Attune®
Knee System

intuition™
INSTRUMENTS

CAS Surgical Technique

Distal Femoral Resection

L

M

Valgus **0.5**

Resection [mm] **+1.0**

Flexion **0.0**

Mount the cutting block adapter to the cutting block. Adjust resection to desired position.

BRAINLAB ☰ Menu 👁 Options 📷 Screenshot Back
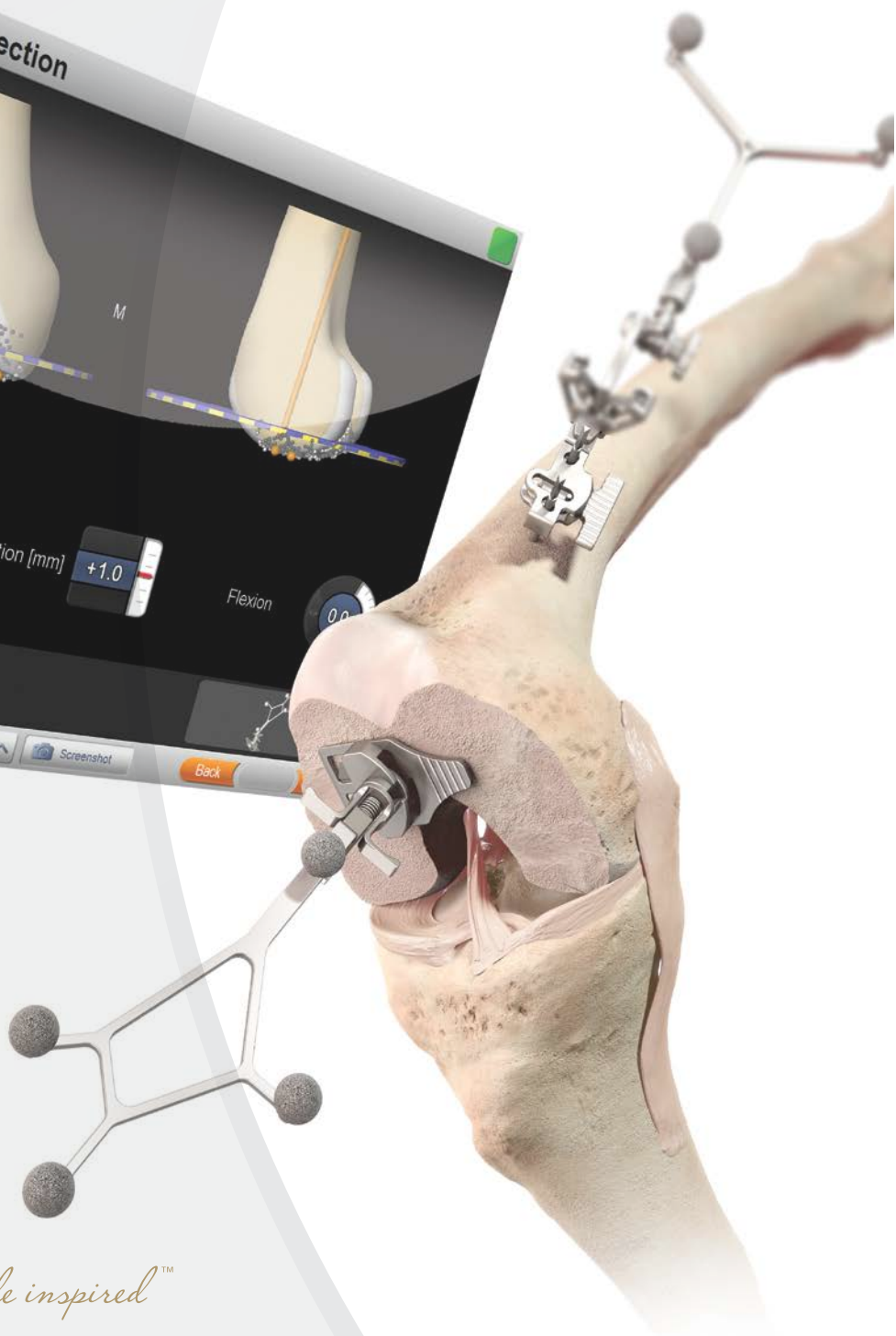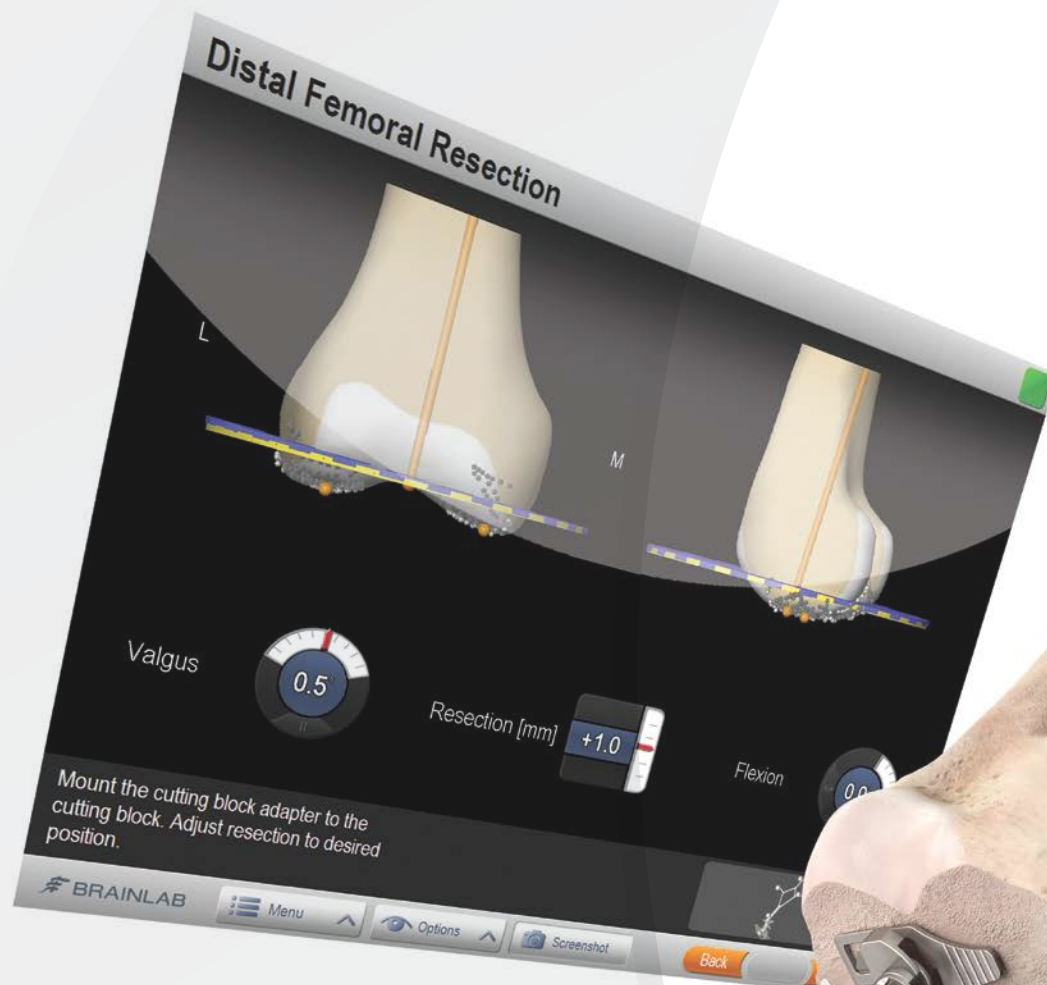
DePuy Synthes
JOINT RECONSTRUCTION
COMPANIES OF Johnson&Johnson

People inspired™

Introduction

This surgical technique provides guidelines for the implantation of the ATTUNE® Knee System Family of Implants with the *DePuy Synthes Companies'* CAS (Computer Assisted Surgery) System, software version 2.6 provided by Brainlab and ATTUNE Knee INTUITION™ Instruments.

This surgical technique goes through a Femur First Hybrid workflow, however the ATTUNE Knee System will allow all available workflow options such as, Tibia First, Femur First and Tibia First Hybrid.

Please refer to Catalogue Number 0612-10-512 Rev.1 for the non-navigated surgical technique.

ATTUNE Knee System Implants are available in four configurations:
• Posterior Stabilized Fixed Bearing (PS FB),
• Posterior Stabilized Rotating Platform (PS RP),
• Cruciate Retaining Fixed Bearing (CR FB) and
• Cruciate Retaining Rotating Platform (CR RP)

The Cruciate Retaining (CR) configurations can also be used for Cruciate Sacrificing (CS) applications.

Contents

Key Surgical Steps Summary

Incision and Exposure

Data Aquisition
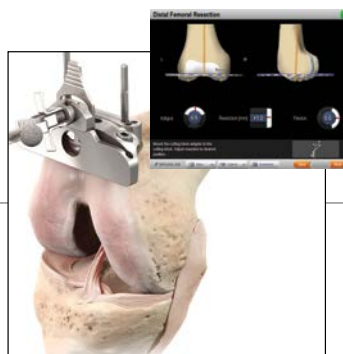
Distal Femoral
Resection Navigation
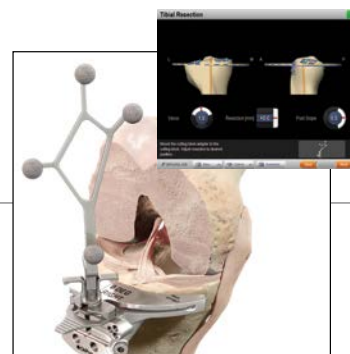
Tibial Resection

Balancing in Extension
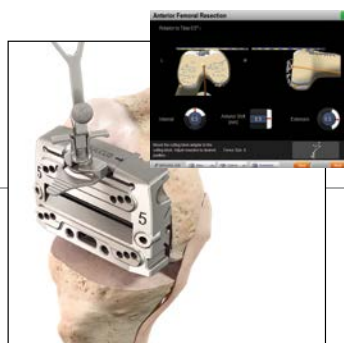
Anterior Femoral
Resection Navigation

Femoral Preparation
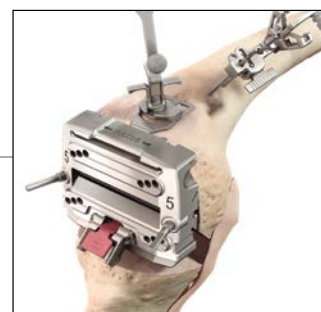
Anterior Femoral
Resection Verification

Trial Reduction

Femoral Lug Hole Preparation

Patella Resection and
Final Patella Preparation
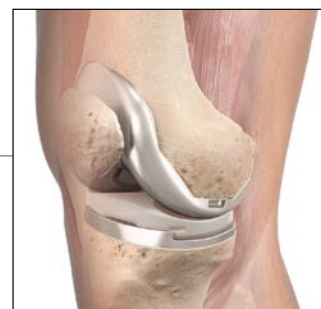
Final Component Implantation

*Note: All resections are done
using a 1.19 mm Saw Blade to
maximize accuracy through the
Slotted Cutting Guides.*

Software Menu Buttons
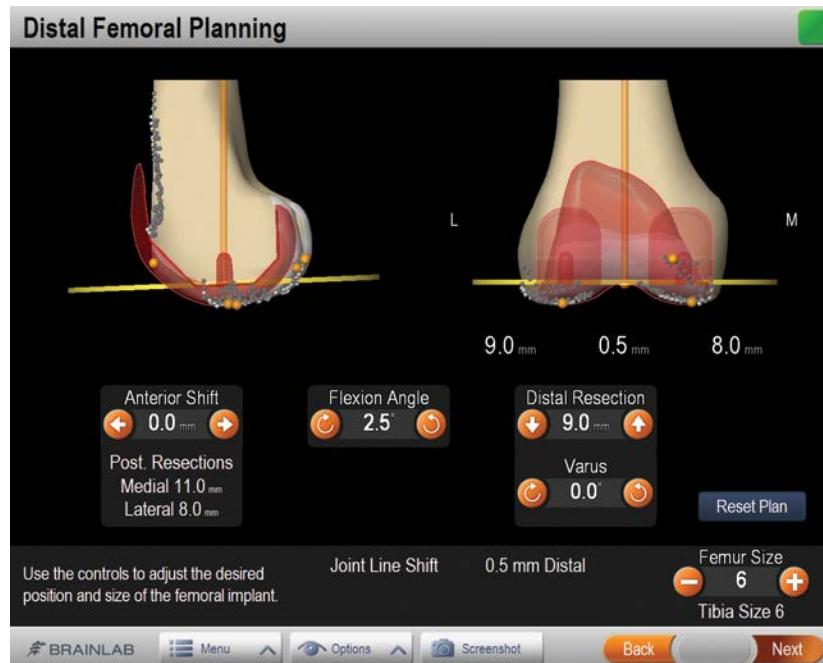
The status field lights indicate that all instruments are visible
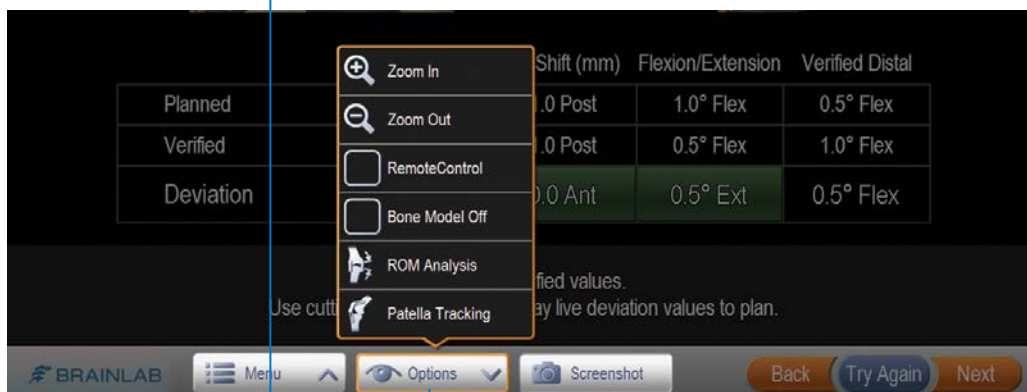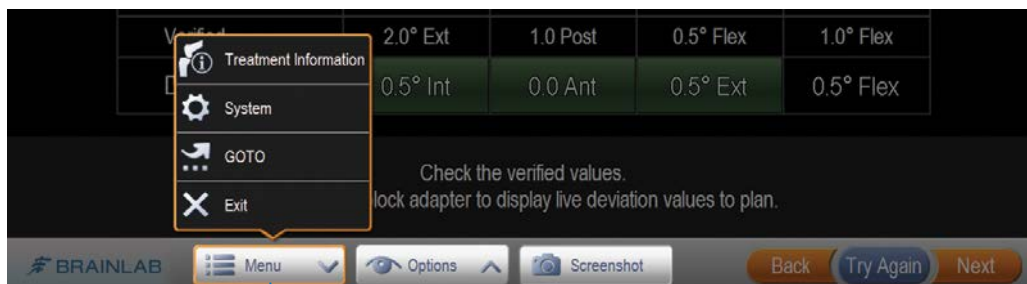
All menu items are stored
in two intuitive sets
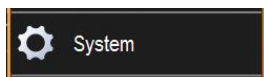
System Button: The following screens show functions that can be accessed when the System button is pressed.

Software Information: provides information about the version of the software that is in use. It also provides numbers for the help desk in Germany and the USA.

Screenshots: gives the option to copy screenshots that have been saved either manually or by default.
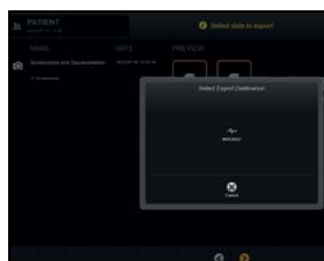
System saves the patient information that can be accessed at a later time. Information can either be transferred to another storage medium or removed from the system permanently.

The surgeon can change the volume/sound settings of the system; i.e., select a beep for when buttons are pressed. The sound can also be turned on or off.

Go To Button: The following screen shows functions that can be accessed when the Go To button is pressed.

The surgeon can access different steps of the surgery when the Go To button is pressed. The surgeon can only activate steps that he/she has already completed.

Arrays Visible: Press this button to go to camera view.
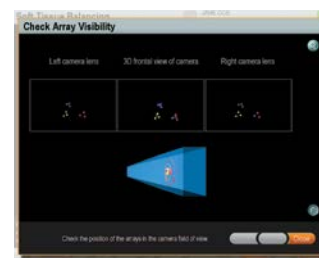
This screen shows that all arrays are visible.

When the arrays are not visible, the box becomes red.

System Profiling
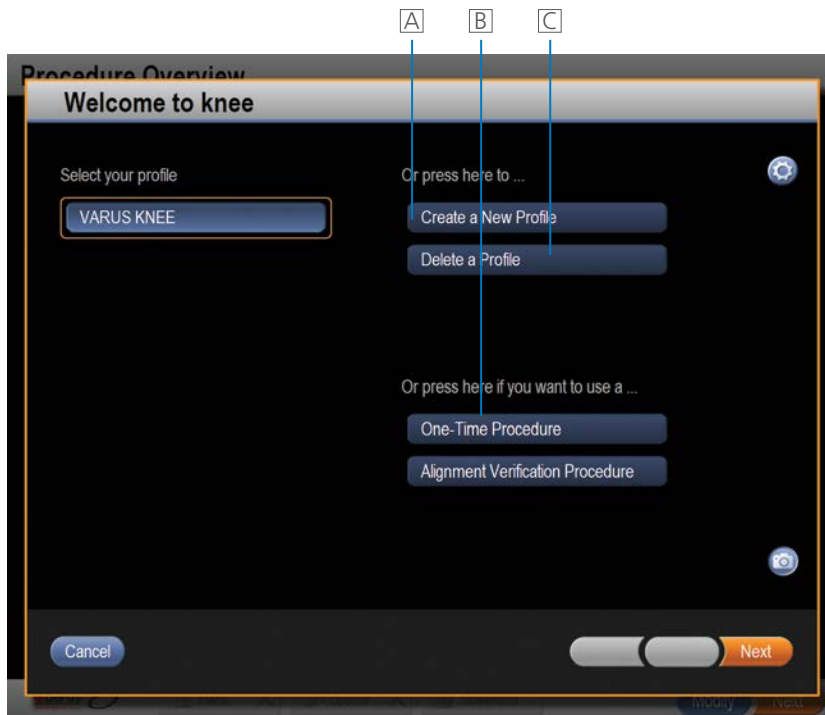
Welcome Screen

Select User Profile

If the surgeon has already created a user profile he/she can select his/her profile and begin by selecting the procedure he/she will use. The surgeon can also create more procedures/workflows under his/her profile name (see below).

A: Create a User Profile

If the surgeon has not already created a profile he/she can select this option and create a profile. The surgeon will be taken to the Enter Profile Name screen, for example, John Smith.

B: One-Time Procedure

The surgeon can choose to use the system to produce a one-time only procedure. By pressing this, the surgeon will be taken to the Choose System Components screen (see page 6).

The settings entered in the one-time procedure will not be saved.

C: Delete a User Profile

It is possible to delete user profiles from the system by choosing the Delete a User Profile button.
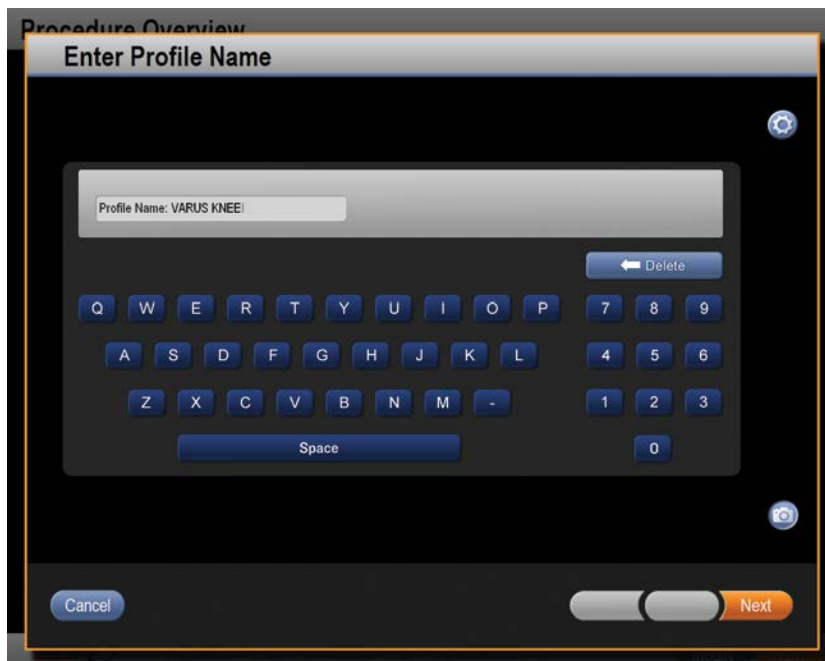
Enter Profile Name Screen

System Profiling

The Choose System Components screen allows the surgeon to choose the implants he/she will be implanting. The surgeon can also select the instrumentation he/she will be using during the surgery.
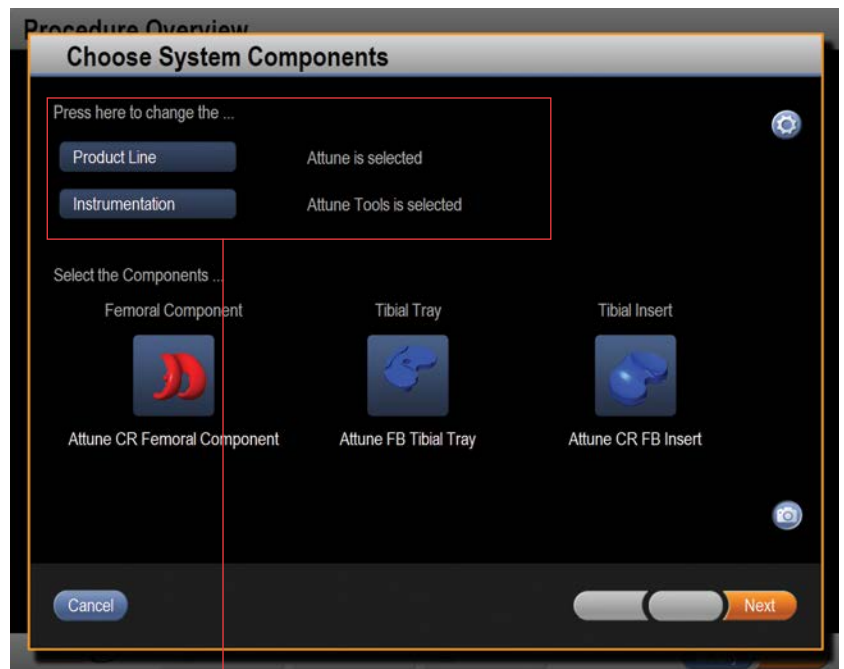
System Components Selection Screen

The Selection screen can be accessed by touching either the Product Line or the instrumentation buttons.
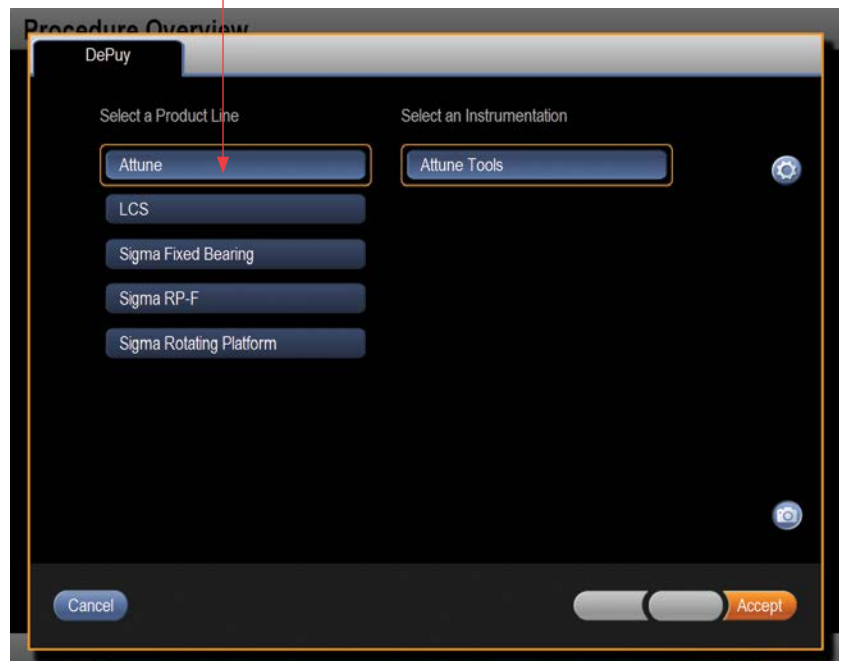
System Profiling
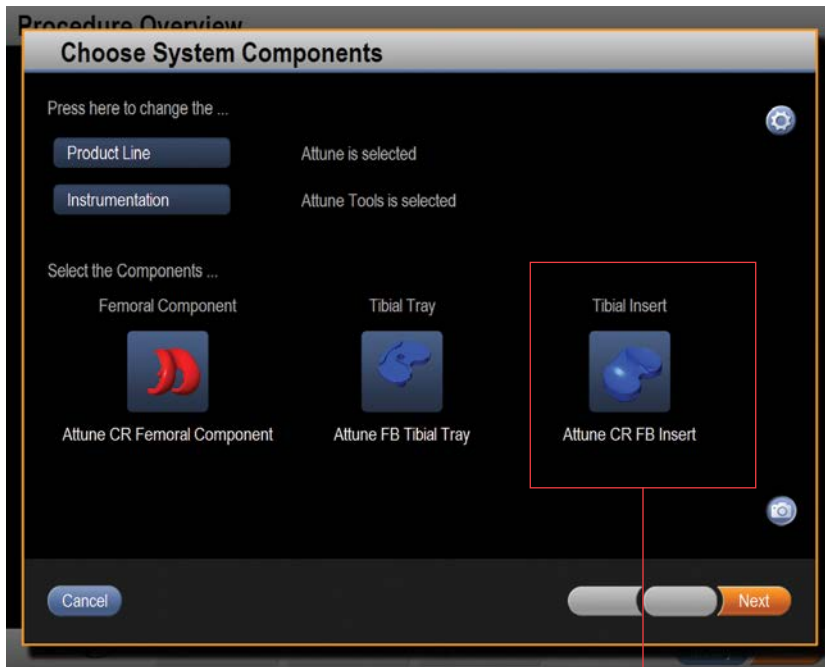
Select the Components

If the implant components that are automatically selected are not what the surgeon wants to use, he/she can touch either the Femur, Tibial Tray or Tibial Insert buttons to change the components.

When the component image is pressed, the component list is displayed. Select the appropriate implant. The surgeon will see a list of compatible components (compatible with the Insert and Tibial Tray selected before) and a list of non-compatible components.

The system will allow a surgeon to select a non-compatible component, but if he/she does so the system will change the other components to match this new selection. A message will appear below the changed implant to notify the surgeon that it was updated.

The surgeon should verify all system components and touch Next after the desired selection is confirmed.

System Profiling

A: Workflow Sequence

After the implant selection is made, the surgeon selects the workflow sequence. Some options may or may not be available, based on the implant that the surgeon has selected. For example, LCS® COMPLETE™ Knee System will only allow the Tibia First option.

ATTUNE System will allow all available options:

• Tibia First: Resect tibia, perform soft tissue balancing, store gap dimensions, resect distal femur, resect A/P femur. This workflow allows for gap equalization and femoral rotation optimization based on tibial resection.

• Femur First: Resect distal femur, resect A/P femur, resect tibia. The system does not perform joint gap equalization, storing of gap information is optional. Femoral rotation is based on anatomical landmarks. (This is a measured resection technique.)

• Hybrid Tibia First: Resect tibia, resect distal femur, perform soft tissue balancing, resect A/P femur. This workflow allows for femoral rotation optimization based on tibial resection. It does not perform gap equalization.

• Hybrid Femur First: Resect distal femur, resect tibia, perform soft tissue balancing and resect A/P femur. This workflow allows for femoral rotation optimization based on tibial resection. It does not perform gap equalization.

System Profiling

A ☐   B ☐
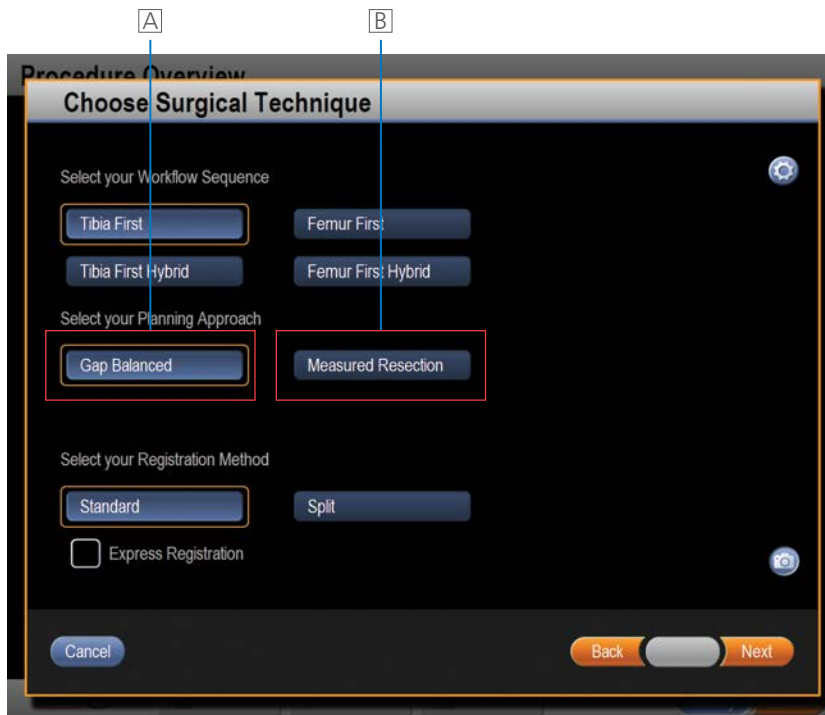
Planning Approach
(There are two approaches available).

A: <u>Gap Balanced:</u> For the Tibia First workflow, the system does gap balancing and femoral rotation optimization.

For Hybrid workflows, the system optimizes femoral rotation only. Gap Balanced approach cannot be used with Femur First workflow.

Tibia First, Gap Balanced is the preferred surgical approach when using Rotating Platform knees as it may help reduce the risk of instability.

B: <u>Measured Resection:</u> This is the measured resection approach where all cuts are made in reference to bony landmarks identified during registration.

No automatic femoral rotation optimization is performed, gap balancing is optional.

The system refers to Epicondylar Line, Posterior Condyles and Whiteside's Line for rotation.

ℹ️ **INFORMATION**

It is possible to do a full gap balanced workflow with the measured resection approach.

System Profiling

Select Registration Approach

A: <u>Standard:</u> All registration is done before any planning or bone resections. Valid for all workflows. Sequence of steps: Femoral registration, tibial registration, tibial planning, tibia resection, soft tissue balancing, store gap information, femoral planning, femoral resection.

B: <u>Split:</u> Valid for Tibia First workflow sequence only. Sequence of steps: Tibial registration, tibial planning, tibial resection, soft tissue balancing, store gap information, femoral registration, femoral planning, femoral resection.

C: <u>Express Registration:</u> When this box is checked, it enables an Express workflow. This system reduces the number of data points that are collected during registration.

- No registration of anterior tibial cortex, and reduced registration of anterior femoral cortex

- Reduced number of data points registered on femoral condyles and tibial plateau. Since the number of data points registered is reduced, extra care must be taken to ensure correct and valid data points (high and low points) are registered

- When enabled, a generic bone image is placed behind the registered points. A custom bone morph is not generated, however accuracy is in no way affected

- If complete registration with bone morph is desired, leave this box unchecked
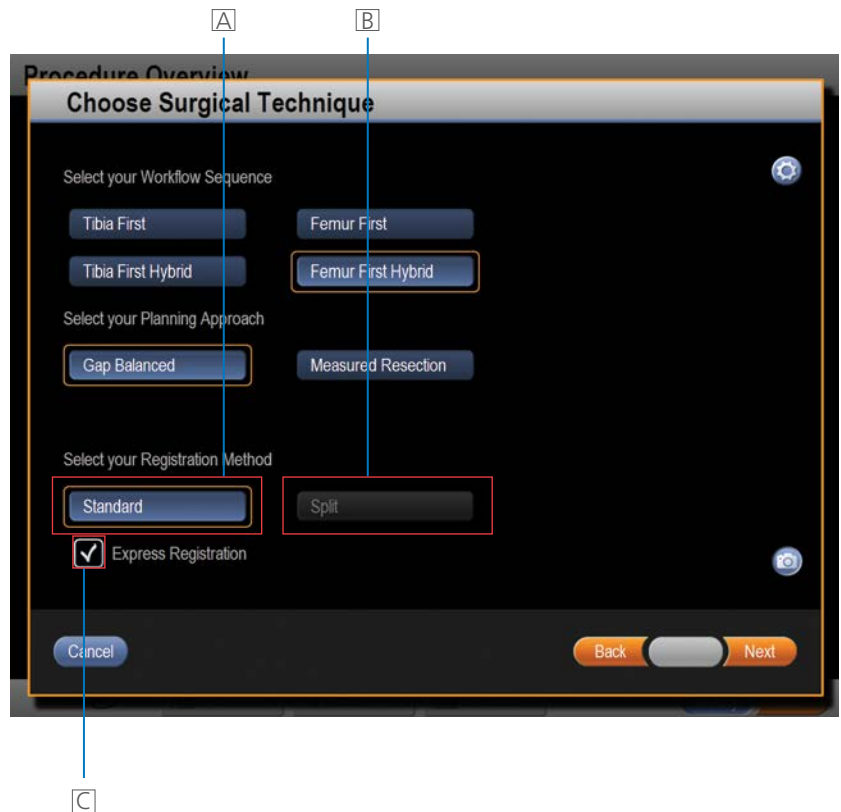
System Profiling

Femoral Rotation and Alignment

Options for Measured Resection

Choose Femoral Alignment screen is available only with Measured Resection workflows and will not appear with Gap Balanced workflows.

A: The surgeon can reference the femoral rotation from either Epicondylar Line, or Posterior Condyles, or Whiteside's Line.

B: A/P alignment of the femur can either be anterior referencing or posterior referencing.

System Profiling

A: Rotation Reference

The surgeon can select the rotation values that are displayed on the femoral planning screen. The system will always reference the femoral rotation from the tibial cut to ensure a rectangular flexion gap for a balanced technique. These numbers show that rotation in reference to the Epicondylar Line, Posterior Condyles and Whiteside's Line. The surgeon can choose to either display or hide the rotation number as it relates to the Epicondylar Line and Whiteside's Line. The rotation value is always displayed as it relates to Posterior Condyles.

B: Navigate To

Planned Resections: Surgeons plan their bone resections on the planning screen, go to the navigation screen and pin the block in place when they achieve all zeros on the navigation screen. This is where they match the yellow (planned) plane with blue (actual) plane.

Navigate To

Bone References: Surgeons plan their bone resections on the planning screen, go to navigation screen and pin the Block in place when they achieve absolute planned values on the navigation screen. When the yellow plane matches with the blue plane, screen displays the actual planned values versus all zeros.
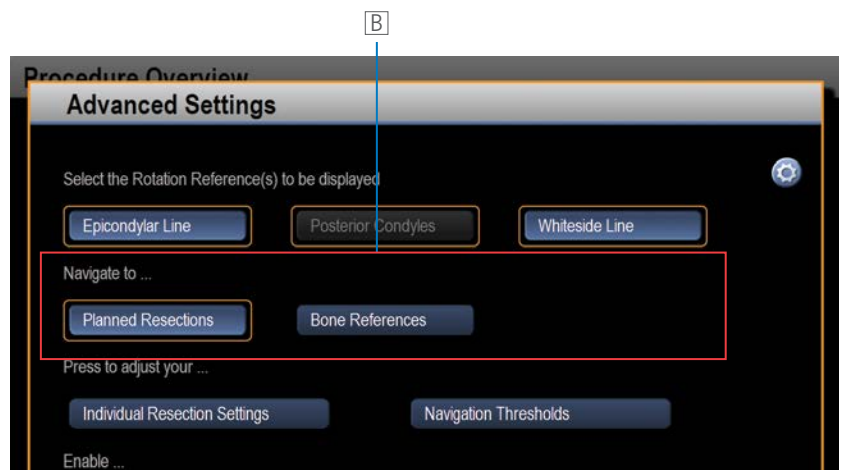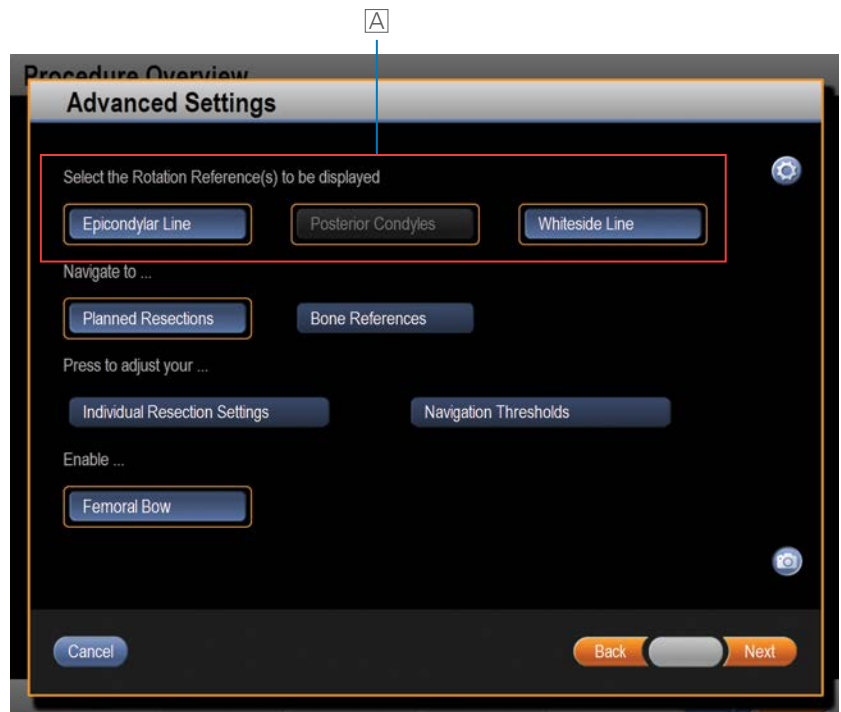
ℹ INFORMATION

If Whiteside's Line is not selected, it will not be acquired during registration.

System Profiling
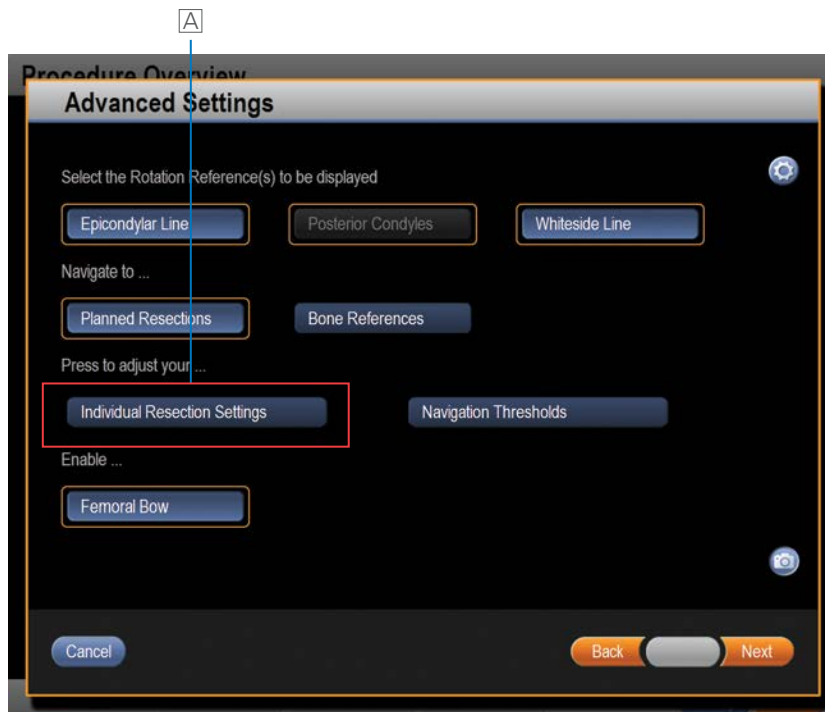
A: Adjust Individual Resection Values

Default values for different bone resections can be set at this step.

This allows the surgeon to individualize bone resection and its orientation.
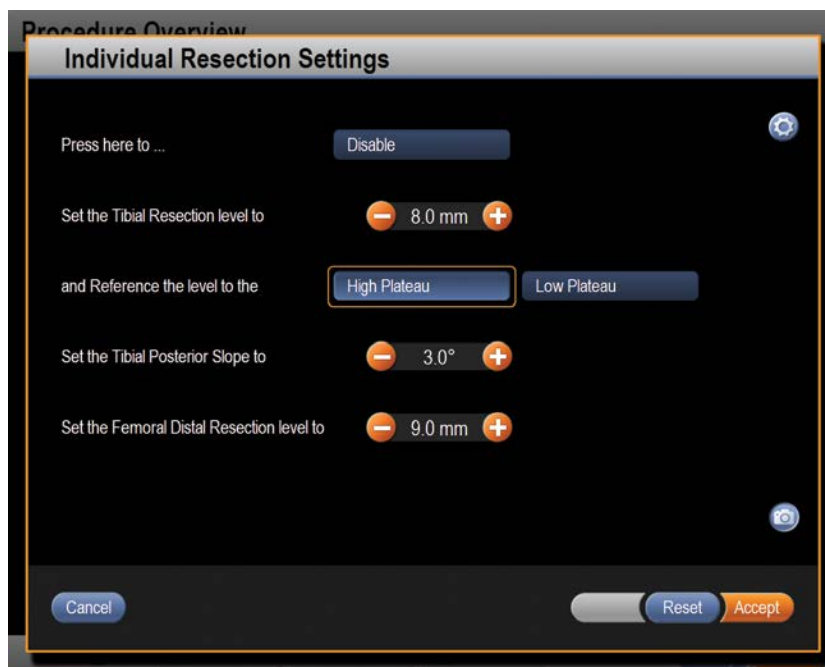
ℹ️ **INFORMATION**

A 9 mm distal resection will match the thickness of the implant.

System Profiling

A: Adjust Navigation Thresholds

This option refers to the dials that are displayed on the navigation screen. Dials turn green when the Cutting Block is within the range set by the surgeon in this step.
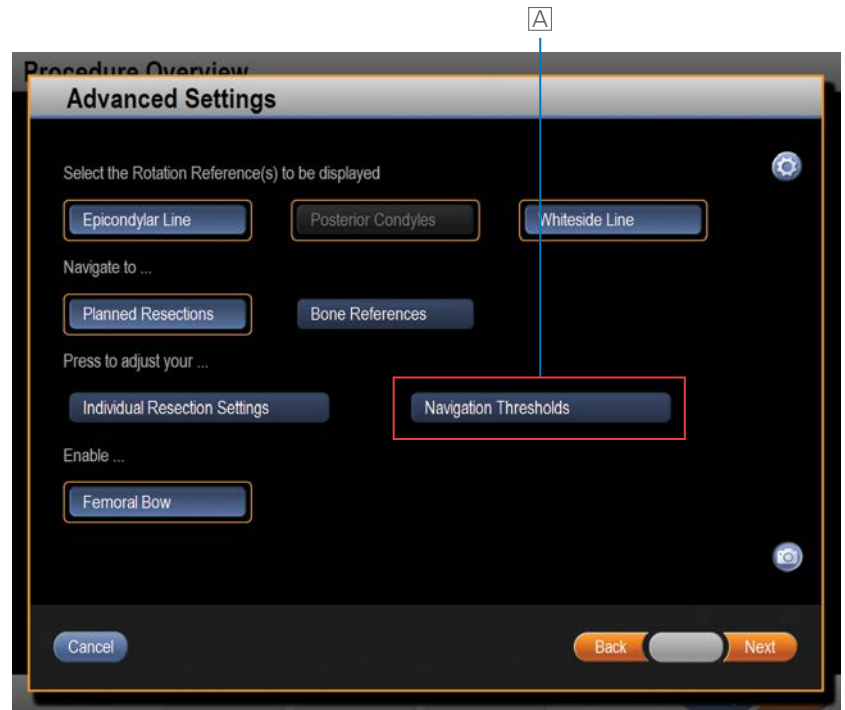
This is only a supplemental visual cue, and does not tell the surgeon if the block should be pinned as soon as dial turns green. The number at the center of the dial will still show the actual numeric position of the Block.

All values can be reset to zero by pressing Reset.

ℹ INFORMATION

+/- 0.5 mm results in a 1 mm threshold, with .5 mm on either side of the planned value.

System Profiling
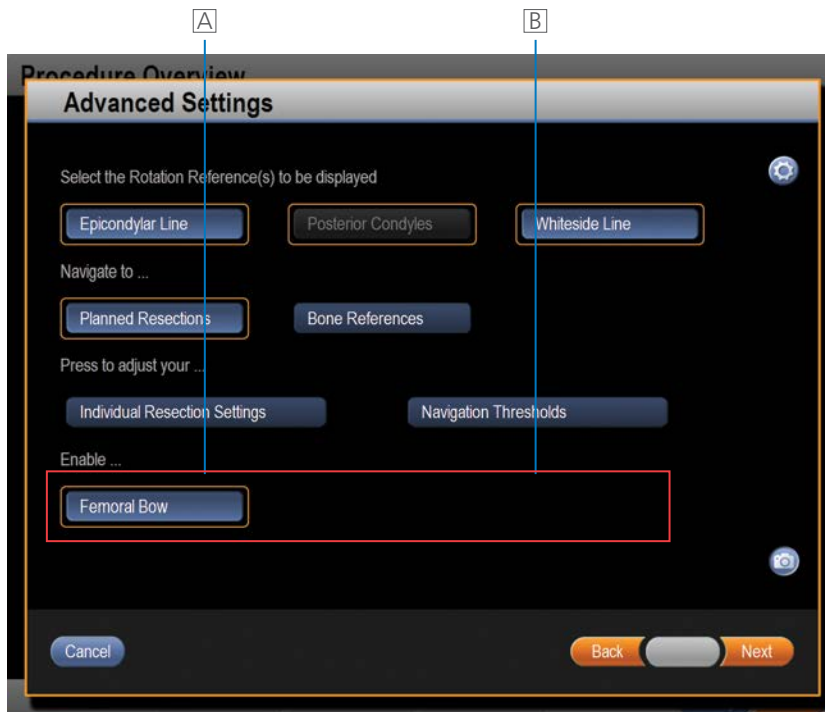
A: Kinematic Analysis

The system displays how the femur is tracking on the tibia with either trials or implant in place at the end of the case.

B: Femoral Bow

The surgeon chooses to either register or not register the femoral bow. If registered, the system suggests femoral component flexion to avoid notching the shaft of the femur in case a positive angle is measured.

If skipped, or if negative angle is measured, the system recommends zero degrees of femoral component flexion during femoral planning. Care should be taken when registering femoral bow to ensure no soft tissue is trapped under the instrument used (see page 35).

If the Cutting Block Adapter is not placed correctly on the bone, the system may register incorrect values affecting femoral implant flexion.

> **i INFORMATION**
>
> *If an angle greater than ten degrees is measured, the system will set the angle to ten degrees and display an error message.*

System Profiling

Confirm Procedure

At this stage the procedure can be confirmed and saved or it can be modified. Press the Modify button to modify the procedure.

To choose another procedure or profile, press the Modify button in order to select a new one.

Enter Patient Name and ID

Enter the patient's name and ID by using the touch screen keyboard. This information will be displayed on all subsequent screens.

Select Treatment Side

Press the appropriate button that corresponds to the knee to be treated.
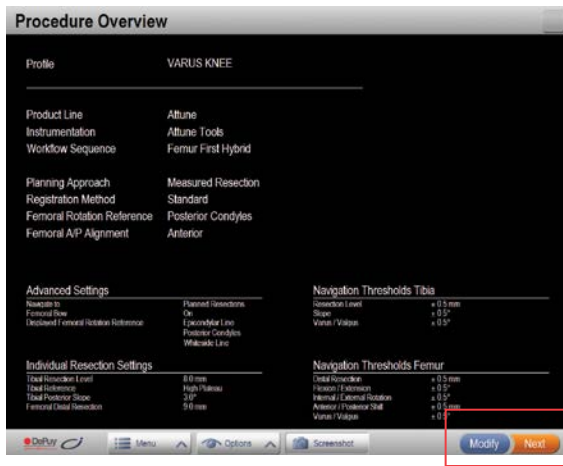
Confirm Procedure Screen
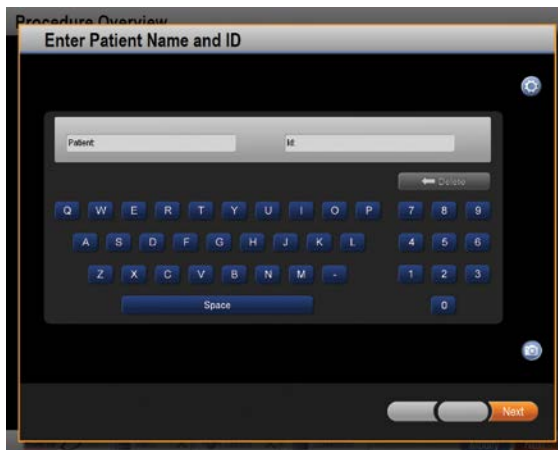
Enter Patient Name and ID Screen

Procedure Selection Screen

Incision and Exposure

The INTUITION Instruments are designed for both standard open and minimally invasive approaches to the knee.

Incision and exposure should be performed using the surgeon's preferred technique.

ℹ **INFORMATION**

Excise any hypertrophic synovium and a portion of the infrapatellar fat pad to allow access to the medial, lateral, and intercondylar spaces.

Before proceeding, consider removing prominent osteophytes, particularly medial and lateral osteophytes, as they can affect soft tissue balancing.

Accurate patella alignment is important for proper placement and tracking. It is recommended not to drill the patella lug holes prior to the trialing step so that correct rotation and position of the patella trial may be assessed.

Pinning

The ATTUNE Knee System has specifically designed pins to increase the stability and functionality of the instruments. The INTUITION Instruments are designed to be used with the Single-Use Pin Pack (2544-00-111) that contains Universal Pins and Threaded Headed Pins.

Universal Pin

The Universal Pin* can be drilled in or hammered in, and drilled out or pulled out using the Pin Jack.

Threaded Headed Pin

The Threaded Headed Pin* is designed to be inserted and removed with a Power Drill. These pins are best used to secure blocks against a flat surface such as cut bone.

*Included in the Pin Pack

Threaded Non-Headed Pin

The Threaded Non-Headed Pin is also available and is designed to be inserted and removed with a Power Drill.

Pin Jack

ⓘ INFORMATION

Steinmann Pins are compatible with all pin holes throughout the INTUITION Instruments.

It is recommended to use Threaded Headed Pins through the divergent holes in the A/P Chamfer Block to provide sufficient stability against the distal femoral cut.

Power Driver

Pinning Technique
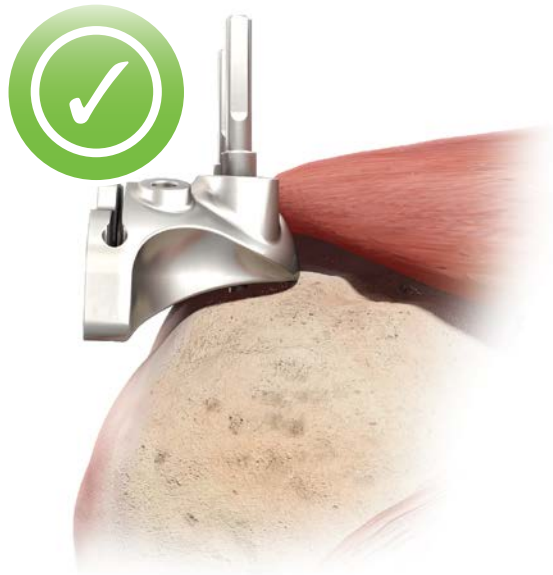
Correct Pinning

Incorrect Pinning

Headed Pins are best used to secure blocks against a flat surface such as cut bone, however, if used on uncut bone with a curved surface, be careful that the Headed Pins are not overtightened as this can lead to tilting and malalignment of the block.

Tibial Array Positioning

The Tibial Array can be placed either inside or outside the incision. If the recommended 2-Pin Array is used for this purpose, either 3 mm, 3.2 mm or 4 mm pins can be used.

The arrays must be placed distant from the intended positions of both the femoral and tibial instruments to avoid any contact during bone resection and drilling.
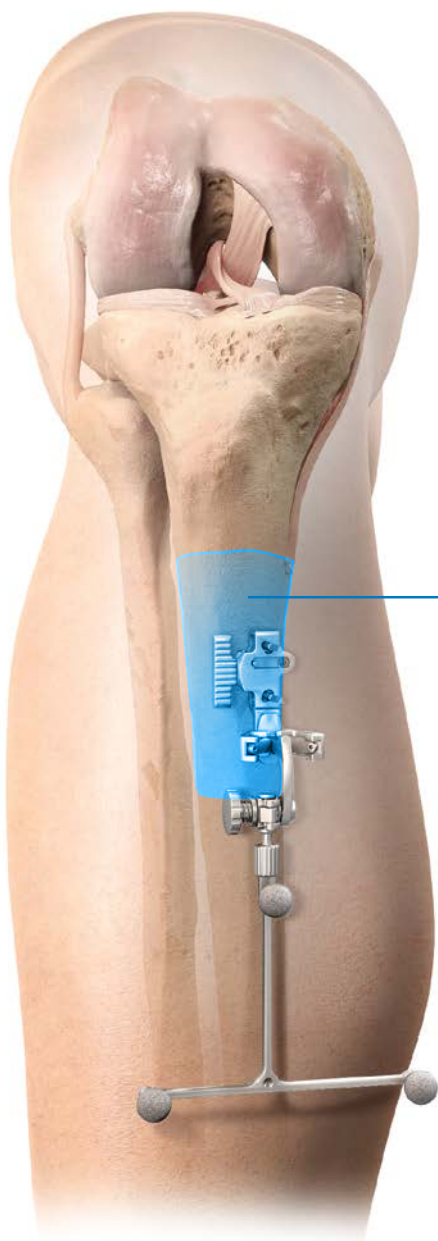
Recommended positioning for the array

Femoral Array Positioning

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.

If the recommended 2-Pin Array is used on the femur, either 3.2 mm or 4 mm pins should be used.

Recommended positioning for the array
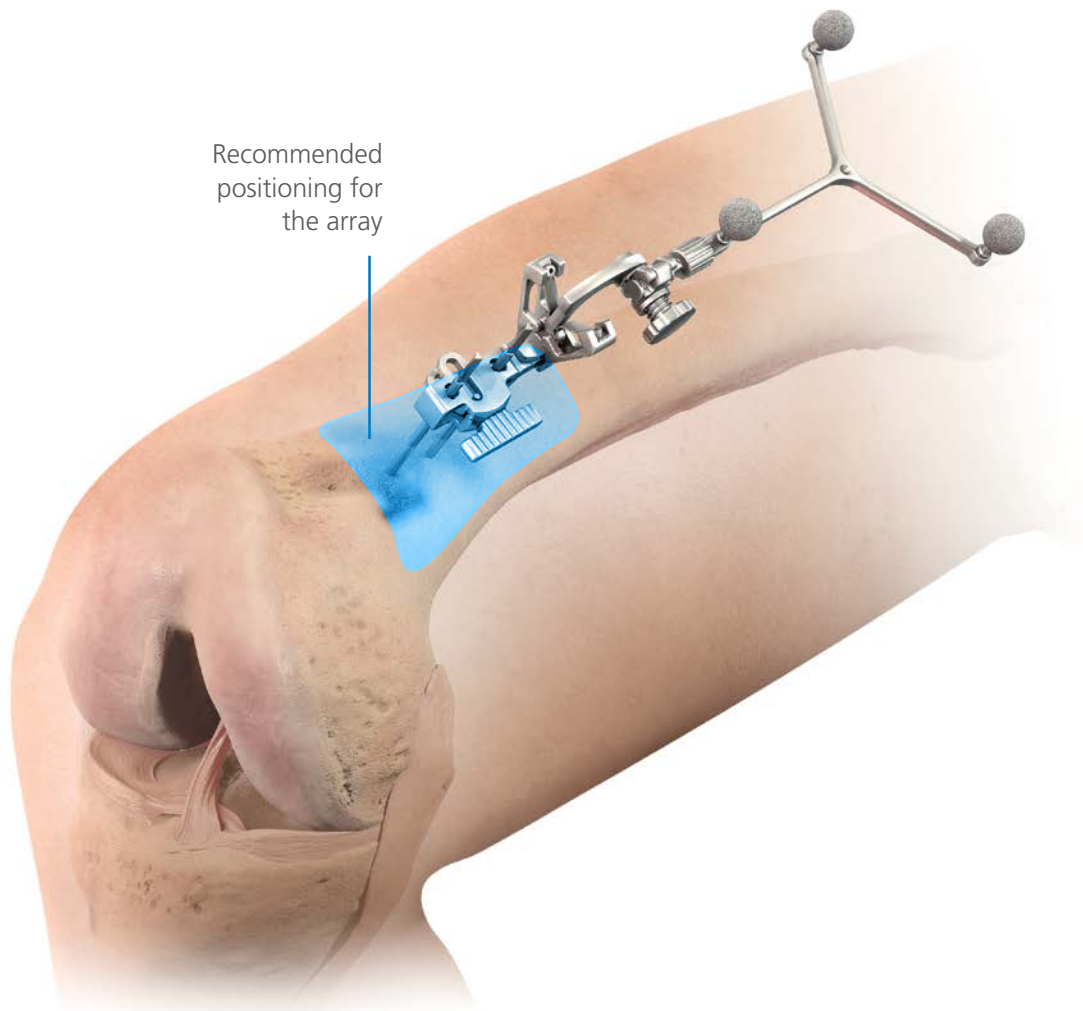
> ### ⓘ INFORMATION
>
> *Care should be taken to position the array clear of the resection guides and any navigated instruments.*
>
> *If the optional 1-Pin Array is used for this purpose, a 5 mm pin must be used for fixation. 1-Pin fixation should be avoided in weak bone quality.*

Tibial Array Fixation

Locking Screw

Place the first pin, measure the distance with the 2-Pin X-Press Bone Fixator and place the second pin.
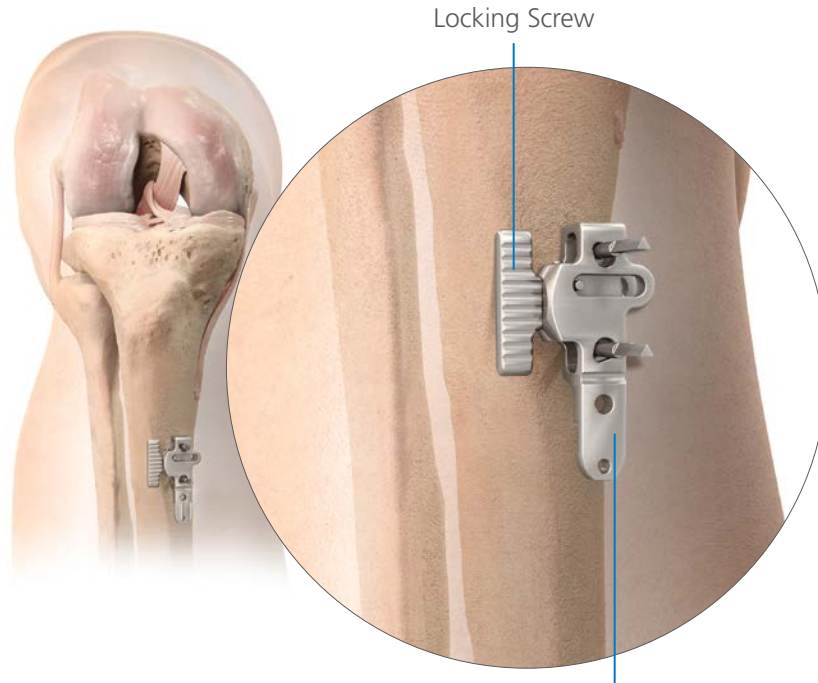
The two pins (either 3 mm, 3.2 mm or 4 mm) are fixed into the tibia. A Drill Guide is used on the pins to avoid any disruption to the soft tissue. The 2-Pin X-Press Bone Fixator is placed on the pins and secured firmly in place with the Locking Screw. The two holes on the array block point distally, with the notch towards the patient.

2-Pin X-Press Bone Fixator

⚠️

The array is then clipped onto the 2-Pin X-Press Bone Fixator. The final position should be adjusted to ensure a clear line of sight between the array and the camera. **Tightening of the array is done using the adjustment screw.** Ensure that the screw is not tightened while in the 'teeth-on-teeth' position.

⚠️ **CAUTION**

The position of the reference arrays must not be moved during the operation as this will lead to inaccurate information being displayed. Make sure all screws are tightened.
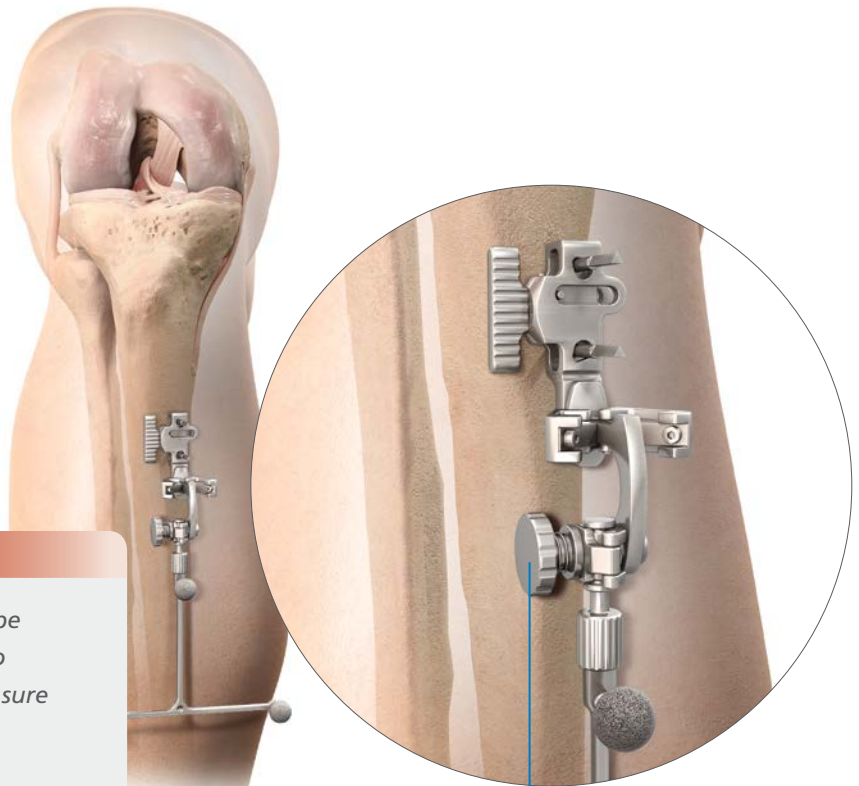
Adjustment Screw

Femoral Array Fixation

A pin position is marked on the femur and a stab incision is made through the soft tissue using a scalpel (if putting the pin through soft tissue).

Using the recommended 2-Pin X-Press Bone Fixator, the pins are drilled into the bone bicortically. The 2-Pin X-Press Bone Fixator should be used with 3.2 mm or 4 mm pins. Alternatively, a single 5 mm bone fixation method can also be used, however this should be avoided in poor bone quality.

⚠️

The final position should be adjusted to ensure a clear line of sight between the array and the camera. **Tightening of the array is done using the adjustment screw.** Ensure that the screw is not tightened while in the 'teeth-on-teeth' position.
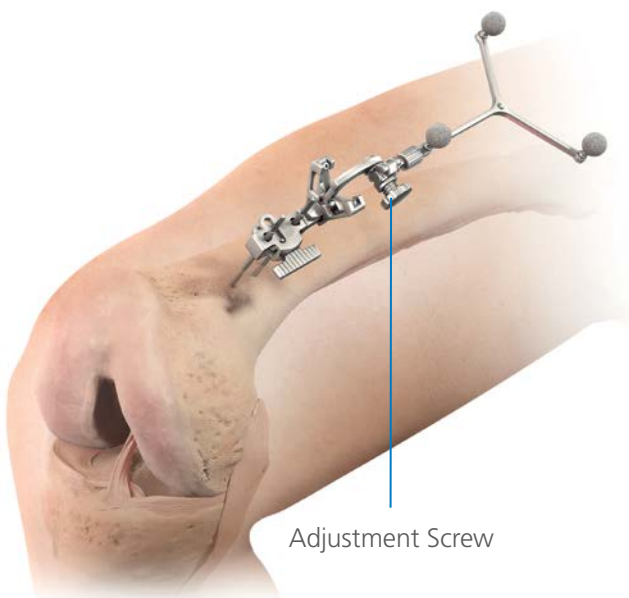
Adjustment Screw

⚠️ **CAUTION**

The position of the reference arrays must not be moved during the operation as this will lead to inaccurate information being displayed. Make sure all screws are tightened.

Camera Alignment
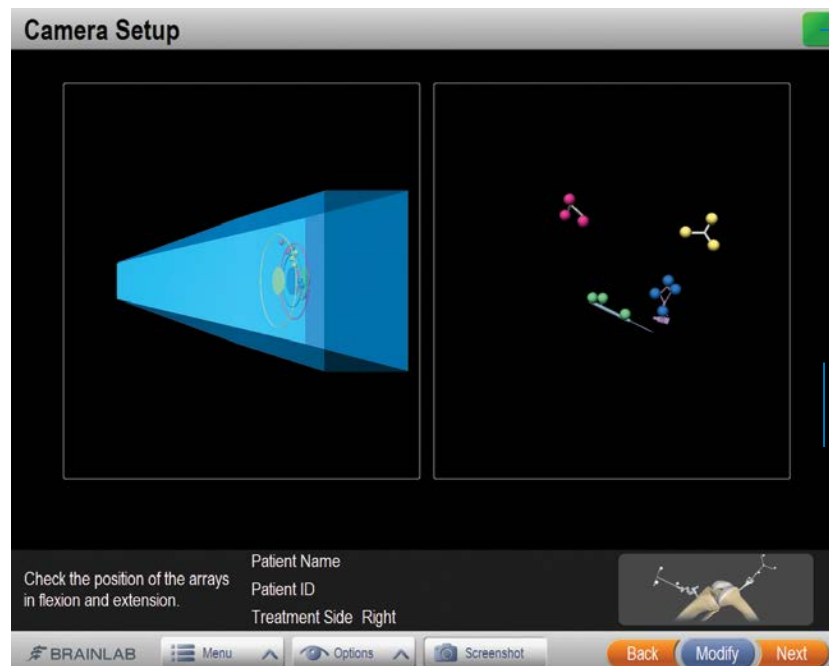
Camera Setup Screen

The status field lights indicate that all instruments are visible

Green: Normal tracking mode
Red: CAS instrument and/or navigation array not visible to camera

The camera alignment window highlights the visibility of the reference arrays to the camera. T and Y Arrays along with other navigated instruments are displayed as different colored dots and circles on the screen. The blue cone represents the camera field of view.

The status field light indicates the visibility of the arrays and instruments. The camera displays can be accessed at any time during the procedure by touching the status field light.

Colored dots represent the positions of the femoral and tibial reference arrays, and the pointer. The software displays the shape of the arrays on the screen to aid differentiating the arrays.

The circles show the position of the instruments in relation to the camera unit's field of view.
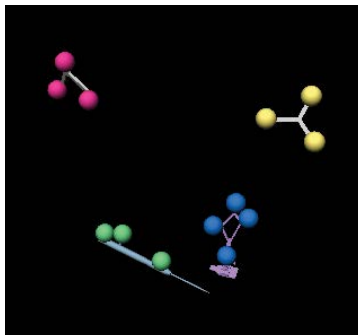
Pink dots: Tibial Array
Yellow dots: Femoral Array
Green dots: Pointer
Blue dots: Additional CAS Tools

> **ℹ INFORMATION**
>
> *The camera should be switched on for 15 - 20 minutes prior to use, as the infrared source needs this 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.*

Registration Methods
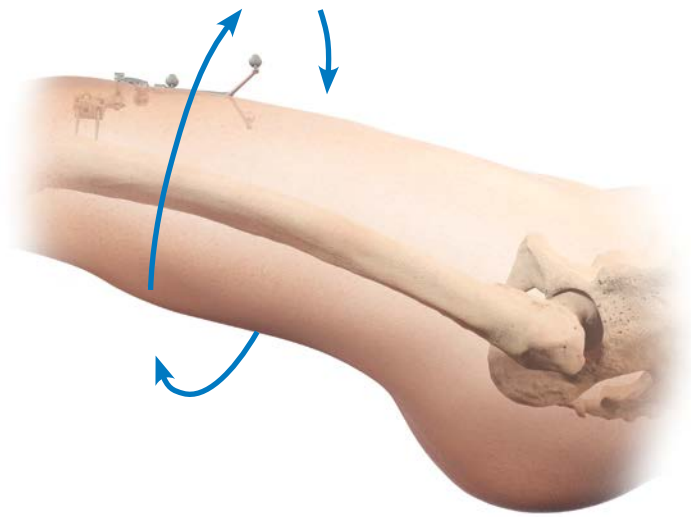
Pivoting

Pivoting involves rotating the femur in a loose arc until a sufficient number of points have been acquired. The software uses this information to determine the rotational center of the femoral head which is the most proximal point of the limb mechanical axis.
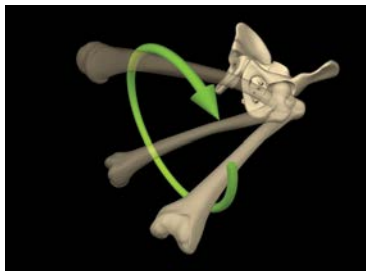
Single Landmark Acquisition

Key single landmarks are registered by touching the appropriate bone structure (or soft tissue covering the bone structure) with the tip of the Pointer and pivoting the Pointer to acquire/register the anatomical landmark. The tip of the Pointer must remain stationary during pivoting.

The following points are acquired in this way:
• Malleoli (medial and lateral)
• Mechanical axes (proximal tibia and distal femur)
• Proximal tibial contour (medial, lateral, and anterior)
• Epicondyles (medial and lateral)
• Femoral anterior sizing point
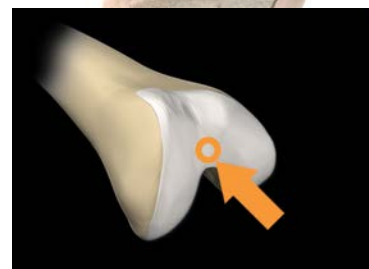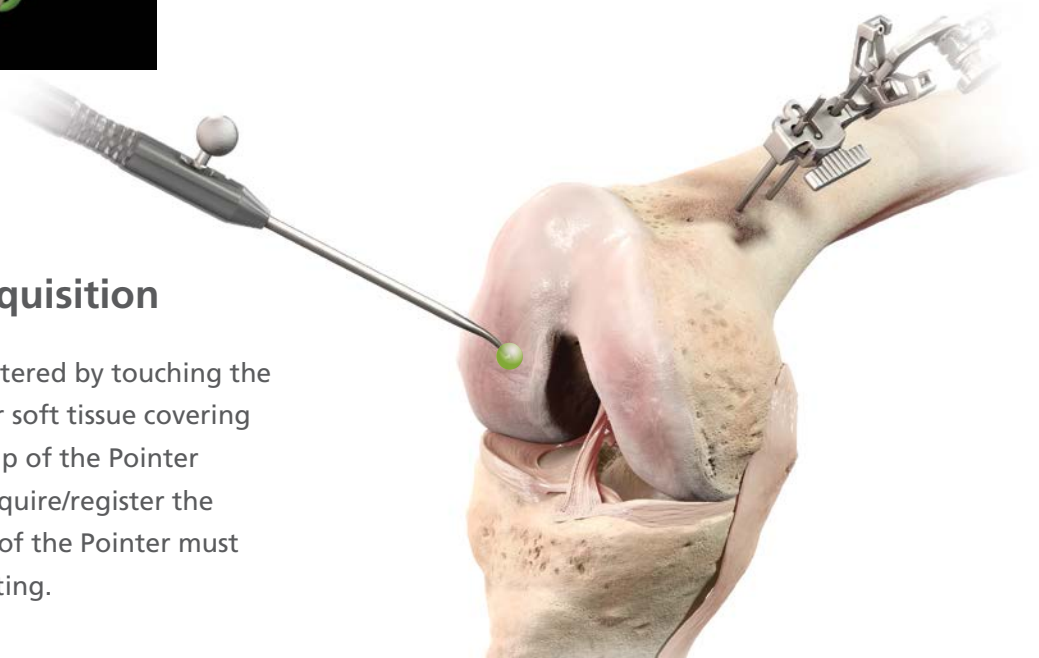
Registration Methods

Acquiring Directions

Some axes and directions are acquired by holding the Pointer absolutely still in a specific alignment. The following directions are acquired in this way:
• Tibial A/P direction
• Whiteside's Line

Multiple Landmark Acquisition

Multiple landmark acquisition registers bone areas. The points acquired are used to calculate resection levels and morph the 3D bone model. Points are acquired by pivoting the Pointer tip and then sliding it along the bone structure.

Dots indicating the registered areas appear on the image of the bone with progress shown on the progress bar. The following points are acquired in this way:
• Tibial plateau (medial and lateral)
• Femoral condyle (medial and lateral)
• Anterior cortex (tibia and femur)
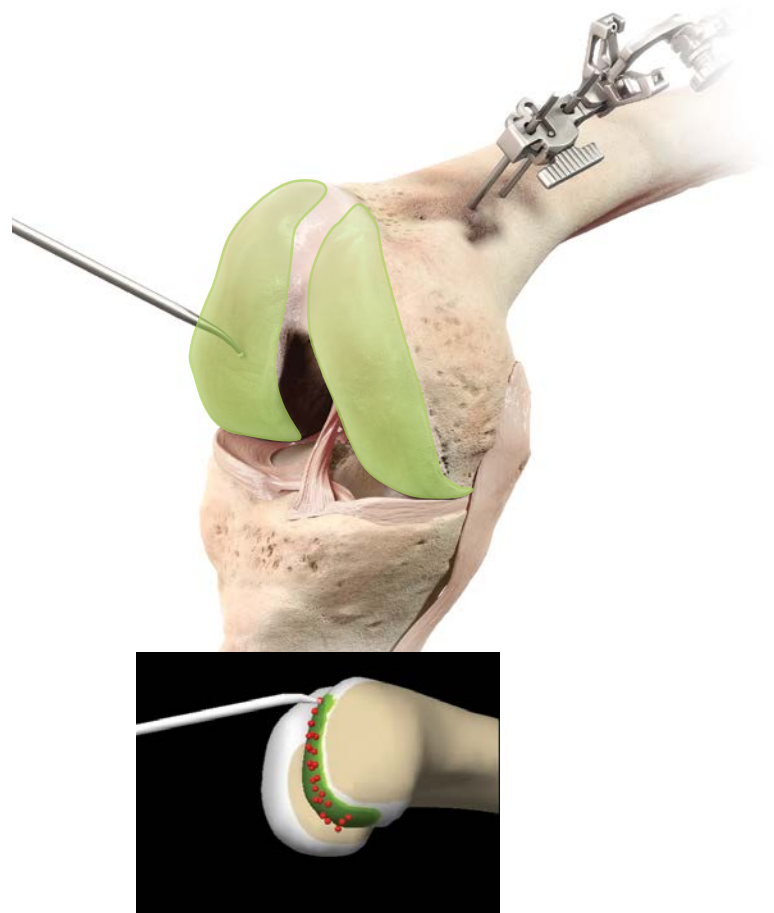
Pointer - Tips and Tricks

1. To acquire points accurately, it is helpful to hold the tip of the Pointer with one hand while pivoting the Pointer with the other. This will ensure that all of the points are registered on the bone, rather than distant from the bone.

Hold the Pointer tip with one hand while pivoting

2. To avoid acquiring unnecessary points before the Pointer is positioned, it may be helpful to cover one of the marker spheres with a hand. This will effectively blind the Pointer from the camera's field of view.

Cover one of the marker spheres to "blind" the CAS camera

3. Make sure all three marker spheres on the Pointer are directed towards the camera unit when acquiring a point.

4. When a point has been successfully acquired, the software will sound an audible 'beep'. This removes the need to refer to the screen as each point is acquired.

> **ⓘ INFORMATION**
>
> *Care should be taken so that the sphere does not become covered by blood or other materials that may affect its visibility to infrared cameras. If at any stage during the procedure the marker spheres become covered with blood or tissue, they may be gently cleaned using a lint-free cloth.*

Calculating the Femoral Head Center

When calculating the rotational center of the femoral head, it is important to make sure that the patient's pelvis is not moved during registration, as this may lead to miscalculation of the femoral head center.

This often occurs in conditions such as:
1. Ipsilateral hip arthritis with restricted hip motion
2. Marked buttock obesity allowing pelvic motion during femoral head center registration.

This point defines the proximal part of the HKA line and femoral mechanical axis.
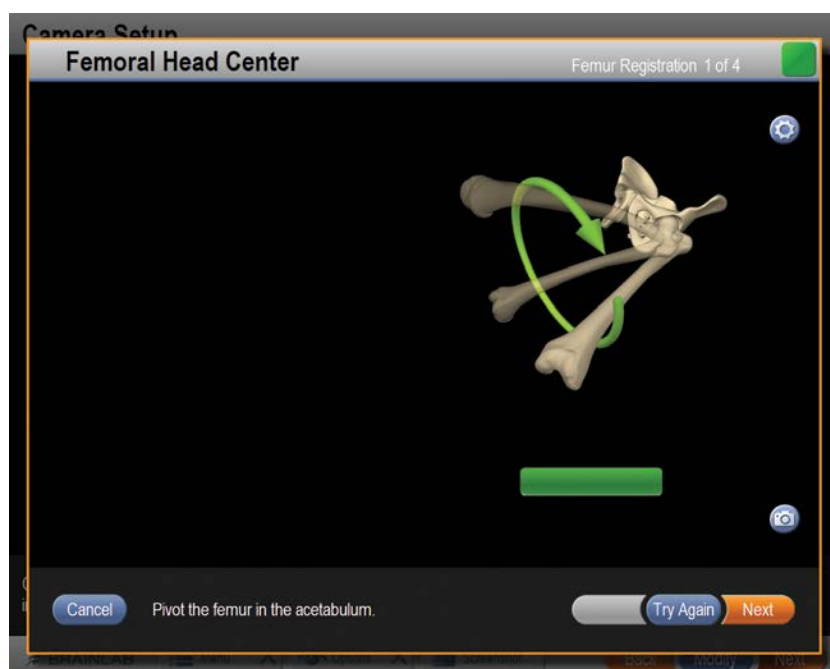
The femur is pivoted using circular motions. The system calculates a series of points to determine the rotational center and will automatically proceed when the rotational center has been accurately calculated. If the level of accuracy is 2.9 mm or better, software automatically progresses to the next step. If it is between 3 mm and 4.9 mm, accuracy value is displayed on screen. Press Next to accept the value or Try Again to re-register. If it is worse than 5 mm, pivoting will restart automatically.

If the accuracy value is still poor after three attempts, system will display a warning to check correct attachment of reference arrays to the bone.

> **ℹ INFORMATION**
>
> *If the surgeon is having difficulty acquiring the femoral head center, it is helpful to have an assistant hold the pelvis firmly.*
>
> *An accuracy of 5 mm corresponds with a deviation of approximately 0.7 degrees with a femur length of 40 cm.*

Femoral Mechanical Axis

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.

Femoral mechanical axis point

The Pointer should be placed slightly medial at the posterior aspect of the femoral notch point (as indicated on screen).

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

> ℹ **INFORMATION**
>
> *It is important that this point is acquired as accurately as possible. If this point is acquired too far anterior, it may exaggerate knee flexion angle. If this point is acquired too far posterior, it may exaggerate knee extension angle.*

Registration of Epicondyles
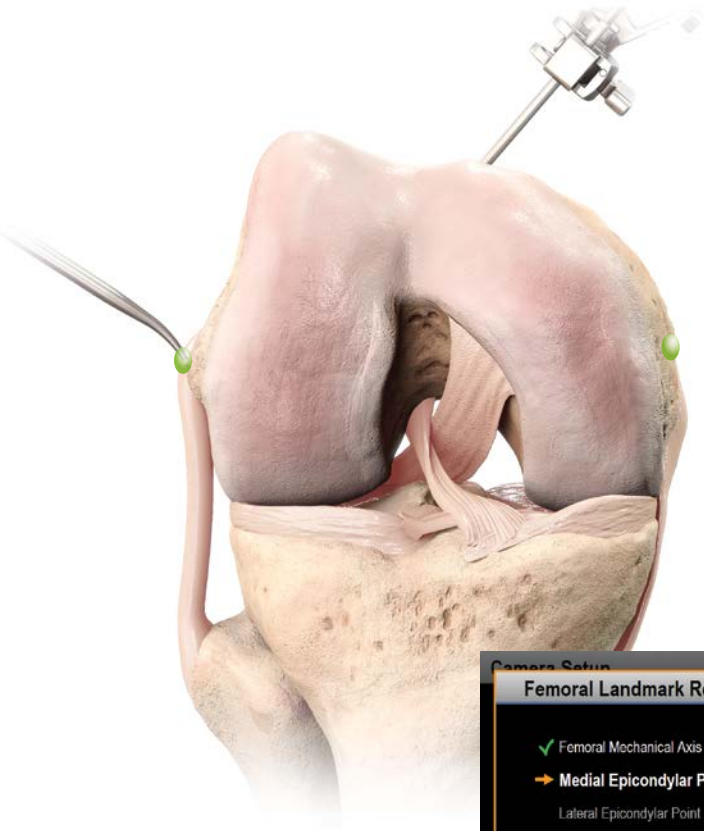
Acquisition of the medial and lateral epicondylar points is used to define the epicondylar axis.
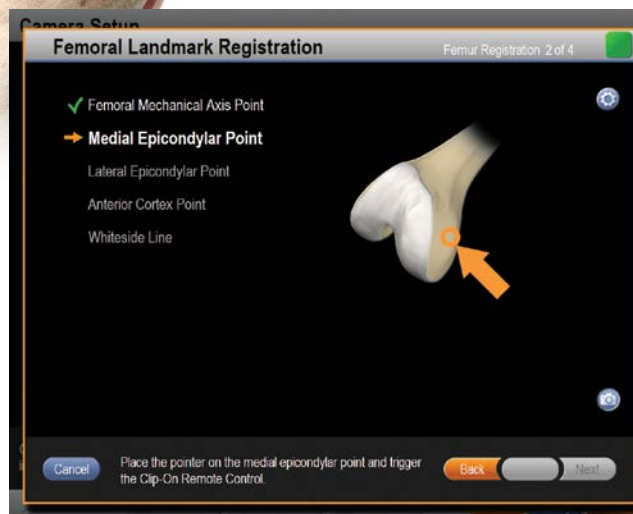
Registration of the Anterior Sizing Point

The femoral anterior sizing point is acquired using the Pointer. Ideally, the Pointer should be placed on a point on the lateral anterior femoral cortex just above the superior border of the patellofemoral articular surface.

It should indicate the place where the superior aspect of the anterior flange of the femoral component would sit flush to the anterior cortex.

This will enable the system to determine the size and position of the femoral implant required.

Femoral Landmark Registration

Femur Registration 2 of 4

- ✓ Femoral Mechanical Axis Point
- ✓ Medial Epicondylar Point
- ✓ Lateral Epicondylar Point
- ➡ **Anterior Cortex Point**
- Whiteside Line

Cancel   Place the pointer on the desired exit point of the anterior femoral resection and trigger the Clip-On Remote Control.   Back   Next

---
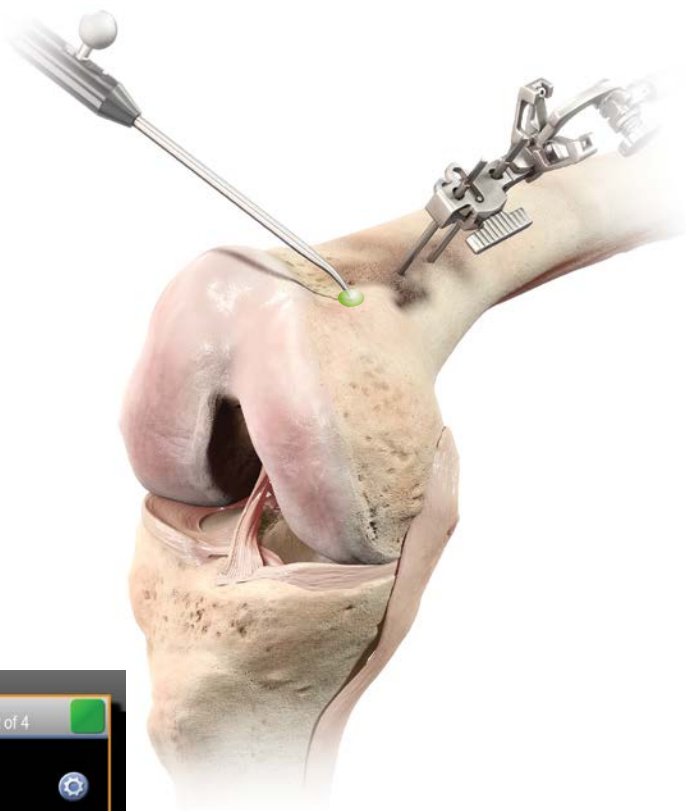
ⓘ INFORMATION

A point should be selected that represents the level of anterior femoral resection, essentially the point where the anterior flange would sit flush on the anterior cortex. Select a lateral point and avoid placement in recessed bone defects to avoid risk of notching of anterior femoral cortex.

Whiteside's Line (Anteroposterior Axis)
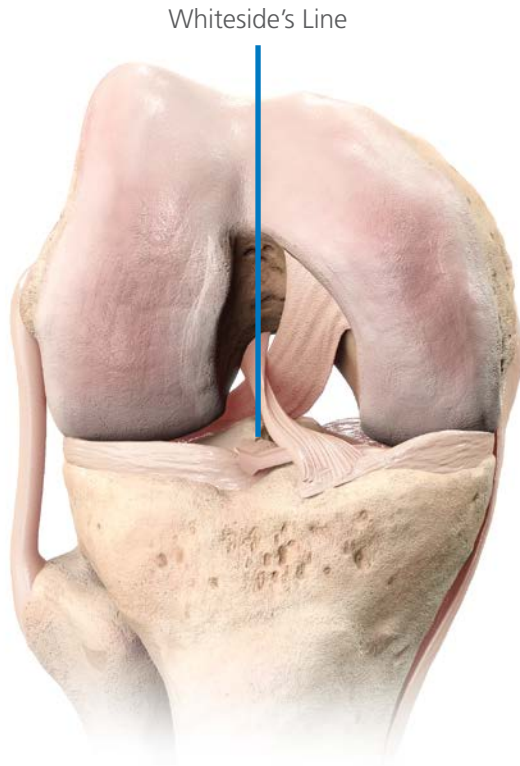
Whiteside's Line

Whiteside's Line is used as an optional reference for femoral component rotational alignment. It may be marked initially using electrocautery. It is easiest to draw by looking along the horizon of the trochlear groove. Once the line is drawn the Pointer can be held along this line.

The Pointer must be held stationary from anterior to posterior while the system acquires this reference.

Femoral Landmark Registration   Femur Registration 2 of 4

✓ Femoral Mechanical Axis Point
✓ Medial Epicondylar Point
✓ Lateral Epicondylar Point
✓ Anterior Cortex Point
➡ **Whiteside Line**

Cancel   Back   Next
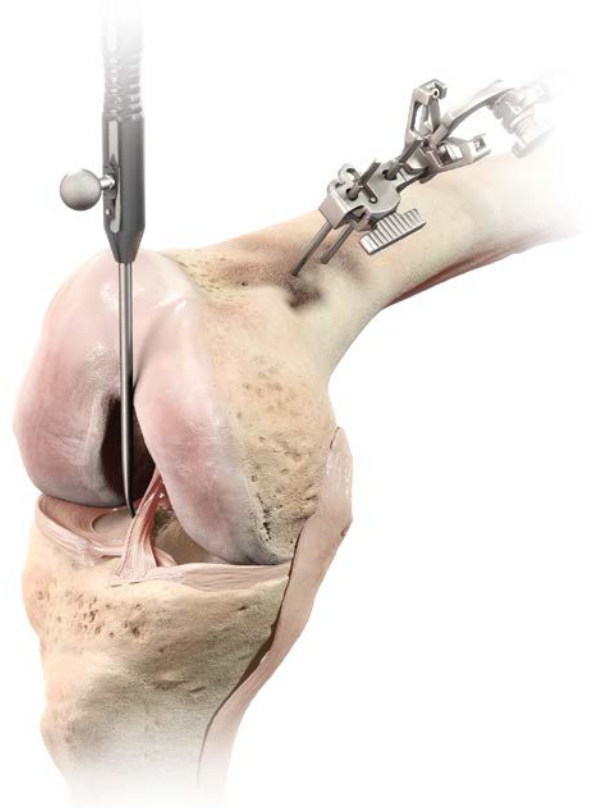
Femoral Condyle Modeling

A fixed 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 points from all the data collected.
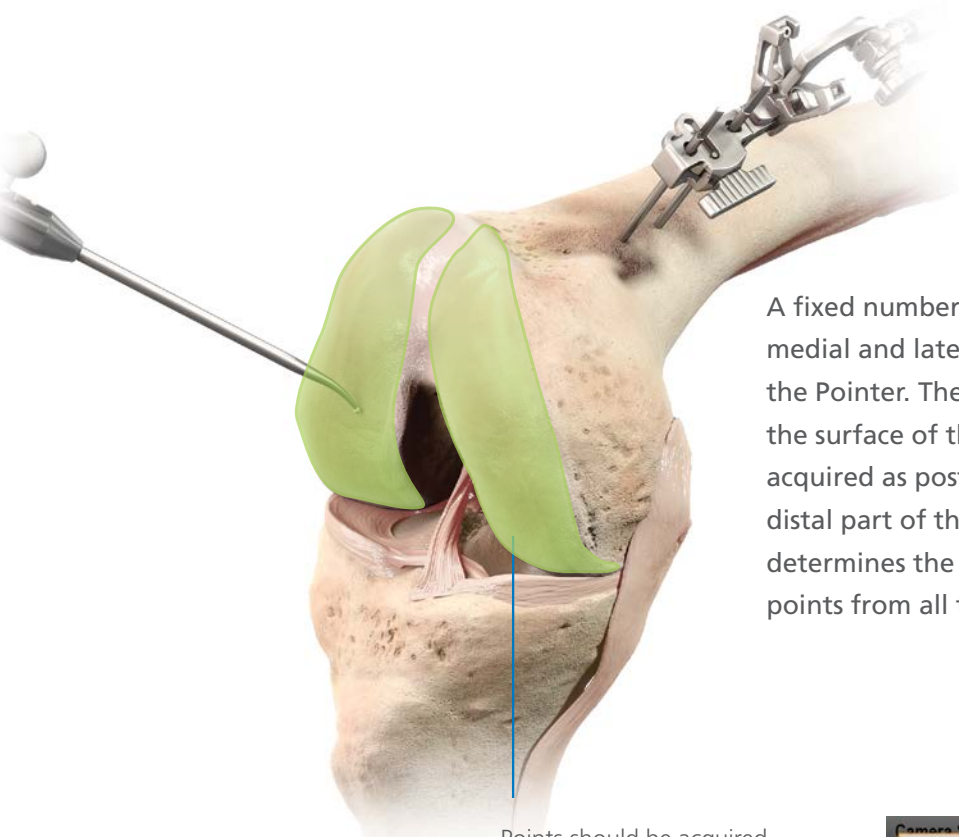
Points should be acquired as posteriorly as possible on the femoral condyles

This allows the software to accurately calculate both the femoral component size and distal resection level. If insufficient posterior or distal points are acquired, the CAS software will ask for the step to be repeated.

The collection of points can be started again by pressing the Try Again button. Care should be taken to remove osteophytes before registration of condyles.

Anterior Cortex
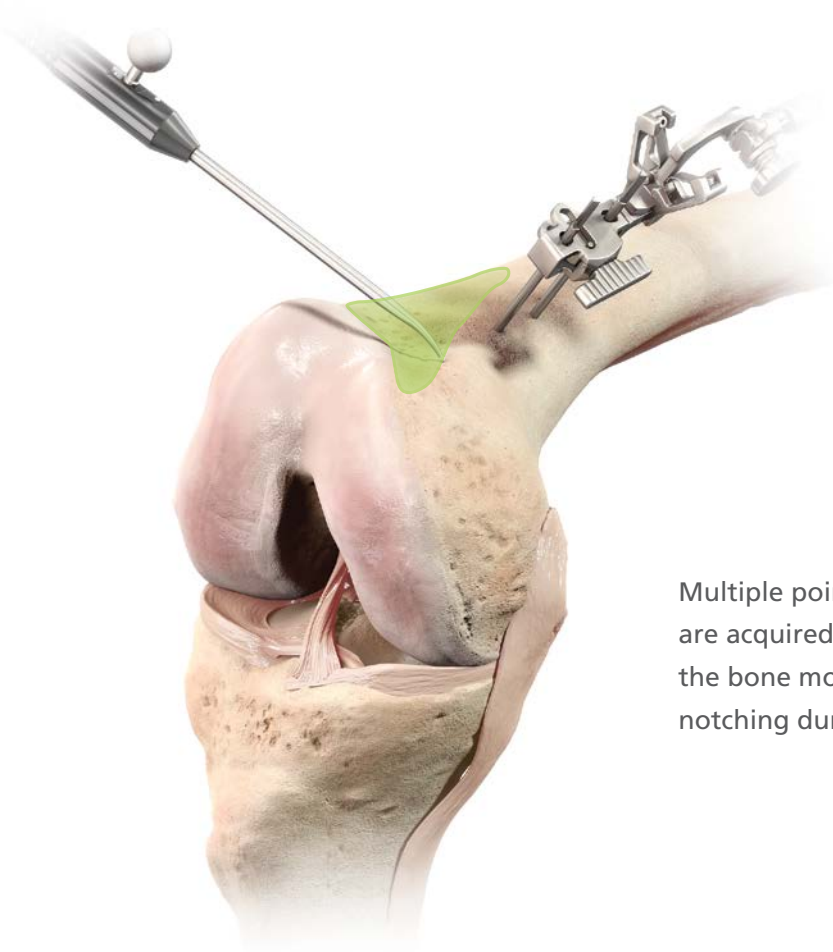
Multiple points along the anterior cortex are acquired using the Pointer to create the bone morph, and to help avoid notching during the planning steps.
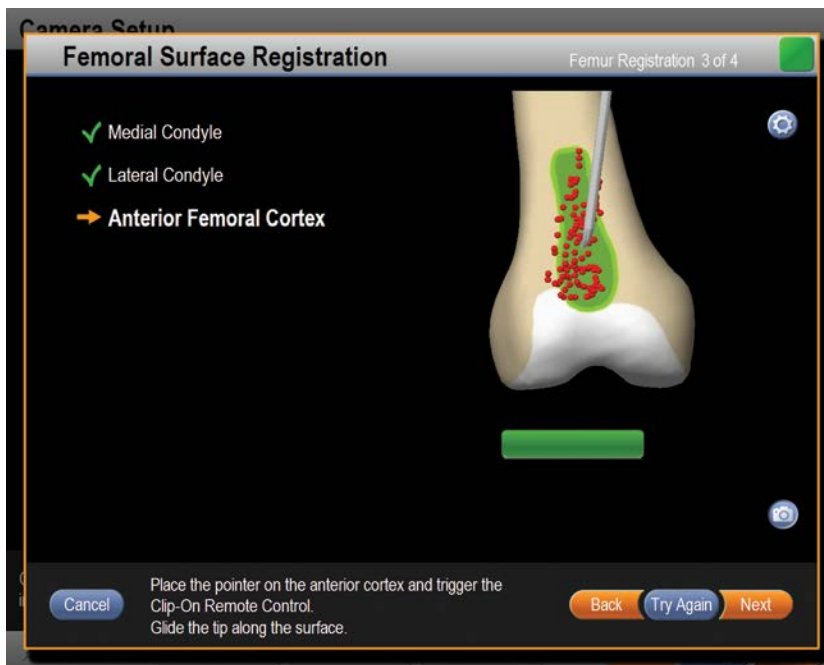
In case the Pointer lifts off the bone, the collection of points can be started again by pressing the Try Again button.

Definition of the Anatomic Axis (Femoral Bow)

Cutting Block Adapter
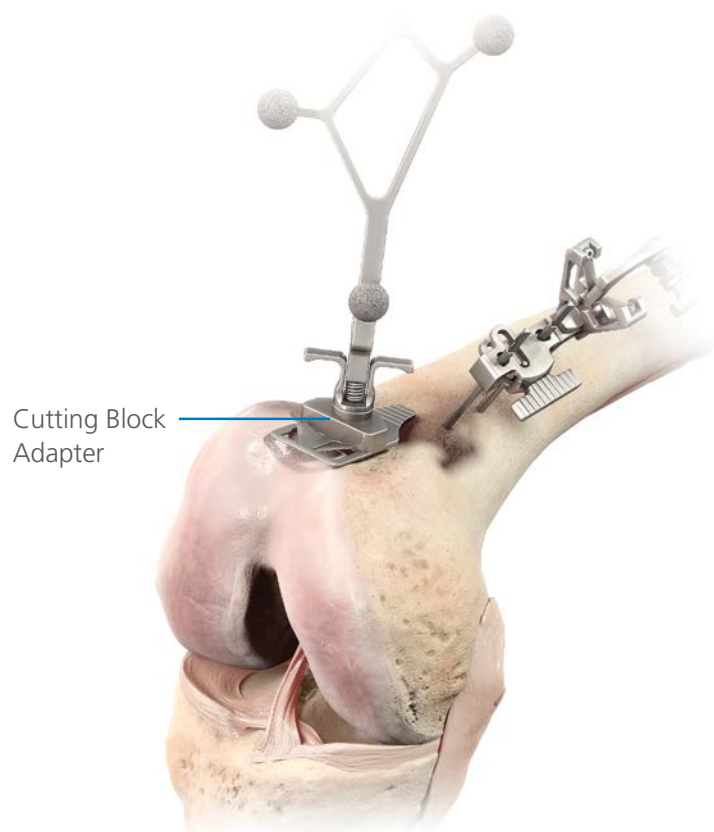
⚠ Place the Cutting Block Adapter on the anterior femur and hold still for a few seconds until the computer registers the anterior cortex reference. This helps determine the anatomic bow of the femur and affects the positioning of the implant for proper flexion and extension.
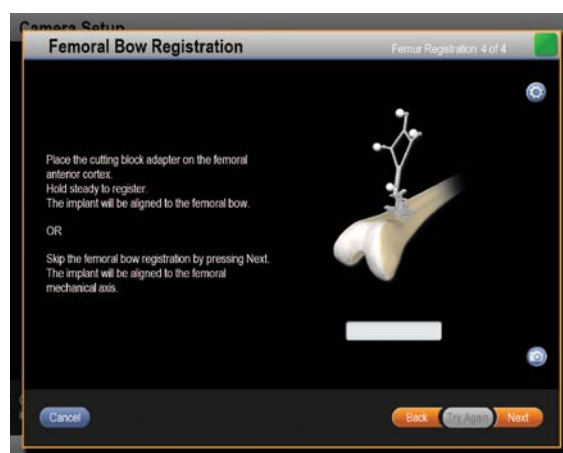
The software will display the angular difference between the mechanical and anatomical axes in the sagittal plane. The femoral component position will be flexed by the same angle to prevent notching of the anterior femoral cortex. Flexion and extension can be adjusted manually during the femoral planning stage. If a negative angle is recorded the angle will be set to zero degrees. If an angle of greater than ten degrees is recorded, femoral flexion angle will be set to ten degrees.

⚠ **CAUTION**

Care should be taken to ensure that the Cutting Block Adapter is sitting on the bone and no significant soft tissue is trapped under it, which may result in an incorrect calculation.

ⓘ **INFORMATION**

This step helps prevent notching in the rare case of distal femoral bowing. If this step is skipped, the risk of anterior femoral notching may be increased.

Femoral Model Calculation and Verification
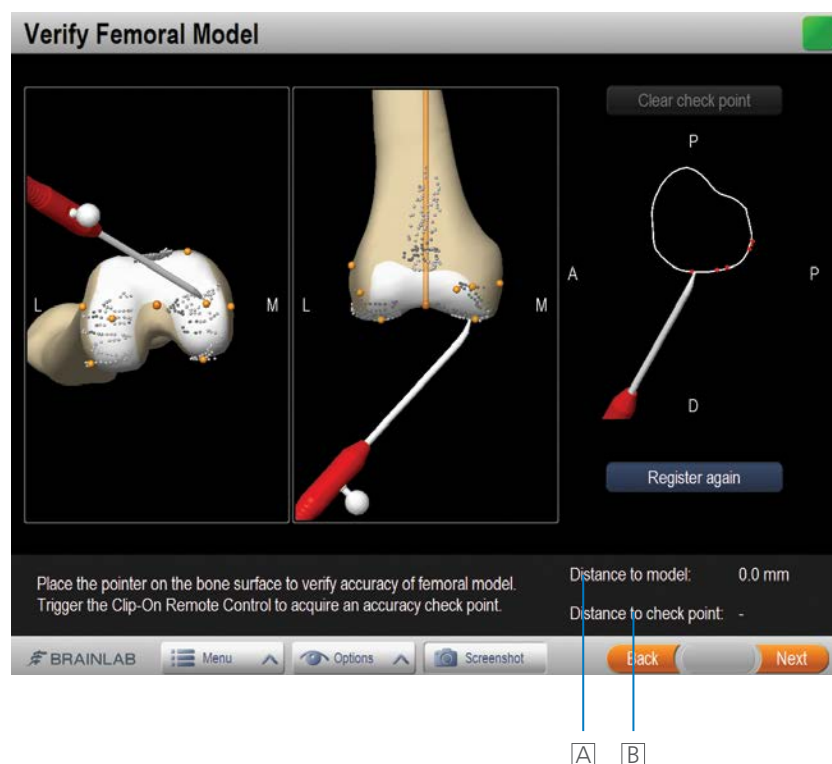
Following registration, the system creates the femoral morph. The accuracy of the morph is checked by holding the Pointer on areas of the femur where points were collected.

A: Distance to Model

The exact deviation from the tip of the Pointer to the model is displayed on the screen as distance to model. The maximum acceptable deviation is less than 2 mm. Acquired points will normally show a deviation of less than 1 mm. Verification of the model will only be accurate in areas where points have been acquired.

B: Array Position Verification

Occasionally, arrays can be bumped intra-operatively. Registration of a check point is useful if the surgeon wants to confirm the position of arrays during the surgical procedure. A point is marked on the bone so it can be identified later. The surgeon registers the check point using the Pointer.

If during the case the surgeon believes he/she is getting inconsistent data as arrays might have been bumped, they can go to the check point to verify position of the arrays (visible in all screens).

Definition of the Malleoli
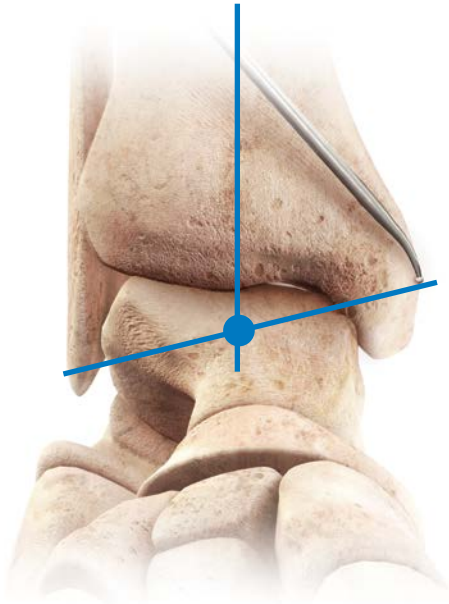
The software uses the medial and lateral malleoli reference points to define the most distal point of the tibial mechanical axis.

The medial and lateral malleoli are defined using the Pointer.

The malleoli can usually be located by palpation before acquiring the points. It is important that draping or bandaging is reduced to a minimum to enable the malleoli to be located.

Place the tip of the Pointer on the medial malleolus and pivot the Pointer. It is important not to move the tip of the Pointer from the bone. 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 distal point of the axis.

> **i INFORMATION**
>
> *It is important that these points are acquired as accurately as possible. If these points are acquired too far anterior, the system may register knee hyper-extension and the surgeon may resect more tibial slope than desired. Similarly, if these points are acquired too far posterior, the system may register knee flexion contracture and the surgeon may resect less tibial slope than desired.*

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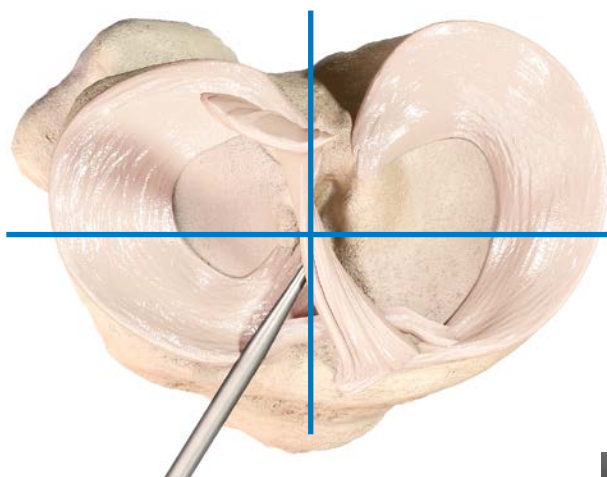
The proximal point on the tibial mechanical axis is defined by acquiring the posterior aspect of the ACL tibial insertion point.

This is indicated by the arrow on the screen. The surgeon can also use the intersection of the mid-coronal and mid-sagittal planes for registration 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.

Proximal point

Distal point

---
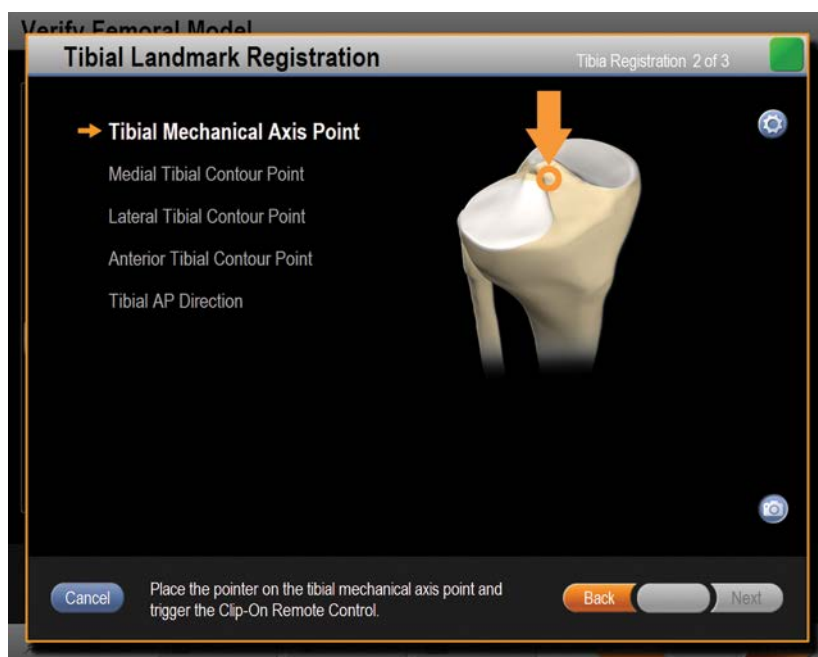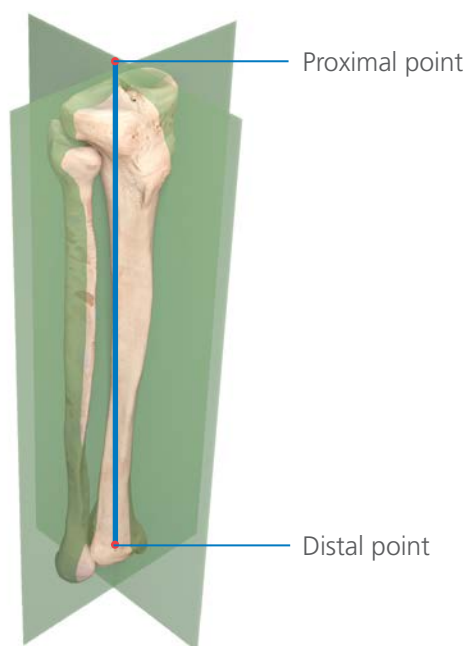
i **INFORMATION**

If the tibial mechanical axis point is acquired too far anterior, the system may register knee flexion contracture and the surgeon may resect less tibial slope than desired. Similarly, if this point is acquired too far posterior, the system may register knee hyper-extension and the surgeon may resect more tibial slope than desired.

Tibial Sizing

After removal of osteophytes, the most medial and lateral points of the proximal tibia are acquired using the pointer (for implant sizing). This is followed by the most anterior point.
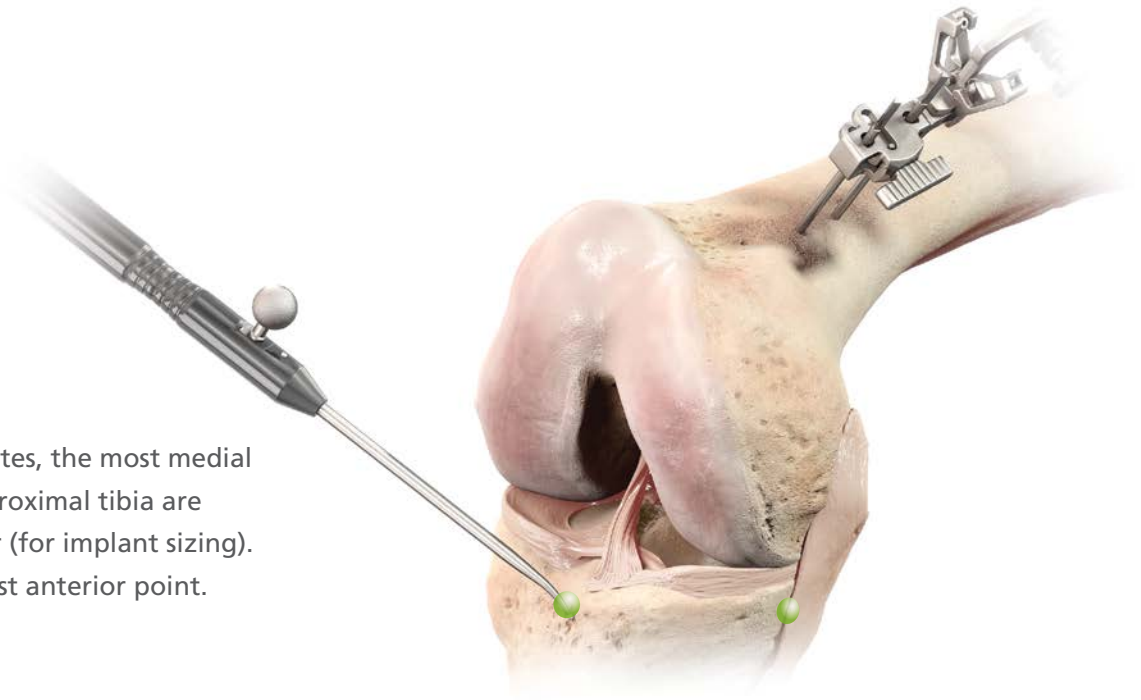
Medial and lateral points should be registered at the expected resection level to avoid over or undersizing of the tibial component.

Registration of medial and lateral points too anterior or too posterior may also lead to undersizing of the tibial component.

> **ℹ INFORMATION**
>
> *Failure to remove osteophytes at this stage may lead to oversizing the implant during implant planning.*

Tibial A/P Direction

The Pointer is placed horizontally in the A/P 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.

Whiteside's line

Medial third of the tibial tubercle
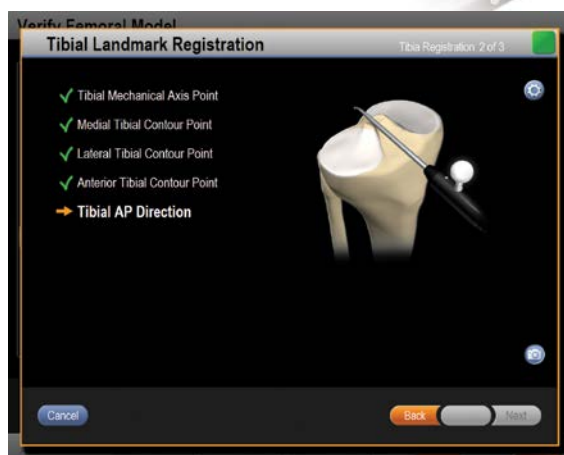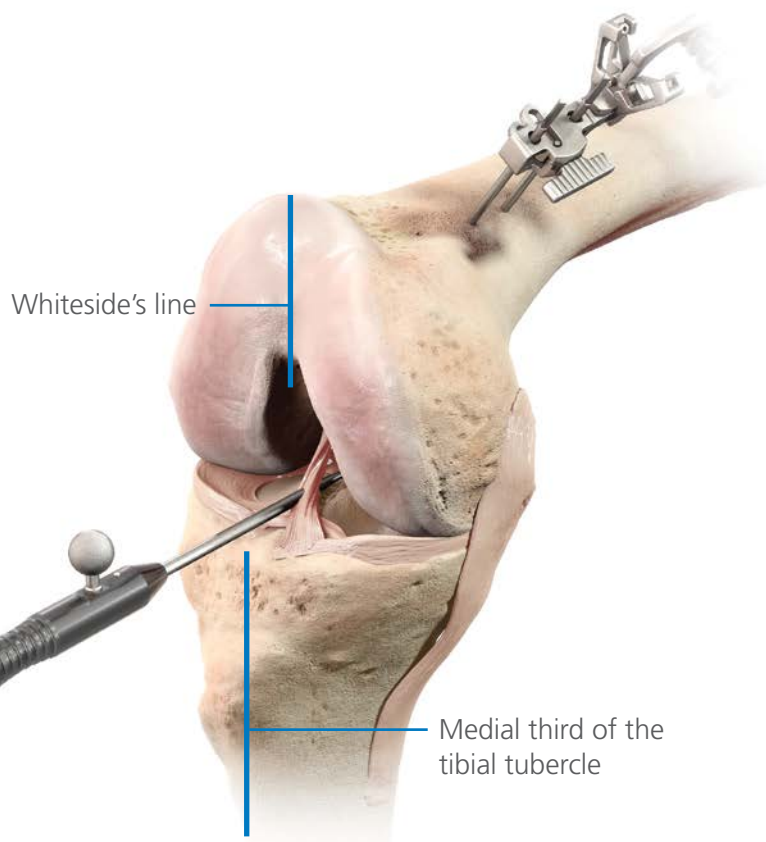
The system determines the direction the tibia is facing and the direction of any intended slope which may need to be cut. The rationale behind this is to avoid a compound tibial slope (oblique tibial slope). Accurate acquisition of the A/P direction will help to avoid an oblique tibial slope in the anteromedial to posterolateral direction or anterolateral to postero-medial 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 A/P slope

Tibial Varus/Valgus slope
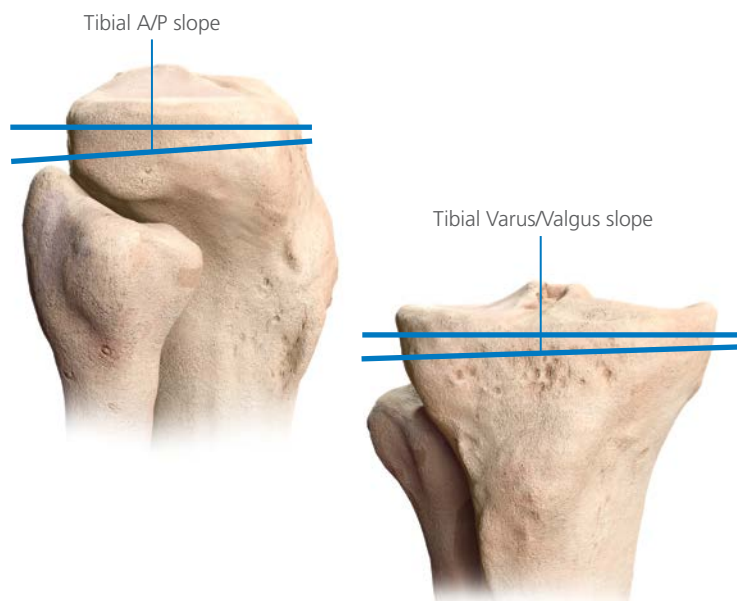
ⓘ INFORMATION

The system uses the Pointer to calculate the direction of slope only, the amount of slope is determined later in the tibial implant planning stages, see page 50 of this surgical technique.

Tibial Plateau Modeling

The next stage of data collection on the tibia involves modeling the tibial plateaus. The Pointer should be placed in the deepest point of the medial tibial plateau.

Commence data collection by performing a pivoting motion, an audible beep will confirm initiation of registration.
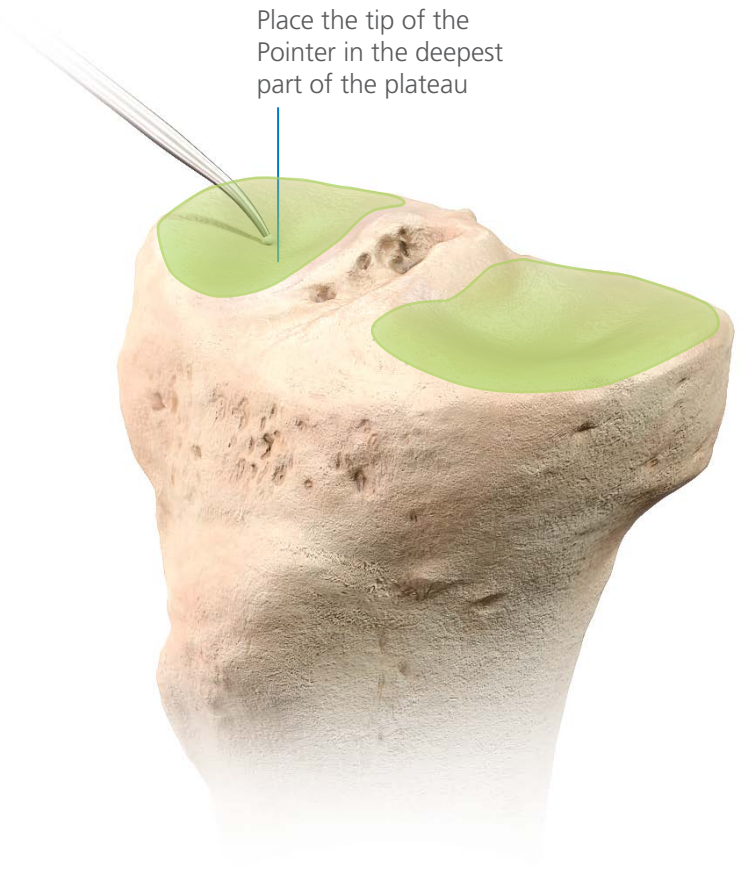
Place the tip of the Pointer in the deepest part of the plateau

6 mm radius

The tip of the Pointer is then moved in a spiral motion from this point outwards. The system determines the lowest point within a radius of 6 mm from the starting point.

The deepest point found is then used to calculate the tibial resection level. Careful consideration should be given if there is bone defect present.
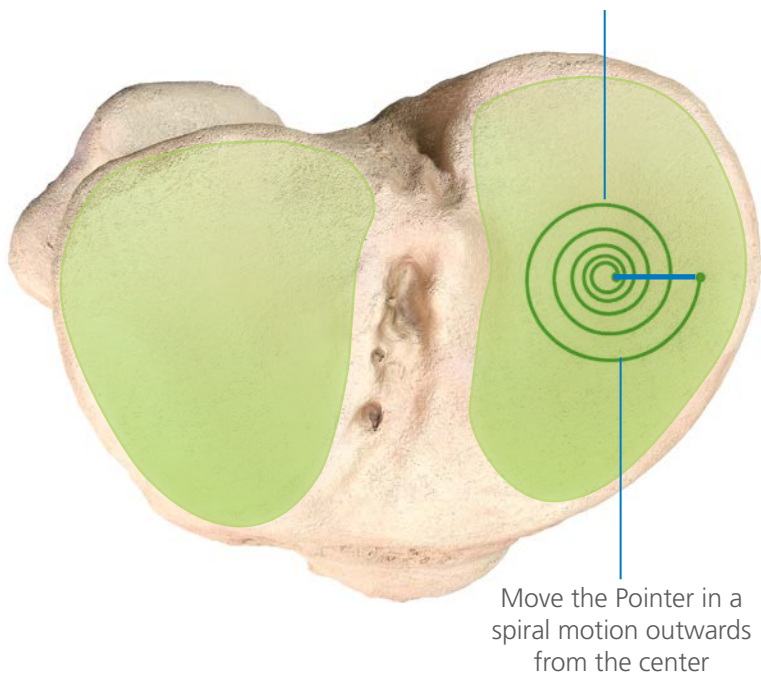
Move the Pointer in a spiral motion outwards from the center

Tibial Plateau Modeling

In cases with a substantial tibial plateau bone defect, the suggested level of resection may need to be adjusted proximally to avoid over-resection of tibial condylar bone.

The rim of the plateau can be mapped to help with morph accuracy. It may be helpful to apply Varus or Valgus stress to the knee joint to allow greater access to the tibial plateau.

The system will automatically proceed to the lateral plateau, which is registered in an identical manner to that of the medial plateau. Remember to start the registration at the lowest part of the tibial plateau.

Start point collection on the rim of the defect, and then move the Pointer up the plateau in a zig zag fashion

Proximally adjusted resection level

8 - 10 mm

2 mm
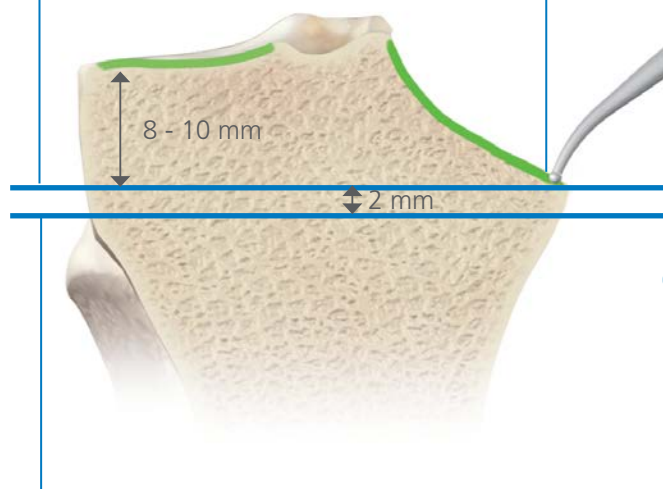
Initial computer suggested level of resection

INFORMATION

The system will default to a minimum of 2 mm from the lowest registered point. In case of marked bone defects, the surgeon may want to adjust resection level proximally to avoid over resection of contralateral plateau.

The ATTUNE System recommends a 9 mm resection off the distal femur. If using a tibial first approach, note that in order to maintain a 9 mm distal cut it may be necessary to adjust the tibial resection distally and resect more than 2 mm off of the affected side.

Tibial Modeling

Points should be acquired around the rim, and as posteriorly as possible
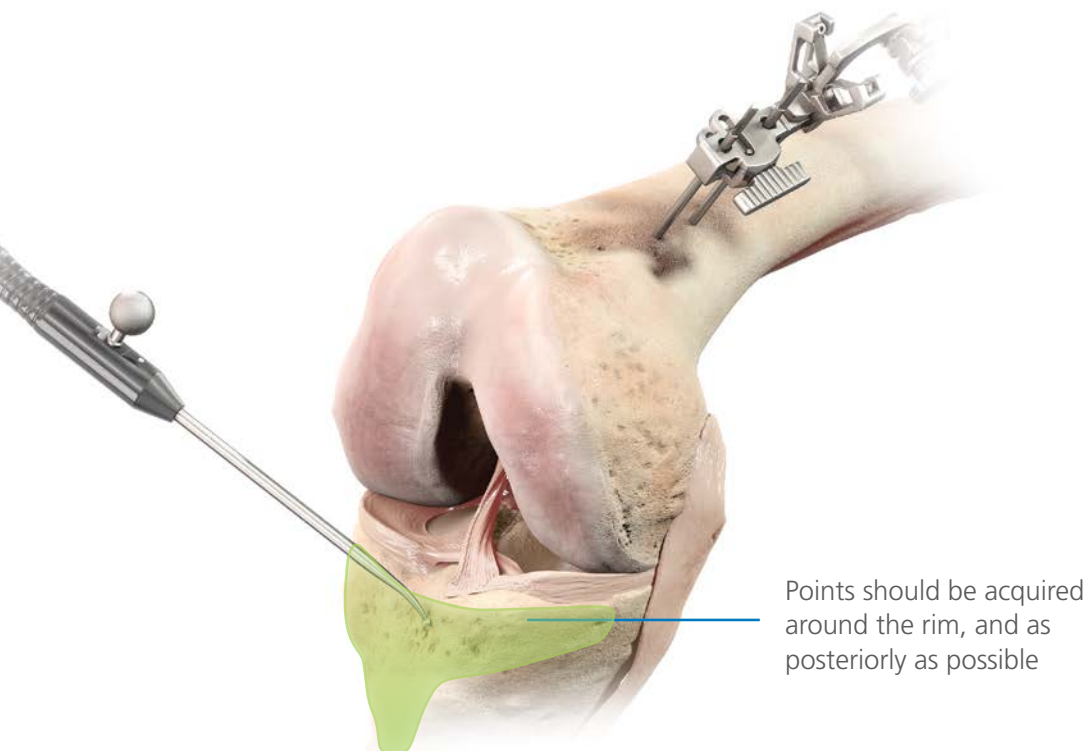
A fixed number of points along the anterior and medial/lateral tibia are acquired using the Pointer. These points are used to further define the bone model. The Pointer is placed on the tibia and pivoted to begin the procedure. A 'beep' will indicate when to begin moving the pointer.
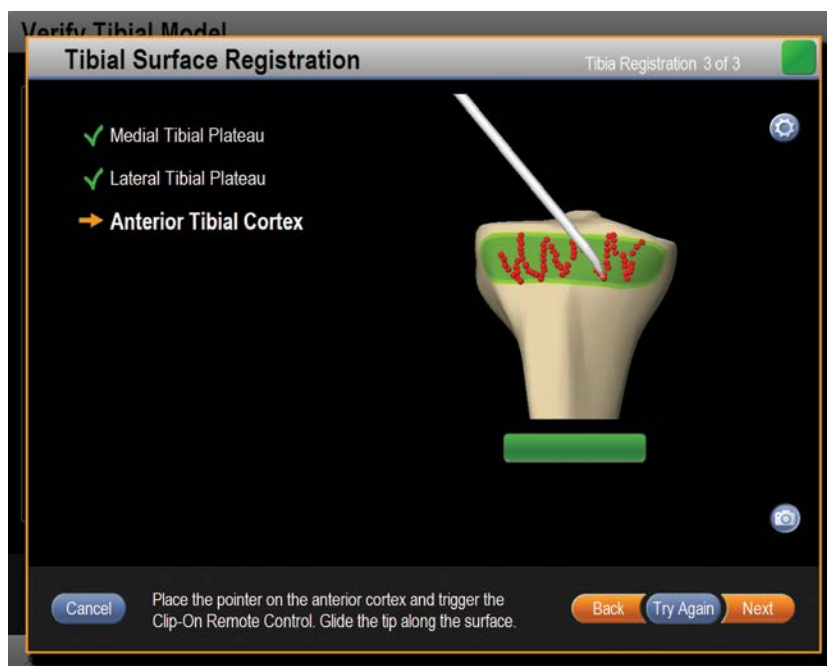
The tip of the Pointer should 'paint' the exposed surface of the tibia making sure it does not leave the surface of the bone. Points should be acquired mainly around the rim and extend as posteriorly as possible.

The system will indicate when enough points have been acquired. The collection of points can be started again by pressing the Try Again button, if necessary.

Tibial Model Calculation and Verification
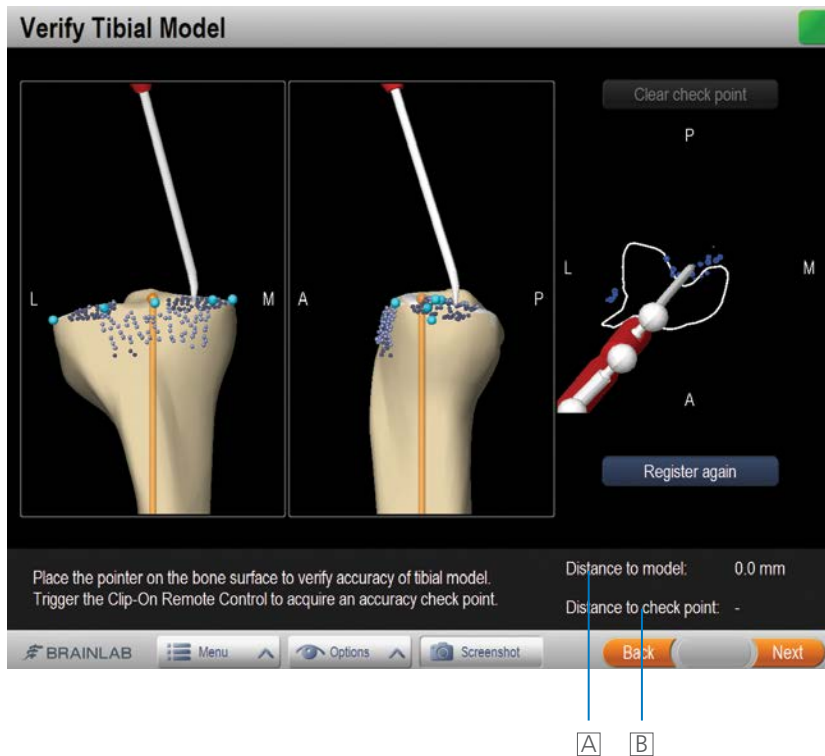
Following registration, the system creates the tibial morph. The accuracy of the morph is checked by holding the Pointer on areas of the tibia where points were collected.

A: Distance to Model

The exact deviation from the tip of the Pointer to the model is displayed on the screen as distance to model. The maximum acceptable deviation is less than 2 mm. Acquired points will normally show a deviation of less than 1 mm. Verification of the model will only be accurate in areas where points have been acquired.

> **ℹ INFORMATION**
>
> *Implant planning is based on acquired points only, not on the morph.*

B: Array Fixation Verification

Occasionally arrays can be bumped intra-operatively. Registration of a check point is useful if the surgeon wants to confirm the position of the arrays during the surgical procedure. A point is marked on the bone so it can be identified later.

The surgeon registers the check point using the Pointer. If during the case the surgeon believes he/she is getting inconsistent data as array might have been bumped, they can go to the check point to verify the position of the arrays. Press the Go To button and access Verify Tibial Model. Place the Pointer on the check point to verify the accuracy of the model.

Initial Leg Alignment

It is important to register the knee joint in extension. The leg is held in extension and Store is pressed to register the patient's preoperative condition. No correction should be made at this point. The leg is held in flexion and Store is pressed to register preoperative maximum flexion (optional). The leg should be held in natural current alignment without attempts to correct the deformity.

• The orange lines on the screen represent the tibial and femoral mechanical axes
• The green line represents the limb (HKA) axis

This optional step allows a comparison to be made between the initial and final alignments at the end of the procedure. Storage of initial leg alignment may be skipped by pressing Next.

Femoral Mechanical Access

HKA line

Tibial Mechanical Access
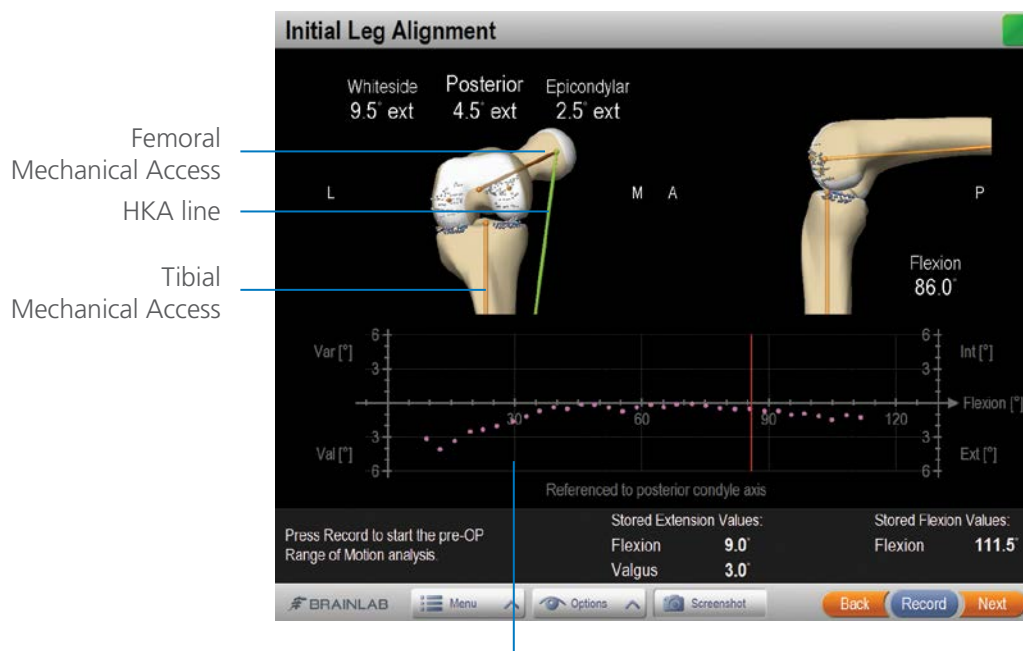
Use this graph to document preoperative deformity and/or preoperative stability. Press "Record" and move the leg through full motion, either with no stress applied (deformity) or with Varus/Valgus stress for stability. Alternatively, perform your usual stability test in extension, mid-flexion and flexion. This data will be shown postoperatively for comparison with the achieved result.

Femoral Implant Planning for Distal Resection

Resection adjustment

Flexion angle adjustment
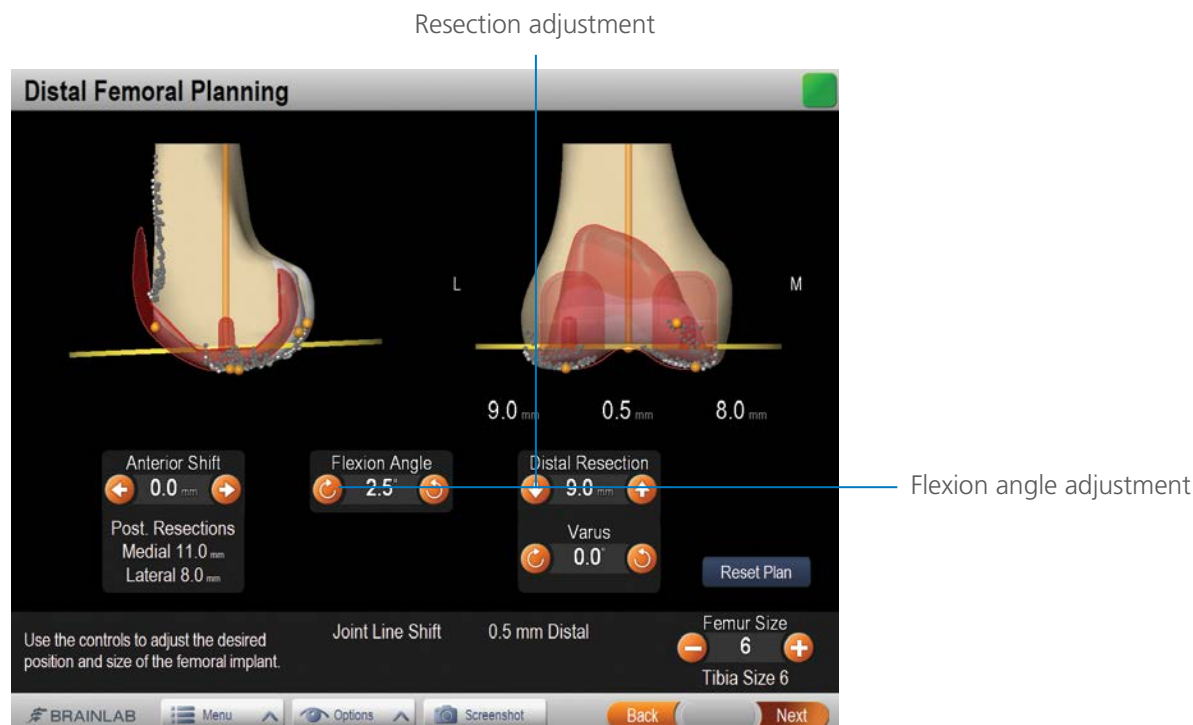
Button functions and screen information

Orange arrows:	Allow repositioning of the femoral component.
Yellow planes:	Proposed cutting planes of the femur.
Orange line:	Femoral mechanical axis line. The image can be zoomed in or out for better viewing using the zoom function on the menu bar.

⚠️

The data gathered during the registration is used to calculate the femoral implant size and position. The distal femoral resection will default to values set in the profile. The recommendations should be thoroughly checked and adjusted as necessary to ensure appropriate resection, implant size and joint line.

If distal femoral resection is more than desired, lower the level of resection. This will result in a smaller extension gap. The Femoral implant can be upsized to reduce the flexion gap.

⚠️ CAUTION

To avoid moving the joint line, the ATTUNE System recommends to take a 9 mm distal cut which will match the thickness of the implant. It is therefore suggested that the plan be modified to maintain this 9 mm distal resection.

ℹ️ INFORMATION

The system does not equalize flexion and extension gaps in this technique. Please refer to page 56 of this technique for details how to achieve this.

For further information on flexion and extension gaps, please refer to the flexion and extension gap chart on page 93 of this surgical technique.

Distal Femoral Resection Navigation
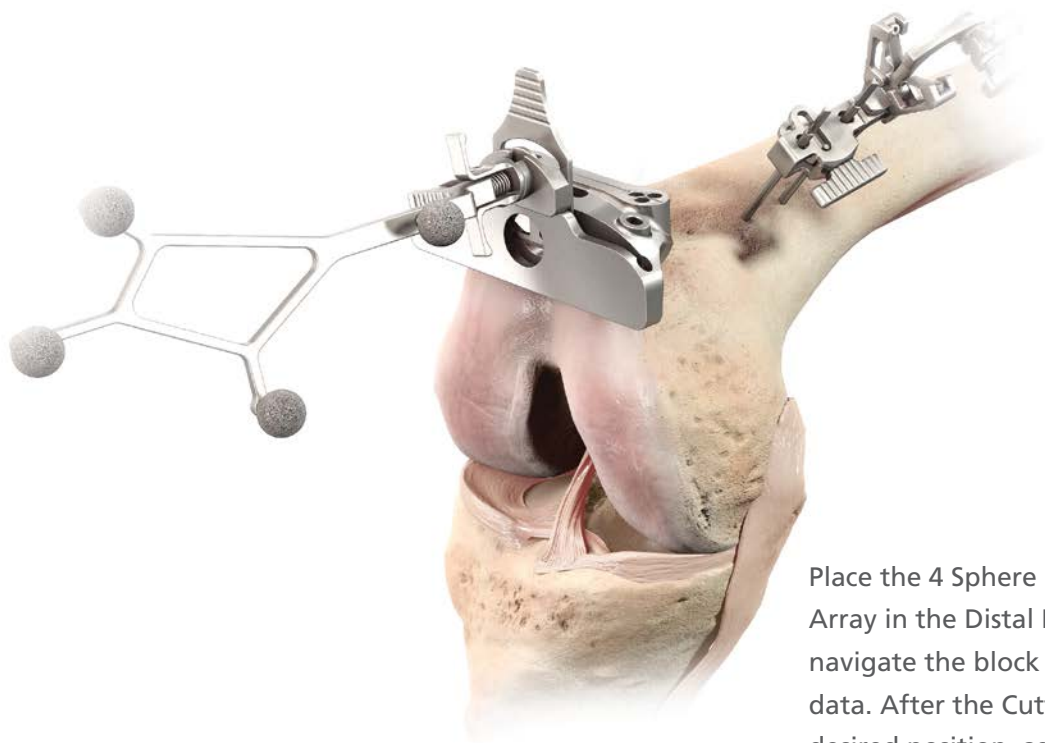
Place the 4 Sphere Universal Cutting Block Adapter Array in the Distal Femoral Cutting Block and navigate the block into place using the on-screen data. After the Cutting Block is navigated into the desired position, as evidenced by the blue plane matching the yellow plane, pin the block in place.

The surgeon can use the dials as visual cues to position the Cutting Block. The dials will-turn green when the Cutting Block is positioned within the thresholds set by the surgeon in the workflow profile.
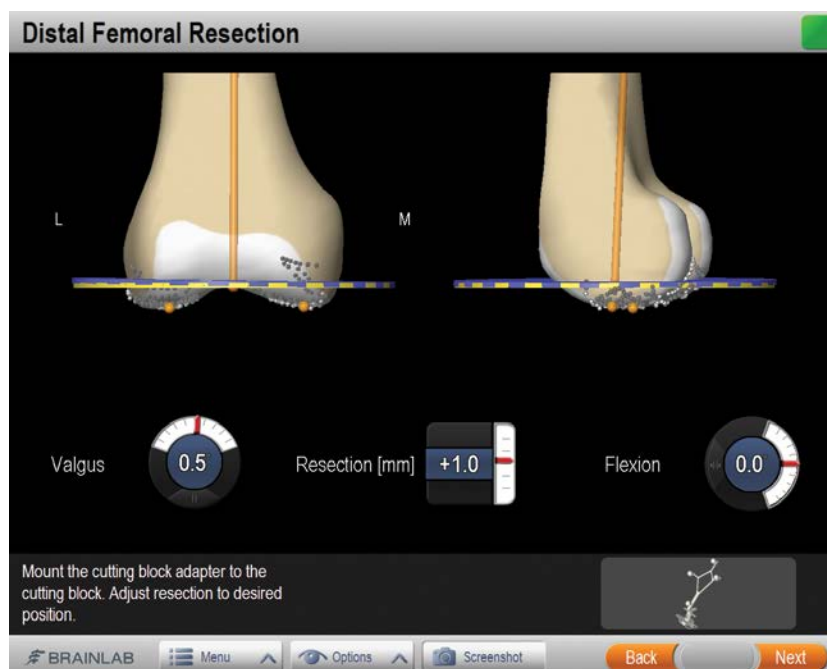
Distal Femoral Resection Navigation

The block is pinned in place on the anterior femur, taking care not to move it in the process. The position of the block should be reconfirmed after placing the first pin. Realign the block if necessary and place the second pin.

The distal femoral resection must always be made through the Saw Capture Slot.
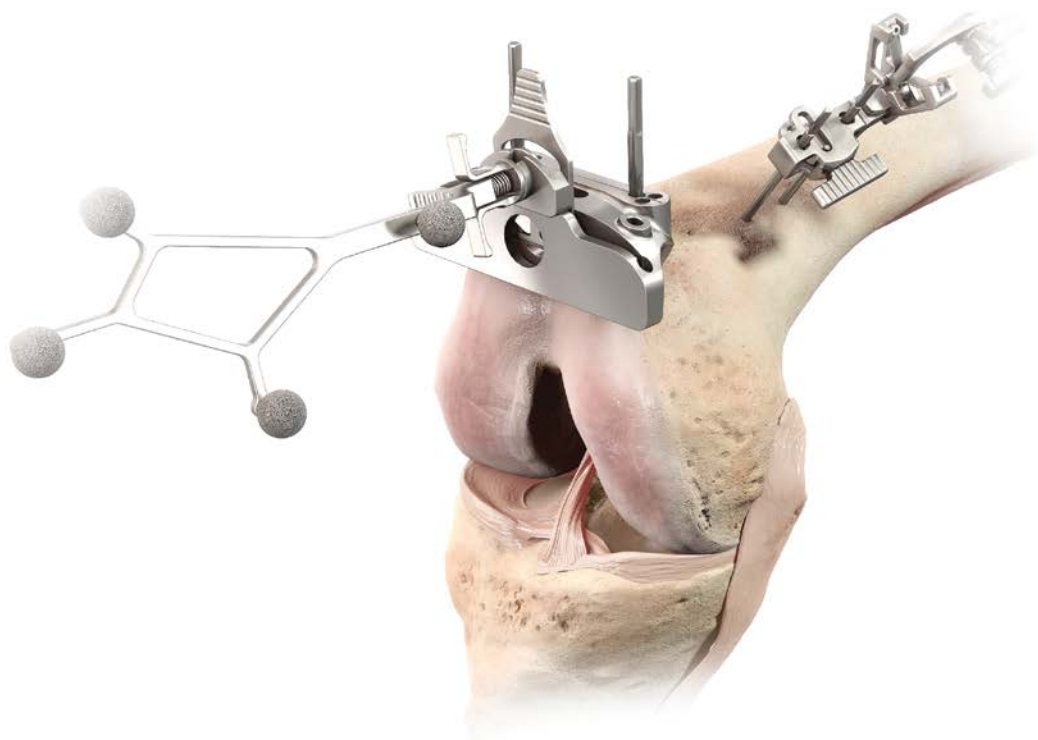
Distal Femoral Resection Verification
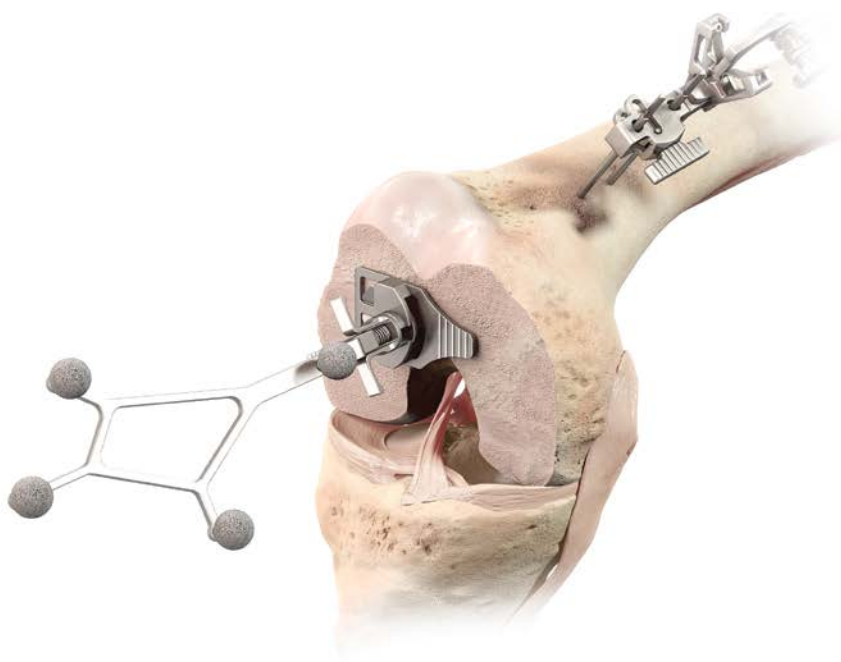
The 4 Sphere Universal Cutting Block Adapter Array is placed flat on the resected plane. The resection data is displayed by holding the 4 Sphere Universal Cutting Block Adapter Array stationary for a few seconds.
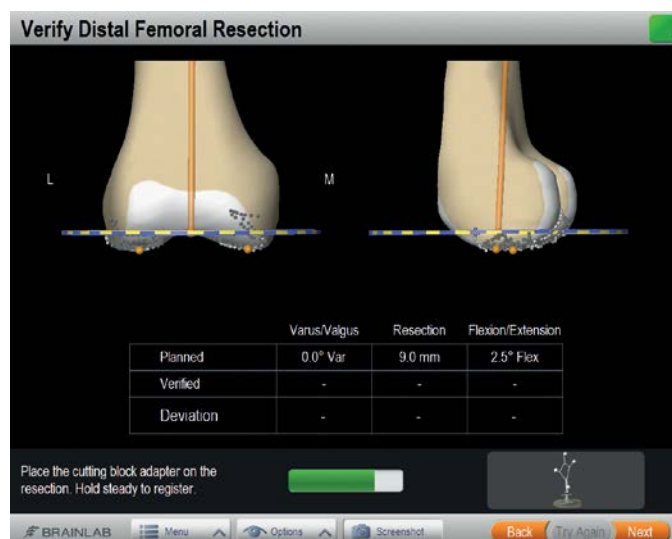
The yellow plane represents the planned plane and the blue plane represents the current plane.

Any difference between the planned and current resection planes can be seen on screen. Any deviation from the plan can be assessed and corrected if deemed necessary. If the tibial cut has been made, the surgeon may place a Spacer Block in the joint to verify balance and long leg alignment.
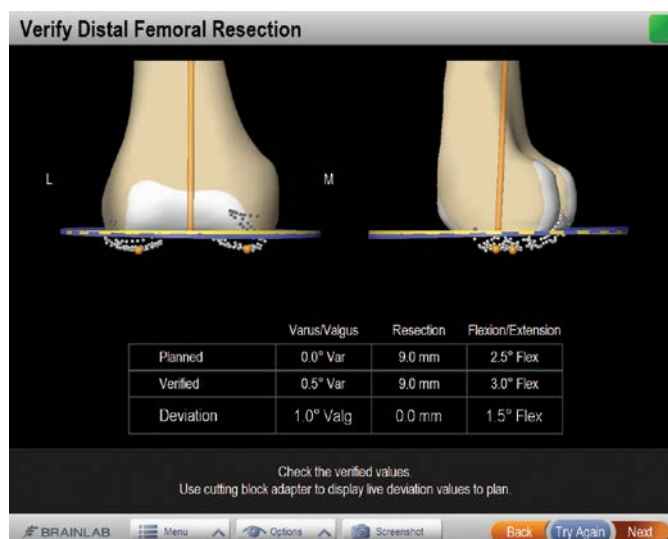
Tibial Implant Planning
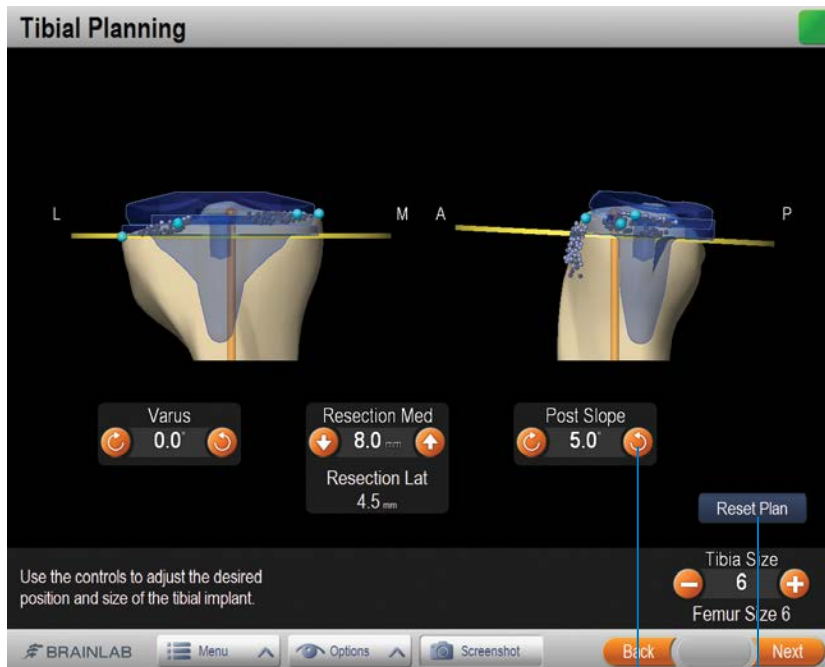
Tibial Implant Planning Screen

Button functions

A: Orange arrows: Allow repositioning of the tibial component.

B: Reset: Restores position and size of the tibial implant to the initial plan suggested by the system.

Yellow line: Tibial resection level.

Tibial resection level
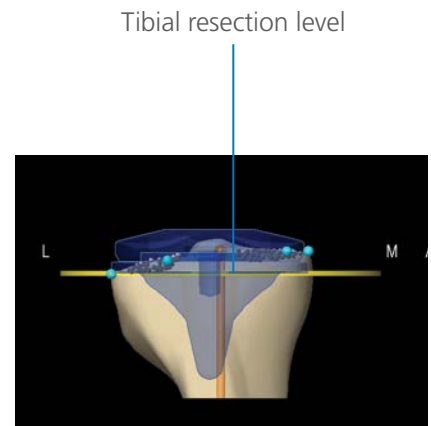
Initial planning and alignment of the implant position is automatically calculated. Tibial slope, Varus/Valgus and resection level can be adjusted on screen at this stage. Note that the level of resection is referenced from either the low or high side as set in the workflow profile.

The system will resect a minimum of 2 mm from the lowest point on the lowest plateau, unless manually adjusted by the surgeon. The minimum composite thickness of the tibial implant (4 mm base +5 mm insert) is 9 mm. It may be necessary to adjust the level to take more than 2 mm in order to maintain the 9 mm distal cut. The tibial component is always positioned against the anterior cortex point registered. The surgeon can change the implant size by pressing either + or - . Light blue points represent the deepest points of the tibial plateaus. The red dot shows the check point.

ⓘ **INFORMATION**

ATTUNE Knee Tibia Slope Recommendations: For a Posterior Stabilized (PS) configuration it is recommended to set the tibial posterior slope at 3 degrees. For a Cruciate Retaining or Cruciate Sacrificing (CR/CS) configuration, a range of 5 - 7 degrees of tibial posterior slope is recommended, attempting to match the patient's native slope.

In PCL-retaining TKA not adding adequate slope may limit the post-operative flexion. The CAS software defaults to 3 degrees for PS and 5 degrees for CR/CS. This can be further adjusted at the planning stage to best match the slope recommendations for individual patients.

Tibial Resection

The 4 Sphere Universal Cutting Block Adapter Array should be positioned in the Saw Capture Slot and the block positioned to align the blue plane (actual) with the yellow plane (planned) on screen. Varus/Valgus, resection level and tibial slope positions should be assessed. The external Tibial Alignment Jig can be used to provide additional guidance if necessary.
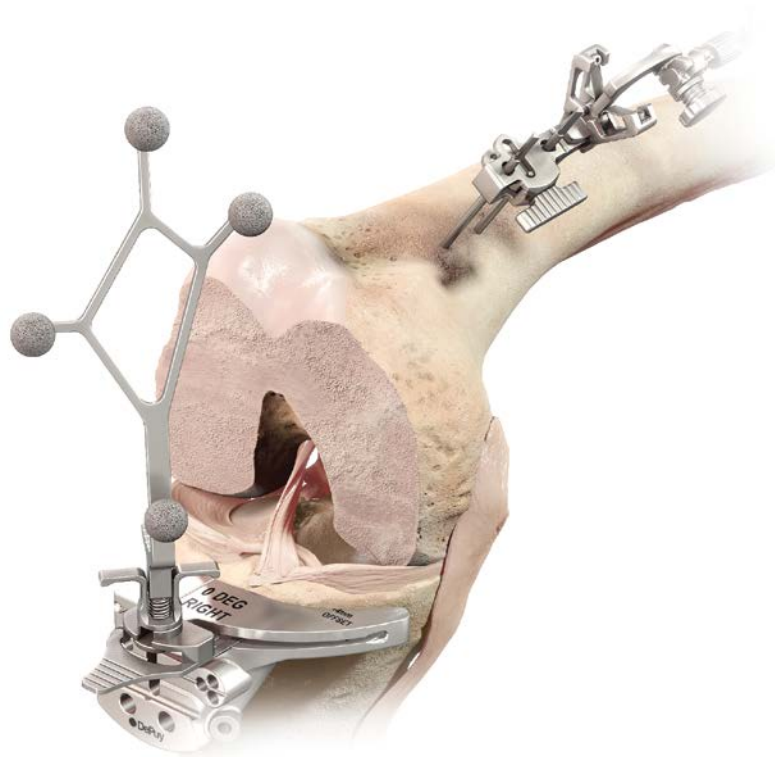
The surgeon should do a visual inspection after positioning the Cutting Block, as per the plan. If the surgeon believes that the resection is in error (either too little or too much or in incorrect orientation), return to the planning screen for adjustment.

The surgeon can use the dials as visual cues to position the Cutting Block. Position the block so that the numeric values are as close to zero as possible.

The dials will turn green when Cutting Block is positioned within thresholds set by the surgeon in the workflow profile.


Varus/Valgus Dial   Resection Height Dial   Tibial Slope Dial
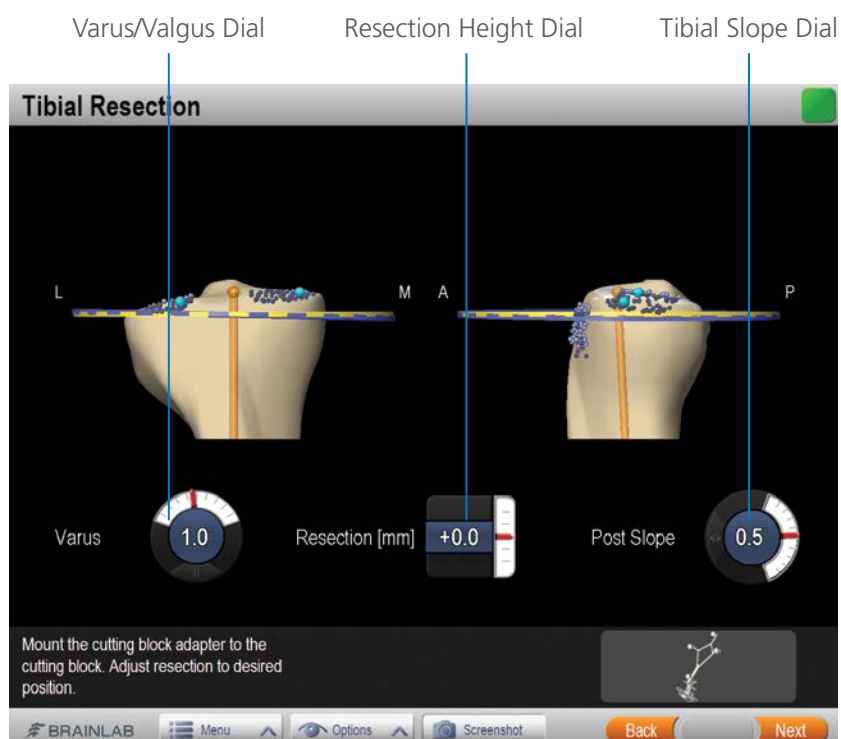
Tibial Resection

The block is held in position and pinned in place. Reconfirm the position of the Cutting Block after placing the first pin. Further adjustment may be necessary.
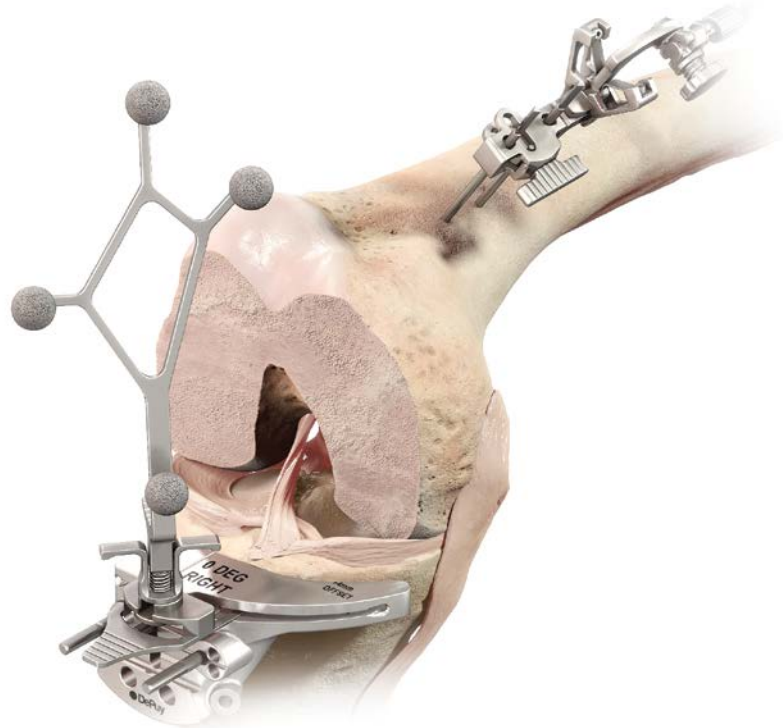
Resect the tibia through the Saw Capture Slot. The tibial resection must always be made through the Saw Capture Slot.

Tibial Resection Verification
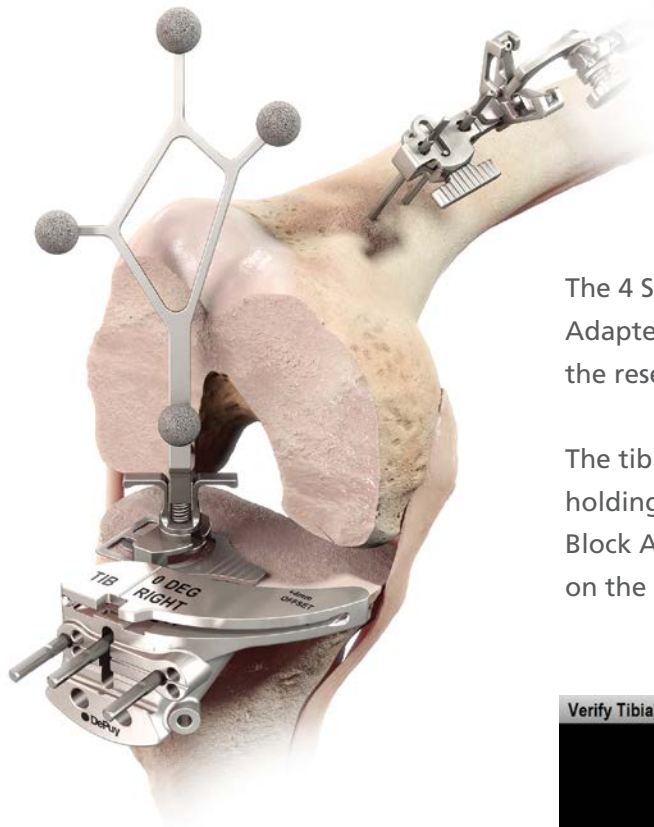
The 4 Sphere Universal Cutting Block Adapter Array is then placed flat on the resected plane.

The tibial resection data is displayed by holding the 4 Sphere Universal Cutting Block Adapter Array for a few seconds on the resection plane.

Any difference between planned and current resection planes can be seen on screen.

The yellow plane represents the planned plane and the blue plane represents the current plane.

Any deviation from the plan can be assessed and corrected if deemed necessary.
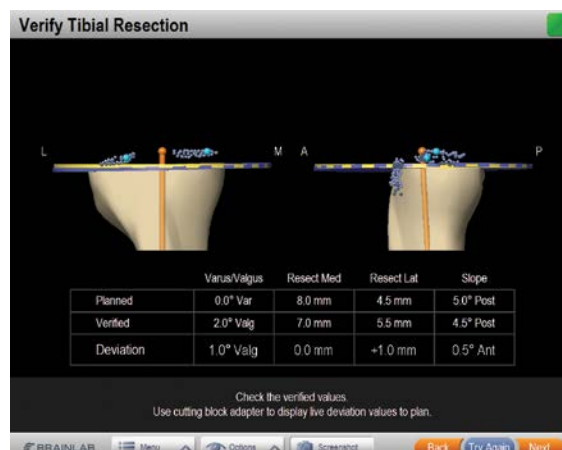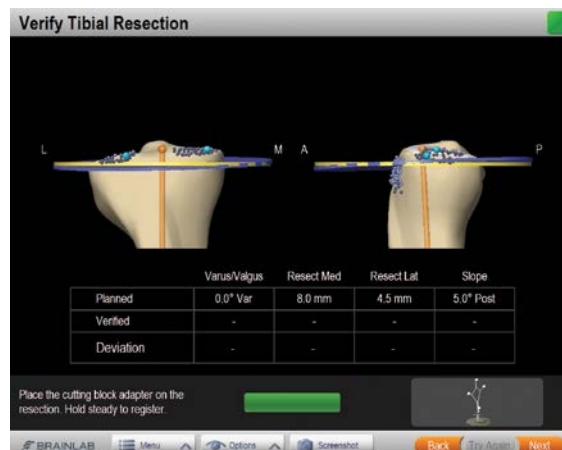
ℹ️ **INFORMATION**

Take care not to apply pressure to the array to allow the spring mechanism to resume in its neutral position.

Verify Tibial Resection

	Varus/Valgus	Resect Med	Resect Lat	Slope
Planned	0.0° Var	8.0 mm	4.5 mm	5.0° Post
Verified	-	-	-	-
Deviation	-	-	-	-

Place the cutting block adapter on the resection. Hold steady to register.

Verify Tibial Resection

	Varus/Valgus	Resect Med	Resect Lat	Slope
Planned	0.0° Var	8.0 mm	4.5 mm	5.0° Post
Verified	2.0° Valg	7.0 mm	5.5 mm	4.5° Post
Deviation	1.0° Valg	0.0 mm	+1.0 mm	0.5° Ant

Check the verified values.
Use cutting block adapter to display live deviation values to plan.

Balancing in Extension

Soft tissue balancing allows assessment of the leg alignment, in order to correct any deformity by successive releases to the relevant structures.

To check the extension gap, fully extend the leg and place the appropriate end of the Spacer Block, with the appropriate Spacer Base and Shim attached between the two resected surfaces. The Block should fit snugly in the extension space. The extension gap should be rectangular with the leg in full extension.

If desired, perform a gentle Varus/Valgus stress test with the Spacer Block in place. Typically 1 mm to 3 mm of opening both medially and laterally is desirable.

Ligament Balancing in Extension
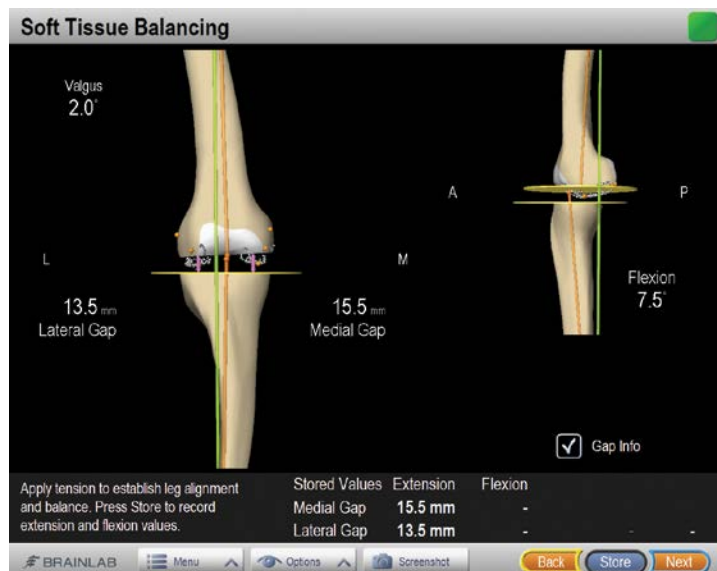
Place a Spacer Block in between distal femur and tibia to distract the knee joint. Assess soft tissue balance and leg alignment. Any Varus/Valgus or leg alignment deviation is shown on the screen.

The values for the extension gap are stored on the CAS software by pressing the Store button.

ℹ INFORMATION

If substantial Varus/Valgus deviation in tissue tension is observed, correction is advised by removal of osteophytes and/or soft tissue release if necessary to achieve balance. If a substantial deviation is seen in the long leg alignment then a recut of the tibia or femur may be required to obtain neutral alignment.

Proper soft tissue balance is especially important in a Rotating Platform (RP) knee construct to reduce the risk of spin out of the tibial insert.

Tensioning the Joint in Flexion

Balanced and appropriate external rotation of the femoral component is important for tibiofemoral stability in flexion and patello-femoral tracking/function.

The purpose of this step of the procedure is to achieve correct femoral component rotation. Move the knee joint gently into 90 - 95 degrees of flexion.

CAS Ligament Tensor

Place a knee tensioning device such as a CAS Ligament Tensor, Lamina Spreaders or a Knee Balancer into the flexion gap. Support the thigh so that its weight does not compress the tensioning device.

Ensure that the femur is upright (i.e., not leaning over to the side) and the tibia is held near zero degrees of internal/external rotation in relation to the femoral axis. The tensioning device should apply independent and equal pressure to the medial and lateral compartments of the knee in flexion.

> **ℹ INFORMATION**
>
> *Make sure the ligaments are tight by crosschecking with the finger tip.*

Tensioning the Joint in Flexion

Crosscheck these values with bony landmarks. The system will adjust the femoral A/P planned resection values to achieve a rectangular flexion space. If excessive rotation of bony landmarks is observed:
- verify registration points are correctly taken
- verify ligaments are tight
- if still rotated more than expected, and all osteophytes are removed, consider soft tissue releases for correction, but note that these releases may have an effect on extension balance
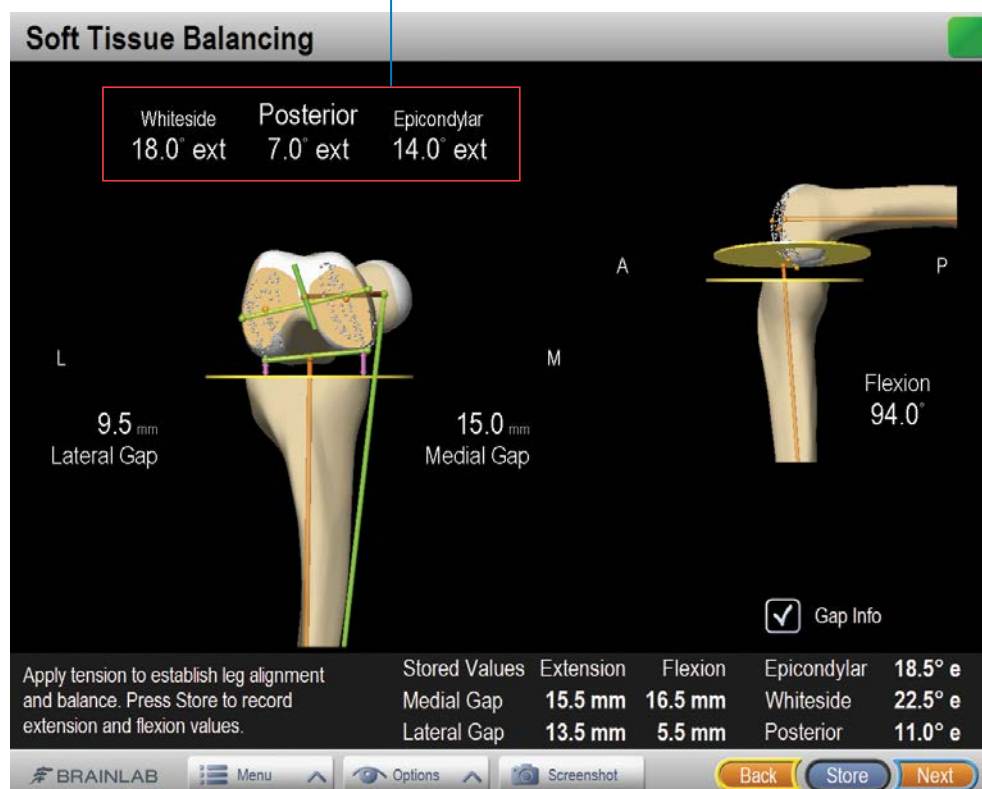
Ligament Balancing in Flexion

Press Store to register the flexion gap.
Press Next to move to next step.

The tensioning device should not move significantly during soft tissue assessment by the surgeon. If it does, repeat the procedure to restore it to its correct position.

Femoral Implant Planning A/P Femoral Resection
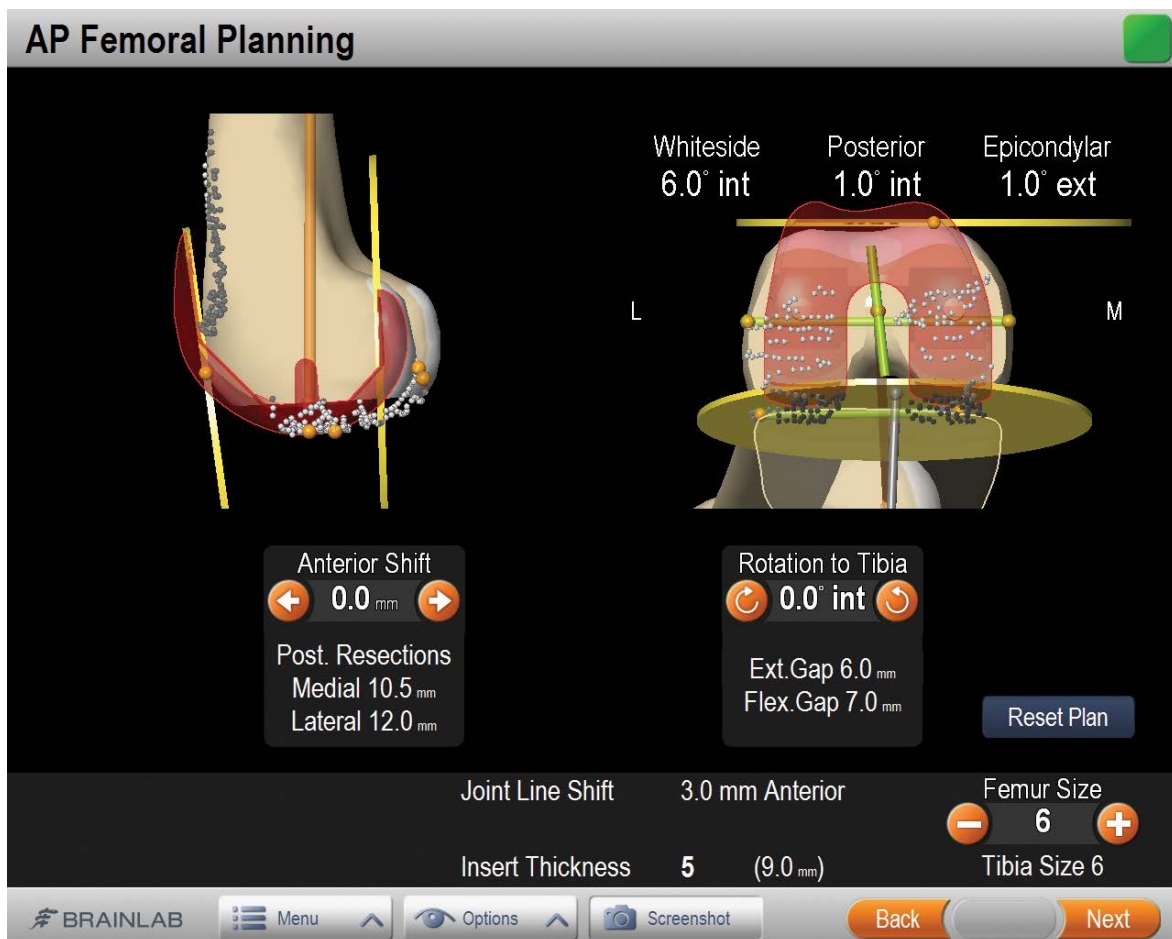
The data gathered during the soft tissue balancing is used to calculate femoral rotation.

Femoral rotation is optimized so that the posterior femoral resection is parallel to the tibial resection to ensure a rectangular flexion space.

References to anatomical landmarks - Epicondylar line, Whiteside's line and posterior condyles is also shown based on preferences saved in the workflow profile.

Differences in the flexion gap and extension gap can be resolved by fine tuning A/P translation and size.

Anterior Femoral Resection Navigation

The correct size A/P Chamfer Block is positioned with the 4 Sphere Universal Cutting Block Adapter Array situated in the anterior femoral resection Saw Capture Slot.
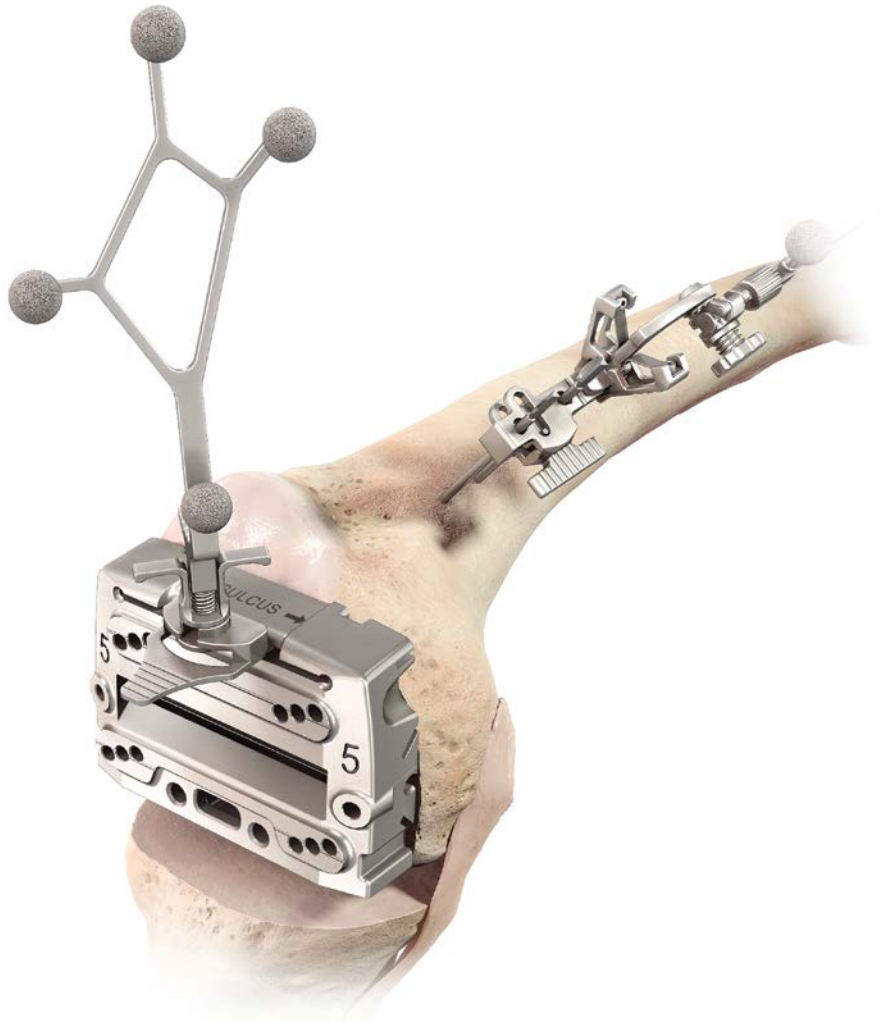
Align the anterior femoral resection planes and using Universal or Non-Headed Pins through the pin holes marked with a center line, drill the first pin to hold the block in place. Reconfirm the positioning according to what is shown on screen, re-adjust if necessary and drill the second pin to secure the block.

Anterior Femoral Resection

Rotation to Tibia 0.5° i

L · M

Internal 0.5

Anterior Shift [mm] 0.5

Extension 0.5

Mount the cutting block adapter to the cutting block. Adjust resection to desired position. Femur Size 6

BRAINLAB · Menu · Options · Screenshot · Back · Next
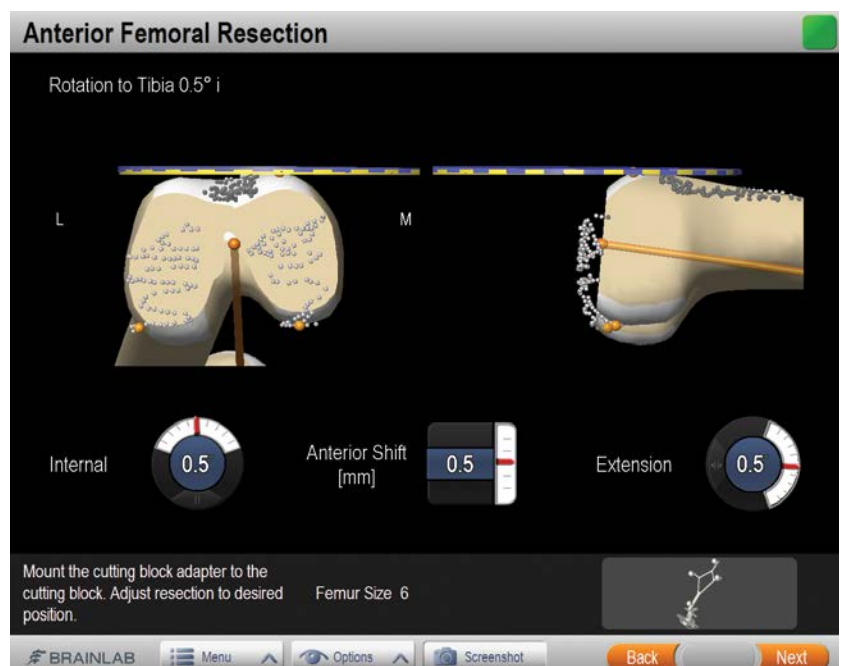
Anterior Femoral Resection

An optional flexion space check can be done here by using a Spacer Block placed below the A/P Chamfer Block with the Modular Posterior Saw Capture removed.

The anterior femoral resection is completed using an Oscillating Sawblade.
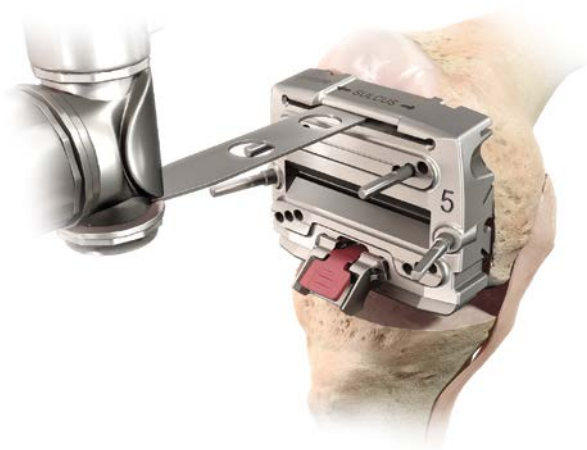
Cutting Block Adapter

The 4 Sphere Universal Cutting Block Adapter Array is then placed flat on the resected surface to confirm the accuracy of resection.
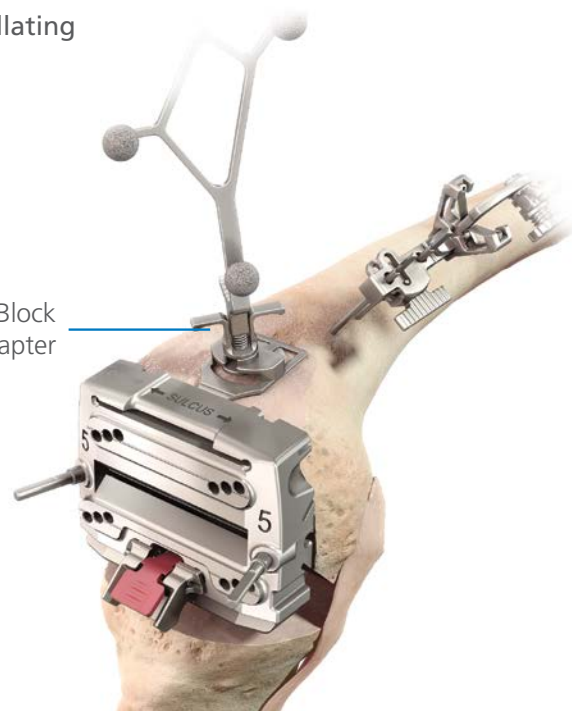
ⓘ INFORMATION

INTUITION Instruments A/P Chamfer Blocks were designed to ensure the femoral trial and implant seats fully on the distal femur by preparing the chamfer cuts with additional clearance. Therefore, a small "gap" may be observed between the femoral trial/implant and the chamfer cuts, particularly the anterior chamfer.

This gap is intentional by design to ensure that fixation is achieved with the distal, anterior, and posterior surfaces.

In this way, the position of the femoral component can be best controlled with regards to flexion and extension gaps.

Good pinning technique is critical to achieving accurate bone cuts during the anterior and posterior resections. The recommended technique is to avoid stripping the Threaded Headed Pins in the divergent pin holes and to retain the straight pins during anterior and posterior resections for added stability.

Anterior Femoral Resection

	Rotation	AP Shift (mm)	Flexion/Extension	Verified Distal
Planned	1.0° Int	0.0 Ant	3.0° Flex	2.5° Flex
Verified	-	-	-	3.0° Flex
Deviation	-	-	-	0.5° Flex

Place the cutting block adapter on the resection. Hold steady to register.
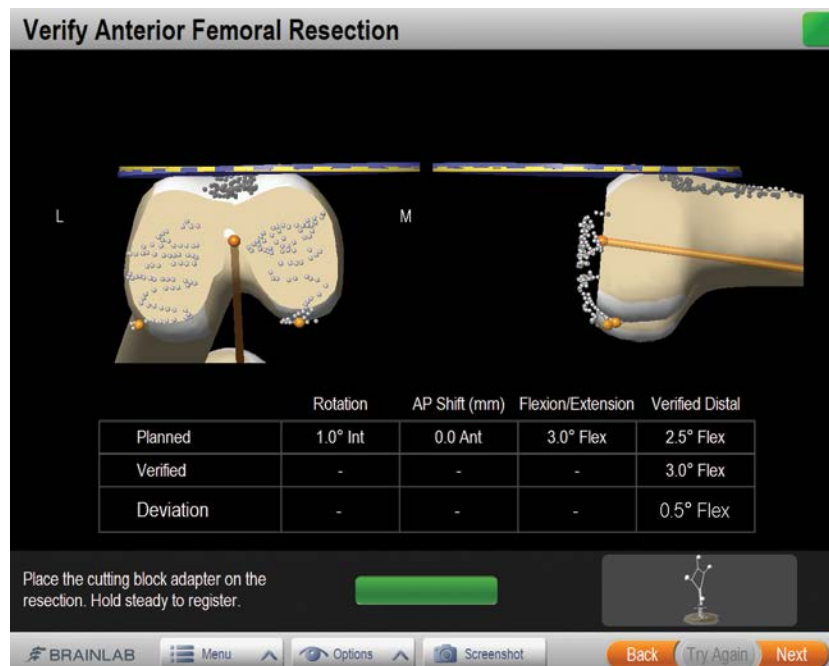
Anterior Femoral Resection Verification Screen

The resection data is displayed by holding the Cutting Block Adapter still for a few seconds.

The yellow plane represents the planned plane and the blue plane represents the current plane.

Any difference between the planned and current resection planes can be seen on the screen.

Any deviation from the plan can be assessed and corrected if deemed necessary.

	Rotation	AP Shift (mm)	Flexion/Extension	Verified Distal
Planned	1.0° Int	0.0 Ant	3.0° Flex	2.5° Flex
Verified	0.5° Ext	1.0 Post	1.5° Flex	3.0° Flex
Deviation	0.5° Ext	0.5 Post	0.5° Ext	0.5° Flex

Check the verified values.
Use cutting block adapter to display live deviation values to plan.
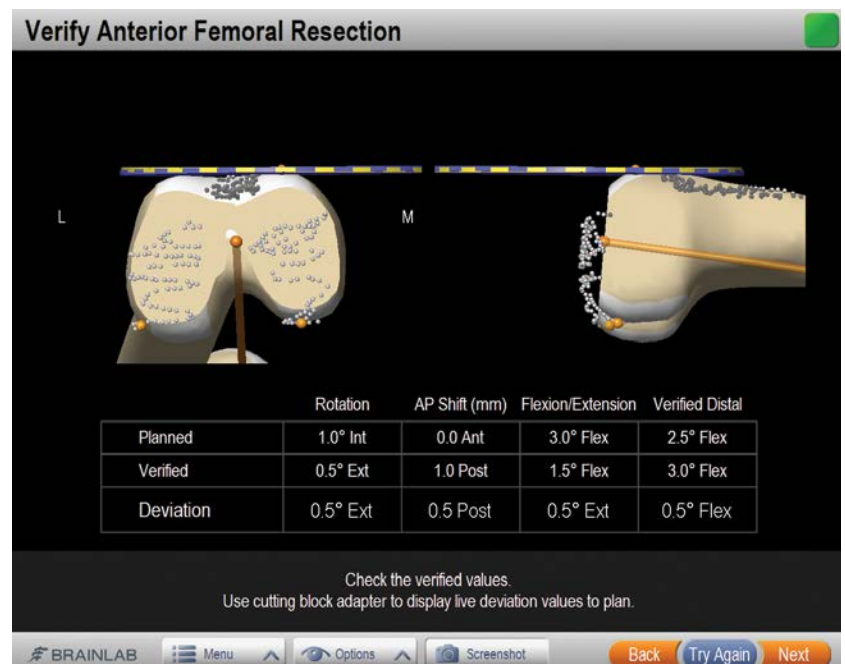
Data showing the difference between the Planned Resection and the Actual Resection

Femoral Preparation

Place Retractors to protect the medial and lateral collateral ligaments and the popliteal tendon. Then resect the anterior and posterior femur.
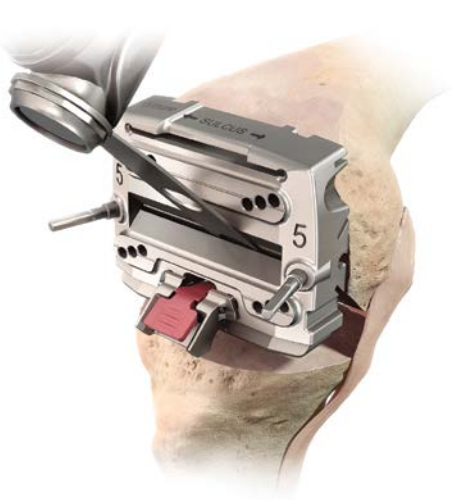
Remove the Universal or Non-Headed Pins and cut the anterior and posterior chamfers.
Remove the Threaded Headed Pins and the A/P Chamfer Block.

ℹ **INFORMATION**

The posterior Saw Captures are open medially and laterally to accommodate complete saw cuts. To reduce the risk of inadvertent Saw Blade kickout, point the Blade slightly toward the midline before starting the Saw.

Posterior Condyle Preparation

Removal of Excess Bone
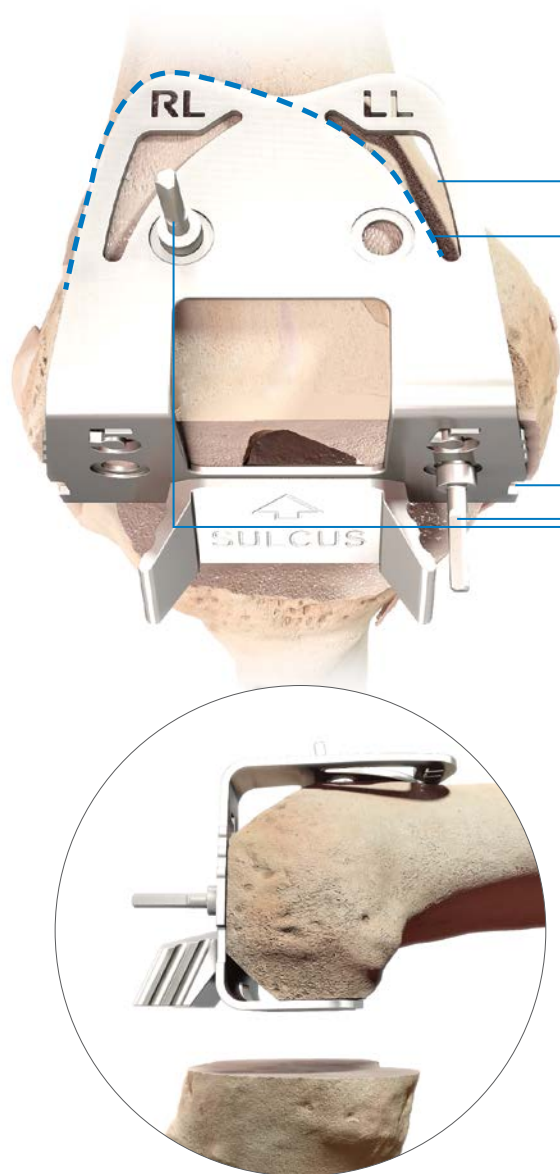
Reference Window

Dotted lines indicate the outer edges of the final component

Cutouts indicate narrow size

For optimal stability, place Base Pins as shown

To avoid impingement in flexion, remove any excess bone between the posterior tibial implant and the posterior femoral condyles in flexion. To aid in osteophyte and excess bone removal, select the Femoral Finishing Guide that corresponds to the femoral trial component size. Push the instrument onto the resected distal femur and position mediolaterally, using the lateral anterior profile of the instrument as a guide. The inner surface of the windows represents the anterior medial aspect of the implant and the outside profile of the anterior face represents the anterior lateral aspect of the implant.

Fix the instrument flush to the distal cut using Base Pins.

---

i **INFORMATION**

The cutouts on the sides of the Femoral Finishing Guide show where the outer edge of the narrow component is located. If there is no cutout, a narrow component is not available for that size. Narrow components are available for sizes 3, 4, 5 and 6.

Base Pin

Posterior Condyle Preparation
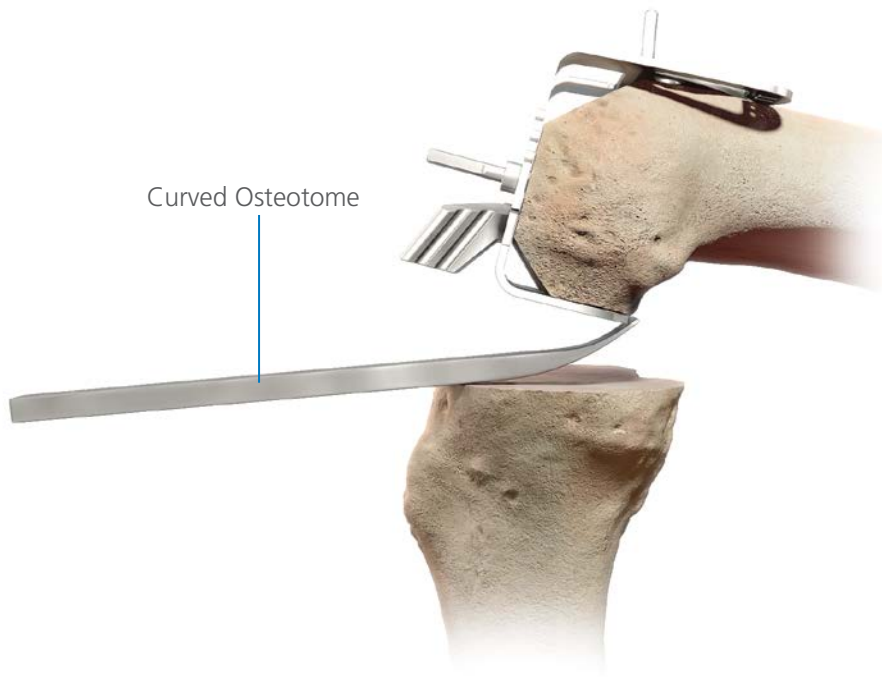
Curved Osteotome

Removal of Excess Bone (Cont.)

With the Femoral Finishing Guide in place, verify that any excess bone or residual osteophytes in the posterior recesses have been removed. If not, use a Curved Osteotome or Gouge to remove any remaining bone that can be seen beyond the end of the Femoral Finishing Guide feet.

Always work carefully under direct vision to avoid damage to the neurovascular structures in the popliteal fossa.

CR Sulcus Preparation

When implanting an ATTUNE Knee System CR Femoral Component, use the Femoral Finishing Guide to perform the sulcus cut. Using the Sulcus Cut Ramp as a guide, remove bone from the sulcus with the Rasp, a 0.5 in. Saw or Osteotome. Then remove the Femoral Finishing Guide.

Sulcus Cut Ramp

Femoral Resection – PS Notch Cuts
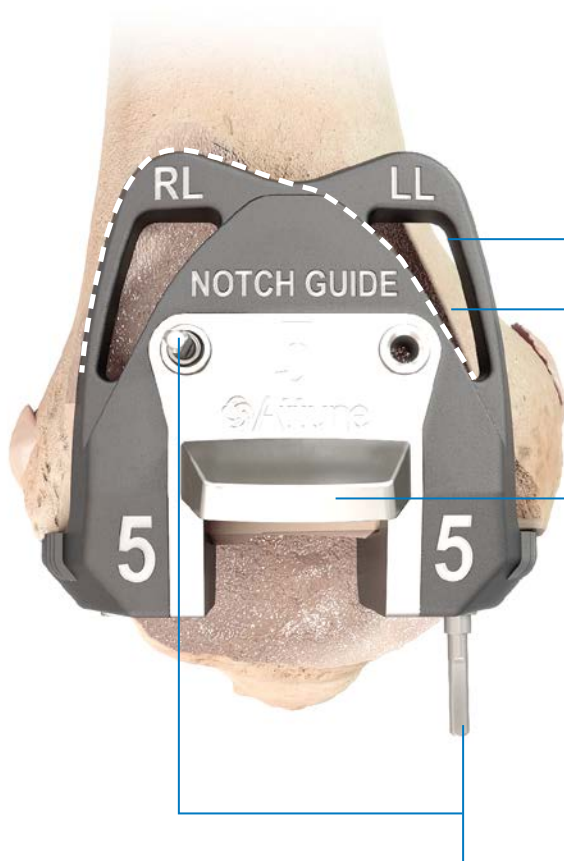
Reference Window

Dotted lines indicate the outer edges of the final component

The tongue of the Notch Guide is extended to provide a long cutting surface for an 18 degree cut

For optimal stability, place Threaded Headed Pins as shown

When implanting an ATTUNE Knee System PS Femoral component, use the Notch Guide to perform the notch cut. The profile of the Notch Guide provides anterior and distal references to the width of the implant. In addition, windows in the Notch Guide provide additional reference.

The inner surface of the windows represents the anterior medial aspect of the implant and the outside profile of the Notch Guide represents the anterior lateral aspect of the implant. The references are designed to confirm optimal component size and position. The tongue of the Notch Guide is extended to provide a long cutting surface for an 18 degree cut.

Position the Notch Guide on the resected anterior and distal surfaces of the femur as far laterally as possible while assuring that the lateral border of the implant does not overhang the lateral femoral cortex. Pin the Guide in place using the Threaded Headed Pins.

ℹ️ **INFORMATION**

The cutouts on the sides of the Notch Guide show where the outer edge of the narrow component is located. If there is no cutout, a narrow component is not available for that size. Narrow components are available for sizes 3, 4, 5 and 6.

Femoral Resection – PS Notch Cuts

Perform the notch cut. ⚠️

18 Degree Cut ——————————

—————————— Reference Window

—————————— Width Reference

—————————— Narrow Size
Reference Cutout

⚠️ **CAUTION**

When completing the notch cut, be careful to avoid excessive angulation of the Saw Blade or penetration past the posterior femoral cortex to avoid injury to the neurovascular structures.

Avoid undercutting the condyles.

Soft Tissue Considerations for Cruciate Retaining Application
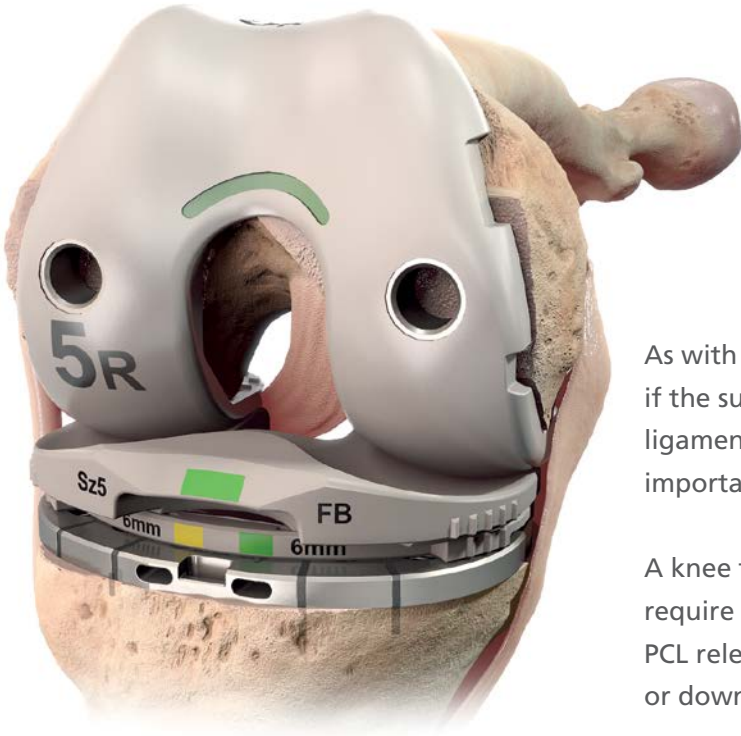
As with any cruciate retaining total knee replacement, if the surgeon plans to preserve the posterior cruciate ligament (PCL), attention to PCL balance is extremely important for proper kinematics of the knee.[1]

A knee that is tighter in flexion than extension may require one or a combination of the following: PCL release, increasing the amount of tibial slope, or downsizing the femoral component.[1]

During trialing, the surgeon should select the trial assembly that provides the greatest stability in flexion while still allowing full extension. Indications of an excessively tight flexion space may include one or more of the following:

• Femoral trial lifting off
• Tibial trial lift off or booking
• Excessive rollback of the femoral component on the tibia

If there is any indication of imbalance, it is not uncommon to perform a gradual release of the PCL.

Trial Reduction

Position the appropriate Femoral Trial onto the femur by hand. Use the Femoral Impactor to impact the trial as necessary.

Color Coded Marking

Narrow Size Reference Cutout
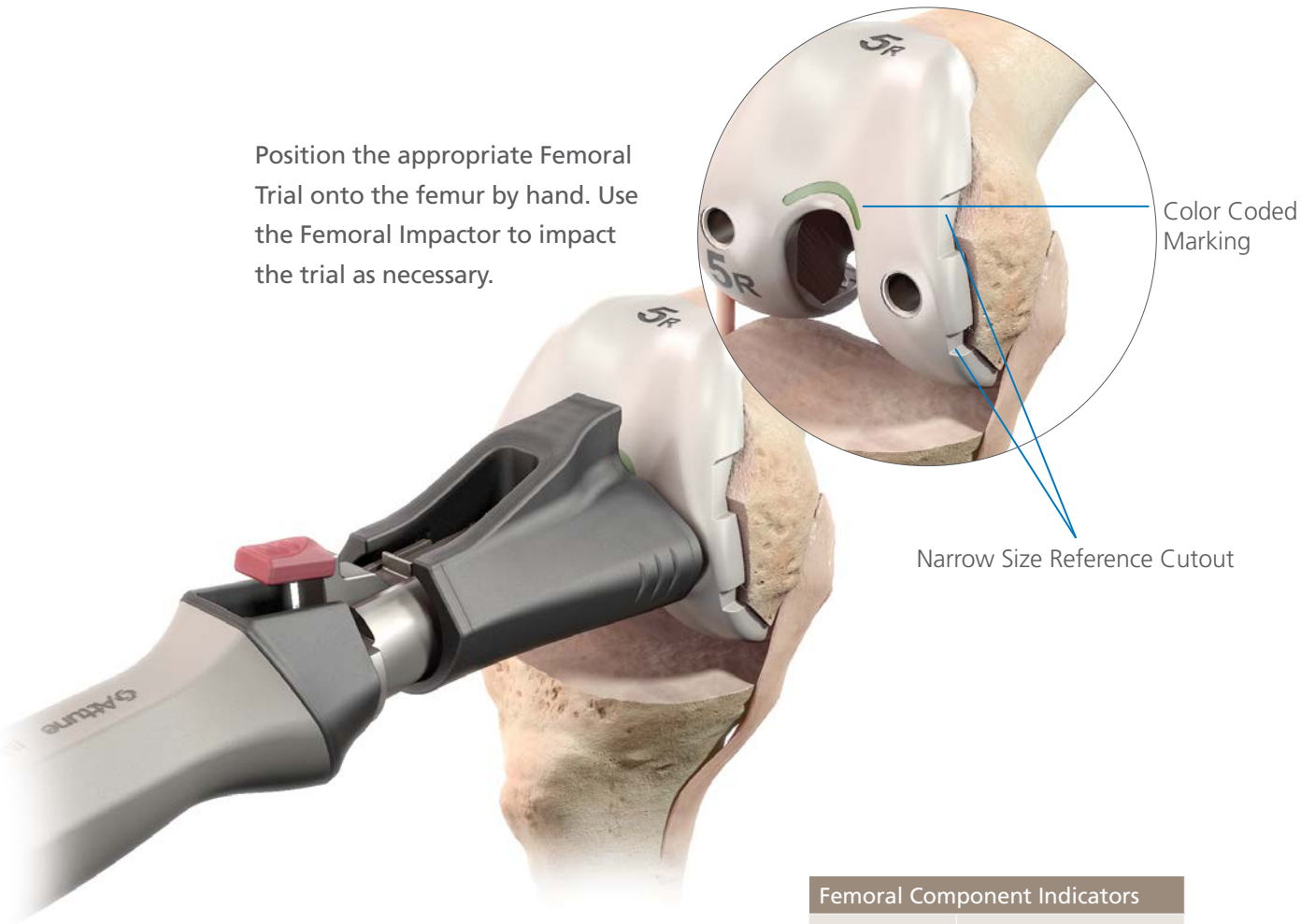
Femoral Component Indicators	
CR	⌒
PS	⌐

ℹ **INFORMATION**

If the trial is not seating properly, the bone cuts may need to be rechecked. Excessive impaction required is a signal that under-resection has occurred of the A/P Chamfer cuts or, in a PS configuration, the Notch Guide cuts. Femur Trial M/L width of box is representative of implant and cement mantle. The Femoral Trial should be fully seated prior to joint reduction.
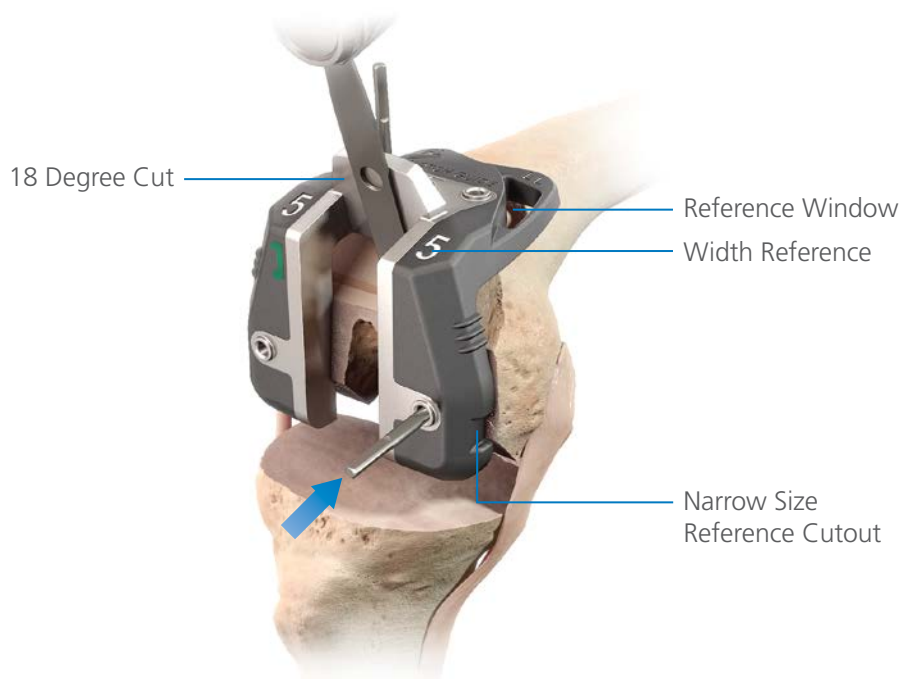
ℹ **INFORMATION**

The cutouts on the sides of the Femoral Trial show where the outer edge of the narrow component is located. If there is no cutout, a narrow component is not available for that size. Narrow components are available for sizes 3, 4, 5 and 6.

Trial Components

Tibial Trial

Attach the Alignment Handle to the appropriate size Tibial Base Trial and place onto the resected tibial surface. Assess the position of the base to maximize tibial coverage while avoiding overhang. For Fixed Bearing, the rotation of the Tibial Base Trial is typically centered on the junction between the medial and central third of the tibial tubercle.

Non-Spiked Evaluation Bullet (Fixed Bearing)

Spiked Evaluation Bullet (Rotating Platform)

Central Mark

Rotating Platform

For Rotating Platform tibial components, secure the Universal Handle to the Spiked Evaluation Bullet and insert the Bullet into the cutout of the Base Trial. Tap down lightly on the Universal Handle to secure the Base Trial to the proximal tibia.

Fixed Bearing

For Fixed Bearing tibial components, insert the Non-Spiked Evaluation Bullet into the cutout of the Base Trial by hand. The Non-Spiked Evaluation Bullet is used when allowing normal internal/external rotation of the tibial component during a range of motion to dictate the optimal placement of the tibial base. The bone can be marked for Base Trial orientation reference.

> **ⓘ INFORMATION**
>
> *When implanting a Rotating Platform it is recommended to use the Impaction Handle to guide in the Spiked Evaluation Bullet.*
>
> *Either Rotating Platform or Fixed Bearing tibial components can be trialed before preparing the tibia.*

Trial Components

CR Articulation Surface

PS Articulation Surface

Shim

Articulation Surface Indicators	
Fixed Bearing	▢
Rotating Platform	⬭
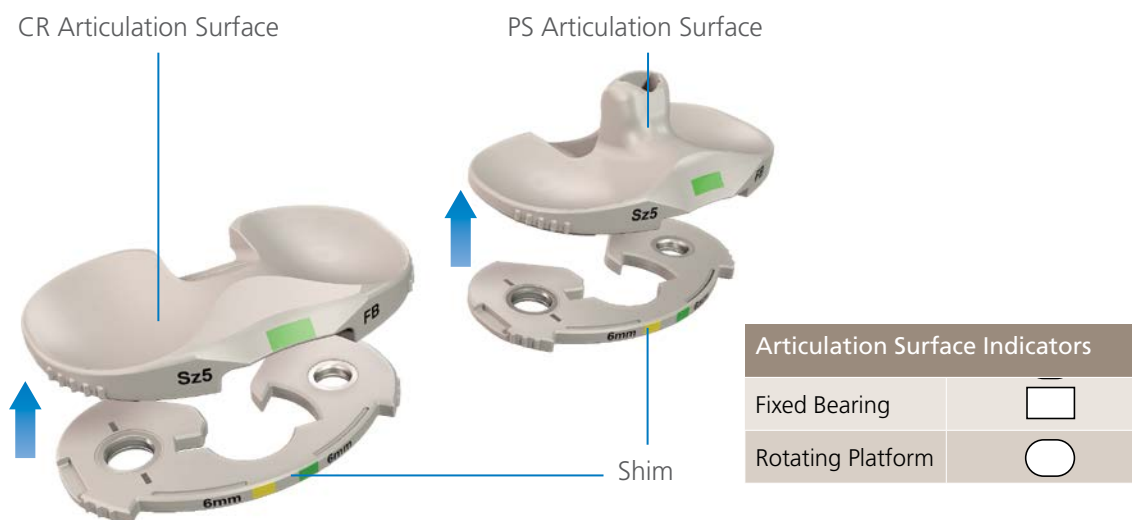
Select the Tibial Articulation Surface Trial that matches the femoral size and style (CR or PS for either Rotating Platform or Fixed Bearing), and attach the corresponding size Shim of the appropriate thickness (5 mm, 6 mm, 7 mm, 8 mm, 10 mm, 12 mm, 14 mm and 16 mm for CR and PS, and in addition 18 mm for PS, for core sizes 3-8). **The thickness markings on the insert trials and the final insert implant indicate the insert thickness without the base thickness included. For further information, see the chart on page 94.**

Rotating Platform

Fixed Bearing

Balseal Damage
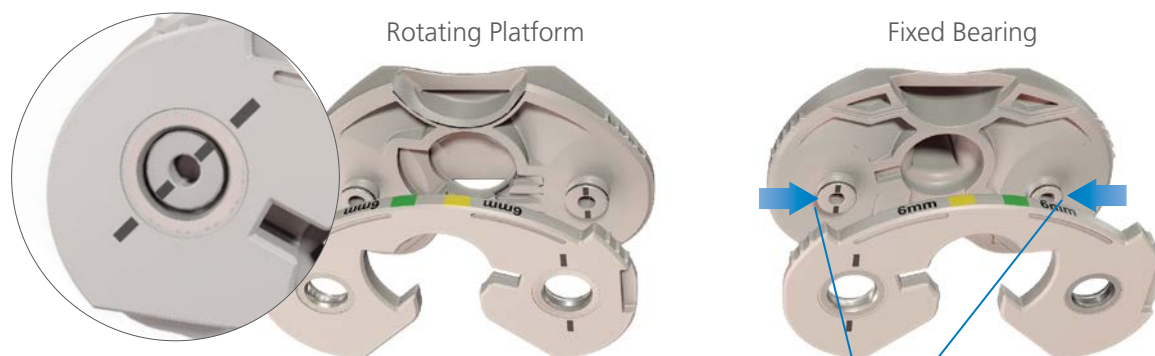
The Shims are reversible to accommodate both Rotating Platform and Fixed Bearing implants. Ensure that the Articulation Surface Trial and Shim are securely engaged, as these two components make up the Insert Trial. Attach the assembly into the Tibial Base Trial.

Check for Balseal damage. If damage is observed, replace the damaged component.
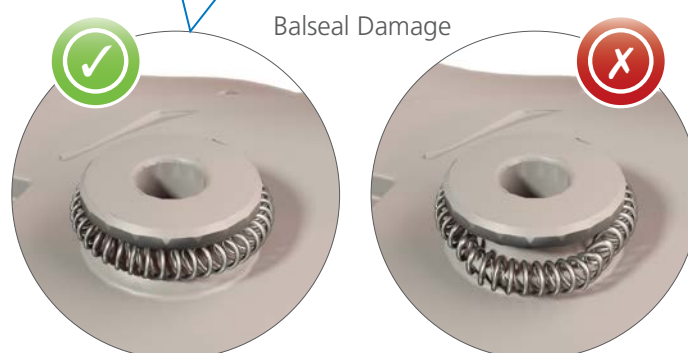
Trial Components

Remove the Alignment Handle from the Tibial Base Trial and, with the trial prosthesis in place, extend the knee carefully, noting the anteroposterior and mediolateral stability, and the overall alignment in the A/P and M/L planes. If there is any indication of instability, use the next thicker Shim and repeat the check. Select the trial assembly that provides the greatest stability in flexion while still allowing full extension. Verify that the posterior femoral condyles are sufficiently prepared to prevent impingement on the tibial insert in deep flexion.
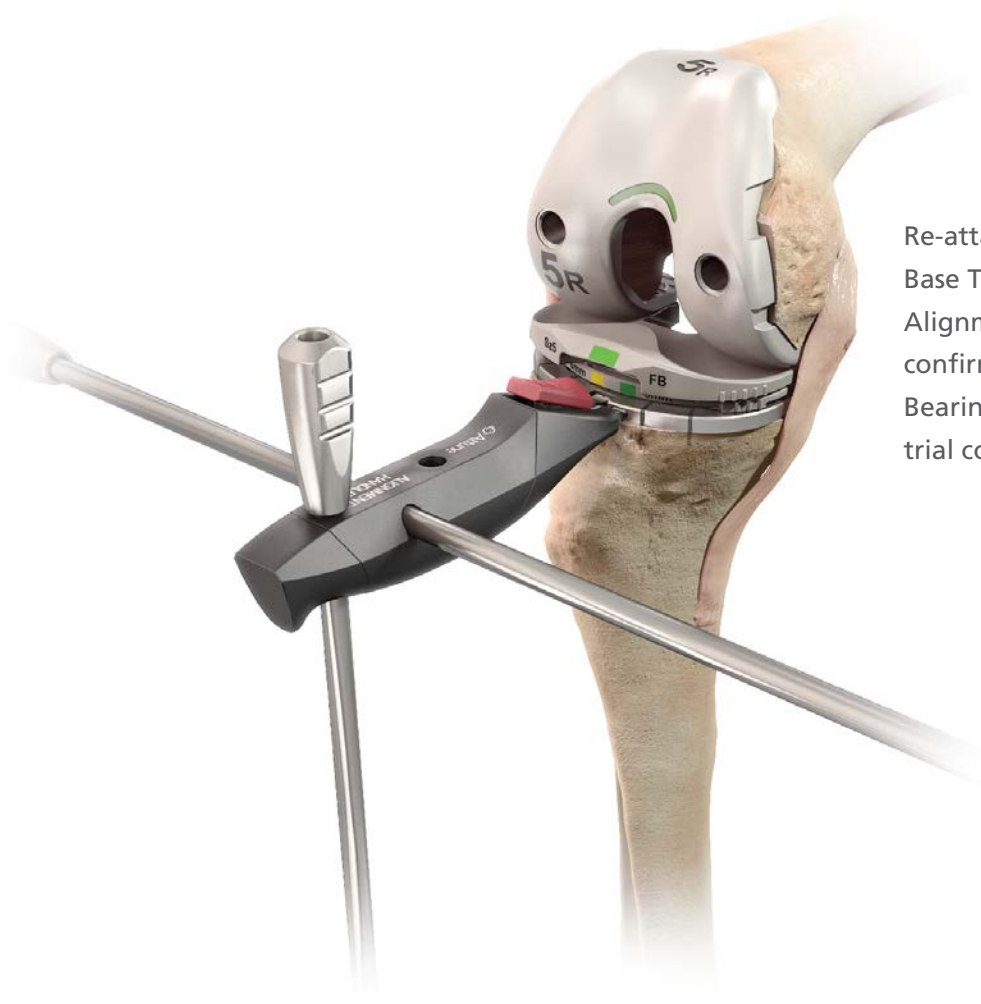
Re-attach the Alignment Handle to the Tibial Base Trial and then attach the two-part Alignment Rod to the Alignment Handle and confirm the overall alignment. For a Fixed Bearing component, mark the position of the trial component on the anterior tibial cortex.

Final Leg Alignment
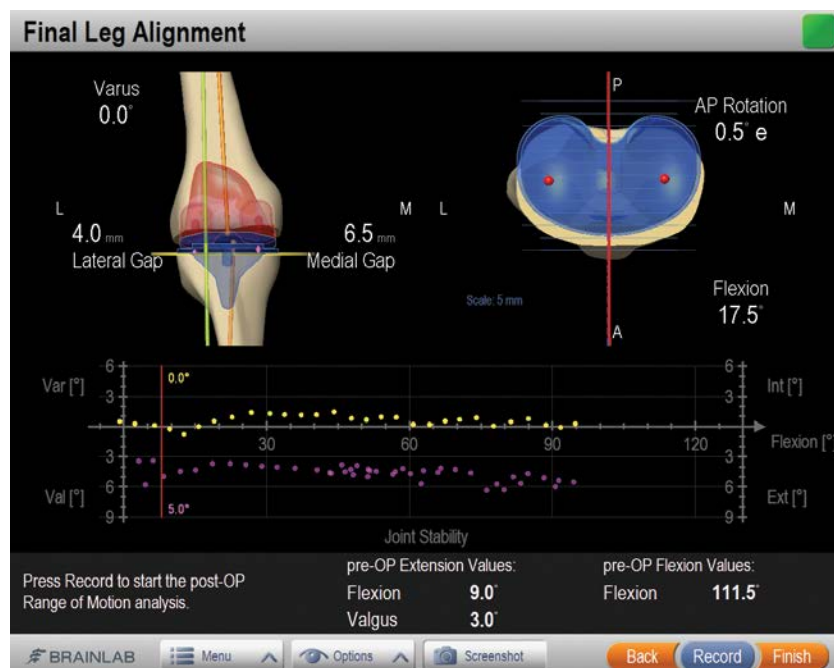
Motion Analysis with Trial Components in Extension

With the trial components in place, the tracking pattern is assessed through a full flexion cycle.

The following points should also be assessed:
- Correct mechanical alignment of the extremity in both sagittal and coronal planes
- Medial and lateral lift-off (using gap data)
- Proper soft tissue balancing in extension and in flexion
- Natural motion without restrictions

Stress test the knee again here by pressing "Record" and moving the leg through a full range of motion. A nice and stable line centered around the 0° line is expected here.

Preoperative data is then converted into a coordinate system for comparison. Final flexion and extension gaps can be stored by pressing the Store button. Press Finish to exit the software.

Remove the arrays when appropriate.

Motion Analysis with Trial Components in Flexion

Extracting Trial Components

Tibial Trial
Extractor
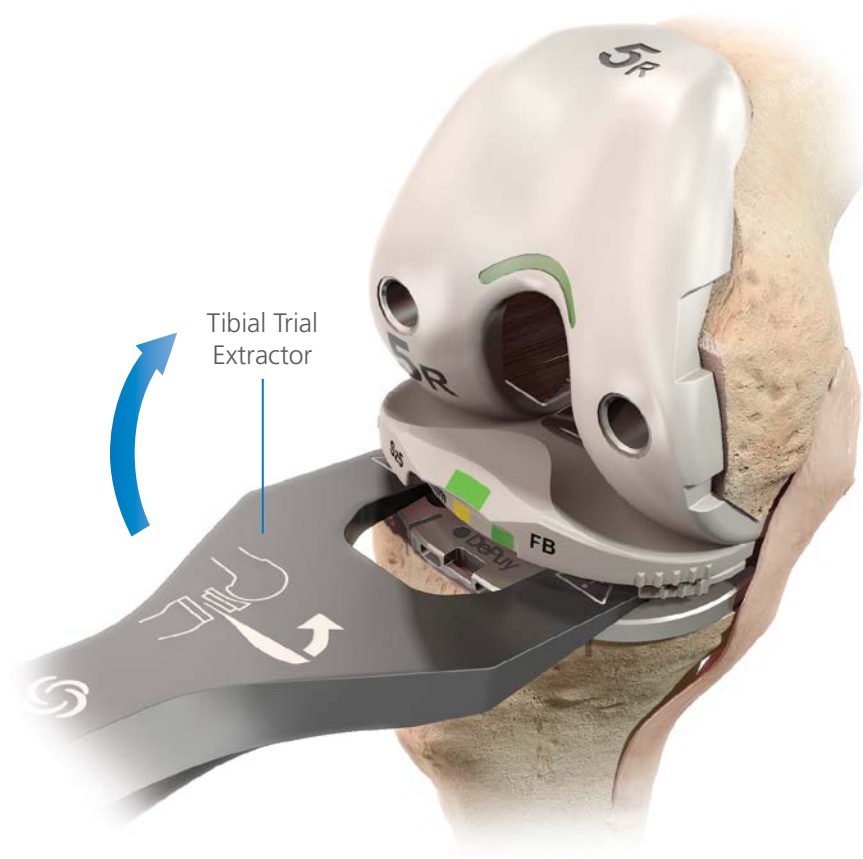
⚠ Fully flex the knee, and remove the Insert Trial.
The Tibial Trial Extractor can be used to aid in the
removal of the Insert Trials.

Insert the Tibial Trial Extractor between the Tibial
Base Trial and the Shim, and lever the handle
upwards toward the femur in order to remove
the Insert Trial.

⚠ **CAUTION**

*Do not insert the Tibial Trial Extractor between the Shim
and the articulation surface to prevent damage to the
connection feature.*

*When removing the Tibial Trials with the Tibial Trial
Extractor, avoid engaging the Keel Punch to prevent
damage to the Tibial Trial Extractor.*

Tibial Preparation

Re-attach the Handle to the Tibial Base Trial and re-insert it on the resected tibial surface, (aligning it with the mark on the bone for a Fixed Bearing Tibial Construct).

Base Pins

Attach the Tibial Drill Tower to the Tibial Base Trial by inserting the spikes on the underside of the Tower through the two inside holes on the anterior aspect of the Base Trial. The spikes provide fixation for both the Drill Tower and the Base Trial. If additional fixation is desired, place Base Pins through the two outside holes on the anterior aspect of the Base Trial. ⚠

If desired, use the appropriate size Tibial Drill Stop.

Use the Tibial Drill to ream the tibia to where the line marked on the side of the Drill aligns to the top surface of the tower. The Line marking corresponds to the Tibial Base size. Bone debris from drilling could prevent the Keel Punch from seating completely in the Base Trial. To prevent this, flush out the cavity after drilling.

Optional Drill Stop

⚠ **CAUTION**

Care should be taken not to protrude through the medial tibial cortex if using the medial Base Pin.

Care should be taken not to overdrill. An optional Drill Stop is available.

Tibial Preparation

Keel Punch

Attach the correct size Keel Punch to the Impaction Handle, and insert the assembly into the Tibial Drill Tower. Impact the assembly into the cancellous bone until the Keel Punch is seated flush on the Tibial Base Trial.

Use the anterior window in the tower to monitor the progress of the Keel Punch while impacting.

Integrated Insertion and Removal
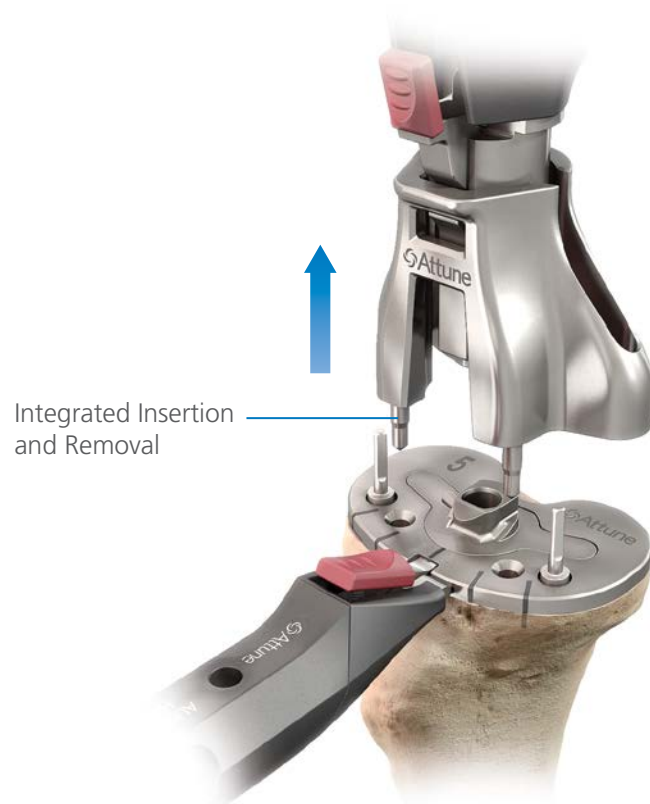
When the Keel Punch is fully seated, the Impaction Handle will automatically disengage from the Keel Punch, allowing the Impaction Handle and the Tibial Drill Tower to be removed together.

ⓘ INFORMATION

Optional: If desired, perform a final trial reduction by inserting the appropriate trial components and repeating the previous trial evaluation.

Patella Resection and Preparation – Instrument Assembly

Patella Resection Guide

Clamp Teeth

Saw Slot

Clamp Trigger

Height Gauge sets Resection Depth to 9.5 mm and can be rotated to find the highest point on the Patella or to be moved out of the way

Release button unclamps the Resection Guide from the bone

Patella Drill Trials

Medialized Dome Patella Drill Trial
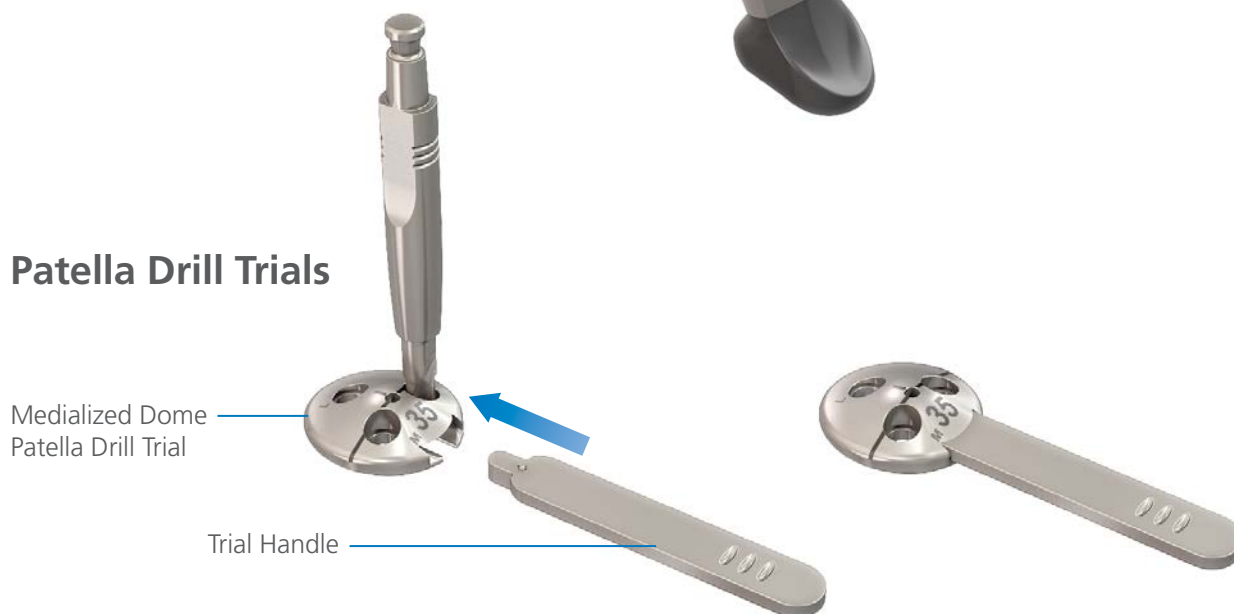
Trial Handle

Assemble by inserting the Trial Handle into the slot on the Drill Trial until it clicks into place

Patella Resection and Preparation – Instrument Assembly

Patella Modular Clamp

Drill Trial

Anatomic Clamp Ring

Clamp Ring

Silicone base protects the implant surface during cement pressurization

Clamp Connection Post attaches to either the Drill Trials or Clamp Ring with a snap-on mechanism

Release button locks and unlocks clamping force
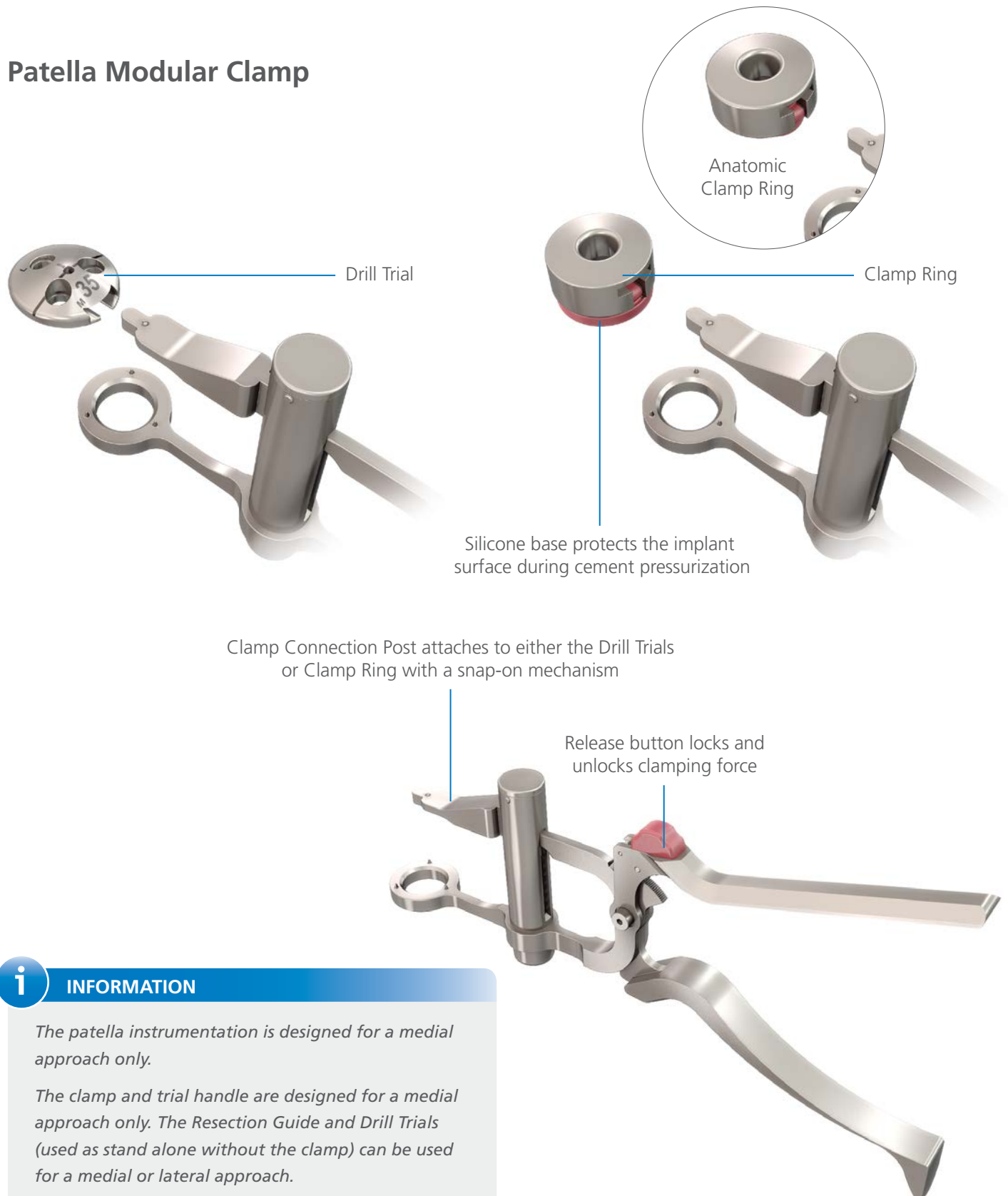
ⓘ **INFORMATION**

The patella instrumentation is designed for a medial approach only.

The clamp and trial handle are designed for a medial approach only. The Resection Guide and Drill Trials (used as stand alone without the clamp) can be used for a medial or lateral approach.

Patella Resection

Use the Caliper to estimate the thickness of the patella and evaluate the level of bone resection. The Height Gauge on the Patella Resection Guide accounts for a resection of 9.5 mm of bone, which is the average thickness of the ATTUNE Knee System Patella Components. ⚠

Patella Guide Shim

Place the leg in extension and evert the patella.

Position the Patella Resection Guide so the Height Gauge is against the articular surface of the patella. Align the serrated jaws at the medial and lateral margins of the articular surface. Engage the largest tooth on the lateral side then engage the largest tooth on the opposite side to temporarily secure the clamp while allowing for rotation of the patella until the inferior and superior orientation is achieved and clamp fully.

⚠ **CAUTION**

If the patellar thickness is less than 21.5 mm, the thickness of the bone remaining after resection would be less than 12 mm and resecting less bone should be considered.

If less resection is required, the Patella Guide Shim is available which reduces the depth of the resection to 7.5 mm.

ℹ **INFORMATION**

The resection extends from the medial chondro-osseous junction to the lateral chondro-osseous junction.

Patella Resection

Perform the resection using an Oscillating Saw through the Saw Capture.
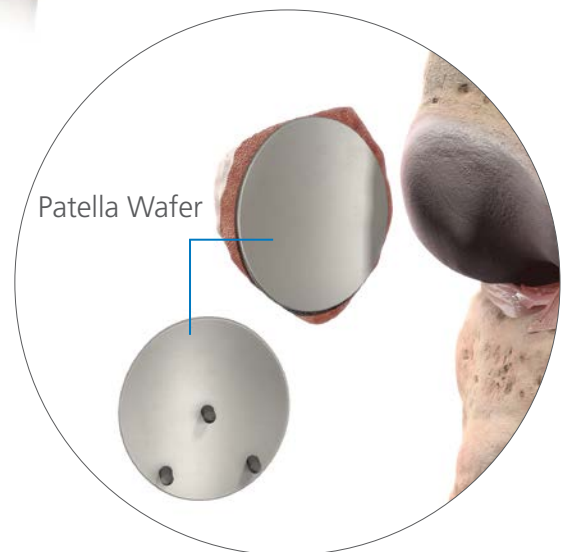
Patella Wafer

If desired, place a Patella Wafer on the resected surface by hand to protect the patellar bone bed.

Patella Preparation

Patella Implant Options

Anatomic Patella

Medialized Dome Patella

Patella Size Chart	
Size	Thickness
29	8.5 mm
32	9 mm
35	9.5 mm
38	10 mm
41	10.5 mm

Two patella options are available, the Medialized Dome Patella or the Anatomic Patella.

The Anatomic Patella is designed to be conforming with the femoral component and has a built in range of +/- 15 degrees freedom of rotation from its optimal position. Therefore, accurate alignment of the Patella Drill Trial is important for proper patella placement and tracking.

The following steps will aid in accurate alignment of both patella designs, but is particularly critical for the Anatomic Patella.

Patella Preparation

Patella Drill Trialing

If used, remove the Patella Wafer from the patella. Place the Patella Drill Trial on the resected patella to assess bone coverage. Select the correct size of Patella Drill Trial for maximum patella bone coverage. Verify the medial lateral location of the patella implant apex relative to the native anatomy ridge.

For an alternative technique, see Appendix 1 on page 92.
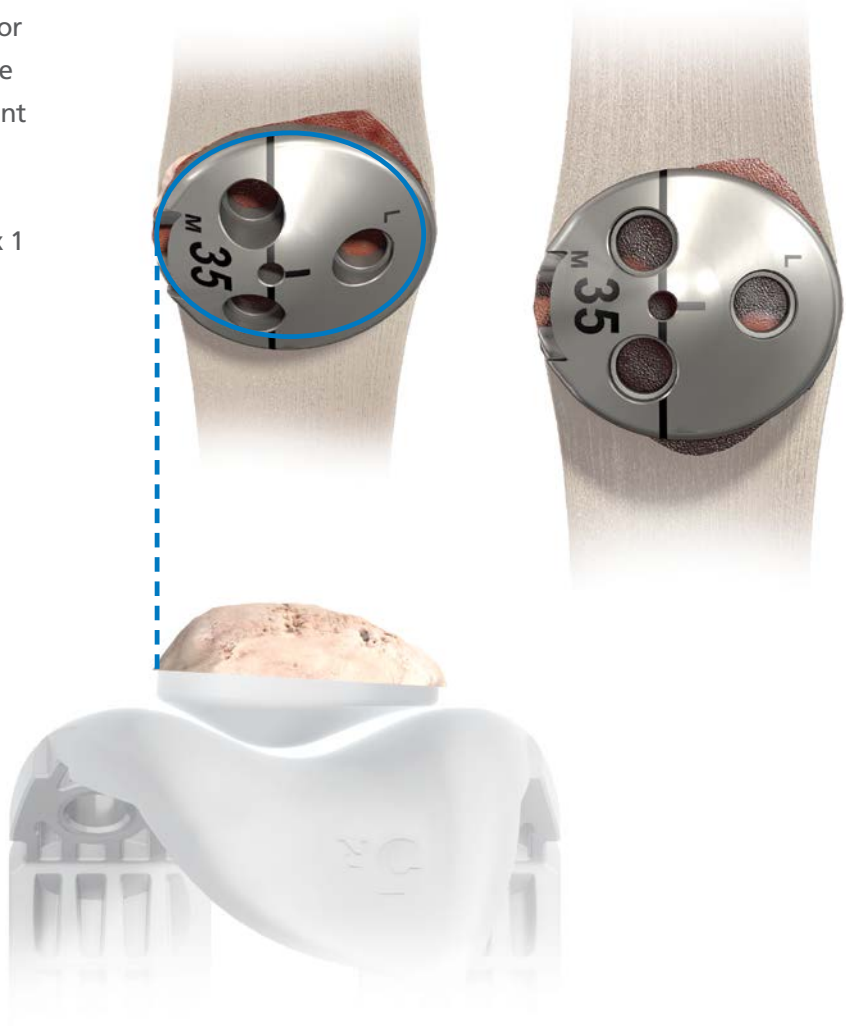
Patella Preparation

Patella Drill Trialing

Press the trial onto the bone manually or with the Patella Modular Clamp and Clamp Ring to engage spikes.

The Drill Trials have one larger central spike to allow engagement of only the central spike so that the Drill Trial may be rotated about the central axis to aid in assessment of its optimal position prior to being fully seated on bone.

Anatomic Patella Drill Trial

Medialized Dome Patella Drill Trial

Large Central Spike
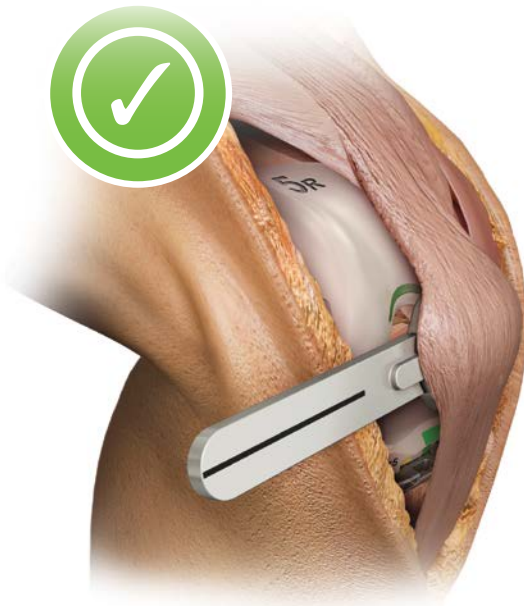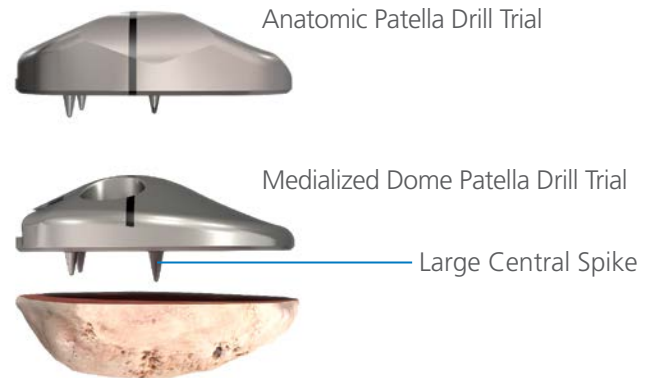
Correct trial handle alignment
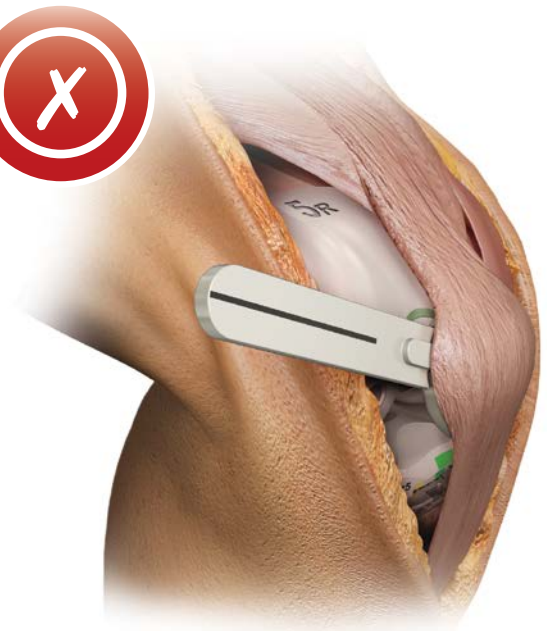
Incorrect trial handle alignment

> ### ℹ INFORMATION
>
> *In a case where a short patella tendon raises concern about the Anatomic Patella contacting the top of the spine of the PS femoral component, it is recommended to downsize the patella, superiorize and medialize its position. If that recommended positioning does not resolve the concern, the surgeon should consider using the medialized dome patella.*

Lug Hole Preparation

Patella/Femoral Lug Drill

Medialized Dome Patella Drill Trial

Anatomic Patella Drill Trial

⚠️

Use the Patella Modular Clamp to secure the Drill Trial if desired. Drill the holes using the Patella/Femoral Lug Drill.

Femoral Lug Hole Preparation

It is recommended to drill the femoral lug holes after Patella trialing with the full trialing construct in place.

⚠️ **CAUTION**

If the surgeon is not satisfied with alignment or tracking of the Anatomic Patella Trial after drilling the peg holes, it is recommended to use a Medialized Dome Patella. The patella peg hole preparation is identical for the Medialized Dome Patella and the Anatomic Patella.

Tibial Base Implantation

Cementing Technique

⚠️

During cementing of implants, movement of the components should be minimized while the cement is curing.

Prepare the sclerotic bone to ensure a continuous cement mantle with good cement interdigitation of 2 mm - 4 mm. This can be done by drilling holes and cleansing the bone with pulsatile lavage, taking care to dry the bone afterwards. Pack residual small cavity bone defects with cancellous autograft, allograft, or synthetic bone substitutes.

Base Protector

Apply a thick layer of cement to the bone, the implant surface or to both.

Cement should be applied to the cleaned and dried prepared tibial plateau. Also, it is critical to ensure that cement fully surrounds the cone of the tibial base implant.

⚠️ **CAUTION**

Blood lamination can reduce the mechanical properties of the cement; therefore, it is vital to choose cement that reaches its working phase quickly. If applying cement to both the implant and bone, implantation should be completed early in its dough state to ensure good cement-cement adhesion and reduce the risk of dry laminations; which can weaken the cement.

Tibial Base Implantation

Carefully insert the Tibial Base, avoiding malrotation. Select the appropriate Fixed Bearing or Rotating Platform Tibial Impactor.

FB Tibial Impactor

RP Tibial Impactor

⚠️ **CAUTION**

To prevent damage to the bearing surface, do not remove the Base Protector before impacting the base.

Care must be taken not to pull cement from under the edge of the implant in order to ensure the edges remain sealed.

With the Tibial Base inserted, impact it with several blows from the Mallet to the top of the Impactor in order to pressurize the cement. Then use a Curette to remove all extruded cement.

Femoral Component Implantation

Rotate thumb wheel to bias the grip arms outward

Rotate side knob clockwise to lock

Grip Arm

Impaction Shoe

Grip Arm

Impaction Shoe
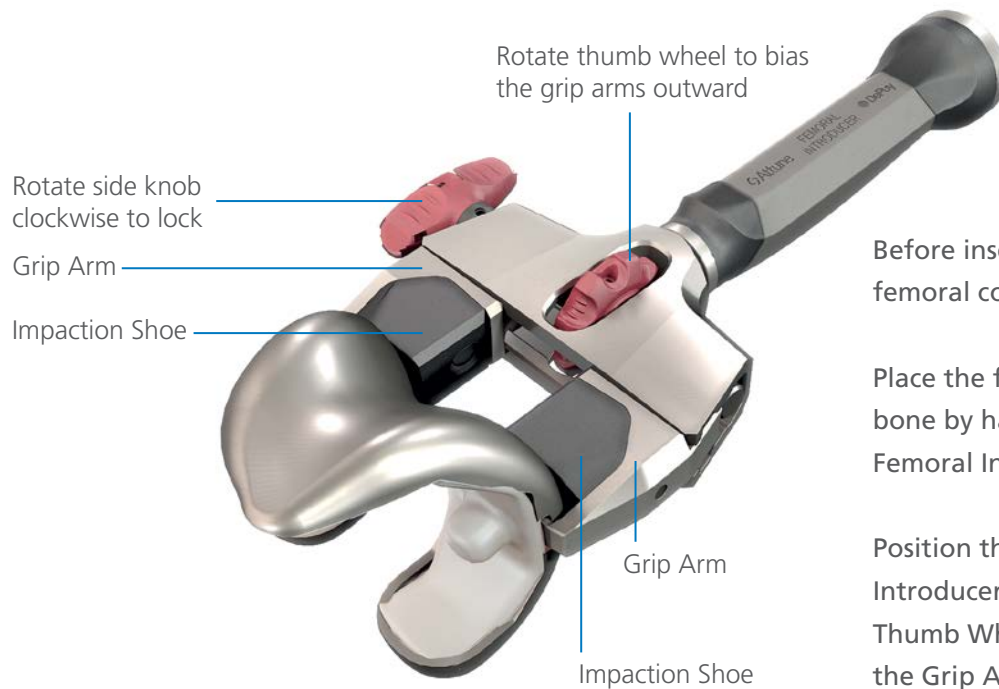
Before insertion, place cement onto the femoral component and the femur.

Place the femoral component onto the bone by hand or, if preferred, use the Femoral Introducer.

Position the femoral component on the Introducer by rotating the red Central Thumb Wheel on the Introducer to move the Grip Arms outward. Then push the femoral component against the impaction shoes, and rotate the Central Thumb Wheel to move the Grip Arms inward so that the arms engage in the slots on the femoral component. Rotate the Side Knob clockwise to lock and secure the implant.

Begin inserting the femoral component by engaging the Femoral Lugs in the lug holes of the distal femur, and deliver several Mallet blows to the Introducer.

To release the Femoral Introducer, rotate the Side Knob counterclockwise and rotate the red Central Thumb Wheel to move the Grip Arms outward.

Femoral Component Implantation
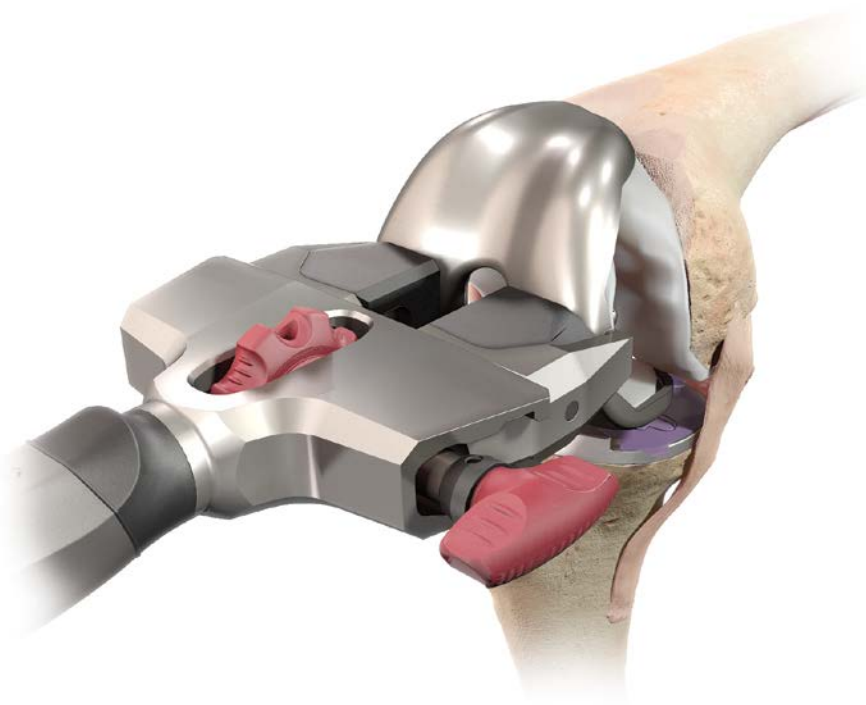
Femoral Impactor

Condylar Impaction
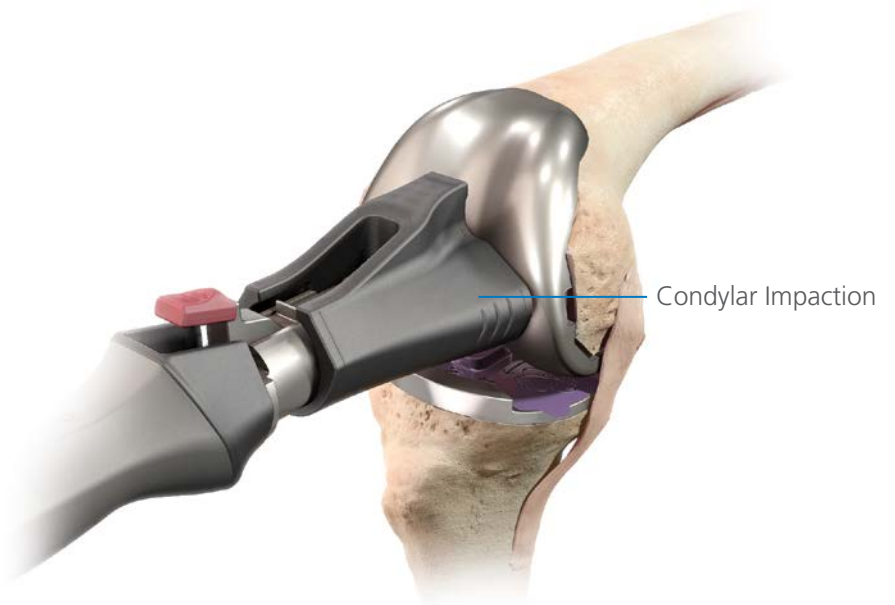
For final femoral component impaction, attach the Impaction Handle to the Femoral Impactor head.

Use a combination of condylar and notch impaction to seat the femoral component. Then use a Curette to remove all extruded cement.

Notch Impaction

ⓘ INFORMATION

The Femoral Introducer is not designed for nor intended to be used for femoral component removal.

Tibial Insert Implantation

A trial reduction may be performed using Insert Trials.

Rotating Platform

For a Rotating Platform implant, place the RP Trial Post into the implanted base component. Then place the Insert Trial over the post and perform the trial reduction. For Rotating Platform components, verify rotational stability with PCL tension. Remove loose fragments or particulates from the Final Tibial Base.

For Rotating Platform tibial components, insert the final Tibial Insert.

Fixed Bearing

For Fixed Bearing components, place the Insert Trial on the Tibial Base. Verify that the Insert Trial does not tilt up off the front of the base during the range of motion test. This could indicate that the PCL is too tight. Remove loose fragments or particulates from the Final Tibial Base.

For Fixed Bearing tibial components, angle the Tibial Insert posteriorly and slide the posterior tabs into the posterior undercuts of the Tibial Base.

Insert slides back and then down

Tibial Insert Implantation

Fixed Bearing Insert Impactor

60°

The Fixed Bearing Tibial Insert is impacted into place on the Tibial Base, using the Fixed Bearing Insert Impactor.

⚠ Position the Impactor at approximately 60 degrees on the insert so that the notch rests on the anterior edge of the center of the insert. Use a Mallet to strike the Fixed Bearing Insert Impactor. Confirm seating by circumferential inspection. Move the leg into extension, and then lift the leg back into flexion for final removal of excess cement.

⚠ **CAUTION**

Care should be taken when flexing the knee past 45 degrees to avoid putting force on the posterior aspect of the tibial base while the cement is curing.

Once all components are implanted, extending the leg will further pressurize the cement. The leg should then remain in extension until the cement hardens for the appropriate time depending on the cement type used.

Final Patella Preparation

Apply cement to the patella implant. Thoroughly clean the cut surface of the patella with pulsatile lavage. Apply cement to the surface of the patella and insert the component.

Medialized Dome
Clamp Ring

Anatomic
Clamp Ring

Connect the appropriate Clamp Ring to the Patella Modular Clamp.

Patella Component Implantation

The Clamp Ring is designed to fully seat and stabilize the implant as the cement polymerizes.

Center the Clamp Ring over the articular surface of the implant and the metal backing plate against the anterior cortex of the patella, avoiding skin entrapment.

Engage the Patella Clamp Handle to firmly hold the Patella Implant until polymerization is complete. Remove all extruded cement with a Curette.

Release the Clamp by unlocking the Locking-Switch on the handle and slightly squeezing the Clamp Handles to disengage the locking mechanism.

Anatomic Patella Clamp Ring

Reduce the patella.

Final Medialized Dome Patella

Final Anatomic Patella

Closure

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

Appendix 1: Optional Patella Drilling Technique

Mark the apex of native patella. In most cases duplication
of the median crest is recommended.

ℹ **INFORMATION**

Prior to resecting the patella a small hole can be drilled
through the apex of the native patella bone (1-2 mm
deeper than the intended amount of resection). Once the
patella has been resected the remainder of the hole will
be present on the resected bone surface.

The Drill Trial has a small hole through the center of the
apex, representing the peak of the patella implant. This
hole can be visually aligned with the pre-drilled hole on
the resected patella surface to aid in anatomic placement
of the trial.

Flexion/Extension Gap Chart

	Loose Extension	Tight Extension	Stable Extension
Loose Flexion	**Cause:** Flexion and extension gaps are too large **Possible Solution(s):** • Thicker tibial insert	**Cause:** Flexion gap is larger than the extension gap **Possible Solution(s):** • Recut distal femur and use thicker insert • Posterior capsular release • Posteriorize the femoral component by 1.5 mm	**Cause:** Flexion gap is larger than extension gap **Possible Solution(s):** • Decrease the tibial slope and use a thicker tibial insert • Recut the distal femur and use a thicker tibial insert • Larger femoral component • Posteriorize the femoral component by 1.5 mm
Tight Flexion	**Cause:** Extension gap is larger than flexion gap **Possible Solution(s):** • Check for osteophytes • Downsize femoral component and use thicker insert • Increase tibial slope • Recess PCL off of femur or tibia	**Cause:** Flexion and extension gaps are too small **Possible Solution(s):** • Thinner tibial insert • Resect additional tibia	**Cause:** Flexion gap is too small **Possible Solution(s):** • Check for osteophytes • Downsize femoral component • Anteriorize the femoral component by 1.5 mm • Increase tibial slope • Recess PCL off of femur or tibia
Stable Flexion	**Cause:** Extension gap is too large **Possible Solution(s):** • Downsize femoral component and increase insert thickness • Increase tibial slope and use thicker tibial insert	**Cause:** Extension gap is too small **Possible Solution(s):** • Recut distal femur • Posterior capsular release • Larger femoral component and thinner insert	**Cause:** Balanced gaps **Possible Solution(s):** • No solution required

Tibial Component Sizing Chart

Trial Insert and Shim Depth	Tibial Insert Depth	+	Tibial Base Depth	=	Implant Construct Thickness
5 mm	5 mm	+	4 mm	=	9 mm
6 mm	6 mm	+	4 mm	=	10 mm
7 mm	7 mm	+	4 mm	=	11 mm
8 mm	8 mm	+	4 mm	=	12 mm
10 mm	10 mm	+	4 mm	=	14 mm
12 mm	12 mm	+	4 mm	=	16 mm
14 mm	14 mm	+	4 mm	=	18 mm
16 mm	16 mm	+	4 mm	=	20 mm
18 mm (PS only)	18 mm (PS only)	+	4 mm	=	22 mm (PS only)
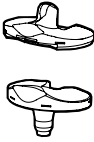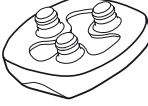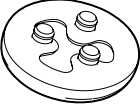
Shim Depth and Final Insert Depth are equal

Depth dimensions are all the same, whether using Cruciate Retaining (CR), Posterior Stabilized (PS), Rotating Platform or Fixed Bearing combinations.

Compatibility Data

SIZE SZ	(femur)	(insert)	1	2	3	4	5	6	7	8	9	10	(tibial base) 29	32	35	38	41
Pink	1	1	1	2	3								29	32	35	38	41
Dark Blue	2	2	1	2	3	4							29	32	35	38	41
Grey	3/3N	3	1	2	3	4	5						29	32	35	38	41
Black	4/4N	4		2	3	4	5	6						32	35	38	41
Green	5/5N	5			3	4	5	6	7					32	35	38	41
Yellow	6/6N	6				4	5	6	7	8				32	35	38	41
Light Blue	7	7					5	6	7	8	9				35	38	41
Red	8	8						6	7	8	9	10			35	38	41
Purple	9	9							7	8	9	10				38	41
Brown	10	10								8	9	10				38	41

Symbols on Surgical Instruments

Some of the instruments have markings on them for guidance.
The interpretation of these markings is as detailed in the table below.

Symbol or Text	Definition
⛲ (cleaning position symbol)	Cleaning position here
(dismantle symbol)	Dismantle for cleaning
🔓	Unlock
🔒	Lock
L	Left
R	Right
LEFT	Left
RIGHT	Right
CR	ATTUNE Cruciate Retaining Implant
PS	ATTUNE Posterior Stabilized Implant
RP	Rotating Platform
FB	Fixed Bearing

Symbol or Text	Definition
L	Lateral
M	Medial
LL	Left Lateral
RL	Right Lateral
SULCUS	Sulcus
FLEXION	Flexion
EXTENSION	Extension
SZ	Size
TIB	Tibia
⚠	Refer to Accompanying Documents
DEG	Degrees

Ordering Information

Product Description	Product Code
Brainlab Knee 2.6	21000-01
T Array	52410
Y Array	52411
2-Pin Bone Fixator	52420
Reflective Marker Spheres	41773
Universal Cutting Block Adapter	41866-77
Pointer	53101

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Germany
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C€
0123

ATTUNE® KNEE SYSTEM FIXED BEARING KNEE

IMPORTANT

This Essential Product Information sheet does not include all of the information necessary for selection and use of a device. Please see full labeling for all necessary information.

INTENDED USE

Total knee arthroplasty is intended to provide increased patient mobility and reduced pain by replacing the damaged knee joint articulation in patients where there is evidence of sufficient sound bone to seat and support the components. Total knee replacement may be considered for younger patients if, in the opinion of the surgeon, an unequivocal indication for total knee replacement outweighs the risks associated with the age of the patient, and if limited demands regarding activity and knee joint loading can be assured. This includes severely crippled patients with multiple joint involvement for whom a gain in knee mobility may lead to an expectation of significant improvement in the quality of their lives.

INDICATIONS

Candidates for total knee replacement include patients with a severely painful and/or severely disabled joint resulting from osteoarthritis, post-traumatic arthritis, rheumatoid arthritis, or a failed previous implant.

CONTRAINDICATIONS

The following conditions are contraindications for total knee replacement:

1. Active local or systemic infection.

2. Loss of bone or musculature, osteoporosis, neuromuscular compromise or vascular deficiency in the affected limb in sufficient degree to render the procedure unjustifiable (e.g., absence of musculoligamentous supporting structures, joint neuropathy).

3. Severe instability secondary to advanced loss of osteochondral structure or the absence of collateral ligament integrity.

NOTE:

Diabetes, at present, has not been established as a contraindication. However, because of the increased risk for complications such as infection, slow wound healing, etc., the physician should carefully consider the advisability of knee replacement in the severely diabetic patient.

WARNINGS AND PRECAUTIONS

CAUTION:

- Tibial insert size should be the same size as the selected femoral component size. Tibial inserts should be within 2 sizes of the tibial base.

- Patella component sizes 38mm and 41mm may be used with all femoral component sizes. Patella component size 29mm may only be used with femoral component sizes 1 through 3. Patella component size 32mm may only be used with femoral component sizes 1 through 6. Patella component size 35mm may only be used with femoral component sizes 1 through 8.

- Implants and trial components from different manufacturers or implant systems should never be used together.

- Knee prosthesis components should never be reimplanted. Even though the implant appears undamaged, the implant may have developed microscopic imperfections which could lead to failure.

- Always use a trial prosthesis for trial purposes. Trials should not be assembled with any components intended for permanent implantation. Trials must have the same configuration size, as the corresponding components to be permanently implanted.

- Do not alter or modify implants in any way.

- Avoid drilling multiple pin holes in the proximal tibia which may affect the compressive strength of the tibia.

- When used with multiple components of a total knee replacement system, the MR compatibility and safety of the entire system of implants has not been evaluated and the entire system of implants has not been tested together for heating or migration in the MR environment. The risks of exposure to MR include heating and/or displacement of a metallic implant. Image artifacts including dead zones and distortion may occur, especially in the immediate area around the implant, requiring optimization of imaging parameters. In line with the recommendations of the American College of Radiology, *DePuy Synthes Companies* of Johnson & Johnson recommends that a professional familiar with the specific MRI apparatus to be used, assess the patient prior to any MRI examination or therapy.

NOTE:

DePuy Synthes Companies' Single Use devices have not been designed to undergo or withstand any form of alteration, such as disassembly, cleaning or re-sterilization, after a single patient use. Reuse can potentially compromise device performance and patient safety.

CAUTION:

The following conditions, singularly or concurrently, tend to impose severe loading on the affected extremity thereby placing the patient at higher risk of failure of the knee replacement:

1. Obesity or excessive patient weight.

2. Manual labor.

3. Active sports participation.

4. High levels of patient activity.

5. Likelihood of falls.

6. Alcohol or drug addiction.

7. Other disabilities, as appropriate.

In addition to the above, the following physical conditions, singularly or concurrently, tend to adversely affect the fixation of knee replacement implants:

1. Marked osteoporosis or poor bone stock.

2. Metabolic disorders or systemic pharmacological treatments leading to progressive deterioration of solid bone support for the implant (e.g., diabetes mellitus, steroid therapies, immunosuppressive therapies, etc.).

3. History of general or local infections.

4. Severe deformities leading to impaired fixation or improper positioning of the implant.

5. Tumors of the supporting bone structures.

6. Allergic reactions to implant materials (e.g. bone cement, metal, polyethylene).

7. Tissue reactions to implant corrosion or implant wear debris.

8. Disabilities of other joints (i.e., hips or ankles).

A higher incidence of implant failure has been reported in paraplegics and in patients with cerebral palsy or Parkinson's Disease.

WHEN THE SURGEON DETERMINES THAT KNEE REPLACEMENT IS THE BEST MEDICAL OPTION AVAILABLE AND DECIDES TO USE THIS PROSTHESIS IN A PATIENT WHO HAS ANY OF THE ABOVE CONDITIONS OR WHO IS SIMPLY YOUNG AND ACTIVE, IT IS IMPERATIVE THAT THE PATIENT BE INSTRUCTED ABOUT THE STRENGTH LIMITATIONS OF THE MATERIALS USED IN THE DEVICE AND FOR FIXATION AND THE RESULTANT NEED TO SUBSTANTIALLY REDUCE OR ELIMINATE ANY OF THE ABOVE CONDITIONS.

The surgical and postoperative management of the patient must be carried out with due consideration for all existing conditions. Mental attitudes or disorders resulting in a patient's failure to adhere to the surgeon's orders may delay postoperative recovery and/or increase the risk of adverse effects including implant or implant fixation failure.

Excessive physical activity or trauma to the replaced joint may contribute to premature failure of the knee replacement by causing a change in position, fracture, and/or wear of the implants. **The functional life expectancy of prosthetic knee implants is, at present, not clearly established.** The patient should be informed that factors such as weight and activity levels may significantly affect wear.

ATTUNE® KNEE SYSTEM – ROTATING PLATFORM

IMPORTANT

This Essential Product Information sheet does not include all of the information necessary for selection and use of a device. Please see full labeling for all necessary information.

INTENDED USE

Total knee arthroplasty is intended to provide increased patient mobility and reduced pain by replacing the damaged knee joint articulation in patients where there is evidence of sufficient sound bone to seat and support the components. Total knee replacement may be considered for younger patients if, in the opinion of the surgeon, an unequivocal indication for total knee replacement outweighs the risks associated with the age of the patient, and if limited demands regarding activity and knee joint loading can be assured. This includes severely crippled patients with multiple joint involvement for whom a gain in knee mobility may lead to an expectation of significant improvement in the quality of their lives.

INDICATIONS

The Rotating Platform (RP) Total Knee System is indicated for cemented use in cases of osteoarthritis and rheumatoid arthritis. The rotating platform prosthesis is indicated for primary total knee arthroplasty or the revision of failed knee prostheses.

CONTRAINDICATIONS

The use of the RP Total Knee System is contraindicated in:

- The presence of osteomyelitis, pyrogenic infection or other overt infection of the knee joint. Every effort should be made to rule out the possibility of pre-operative sepsis in a patient who has one or more of the following abnormalities:

  - Fever or local inflammation;

  - Rapid destruction or bone resorption apparent on x-rays;

  - Elevation of the erythrocyte sedimentation rate or white blood cell count unexplained by other disease or a marked shift in the white blood cell differential count.

- Patients with any active infection at sites such as the genitourinary tract, pulmonary system, skin or any other site. Should a patient have any infection prior to implantation, the foci of the infection must be treated prior to, during and after implantation.

- Patients with loss of musculature or neuromuscular compromise leading to loss of function in the involved limb or in whom the requirements for its use would affect recommended rehabilitation procedures.

- Patients with severe osteoporosis or other metabolic bone diseases of the knee;

- Patients with any of the following conditions:

  - Lesions of the supporting bone structures (e.g. aneurysmal or simple bone cysts, giant cell tumor or any malignant tumor),

  - Systemic and metabolic disorders leading to progressive deterioration of solid bone support,

  - The presence of severe instability secondary to advanced loss of osteochondral structure or the absence of collateral ligament integrity, fixed deformities greater than 60° of flexion, 45° of genu varus or valgus,

  - Known drug or alcohol addiction,

  - Skeletally immature individuals and the presence of allergic reaction to implant metals or polyethylene are also contraindications for the use of all device configurations of the RP Total Knee System.

WARNINGS AND PRECAUTIONS

- The correct selection as well as the correct seating/placement of the prosthetic implant is extremely important. During surgery, particular attention to tracking of the patella is also required for a successful result. Thus, failure to use the optimum size implant, failure to adequately seat the component adjacent to adequate bone and failure to ensure that the component is stable may result in dislocation, subsidence, fracture or loosening of the components. The proper size selection, the choice of and careful use of the components and the use of trial prostheses are imperative.

- The RP inserts should be the same size as the selected femoral component. The RP inserts articulate with the RP primary bases. RP tibial inserts should be within 2 sizes of the RP tibial base.

- RP Total Knee components, instruments and trial prostheses should not be used together with those of another manufacturer. Because dimensional compatibility cannot be assured, adverse outcomes can result from the use of components from different manufacturers.

- A post-operative management program is vital. It is recommended that the program be modified according to the condition of the patient and the extent of soft tissue and ligament reconstruction.

- The safety and effectiveness of the cemented use of the RP Total Knee in patients under 41 years of age have not been established.

- The implantation of the RP insert and femoral component will not in itself guarantee a high level of post-operative flexion. The degree of post-operative flexion is multi-factorial. These factors include, but are not limited to, surgical technique, patient build, pre-operative flexion and age.

- When used with multiple components of a total knee replacement system, the MR compatibility and safety of the entire system of implants has not been evaluated and the entire system of implants has not been tested together for heating or migration in the MR environment. The risks of exposure to MR include heating and/or displacement of a metallic implant. Image artifacts including dead zones and distortion may occur, especially in the immediate area around the implant, requiring optimization of imaging parameters. In line with the recommendations of the American College of Radiology, *DePuy Synthes Companies* recommends that a professional familiar with the specific MRI apparatus to be used, assess the patient prior to any MRI examination or therapy.

PRECAUTIONS:

The surgeon should discuss all physical and psychological limitations inherent to the use of this device with the patient pre-operatively. Particular discussion should be directed to the issues of premature weight bearing, activity levels and the necessity for periodic medical follow-up.

Surgeons should not begin the clinical use of any knee prosthesis before they have thoroughly familiarized themselves with its specific implantation technique. Certain methods may change with time as further clinical experience is gained. Such changes are presented at regularly scheduled surgical instruction courses for which periodic attendance is advised. Surgical technique brochures, course schedules, and course recordings are available from *DePuy Synthes*. Particular attention should be paid to the handling of the components.

NOTE: *DePuy Synthes Companies'* Single Use devices have not been designed to undergo or withstand any form of alteration, such as disassembly, cleaning or re-sterilization, after a single patient use. Reuse can potentially compromise device performance and patient safety.

Reference

1. Scott, R.D. & Chmell, M.J. (2008). Balancing the posterior cruciate ligament during cruciate retaining fixed and mobile-bearing total knee arthroplasty. Description of the pull-out lift off and slide-back tests. The Journal of Arthroplasty, 23(4), 605-608.

DePuy Synthes *People inspired*™
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