

AMPLIVISION®

Computer-assisted
surgery
Standard Protocol



AMPLITUDE®

Surgical
Technique
Hip

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AMPLIVISION®

AMPLIVISION® is a surgical aid that allows the surgeon to view data in real time during the surgery. The software also simulates the postoperative outcome based on the real time data, each step of the way.

For total hip arthroplasty, it assists the surgeon in:

- Preserving leg length
- Optimising offset
- Determining the joint centre
- Viewing and resolving implant impingement during mobility testing

AMPLIVISION® is designed to be used with various surgical techniques:

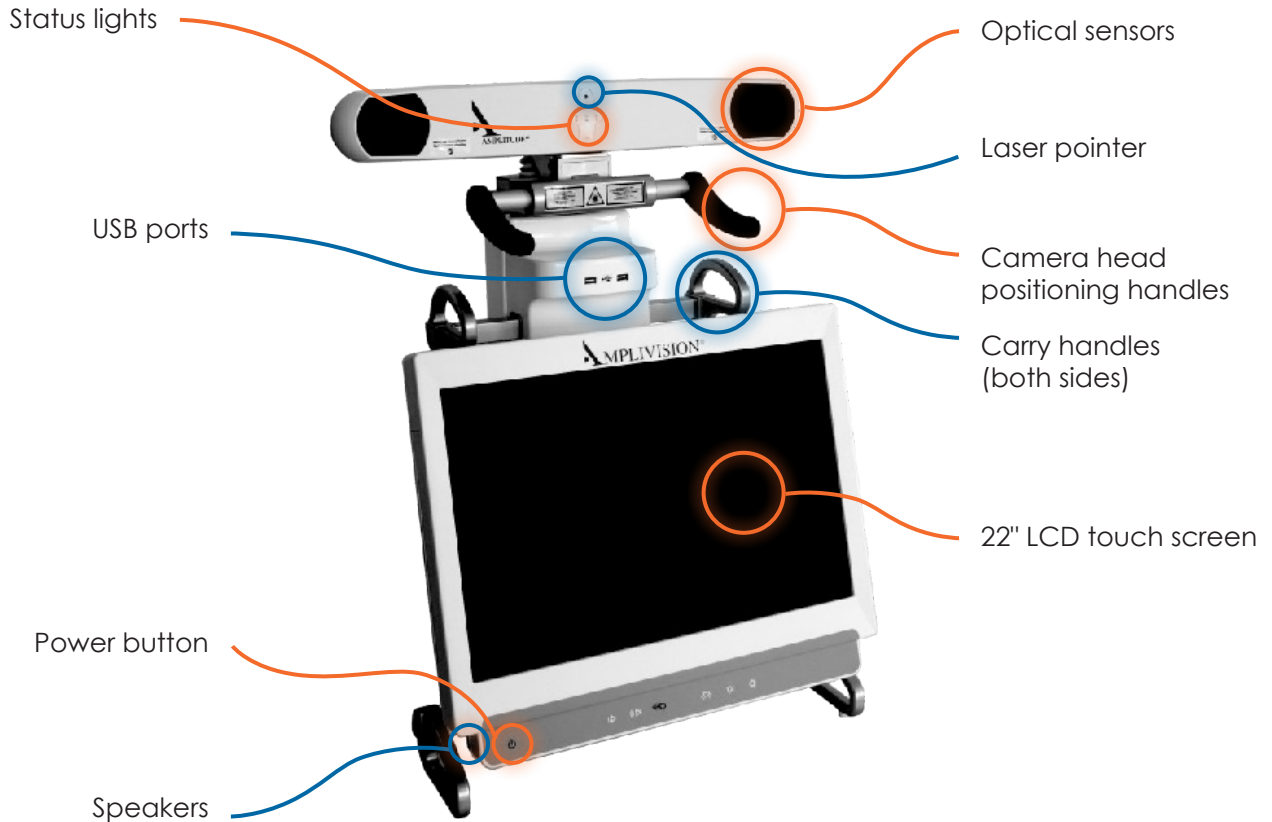
- The simulated outcome is independent of the surgical approach
- Two protocols are available for hip surgery:
 - > A "Standard" protocol that guides the surgeon through all the surgery steps
 - > A "Fast" protocol that provides the key surgery data (height / offset / impingement) more quickly

This surgical technique document corresponds to the Standard protocol.

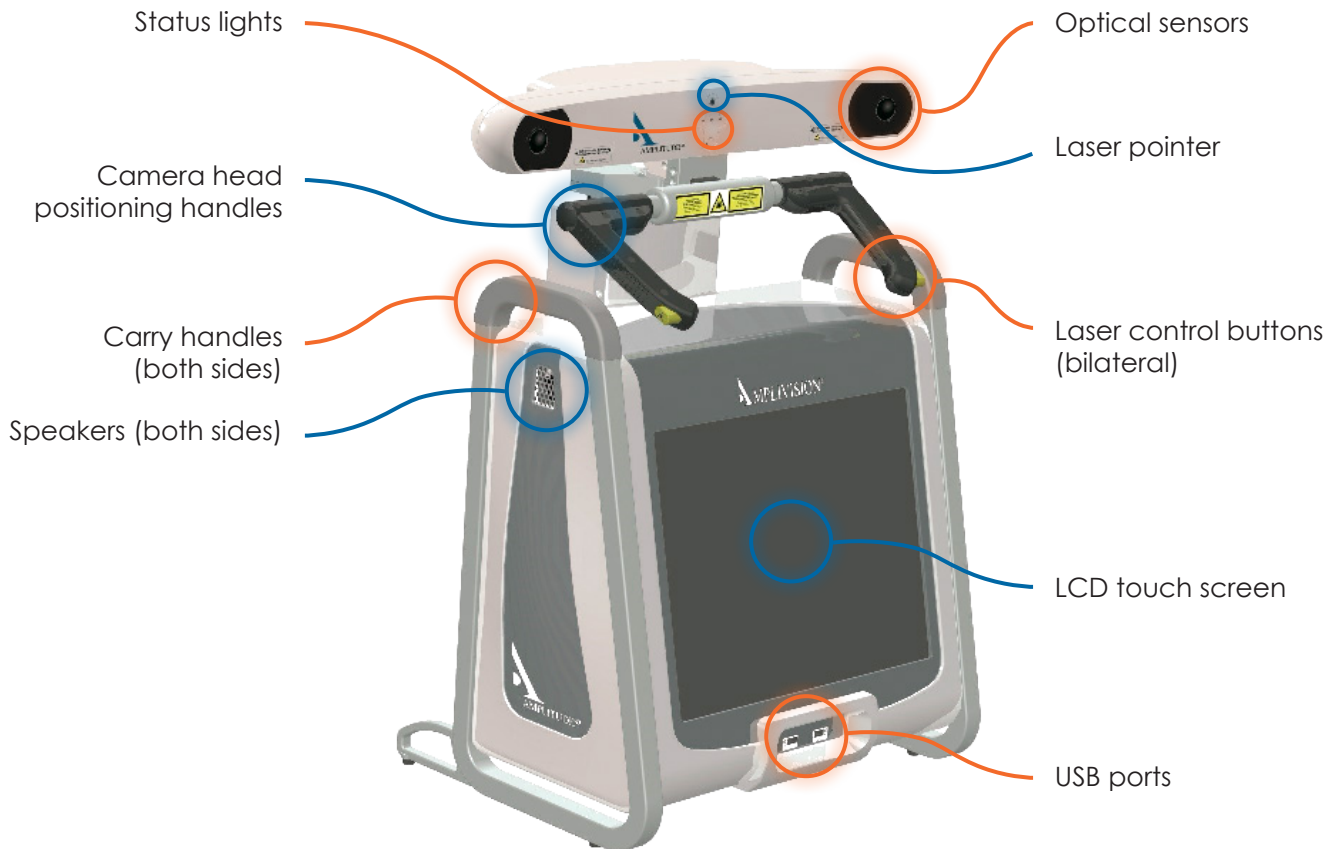
Information about most of Amplitude's implants is already integrated into AMPLIVISION®. Implant-specific instrumentation is available for each procedure.



WORKSTATION COMPONENTS: FRONT

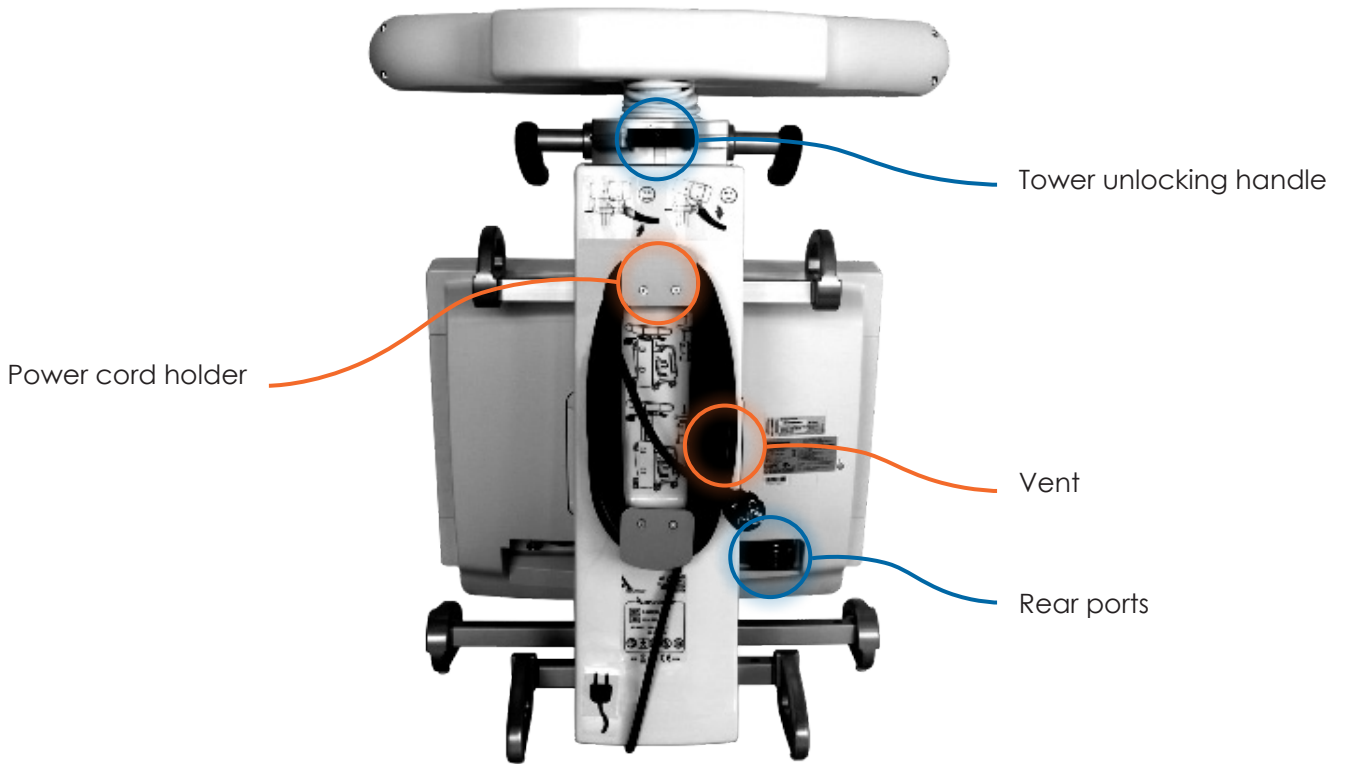


V3 Workstation

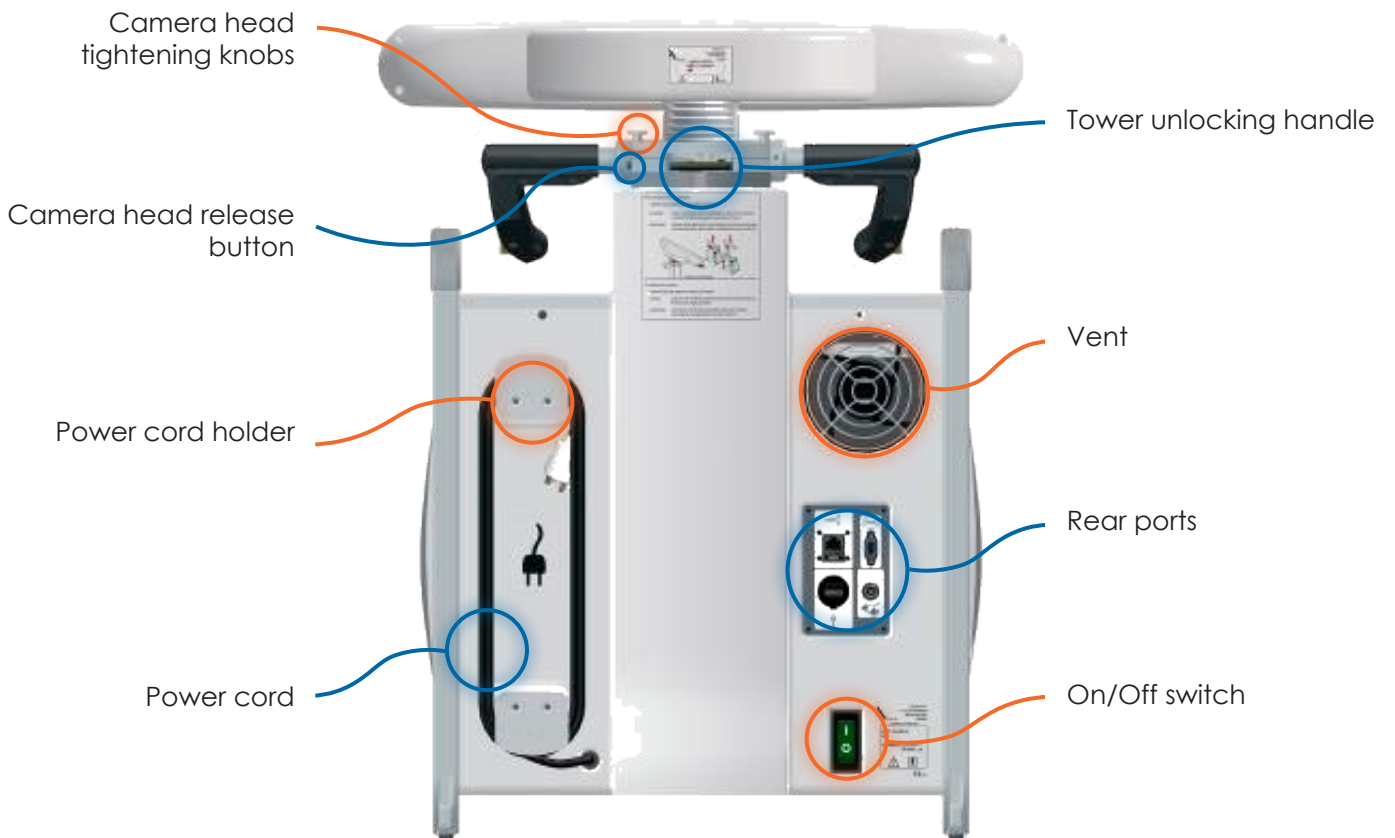


V2 Workstation

WORKSTATION COMPONENTS: REAR



V3 Workstation



V2 Workstation

WORKSTATION CONFIGURATION



Place the workstation on a stable table or operating room cart. Refer to Appendix A for how to unpack the workstation from its shipping trunk.

Clean the workstation according to the instructions in the user manual or “Options menu”.

Connect the pedal to the back of the V2 Workstation or to the side of the V3 Workstation and slide it into its protective cover (found in the trunk).

Plug in the workstation's power cord.

Position the workstation near the patient.

IMPORTANT

The workstation must be at least 1.5 m from the patient.

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

Unlock the adjustable tower: press on the locking lever and let the tower rise freely until it reaches its maximum height.

Turn the power on:

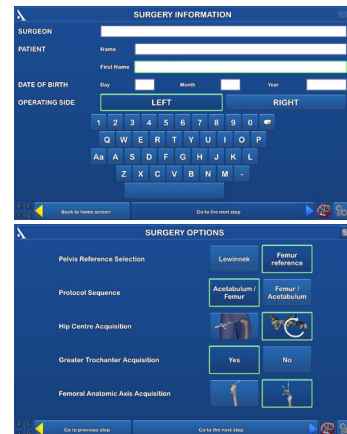
- > V2 Workstation: Find the green button on rear of workstation; set it to the “I” position.
- > V3 Workstation: Press power button at lower left portion of screen; it will turn green when the power is on.

SUMMARY OF SURGICAL TECHNIQUE

1 Launching the software



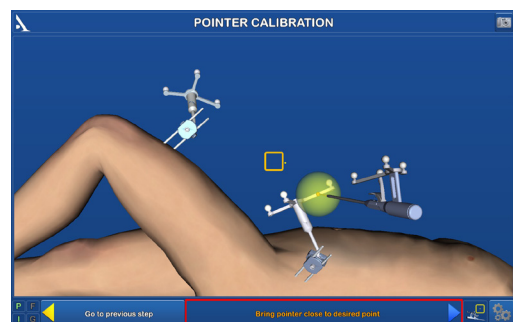
2 Patient data and surgical preferences



3 Camera setup and calibration



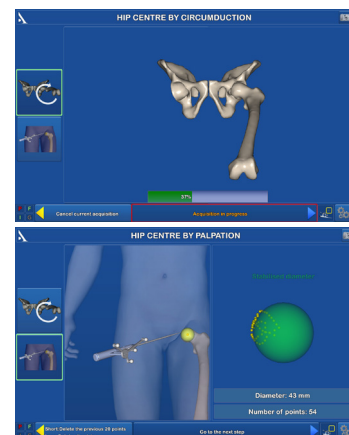
4 Placing the arrays and probe calibration



5 Transfer position



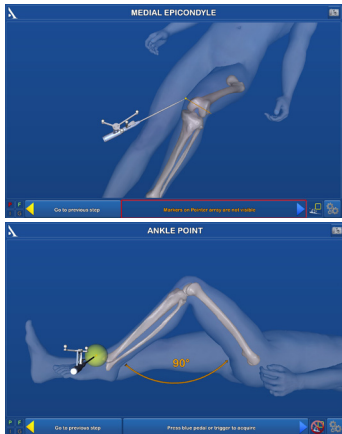
6 Acquiring the hip center



SUMMARY OF SURGICAL TECHNIQUE

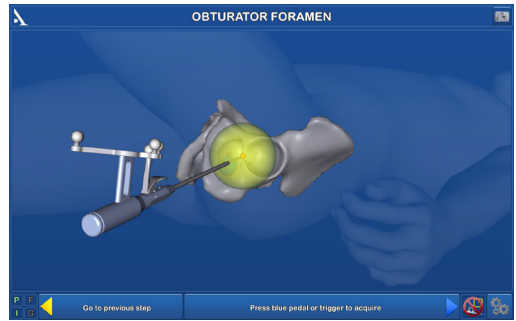
7

Acquiring knee and ankle center



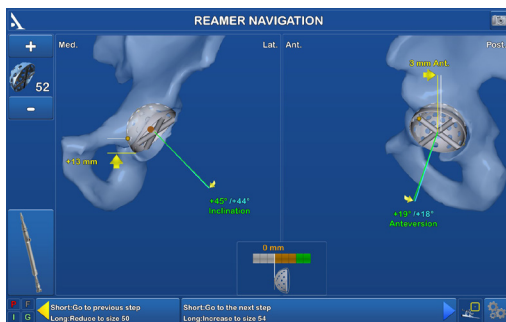
8

Acquiring the acetabulum



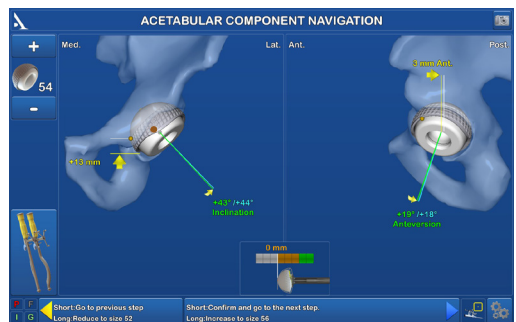
9

Reamer navigation



10

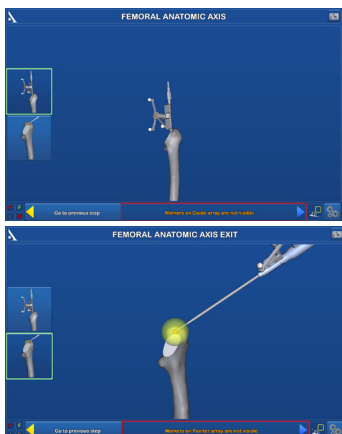
Acetabular navigation



Calibrer impacteur selon modèle utilisé

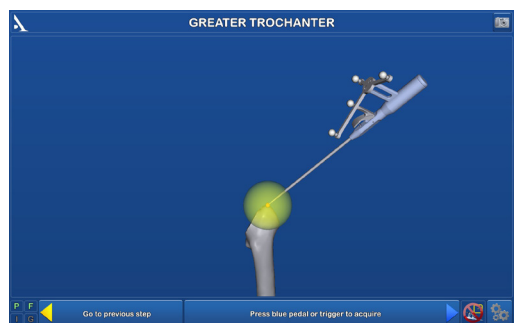
11

Acquiring the femur's anatomical axis



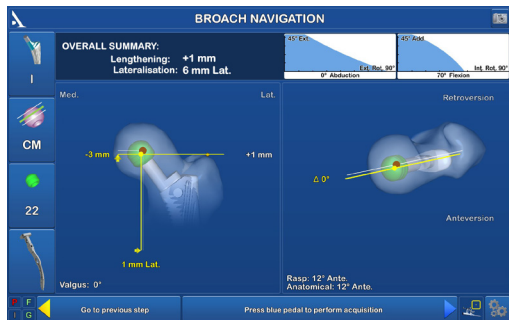
12

Acquiring the greater trochanter

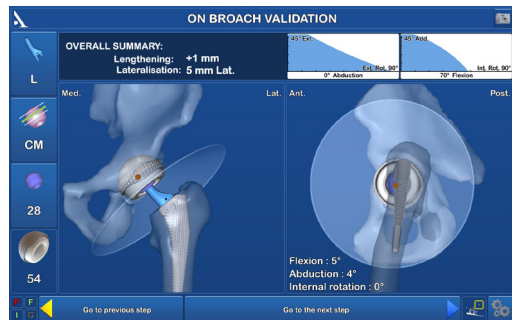


SUMMARY OF SURGICAL TECHNIQUE

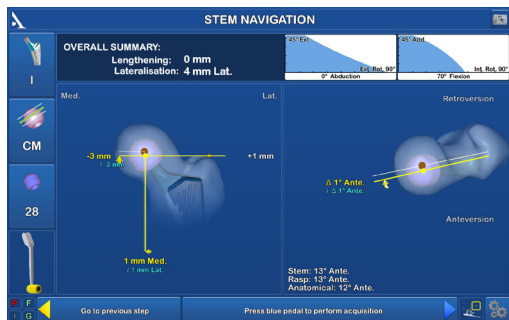
13 Broach navigation



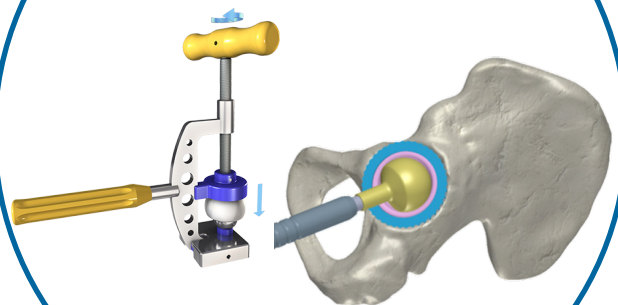
14 Validation with trial implants



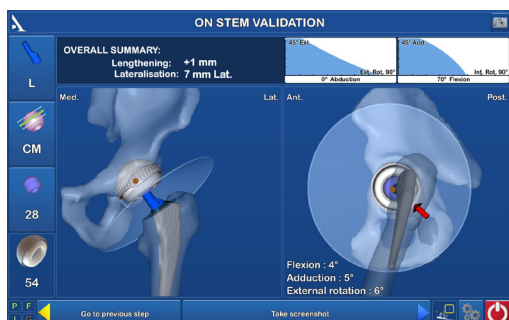
15 Stem navigation



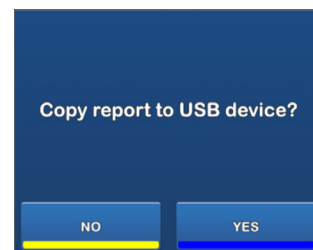
16 Liners and head insertion



17 On-stem navigation



18 Saving the surgery report





PREPARATION

LAUNCHING THE SOFTWARE

Use the touch screen to select the desired cup and femoral stem.

The screenshot shows the 'SURGERY INFORMATION' form. It has several input fields: 'SURGEON' (a single line), 'PATIENT Name' (a single line), 'PATIENT First Name' (a single line), 'DATE OF BIRTH' (Day, Month, and Year fields), and 'OPERATING SIDE' (LEFT and RIGHT buttons). A virtual keyboard is overlaid on the form, with the 'LEFT' button highlighted. At the bottom, there are two buttons: 'Back to home screen' (with a yellow arrow icon) and 'Go to the next step' (with a blue arrow icon).

Use the virtual keyboard to enter the following information:

- Surgeon name
- Patient name
- Patient's 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 back to the welcome screen, press the yellow pedal or yellow arrow on the screen.

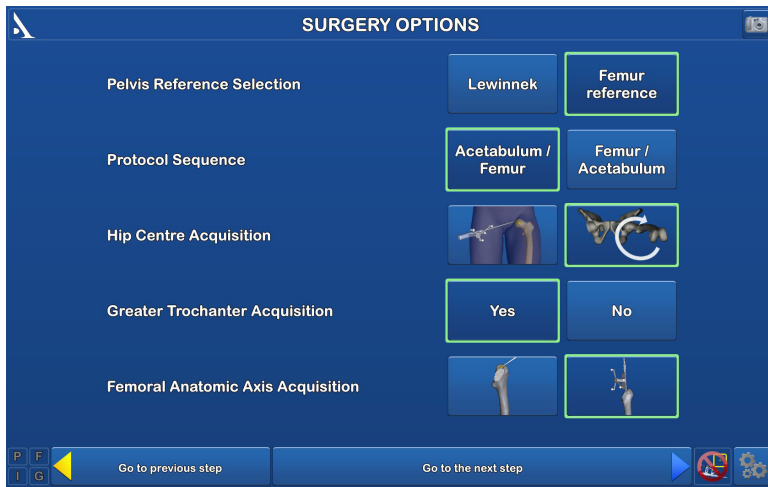
REMINDER

The purpose of this surgical technique is to provide instructions on how to use the instrumentation properly. The surgeon is fully responsible for choosing and performing the approach and surgical technique.

NOTE:

This surgical technique follows an acetabulum/femur protocol. Reversing this sequence requires slightly different steps, but overall, the use of the system remains the same.

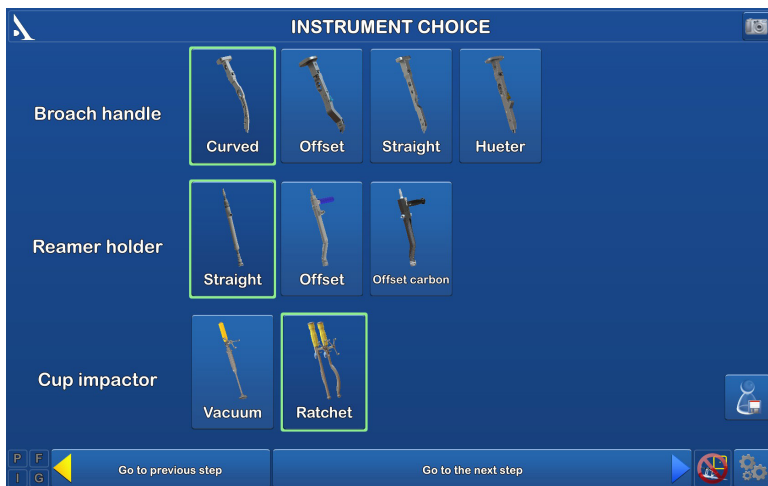
CONFIGURING THE SURGERY-RELATED OPTIONS



Select the desired surgery protocol on the screen:

- Pelvis coordinate reference system: Lewinnek plane or femur reference
- Protocol order: acetabulum then femur, or the opposite
- Acquisition method for hip centre: acquisition of femoral head or circumduction movement of the patient's leg
- Whether the greater trochanter will be acquired (optional)
- Acquisition method for femur anatomical axis: by selecting a point at the medullary canal's exit or by using the reamer

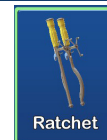
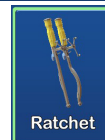
To go to the next step, press the blue pedal or the blue arrow on the screen.



Select the instrumentation that will be used for surgery:

- Broach handle: Straight, Offset, Curved, Hueter Straight
- Reamer holder: Straight, Metal Offset, Carbon Offset
- Cup impactor: depends on chosen cup (see below)

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



The preferences can be saved to the user profile for future surgical procedures.

(see Appendix F)

PLACING THE ARRAYS



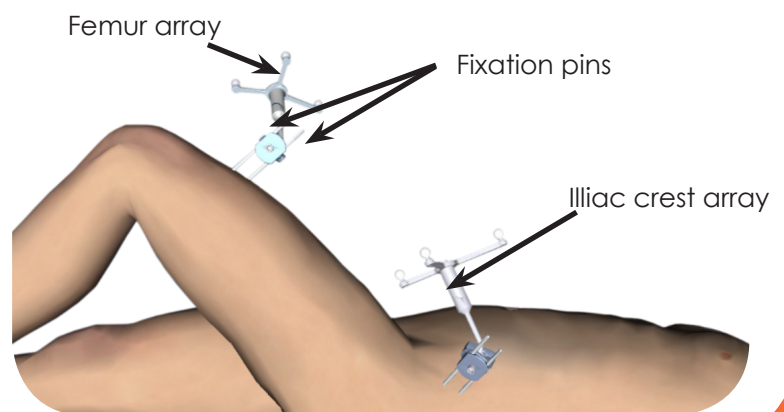
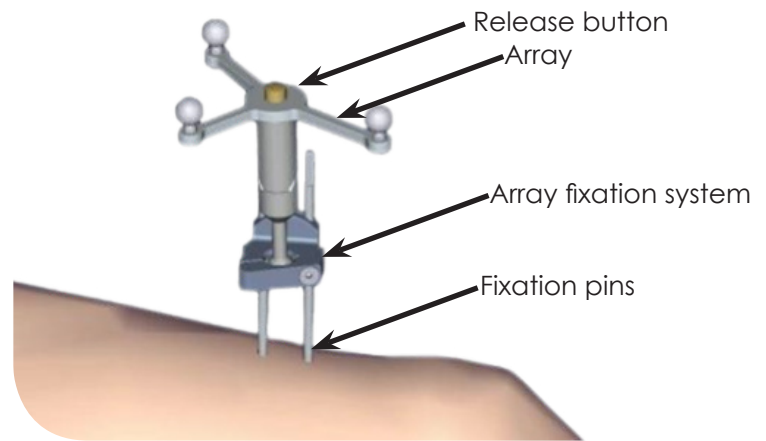
Clip the round markers to the arrays:

- 3 for the I (iliac crest) array
- 3 for the F (femur) array
- 4 for the P (probe) array
- 3 for the G (guide) array

Put the two fixation pins in the iliac crest and install the array fixation system (preferably the straight version):

- Insert the first pin, making sure it crosses the 1st cortex so the pin is stable.
- Place the array fixation support onto the first pin to get the proper spacing for the second pin.

Clip the I 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.

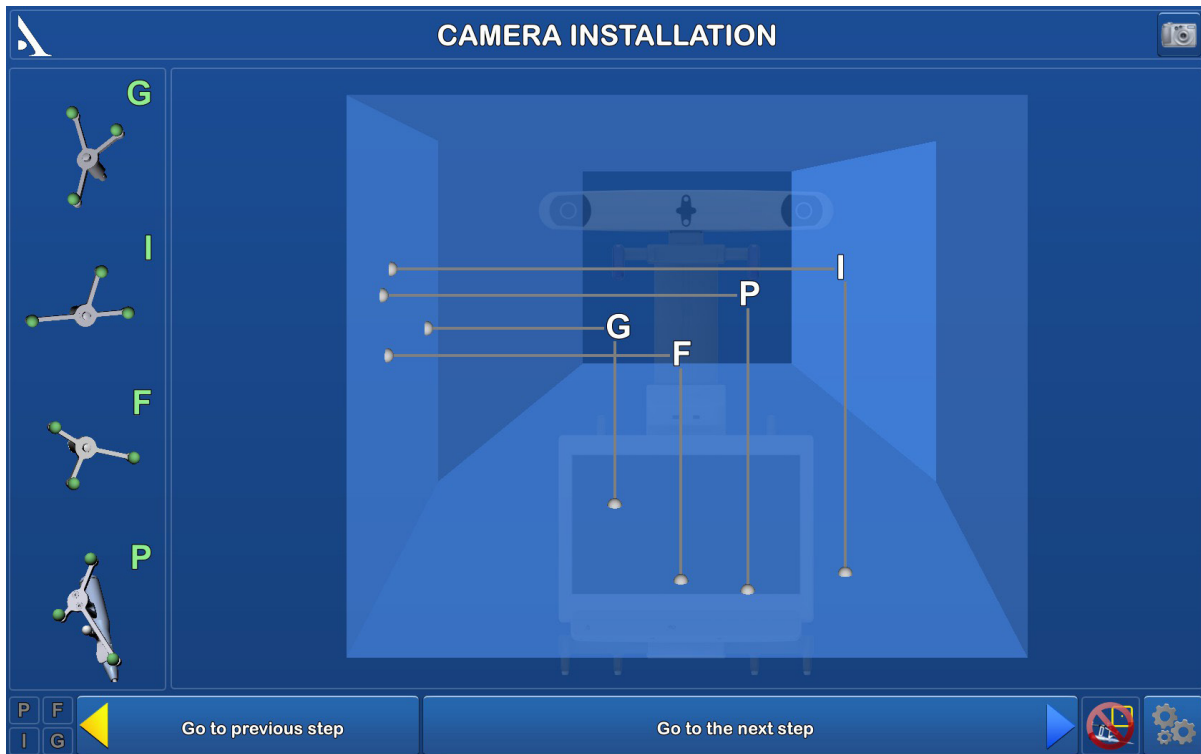
Insert two fixation pins on the lateral side of the femoral shaft: go through the 1st cortex and then into, but not through, the 2nd cortex. Place the fixation support (preferably the curved version) onto these pins.

Clip the F array on the moveable part of the support.

Orient and secure the F array so that it is always visible to the camera whether the hip is dislocated or reduced.

WORKSTATION SETUP

SETTING UP THE CAMERA



Position the camera head so the letters corresponding to the F and I 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:

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

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

WORKSTATION SETUP (CONTINUED)

SCREEN CALIBRATION



Aim the probe 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 probe, 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.

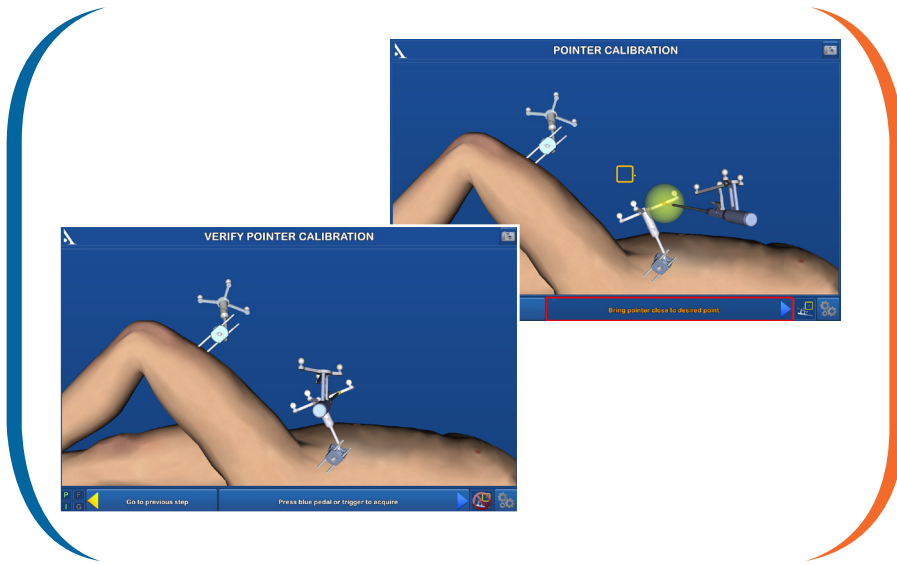
IMPORTANT

The user must make sure the arrays used in this step are fully visible.
These steps can be saved to a USB drive at the end of the procedure.

To recalibrate the camera position at any time:

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

CALIBRATION



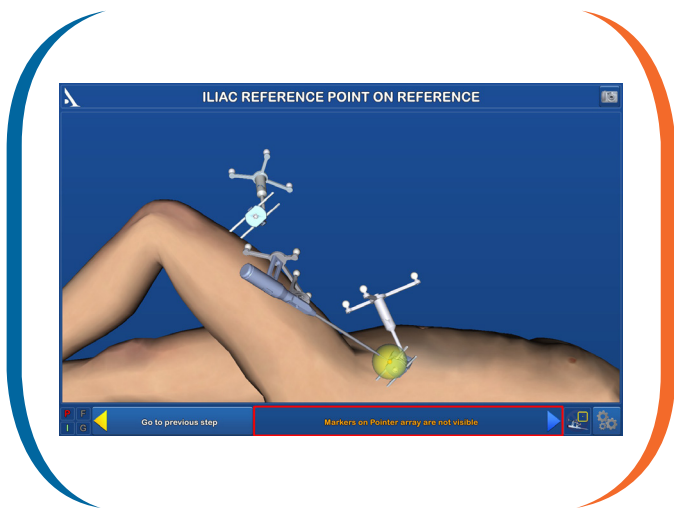
CALIBRATING THE PROBE

To define the exact position of the probe's tip:

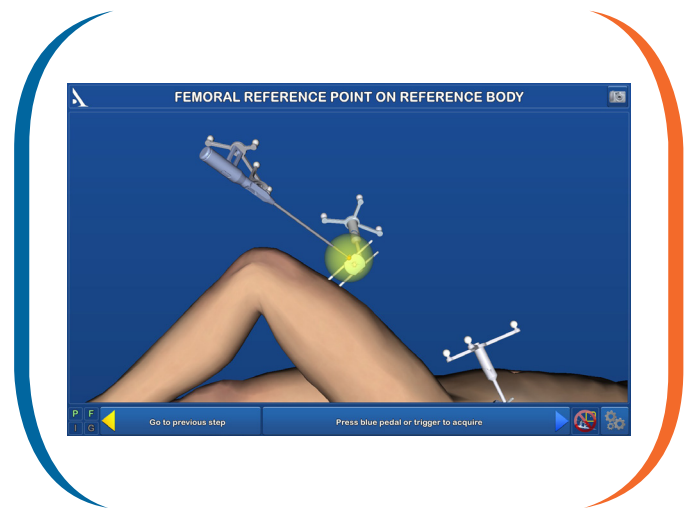
- Calibrate the probe by placing its tip in the conical calibration mark on one arm of the I array and press the trigger to confirm.
- Without lifting the probe tip, change the probe's orientation slightly and then confirm again.

CALIBRATING THE ARRAYS

This step validates the final position of the I and F arrays on their respective fixation supports. At any point during the procedure, the surgeon can check to make sure this position has not changed.



Iliac crest reference point: Place the probe tip in one of the two conical calibration marks on the I array support and confirm.



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

At any time during the procedure, place the probe tip on the previously acquired iliac crest and/or femur reference point. The words "Iliac OK" and/or "Femur OK" will appear in the lower left corner of the screen if the array has not moved relative to its support.

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

However, there is no way to check whether the array-support combination has moved. If in doubt, continue the procedure with conventional instrumentation.



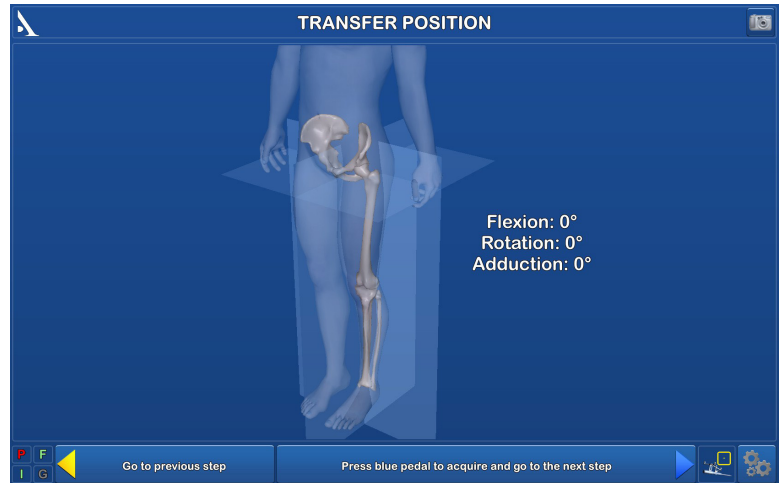
**PATIENT
ANATOMY
ACQUISITION**

TRANSFER POSITION

Set the femur's position relative to the pelvis so that it simulates the patient's standing position (transfer position).

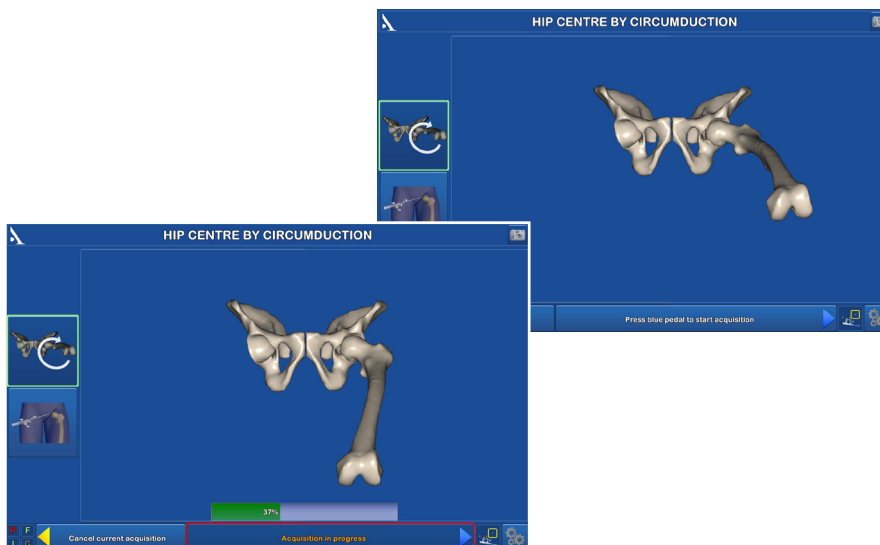
- Flexion: 0°
- Rotation: 0°
- Adduction: 0°

Press the blue pedal to validate this position.



ACQUIRING THE HIP CENTRE

METHOD 1: USING A CIRCUMDUCTION MOVEMENT OF THE PATIENT'S LEG



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

Press the blue arrow (or 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 will automatically go 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.

Open the joint and cut the femoral neck.

ACQUIRING THE HIP CENTRE

METHOD 2: BY ACQUIRING POINTS ON THE FEMORAL HEAD

After opening the joint, remove any peripheral osteophytes and resect the joint capsule.

> If the femoral head is being dislocated AFTER the femoral neck is cut:

Rotate the femur to expose as much of its surface area as possible.

> If the femoral head is being dislocated BEFORE the femoral neck is cut:

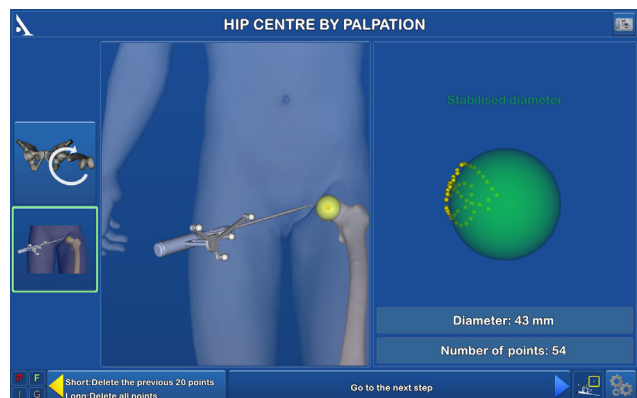
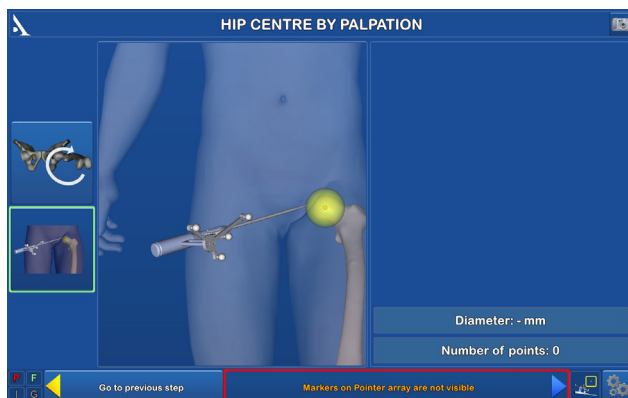
Dislocate the femoral head.

Place the probe's tip on the femoral head and press the trigger to start acquiring points. Points should be acquired in non-damaged areas of the femoral head.

Stop acquiring points when the femoral head diameter shown on the screen no longer changes.

Press the blue pedal to save the data and go to the next step.

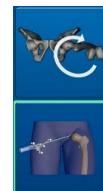
Cut the femoral neck (if points were acquired before the femoral neck cut).



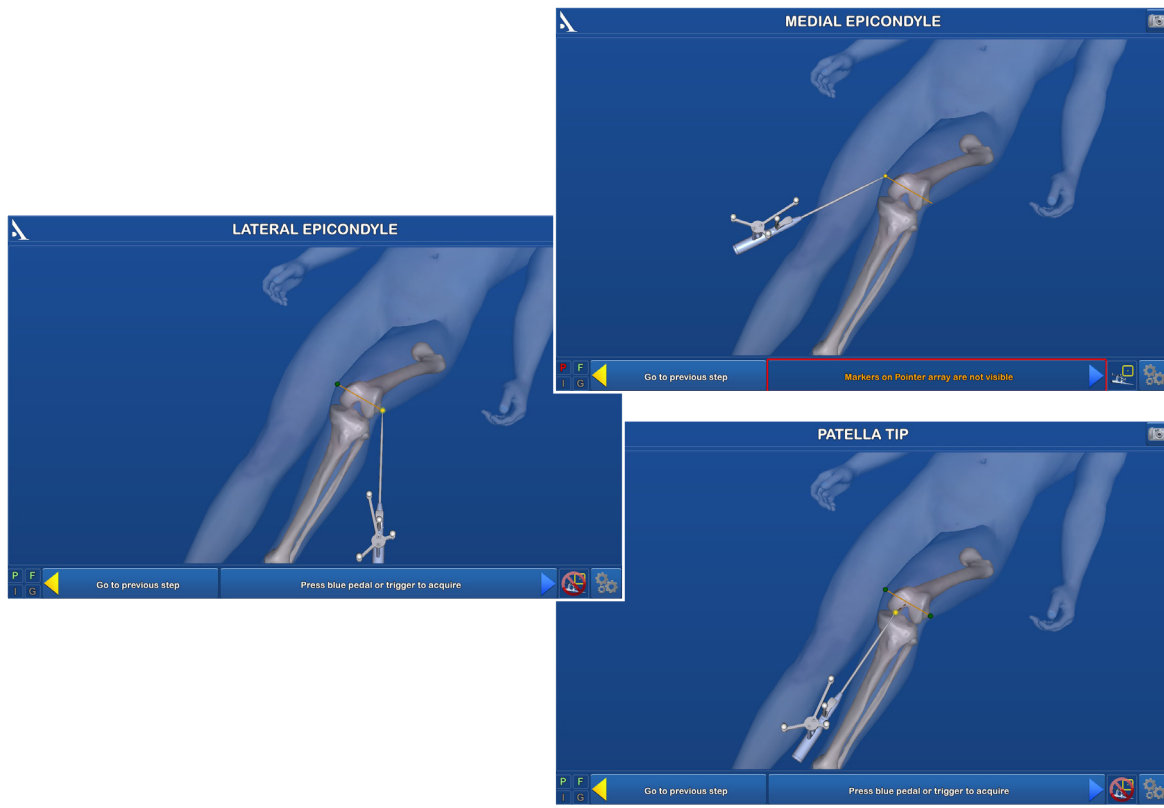
IMPORTANT

The acquisition of points can be interrupted by releasing the trigger; press the trigger again to restart the acquisition. It is preferable to acquire points with the probe in many different orientations so that the femur shape on the screen is as close as possible to the true shape. A minimum of 15 digitised points are needed to complete this step.

Use the buttons on the left side of the screen to switch between methods.



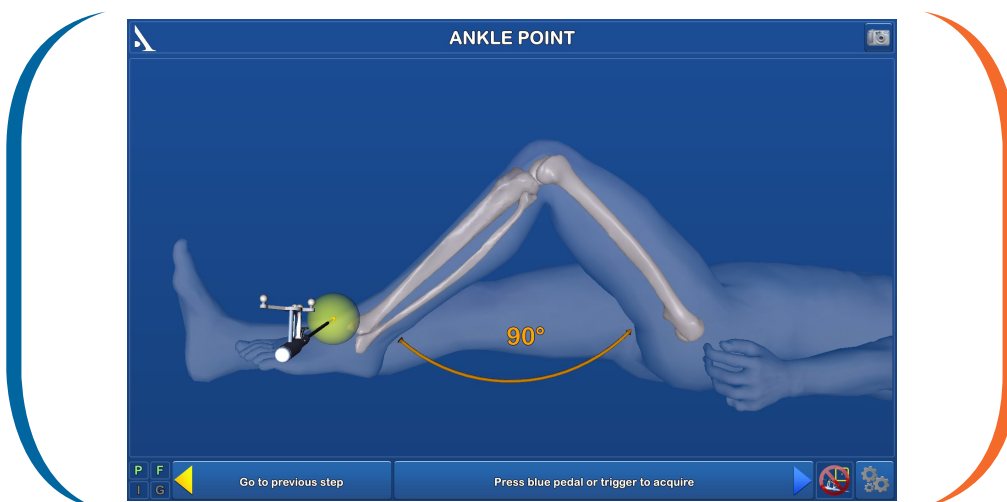
ACQUIRING THE KNEE CENTRE



Acquire the following points on the knee using the probe:

- Medial epicondyle
- Lateral epicondyle
- Apex of patella at the level of the knee's centre (or the popliteal fossa, failing this)

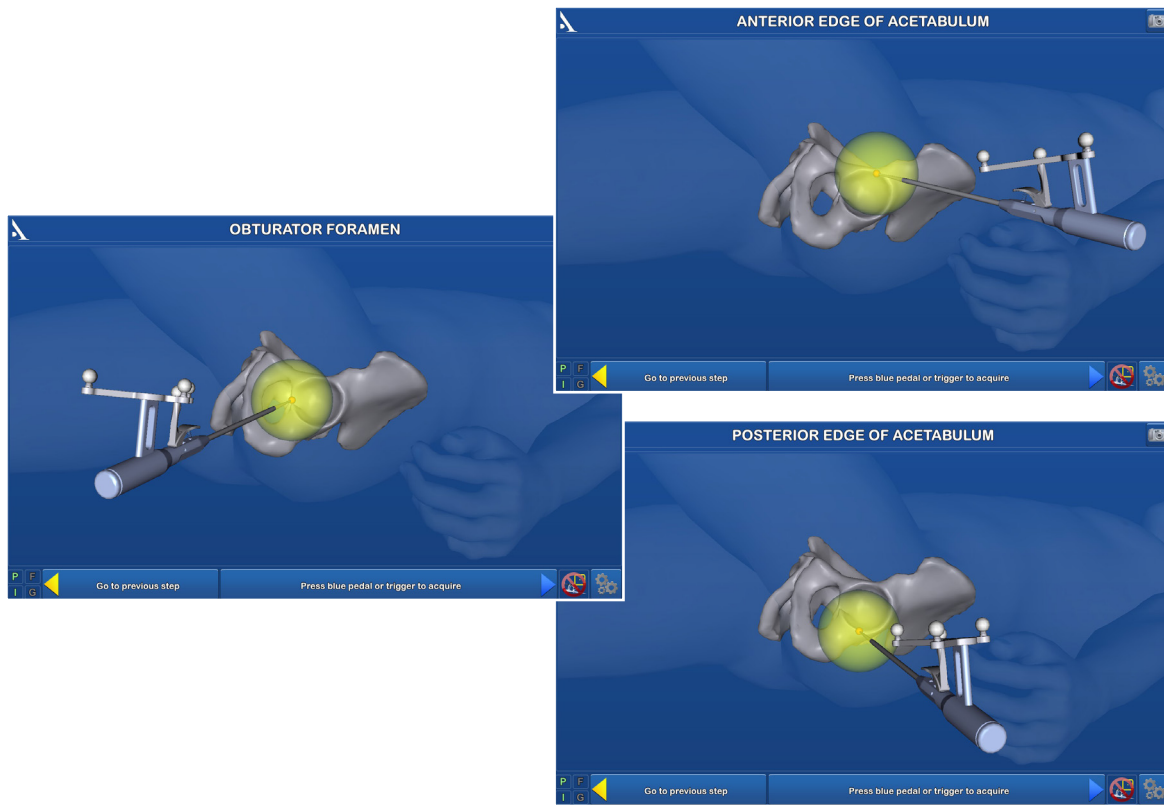
ACQUIRING THE ANKLE CENTRE



Flex the knee 90° and place the probe tip in the centre of the ankle at a point that is both in the tibial axis and between the malleoli.

The knee must be flexed to 90° because the sagittal femoral plane will be calculated using this ankle point.

ACQUIRING THE ACETABULUM



Remove any peripheral osteophytes, then acquire the following points using the probe:

- Apex of the obturator foramen
- Anterior edge of acetabulum
- Posterior edge of acetabulum (diametrically opposed to previous point)
- Surface of the quadrilateral plate in axis of acetabulum.

The last point serves as a depth reference when reaming the acetabulum during navigation.



IMPLANT NAVIGATION

ACETABULUM MENU



This screen is used to:

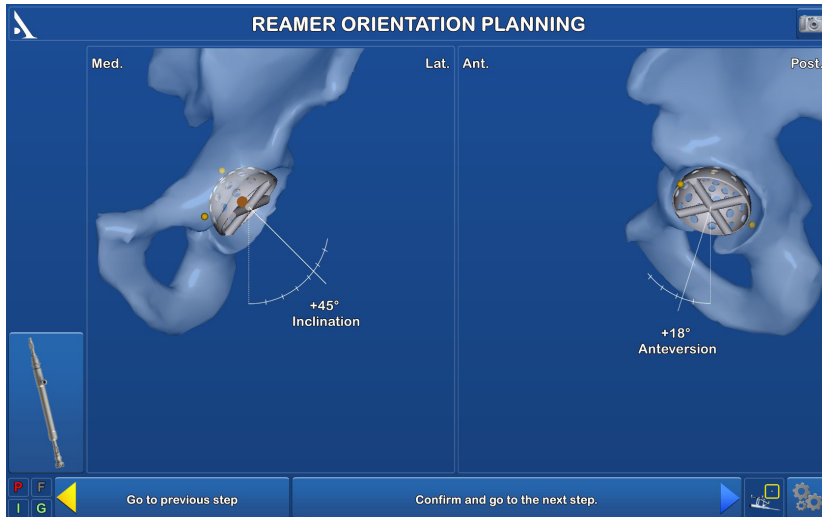
- re-acquire the patient's anatomy
- access the reamer navigation screen
- access the acetabular cup navigation screen.

A short tap of the blue pedal will bring the surgeon directly to the reamer navigation screen.

A long press of the blue pedal will bring the surgeon directly to the acetabular cup navigation screen.

Return to this screen at any time by pressing the "Acetabulum Menu" button in the "Options" menu (see Options menu details in Appendix D).

REAMING PLANNING



Place the G array on the chosen reamer holder and assemble the reamer.

Position the reamer in the acetabulum and orient the instrument to achieve maximum bone coverage.

The orientation is shown on the screen.

Confirm the orientation by pressing the blue pedal.

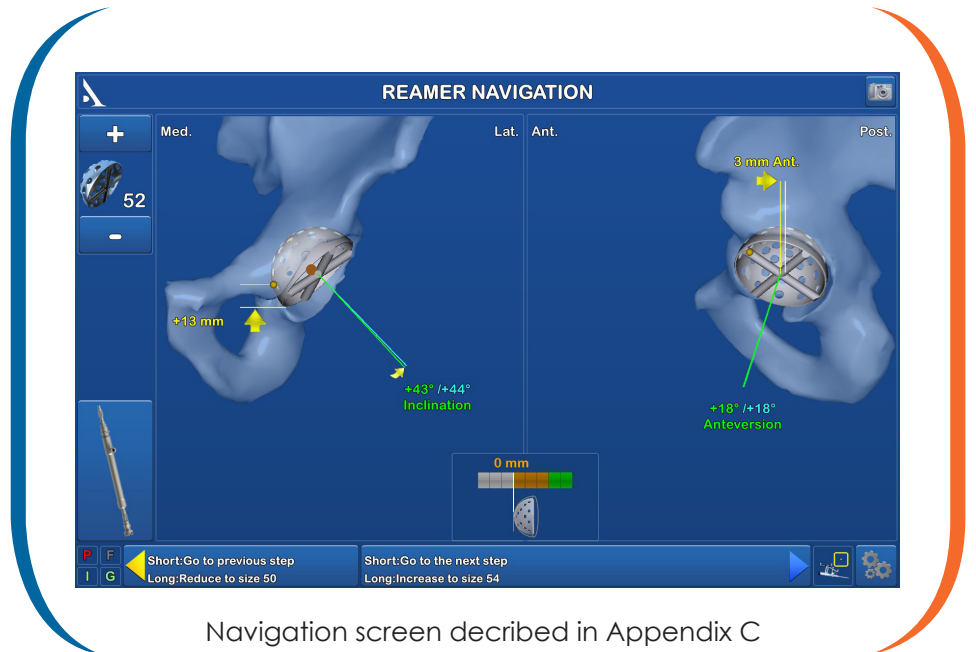
This step sets the orientation goal for the following navigation screen.

REAMER NAVIGATION

Start reaming with the smallest available reamer.

Set the reamer diameter on the screen:

- By using the probe or touch screen, press the "+" button to select a larger reamer and the "-" button to select a smaller reamer.
- By a long press of the pedals – blue pedal for larger diameter, yellow pedal for smaller diameter (until there is an audible beep).



Navigation screen described in Appendix C

Make sure to change the reamer diameter on the screen when a new reamer is used.

The reamer holder's current orientation is shown in yellow on the screen while the orientation chosen in the previous step is shown in blue. The orientation value turns green when the current orientation matches the planned value.

Once reaming is completed, confirm the reamer holder's final position by pressing on the blue pedal.

If navigation is used with only one reamer (e.g. the last one), make sure the diameter shown on the screen is the same as the diameter of the reamer before confirming this step.

IMPORTANT

The type of reamer holder being used can also be changed on this screen. As shown below, the curved reamer holder (metal or carbon) can be selected by pressing the reamer holder selection button in the lower left corner of the screen.

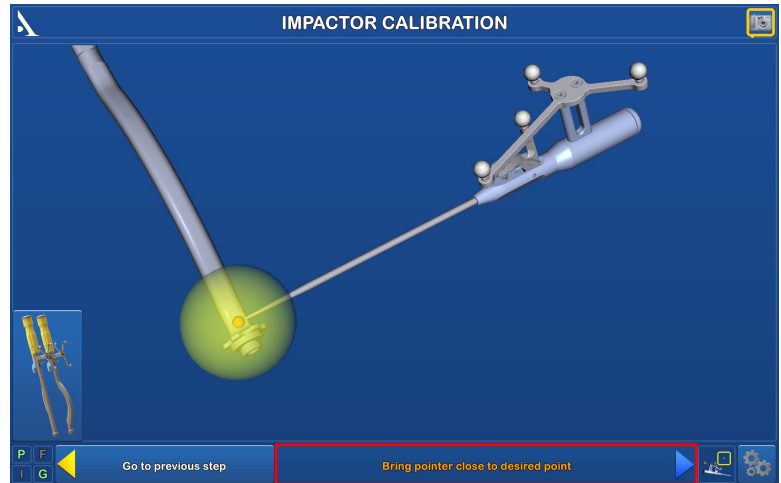


IMPACTOR CALIBRATION

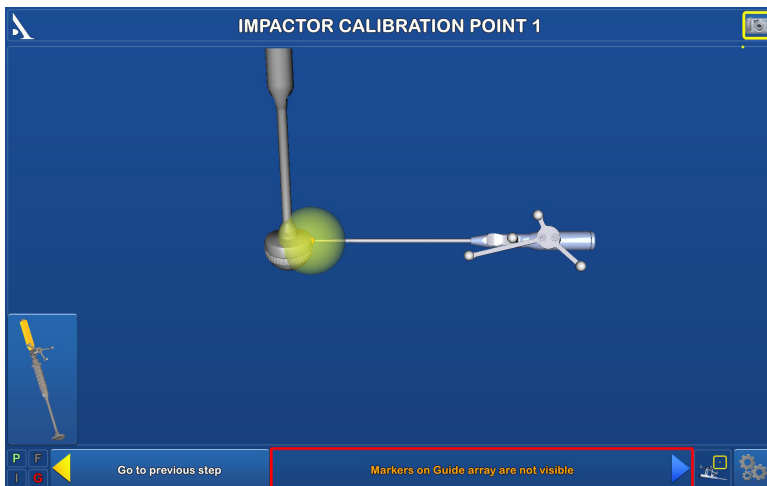
Depending on the cup being used, the impactor may need to be calibrated.
Place the G array on the chosen impactor.

RATCHET IMPACTOR

To acquire the position of the cup impactor, place the probe tip in the conical calibration mark on the tip of the straight or curved impactor.



VACUUM CUP INSERTER



To acquire the position of the vacuum cup inserter, place the probe tip in the conical calibration mark on the inserter's tip, following the instructions on the screen.

The calibration is used to estimate the size of the chosen cup.



IMPORTANT

The type of impactor can be changed during this step by pressing the button in the lower left corner of the screen. The new impactor will need to be calibrated before it is used.

Only the impactors described above need to be calibrated. **The EQUATEUR[®] and HORIZON[®] II with holes impactors do not need to be calibrated.**

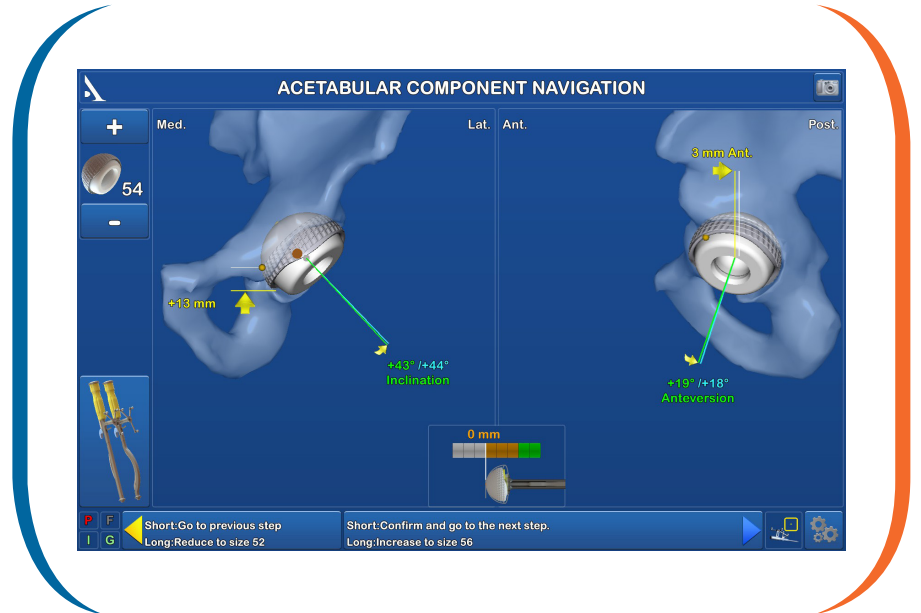


The buttons on the left side of the screen can be used to switch between modes.

ACETABULAR CUP NAVIGATION

Hold the cup as described in the surgical technique documents specific to the implant and type of impactor being used.

Position the impactor in the acetabulum based on the desired inclination and anteversion values.



If navigation was used during reaming, the software displays the cup diameter that corresponds to that of the navigated reamer. If navigation was not used during reaming, make sure the correct diameter is shown on the screen, because the software defaults to the smallest size.

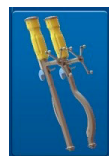
Impact the chosen cup while keeping track of the distance between the inferior edge of the cup and the obturator foramen, and the distance between the centre of the cup and the centre of the acetabulum.

Confirm its position.

For the SATURNE[®] cup, finish impacting it using the dual mobility cup final impactor.

Remove the impactor in a manner suited to the model used:

- lift the blue button for ratchet impactors



- unscrew the vacuum cup inserter or the straight and offset impactors



IMPORTANT

The type of impactor can be changed during this step by pressing the button in the lower left corner of the screen. The new impactor may need to be calibrated before it is used, depending on the model.

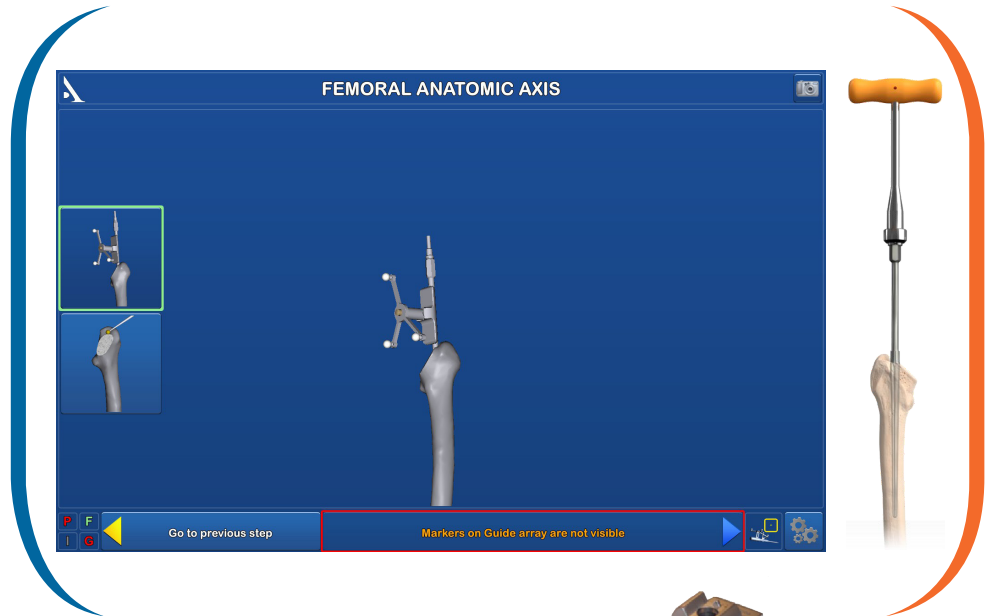
To use a different cup, press the button that corresponds to the cup being navigated. Depending on which cup is chosen, the software may ask you to recalibrate the impactor.

ACQUIRING THE FEMUR'S ANATOMICAL AXIS

METHOD 1: USING THE REAMER

Assemble the box chisel onto the broach handle to start preparing the metaphysis according to the preoperative plan. This step is important to avoid varus positioning of the stem.

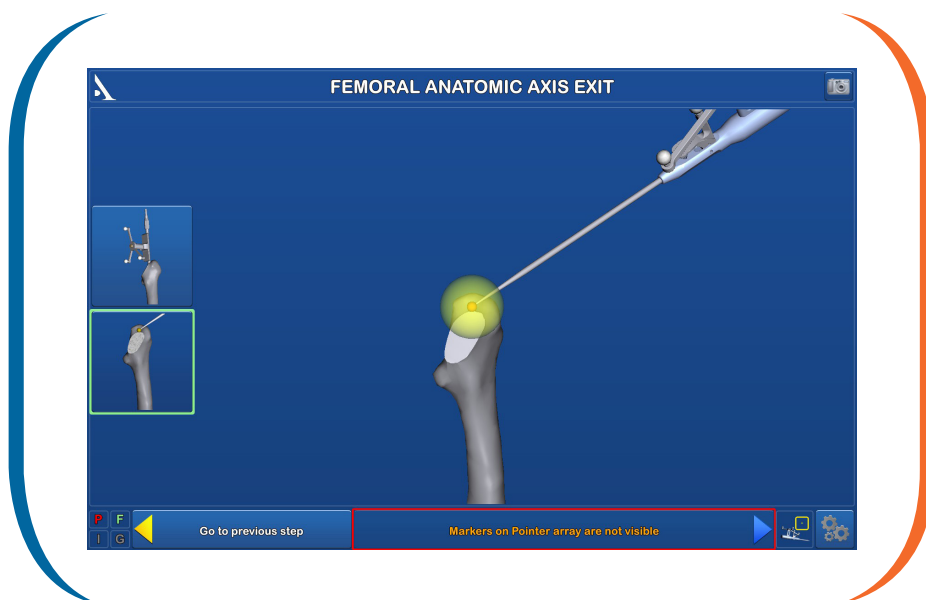
Assemble the 12 x 10 reamer with the reamer holder and push them down into the medullary canal to prepare it for broaching.



Place the G array on the reamer support to acquire the reamer's alignment.

Place the support's "V" on the shaft of the reamer (on the round cross-section, not the handle) and confirm its position.

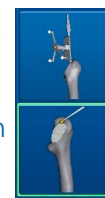
METHOD 2: USING THE EXIT OF THE MEDULLARY CANAL



Acquire a single point on the cortex of the femoral neck cut that represents the exit of the medullary canal, making sure that its position in the frontal and sagittal planes is correct.

NOTE

The method used to acquire the femoral anatomical axis can be changed using the button on the left side of the screen.



ACQUIRING THE GREATER TROCHANTER (OPTIONAL)

Set the probe tip on the greater trochanter and press the trigger to acquire this point.

This is needed to define the height of the prosthetic femoral head centre, relative to this bone landmark on the screen in the broach navigation and femoral stem navigation steps.

This step is optional.



FEMUR MENU

This screen is used to:

- Re-acquire anatomical data
- Access the broach navigation
- Access the femoral stem navigation.

The surgeon can skip the broach navigation step and go directly to the femoral stem navigation.



A short tap of the blue pedal will bring the surgeon directly to the broach navigation screen.

A long press of the blue pedal will bring the surgeon directly to the femoral stem navigation screen.

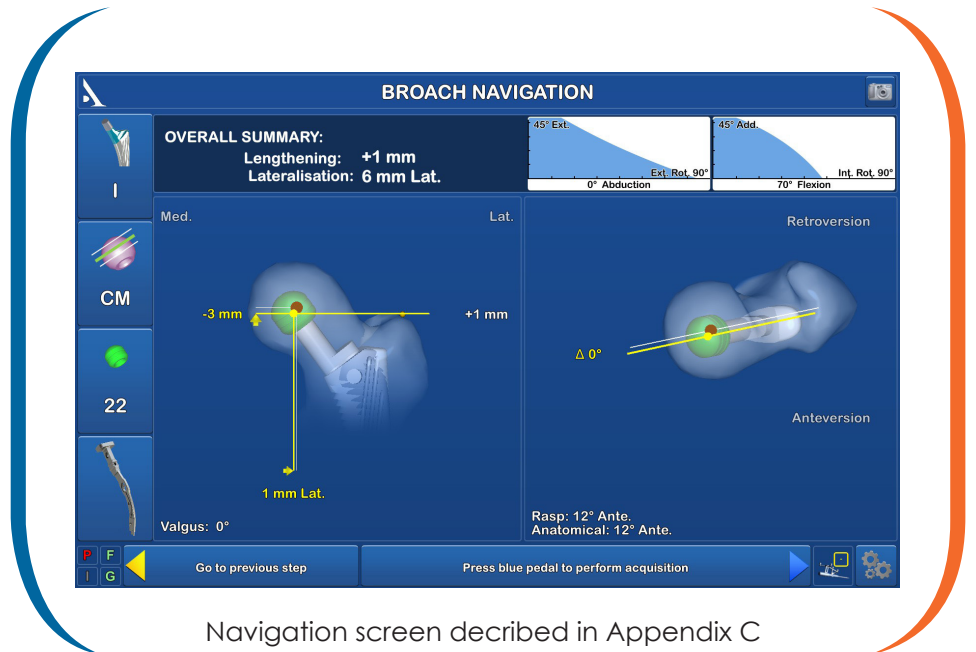
Return to this screen at any time by pressing the "Femur Menu" button in the "Options" menu (see details in Appendix).

BROACH NAVIGATION

Assemble the size 1 femoral broach with the broach handle (model chosen at start of procedure) then place the G array on the handle.

As you push the broach into the femoral shaft **check the position** of the replacement joint centre on the screen (relative to patient's anatomy):

- height
- medialisation or lateralisation
- anteversion or retroversion.



Navigation screen described in Appendix C

The values shown are based on the type of stem/neck chosen and the femoral head's diameter and length displayed on the screen.

When the optimal broach size has been reached, leave the broach (and the broach handle) in the femur and adjust the extramedullary portion.

The summary shows the overall leg lengthening and lateralisation / medialisation, meaning that both the position of the cup **AND** the femur are taken into account.

The **two stability curves** show the positions where prosthetic impingement may occur. There are two curves. In the left one, adduction is fixed at 0° to represent standing and in the right one, flexion is fixed at 70° to represent sitting. In the left curve, the combinations of extension and external rotation that will not cause impingement are shown in blue. In the right curve, the combinations of adduction and internal rotation that will not cause impingement are shown in blue. These curves take the following information into account:

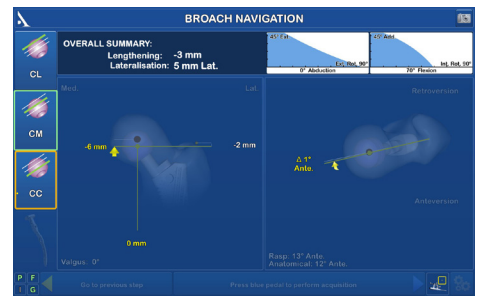
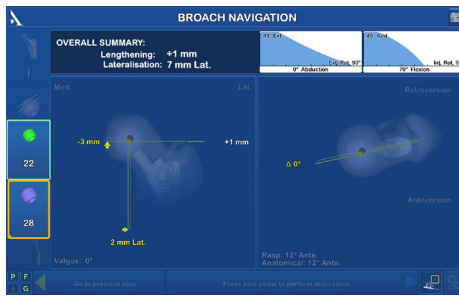
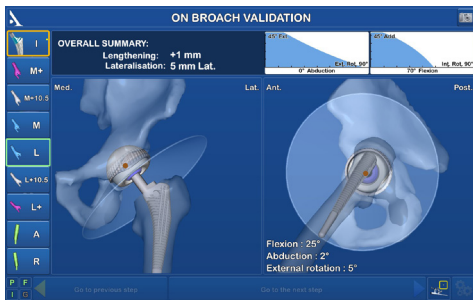
- orientation and position of acetabular cup (or reamer)
- orientation and position of stem (or broach)
- neck length
- neck type.

The postoperative range of motion is represented by these two curves. The expanse of the blue area is updated in real time based on the position of the broach and the type of neck chosen; these are relative to the acetabular cup.

The goal is to select implant parameters that result in the largest possible blue area in both curves **along with the best overall configuration.**

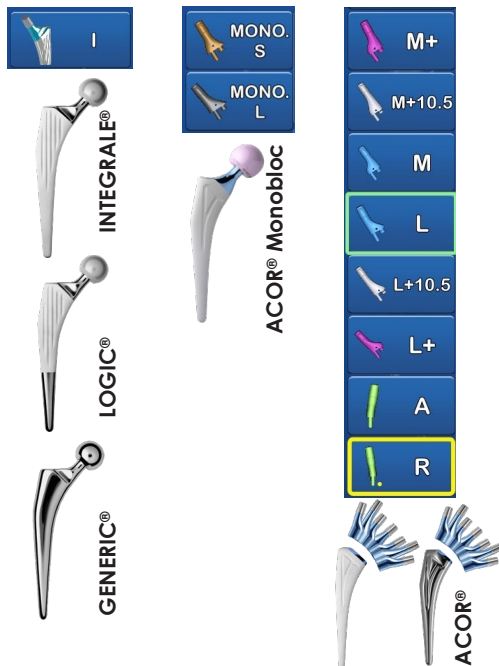
BROACH NAVIGATION (CONTINUED)

To modify the simulated joint centre position, use the probe to alter the parameters on the left side of the screen. When one parameter is selected, the background darkens and the various available settings will appear. When one of the options is highlighted, the stability curves and summary are updated in real time. The following parameters can be adjusted:



Stem neck

Choose between neck for monoblock stem and various modular necks.



Femoral head diameter

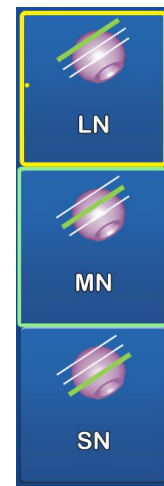
Select desired diameter from those available for the current cup.



Head length

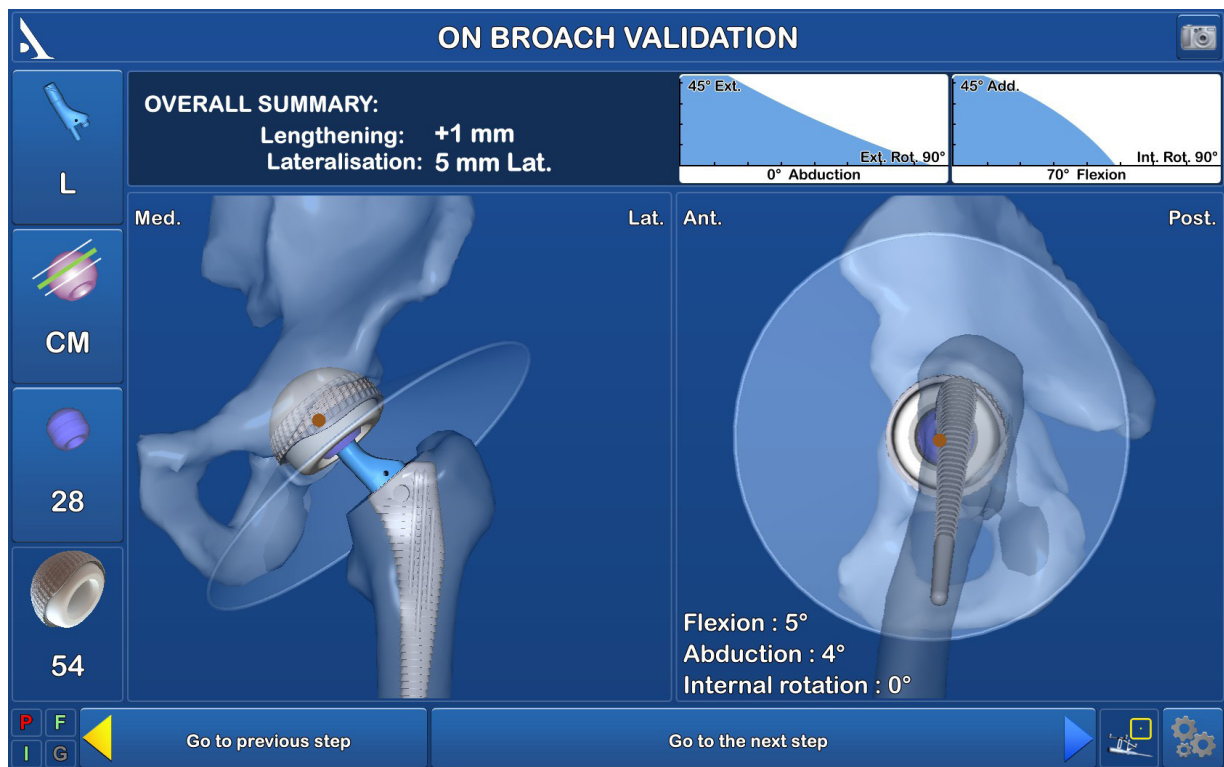
Select short (S), medium (M) or long (L) depending on the femoral head diameter selected.

Attention: see limitations on modular neck combinations in the following pages.



Once the desired joint rotation centre position has been achieved, confirm the broach's position by pressing the blue pedal, then detach the broach handle, but leave the broach in the femur.

VALIDATION WITH TRIAL IMPLANTS



Navigation screen described in Appendix C

Insert the trial liner, the trial neck, and the trial head of the diameter and length chosen during the broach navigation step; the selections are shown on the left side of the screen.

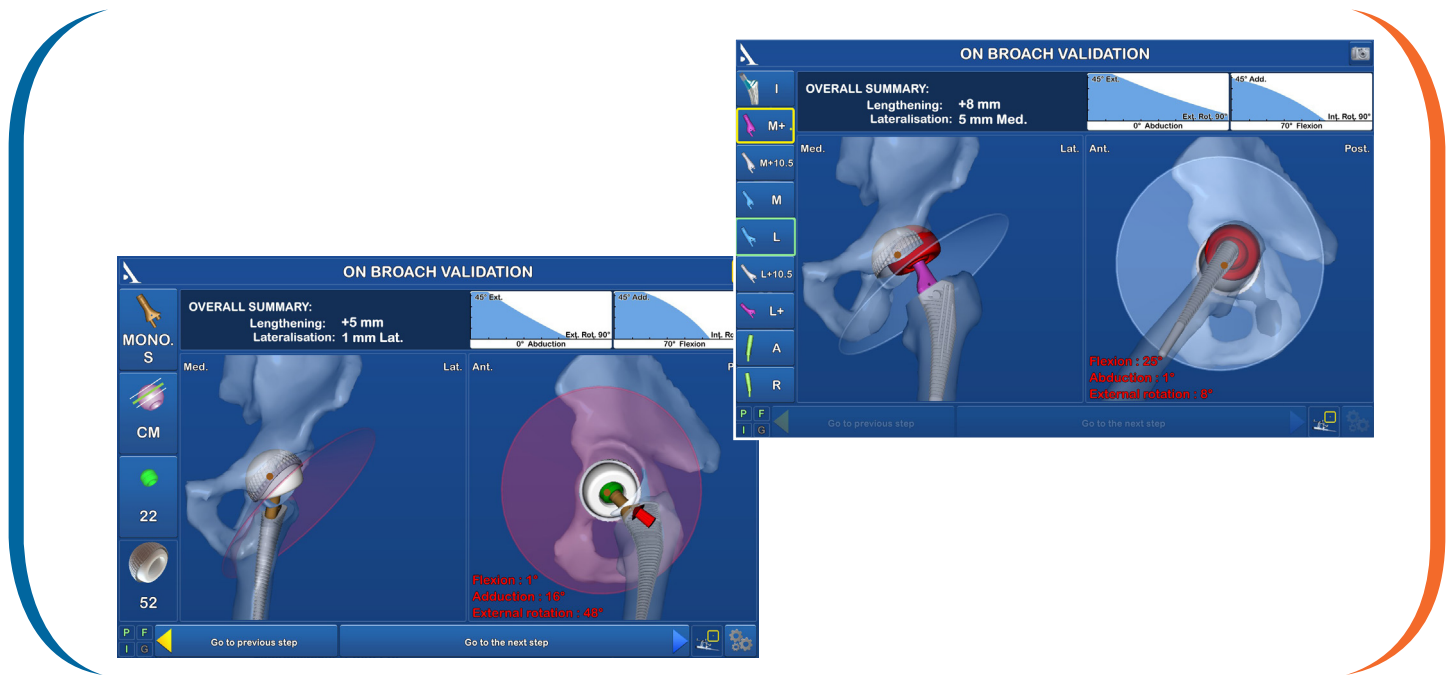
Reduce the joint using the head impactor mounted on the universal handle.

Test the range of motion and joint stability, and then check the length to validate the extramedullary settings.

Keep track of the following parameters on the screen:

- diameter and length of the femoral head
- position of leg during extension, abduction and external rotation
- diameter of acetabular cup
- overall joint data: lengthening or shortening of leg; medialisation or lateralisation of hip centre.

VALIDATION WITH TRIAL IMPLANTS (CONTINUED)



If needed, use a different trial neck or change the diameter and/or length of the trial femoral head. Make sure these changes are reflected in the parameters on the screen.

Repeat the trials until the trial head and neck combination providing the best stability and range of motion are found.

The range of motion cone becomes red if the leg position causes implant impingement. A red arrow indicates the location of the impingement. The system will beep and the numbers describing the impinged leg position will become red. The values remain frozen in the impinged position to make it easier to determine the problematic value on the screen.

If dislocation occurs, the red-coloured head will be outside the acetabular cup. The system will beep and the numbers describing the disassembled position will become red.

For stems with a modular neck, please consult the following table for acceptable neck/head combinations:

		Femoral heads			
		Short neck	Medium neck	Long neck	Extra long neck
L/M neck	Lateralised and medialised versions	✓	✓	✓	✗
Ante/retro neck	Anteverted and retroverted versions	✓	✓	✓	✓
L/M+ neck	Lateralised version	Maximum patient weight 90kg	Maximum patient weight 90kg	Maximum patient weight 90kg	✗
	Medialised version	✓	✓	✓	✗
L/M+10.5 neck	Lateralised and medialised versions	Maximum patient weight 90kg	Maximum patient weight 90kg	✗	✗

STEM IMPACTION

Once all the parameters have been validated, confirm this step and extract the broach from the femur using the broach handle, along with the trial liner. Keep the chosen broach, trial neck and trial femoral head on the table to serve as a reference for the final implanted components.



With a monoblock stem:

Select the G array femoral stem support that matches the patient's position (supine or lateral decubitus) and operated side, and then clip the support onto the taper of the chosen femoral stem. You must hear a "click".

Assemble the G array with the selected support.

With a modular stem:

Select the G modular femoral stem support that matches the approach used and operated side, and screw it into the hole in the stem using the round tip mounted on the universal handle.

Assemble the G array with the G modular stem support.

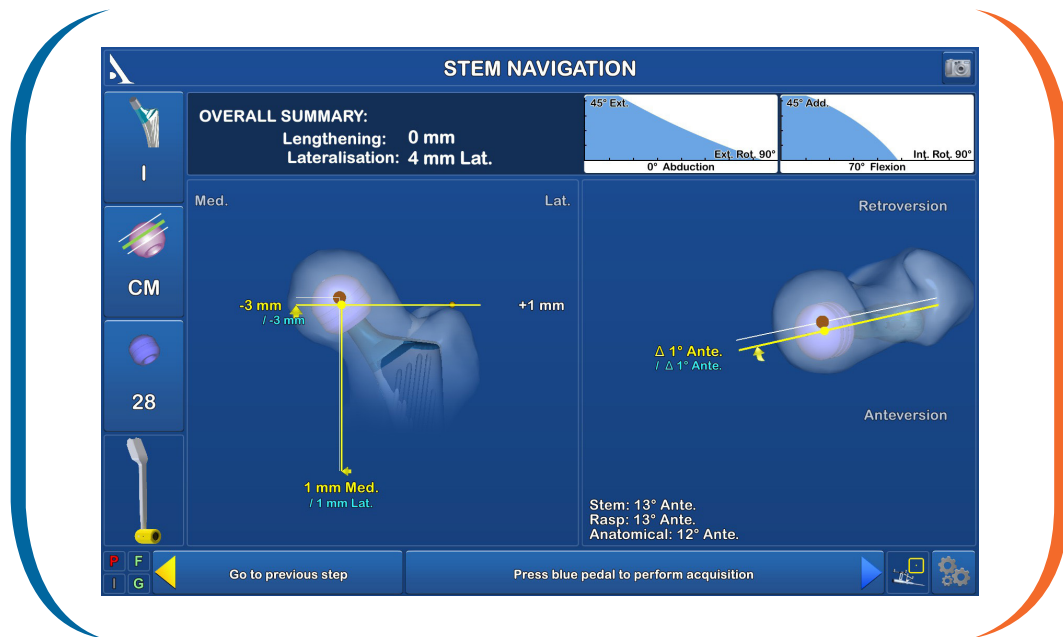
Place the stem corresponding to the size selected during the trials into the femur. Do not touch the head impaction area.

Insert the stem impactor in the impaction hole on top of the stem being implanted.

Impact the stem until the HA limit corresponding to the appropriate depth is reached.

For a modular stem, impact the modular neck using the head-neck impactor mounted on the universal handle. The impactor has a cavity where the proximal part of the modular neck is inserted. Three hard taps with a 300 g hammer are recommended for the impaction.

STEM NAVIGATION



Keep track of the progress of the femoral stem insertion on the screen. It is shown relative to the centre of the native femoral head (red point):

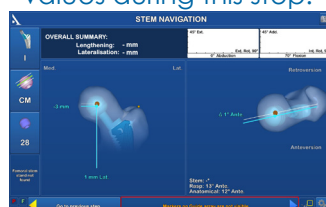
- The height value shown in yellow is the distance between the centre of the native femoral head and the centre of the prosthetic femoral head on the implanted stem. The blue numbers below it are those obtained during broach validation.
- The lateralisation/medialisation value shown in yellow is the distance between the centre of the native femoral head and the centre of the prosthetic femoral head on the implanted stem. The blue number below it is the distance between the centre of the native femoral head and the centre of the prosthetic femoral head on the broach.
- The anteversion of the native femoral head on the broach and the implanted stem are shown on the right side of the screen. This is the difference between the anteversion of the head centre on the stem and the native head centre.

Review the overall navigation data at the top of the screen and change the available parameters as needed. Once all the parameters have been validated, confirm the step and remove the array from the stem.

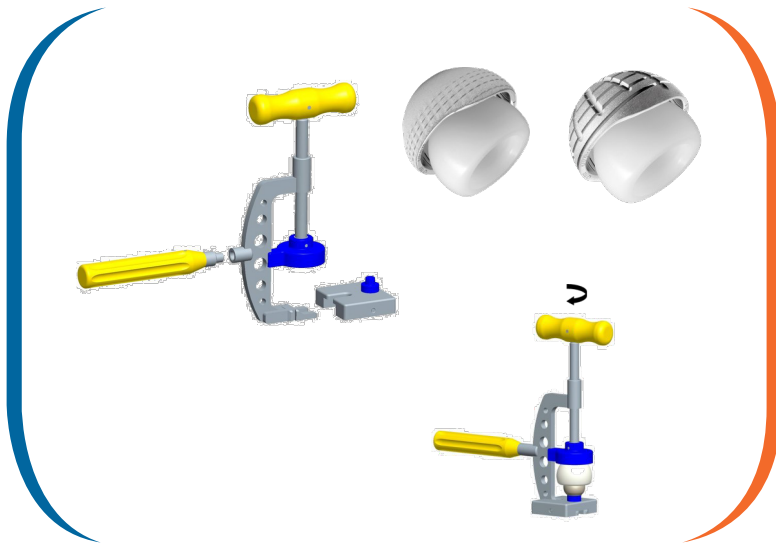
IMPORTANT

If the broach navigation step was not performed, the chosen femoral stem will be positioned relative to the femoral anatomical axis and the centre of the patient's original femoral head.

The saved broach will be displayed in blue on the screen until the software detects the presence of the stem. The values shown in blue are those saved when the broach was validated. They will be compared with the stem's values during this step.



INSERTING THE CHOSEN IMPLANTS



Secure the handle and the baseplate in the dual mobility cup press.

Place the chosen femoral head on the baseplate.

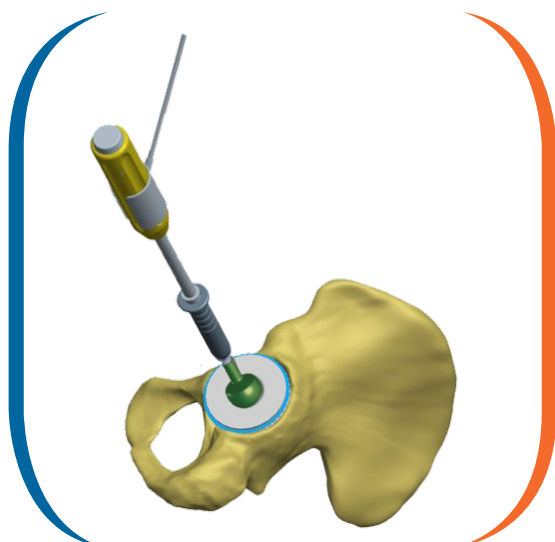
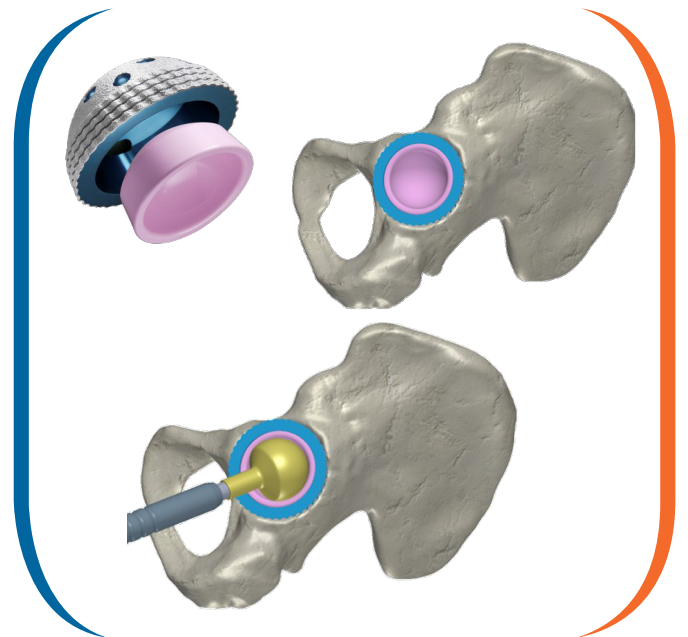
Place the liner on the head and turn the T-handle on the press until the liner's retaining mechanism has been cleared. Once beyond the retaining threshold, turn the T-handle one or two more times to eliminate any air caught between the head and liner.

Make sure the head can move within the liner.

After cleaning and drying out the implanted cup, slide the chosen BIOLOX[®] delta ceramic liner along the cup's Morse taper.

Check the liner positioning by running your finger along the cup's edge; the combined edges of the metal cup and ceramic liner must be completely flat.

Place the cup impactor tip (blue for liner with 28 mm head, yellow for liner with 32 mm head and grey for liner with 36 mm head) on the universal handle and impact the liner.



Assemble the liner impactor or impactor for hooded liner with the universal handle.

Place the chosen liner on the liner impactor; hold it in place and screw in the universal handle as far as it will go. Make sure the liner is securely connected to the impactor.

Impact the liner in the cup. Loosen the universal handle before removing the entire instrument from the cup. Finalise the impaction with the final cup impactation tip.

INSTALLING THE FEMORAL HEAD

METAL HEAD

Make sure the taper is clean, dry and undamaged.

Use the head and neck impactor mounted on the universal handle to impact the head.

CERAMIC HEAD

Before attaching a ceramic head to the femoral stem:

- **Carefully rinse** and dry the stem's taper
- Meticulously inspect the stem's taper and the female head taper and remove **any foreign bodies**.

Manually place the head on the stem taper by gently turning it while pushing it along the taper axis until it is firmly seated.

To finalise the fixation of the head onto the neck taper, use the head impactor and give it a slight hammer tap along the axis.

HELPFUL HINT

When implanting a ceramic head with a dual mobility cup, **partially impact** the head into the liner so that it can still turn when inserting it on the stem's taper. The head's impaction in the liner will be finalised when it is impacted on the taper.

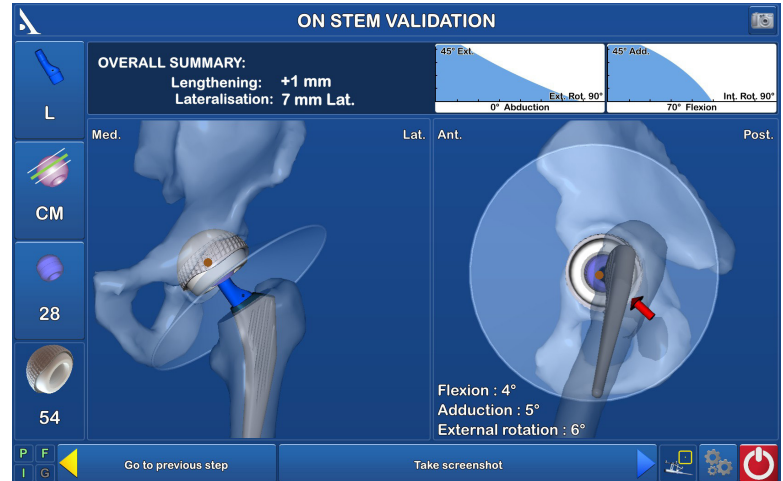
Reduce it using the liner impactor tip and the universal handle, making sure there are no foreign bodies between the head and liner, or between the liner and cup if using a dual mobility cup.

ON-STEM VALIDATION

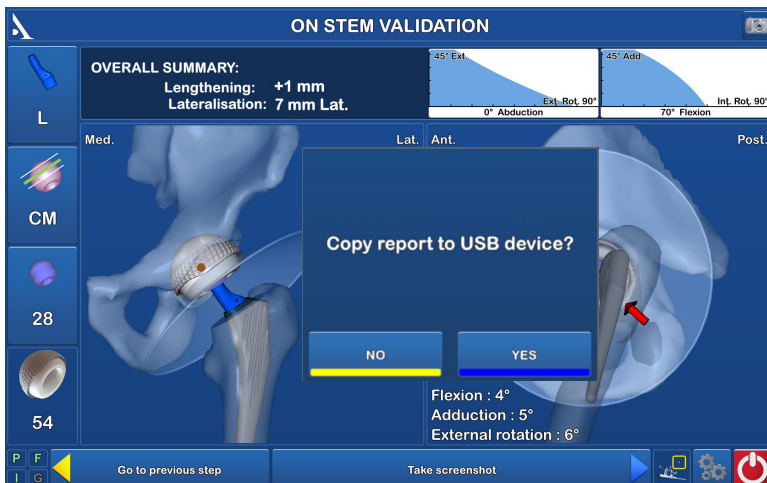
Test the joint's stability and range of motion.

Keep track of the following parameters on the screen:

- head diameter
- position of leg during extension, abduction and external rotation
- diameter of acetabular cup
- overall joint data: lengthening or shortening of leg; medialisation or lateralisation of hip centre.



SAVING THE SURGERY REPORT



Press the  button to exit the application:

- it will be visible immediately after the last step of the "On-stem validation" procedure OR
- it can be found on the "Options" page at any point during the procedure.

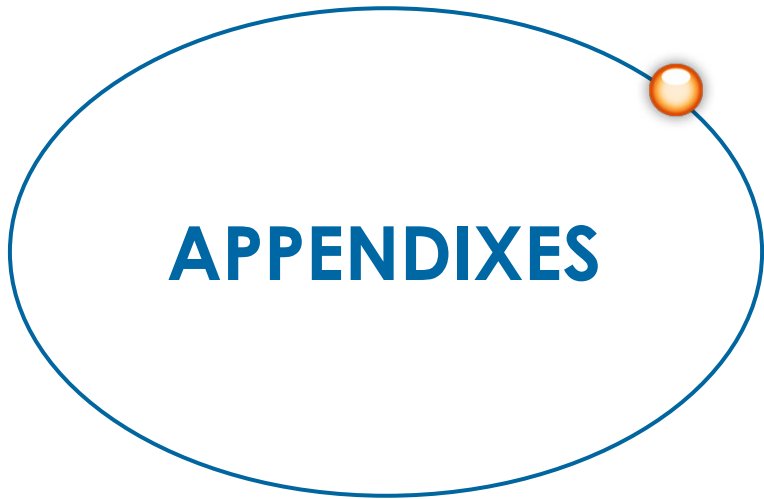
The message "Do you really want to exit?" will appear. Press "Yes" to confirm.

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 near the screen (see V2 and V3 workstation descriptions for slot locations) and confirm that you want to save the report.

If necessary, perform implant removal as described in the surgical technique specific to that implant.



APPENDIXES

UNPACKING THE WORKSTATION



Front

Latch



Storage area for pedal, workstation cover and manual

Shipping trunk for V2 Workstation



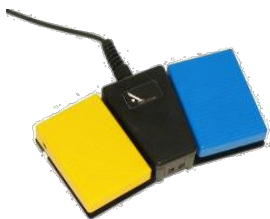
Front

Latch



Storage area for pedal, workstation cover and manual

Shipping trunk for V3 Workstation



Pedals for V2 Workstation



Pedals for V3 Workstation

To unpack the Workstation, unlock the four latches on the shipping trunk. Open the front panel and take out the workstation, pedal and pedal cover.

STORING THE WORKSTATION

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

Confirm that you want to shut down the system. The system will shut down.

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

Disconnect the pedal.

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

Clean the workstation and pedal according to the instructions in the user manual located in the shipping trunk and in the "Options" menu.

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

Put the workstation back into the shipping trunk.

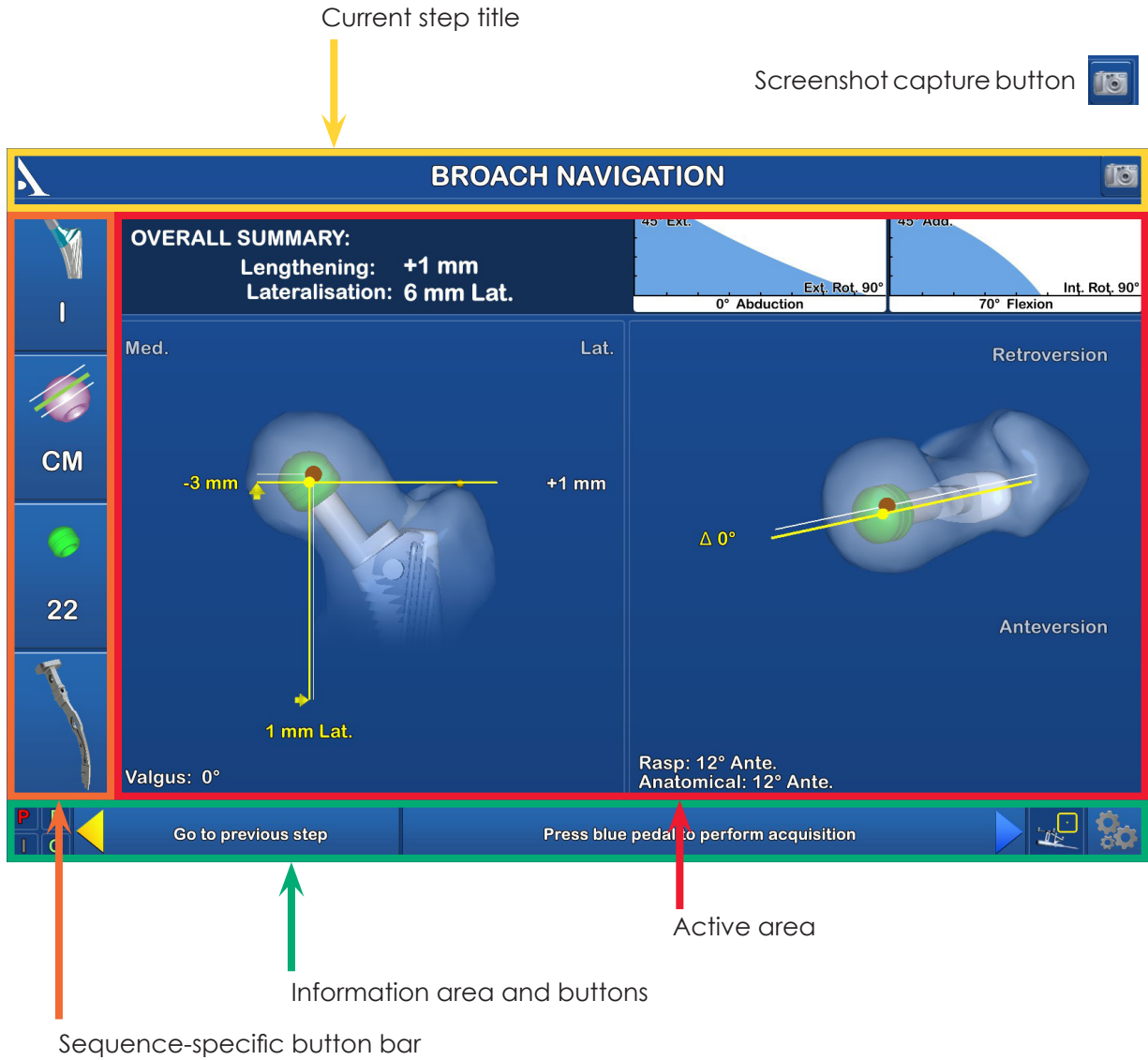
Place the pedal and covers in the shipping trunk.

Lock the four latches on the shipping trunk.

APPENDIX C

SCREEN LAYOUT

GENERAL INTERFACE



Yellow pedal: action carried out when pedal is pressed

Blue pedal: action carried out when blue pedal is pressed

Options Menu



Visibility of each array :

Green : visible

Red : Not visible

Indicates whether probe can be used as a mouse on screen

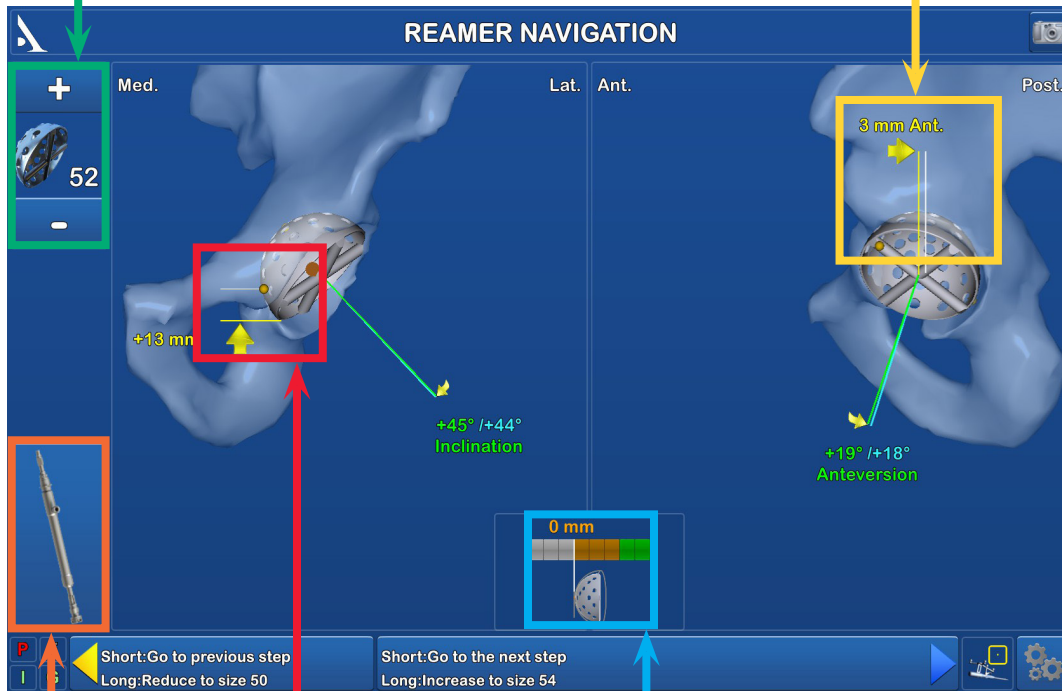
APPENDIX C

SCREEN LAYOUT

REAMER/ACETABULUM NAVIGATION

Buttons used to select reamer diameter

Distance between reamer center and acetabular center in the sagittal plane



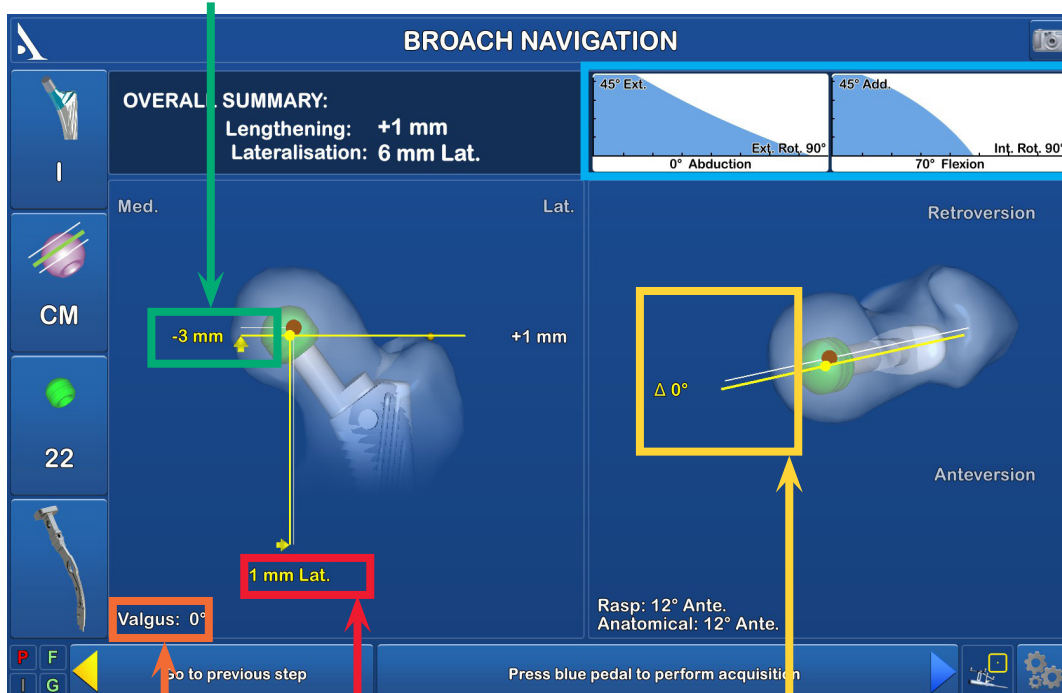
Button used to select reamer handle

Distance between the inferior rim of the reamer and the obturator foramen

Distance between the acquired point in the acetabulum bottom and the reamer

BROACH/STEM NAVIGATION

Lengthening or shortening relative to centre of femoral head



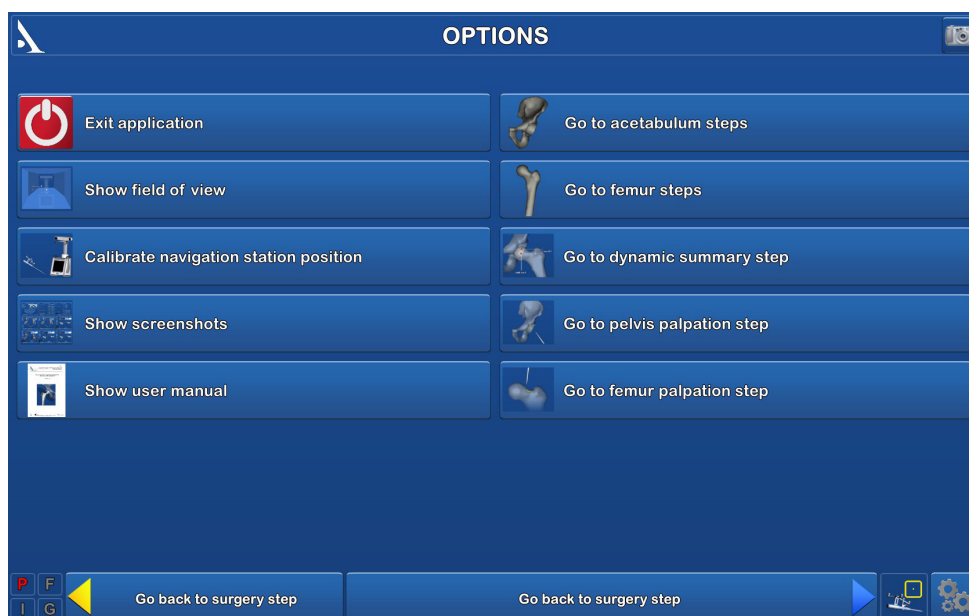
Stability curves

Varus or valgus of broach relative to broach reference

Lateralisation or medialisation of joint centre relative to patient's anatomy

Anteversion or retroversion of broach relative to patient's anatomy

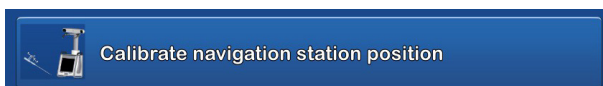
OPTIONS MENU



Used to exit the software. This is also available at the final navigation step.



Show the camera field of view to locate the arrays.



Redefines station position relative to the operator.



Show screenshots of validated steps and those manually snapshotted.



Show the software manual.



Allows to come back to the acetabulum navigation anytime: anatomical acquisition, reamer navigation, acetabulum navigation.



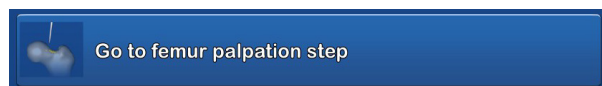
Allows to comeback to femur navigation anytime: anatomical acquisition, broach navigation, stem navigation.



Jump to the dynamic summary step.



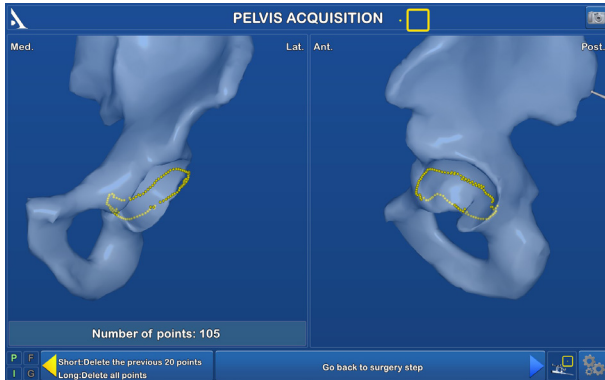
Allows to go to the palpation step of additional points around the pelvis (optional, see Appendix E)



Allows to go to the palpation step of additional points on the femur (optional, see Appendix E)

ACQUISITION OF POINTS BY PALPATION

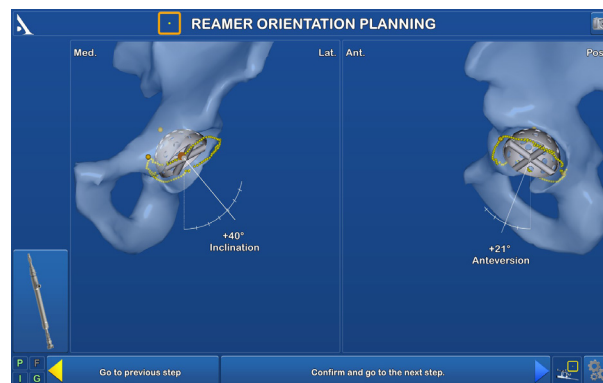
ACQUIRING THE ACETABULAR RIM



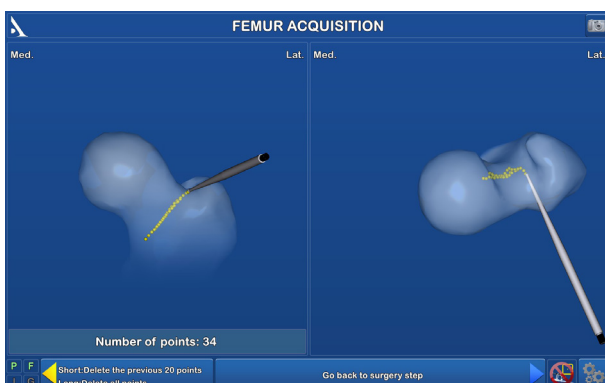
Points around the acetabular rim can be acquired to get a better idea of the cup's position and coverage within the pelvis. These points will be used during reaming and/or when implanting the chosen cup. This screen can be accessed in the "Options" menu.

Use the probe to acquire points around the acetabulum rim. Press the blue pedal when done.

The acquired points will be transferred to the reaming and cup navigation steps and will be used to model bone contours.



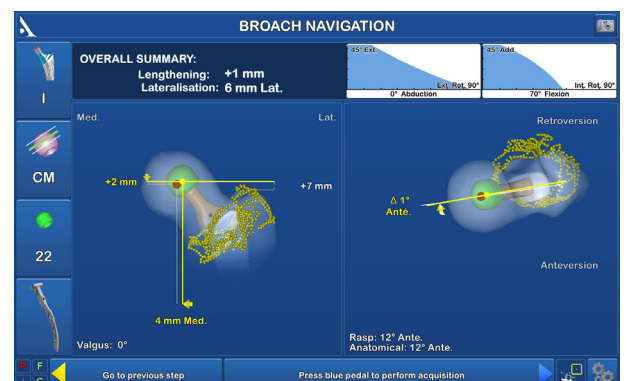
ACQUIRING THE FEMORAL NECK CUT



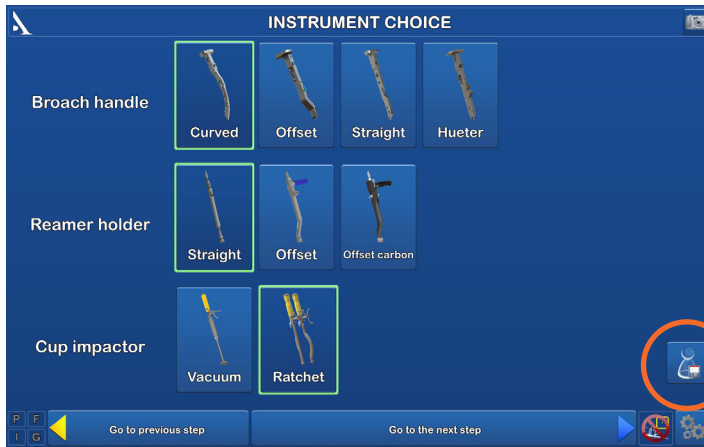
Points on the femur can be acquired to get a better view of the neck cut and to help determine the height of the broach. These points will be used during the broach and/or stem navigation steps. This screen can be accessed in the "Options" menu.

Use the probe to acquire points on the greater trochanter and the femoral neck cut. Press the blue pedal when done.

The acquired points will be transferred to the broach navigation and stem navigation steps and will help to visualise the neck cut.



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
- Pelvis coordinate reference system
- Protocol order
- Method used to acquire hip centre
- Whether greater trochanter was acquired
- Method used to acquire anatomical axis
- Type of broach handle used
- Type of reamer holder used
- Type of cup impactor used (if applicable)

Working with user profiles:

For future surgical procedures with navigation, plug in the USB drive to automatically load the surgeon's name and preferences.

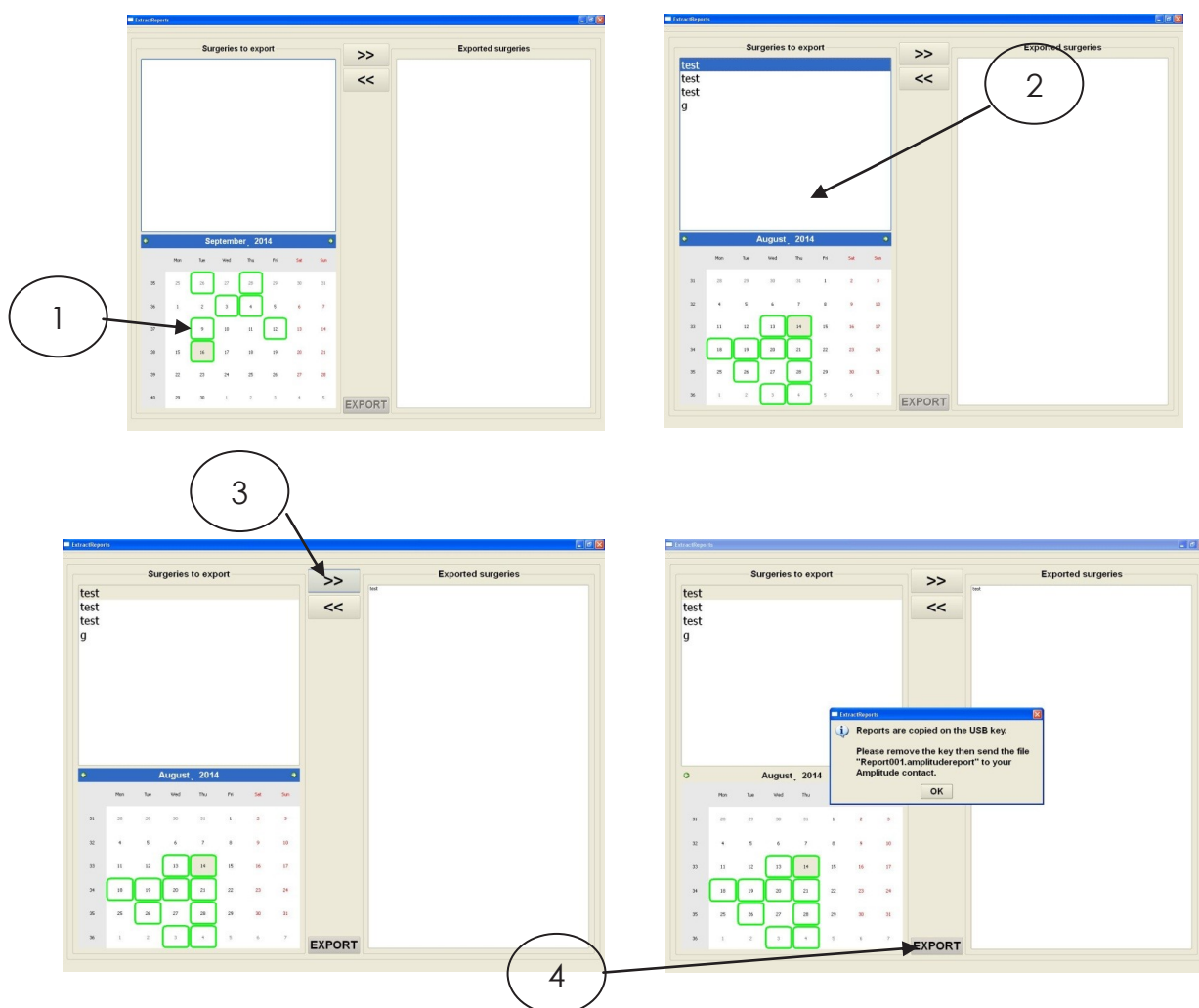
At this point, the software will go from the "Information" page to the "Camera Setup" page and will skip the "Surgery-related options" page.

IMPORTANT

To change a saved parameter, press the button at the lower right corner of the "Information" screen.



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".

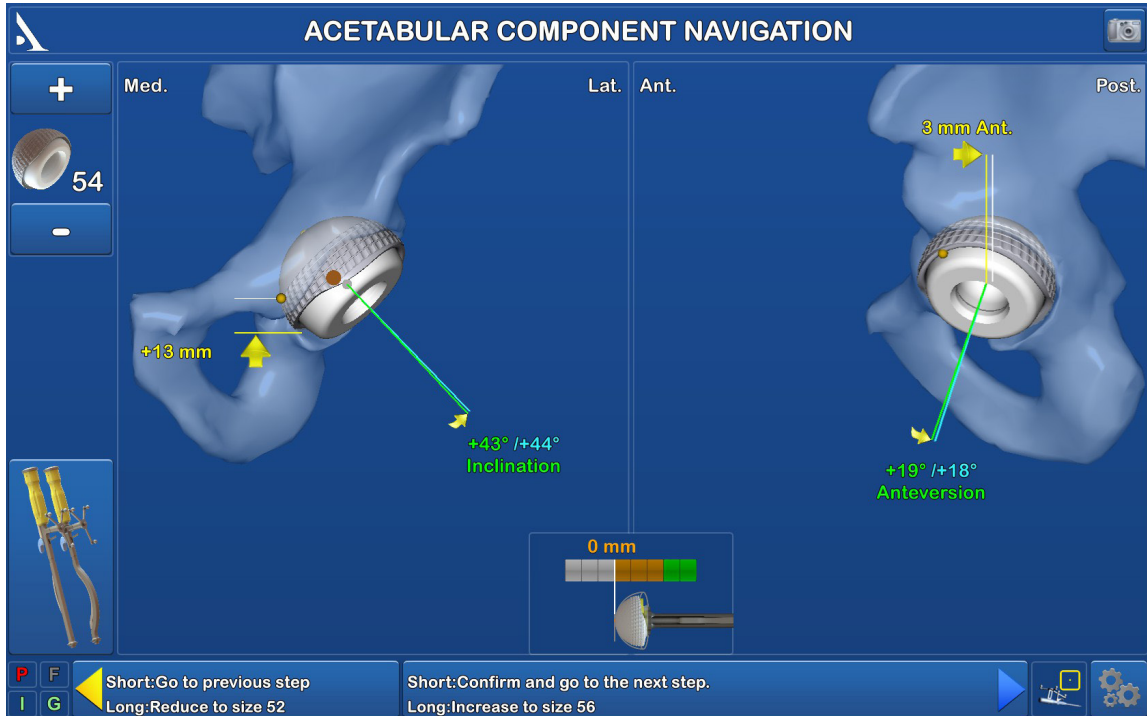
A calendar will appear. The dates on which surgery reports were saved will be highlighted in green. Select the dates corresponding to the procedure(s) (1). For each date, AMPLIVISION® lists available reports in the "Surgeries to export" window (2).

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

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

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

CHANGING THE CUP MODEL



If needed, the type of implant can be changed during the procedure.

Select the image that corresponds to the current implant in the upper-left corner of the screen.

The available cups will be shown on the screen; select the desired cup and confirm.

IMPORTANT

If changing from a HORIZON® II or EQUATEUR® cup to a SATURNE® cup, the software will ask you to calibrate the impactor again.

If the incorrect implant is selected or the impactor is not available, press the yellow pedal while at the impactor calibration screen to get back to the acetabular cup navigation screen.



INSTRUMENTATION

INSTRUMENTATION

INSTRUMENTATION

In addition to the stem and cup instrumentation, the following are required:

- > AMPLIVISION® Navigation Station
- > Sterile, single-use AMPLIVISION® markers (14 per pack) (Product No. 3-0400902)
- > AMPLIVISION® Hip Navigation Instrumentation (Product No. 2-0199945).
If using the INTEGRALE®, LOGIC® or GENERIC® stem, order stem instrumentation (2-0199957) and the accompanying set (2-0199945).

Sterile markers:

The arrays must be equipped with markers to be visible to the camera. These markers are attached through the nipples on the arrays (3 for the F, I and G arrays; 4 for the probe).



Single-use AMPLIVISION® pins:

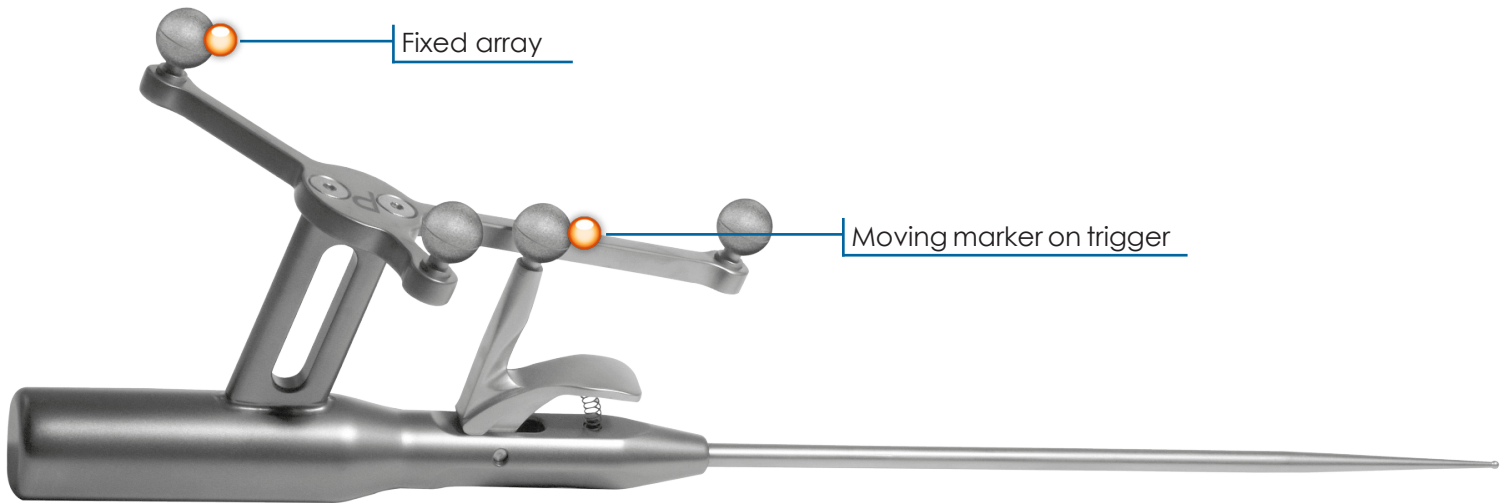
Single-use, Ø4 diameter, 150-mm long conical pins are available in packs of 4 (Product No. 2-0252200). These pins will be inserted into the femur and iliac crest; the array supports will be mounted on the inserted pins.



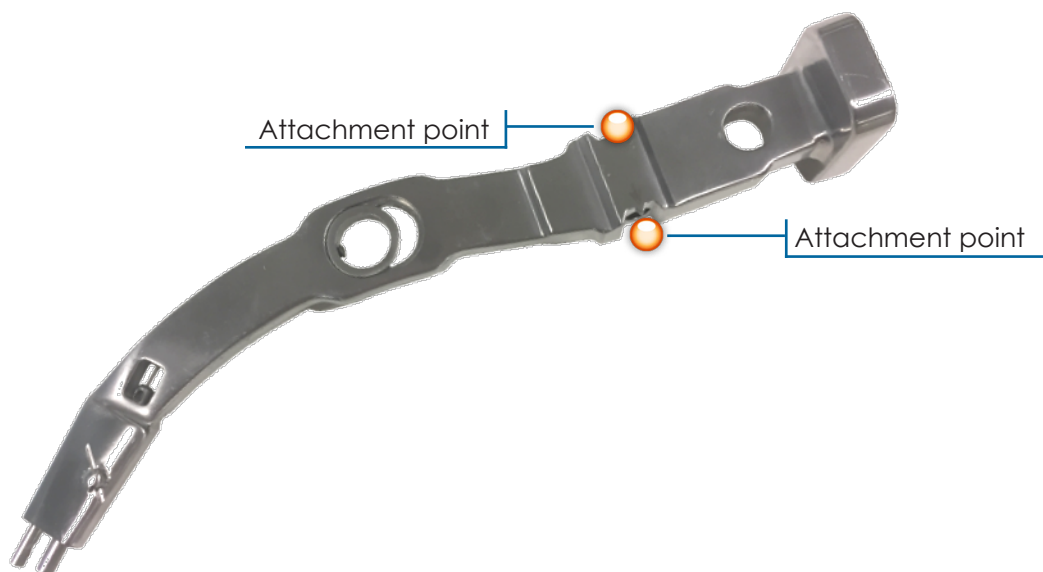
INSTRUMENTATION

OTHER NAVIGATION INSTRUMENTS (NOT IMPLANT SPECIFIC)

> **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.



> **Broach handle for navigation:** Each broach handle for navigation procedures has two attachment points for the G array (one on each side). The array can only be assembled in one direction into each attachment point.



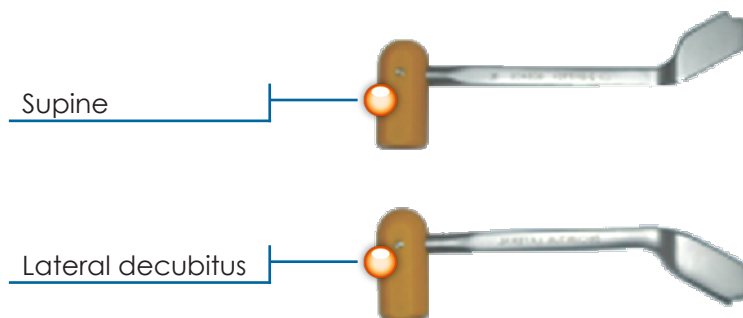
INSTRUMENTATION

OTHER NAVIGATION INSTRUMENTS (NOT IMPLANT SPECIFIC)

> **CR support for measurement of reamer axis:** This instrument is specific to surgical navigation; it is used to acquire the femur's anatomical axis. It is placed on the reamer shaft and must be used with the G array.



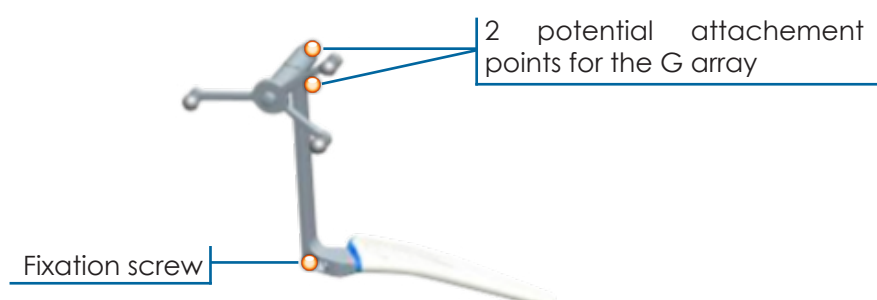
> **G supports for navigation of monoblock stem:** These instruments are used during navigation of the implanted stem. The G support is clipped on the Morse taper of the inserted stem. One version is used when the patient is in lateral decubitus position and the other version is used when the patient is supine. The G array is positioned differently to ensure its visibility.



> **G supports for navigation of modular stem:** There are 2 versions:

- One version when the anterior approach is used to operate on the left leg; this support is also used when the posterior approach is used to operate on a right leg. The instrument has the following markings: Ant. G / Post D.
- One when the anterior approach is used to operate on the right leg; it is also used when the posterior approach is used to operate on a left leg. The instrument has the following markings: Ant. D / Post. G.

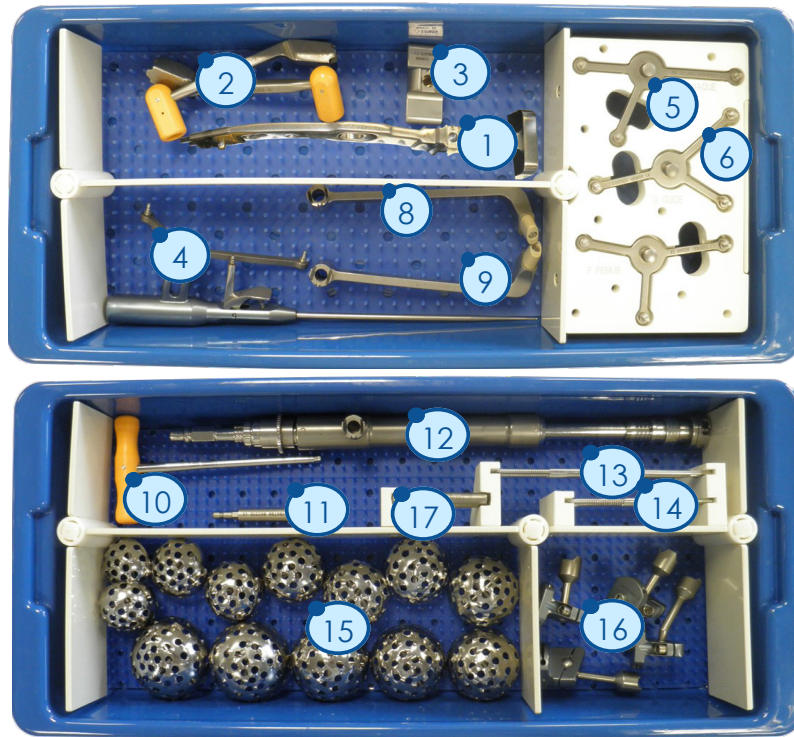
This instrument is used during navigation of the implanted stem. Its oblong-shaped tip is placed in the elongated hole on the implanted stem and screwed using the round tip mounted on the universal handle. The G array can be placed on either side of the support. Choose the side where the array will be most visible to the camera based on which side is being operated on and the surgical approach.



INSTRUMENTATION

HIP NAVIGATION SET

2-0199945



Rep	Description	Reference	Qty
1	Curved broach handle – navigation	2-0117803	1
2	G array support for stem navigation – lateral and <u>supine</u> position	2-0117700 and 2-0117701	1 each
3	CR support – measurement of reamer axis	2-0116600	1
4	Probe for hip navigation	2-0116800	1
5	I array, Iliac crest navigation	2-0117300	1
6	G array, Instrumentation navigation	2-0117500	1
7	F array, femur navigation	2-0117400	1
8	G array support for navigation – modular stem Ant. R. / Post. L.	2-0193401	1
9	G array support for navigation – modular stem Ant. L. / Post. R.	2-0193402	1
10	H5 Screwdriver	2-0200800	1
11	Cup impactor body	2-0190700	1
12	Straight reamer holder – navigation	2-0118000	1
13	Conical Threaded Pins AMPLIVISION Ø4 length 150mm	2-0235500	4
14	Conical Threaded Pins AMPLIVISION Ø4 length 100mm	2-0235900	4
15	Acetabular Reamer D42 to D64	2-0192942 to 2-0192964	1 each
16	Straight and <u>inclined</u> fixation system, navigation geometry	2-0117100 and 2-0117200	2 each
17	Universal quick release adaptor for pin	2-0201100	1
17	AO quick release adaptor for pin	2-0201200	1

NOTES

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