amplivision

amplitude

Surgical Technique

Computer Assisted Surgery
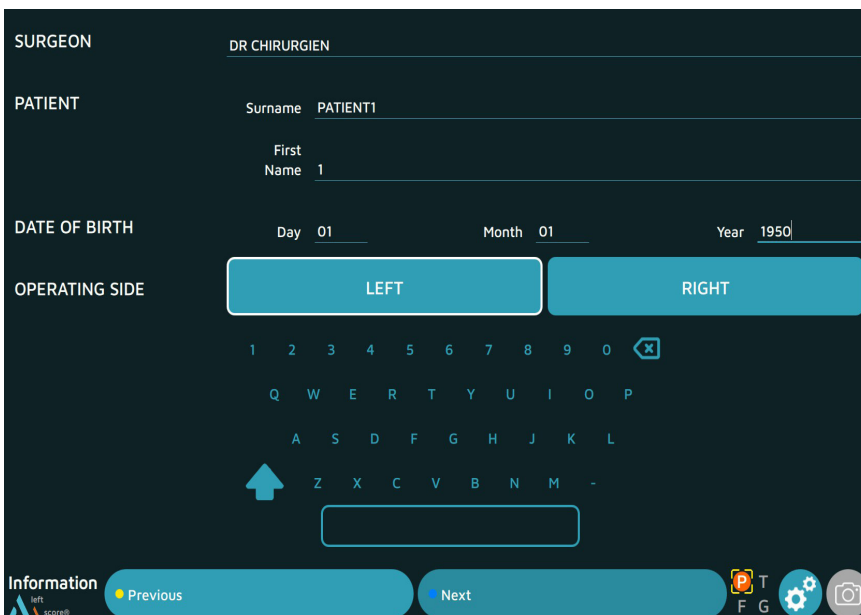## 5-in-1 Global Planning

Summary

Introduction

- This Surgical Technique Supplement describes the use of the 5-in-1 Computer-Assisted Surgery software AKN (Advanced Knee Navigation) for implanting AMPLITUDE's Total Knee Arthroplasty (TKA) systems.

- This sofware is used to navigate the tibial resection and the 5-in-1 femoral resections.

- It replaces the following paragraphs in the conventional Surgical Technique documents:

- For the SCORE TKA with 5-in-1 instrumentation: **TO.G.008**
    - From the "Intramedullary tibial aiming" to the "Combined tibial aiming" paragraph.
    - From the "Flexion and extension gaps" to the "Setting up threaded pins" paragraph.
    - The "Mediolateral femoral adjustment" paragraph.

- For the SCORE II TKA with 5-in-1 instrumentation: **TO.G.008** and **TO.G.013**
    - From the "Intramedullary tibial aiming" to the "Combined tibial aiming" paragraph.
    - From the "Flexion and extension gaps" to the "Setting up threaded pins" paragraph.
    - The "Mediolateral femoral adjustment" paragraph.

- For the ANATOMIC TKA with 5-in-1 instrumentation: **TO.G.001**
    - From the "Intramedullary tibial aiming" paragraph to the "Pins insertion" paragraph.
    - From the "Flexion and extension gaps" to the "Pins insertion" paragraph.
    - The "Femoral preparation guide placement", "Placement of trial femoral component", "Placement of trial tibial baseplate" paragraphs.

Starting the software
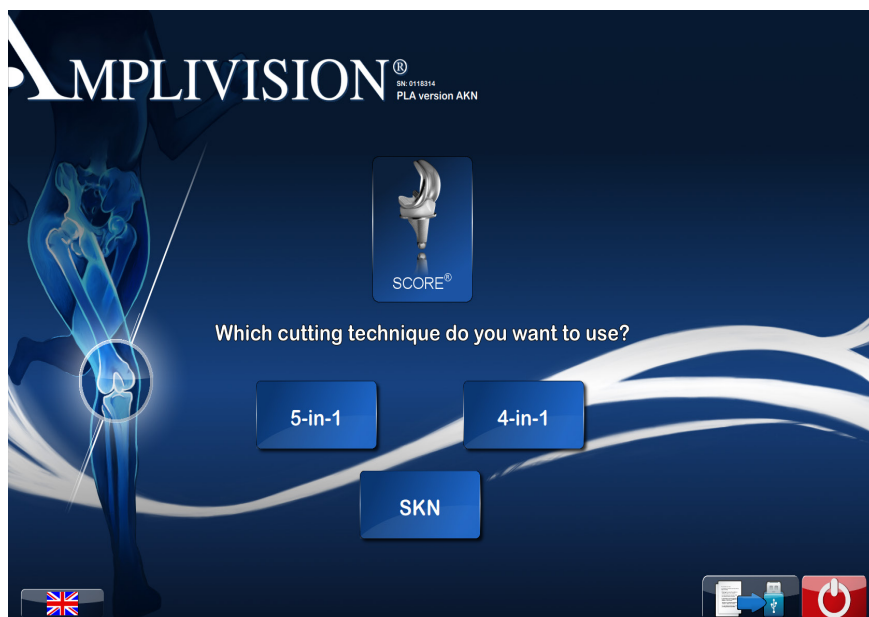

On the touch screen

- Select the language.

- Select the knee.

- Select the implant.

- Select the **5-in-1**.

- 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 pedal or Next on the screen.

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

User settings

Surgical protocol
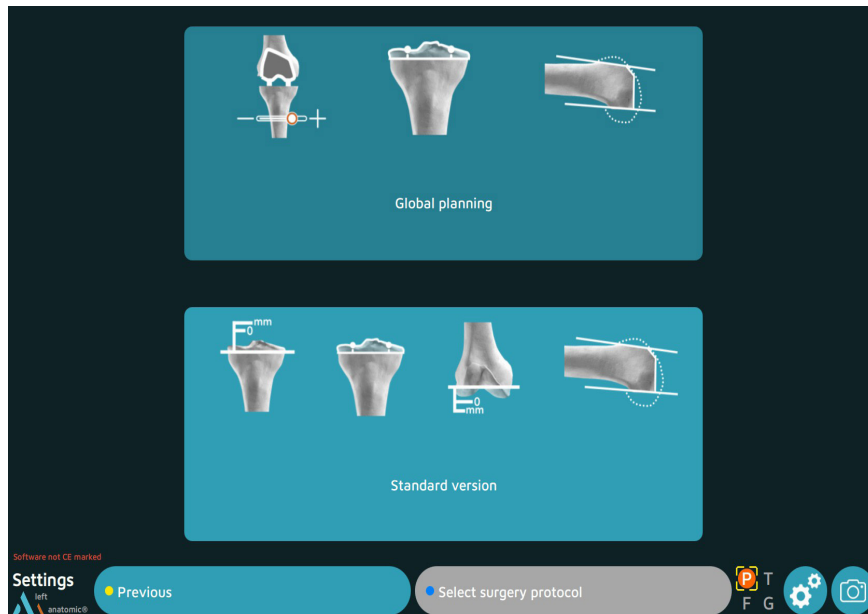
- Select the « **Global planning** » workflow described in this Surgical technique document.

Description of the 2 workflows:

Global planning
This workflow allows to perform the resections based on Mecanichal alignment (MECA), Kinematic Alignment (KA,rKA) and Functional Alignment (GAPS).

Standard version
This workflow allows to perform a standard 5 in 1 surgical workflow.
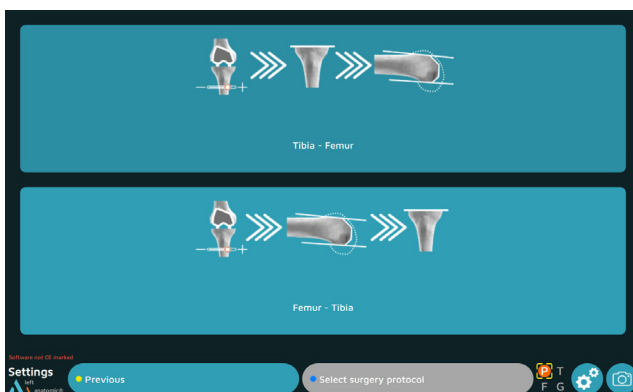
Select the worflow :
- Global planning then tibial resection then femoral resections.
- Global planning then femoral resections then tibial resection.

User settings

Registrations options

- Configuring the surgery-related options:
    ### Three methods can be used to define the tibial rotation reference:
    - **Acquire two points on the tibial plateau** to define the frontal plane (default).
    - **Acquire sagittal axis** by placing the probe tip along the sagittal axis (Akagi's line).
    - Acquire sagittal plane by placing the probe tip along **the sagittal axis** (Akagi's line) and **then one additional point on medial side of tibial tuberosity** to define the sagittal plane.

    ### Two navigation methods can be used for the tibial cut:
    - Using tibial navigation alignment device to navigate the pins of the tibial resection guide.
    - Using universal alignment device to navigate the tibial resection guide.

    ### Configuration
    - Selection of the registration of the confidence points.
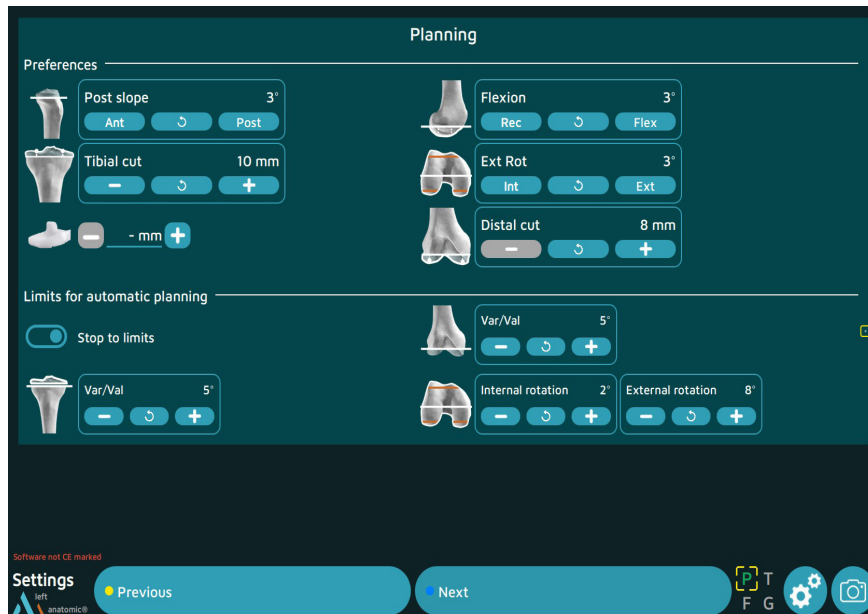   - Selection of the cursor calibration.

    ### Trial implants :
    - No acquisition.
    - Femoral component first and then tibial baseplate.
    - Tibial baseplate first and then femoral component.

- Press the blue pedal to continue to the next step.

User settings

Planning options

Preferences

The preferences allows to pre-positionned the implants regarding 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 beynod 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.
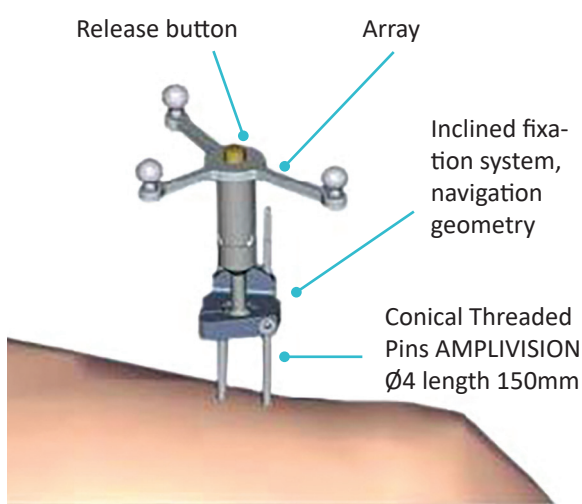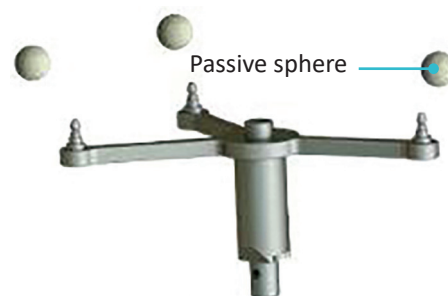
During the planning all the values can be changed.

- Press the blue pedal to continue to the next step.

Set up

Setting up of the arrays

- Clip the AMPLIVISION sterile Passive spheres 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

Passive sphere

Release button   Array

Inclined fixation system, navigation geometry

Conical Threaded Pins AMPLIVISION Ø4 length 150mm

- The Conical Threaded Pins AMPLIVISION Ø4 length 150mm 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.
- Position 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).
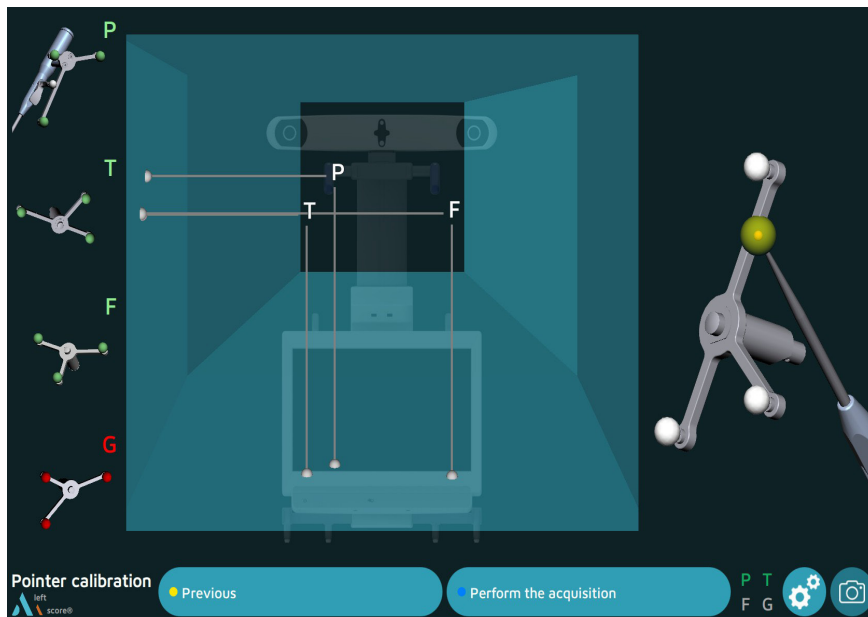

F array, femur navigation

T array, tibia navigation

Conical Threaded Pins AMPLIVISION Ø4 length 150mm
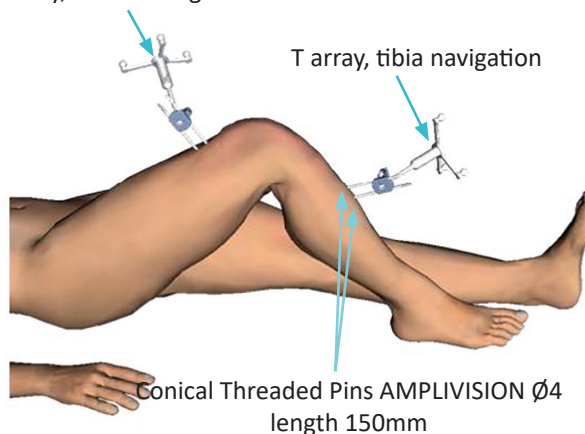
Set up

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® V3 or V2 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).
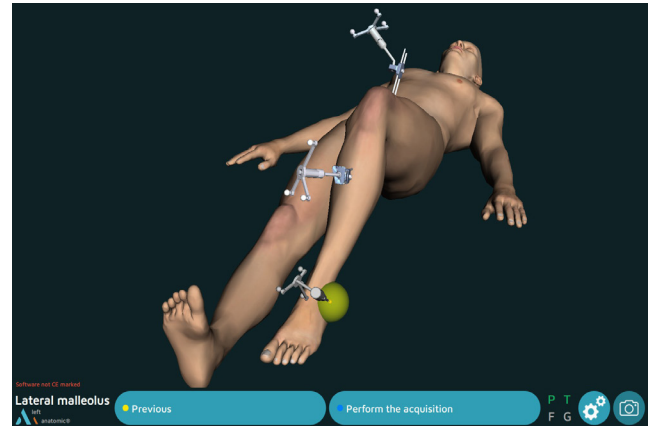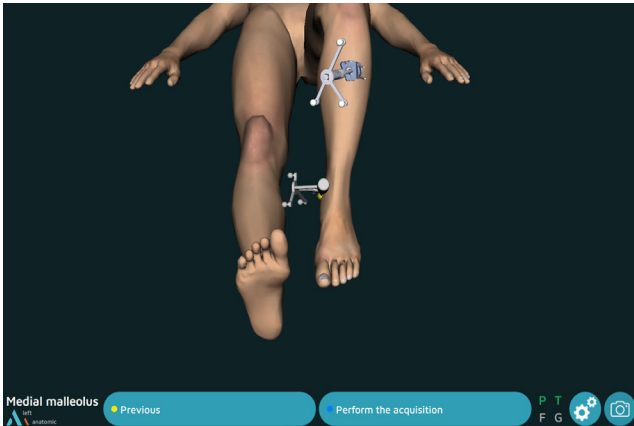
Probe calibration

To define exactly the position of the probe tip:

- Calibrate the probe by placing its tip in the conical calibration mark on one arm of the T array.

- Press trigger to confirm.

- Without lifting the probe tip, change the probe's orientation slightly.

- Press the trigger to confirm.

Tibial and femoral registrations
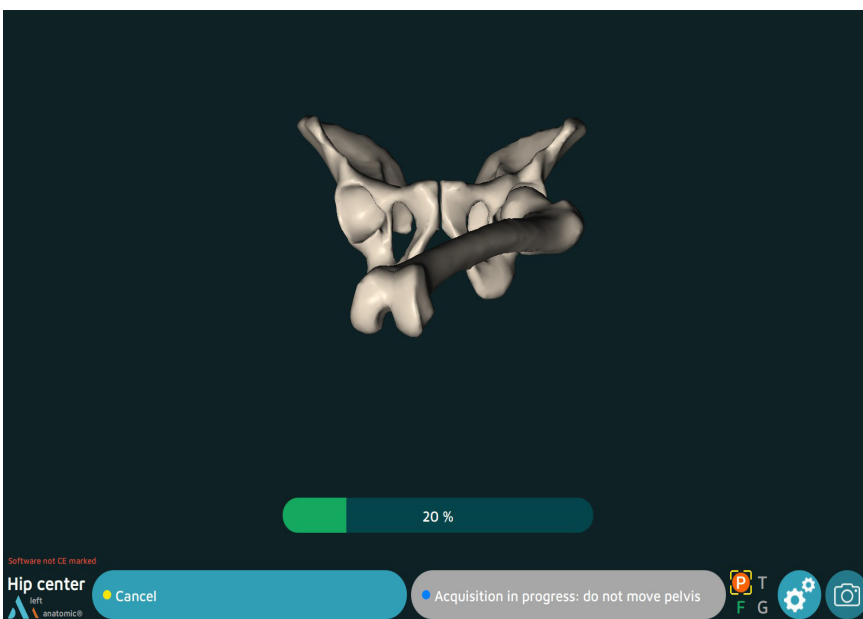
Ankle center registration

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.

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.

Tibial and femoral registrations

Tibial center registration
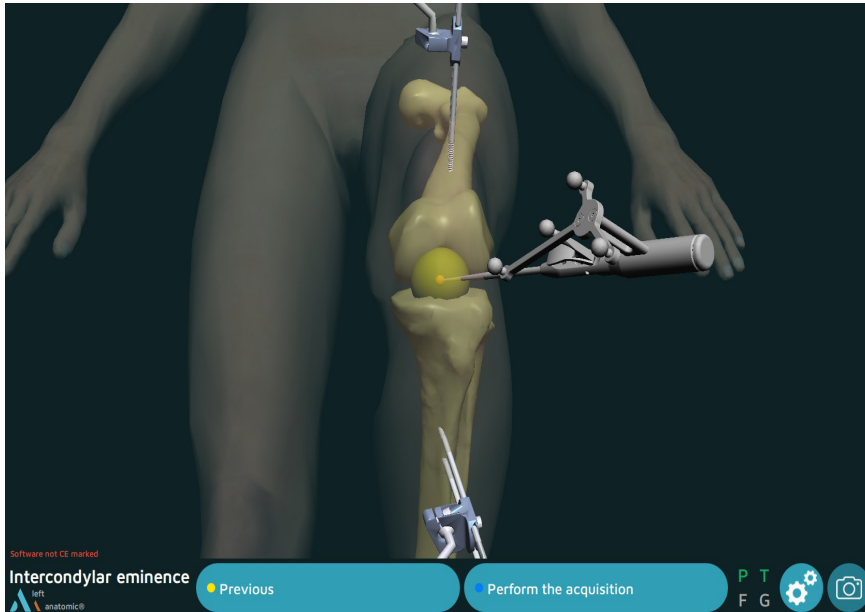
- Place the probe tip on the middle of the intercondylar eminence on the axis of the tibial shaft.

- Press the trigger to confirm.
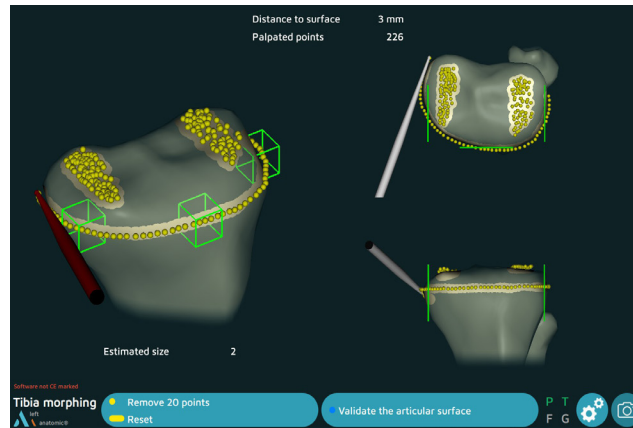
Tibial reference rotation

Sagittal axis regarding Akagi's line

- 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.

Tibial and femoral registrations

Tibial bone surface registration

The goal of this step is to register the tibial bone surface.

• 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.

• 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 in the middle 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.

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.
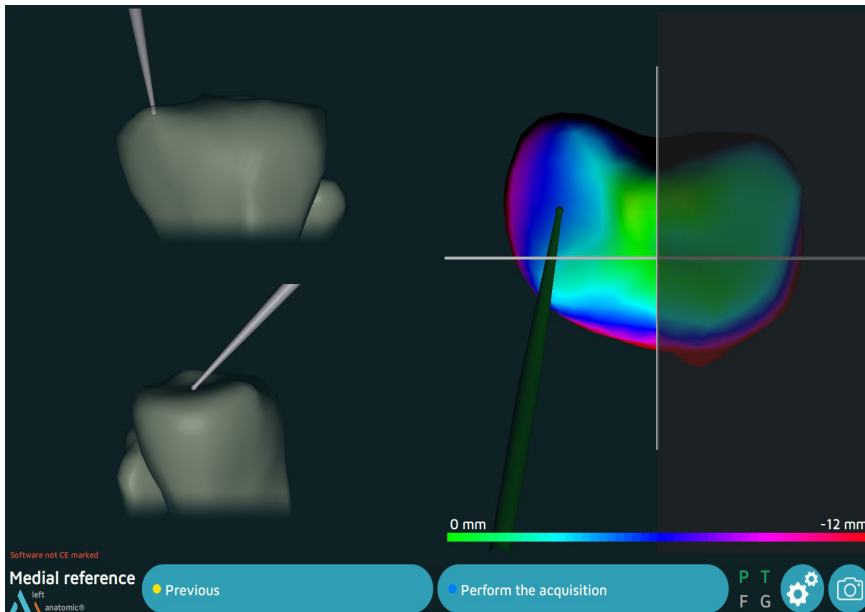
Removal of acquired points

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

Press and hold down the yellow pedal (for at least 2 seconds) to erase all the acquired points.
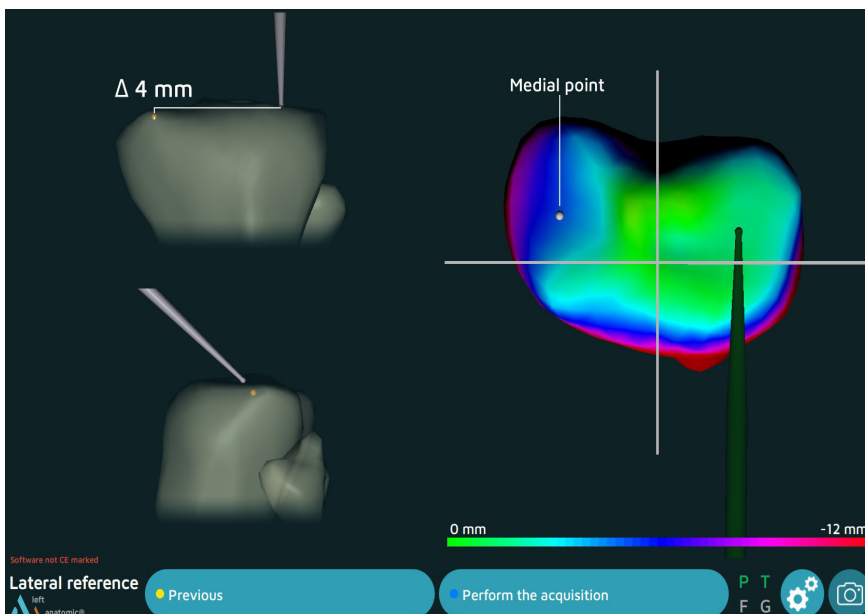
If the contour accuracy is satisfactory, confirm this step and go to the next step.

Tibial and femoral registrations

Reference points

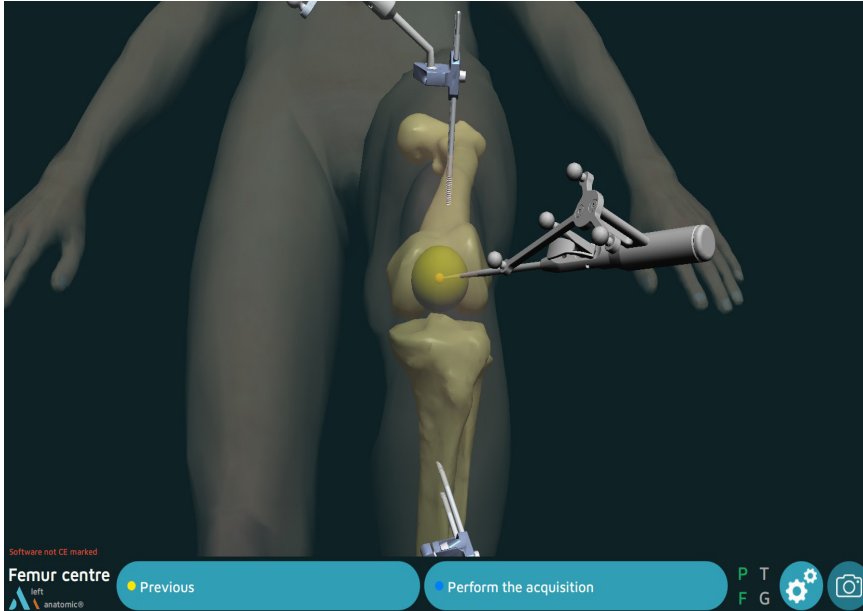- Place the probe tip on the medial tibial bone surface.
- Confirm.

- 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.

Tibial and femoral registrations
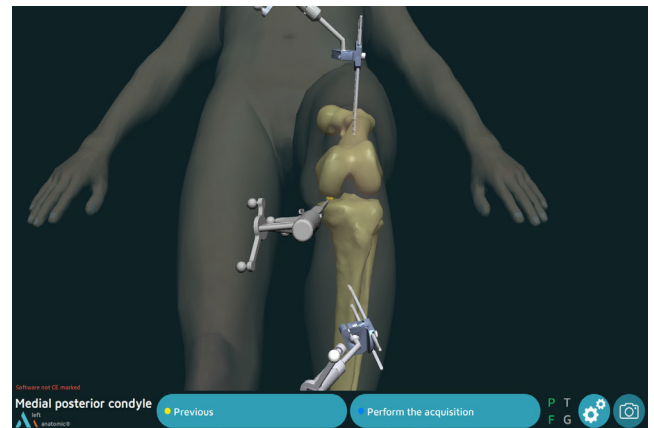
Top of the intercondylar notch registration

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

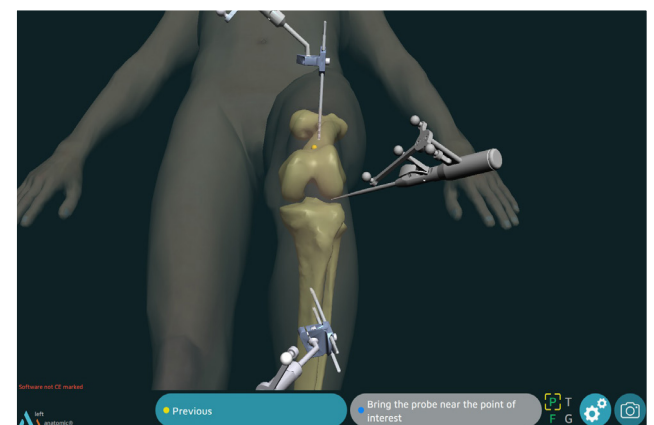> **NOTE**
> The femoral mechanical axis is calculated using the hip centre and the top of the intercondylar notch.

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.

Tibial and femoral registrations

Femoral anterior cortex registration
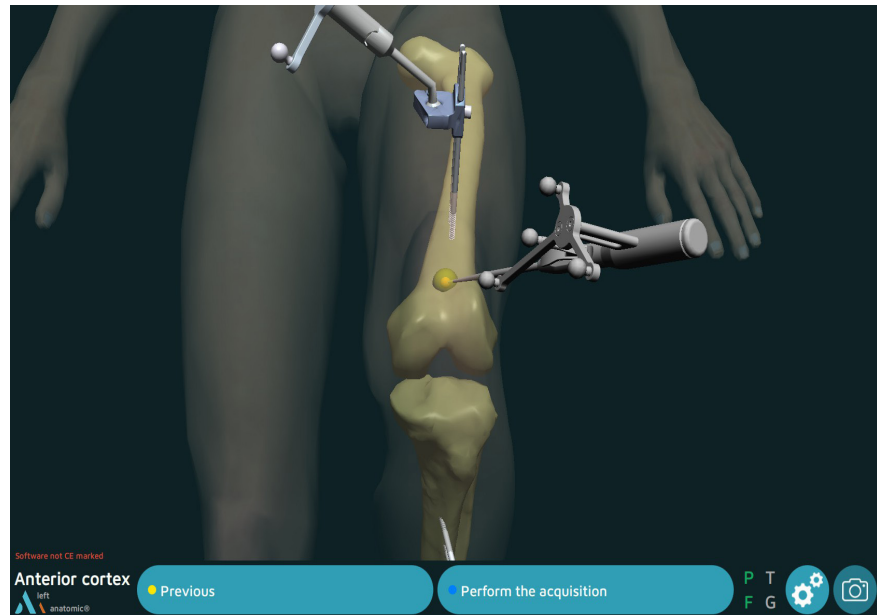
- Place the probe tip on the anterior femoral cortex.
- Confirm.

Tibial and femoral registrations

Femoral registration

- The goals of this step are to acquire the femoral bone surface.

- Place the probe tip on the bone surface.

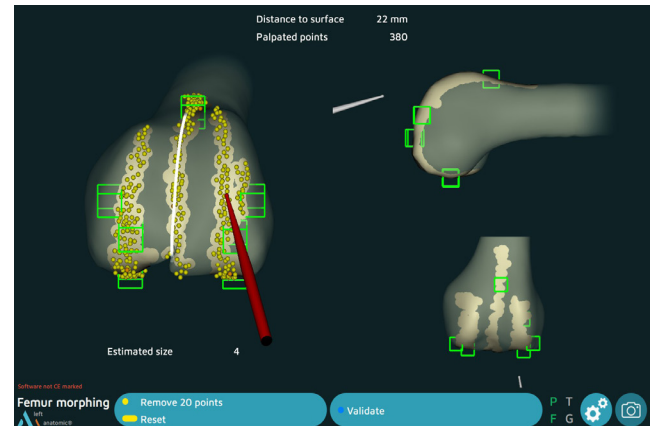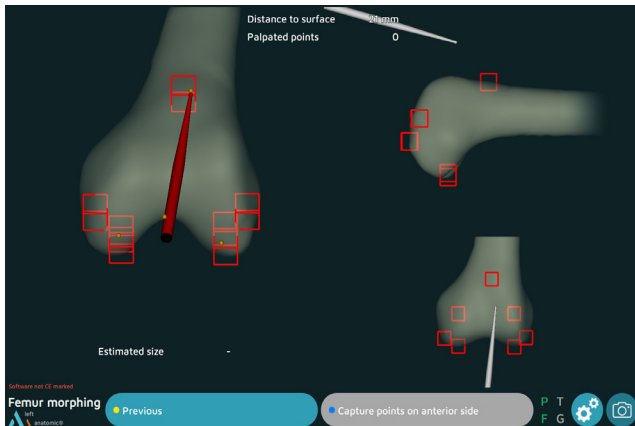- Press the trigger : the system will beep to indicate the start and end of the acquisition.

- It is best to draw the contour of the femur carefully.

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 middle of the screen 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 estimated 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
femoral 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.

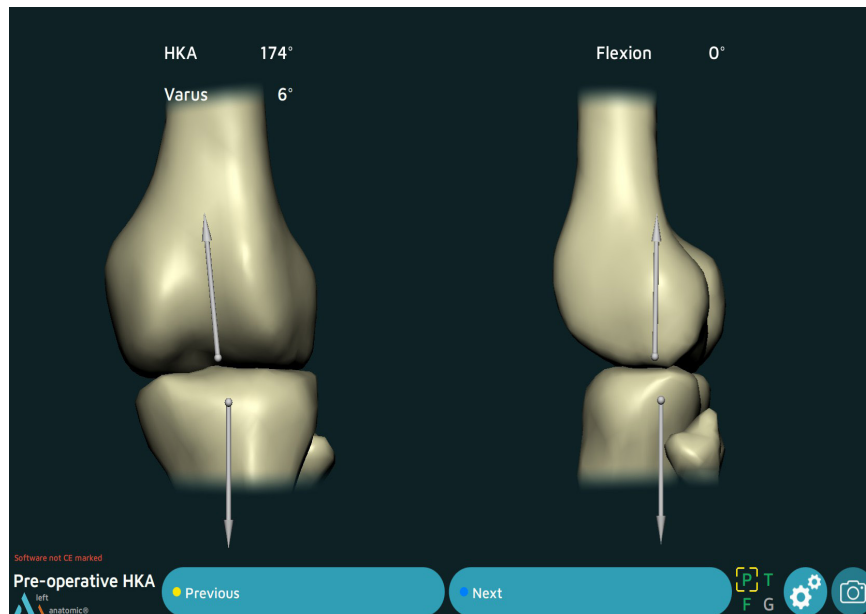## Removal of acquired points

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

Press and hold down the yellow pedal (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 and femoral registrations

Pre-operative alignment

- The software allows to visualize the pre-operative HKA.

Planning

AKN Planning software

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

By default the first proposed alignement is based on the user settings.

The **Mechanical Alignment** (MECA):

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 ou 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 with thicknesses of the resections which 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 on both medial and lateral sides.

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.
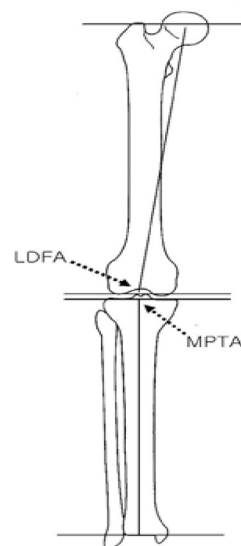
The **Functionnal Alignment** (GAPS):

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 10 mm), next it is calculating the height and orientation of the femoral resection in order to balance the gaps at 10 mm (corresponding to the thickness of the choosen insert or at 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.

Planning

Planning screen - Amplivision

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 grey when a value is changed.

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

Reset button for gaps registration

Current step
Operated side
Implant name

LDFA value in degree

Notching value in mm

MPTA value in degree
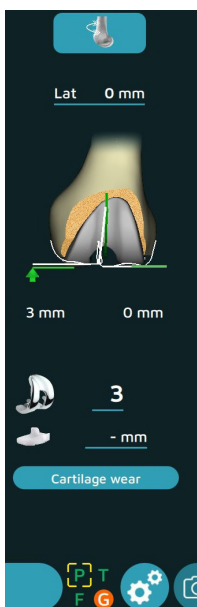
Trochial view modification:
- Free mode associated with leg flexion
- 30° or 60° or 80° mode

Overhang values of the anatomical flanges versus prosthetic flanges at the different selected angle
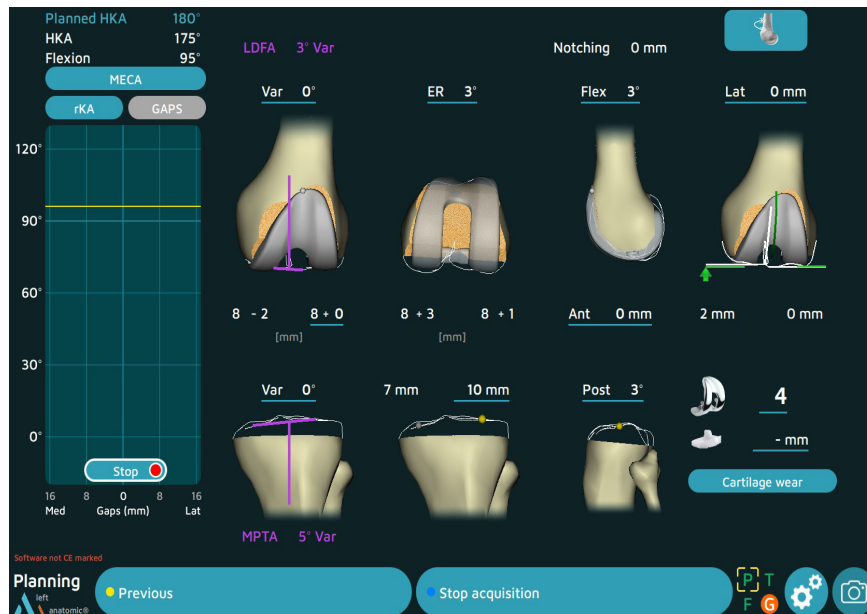
Adjustment of the size of the femoral implant
Adjustment of the tibial implant thickness

Adjustment of the thickness of the cartilage wear

Cartilage wear		
	Med	Lat
Femur Distal	2 mm	0 mm
Tibia	2 mm	0 mm

Validate

Planning

Registration of the gaps

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

The registration of these 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.
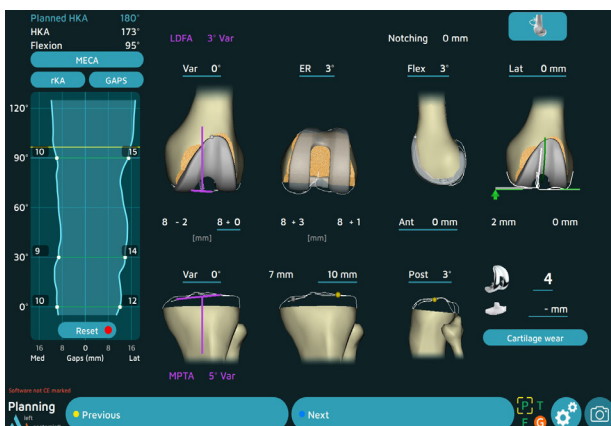
The button **Stop** located under the curve or the blue pedal allows you to stop the registration

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

Planning

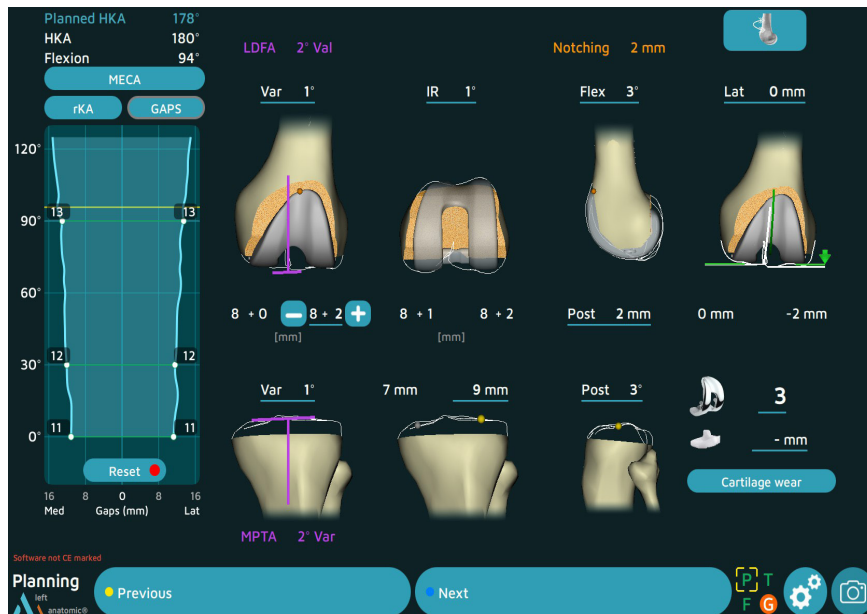## Mechanical alignment (MECA)

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

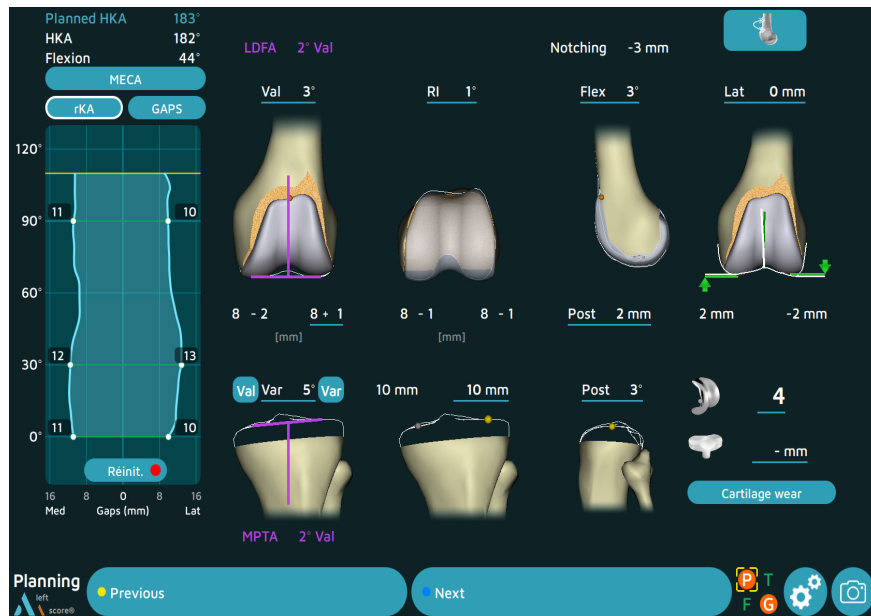The button MECA is circled with a white line to show taht this mode is active.

The parameters that are underlined in blue can be modified.

- Target the screen with the probe.
- 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 screen with the probe.

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

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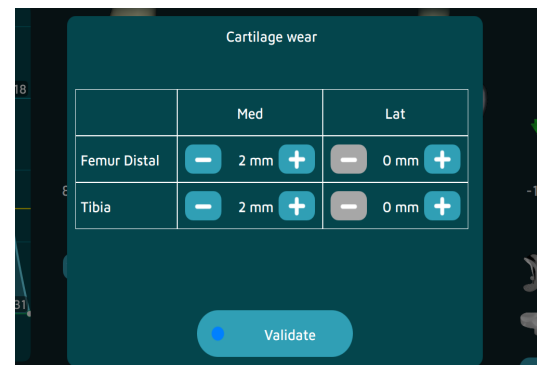
The values of LDFA and MPTA are then recalculated according to these wears and the software modifies the orientations according to these new values : tibial resurfacing (tibial cut height at 10 mm - cartilage wear) et femoral resurfacing (distal and posterior femoral cut heights at 8 mm - cartilage wear).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

The parameters that are underlined in blue can be modified.

- Target the screen with the probe.

- 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 in white 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.

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 with the cursor.
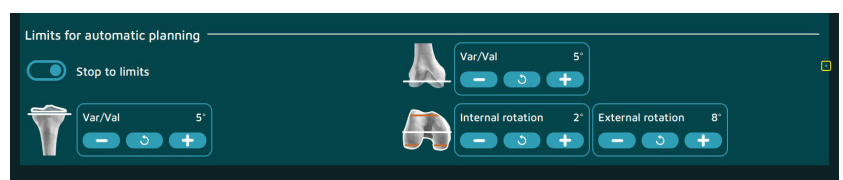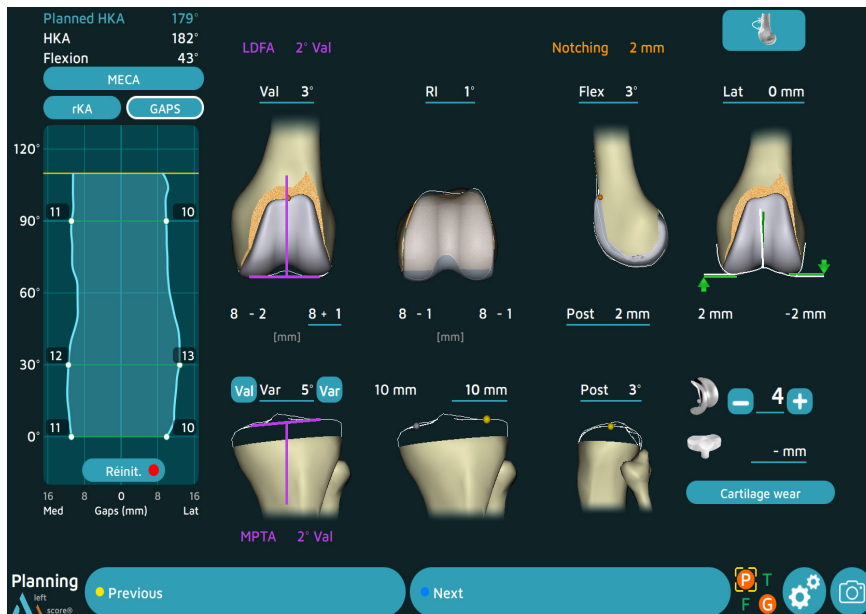
- Target the screen with the probe.

- 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.

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

Tibial navigation

Tibial alignment guide navigation

- Bend the knee.

- Assemble the Tap for navigation into the power tool.

- Drive it into the tibia along the shaft axis, but leave a few threads showing. Manually finish screwing in the tap with the universal T-handle.

- Secure the G array to the Alignment guide for tibial navigation.

- Place the guide on the Navigated Tibial Arm.

- Secure the components together by tightening the side screw.

- Place the Navigated Tibial Arm over the tap.

- Preset the rotation by putting the bracket in the sagittal axis (0° rotation).

- Lock the rotation by turning the side screw on the bracket.

- Calibrate the Alignment guide for tibial navigation : place the probe tip in one of the three conical marks on the guide and confirm.

- Repeat with the two other marks. The mark will turn green on the screen once it has been acquired.

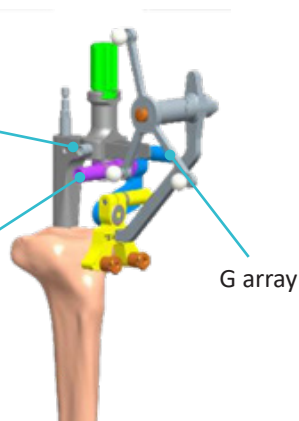*Calibration marks can be acquired in any order.*
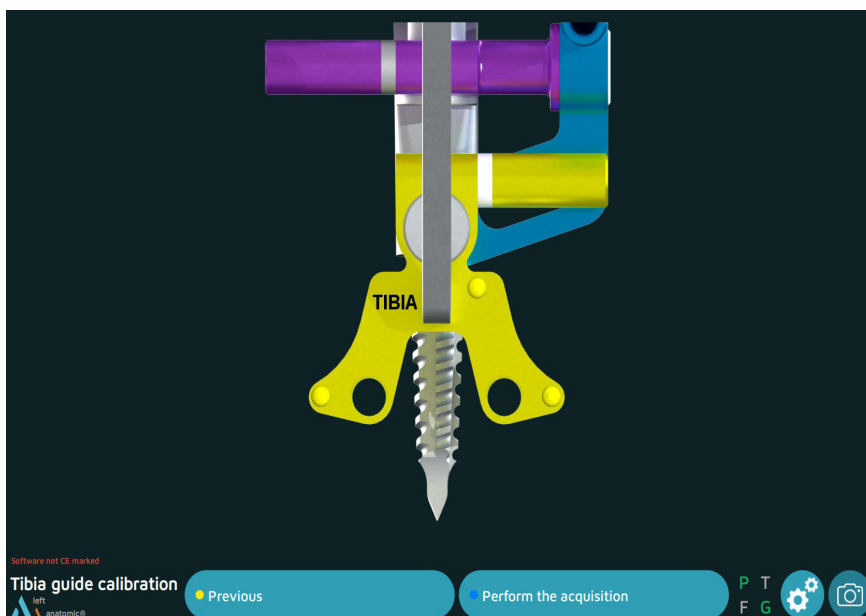
NOTE
Refer to the end of the document for Alignment guide for tibial navigation assembly.

Locking of resection height adjustment
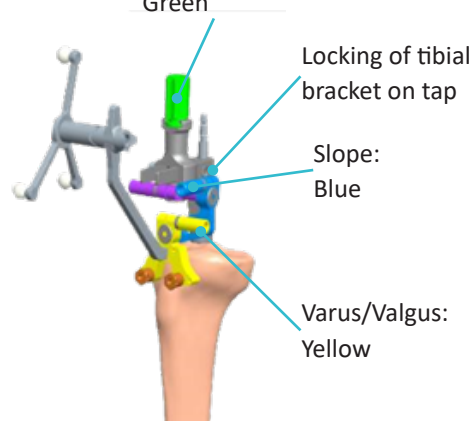
Axial rotation: Purple

G array

Resection height: Green

Locking of tibial bracket on tap

Slope: Blue

Varus/Valgus: Yellow

Tibial navigation

Tibial resection

The three previously confirmed parameters for the position of the tibial resection plane are shown on the screen. Each of these parameters is shown on a different colored bar. These colours match the colours on the component of the tibial alignment guide used to adjust that particular parameter.

Two values are shown for each parameter:

  - The planned value is in blue; this is the target value.

  - The navigated value remains in white as long as the guide is not in the correct position. It will turn green when the value is within ± 1 mm or ± 1° of the planned value.

- Adjust the parameters one at a time :

    - set the slope : loosen the **blue** binding screw using the H5 screwdriver

        adjust the guide's position until the navigated value turns green

        retighten the screw

   - set the varus/valgus using the yellow screw as previously

- Then, by the end, adjsut the height of the cut (**green** thumb knob)

Once the guide is correctly positioned, the value and resection plane are shown in green. Once the navigated values have been adjusted and have stabilised, the words « Insert pins, confirm and cut » will appear.

- Insert the Headless pins length 80 mm into the two Guiding Sleeve - Tibial Navigation.

- Use the Universal quick release adaptor for pin or Pin Driver AO to insert the pins into the bone.

- Check that the tibial alignment guide has not moved.

- Confirm the position.

- Carefully remove the two Guiding Sleeve - Tibial Navigation.

- Loosen the height adjustment screw.

- Slide the alignment guide off the tibial bracket.

- Loosen the screw for the tibial bracket on the tap.

- Remove the tibial bracket, and then remove the tap using the universal T-handle.

- Place the Tibial resection guide (or the 4T Tibial Resection Guide - 0°) on the Headless pins (0 holes).

- Perform the tibial cut (described in the Conventional Surgical Techniques 5-in-1 TO.G.008 for SCORE and SCORE II Knees and TO.G.001 for ANATOMIC Knee).

Tibial navigation

Registration of tibial resection plane
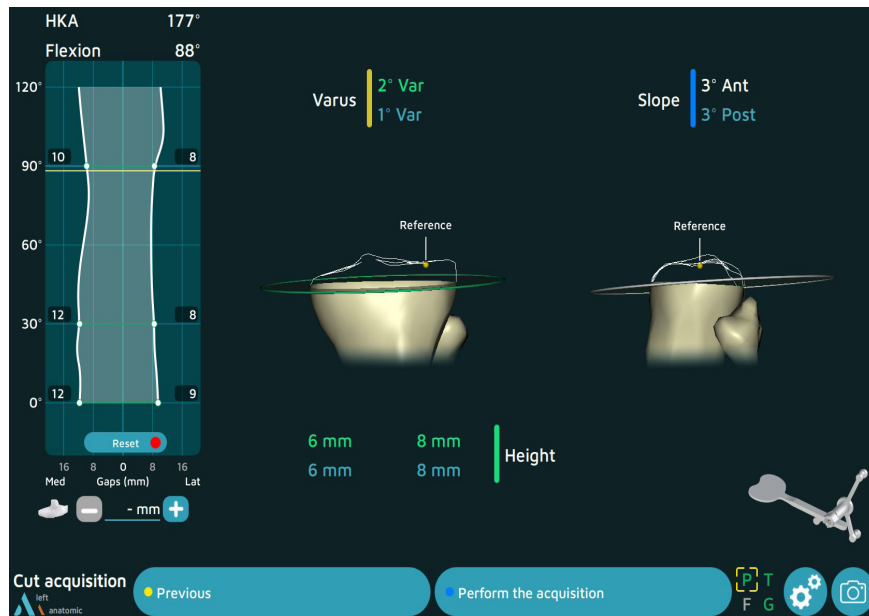
- Place the G array on the Measuring Plate for Tibial Resection –Navigation.
- Position the plate on the tibial cut and confirm its position.

Femoral navigation
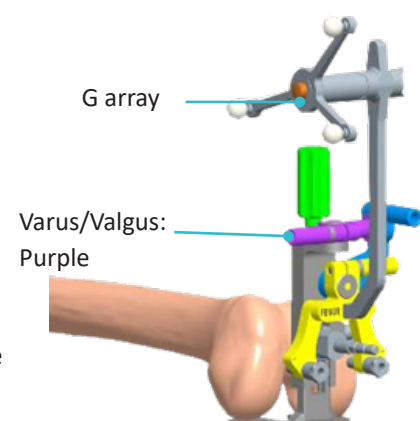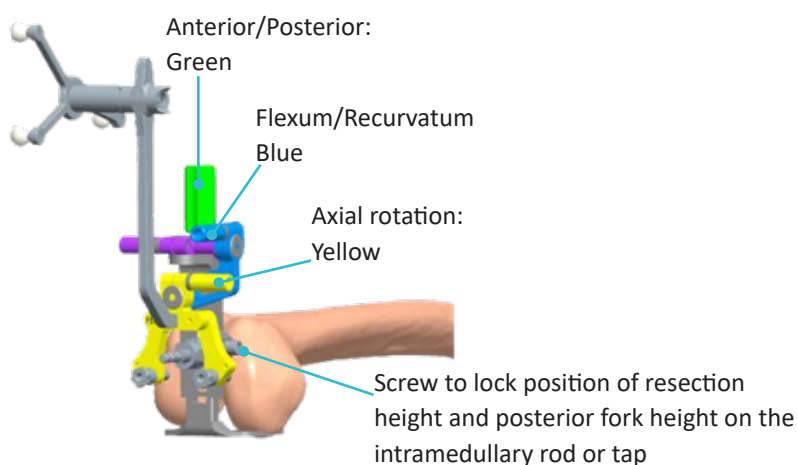
Femoral alignment guide calibration

- Bend the knee to 90°.

- Assemble the tap onto the power tool.

- Drive it into the femur along the shaft axis, but leave a few threads showing. Manually finish screwing in the tap with the universal T-handle.

- Secure the G array to the Alignment guide for femoral navigation.

- Assemble the femoral alignment guide and the Removable valgus guide - Femoral navigation on the tap.

- Place the valgus barrel (make sure the correct side is chosen and the label is visible to the surgeon) and ensure the posterior forks touch the posterior condyles.

- Calibrate the femoral alignment guide by placing the probe tip in one of the three conical marks on the guide and confirm.

- Repeat with the two other marks. The mark will turn green on the screen once it has been acquired.

Calibration marks can be acquired in any order.

NOTE
Refer to the end of the document for Alignment guide for femoral navigation assembly

Anterior/Posterior: Green

Flexum/Recurvatum Blue

Axial rotation: Yellow

Screw to lock position of resection height and posterior fork height on the intramedullary rod or tap

G array

Varus/Valgus: Purple

Femoral navigation

Navigation of femoral cuts

The four parameters on the screen can be adjusted before placing the femoral pins so that the femoral cuts can be carried out as planned in the previous steps. Each of these parameters is shown on a different colour bar. These colours match the colours on the component of the tibial alignment guide used to adjust that particular parameter.

- *Two values are shown for each parameter:*

    - The planned (target) value to be achieved is in blue,

    - The navigated value remains white as long as the guide is not in the correct position. It will turn green when the value is within ± 1 mm or ± 1° of the planned value.
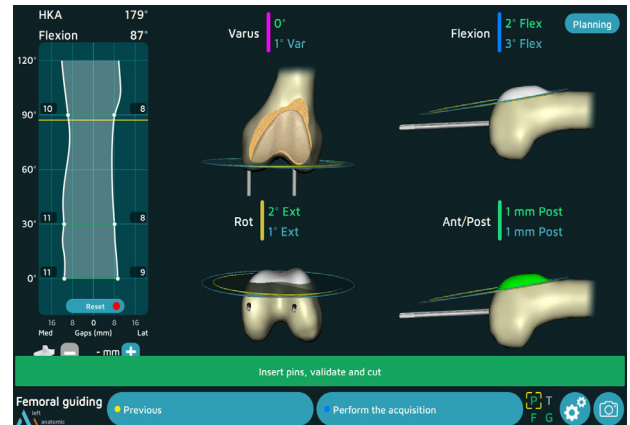
- Adjust the parameters one at a time.

    - set the flexum/recurvatum :   loosen the **blue** binding screw using the H5 screwdriver.

         adjust the guide's position until the navigated value turns green

         retighten the screw.

    - set the valgus/varus using the **pink** screw as described previously.

    - set the rotation using the **yellow** screw as described previously.

- Then, by the end, adjust the anteroposterior position (green thumb knob) .

- Once the guide is correctly positioned, the value and resection plane will be shown in green.

- Evaluate the size of the anterior cut relative to the anterior cortex on this view. Once the navigated values have been adjusted and have stabilised, the words « Insert pins, confirm and cut » will appear.

- Insert the Smooth pins Ø4, length 90 mm into the two Drill guides for pin Ø4 while making sure the values are unchanged.

- Check that the femoral alignment guide has not moved.

- Confirm the position.

- Carefully remove the two drill guides.

- Loosen the screw used to lock the resection height adjustment.

- Slide the alignment guide off the tap.

- Remove the tap using the universal handle.

- Place the Femoral resection guide (or the IMA Femoral Resection Guide) corresponding to the planned size (and shown on the screen) on the two femoral pins.

- Perform the femoral cuts (described in the Conventional Surgical Techniques 5-in-1 TO.G.008 for SCORE and SCORE II Knees and TO.G.001 for ANATOMIC Knee).
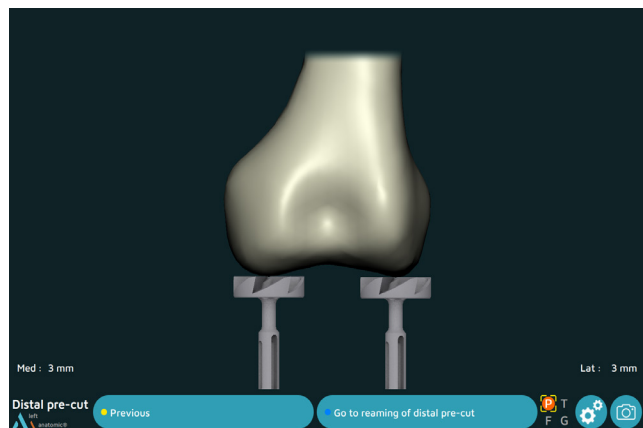
Femoral navigation

If a distal femoral precut is needed

Planning for 8+2 mm distal cut

- Insert the pins.

- Perform the precut with the Distal femoral reamer (as shown on the screen).

- Position the reamer on the femoral pin on the appropriate side and slide it up against the condyle.

- Set the stop to the resection value shown on the screen (2 mm increments).

- Assemble the reamer on the power tool and make the distal precut.

- Next, place the femoral resection guide corresponding to the planned size (and shown on the screen) on the two femoral pins and continue with the protocol shown on previous page.

Femoral navigation

Femoral preparation guide placement

This step only applies to the ANATOMIC TKA.

For ANATOMIC:

- Choose the same size of Femoral preparation guide as the 5 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 (white value becomes green at +/-1mm).

- 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.FR.014 for ANATOMIC knee).
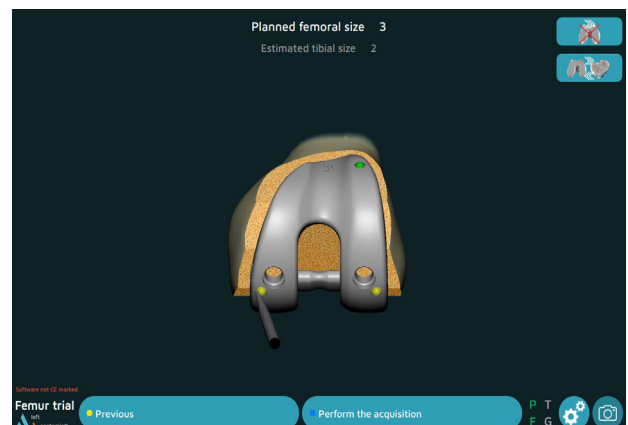
NOTE

This step is optional. If centring the guide without navigation assistance, skip this step by pressing the blue pedal, probe or click on Perform the acquisition.

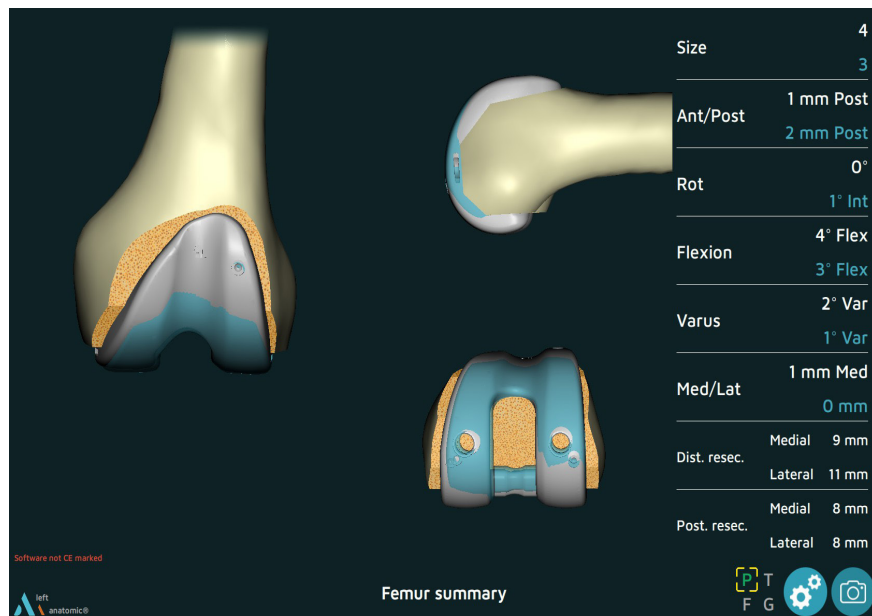## Placement of the trial femoral component

For SCORE, SCORE II and ANATOMIC TKA:

- Select the trial femoral component of the same size as the 5 in 1 resection guide used in the previous steps (the planned size is shown on the screen) and of the same operated side.

- Place the probe tip on the conical mark located on the front of the trial femoral component. For SCORE and SCORE II TKA, 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).

Trials registration

Femoral summary

Size		4
		3
Ant/Post		1 mm Post
		2 mm Post
Rot		0°
		1° Int
Flexion		4° Flex
		3° Flex
Varus		2° Var
		1° Var
Med/Lat		1 mm Med
		0 mm
Dist. resec.	Medial	9 mm
	Lateral	11 mm
Post. resec.	Medial	8 mm
	Lateral	8 mm

Software not CE marked

left
anatomic®

Femur 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 pedal to confirm and continue to the next step.

Trials registration

Placement of the trial tibial baseplate

For the SCORE® and SCORE® II TKAs: 2 possibilities
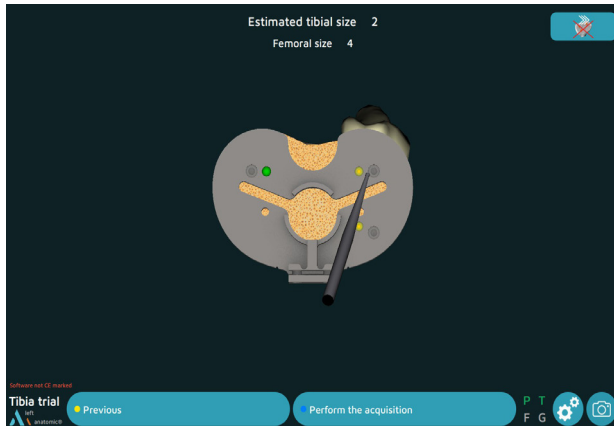
Acquisition of trial baseplate position using conical calibration marks:

- 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.
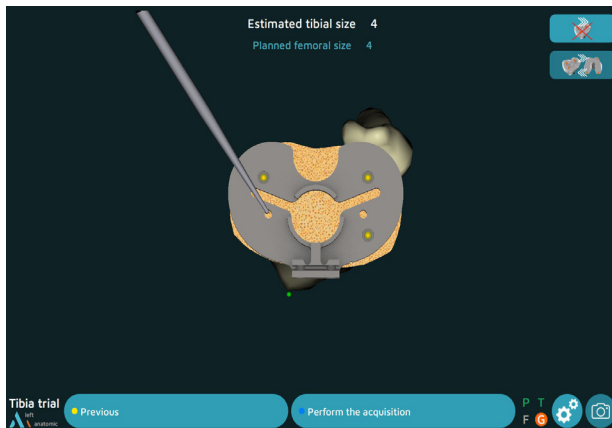
Detection of the G array by the camera
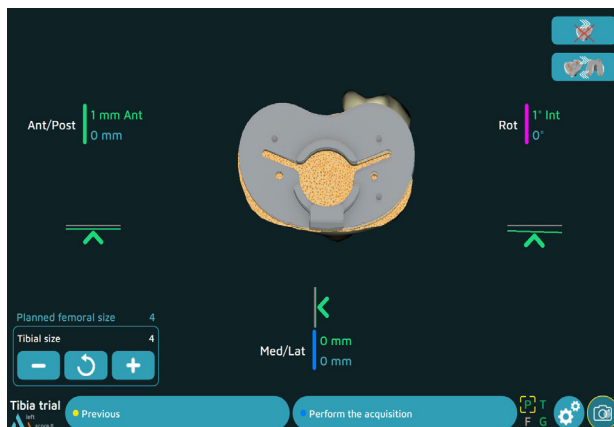
Navigation of trial baseplate position with universal handle:

- Secure the G array support to the universal handle.

- Select the appropriate tibial baseplate (the estimated size is shown on the screen and can be changed) and secure it to the universal handle.

- Place the trial tibial baseplate on the tibial cut and vizualize 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 pedal.

Trials registration
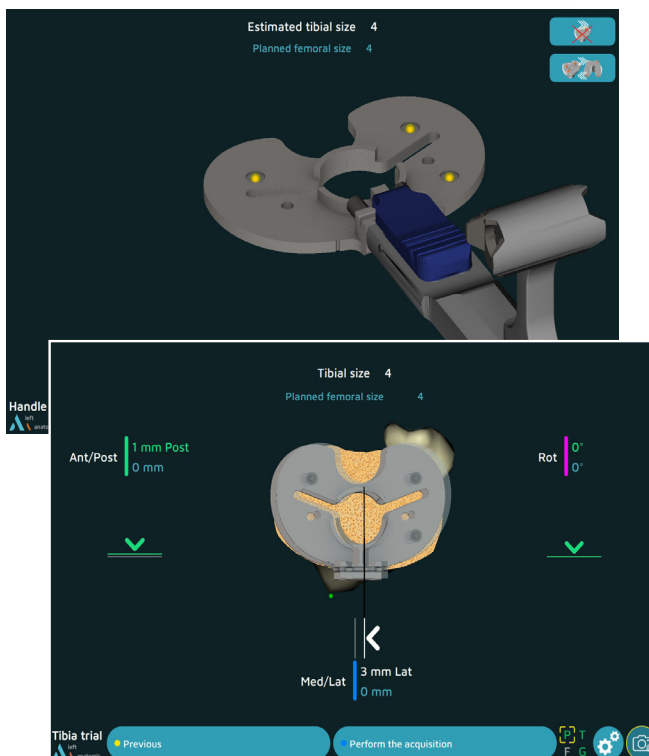
Placement of the trial tibial baseplate

For the ANATOMIC TKA: 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 vizualize 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 pedal.
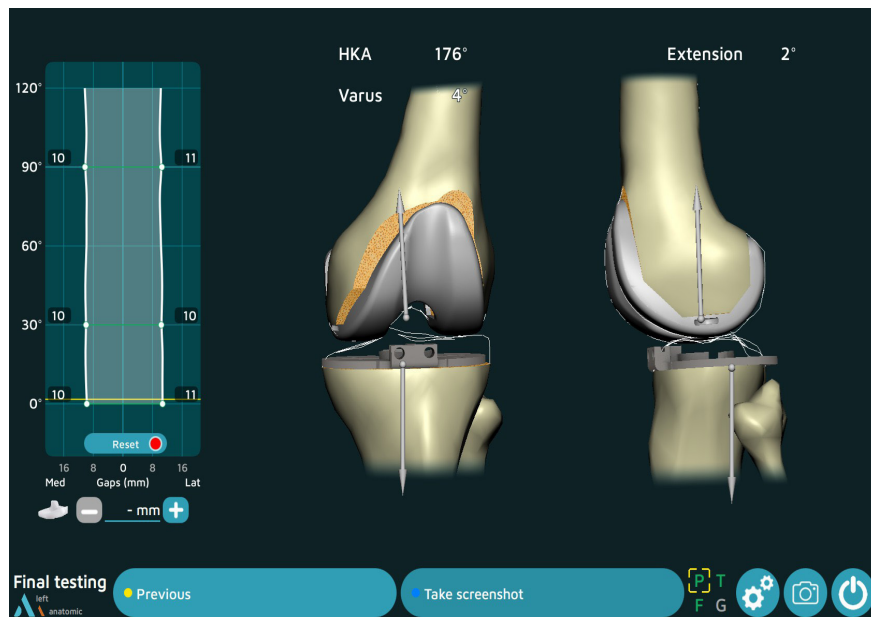
Trials registration

Tibial summary

- Visualize the trial implant's position in grey.

- The size and final position of the implant are shown in white; the planned values are in blue.

- Press the blue pedal to confirm and continue to the next step.
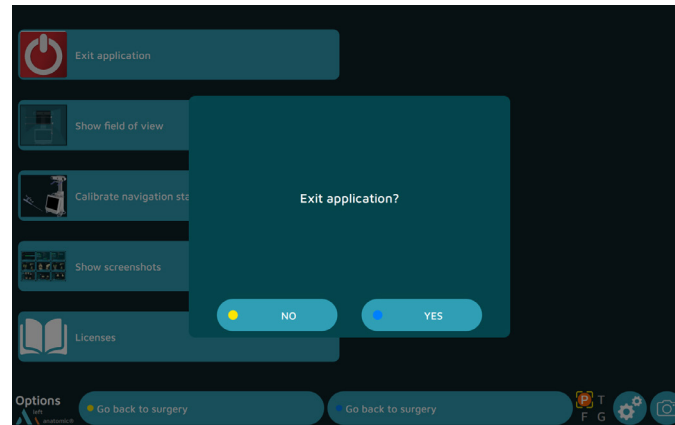
Final test

Post-operative alignment

- At this step, the software allows to register the curves and the final HKA and varus are 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 pedal (or the blue button).

**All navigation steps have been completed.**

Refer to the following Surgical Techniques documents: TO.G.008 for SCORE, TO.G.013 for SCORE II and TO.G.001 for ANATOMIC 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 « Exit application ? » will appear. Press « Yes » to confirm.

- The message « Copy report to USB memory stick? » will appear.

- Indicate whether you want to create a backup copy of the surgery report by pressing the « Yes » or « No » button.
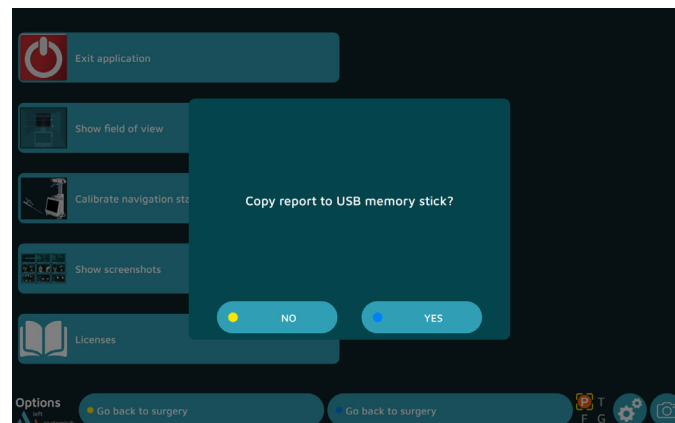
- A message will appear asking you to insert a USB drive. Insert the USB drive in the slot close to the screen and confirm that you would like to backup the report.

- 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 ![power] 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 NO205 (AMPLIVISION V3) or NO114 (AMPLIVISION V2) User Manual for instructions on how to store the workstation.

Instrumentation

- In addition to the mechanical instrumentation described in the Surgical Technique documents (TO.G.008 for SCORE, TO.G.013 for SCORE II and TO.G.001 for ANATOMIC), he following are required:

  - AMPLIVISION Navigation Station

  - NDI Passive Spheres

  - The AMPLIVISION Navigation Set : 2-0299916

NDI Passive Spheres - 30 pheres (2x15) (Product No. 8800966)

NDI Passive Spheres - 15 spheres (5x3) (Product No. 8800738)

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

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

AMPLIVISION Navigation set

Item	Name	Reference	Qty
1	Probe knee navigation	2-0215700	1
2	Conical Threaded Pins AMPLIVISION Ø4 length 150mm	2-0235500	5
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	Tap for navigation	2-0207500	1
8	Navigated Tibial Arm	2-0210000	1
9	Alignment guide for tibial navigation	2-0209600	1
10	Guiding Sleeve - Tibial navigation	2-0207600	2
11	Removable valgus guide - Femoral navigation	2-0209800	1
12	Alignment guide for femoral navigation	2-0209700	1
13	Drill guide for pin Ø4	2-0203500	2
14	Distal femoral reamer	2-0210100	1
15	Spacer navigation	2-0211100	1
16	Half-wedge height 2 mm	2-0211202	2
17	Half-wedge height 4 mm	2-0211204	2
18	Half-wedge height 6 mm	2-0211206	2
19	Full wedge height 2 mm	2-0211302	1
20	Full wedge height 4 mm	2-0211304	1
21	Measuring Plate for Tibial Resection –Navigation	2-0217300	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.

Fixed array

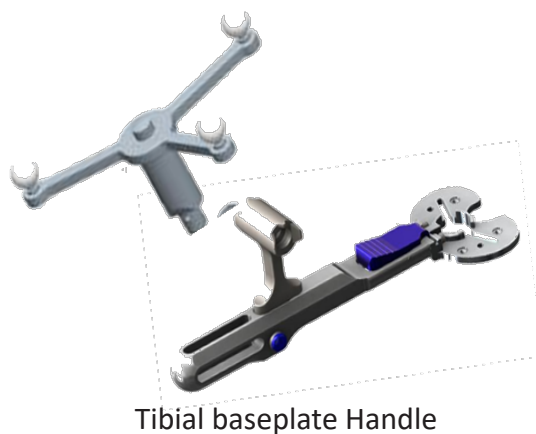Moving passive sphere on trigger
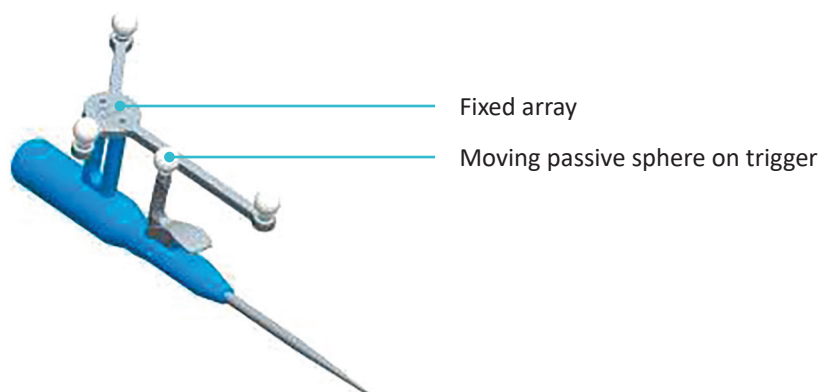
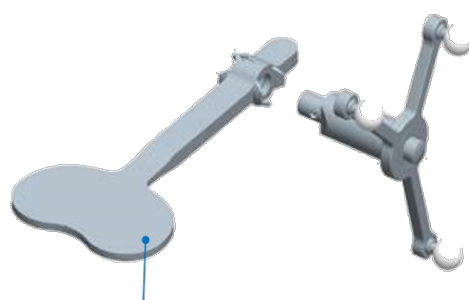### Universal handle and measuring plate:

- The Universal Handle (for SCORE® baseplate), The tibial baseplate handle (for ANATOMIC® baseplate) and tibial cut measuring plate each have one or two attachment points for the G array (one on each side). The array can only be assembled in one direction into each attachment point.
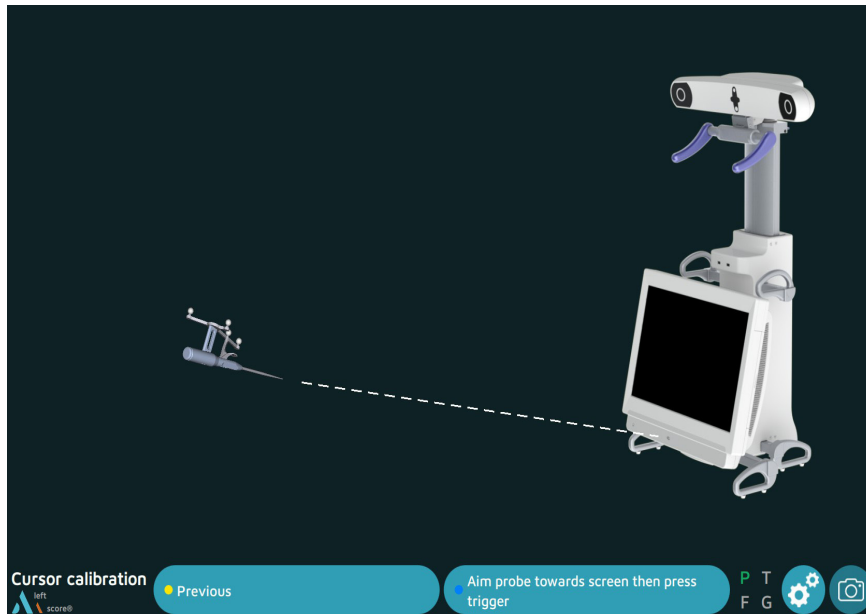

Universal Handle

Tibial baseplate Handle

Measuring plate for tibial resection place

Option : calibration of the cursor

- From this step on, the AMPLIVISION system can be controlled with:
    - the pedal,
    - 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 bottom right corner of the screen.

NOTE
If cursor calibration is not initially selected, the cursor calibration 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 : confidence points on arrays

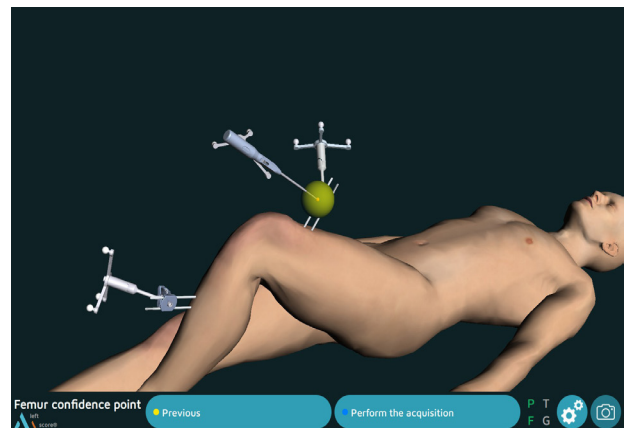## Tibial confidence point on the array

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.

- Place the probe tip in one of the two conical calibration marks on the T array support.
- Confirm.
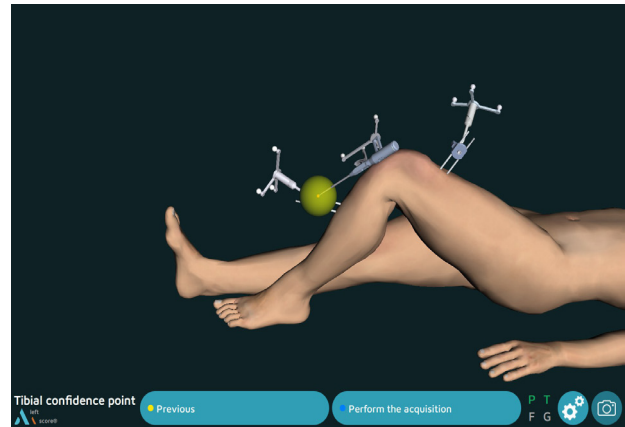
Femoral confidence point on the array

- Place the probe tip in one of the two conical calibration marks on the F array support.
- Confirm.

At any time during the procedure, place the probe tip on the previously acquired tibia and/or femur reference point. The words « Confidence point Femur OK » and/or « Confidence point 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.

NOTE

If during the procedure there is any doubt as to whether the arrays will hold up to the initial acquisitions, continue the procedure with the conventional technique.

NOTE

There is no way to check if the array–fixation support combination has moved. If in doubt, continue the procedure without navigation.
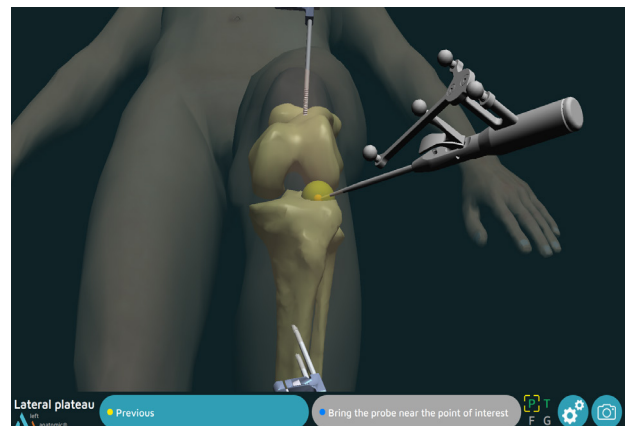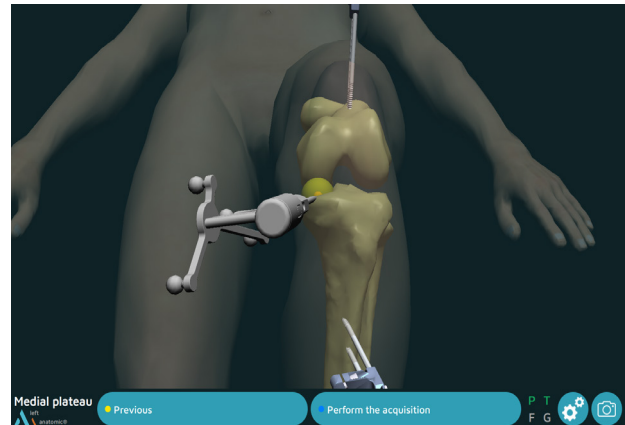
Option : tibial rotation reference

Tibial plateau references

Acquisition of two points on the tibial plateau selected as rotational reference:

- The frontal plane will run along the line formed by the two points acquired on the tibial plateaus.

- A line can be made on the tibial plateau with electrocautery to help with this acquisition.

- Place the probe tip on the middle of the medial plateau on the previously drawn line.

- Press the trigger to confirm.

- Place the probe tip on the middle of the lateral plateau on the previously drawn line.

- Press the trigger to confirm.

NOTE

The tibial axis is defined using the ankle centre (the point midway between the malleoli) and the point in the middle of the intercondylar eminence. Using the tibial axis and the frontal axis, the AMPLIVISION® system calculates the frontal plane and estimates the sagittal and transverse planes.

Option : tibial rotation reference

Tibial sagittal axis + ATT

Acquisition of tibial sagittal axis and a single point on medial aspect of tibial tuberosity selected as rotational reference:

- After the middle of the intercondylar eminence has been acquired, 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.

- Acquire one point on the medial aspect of the tibial tuberosity.

NOTE
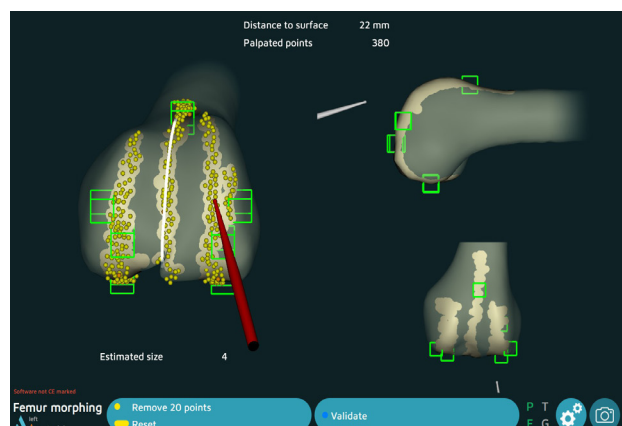The point acquired on the tibial tuberosity will be shown in green on the tibia views.

NOTE
The tibial axis is defined using the ankle centre (the point midway between malleoli) and the point in the middle of the intercondylar eminence. Using the tibial axis and the sagittal axis, the AMPLIVISION® system calculates the sagittal plane and estimates the sagittal and transverse planes.
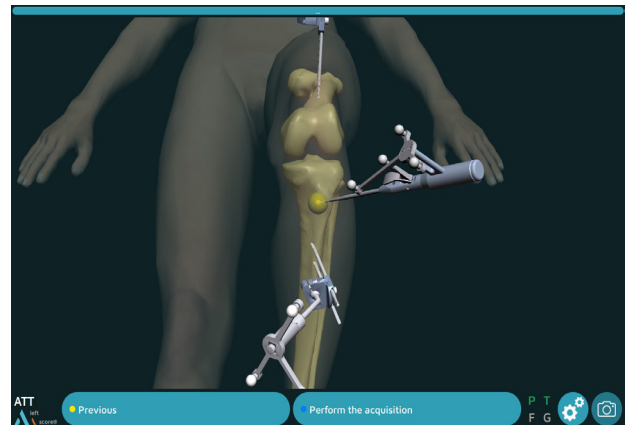
Trochlea line

- A white line corresponding to the anatomical Whiteside's line is displayed when points are acquired at the base of the trochlea.

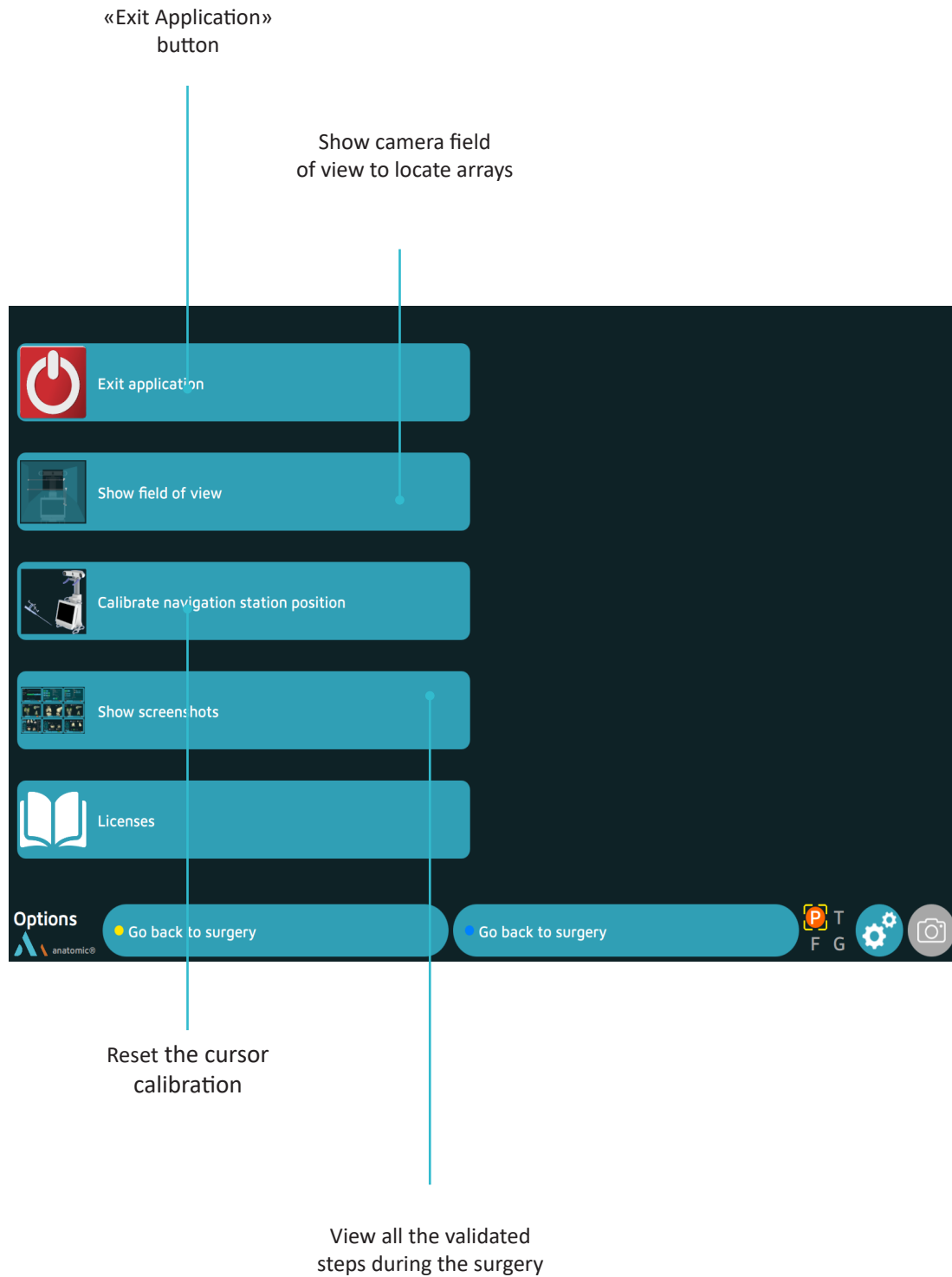# Appendix A

Screen layout

Size 3

Post slope 3°
Ant | Post

Height 10 mm

Ant/Post 0 mm
Post | Ant

Med 1 mm
Med | Lat

Var/Val 0°
Val | Var

Int Rot 6°
Int | Ext

Reference

Software not CE marked

Tibia planning
left
anatomic®

Previous | Confirm plan

P T
F G

Current step
Operated side
Implant

Button next and previous

Screenshot

Menu : Options

Visibility of each array:
Green - visible
Orange rounded - not visible

Appendix B

Menu options

«Exit Application»
button

Show camera field
of view to locate arrays

Exit application

Show field of view

Calibrate navigation station position

Show screenshots

Licenses

Options

anatomic®

Go back to surgery

Go back to surgery

Reset the cursor
calibration

View all the validated
steps during the surgery

Appendix C

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.
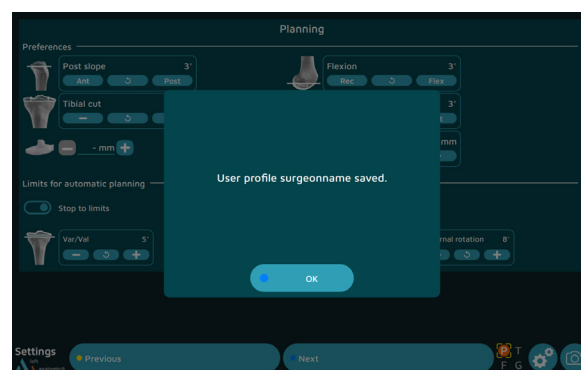
### Working with a user profile
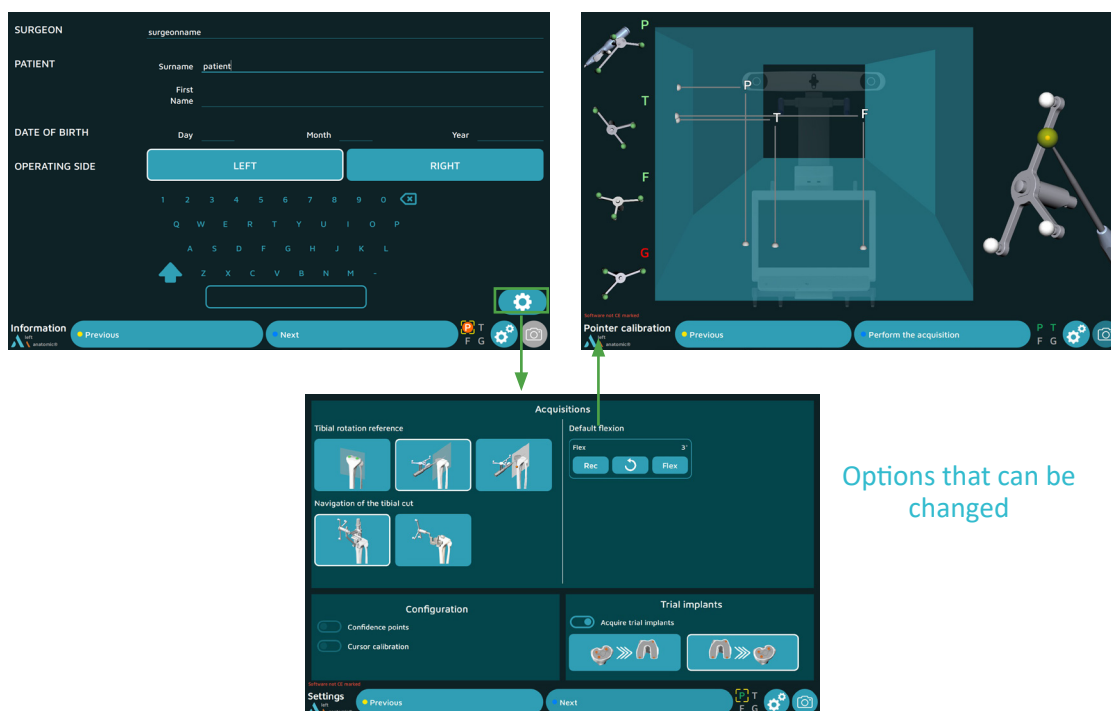
Options that can be changed

- 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.
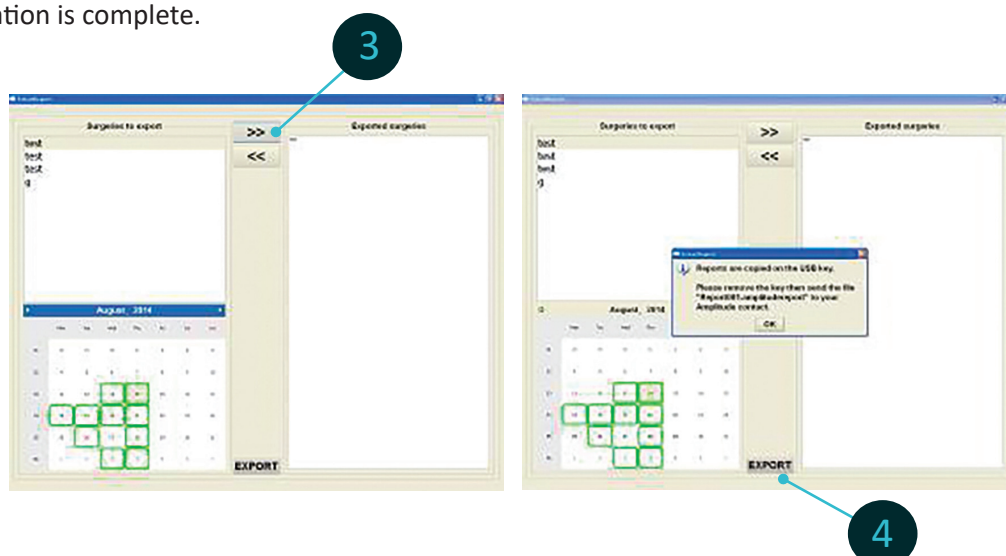
Appendix D

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.
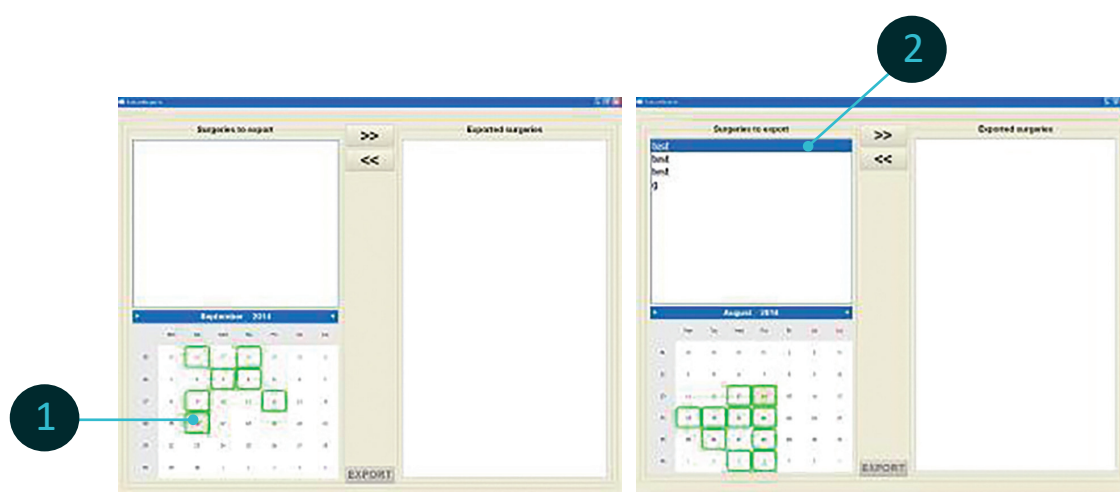
- Use the touch screen to select the reports to be exported and then press the button to move them to the « Exported surgeries » window.
- Insert the USB drive and press the button to copy these reports to it. A message will appear when the operation is complete.
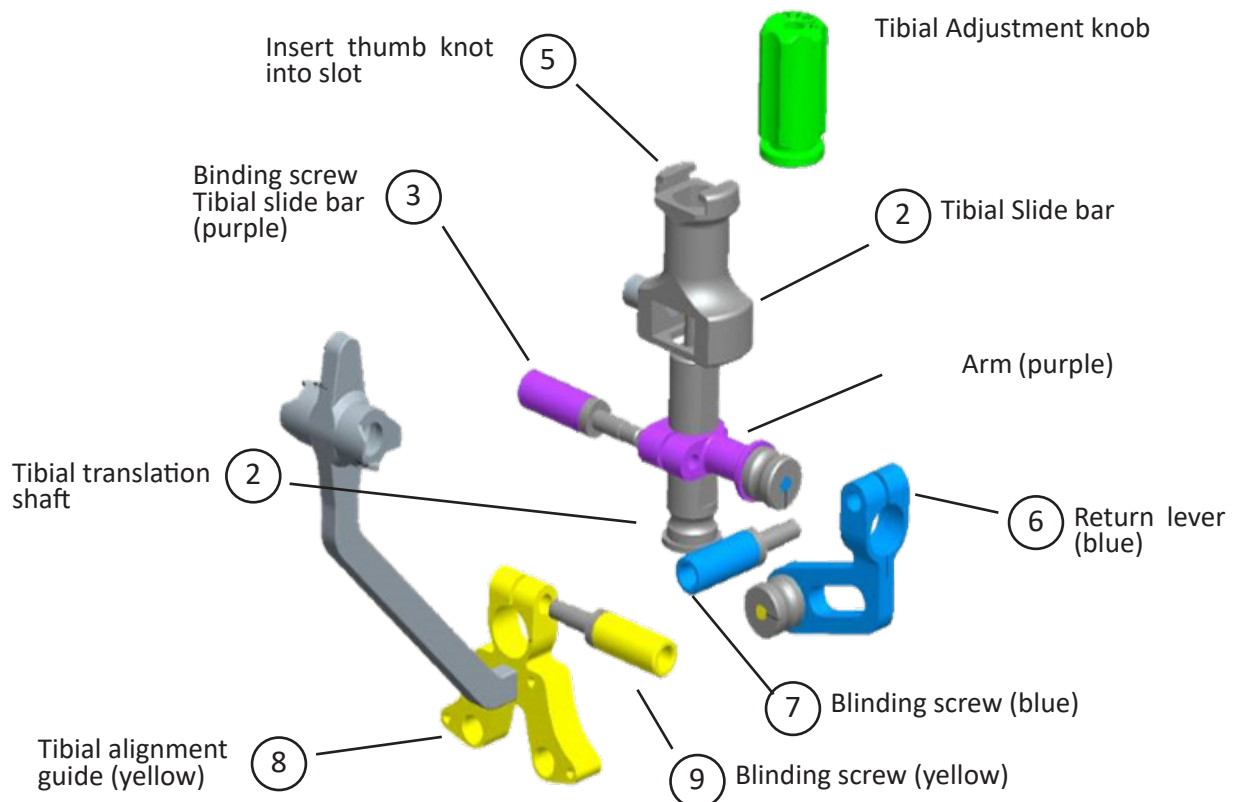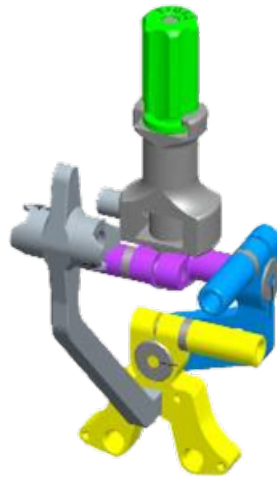

NOTE

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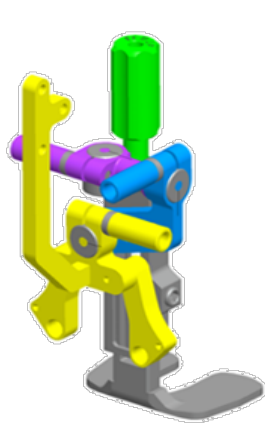Contact AMPLITUDE to obtain access to the desired report

Appendix E

Assembly of the alignment guide for tibial navigation

Make sure all dials are set to neutral before the procedure

Insert thumb knot into slot ⑤

Tibial Adjustment knob

Binding screw Tibial slide bar (purple) ③

② Tibial Slide bar

Arm (purple)

Tibial translation shaft ②

⑥ Return lever (blue)

⑦ Blinding screw (blue)
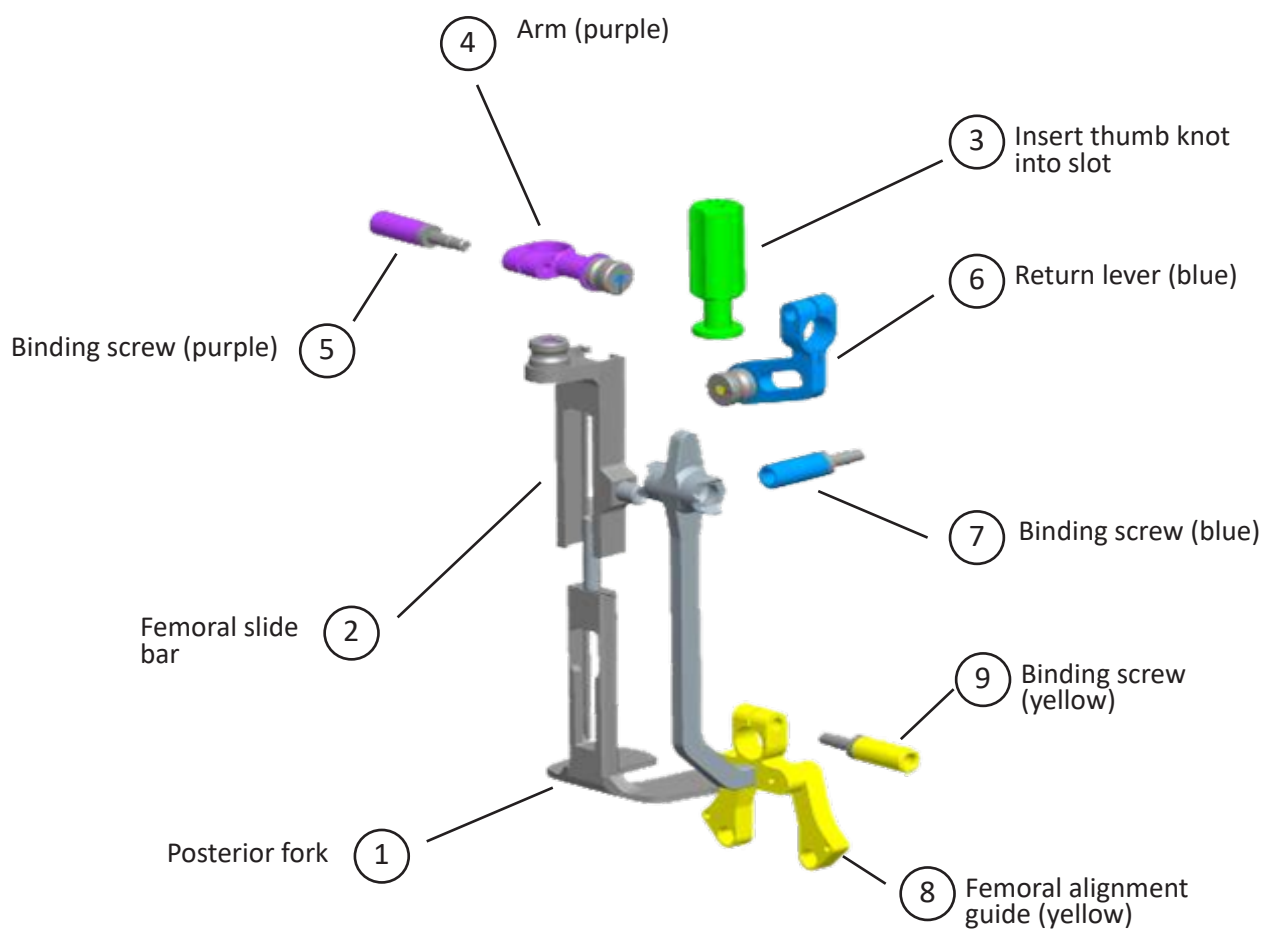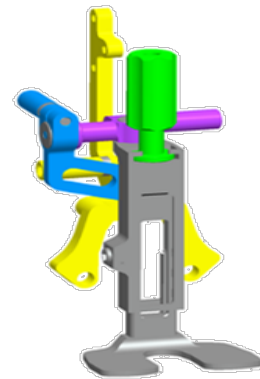
Tibial alignment guide (yellow) ⑧

⑨ Blinding screw (yellow)

Appendix F

Assembly of the alignment guide for femoral navigation

Make sure all dials are set to neutral before the procedure

4 — Arm (purple)

3 — Insert thumb knot into slot

6 — Return lever (blue)

Binding screw (purple) — 5

7 — Binding screw (blue)

Femoral slide bar — 2

9 — Binding screw (yellow)

Posterior fork — 1

8 — Femoral alignment guide (yellow)

NOTES

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