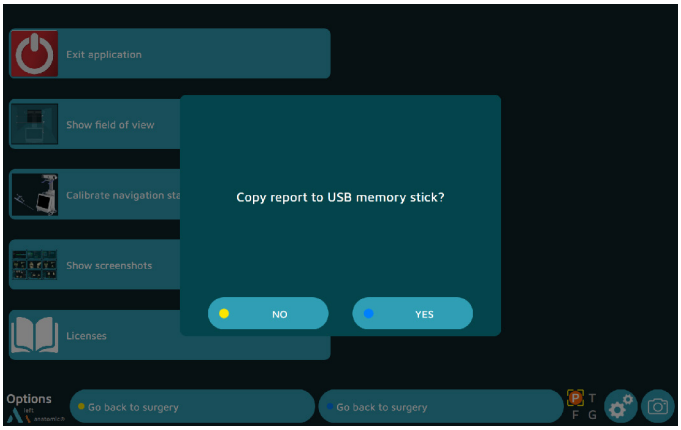
Refer to the following Surgical Techniques documents: TO.G.009 for SCORE, TO.G.013 for SCORE II, TO.G.002 for ANATOMIC and TO.G.041 for TRAX CR for the following steps:

- Femoral preparation
- Tibial preparation
- Patellar preparation
- Postioning of final implants

# Surgery report

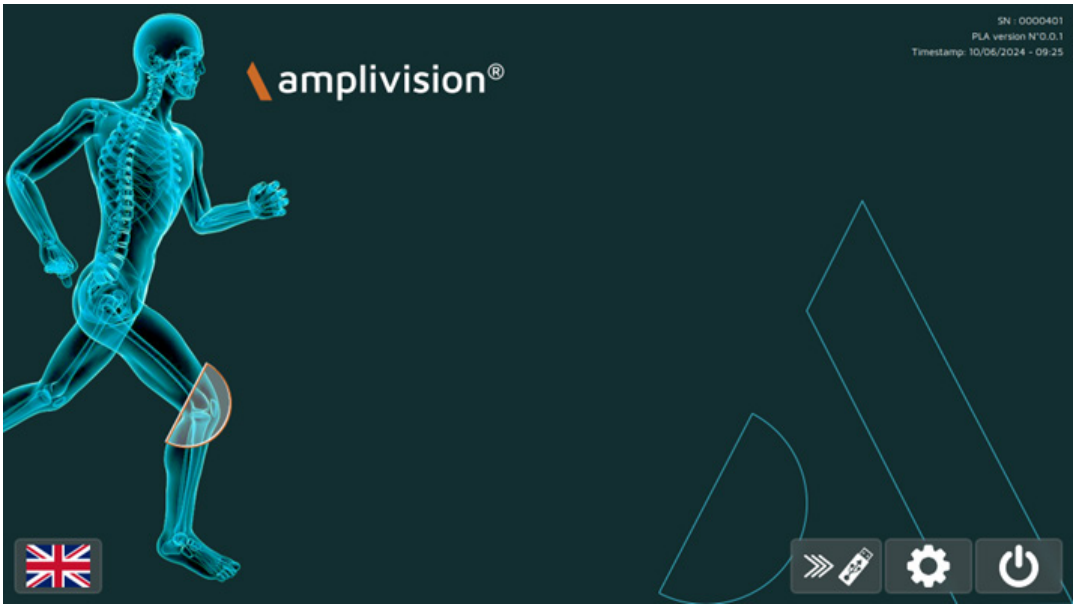



- Press the button to exit the application.
  - It is directly available after the last step of the « Final testing » procedure or
  - It can be found on the « Options » page at any point during the procedure.
- The message « Do you really want to exit? » will appear. Press « Yes » to confirm.
- The 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 close to the screen 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
  - Bone resection pages
  - Implant size and position planning pages
  - Postoperative validation pages.

# Powering down the workstation




- Press the button at the the lower right corner of the screen.
- Confirm that you want to shut down the system.
- The system will shut down.
- Refer to the AMPLIVISION NO229 (AMPLIVISION V4) User Manual for instructions on how to store the workstation.

# Instrumentation

- In addition to the mechanical instrumentation described in the Surgical Technique documents, the following sets are required:
  - AMPLIVISION Navigation Station (version 4 at minimum)
  - Standard non sterile sawblade for robot (2-1202001)
  - Sterile Drape (E6843)
  - Anatomic - Femoral prep (2-02999153) ; Anatomic Femoral trials (2-02999154) ; Anatomic Tibial trials (2-02999155)
  - SCORE II - Femoral trials (2-02999148) ; SCORE II - Tibial trials (2-02999149)
  - TRAX - Femoral trials (2-02999105) ; TRAX - Tibial trials (2-02999104)

### NDI Passive Spheres - 18 pheres (2x9) (Product No. 8800965)

- The probe and G-array must be equipped with passive spheres to be visible to the camera. These passive spheres are attached through the nipples on the array (4 for the probe P and 3 for the G arrays).

### Projection resistant sterile markers - 16 markers (Product No. 2-0301000)

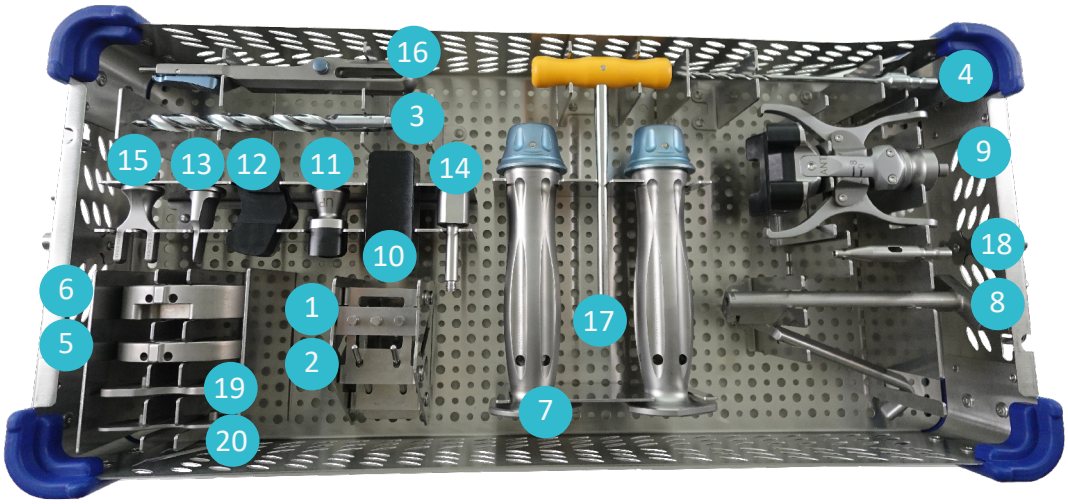
### Single-use Conical Threaded Pins AMPLIVISION Ø4 length 150mm (Product No. 2-0252200):

- 4 Single-use Conical Threaded Pins AMPLIVISION Ø4 length 150mm, are available upon request. They are inserted in the femur and the tibia and array fixation supports are placed on these pins which are inserted in the femur and the tibia.

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

# Instrumentation

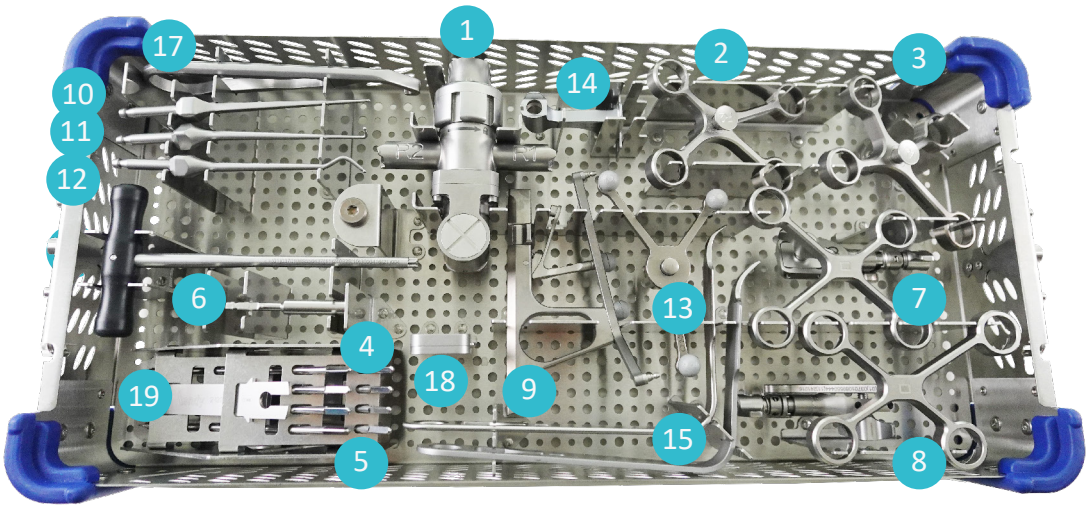
## Instrumentation set andy Universal 2-02999161




| Item | Name | Reference | Qty |
|---|---|---|---|
| **1** | Headed pin length 30 mm | 2-0201301 | 3 |
| **2** | Threaded Non-Headed Pin Lg 80mm | 2-0255402 | 2 |
| **3** | Intramedullary drill bit | 2-0200100 | 1 |
| **SUBSTITUTE** | Intramedullary Hall drill bit Ø 10 mm | 2-0245400 | 1 |
| **4** | Drill bit Ø3.2 length 145 mm | 2-0102400 | 1 |
| **SUBSTITUTE** | Hall Ø 3.2 drill bit Length 145 mm | 2-0248700 | 1 |
| **5** | Spacer Base 10mm | 2-0255510 | 1 |
| **6** | Spacer Base 18mm | 2-0255518 | 1 |
| **7** | Modular Handle | 2-0255300 | 2 |
| **8** | Specific pin extractor | 8-0202700 | 1 |
| **9** | Femoral Impactor / Extractor | 2-1201300 | 1 |
| **10** | Femoral Impactor - Universal | 2-0241200 | 1 |
| **11** | Insert Impactor - Universal | 2-0241300 | 1 |
| **12** | Tibial Impactor - Universal | 2-0241900 | 1 |
| **13** | Insert Extractor | 2-0241500 | 1 |
| **14** | Tibial Baseplate Extractor | 2-0241600 | 1 |
| **15** | Modular Tibial Stem Wrench | 2-1201000 | 1 |
| **16** | Tibial baseplate handle | 2-0223500 | 1 |
| **17** | H5 Screwdriver | 2-0200800 | 1 |
| **18** | AO Pin driver | 2-1201100 | 1 |
| **SUBSTITUTE** | HALL Pin driver | 2-1201200 | 1 |
| **19** | Spacer Block 2mm | 2-0255602 | 1 |
| **20** | Spacer Block 4mm | 2-0255604 | 1 |

# Instrumentation

## Instrumentation set andy Dedicated 2-02999162




| Item | Name | Reference | Qty |
|---|---|---|---|
| **1** | Robotic oscillating saw attachment | 2-1201800 | 1 |
| **2** | Motor array R1 | 2-1202002 | 1 |
| **3** | Motor array R2 | 2-1202003 | 1 |
| **4** | Conical Threaded Pins AMPLIVISION Ø4 length 150mm | 2-0235500 | 4 |
| **5** | Conical Threaded Pins AMPLIVISION Ø4 length 100mm | 2-0235900 | 4 |
| **6** | Pin Driver AO | 2-0201200 | 1 |
| **SUBSTITUTE** | Pin Driver – Zimmer / Hall | 2-0246300 | 1 |
| **7** | Tibial array | 2-1202200 | 1 |
| **8** | Femoral array | 2-1202300 | 1 |
| **9** | Modular Probe | 2-1202400 | 1 |
| **10** | Probe tip - Straight | 2-1202700 | 1 |
| **11** | Probe tip - Curved | 2-1202701 | 1 |
| **12** | Probe tip - 90° | 2-1202702 | 1 |
| **13** | G array, Instrumentation navigation | 2-0117500 | 1 |
| **14** | Reversible plate | 2-1202600 | 1 |
| **15** | Collateral Ligament Retractor | 2-0238103 | 2 |
| **16** | T30 screwdriver | 2-1202100 | 1 |
| **17** | Robotic tightening wrench | 2-1202800 | 1 |
| **18** | Sawblade cap | 2-1202500 | 1 |
| **19** | Standard non sterile sawblade for robot | 2-1202001 | 1 |

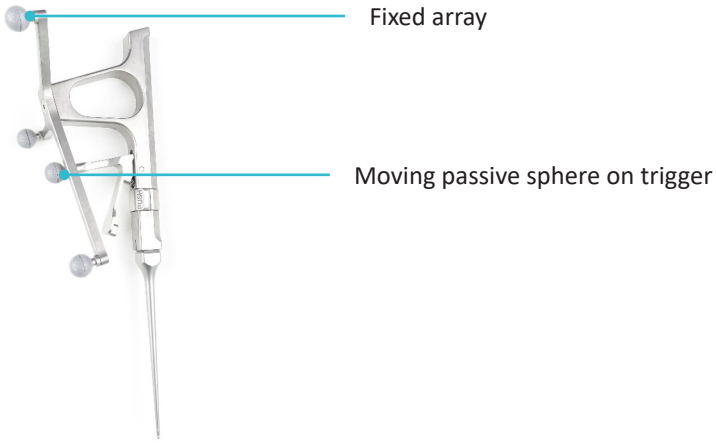
# Instrumentation

## Instruments

### Probe knee navigation:

- This instrument is used to acquire specific points and areas on the patient's anatomical structures.

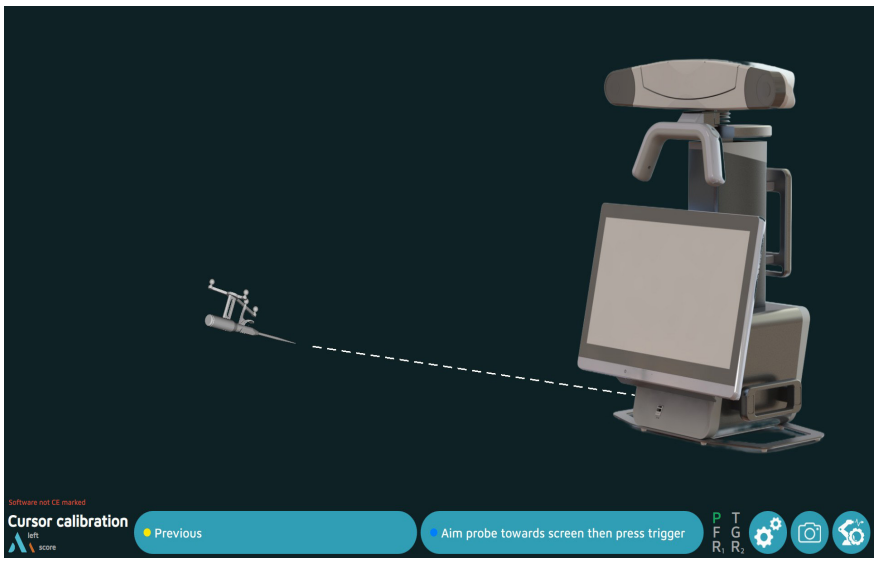
  It is also used to remotely control certain active elements on the screen. The probe must be fitted with four passive spheres, one of them being on the trigger.




### Universal guide:

The universal alignment guide is used to acquire the cuts once they have been made.

# Option : Cursor calibration




- From this step on, the AMPLIVISION system can be controlled with:
  - the amplivision footswitch,
  - the touchscreen of the AMPLIVISION workstation.
  - the probe: target the center of the AMPLIVISION screen with the probe and press the trigger to confirm.

- The system will capture screenshots when:
  - the user validates a step,
  - the user presses the screen capture button at the lower-right corner of the screen.

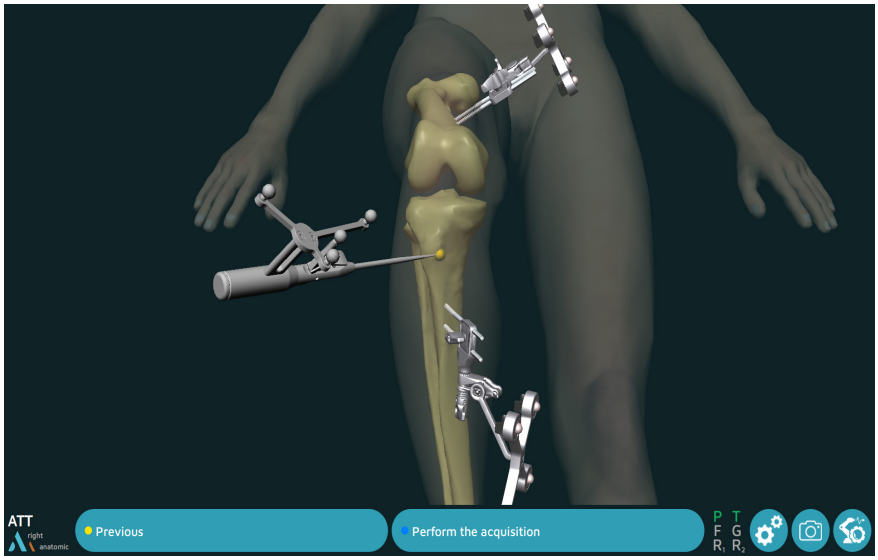
**NOTE**

If screen calibration is not initially selected, the station position is set by default.

**NOTE**

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

# Option : Anterior Tibial Tuberosity (ATT)

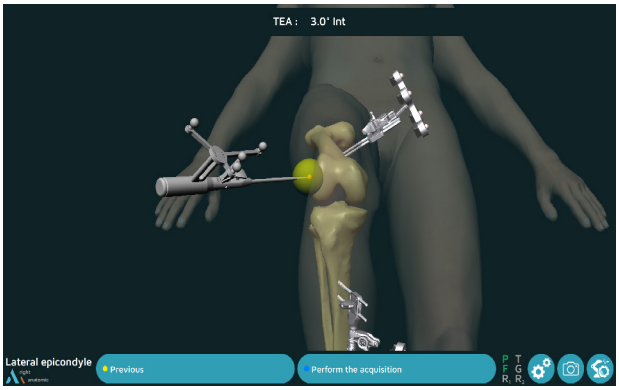



- Acquire one point with the Probe tip on the medial aspect of the anterior tibial tuberosity (ATT).
- Press the trigger to confirm.

# Option : femoral rotation

## Transepicondylar axis registration

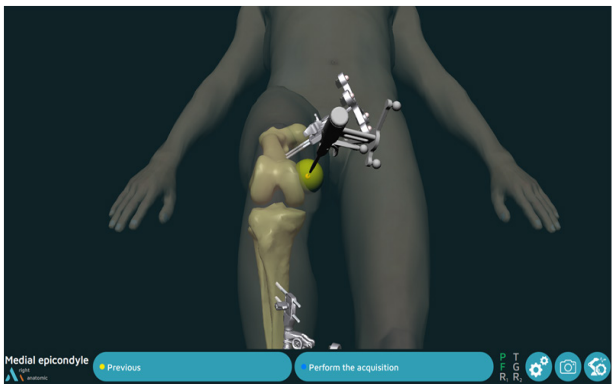
- Place the probe tip on the medial epicondyle
- Confirm



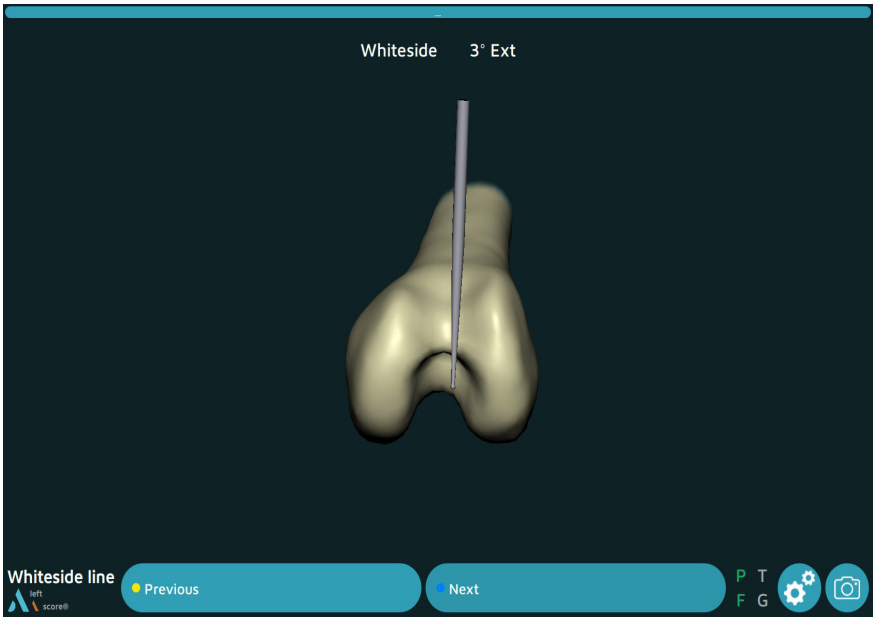

- Place the probe tip on the lateral epicondyle

*The angle between the transepicondylar axis and the posterior condyles is displayed.*

- Confirm



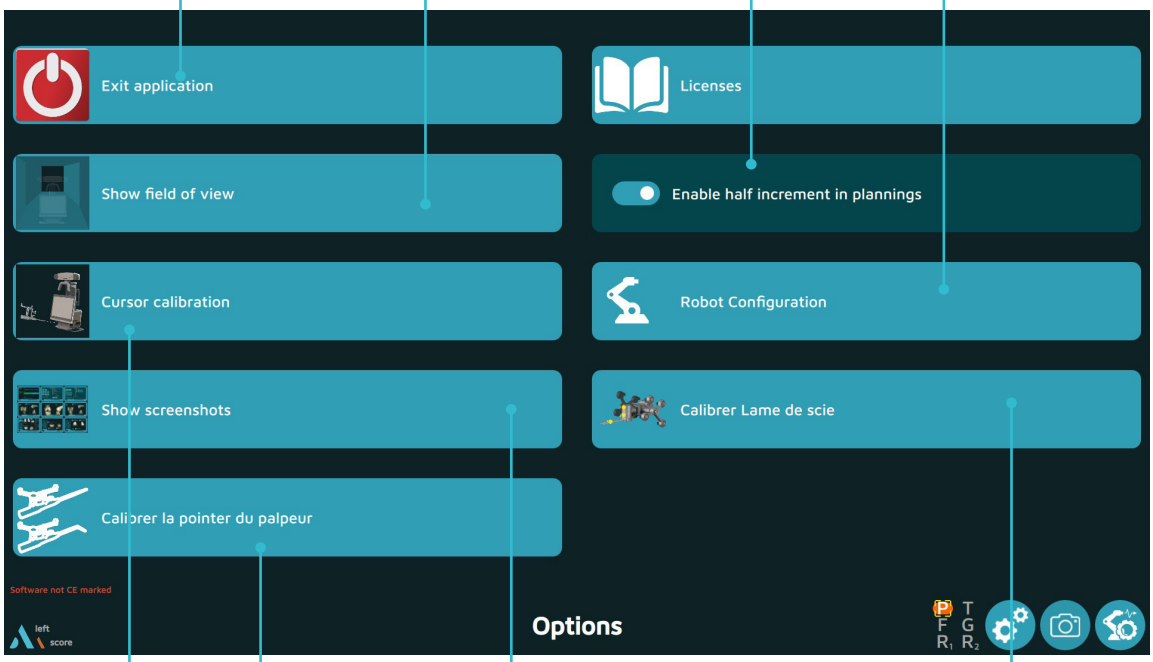

## Whiteside line registration




- Place the probe tip following the whiteside line : the angle between the Whiteside line and the posterior condyle is displayed
- Confirm

# Appendix A

## Menu Options

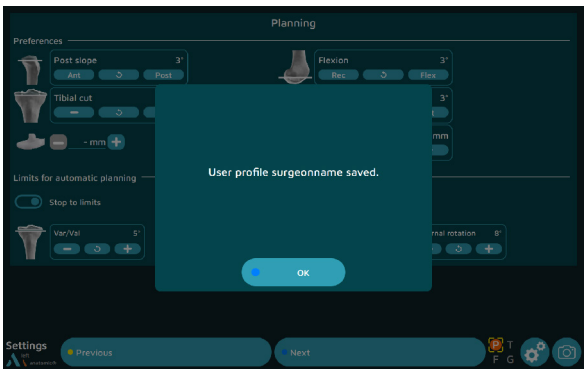


# Appendix B

## User profile

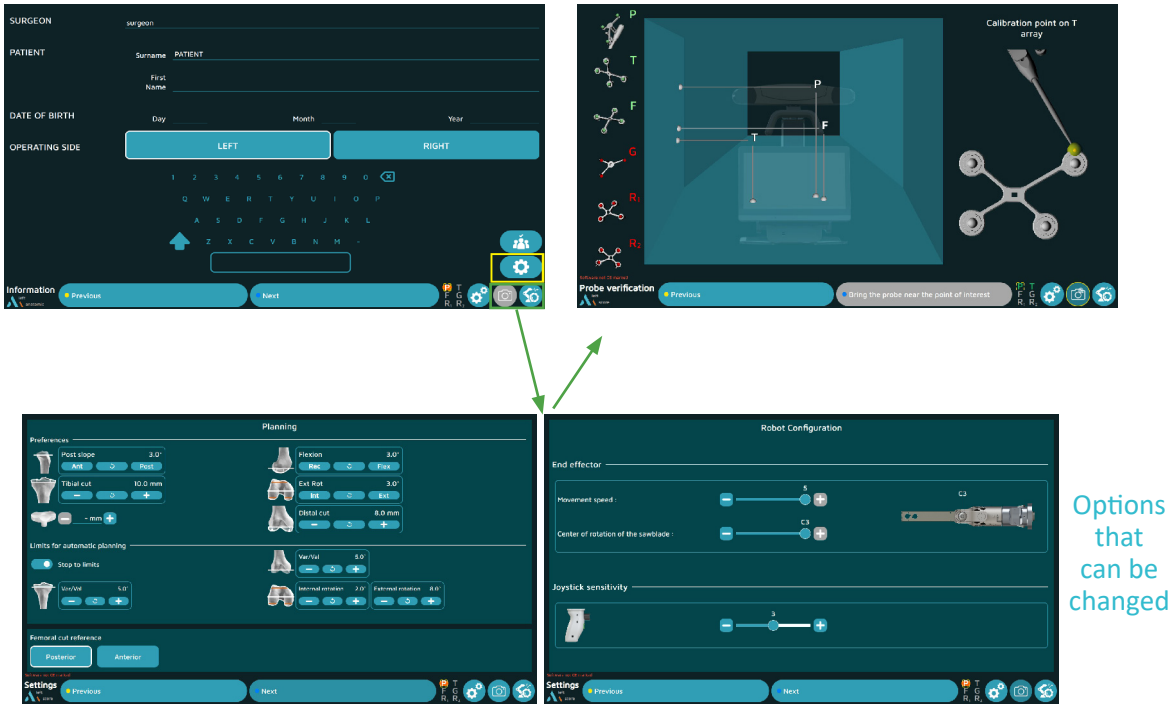
### Saving a user profile

- Once the surgery-related options have been selected and the surgical workflow chosen, a saving of the user profile on a USB key is automatically launched.




- The following will be saved on the USB key:
  - The surgeon's name,
  - The selected workflow and the order of the cuts
  - All the selected options
  - All robot configuration settings

### Working with a user profile




Options that can be changed

- 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 «Surgery-related options» page.
- To change a saved parameter, press the button  at the lower right corner of the «Information» screen.

# Appendix C

## 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

1. When the AMPLIVISION welcome screen appears, press the USB key button

- Select the Reports to export either by:

2. Selecting the dates corresponding to the procedure(s) on the calendar. The dates on which surgery reports were saved will be highlighted in red.
3. Searching by text (surgeon name, patient name.
4. The list of searched reports appears in the « Available reports » window. Select the chosen reports and press the arrow to add them to «Reports to export». If you press the triple arrow, all will be added to «Reports to export» 5

- Repeat the steps until all reports to export are listed.
- Insert the USB key and press on the USB key button to start the copy. A message will appear when the operation is complete.


**NOTE**

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

# Appendix D

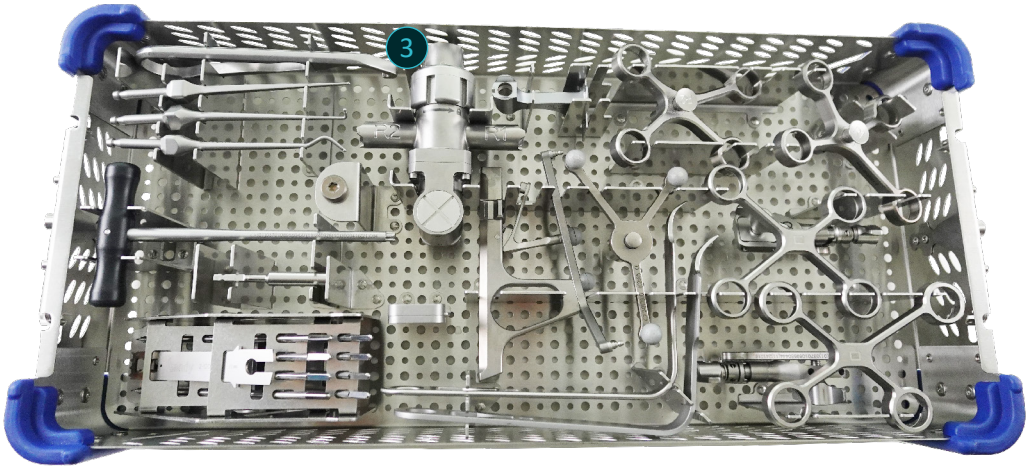
## Motor attachment dissasembly

Once the resections are done, the robot is removed from the sterile field. Surgeon moves on to the next steps of the total knee arthroplasty.

The motor attachment must be dissasembled after a waiting period of 10minutes to ensure temperature drop (for user safety reasons).

The procedure is the following:

1. Using the T30 screwdriver, remove the sawblade from the motor attachment.
2. Remove the blade screw completely to place it in the instrument set for cleaning and sterilization.
3. Using the thightening wrench, unscrew the motor attachment from the robotic arm.
4. Remove the sterile drape from the robotic arm.
5. Using a wipe, clean the surface of the robot and cart.

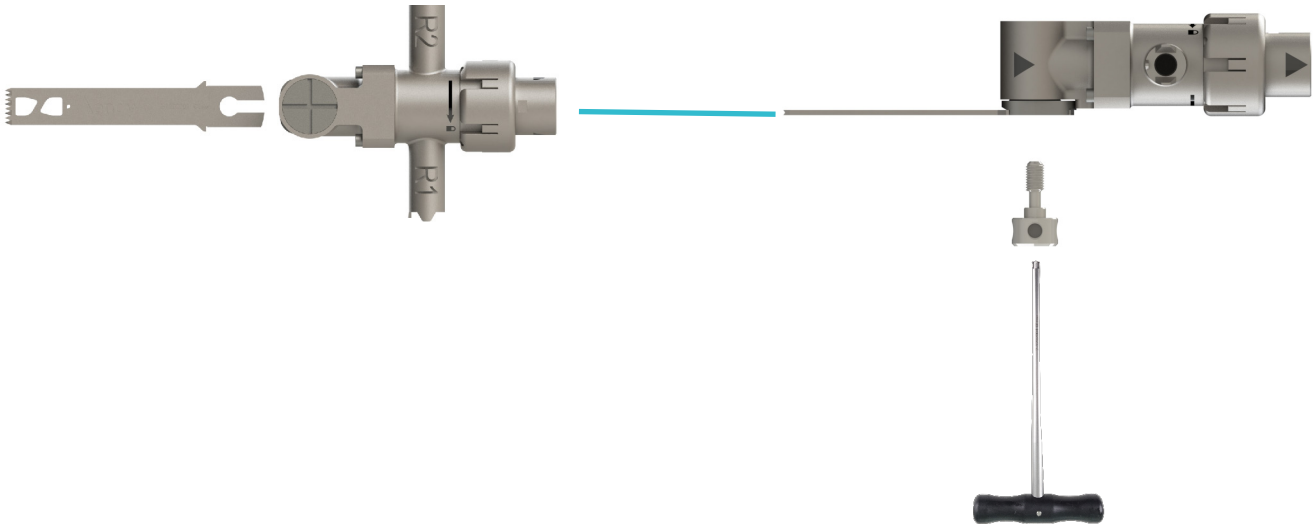


# Appendix E

## Robotic oscillating saw attachment

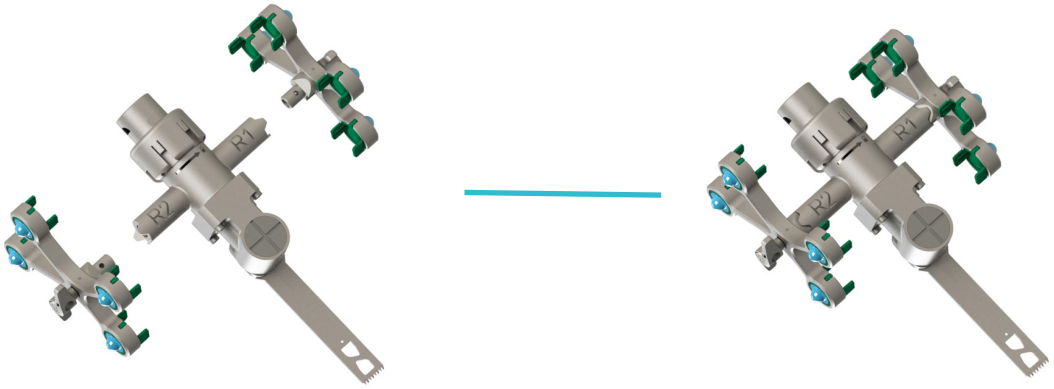
### Blade assembly

- Insert the blade into the saw attachment
- Lock the blade by fixing the blade screw with the T30 screwdriver



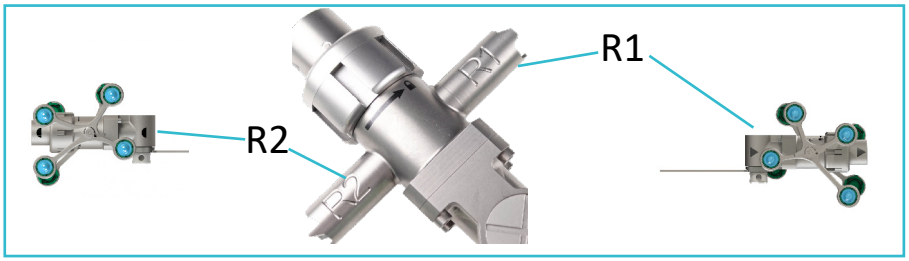

### Arrays assembly

- Screw the Motor array R1 and Motor array R2 on the saw attachment




**NOTE**

Make sure to correctly position R1 and R2 according to the marking on the saw attachment.

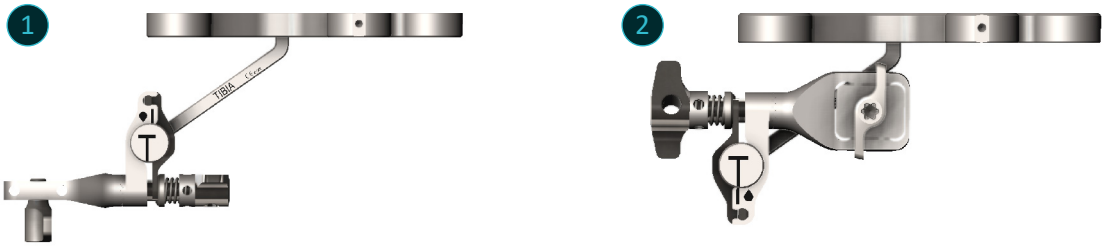


# Appendix F

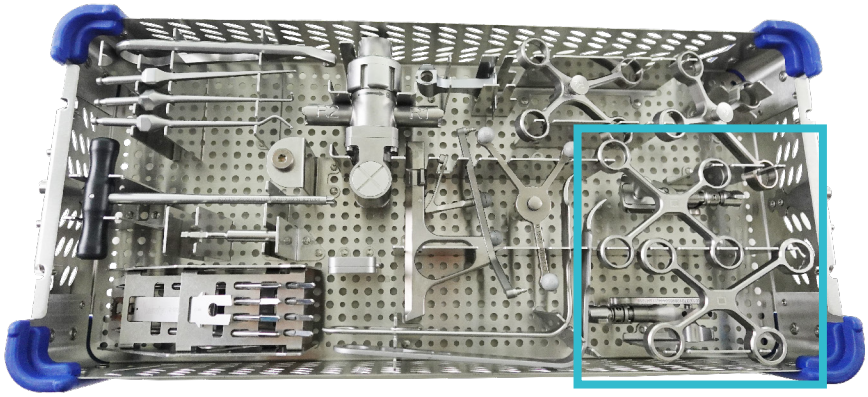
## Arrays Assembly-Dissassembly

The tibial and femoral arrays are designed with two positions:

1. Surgical position
2. Cleaning position

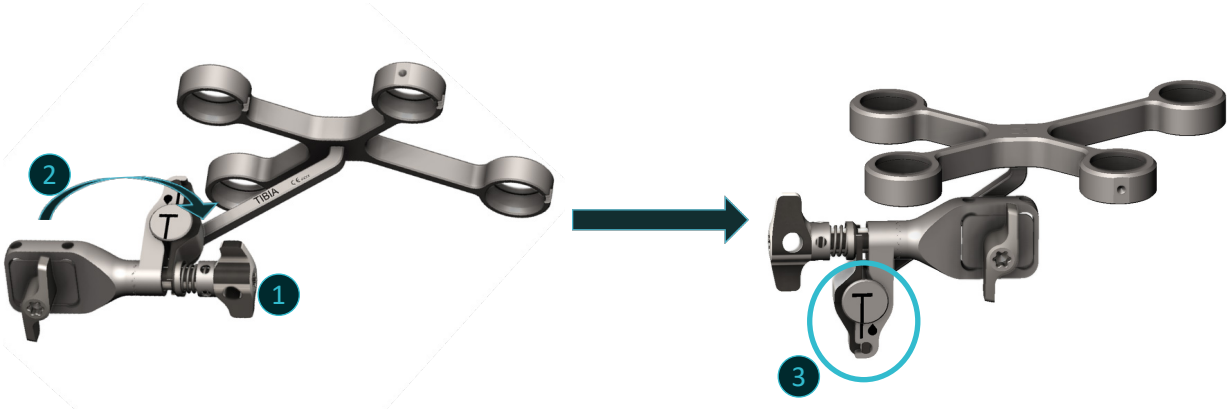



The arrays must be in the cleaning position to be placed in the instrument tray:



The following steps must be followed to switch from the surgical position to the cleaning position:

1. Completely unscrew the locking screw
2. Rotate the pin set around the «T» axis (or «F» axis)
3. Make sure the T-axis (or F-axis) is aligned with the marked line



# Appendix G

## Light indicators

| Color | State | Description | Exemple of situation |
|---|---|---|---|
| White | Blinking | *Proceed to start-up procedure* | *After robot start-up procedure step 4* |
| Blue | Fixed | *Start-up procedure completed and arrays visible* | *Robot ready for use* |
| Blue | Blinking | *Start-up procedure completed and arrays not visible* | *Robot away from Amplivision camera* |
| Green | Fixed | *Robot aligned with targetted resection plan* | *Robot ready for blade activiation and bone resection* |
| Red | Blinking | *Safety indicator* | *Stop on-going action and check potential warning on Amplivision screen* |
| Red | Fixed | *Robot is in default* | *Pontential restart necessary* |

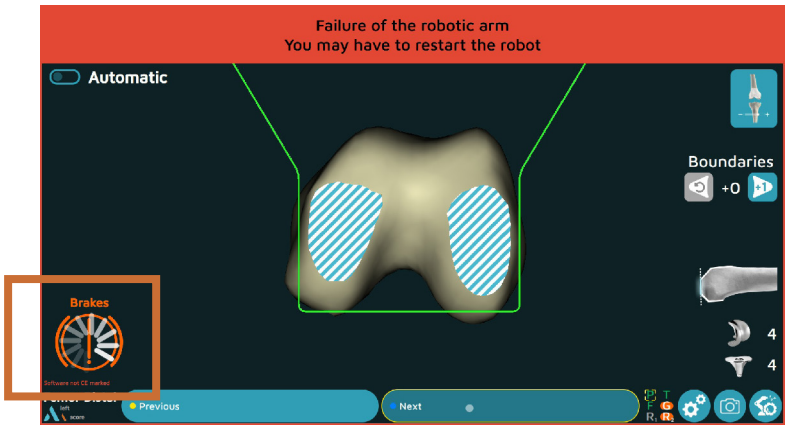
# Appendix H

## Break security

In a few situations, the robot can go into security for a couple of seconds:

- Excessive force applied on the robotic arm
- Sawblade is locked in bone during resection
- Sudden movement of the robotic arm

The logo below will be visible on the screen for a few seconds. When it disappears, you can restart the alignment on the cutting plane and resume resection.



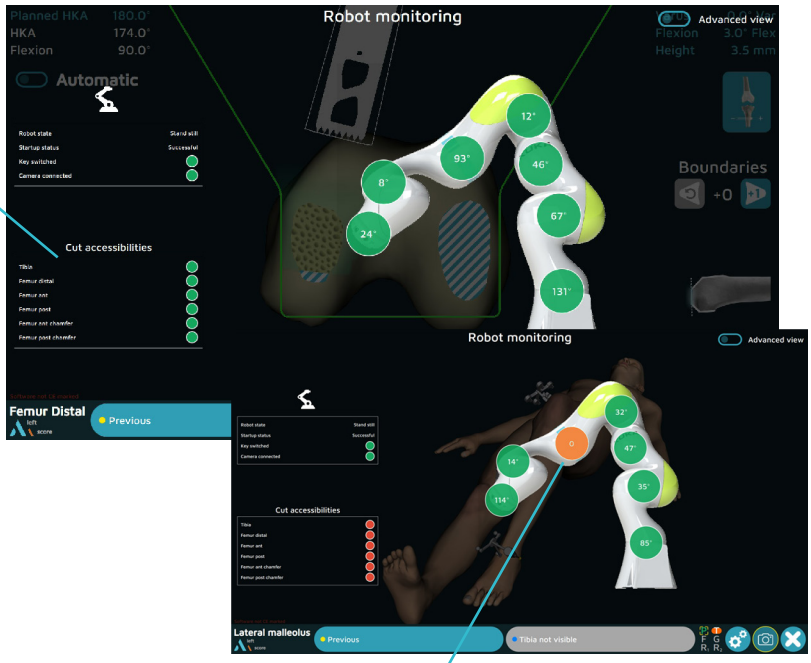
# Appendix I

## Robot monitoring

In the case that the robot indicates the impossibility to align the sawblade on the resection plane, it is possible to monitor the robot's axis position. In that case, from any steps of the surgical flow, press the setting button:  and select «robot configuration».


**Verify the cut accessibilities:**

- If all indicators are in green go back to the surgical flow.




- If one or more of them is red: Verify the robot's axis. If one (or more) angle is red, use the handguiding button to replace the robotic arm in a better position or use the L/R button on the cart to replace the robot is a standard position.
- Re-start alignment on the resection plane (with the robot footswitch or joystick green button).

# Appendix J

## Powering down of the robot

The following steps must be followed to turn the robot off:

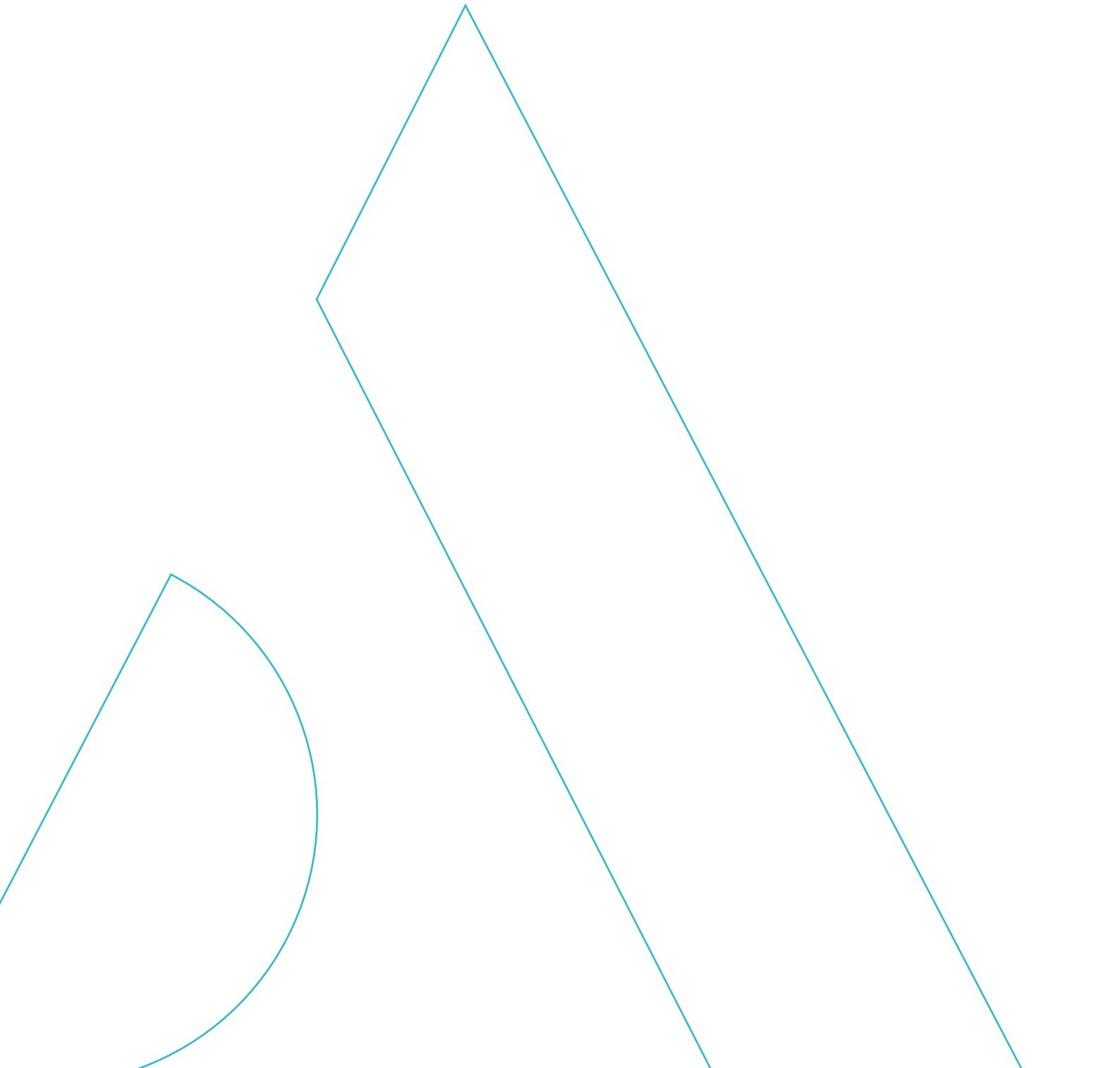
1. Disengage the stabilizers
2. Position the Robotic Arm in the storage position, (long press of the storage position button on the control pannel of the cart).
3. Once in position, the storage position button remains light.
4. Turn the key-switch to the OFF position
5. Wait until all light indicators are off (except power indicator).
6. The power cord can be unplugged safely.
7. The various connection cables and hands-free actuator cable can be unplugged and stored in the accessories holders on the rear of the Cart.

**Storage position**

# NOTES

# NOTES

# NOTES



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Reference: TO.G.060/EN/A