

AMPLIVISION®



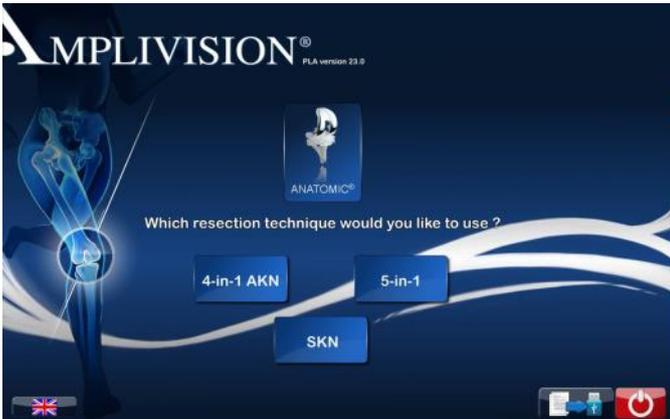
Surgical Technique
SKN
(Smart Knee Navigation)

- This Surgical Technique Supplement describes the use of the SKN computer-assisted surgery software for implanting Amplitude's total knee arthroplasty (TKA) systems.
- This software is used to navigate the height of the tibial and femoral cuts, and to verify them using the mechanical axis of the tibia and femur.
- This Supplement replaces the following in the TO.G.GB.009 (SCORE® TKA 4-in-1) and TO.G.GB.013 (ANATOMIC® TKA 4-in-1) conventional surgical technique documents:
 - Paragraphs on the distal femoral cut
 - Paragraphs on tibial alignment
 - Paragraphs on the tibial cut



PREPARATION PHASE

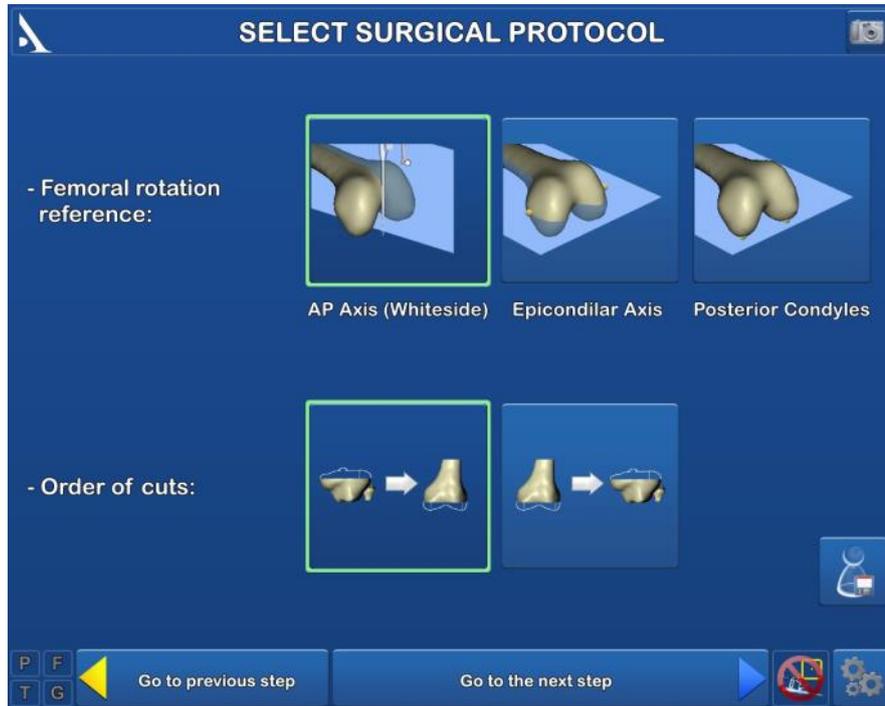
STARTING THE SOFTWARE



- Press the touch screen to select the preferred system language.
- Select "Knee", then select the implant and the SKN protocol.

- On the "Information" page, input the required information using the virtual keyboard.
 - Surgeon name
 - Patient name
 - Patient date of birth (optional)
 - Operated side (select right or left)
- To go to the next step, press the blue pedal or the blue arrow on the screen.
- To go to the previous step, press the yellow pedal or yellow arrow on the screen.

SURGICAL PROTOCOL SELECTION



- Configuring the surgery-related options:
 - Three methods can be used to define the femoral rotation reference:**
 - Perpendicular to the **AP (sagittal) axis**
 - Using the **transepicondylar axis**
 - Using the **posterior condylar axis**
 - Order of cuts:**
 - Tibial cut first then distal cut
 - Distal cut first then tibial cut
- Press the blue pedal to go to the next step.

PREPARATION PHASE



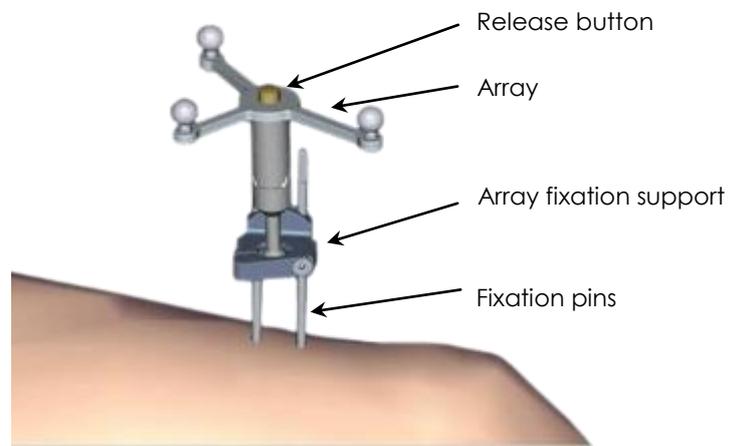
- Clip the round markers to the arrays:
 - 3 for the Tibia (T) array
 - 3 for the Femur (F) array
 - 4 for the Pointer (P) array
 - 3 for the Guide (G) array

- The pins 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.

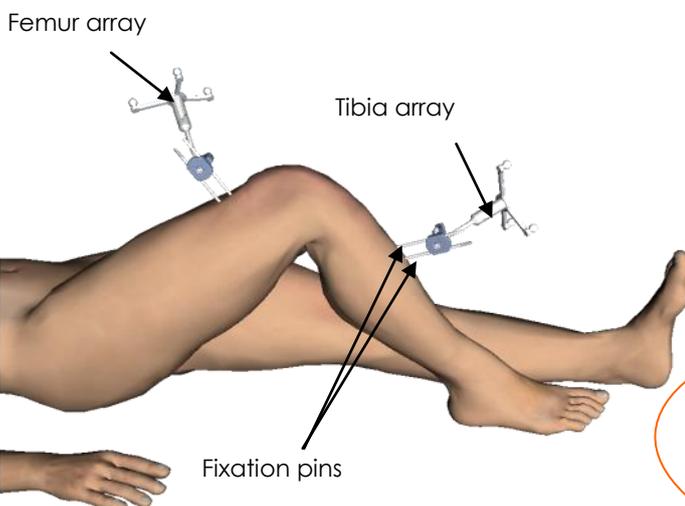
Note

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 array fixation support on the first pin to get the proper spacing for the second pin.



- Clip the F array on the moveable part of the support, making sure the arrows are aligned correctly.
- If the array needs to be removed during the procedure, it can be returned to the same position on the support.
- Orient the array towards the camera head and lock the fixation support.
- Position and secure the arrays so they are always visible to the camera head, whether the knee is flexed or extended.



IMPORTANT

Once the knee joint has been opened and exposed with the retractors provided, any osteophytes must be removed in order to acquire correct joint surfaces, otherwise the implant selected may be too large or too small

WORKSTATION INSTALLATION

SETTING UP THE CAMERA

- Position the camera head so the letters corresponding to the F and T arrays are in the middle of the field of view.
- The laser located in the positioning handles on the camera head (V2 Workstation) or between the two optical sensors (V3 Workstation) makes this adjustment easier.
- Confirm that the P array is visible.

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

- Any marker 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 markers).



CALIBRATING THE USER AND SCREEN



- Aim the pointer at the centre of the AMPLIVISION® screen and press the trigger to confirm.
- From this step on, the AMPLIVISION® system can be controlled with:
 - the pointer, by pressing the trigger to confirm,
 - the pedal,
 - the touchscreen of the AMPLIVISION® workstation.
- The system will capture screenshots when:
 - the user validates a step,
 - the user presses the screen capture button at the upper-right corner of the screen.

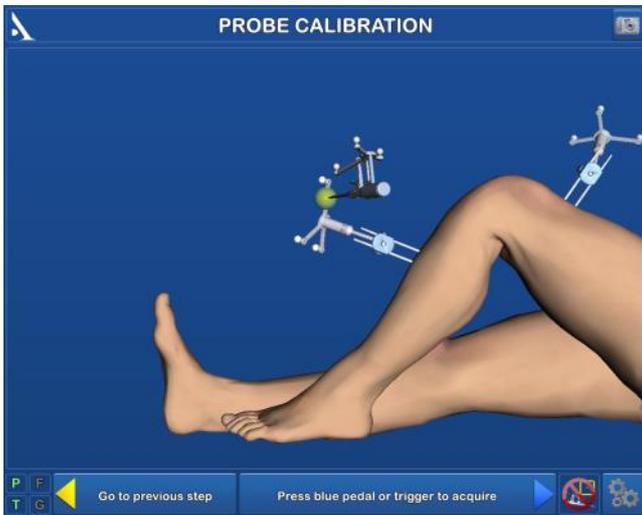
Comments:

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.

CALIBRATING THE POINTER



To define exactly the position of the pointer tip,

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

Note

This step can be done while holding the T array by hand if the array fixation support has not been placed in the tibia (no tibial navigation performed)

Note

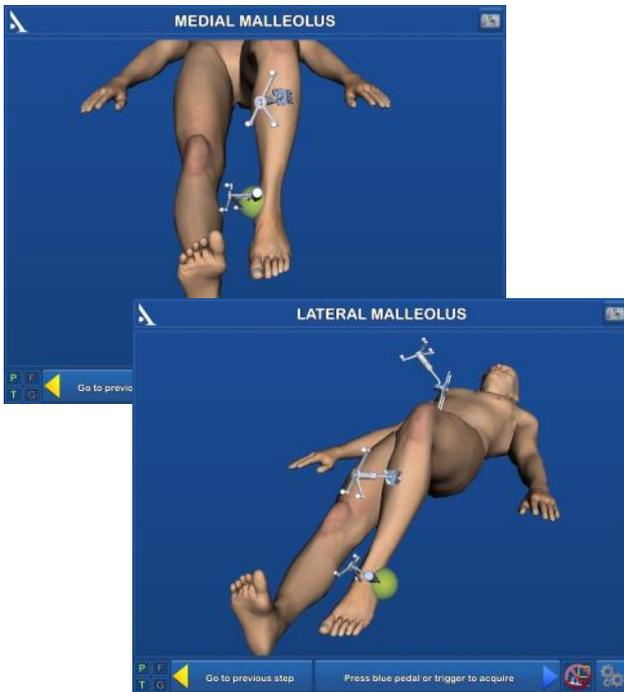
If at any time during the procedure there is uncertainty about the position of the arrays relative to the initial acquisitions, switch to the conventional method



TIBIAL ACQUISITIONS

- If the procedure is being done with the tibial cut first, following the steps below.
- If the procedure is being done with the distal cut first, follow the steps on page 14.

ANKLE CENTRE ACQUISITION



MEDIAL MALLEOLUS

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

LATERAL MALLEOLUS

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

CENTRE OF TIBIA ACQUISITION

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



TIBIAL ROTATION REFERENCE

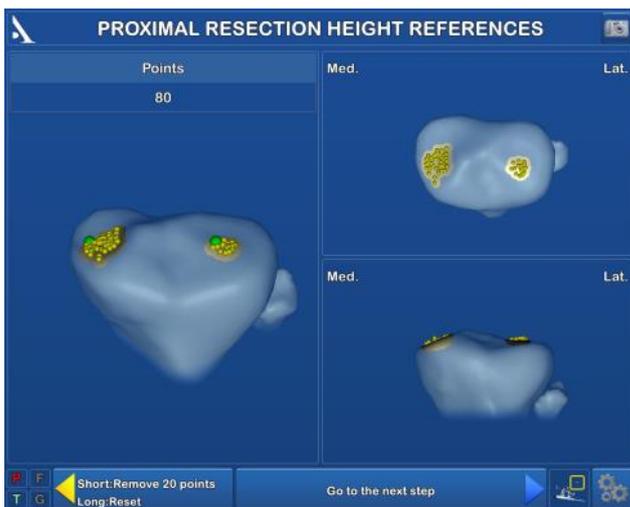


- Place the pointer tip on the intercondylar eminence and turn the body of the pointer.
- Once it corresponds to the desired sagittal plane orientation, confirm its position.

PROXIMAL RESECTION HEIGHT REFERENCES



or



Two options for acquiring the proximal resection height reference:

– **Acquisition of one point on each tibial plateau:**

- Palpate one point on the plateau and validate by pressing the trigger.
- Repeat on the contralateral plateau.
- These two points will serve as references for the proximal resection height in each compartment.

– **Acquisition of one area on each tibial plateau:**

- On each plateau, place the pointer tip on the bone surface. Press and hold trigger then move the tip along the surface being acquired.
- At any time, the surgeon may release the trigger, move the pointer tip to another location and then press the trigger again to continue the acquisition.
- 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
- The most distal points will be calculated automatically and saved as the resection height reference (green points).

IMPORTANT

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

Note

It is important to acquire points at the bottom of the plateau, not the ones on the side of it

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

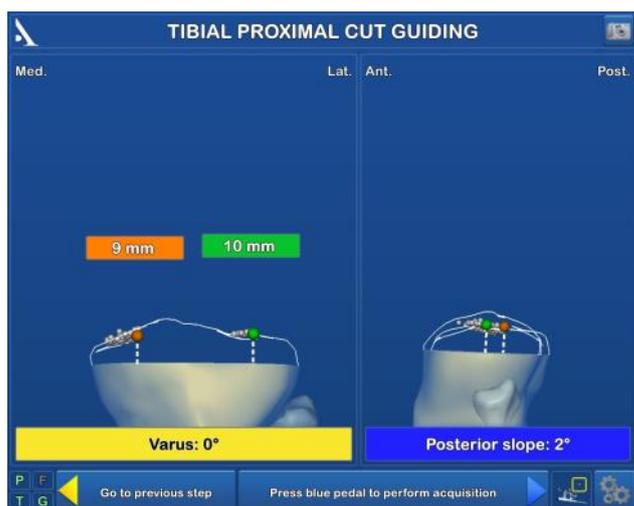
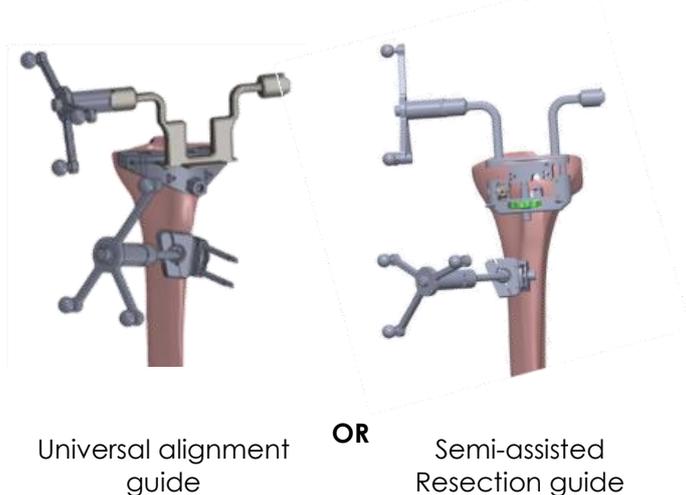


TIBIAL NAVIGATION

TIBIAL CUT GUIDING

This step can be performed using either:

- the universal alignment guide, or
- the semi-assisted resection guide.



If using the universal alignment guide:

- Secure the G array to the universal alignment guide.
- Position the alignment guide's plate in the tibial resection guide's slot.
- Adjust the positioning until the guide is in the position needed to perform the tibial cut. The resection height is shown in the green rectangle on the screen, the contralateral bone cut in the orange rectangle, the varus/valgus in the yellow rectangle and the slope in the blue rectangle.
- Once the resection guide's position is set, put two pins in the guide's "O" holes.
- Remove the universal alignment guide from the slot in the resection guide.
- Secure the resection guide with three headed pins, and then perform the tibial cut.
- Once the tibial cut has been made, it can be verified by placing the universal alignment guide on the cut surface. Press the blue pedal to validate and go to the next step.

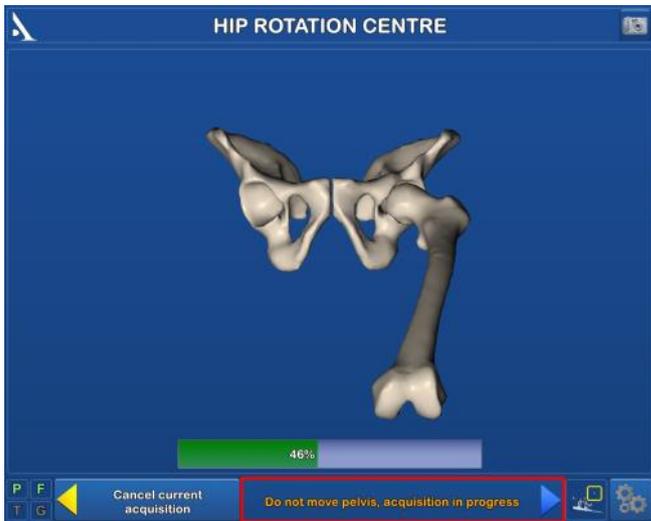
If using the semi-assisted resection guide:

- Secure the G array to the semi-assisted resection guide.
- Adjust the positioning to get close to the position needed to perform the tibial cut. Place a headless pin in the alignment hole to stabilise the guide.
- Adjust the parameters to obtain the desired settings. The resection height is shown in the green rectangle on the screen, the contralateral bone cut in the orange rectangle, the varus/valgus in the yellow rectangle and the slope in the blue rectangle.
- Once the resection guide's position is set, put two pins in the guide's "O" holes.
- Secure the semi-assisted resection guide, perform the tibial cut and remove the guide.
- Once the tibial cut has been made, it can be verified by placing the universal alignment guide on the cut surface. Press the blue pedal to validate and go to the next step.



**FEMORAL
ACQUISITIONS**

HIP CENTRE ACQUISITION



- Extend the patient's leg and grasp his/her ankle.
- Press the blue pedal to start the data acquisition.
- Move the leg in a small circle (15 cm knee displacement) until the system has acquired 100% of the points it needs.
- Once the acquisition is finished, the system will calculate the hip centre. If the result is acceptable, the system automatically goes to the next step. If it is not acceptable, the system will prompt the user to restart the acquisition. During this step, the system will beep once when the acquisition starts and once when it ends. A status bar shows the progress being made during the acquisition.

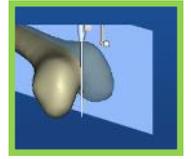
TOP OF INTERCONDYLAR NOTCH ACQUISITION

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

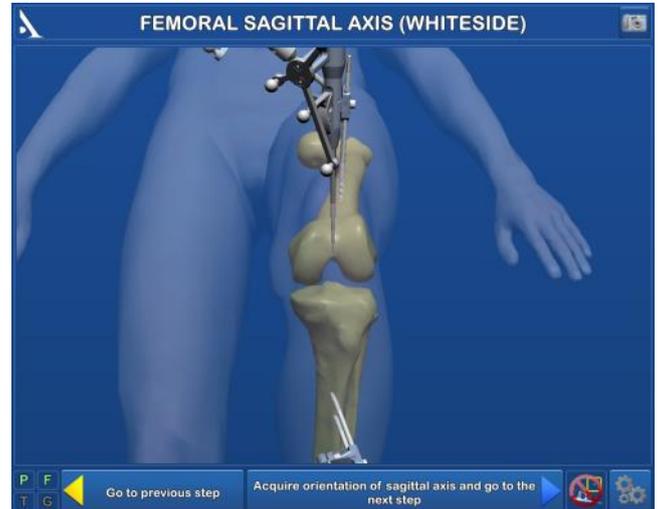


FEMORAL ROTATION REFERENCE

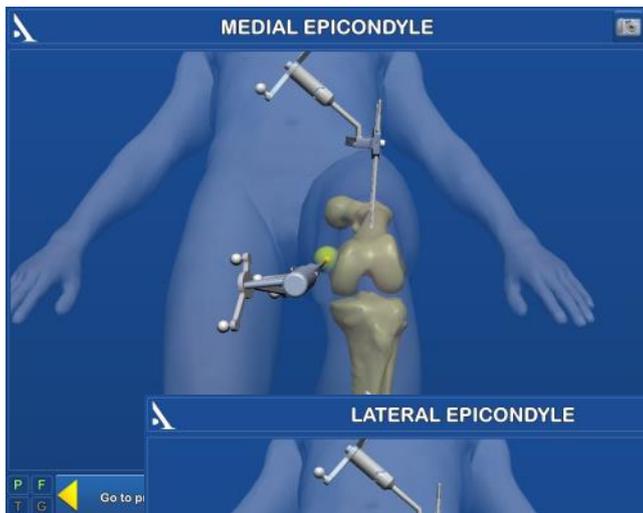
If the acquisition of the **femoral sagittal axis** (Whiteside's line) was selected as a femoral rotation reference:



- Place the pointer in the middle of the femur and align the body of the pointer with the femur's sagittal axis.
- Press the trigger to validate.

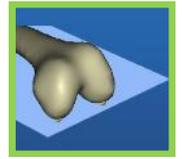


If the acquisition of the **transepicondylar axis** was selected as a femoral rotation reference:

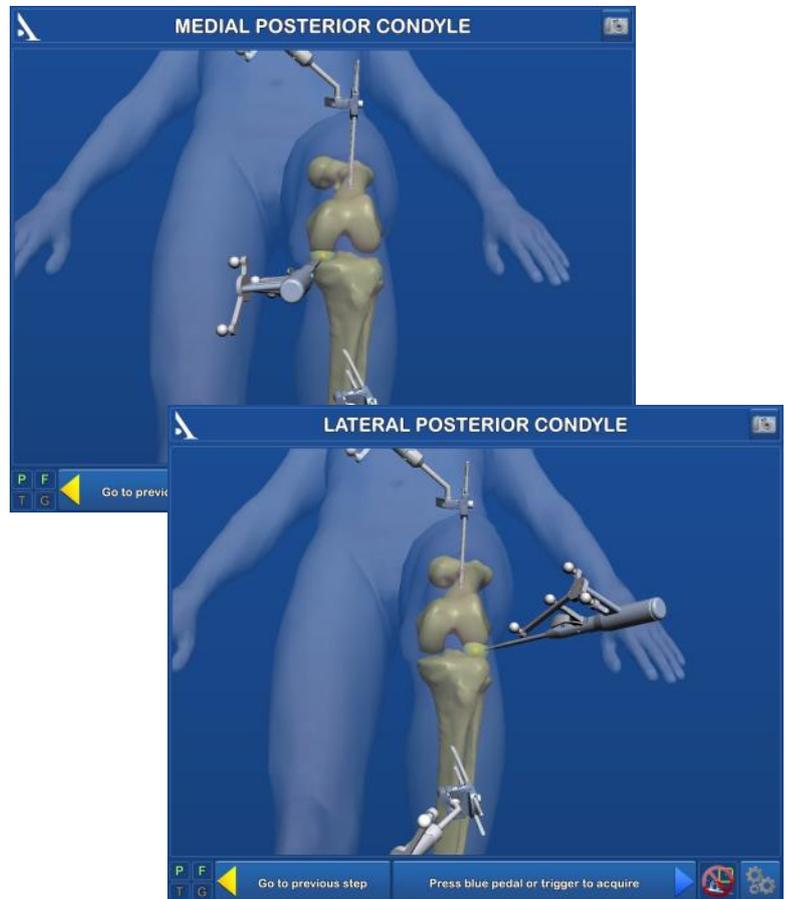


- Place the pointer on the medial epicondyle and press the trigger to validate this point.
- Repeat on the lateral epicondyle.
- The transepicondylar axis will be calculated using these two points.

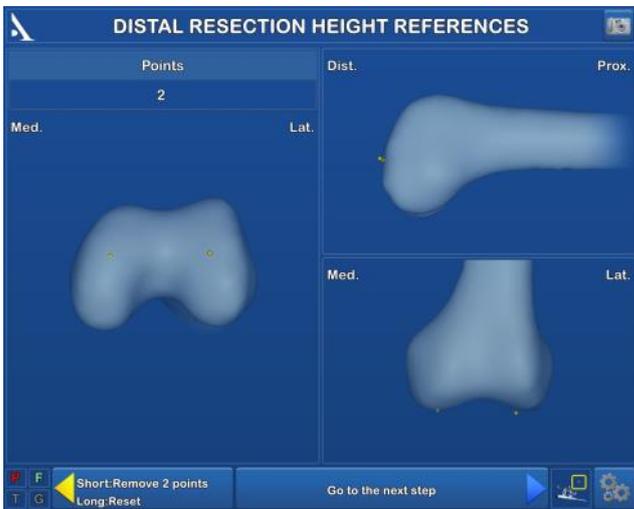
If the acquisition of the **posterior condylar axis** was selected as a femoral rotation reference:



- Place the pointer tip at the top of the medial posterior condyle and confirm; do the same for the top of the lateral posterior condyle.
- The posterior condylar axis will be calculated using these two points.



FEMORAL ACQUISITION



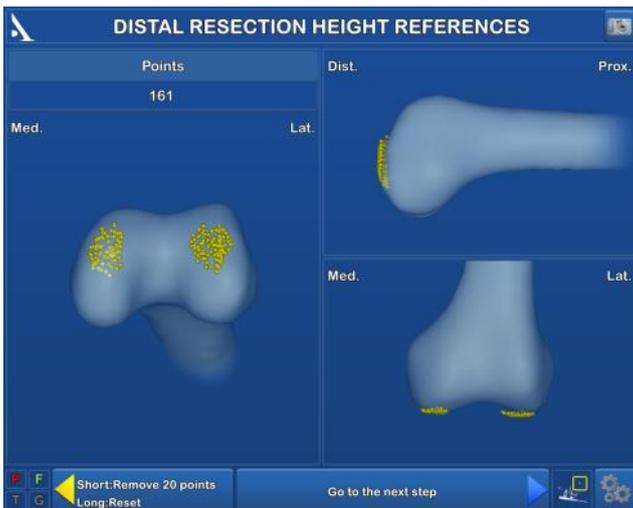
Two options for acquiring the distal resection height reference:

– **Acquisition of one point on each of the distal condyles:**

- Place the pointer on the condyle and press the trigger to validate.
- Repeat on the contralateral condyle.
- These two points will serve as references for the distal resection height.

– **Acquisition of one area on each distal condyle:**

- On each distal condyle, place the pointer tip on the bone surface. Press and hold trigger then move the tip along the surface being acquired.
- At any time, the surgeon may release the trigger, move the pointer tip to another location and then press the trigger again to continue the acquisition.
- 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.
- The most distal points will be calculated automatically and saved as the distal resection height reference.

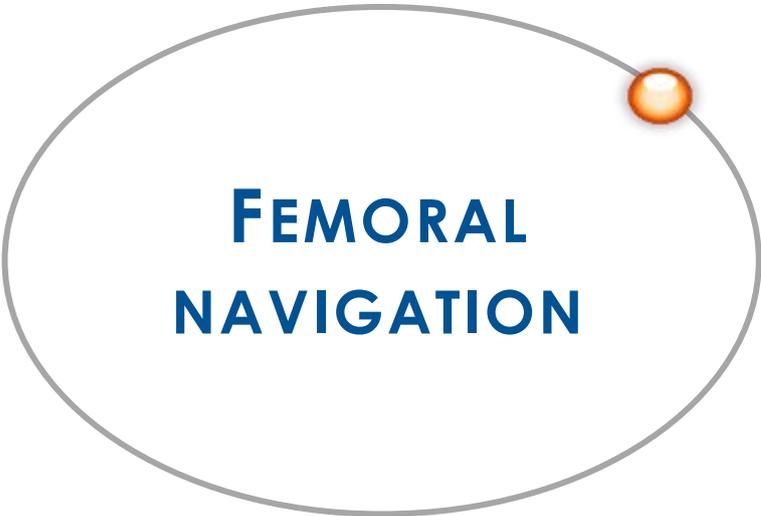


IMPORTANT

Make sure the pointer tip is always in contact with the femoral bone surface when the trigger is pressed

Note

It is important to acquire the points in the central area of the distal condyles while avoiding any peripheral osteophytes.

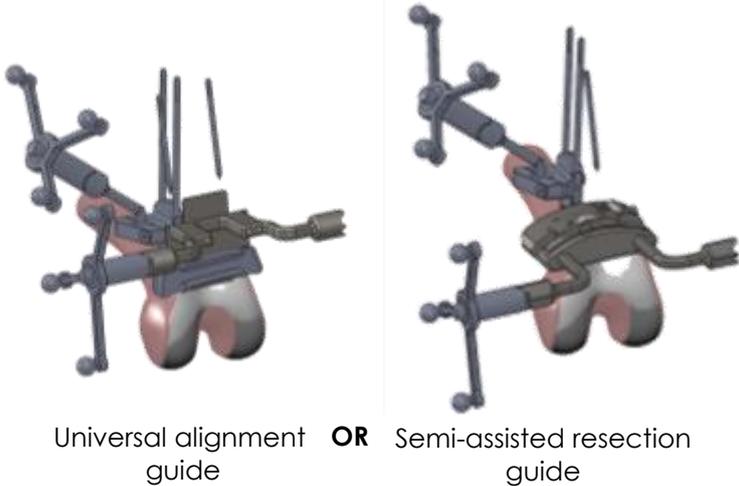


**FEMORAL
NAVIGATION**

DISTAL CUT GUIDING

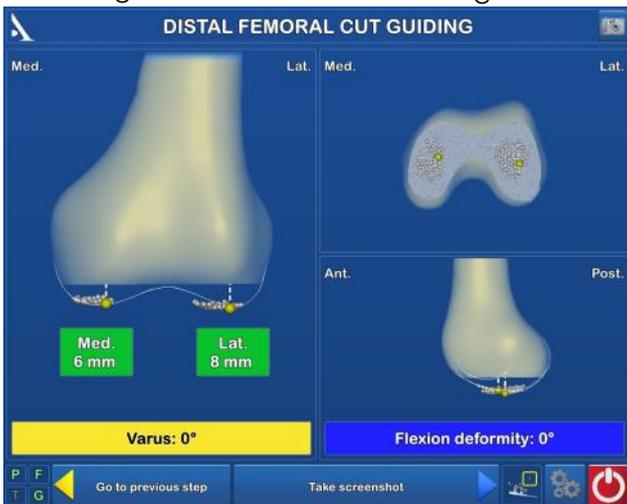
This step can be performed using either:

- the universal alignment guide, or
- the semi-assisted resection guide.



If using the universal alignment guide:

- Secure the G array to the universal alignment guide.
- Position the alignment guide's plate in the distal resection guide's slot.
- Adjust the positioning until the guide is in the position needed to perform the distal cut. The resection height is shown in the green rectangle on the screen, the varus/valgus in the yellow rectangle and the flexion in the blue rectangle.
- Once the resection guide's position is set, put two pins in the guide's "O" holes.
- Remove the universal alignment guide from the slot in the resection guide.
- Secure the guide with converging pins, perform the distal cut and remove the resection guide.
- Once the distal cut has been made, it can be verified by placing the universal alignment guide on the cut surface. Press the blue pedal to validate and go to the next step.

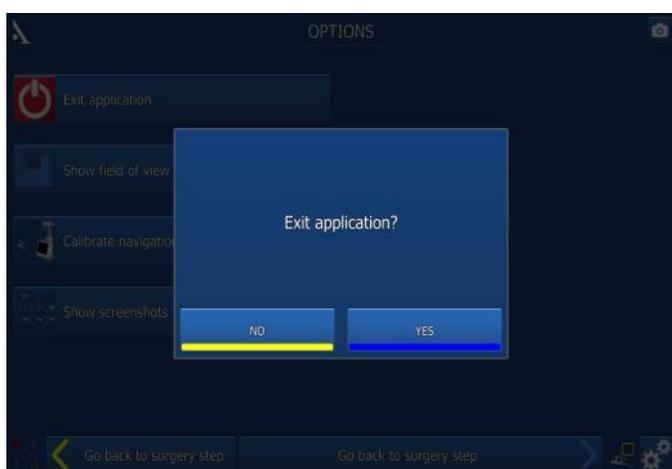


If using the semi-assisted resection guide:

- Secure the G array to the semi-assisted resection guide.
- Adjust the positioning to get close to the position needed to perform the distal cut. Place a headless pin into the alignment hole to stabilise the guide.
- Adjust the parameters to obtain the desired settings. The resection height (which can be adjusted using the green thumb knob) is shown in the green rectangle on the screen, the varus/valgus in the yellow rectangle and the flexion in the blue rectangle.
- Once the resection guide's position is set, put two pins in the guide's "O" holes.
- Secure the guide, perform the distal cut and remove the guide.
- Once the distal cut has been made, it can be verified by placing the universal alignment guide on the cut surface. Press the blue pedal to validate and go to the next step.

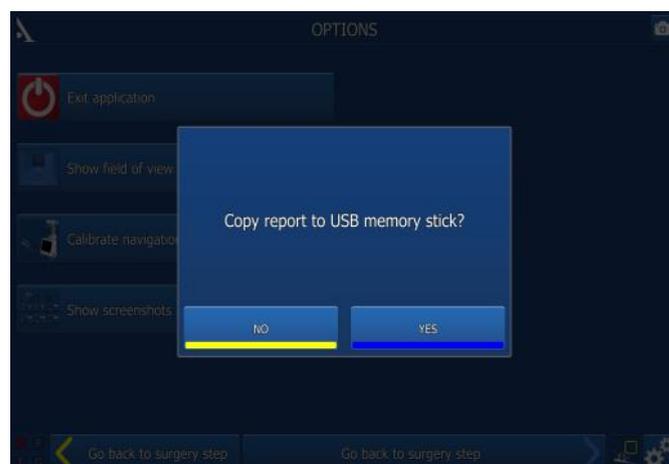
- All navigation steps have been completed.
- Refer to the Surgical Technique documents TO.G.GB.009 (SCORE® TKA) and TO.G.GB.013 (ANATOMIC® TKA) for the other steps:
 - Continuation of femoral resection
 - Femoral preparation
 - Tibial preparation
 - Patellar preparation
 - Insertion of chosen implants

SAVING THE SURGERY REPORT



- Press the  button to exit the application:
 - It is available immediately after the last step,
 - 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
 - Proximal resection height references
 - Proximal cut guiding
 - Distal resection height references
 - Distal cut guiding



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® NO114 User Manual for instructions on how to store the workstation.



INSTRUMENTATION

INSTRUMENTATION SET

- In addition to the mechanical instrumentation described in the Surgical Technique documents (TO.G.GB.009 for SCORE® and TO.G.GB.013 for ANATOMIC®), the following are required:
 - AMPLIVISION® Navigation Station
 - Sterile, single-use markers (14 per pack)
 - The **Universal Navigation Set**.

Sterile Markers (Product No. 3-0400902):

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



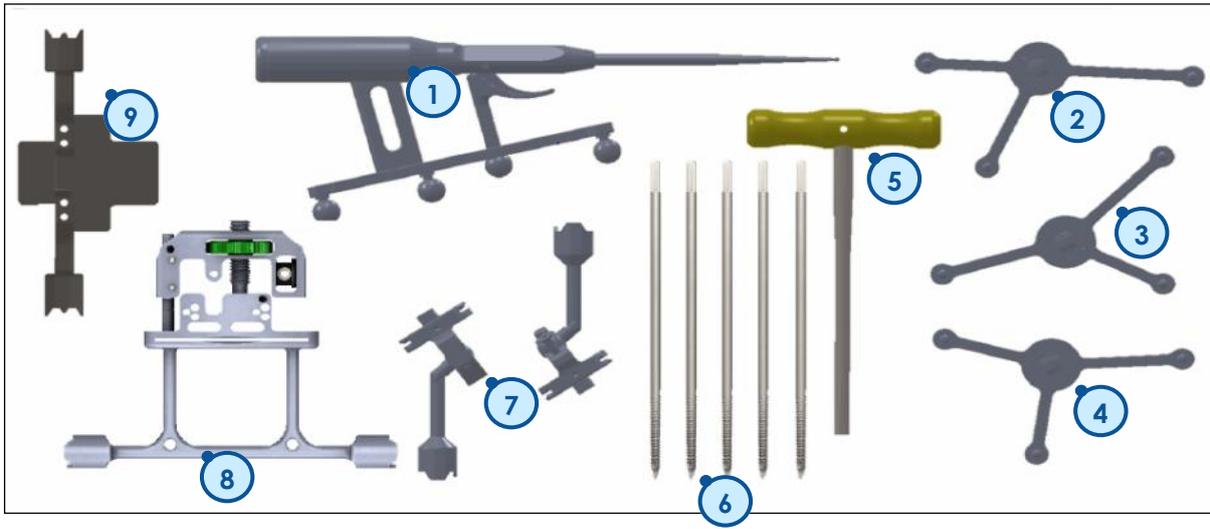
Single-use Conical Threaded Pins AMPLIVISION® (Product No. 2-0252200):

- 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.



UNIVERSAL NAVIGATION SET

2-0299946

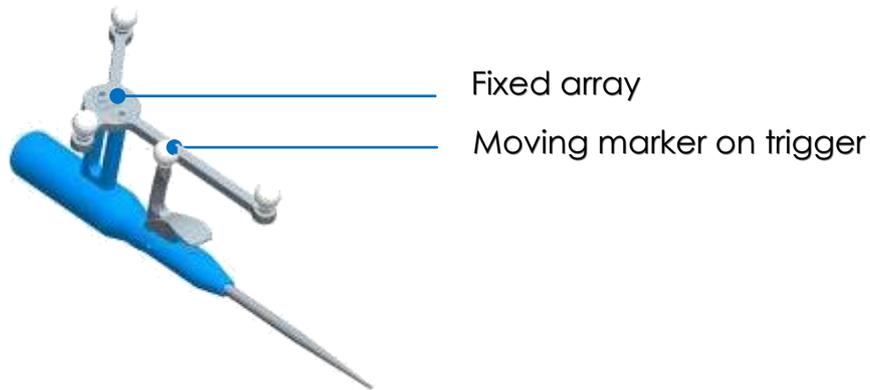


Item	Name	Product No.	Qty
1	Probe, knee navigation	2-0215700	1
2	T array, tibia navigation	2-0215800	1
3	F array, femur navigation	2-0117400	1
4	G array, Instrumentation navigation	2-0117500	1
5	H5 Screwdriver	2-0200800	1
6	Conical Threaded Pins AMPLIVISION Ø4 length 150mm	2-0235500	5
7	Inclined fixation system, navigation geometry	2-0117200	2
8	Semi-assisted resection guide	2-0232500	1
9	Universal guide	2-0229000	1

INSTRUMENTS

Probe:

- 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 markers, one of them being on the trigger.



Semi-assisted resection guide:

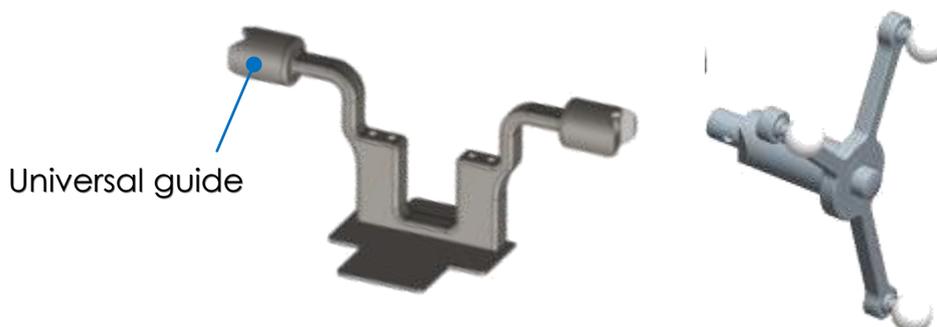
- The semi-assisted resection guide is used to make the distal cut and the tibial cut, once its position has been established. There are two attachment points for the G array (one on each side). The array can only be assembled in one direction into each attachment point.



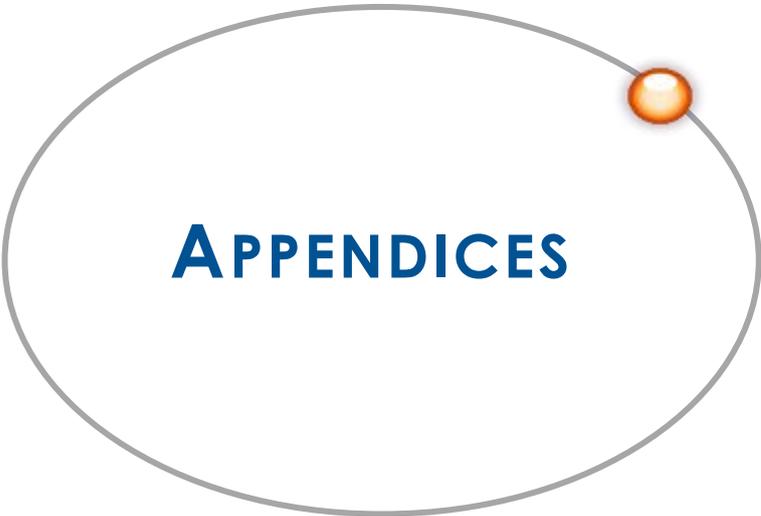
Semi-assisted resectino guide

Universal guide:

- The universal alignment guide is inserted into slots in the resection guide to navigate the position of these guides. It is also used to acquire the cuts once they have been made. There are two attachment points for the G array (one on each side). The array can only be assembled in one direction into each attachment point.



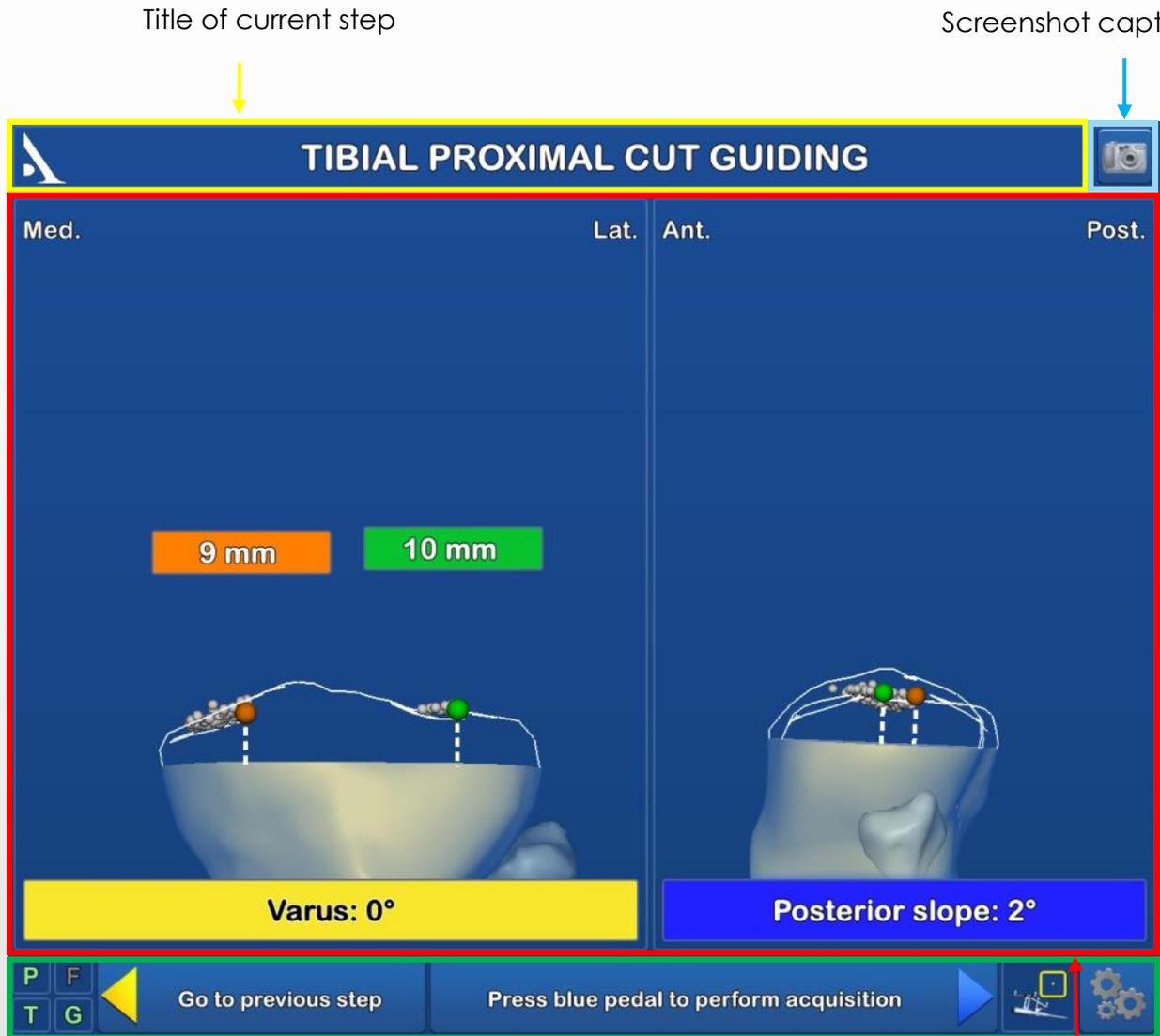
Universal guide



APPENDICES

APPENDIX A

SCREEN LAYOUT



Title of current step

Screenshot capture button

Information area and buttons

Active area

Yellow pedal: indicates action carried out when pedal is pressed

Blue pedal: action carried out when pedal is pressed

Menu: Options



Visibility of each array:
Green - visible
Red - not visible

Indicates if pointer can be used as a mouse on screen

APPENDIX B

OPTIONS MENU DESCRIPTION

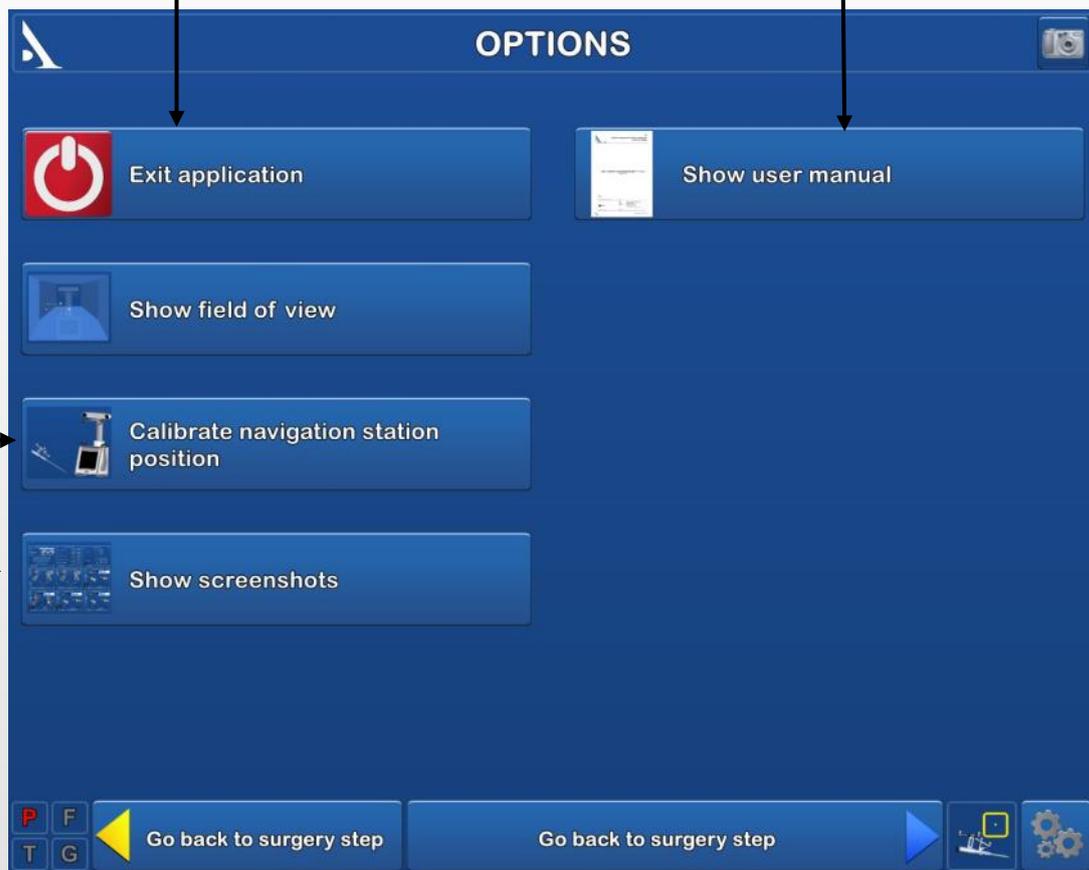
The "Exit Application" button will only be active during the final step
To exit the application before the final step, go to the "Options" menu to select it

Show user manual

Show camera field of view to locate arrays

Reset navigation station position relative to surgeon position

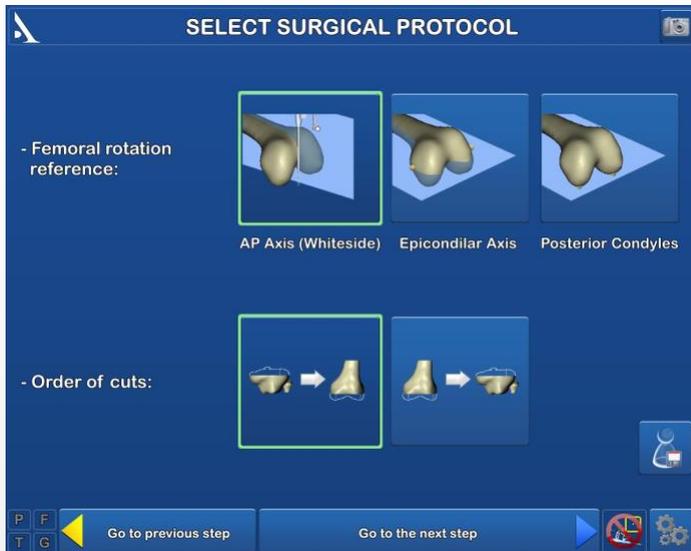
View all the validated steps during the surgery



APPENDIX C

USER PROFILE

SAVING A USER PROFILE



- Once the surgery-related options have been selected, a user profile can be created by pressing the "Save User Profile" button 
- The following information will be saved to a USB drive:
 - Surgeon name
 - Preferred tibial rotation reference
 - Preferred navigation method for tibial cut
 - Preferred trial implant acquisition order
 - The flexion deformity reference selected
 - The default flexion deformity value selected
 - The anatomical parameters and optional sequences selected.

WORKING WITH USER PROFILES

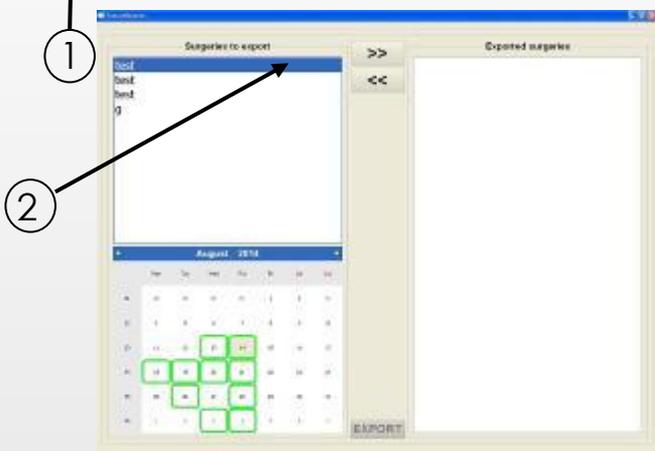
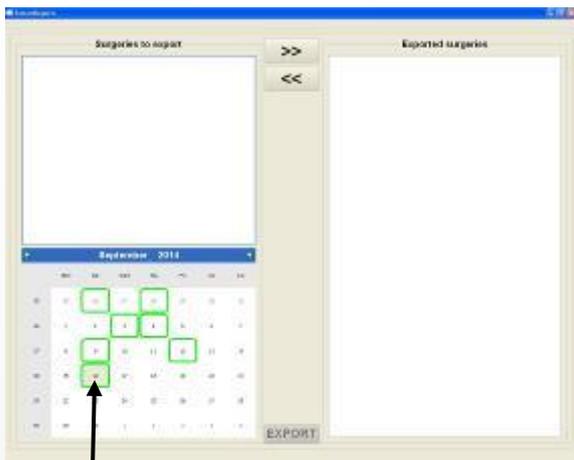


Options that can be changed

- 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



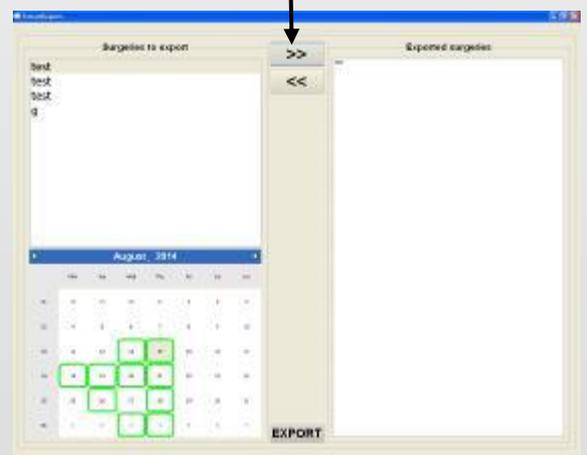
If a saved surgery report is not transferred to a USB drive, it can still be retrieved at a later date.

- 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".
1. 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.

2. & 3. Use the touch screen to select the reports to be exported and then press the button  to move them to the "Exported surgeries" window.

4. Insert the USB drive and press the **EXPORT** button to copy these reports to it. A message will appear when the operation is complete.

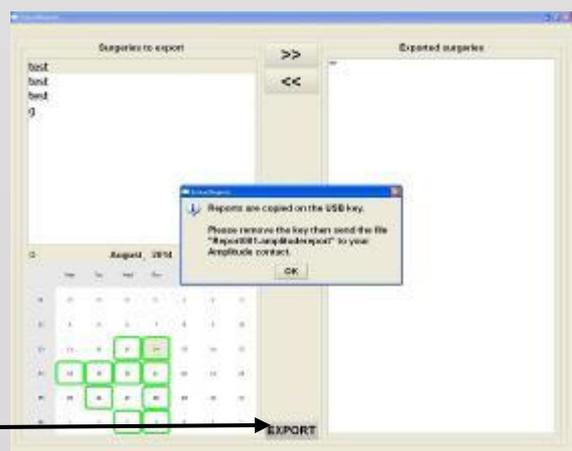
3



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

4





Customer Service - France:

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01700 Neyron, France
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Fax: +33 (0)4 37 85 19 18

E-mail: amplitude@amplitude-ortho.com

Customer Service-Export:

11, cours Jacques Offenbach. Zone Mozart 2,
26000 Valence, France
Phone: +33 (0)4 75 41 87 41
Fax: +33 (0)4 75 41 87 42

Internet: www.amplitude-ortho.com