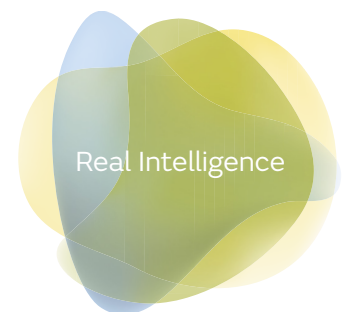


Surgical Technique
Tibia First



Purpose

This Surgical Technique is based on the RI.KNEE NAVIGATION software. It documents how RI.KNEE NAVIGATION may be used in a clinical setting, but it is not meant as a replacement to the Brainlab KNEE3 Software User Guide. For questions regarding recommended use of Brainlab equipment and/or software, always refer to the RI.KNEE NAVIGATION Software User Guide as your first level of product support. The training provided to the customer is based on the product-specific training requirements. Users must be trained and qualified to operate the RI.KNEE NAVIGATION. Contact Smith+Nephew if new users require training.

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Camera Placement

The ideal position for the camera is at a distance of about 1.0m to 1.5m on the opposite side of the surgeon's position on the table, approximately between 90° and 45° towards the foot of the patient. The camera is equipped with a laser pointer. Point the laser at the center of the knee joint when the knee is in flexion for best positioning.

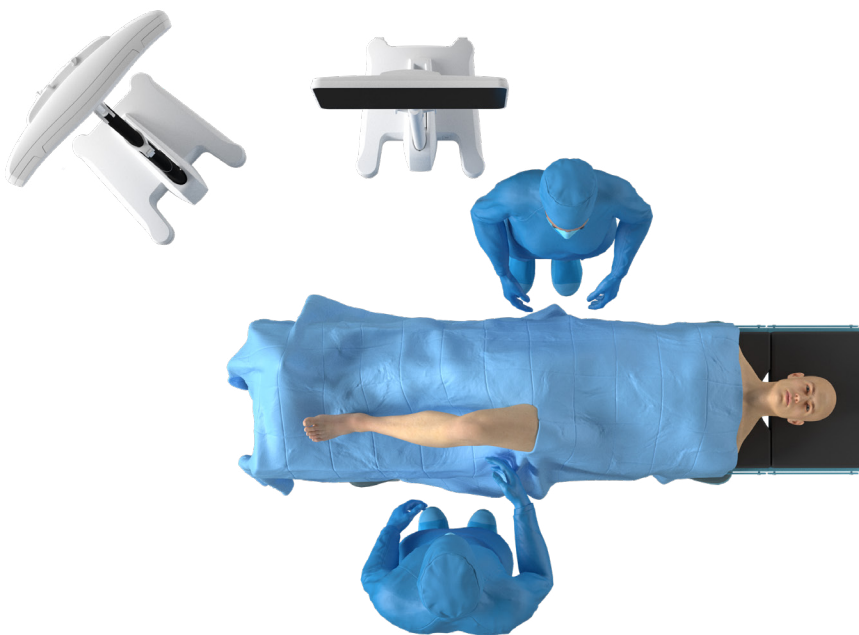
The camera should be switched on for several minutes prior to use, as the infrared source needs some time to reach maximum efficiency. Any light sources or highly reflective objects should not be within the camera's field of view, as reflections can interfere with the procedure.

Screen Placement

A good position for the display is on the opposite side of the surgeon's position next to the camera.

User interaction with the touchscreen is reduced to a minimum through an adaptive workflow. Nevertheless, sometimes it may be necessary to make inputs on the screen (e.g. to adjust implant size). The sterile monitor drape can optimize operating the navigation system.

Art. no. 18071-50A Disposable Sterile Monitor Drapes 40 pcs



Software Start & Patient Selection

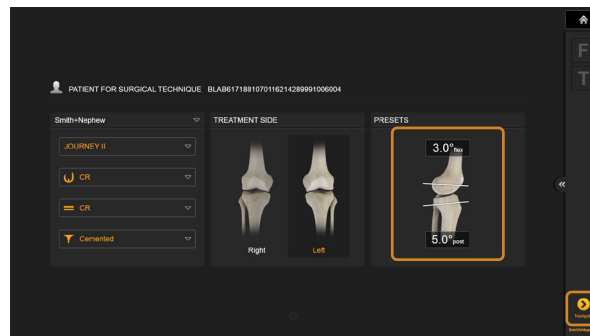
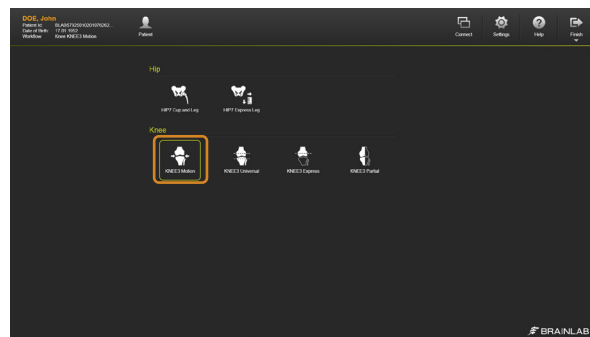
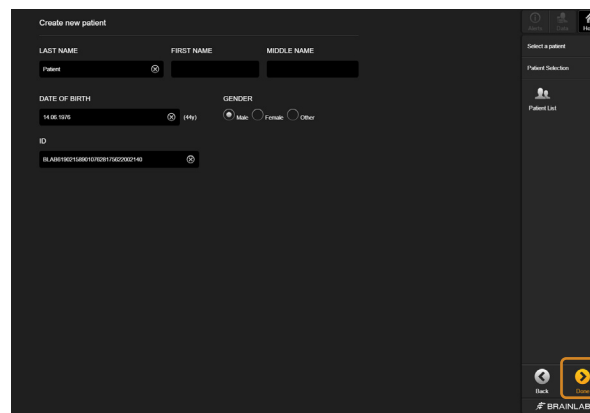
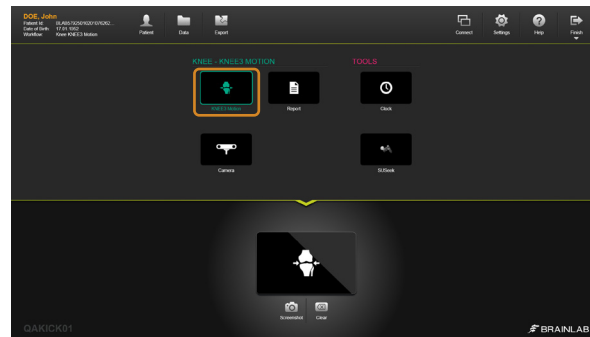
Switch on the navigation system. Enter the patient name and ID in the patient selection screen or select a patient from the patient list and press “Select” to proceed. To start the knee application, press the “KNEE3 Motion” icon.

In the RI.KNEE NAVIGATION application, select the implant and the treatment side and adjust the Resection Presets if desired.

The default resection settings are based on the implant specifications, e.g. 3° of posterior tibia slope. Femoral component flexion is set to 3° by default.

Note: Femoral component flexion in RI.KNEE NAVIGATION is shown relative to the femoral mechanical axis. Conventional instrumentation uses either the distal anatomical axis or the femoral mid-shaft axis instead. Thus, depending on the patient population, neutral anatomical flexion corresponds to 3°-5° of flexion relative to the mechanical axis.

To proceed, press “Navigate”.



CLEARLENS Tracking Array Preparation

At the scrub table, prepare the CLEARLENS reusable instruments with the CLEARLENS disposable tracking arrays. Tibia- and femur-arrays as well as arrays for pointer and plane tool are needed for a surgery.



Art. no. 53236
CLEARLENS Tracking
Array Set For Knee

To assemble the bone reference array and the two pin bone fixators, make sure the locking screw on the spring loaded ring interface is loosened. Snap the CLEARLENS Tracking Array into the interfaces of the corresponding reusable CLEARLENS bone fixators, making sure the array has fully engaged. If the arrays are not fully seated in the interfaces, the instruments might not be detected at the correct orientation and position. Do not tighten the locking screw yet.



The Y-shaped array, marked with the letter "F", is placed in a two-pin bone fixator, which is attached to the femur; the T-shaped array, marked with the letter "T" is mounted on the tibia. During navigation they define the position of the bones.



Art. no. 53239A
CLEARLENS Bone
Fixator 2-Pin – Left

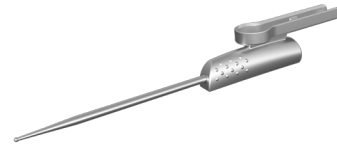


Art. no. 53240A
CLEARLENS Bone
Fixator 2-Pin – Right



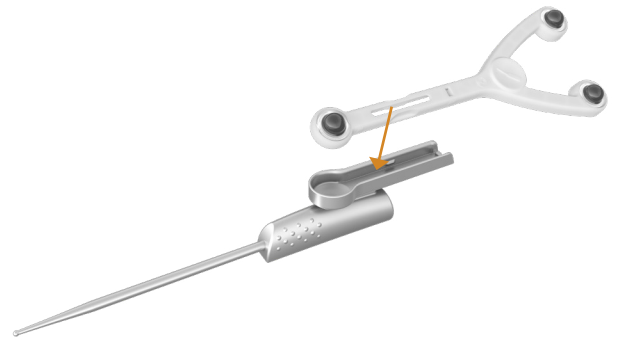
Pointer and Plane Tool Preparation

The pointer is used for registration of anatomical landmarks and measurements throughout the case.



Art. no. 53237A
CLEARLENS Pointer
Handle - Knee

Assemble the pointer by snapping the pointer array into the array interface. Make sure the array is fully seated to ensure the instrument is detected at the correct orientation and position.



The plane tool is used for navigating the tibial and femoral cutting guides and to verify the bone resections. The cutting block adapter foot of the plane tool is inserted into the cutting block while fixing the block onto the bone. The verification plate is used to verify resections.



Art. no. 53238A CLEARLENS
Plane Tool Interface



Incision & Exposure

Incision and exposure to the knee joints should be performed based on the surgeon's choice of technique. RI.KNEE NAVIGATION instruments support all standard approaches.

The incision must allow good exposure of the compartments to be resurfaced.

After initial exposure, assess the extent of arthritic damage and the ligaments including the ACL and remove all prominent osteophytes from the medial (or lateral) edges of femur and tibia and in the intercondylar notch as they may affect soft tissue balancing.

Reference Marker Placement

The reference marker arrays are used to identify position and orientation of the navigated instruments and the patient's anatomy. RI.KNEE NAVIGATION instruments are designed to be used with a variety of pins. It is recommended to use 3.2mm self-drilling, self-tapping pins. Please refer to the respective user guide for drilling, if using different pins.

Art. no. 54932A
Adapter For AO
Coupling (for 54922)

Art. no. 54922
Disposable Schanz Screw
(AO) 3,2mm x 100mm

Art. no. 54908
Disposable Schanz Screw
(AO) 4mm x 125mm

Tibia

The tibial array can be placed either inside or outside the incision. The pins need to be placed distant from the intended positions of both the femoral and tibial instruments to avoid any contact during bone resection and drilling.

When placing the pins inside the incision, a position slightly medial of the anticipated position of the cutting block, angled slightly downwards is recommended.



Alternatively, the pins can be placed through small stab incisions mid-shaft on the anterior tibia.

If the pins are angled slightly to the medial side, extra medullary tibial instrumentation can be used for cutting block placement and adjustment, providing additional stability.

Please refer to standard instructions for the placement of pins and screws, such as the AO Guidelines, for exact safe zones for angulation and placement of the pins.

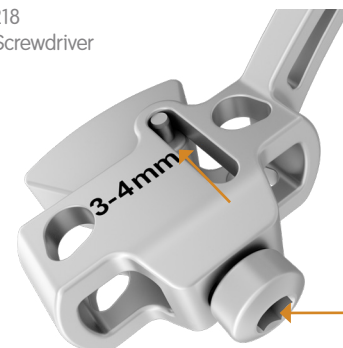


Place the first pin directly at the desired location. Slide the bone fixator 2-pin over the first pin with the fixation screw open. Place the second pin, drilling through the second pinhole in the 2-pin bone fixator. Tighten the fixation screw securely using the hex screwdriver .

Art. no. 53239A
CLEARLENS Bone
Fixator 2-Pin – Left

Art. no. 53240A
CLEARLENS Bone
Fixator 2-Pin – Right

Art. no. 53218
3. mm Hex Screwdriver

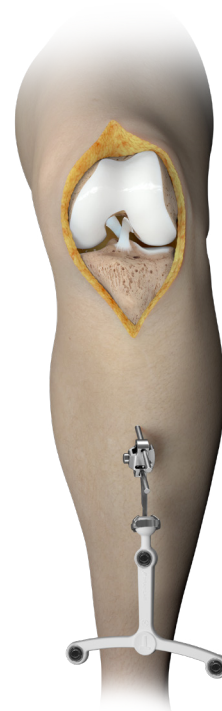
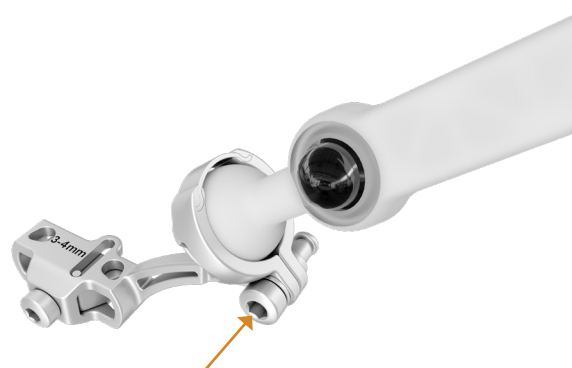


Tibia

The reference array's ball joint allows adjusting the orientation towards the camera. The recommended orientation of the T-reference is rotated towards the camera, slightly tilted upwards parallel to the tibia.



Make sure the interface (ball/ring) has fully engaged when inserting the array in the 2-pin bone fixator. Check if the array is visible to the camera throughout a full flexion/extension cycle. Once a suitable orientation of the array relative to the camera has been found, tighten the locking screw using the hex screwdriver. Make sure to tighten the screw up to the end stop to guarantee rigid fixation, preventing loosening of the tibial array.



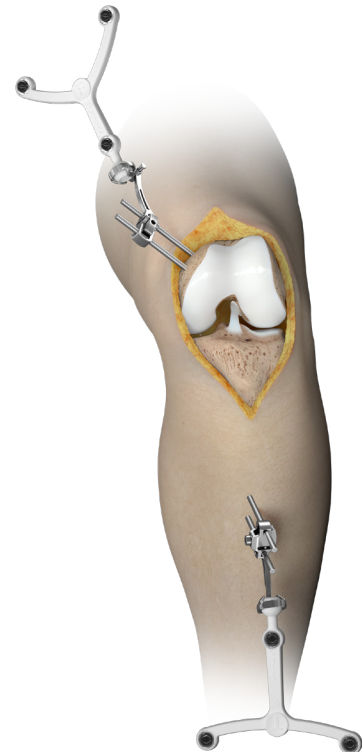
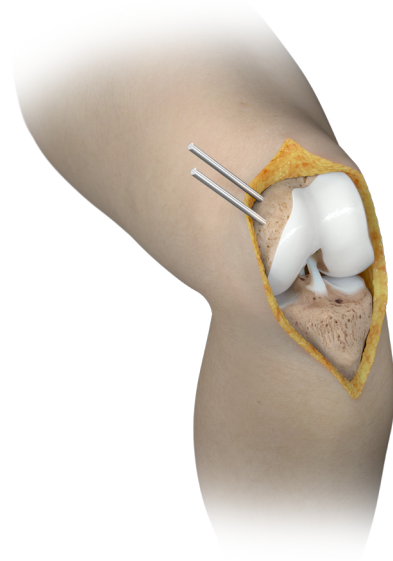
Femur

The femoral array can be placed either inside or outside the incision. If placed outside the incision, care must be taken to limit soft tissue damage. Excess stress on pin fixation must be avoided during range of motion intra-operatively.

When placing the reference array inside the incision, make sure to leave sufficient space for femoral instrumentation. Consider the location of the bone resections to avoid impingement of the saw blade with the fixation pins.

Place the first pin directly at the desired location, slide the Bone Fixator 2-Pin over the first pin and place the second pin through the pinhole. Tighten the fixation screw securely .

The recommended orientation of the femur reference is rotated towards the camera, substantially tilted upwards from parallel to the femur. This will allow the femoral reference array to maintain visibility to the camera even in deep flexion.



Registration

Before starting registration of the anatomical landmarks, check the reference array stability and visibility. Make sure the pointer is visible to the tracking camera.

On the femur, the following bone landmarks are registered:

- Femoral Head Center
- Distal Femoral Axis Point
- Medial and lateral epicondyles
- Whiteside's Line (optional)
- Medial and lateral femoral condyles (optional)
- Anterior Cortex

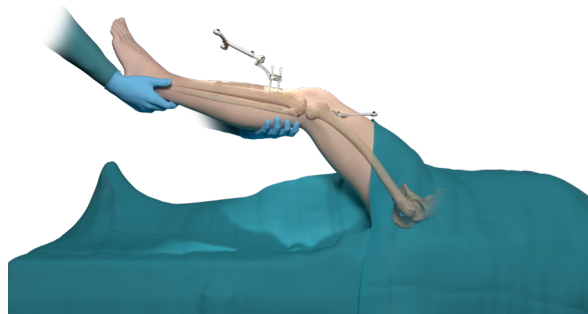
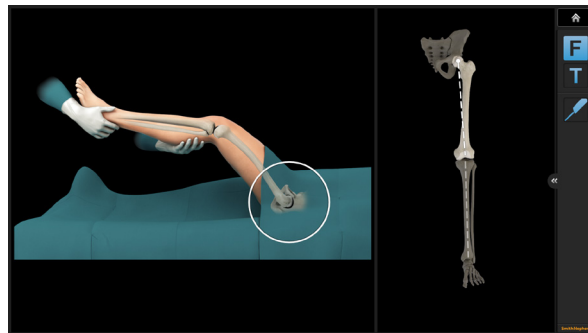
Femoral Head Center

The femoral head center defines the proximal end point of the Mikulicz Line and femoral mechanical axis.

The navigation system will produce a humming visibility sound while the femur reference is visible (if turned on in Settings, see Appendix).

Bring the leg from flexion to extension and back, then slightly rotate the leg externally and repeat the flexion-extension movement. Alternatively, apply circular motions of the femur around the hip center. The system calculates a series of points to determine the rotational center and will automatically proceed when the rotational center has been accurately calculated.

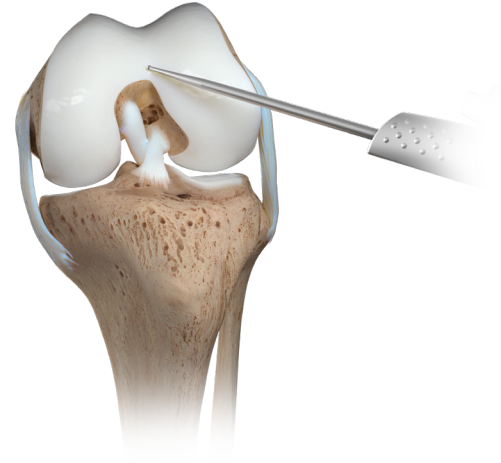
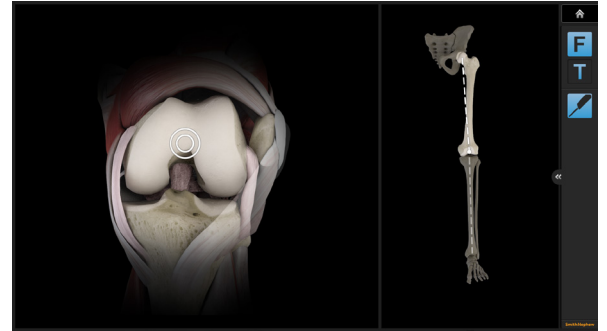
Do not move the camera during this registration step. Make sure that the patient's pelvis is not moved during registration. In case of difficulties acquiring the femoral head center with sufficient accuracy, it is helpful to have an assistant hold the pelvis firmly.



Distal Femoral Mechanical Axis Point

Defining the femoral mechanical axis is important for determining the varus/valgus and flexion/extension alignment of the femoral component, as well as overall leg alignment. Care should be taken to be as accurate as possible when collecting this point. The pointer should be placed slightly in medial at the posterior aspect of the femoral notch point (as indicated on screen) and pivot the pointer.

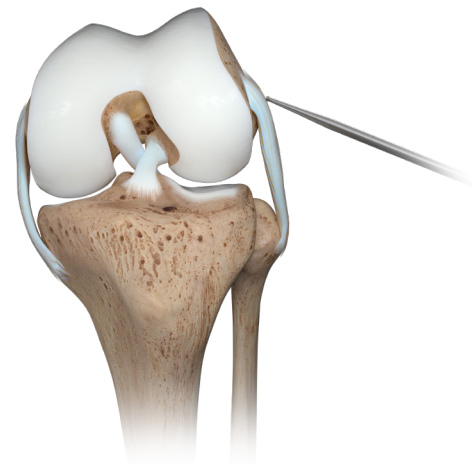
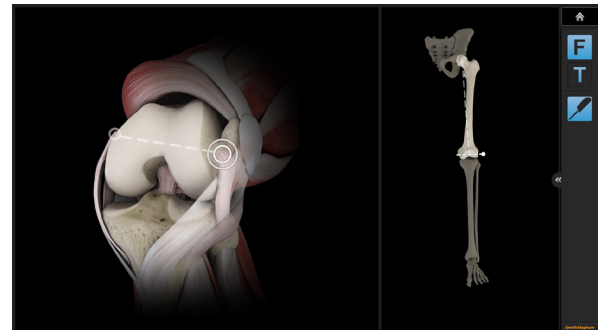
The acquisition of this point along with the femoral head center completes the femoral mechanical axis.



Epicondylar Line

The medial and lateral epicondylar points define the transepicondylar axis and the femoral A/P direction. The transepicondylar axis can be used as optional rotation reference for femoral component rotational alignment.

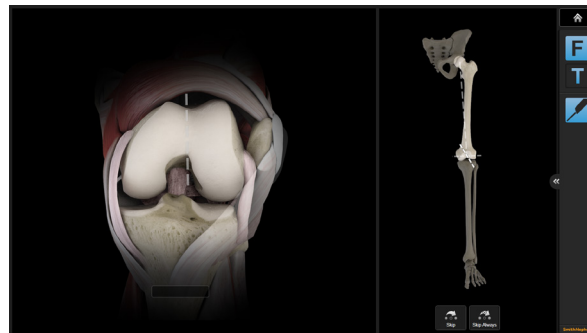
Note: It has been shown in various studies that the epicondylar axis might be difficult to locate in particular in knees with large deformities. It is recommended to use the surgical transepicondylar axis as defined by the most prominent points on the medial and lateral epicondyles, but keeping in mind the variability of that landmark in particular in deformed knees when using it as the main rotation reference.



Whiteside's Line

Whiteside's Line is used to define an optional reference for femoral component rotational alignment. It may be marked initially using electrocautery or a sterile pen. It is easiest to draw by looking along the horizon of the trochlear groove. Align the pointer along the line marked and hold the pointer still for two seconds to register.

Note: This registration step is optional and can be skipped if desired. This will result in no rotation to Whiteside's Line being displayed during navigation and planning.



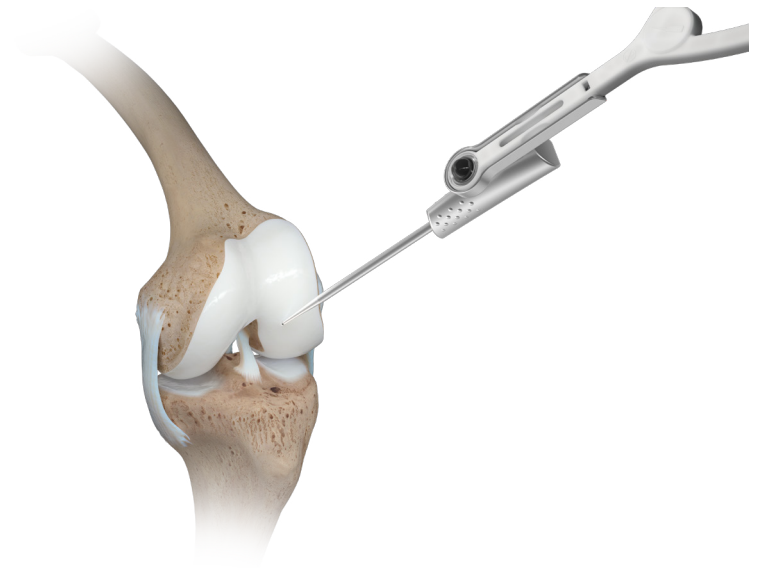
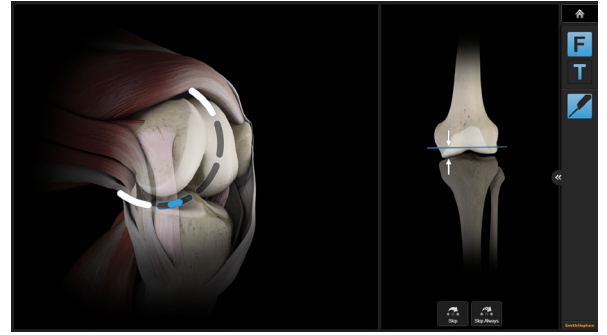
Femoral Condyles

A number of points along the surface of the medial and lateral condyles are acquired using the pointer. The tip of the pointer should “paint” the surface of the condyles. Points should be acquired as posteriorly as possible and along the distal part of the affected condyles. The system determines the most distal and most posterior condylar points from all the data collected.

Start with pivoting on the distal aspect of the condyle, then move to posterior in a zig-zag motion to make sure to cover the most prominent points of the condyles.

The screen shows the current position of the pointer in one of the five sectors. In each sector, a certain number of points need to be collected. The software will proceed once all sectors are covered.

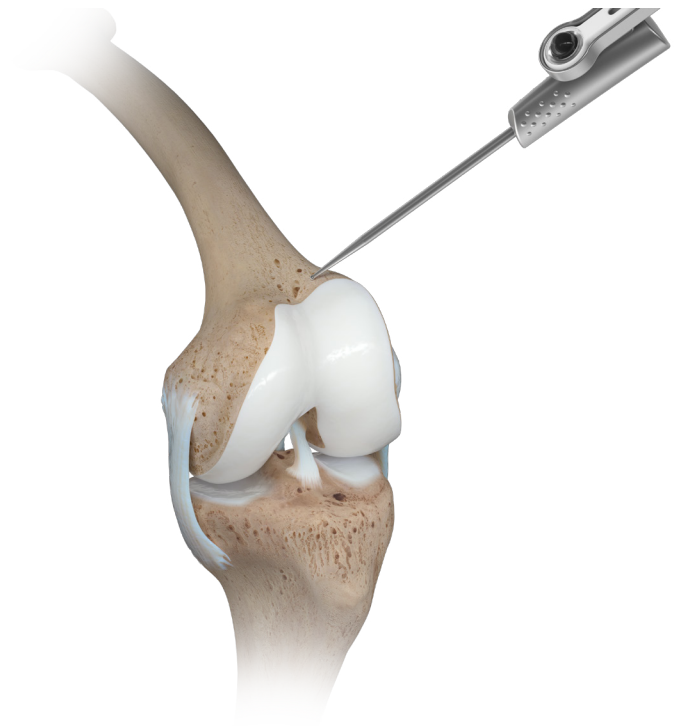
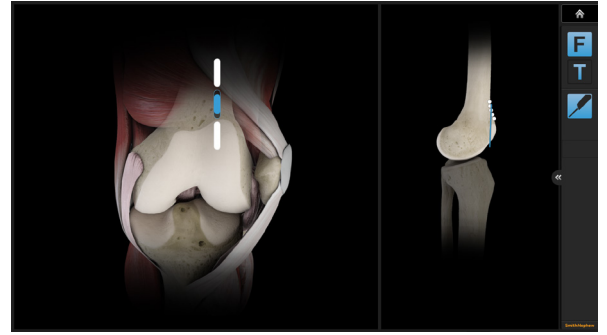
Note: Registration of one or both condyles can be skipped, in particular if, for example, revising from a partial to a total knee replacement with a natural condyle missing. A skipped condyle will result in no resection levels or joint line information being displayed on the respective side, as well as no rotation to the posterior condylar line being shown during navigation and planning. All other functionalities, including gap calculations, are not affected.



Anterior Cortex

A number of points along the surface of the anterior cortex are acquired using the pointer. To register, put the pointer tip on the anterior femoral cortex and pivot the pointer to start the acquisition. Slide the pointer over the bone surface to “paint” the surface of the cortex. Points should be acquired up to the superior border of the femoral implant.

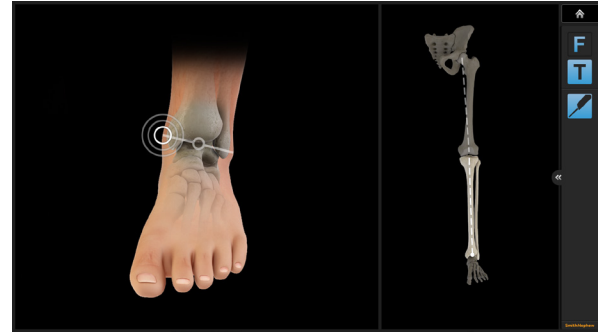
The anterior cortex is used as a reference for the exit of the anterior cut plane and determines the femoral component’s AP position and sizing.



Tibia

On the tibia, the following bone landmarks are registered:

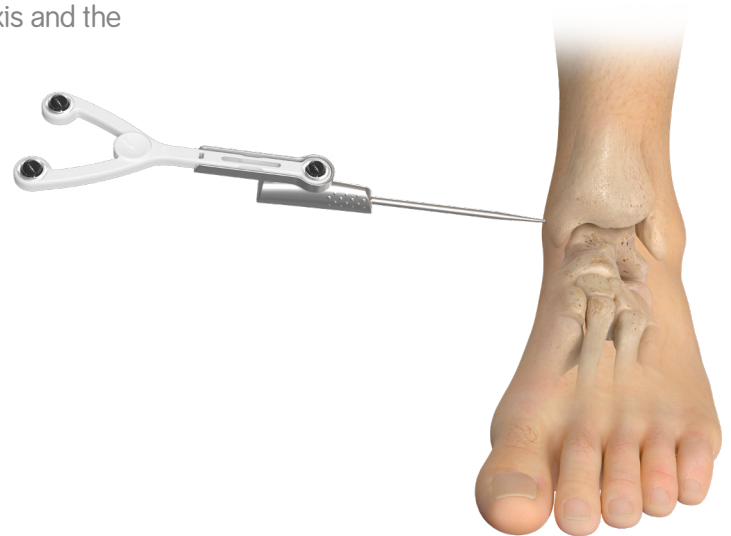
- Medial and lateral malleolus
- Proximal tibial mechanical axis point
- Tibial AP direction
- Medial and lateral tibial plateau (optional)



Malleoli

The malleoli can usually be located by palpating of the most prominent point of the malleoli before acquiring the landmarks. It is important that draping or bandaging is reduced to a minimum to enable the malleoli to be located and registered accurately.

Place the tip of the pointer on the medial malleolus and pivot the pointer. Once the system has registered the medial malleolar points, the lateral malleolar point can be registered in the same way. Acquiring the malleoli defines the most distal point of the tibia mechanical axis and the Mikulicz line.

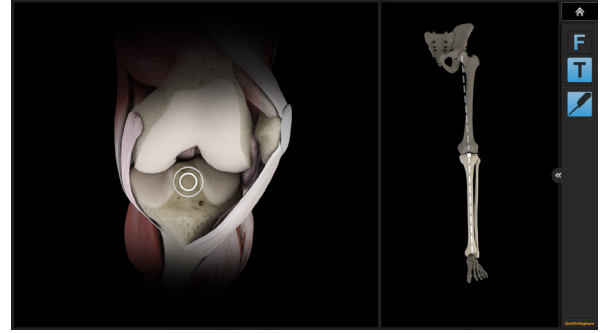


Proximal Tibial Mechanical Axis Point

The proximal point on the tibial mechanical axis is defined by acquiring the posterior aspect of the ACL tibial insertion point.

This is indicated by the circle on the screen. Additionally the intersection of the mid-coronal and mid-sagittal planes can be used for the identification of this point.

The definition of the mechanical axis is the basis for all further calculations and should be acquired as accurately as possible. Final implant position will be referenced to the mechanical axis.

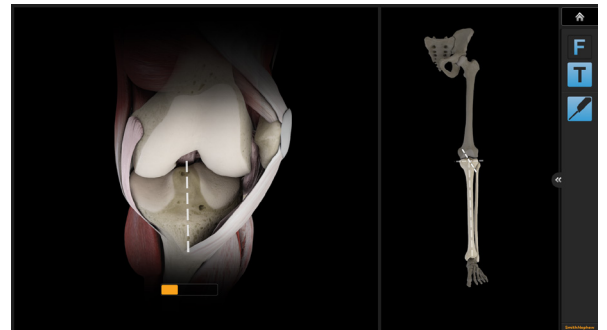


Tibial AP Direction

The pointer is placed horizontally in the anterior-posterior (AP) direction, so that it lies on the tibial eminence. The handle should be in line with the medial third of the tibial tubercle. The pointer is held in place for a few seconds to allow the system to calculate the direction only, the amount of slope is determined during the tibial resection navigation step.

The system determines the direction the tibia is facing and the direction of any intended slope which may need to be cut. The rationale behind this is to avoid a compound tibial slope (oblique tibial slope). Accurate acquisition of the AP direction will help to avoid an oblique tibial slope in the anteromedial to posterolateral direction or anterolateral to posteromedial direction.

Compound slope can put the tibial component into varus or valgus and lead to poor tibial/femoral contact. This can in turn lead to malalignment.



Tibial Plateau

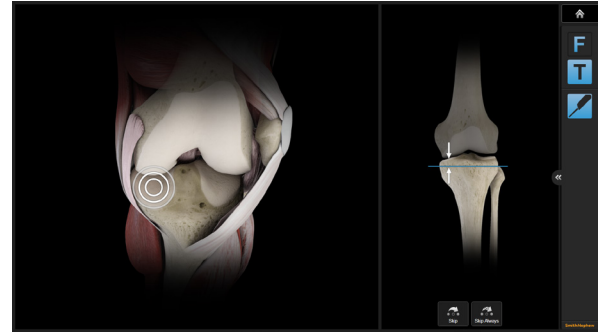
A single point on each plateau is used to calculate the tibial resection level. Careful consideration should be given if there is bone defect present. The software will show resection height numbers from this reference point.

The default resection height will always be measured from the high plateau. Manual adjustment of the resection level may be performed as indicated to accommodate specific anatomies or severe defects.

Once the medial plateau point is registered, the system will proceed to the lateral plateau, which is registered in an identical manner.

The resection height displayed during tibial navigation is based on measurements from the resection plane to the registered plateau points.

Note: Registration of one or both tibia plateau points can be skipped, in particular if for example in a revision from a partial to a total knee replacement one plateau is missing. A skipped condyle will result in no resection levels being displayed on the respective side during navigation and planning. All other functionalities, including gap calculations, are not affected.



Surgical Technique Overview

This document describes a tibia first technique; however, RI.KNEE NAVIGATION does not use predefined workflows leading the surgeon in a particular sequence of resections. The software instead simply follows the sequence of steps performed surgically. Nevertheless, depending on the sequence of resection, surgical considerations at each step might be slightly different, due to the available options for cutting block positioning.

Femur First Technique

Femur first techniques are probably the most common technique for total knee replacement.

Note: In contrast to conventional femur first techniques, using computer navigation with RI.KNEE NAVIGATION, the final implant stability effect of the tibial resection, while not being performed, can still be anticipated during the femoral resection steps, potentially enabling the surgeon to use that information to alter the femoral component position slightly to accommodate for potential unbalanced gaps.

An extension gap first balancing technique, with tibial resection performed after the distal femoral resection, does enable the surgeon to use a fixed spacer block to balance the knee joint in extension and subsequently adjust the flexion gap to the established extension gap during positioning of the anterior resection.

Tibia First Technique

In contrast to the femur first techniques, the tibia first technique allows access to the back of the joint and at least partial removal of osteophytes for balancing, before any compromises have been made on the femoral cuts. Therefore, this technique offers the most options to achieve balanced gaps in extension and flexion using the desired implant size.

If no other surgical considerations stand against this approach, this sequence of steps is recommended.

Adaptive Workflows

RI.KNEE NAVIGATION follows the user. It automatically identifies the current treatment step and displays the matching content on the screen. If for example the tibia cutting block with the Plane Tool is positioned on the tibia cortex the software displays tibia cut navigation values.

The following navigation steps are available:

- Tibia cut navigation
- Anterior femur cut navigation
- Distal femur cut navigation

Simply use the Plane Tool for navigation or the pointer for measurements and the software will automatically display the according information.

Note: The order of cuts can be chosen by the user and is not predefined in the software.

When no tool (Plane Tool, Pointer) is used, the software displays the leg alignment screen. It allows evaluating leg axis and flexion range as well as joint stability.

When the software detects that a cutting block is positioned on the bone, it displays all relevant information for the respective resection. All values are calculated relative to bone references.

Blue lines show the current cut position relative to bone landmarks. White lines represent the planned and yellow lines the verified cut.

Note: All values are referenced to bone landmarks. If you want to navigate to your planned resections you can use the yellow lines as visual guide.

Tibia First Technique

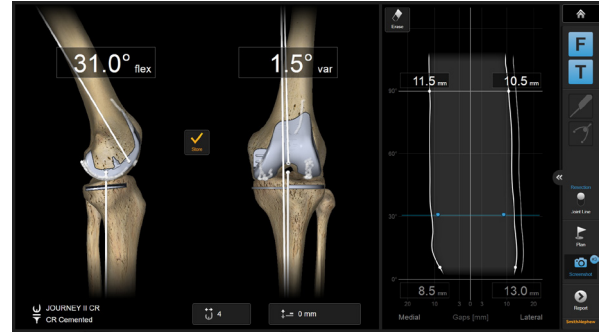
Initial Leg Alignment - Screen Layout

After the registration process is finished, the screen splits into two parts:

The left hand side of the screen shows the current bony anatomical situation and measurements regarding the implant position, the right hand side shows the expected stability of the knee joint after implantation, even if no resections have been done yet.

The software uses the planned, the live navigated current or the verified resection plane position to calculate the predicted stability. All calculations are based on the virtual final implant position; therefore at any time in the procedure, the numbers denote the same values.

Initially, the implant is virtually placed based on measured resection principle philosophy, with no distal joint line shift, anterior femoral alignment, and the femoral component's default rotation to the posterior condyles. The standard resection height values are defined by the implant. As the surgeon makes changes to the planned implant position throughout the procedure, the implant position and the stability graph is updated accordingly.

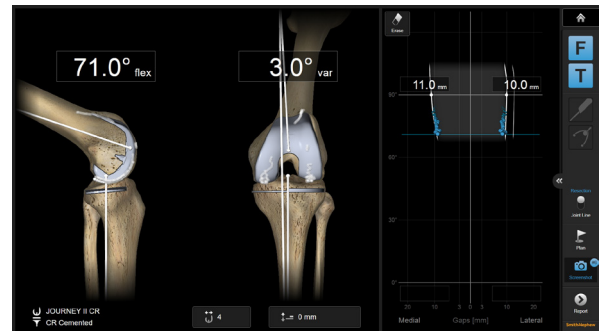


Varus/Valgus Stress Testing

Bring the leg into full extension and apply varus and valgus stress to test stability and check for fixed flexion or other deformities. Bring the leg into maximum flexion, again applying varus and valgus stress during the movement. The stability graph on the right now shows the calculated implant stability assuming the implant position on the left side of the screen.

The stability is represented by the medial and lateral gap, displayed as curves in the graph. The gap value is calculated as the distance from the tibial resection to the prosthetic condyles throughout the registered range of motion.

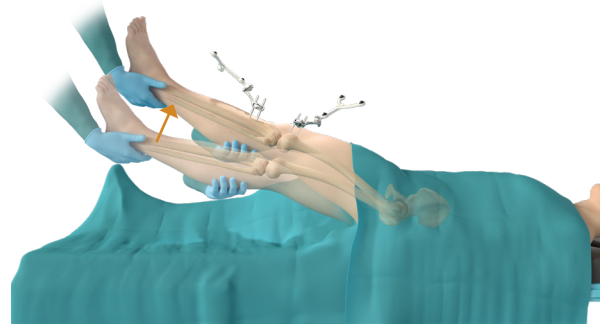
At this stage, based on the alignment information, decisions might be already derived regarding potentially necessary releases. In case of fixed flexion deformities, full extension might not yet be reached.



Storing Pre-operative Alignment

To store the pre-operative alignment, bring the leg in full extension without applying stress, then lift the fully extended leg approximately 10 cm. The software will interpret the lifting gesture and store the alignment.

Alternatively, pressing the “Store” button on screen will store the alignment.



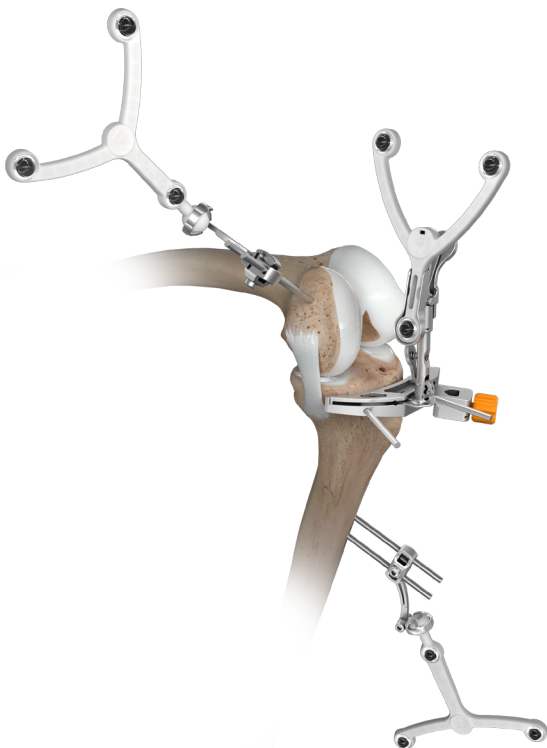
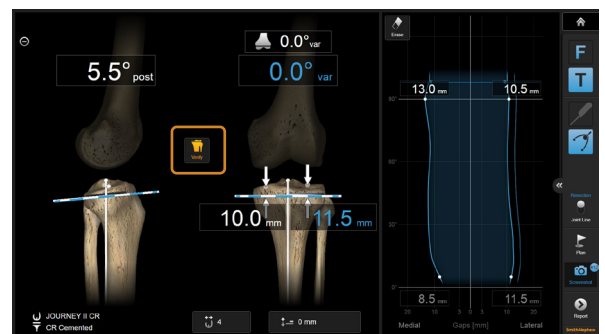
Tibial Resection

In a tibia first balanced technique, next step is the tibial resection. Attach the navigation plane tool to the tibial cutting block for your implant. You may use the conventional extramedullary alignment tools, or simply the block alone.

The software automatically switches to the tibial navigation information, as soon as the resection block with the plane tools is close to the right position. The white plane displayed on screen represents the planned position of the resection. The current position of the resection plane is indicated by the blue plane.

Art. no. 53202 Knee
Plane Tool - Cutting
Block Adapter

Art. no. 53238A
CLEARLENS Plane
Tool - Interface



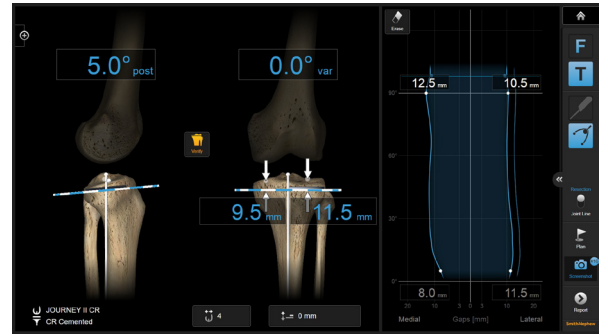
Stability Information

To indicate live navigated values, the stability graph changes to blue color while navigating the tibial cutting block to the desired location. The stability graph on the right shows the effect of the current cutting block position on the final result in real time.

Increasing the tibial resection height will open flexion and extension gaps equally, while decreasing the resection height will close both, the flexion and extension gaps.

In particular with flexion instabilities that might already be apparent at that stage, this information can be used to potentially decide for more or less conservative tibial resections.

Note: The flexion gap is heavily affected by femoral sizing. Crosscheck the femoral size determined by the software with the preoperatively planned size. In case the software selected a different femoral component size, change it using the sizing button at the bottom of the screen.



Placement of Cutting Block & Resection

Once the cutting block is at the desired position, drill the first pin fixing the cutting block, while constantly checking for changes in alignment, specifically slope, during drilling. Place the second pin, focusing on varus/valgus position and correct possible alignment deviations. If necessary, put additional oblique pins to increase cutting block fixation and perform resection.

Cut Verification

After resection and clean up of the resected surface, assemble the plane tool to the bone verification plate. Position the plane tool on the resected surface. Inaccuracies introduced by saw blade deformation or cutting block movement can easily be detected. The software recognizes the verification step and automatically stores the position and updates the stability information as soon as the tool is held still for two seconds. Alternatively, the “Verify” button on screen or the blue footswitch pedal can be used to store the verified resection.

In case of deviating from the initial plan, the stability graph immediately shows the effect on final stability. This allows assessing the influence of cut deviations on the final result, helping to decide if changes to the resection will be necessary, or if the deviations can be accepted.

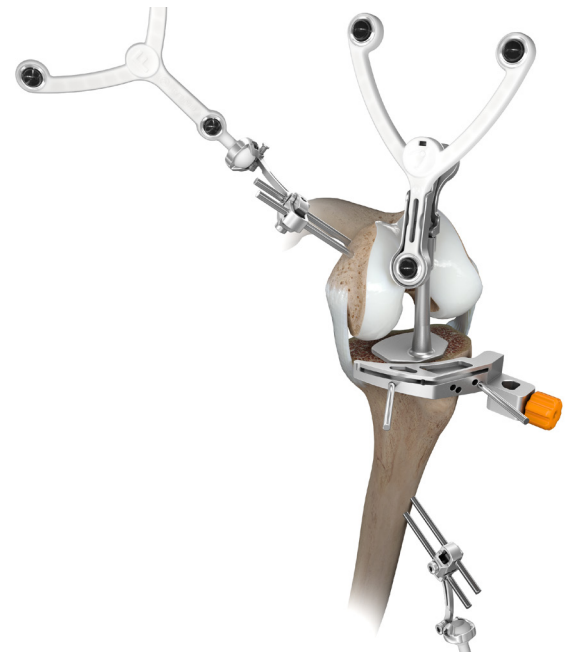
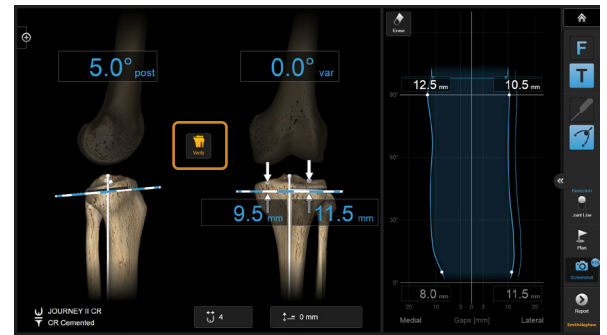
Crosscheck the result of the resection using the displayed numbers with respect to the bone landmarks and with respect to the calculated final stability outcome.

Note: The verification of a resected surface will adjust the plan accordingly for the subsequent steps, therefore showing the yellow plane at the same location as the blue plane.

Art. no. 53202 Knee Plane Tool – Cutting Block Adapter

Art. no. 53204 Knee Plane Tool – Bone Verification Plate, Small

Art. no. 53238A CLEARLENS Plane Tool - Interface



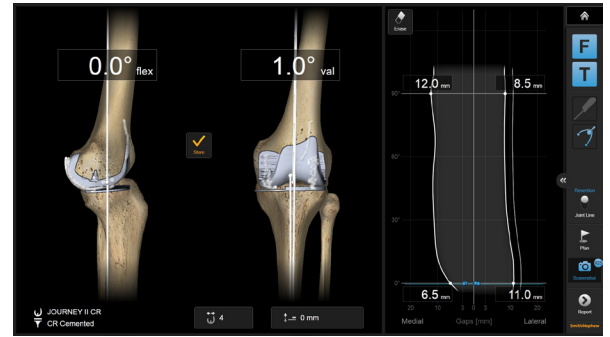
Range of Motion & Extension Balancing

After tibial resection, remove remaining osteophytes and start addressing potential fixed flexion deformities.

In full extension, check the medial and lateral gaps for symmetry and stability. In case of asymmetry, consider additional osteophyte removal or additional releases to achieve symmetry. The effect of releases can immediately be visualized by applying medial or lateral stress in the according flexion range. This can be performed either by using lamina spreaders, tibial trial components or any spreading device.

Note: In particular in case of fixed flexion deformities, or posterior condylar osteophytes, the knee joint might at that stage be able to reach full extension only while compressing the extension gap. In this case remaining posterior osteophytes tend to tighten the posterior capsule such that the anterior aspects of the extension gaps collapse while the leg is extended.

On the stability graph, this will be indicated by converging lines when getting close to full extension (see figure on the right). In such case, you might want to leave the flexion-extension imbalance for now to address it at a later stage when the posterior part of the joint is fully accessible.

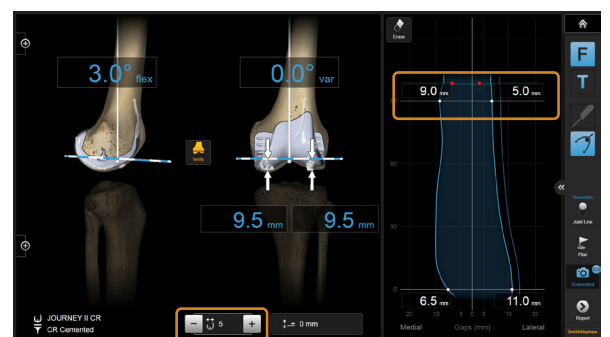
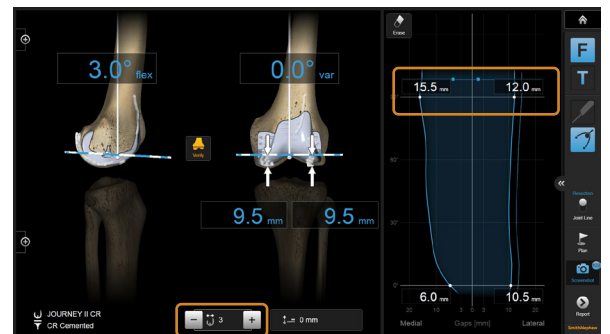


Femoral Sizing

Initially, the plan for the femoral component is based on the manufacturer specifications following a measured resection philosophy. Femoral sizing is based on the AP dimensions of the registered femur. Resection height values are based on the registered femoral landmarks.

Make sure that the software is using the same femoral component size you are using for this patient. If the femoral component size deviates from the pre-operatively planned size, change it using the controls on the bottom of the screen.

Note: The femoral component flexion is shown in relation to the femoral mechanical axis, while conventional instrumentation is using anatomical axes instead. Depending on the type of intramedullary rod, a neutral component flexion is based either on the distal anatomical axis, or the femoral mid-shaft axis. Depending on your particular patient population, this axis might be in 3°-5° of flexion to the mechanical axis.



Distal Femoral Resection

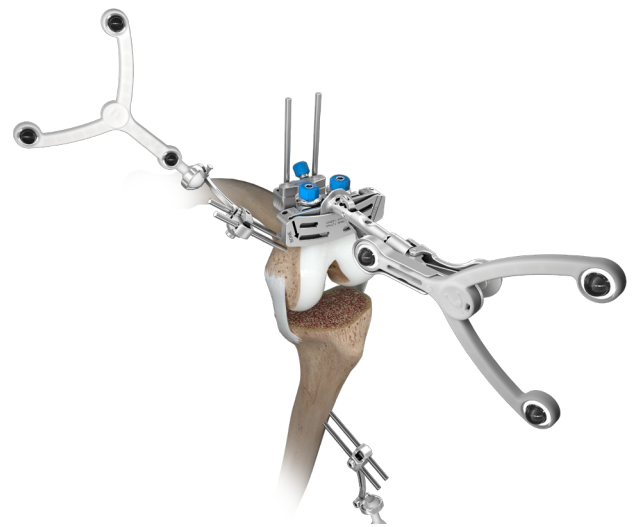
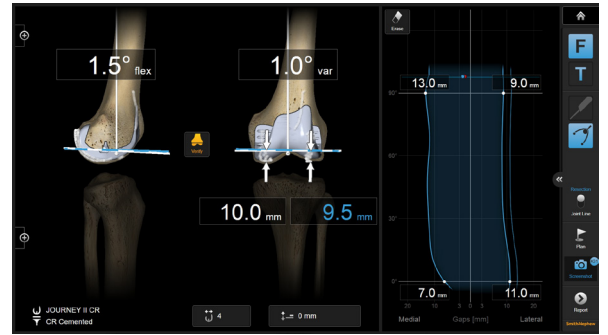
Place the cutting block adapter in the saw slot of the distal femoral cutting block. When placing the cutting block near the distal femoral condyles, the software will automatically enter navigation mode.

At this point a potential inequality of extension and flexion gap can already be addressed by altering the cutting block position. The extension gap can be decreased or increased by shifting the cutting block more distally or proximally. The flexion gap can be decreased by slightly flexing the distal cut and therefore the femoral component. Make sure the gap values are in the same range (fine tuning gaps is still possible with the next resections)

Note: Alternatively, consider under correcting the preoperative deformity, or deliberately accept slight remaining instability. Asymmetry of the extension gap can be addressed by either additional soft tissue releases or by considering anatomical alignment by positioning the femoral component in slight varus.

The effect of the current cutting plane position on the postoperative outcome will be shown in real time in the stability graph.

Once the cutting block is at the desired position, drill the first pin fixing the cutting block, while constantly checking for changes in alignment during drilling. Place the second pin, correcting for possible alignment deviations. If necessary, fix the block with additional oblique pins to increase cutting block stability and perform the resection.



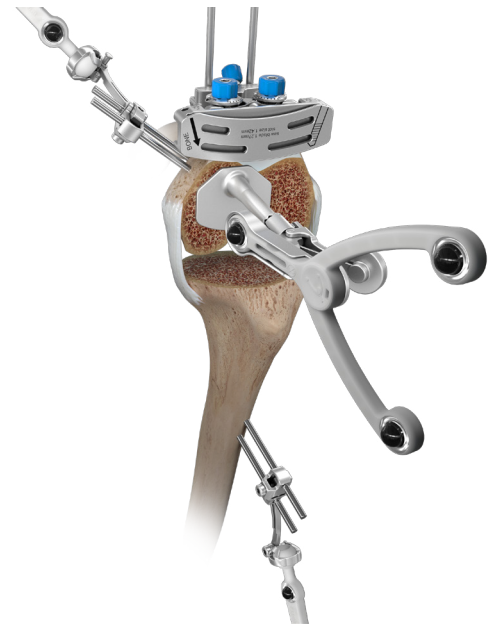
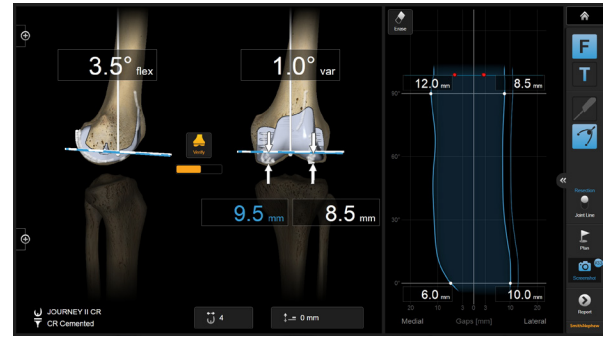
Art. no. 53204 Knee
Plane Tool – Cutting
Block Adapter

Art. no. 53238A
CLEARLENS Plane
Tool - Interface

Distal Cut Verification

After the resection has been performed, verify the cut using the plane tool with the verification plate. Verifying the resection will immediately show the effect of potential deviations from the desired position, making it easy to judge if the deviation can be accepted or need reassessment of the cut.

Position the plane tool on the resected surface and hold it still for two seconds to record the position and to update the joint stability graph.



Art. no. 53204 Knee
Plane Tool – Bone
Verification Plate, Small

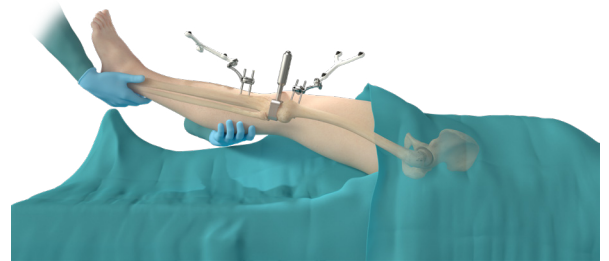
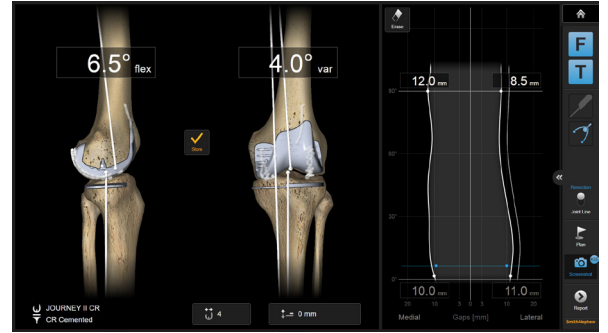
Art. no. 53238A
CLEARLENS Plane
Tool - Interface

Balancing in Extension

After having performed and verified the distal resection, bring the leg in full extension. Use a fixed spacer block to assess long leg alignment and extension stability while applying varus and valgus stress.

If the desired correction and stability in extension is achieved, continue with preparation of the anterior femoral resection.

Note: Make sure that both Tibia and Femur reference are visible to the camera, such that the navigation system can analyze the effect of releases.



Balancing in Flexion - Anterior/Posterior resections

Place the plane tool in the anterior cutting slot of the 4-in-1 block and place it on the distal femoral resection to enter navigation mode. At this point, the flexion gap can be modified to match the extension gap and to achieve a symmetric flexion space.

Shift the cutting block slightly posterior, if the flexion gap is larger than the extension gap. If the block is shifted posteriorly, crosscheck the AP position using conventional instrumentation to prevent notching. If the flexion gap is much smaller, consider downsizing the femoral component. If the flexion gap is much larger than the extension gap, consider upsizing.

For a given medial/lateral flexion gap mismatch, there are usually three options to achieve a balanced gap:

1) Adjust femoral component rotation:

Internal rotation of the 5-in-1 block (or 4-in-1 block) will close the medial and open the lateral flexion space, while external rotation will open the medial and close the lateral compartment of the joint in flexion. Rotate the cutting block until medial and lateral flexion gaps are equalized.

Cross check the rotation with anatomical landmarks. Care should be taken to avoid excessive axial rotation, which is often associated with patellar maltracking. Assess the rotation values displayed on screen. If rotation exceeds the acceptable values, consider reducing rotation and accepting slight instability in flexion.

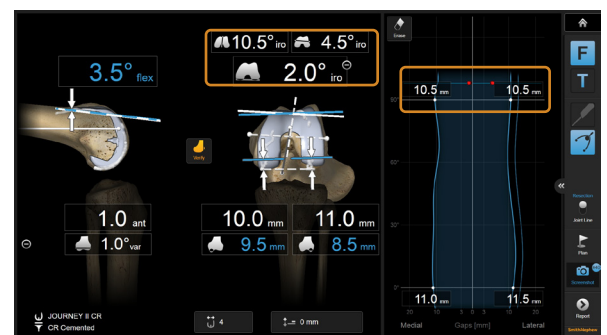
For complex cases, it might be helpful to enter the planning mode to adjust axial femoral component rotation. With increased navigation experience, the rotation might be adjusted directly on the navigation screen without entering the planning mode

2) Perform additional soft tissue management:

An imbalance can be the sign for an incomplete release. In particular, make sure to remove all osteophytes. Always consider the effect of the particular release for the extension gap as well to avoid over releasing.

3) Accept a remaining instability:

Natural knees commonly tend to have a laxer lateral compartment, particularly in flexion. Thus a slight lateral instability can be accepted in order to avoid excessive rotation.



Note: The most appropriate balancing solution for a particular patient might be a combination of all three options described.

For JOURNEY[®] II, complete the cuts in the order indicated on the 5-in-1 non-spiked cutting block:

- 1 Anterior
- 2 Anterior Chord
- 3 Posterior
- 4 Posterior Chamfer
- 5 Anterior Chamfer

Note: While performing the posterior and posterior chamfer resections use careful placement of retractors to protect the Popliteus Tendon attachments to the femur. Releasing the Popliteus Tendon can destabilize the knee laterally in flexion.



Art. no. 53204 Knee
Plane Tool – Cutting
Block Adapter

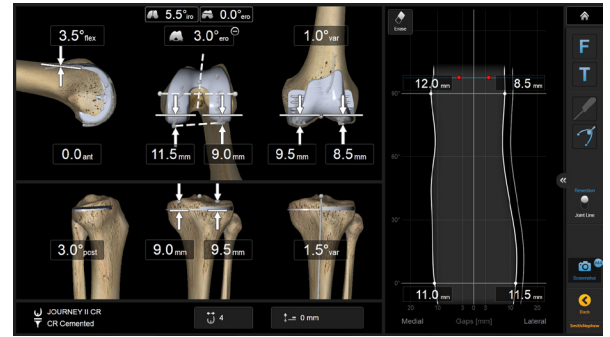
Art. no. 53238A
CLEARLENS Plane
Tool - Interface

Full Planning Mode

All steps of the algorithm can be performed instantly and on the fly while placing the cutting block to the relative resection positions.

In cases with larger deformities, where the solution might not be directly obvious, switch to full planning mode. Here you can plan all resections simultaneously on one screen to find the best solution.

Always keep in mind that imbalance on the screen might denote incomplete releases or incomplete storing of maximum gaps, in particular after performing releases. Therefore, if in doubt, always cross-check the ligament situation by applying medial or lateral tension to see if the number on screen match with the actual ligament situation.



Anterior Cut Verification

After performing the anterior resection, verify the cut. Verifying the resection will update the software with the current cut position information for the final balancing step as well as for documentation in the patient report. In particular the verification of the anterior resection is easily missed, since it is the final step before making all remaining cuts and placing the trial implant.

Place the plane tool on the cut surface and hold it still for two seconds to record the position.

Ensure the anterior resection has been verified before proceeding to the next step. Once the anterior resection has been verified, the stability graph will change from white to yellow, indicating that all resections have been verified and that the final stability graph is updated accordingly.



Art. no. 53202 Knee Plane Tool – Cutting Block Adapter

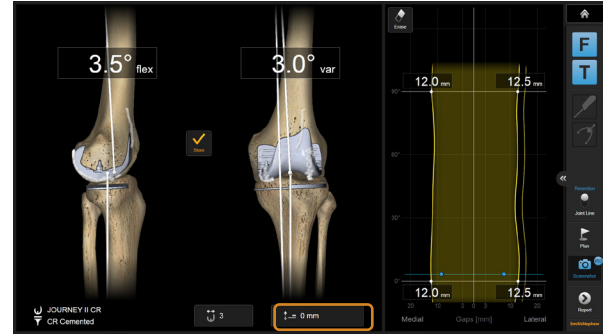
Art. no. 53204 Knee Plane Tool – Bone Verification Plate, Small

Art. no. 53238A CLEALRENS Plane Tool - Interface



Trialing & Closure

After insertion of the trial components and the insert, clear the information in the stability graph by pressing the “Erase” button. Record the final stability, range of motion and alignment situation for case documentation.

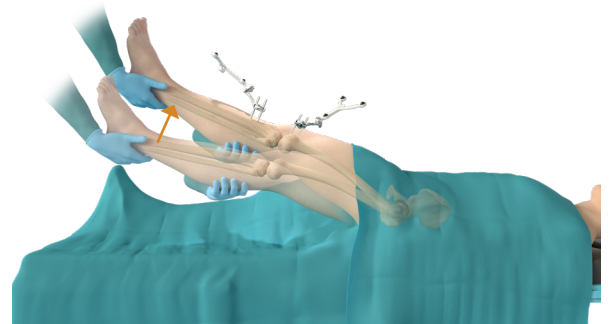
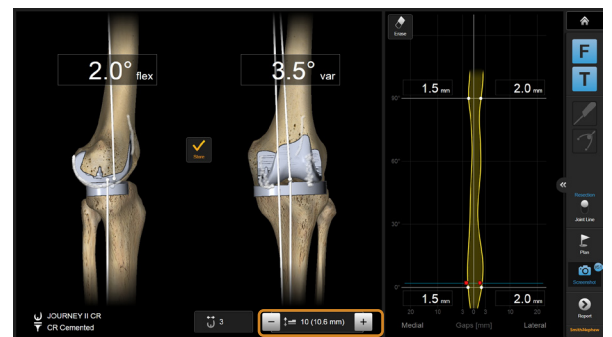


You may want to select the tibial insert thickness currently used to make the graph reflect the actual situation.

To store the alignment, bring the leg in full extension without applying stress, then lift the fully extended leg approximately 10 cm. The software will interpret the lifting gesture and store the alignment.

Alternatively, pressing the “Store” button on screen.

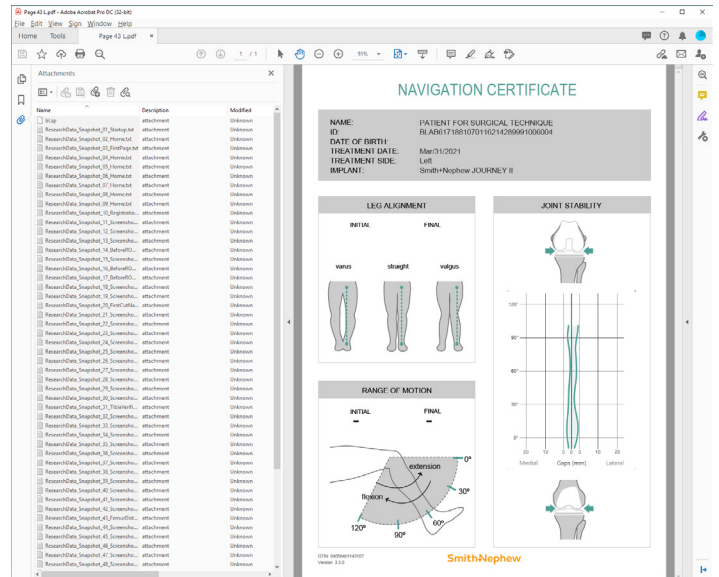
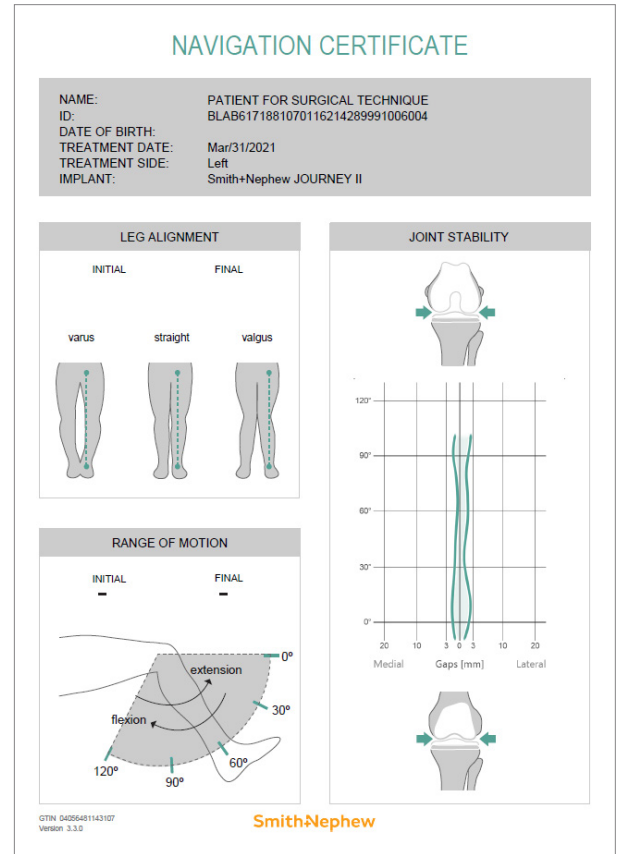
Close the knee in layers using the surgeon’s preferred technique.



Patient Report

After finishing the procedure, press the “Done” button to access the patient report. This report contains information in a simplified language for printing it for the patient.

Additional data, in particular for research purpose, can be found in the PDF attachment which can be reached via the paperclip in the PDF file.



Tibia First Balanced Technique Overview

- 1 Perform tibial and femoral registration
- 2 Perform initial stability and alignment assessment using the Joint Stability Graph
- 3 Use the plane tool with the tibial block to position the tibial cutting block
 - Watch out for potential fixed flexion deformities. Converging lines in the graph in extension might indicate tight posterior capsule. Consider conservative tibial resection if full extension cannot be reached before tibial resection
 - Pin the block and perform resection
- 4 Verify tibial resection
- 5 Use spring tensor on tibial cut to record stability over full range of motion while applying varus/valgus stress
- 6 Use the plane tool with the distal cutting block to position the distal cutting block
 - Adjust femoral flexion angle
 - a. Femoral Flexion should be between 0° and 3° depending on patient anatomy
 - b. If flexion gap is too large, try to increase femoral flexion angle, which closes the flexions gap
 - Adjust distal resection level to make extension gap equal to flexion gap. Increase resection to open extension gap. Decrease resection to close extension gap
 - Pin the block and perform resection
- 7 Verify distal femoral resection

- 8** Place the cutting block adapter in the anterior cutting slot of AP resection block and navigate the block using the onscreen data
- Crosscheck for correct implant sizing with anatomical situation (conventional sizing guide). Change size suggested by the software if necessary
 - Adjust femoral rotation
 - a. Femoral rotation should be adjusted to equalize medial and lateral gaps. Crosscheck that rotation is not too far from what anatomic landmarks suggest (3...5° int/ext. rotation max)
 - b. If in anatomically neutral rotation the medial and lateral gaps are unequal, basically there are three options:
 - i. Adjust bone cuts away from anatomical landmarks, towards what gaps dictate. Consider patellar tracking.
 - ii. Apply (additional) soft tissue releases. Make sure to remove all osteophytes. Consider the effect of the particular release for the extension gap – do not over release!
 - iii. Accept a certain remaining instability. In particular on the lateral side, a slightly larger gap is common in natural knees.

In most cases, it might be a combination of the three above mentioned options.

- c. Pin the block & perform resection

9 Verify anterior resection

10 Perform implant trialing

- Erase the stability graph
- Re-record the stability graph with the trial implants in the joint
- Adjust insert thickness if necessary

Joint Line Mode

By pressing the “Joint Line” button you can switch to joint line mode for femoral resections. Instead of resection heights the software displays the joint line shift for the selected implant component during femur navigation.

Note: Resections are calculated perpendicular to the cuts. Joint line values are the distance between the most distal implant point to the most distal condyle surface point in femur axis direction.

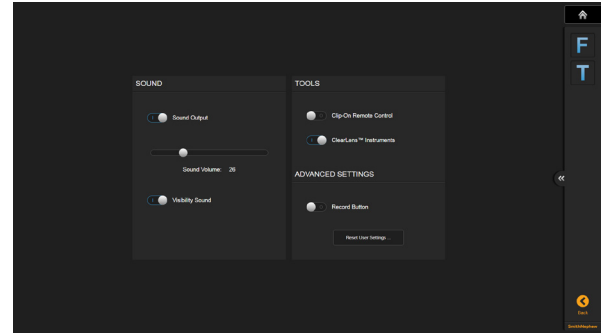
When the femur component is flexed resection plus distal implant thickness may not equal the joint line shift!

Settings

Some application settings, including sound volume controls, can be accessed from the menu drawer on the right part of the screen.

Clip-On Remote

The use of the optional disposable clip-on remote control can be enabled for registration of the anatomic landmarks in Settings. When turned on, hold the tip to the indicated landmark and press the “Control” button. The remote control reacts upon pressing the button, not upon releasing. If the tip moves during registration, the point is not acquired.



Art. no. 53153
Disposable Clip-On
Remote Control (20 pcs)

Article List

Catalog number

Description

Pointer

53237A CLEARLENS Pointer Handle - Knee



53237-10 CLEARLENS Pointer Gauge – Knee

Array fixation

53239A CLEARLENS Bone Fixator 2-Pin - Left



53240A CLEARLENS Bone Fixator 2-Pin - Right



CLEARLENS Tracking Arrays

53236 CLEARLENS Tracking Array Set For Knee

53236-01 CLEARLENS Tracking Array Tibia



53236-02 CLEARLENS Tracking Array Femur



53236-03 CLEARLENS Tracking Array Pointer



53236-04 CLEARLENS Tracking Array Plane Tool



Catalog number

Description

Plane Tool

53238A

CLEARLENS Knee Plane Tool - Interface



53202

Knee Plane Tool – Cutting Block Adapter



53203

Knee Plane Tool – Bone Verification Plate



53204

Knee Plane Tool – Bone Verification Plate Small



This technique is for informational and educational purposes only. It is not intended to serve as medical advice. It is the responsibility of the treating physicians to determine and utilise the appropriate products and techniques according to their own clinical judgment for each of their patients. For more information on the products shown in this surgical technique, including indications for use, contraindications, effects, precautions and warnings, please consult the Instructions for Use (IFU) for the product.

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