VELYS™

ROBOTIC-ASSISTED SOLUTION
Tibia First Approach

Surgical Technique - Software v1.6

DePuy Synthes
THE ORTHOPAEDICS COMPANY OF Johnson&Johnson

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Introduction

Overview and Objectives

The following VELYS™ Robotic-Assisted Solution for Total Knee Surgical Technique provides a guideline for the implantation of the ATTUNE™ Total Knee System using the VELYS™ Robotic-Assisted Solution from DePuy Synthes, and either the INTUITION™ Instruments, or the INTUITION™ Essential Instruments.

The surgical procedure follows a "Tibia First" workflow.

This surgical technique must be used in conjunction with:
- The VELYS™ Robotic-Assisted Solution Application for Total Knee Version 1.6
- The VELYS™ Robotic-Assisted Solution for Total Knee User Guide which describes in detail the functionalities of the system
- The ATTUNE™ Total Knee System INTUITION™ Instruments Surgical Technique
- The ATTUNE™ Revision Knee System Fixed Bearing Surgical Technique if an ATTUNE™ Revision Tibial Base is used

Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.

Introduction

Key Surgical Steps Summary
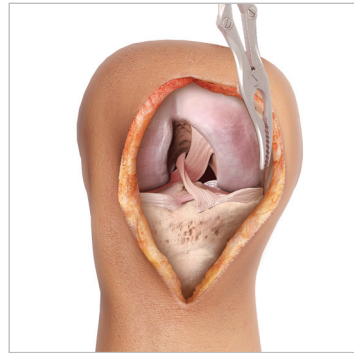
Incision, Exposure and
Removal of Osteophytes
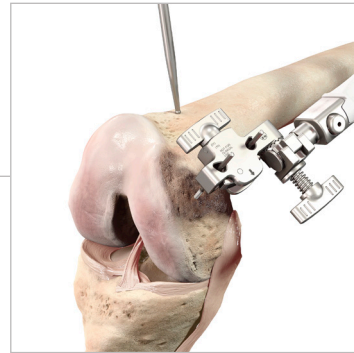
Bony Landmarks
Acquisition
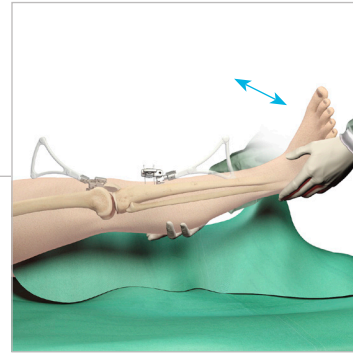
Initial Leg Alignment
and ACCUBALANCE™
Graph Recording
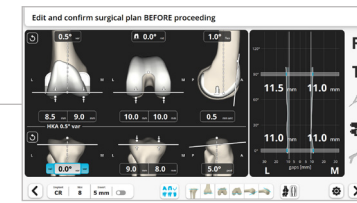
PROADJUST™
Surgical Planning

Tibial Robotic Resection
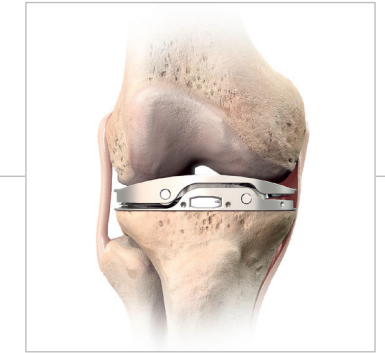
ACCUBALANCE™ Graph
Update
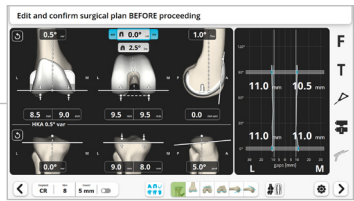
PROADJUST™ Surgical
Planning Update - Femur

Distal Femoral
Robotic Resection

Anterior, Posterior,
and Chamfer Femoral Robotic
Resections

Trial Reduction*
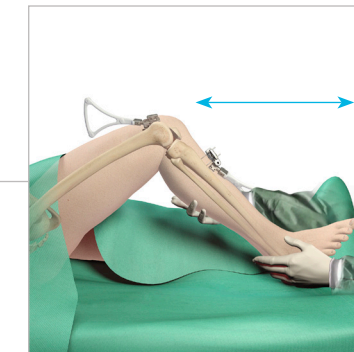
Leg Alignment and
ACCUBALANCE™ Graph
Recording with Trial Implants

Tibial Preparation*

Femoral Lug
Hole Preparation*
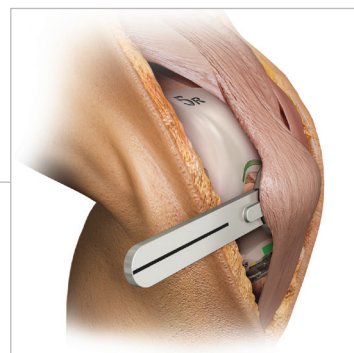
Patella Resection and
Final Patella Preparation*

Final Component
Implantation*
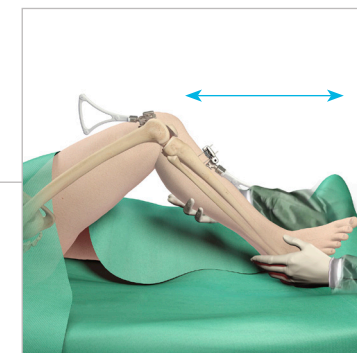
Leg Alignment and ACCUBALANCE™ Graph
Recording with Final Implants (Optional)

* This step can be performed using either the INTUITION™ Instruments, or the INTUITION™ Essential Instruments

Introduction

System Overview

The VELYS™ Robotic-Assisted Solution's Operating Platform includes two stations:

Base Station: Consoles driving the Robotic-Assisted Device and the Saw, Camera, Touchscreen, and Footswitch

Satellite Station: Robotic-Assisted Device, Transfer Mechanism, and Touchscreen

Satellite Station Touchscreen

Camera

Robotic-Assisted Device

Base Station Touchscreen

Transfer Mechanism

Consoles

Footswitch

Satellite Station
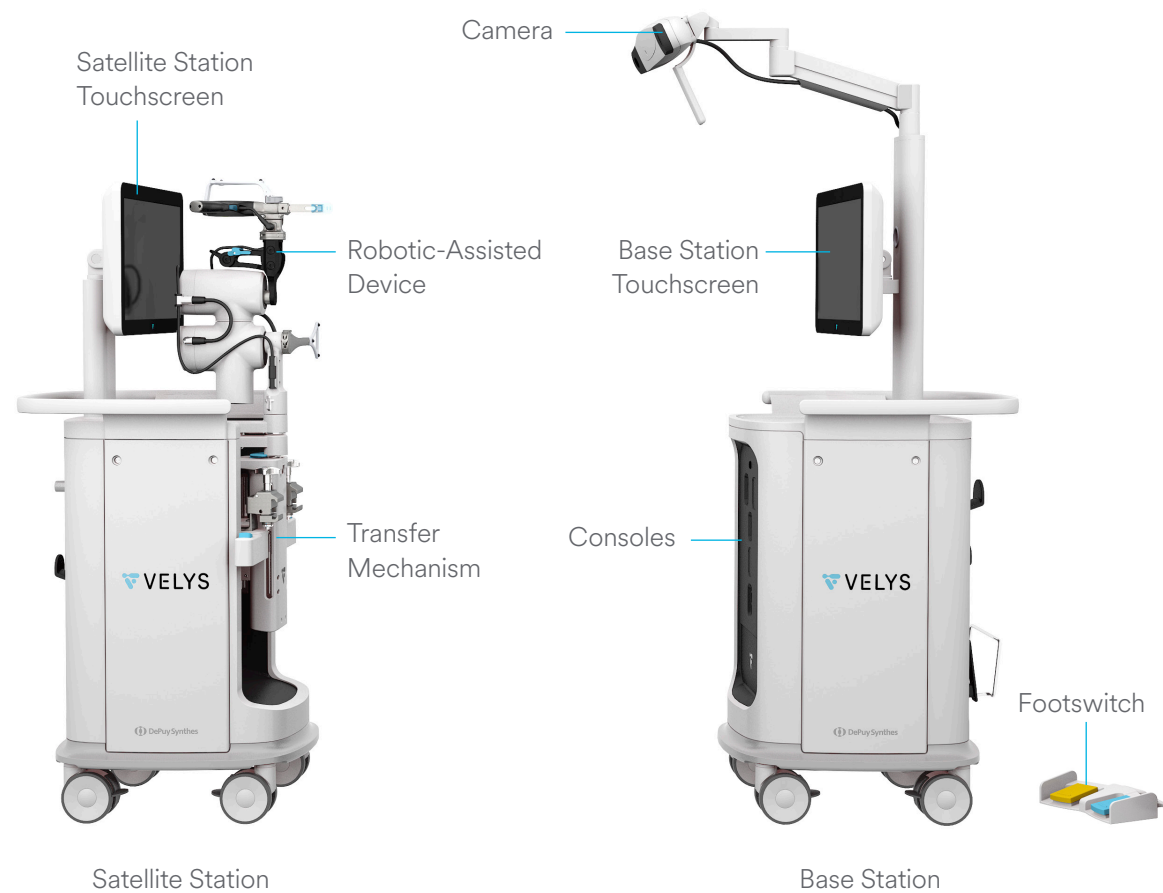
Base Station

The Base Station hosts the consoles running the application and houses the Camera. The Base Station can be moved to adjust the position of the Camera.

Satellite Station
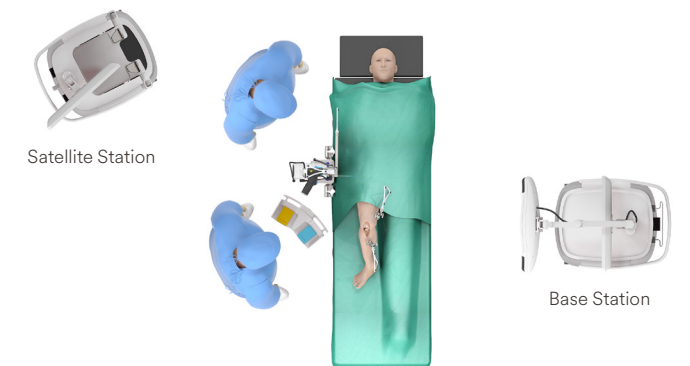
Base Station

The Robotic-Assisted Device remains held by the Transfer Mechanism of the Satellite Station when not in use. During the procedure, the Satellite Station is used to position and attach the Robotic-Assisted Device to the ipsilateral side rail of the operating table at the level of the hip center.

> ■ **Note:**
> The Robotic-Assisted Device may be transferred to the OR table before or after surgical exposure or after PROADJUST™ Surgical Planning, depending on surgeon preference (see Robotic-Assisted Device Positioning).

Robotic-Assisted Device

Holding Arm   Side Rail
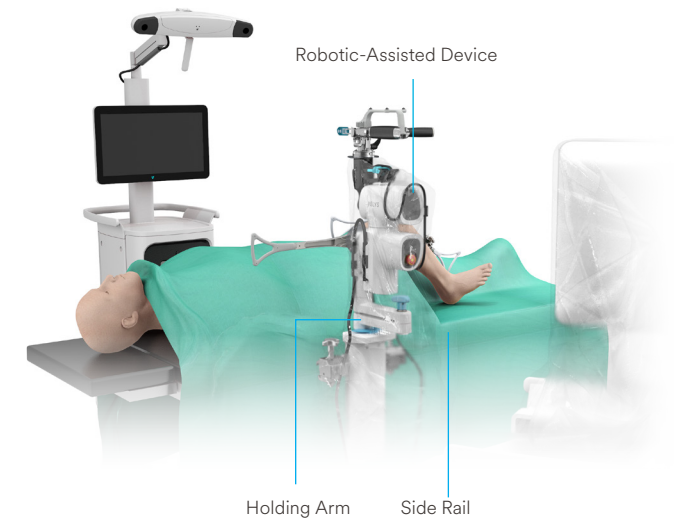
Introduction

System Overview

During the procedure, the Satellite Station is covered by a sterile drape.

> **■ Note:**
> The user should not rotate the screen of the Satellite Station once the satellite station is draped. This could change the position of the slit in the drape at the back of the Satellite Station, which may inhibit access to the crank at the back. Adjusting the orientation of the screen slightly is acceptable.

The height of the Robotic-Assisted Device can be adjusted by pressing the Holding Arm Vertical Adjustment Button. The Robotic-Assisted Device can move horizontally by unlocking the Holding Arm Horizontal Adjustment. See Robotic-Assisted Device Positioning for the recommended position for execution of the resections.

> **▲ Caution:**
> When manipulating the Horizontal Adjustment Locking Mechanism, ensure there is some slack in the Device Drape to avoid perforation of the Drape.

The Camera, on the Base Station, tracks the position and orientation of bones (tibia and femur), instruments (Pointer), Robotic-Assisted Device, and Saw *via* the PURESIGHT™ Hydrophobic Optical Reflectors attached to the Arrays.

> **▲ Caution:**
> The required PURESIGHT™ Reflectors must remain visible to the Camera.
>
> - Any debris (blood or tissue) on the Reflectors obscure their visibility to the Camera. Minimize touching the Reflectors directly and wipe any debris from them
>
> - Maintain a clear line of sight between the Arrays and the Camera

Vertical Adjustment Button

Hip Center

Horizontal Adjustment Locking Mechanism
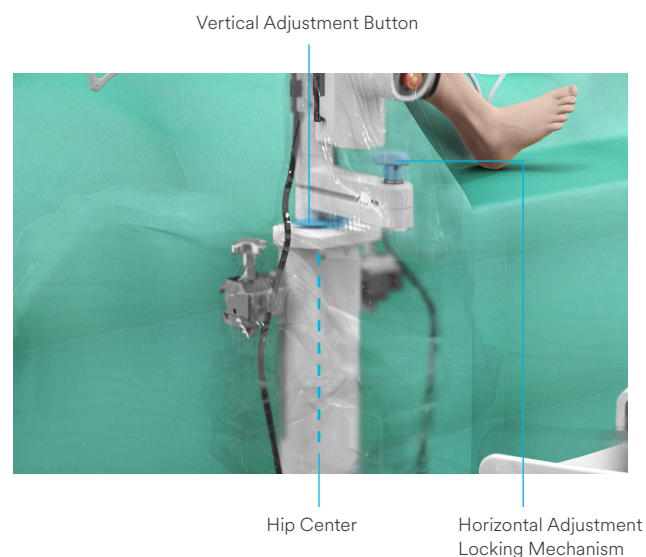
> **■ Note:**
> To minimize interference with the Camera, keep bright light sources or highly reflective objects out of the Camera's field of view.

The Saw is attached to the Planar Articulation of the Robotic-Assisted Device. The Planar Articulation enables the NATURAL CONTROL™ Technology which provides free movement of the Saw within the resection plane. This plane is set using the ADAPTIVE TRACKING™ Technology, where the Robotic-Assisted Device adjusts and controls the plane using the position of the PURESIGHT™ Reflectors tracked by the Camera.

When not in use, the Saw is maintained and locked on the folded Planar Articulation. When ready to use, the Saw is unlocked by sliding the blue Planar Articulation Lock on the Planar Articulation.

Planar Articulation Lock

Saw

Arrays

Planar Articulation

Status Indicator

Arrays
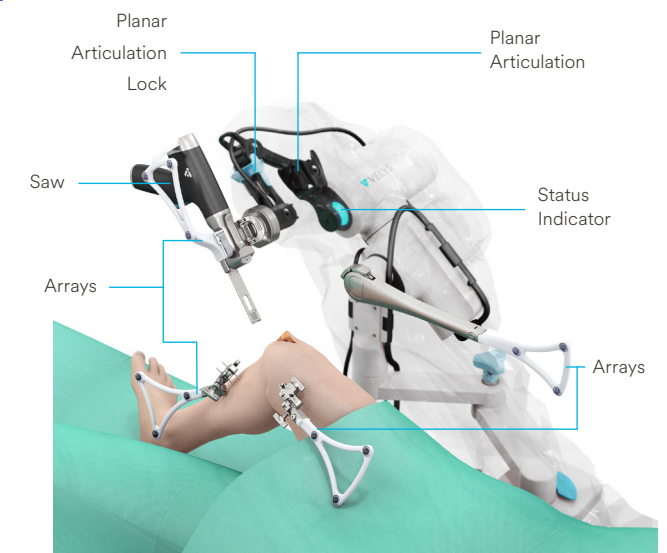
Display Screen

Each screen will display the following content:

Desk
This area displays the *current step information* and permits user inputs throughout the procedure.

During acquisitions two buttons are displayed at the bottom of the desk:

◉ Start   Execute the acquisition

⊗ Stop   Cancel the acquisition

Header

Array Status Bar

Desk

Footer
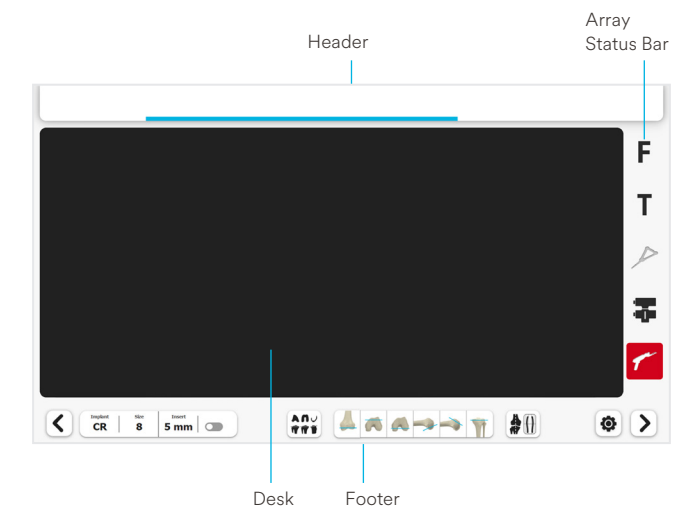
Introduction

Header

The Header displays user instructions for each step. The following color-code is used within the Header to provide additional information to the user:

	Color	Example of instruction
Instruction	White	Press and hold blue foot pedal to reach distal plane
Ongoing action	Blue bar	Robotic Device moving to distal plane
Successful completion	Green	Final position reached
Error, action required	Red	⚠ Release blue foot pedal

Array Status Bar

The Array Status Bar indicates the status of the five arrays. Each icon corresponds to its respective array as shown:

F	Femur
T	Tibia
✐	Pointer

🔧	Robotic-Assisted Device
🪚	Saw

> ■ **Note:**
> To complete a step or an action, the required arrays **must** be visible to the Camera.

There are three status options for the arrays:

✐ Black: Array visible

✐ Grey: Array not required and not visible

✐ Red: Array required and not visible

Footer

The area at the bottom of the screen has interactive buttons. The most frequently used buttons include:

|		
❯	Next	Acknowledge the information and advance to next screen
❮	Back	Go back to previous screen
⚙	Toolbox	Access the Toolbox

There are different status options for the buttons:

❯	Black	Button is active
❯	Grey	Button is inactive or more action is required
⚙	Blue	Current screen

During acquisitions, the footer will display additional buttons.

Acquisition Toolbar

	Acquisition	Go to the acquisition screen indicated, e.g. lateral distal condyle
	Confirmation of Landmarks	Go to the Confirmation of Acquired Landmarks screen

At the initial Leg Alignment and ACCUBALANCE™ Graph Recording screen and beyond, the footer will display additional buttons.
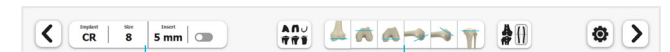
Implant Toolbar   Resection Toolbar

	Planning	Go to PROADJUST™ Surgical Planning screen
	Resection	Go to the resection screen indicated, e.g. anterior femoral resection
	Alignment and Graph	Go to the Leg Alignment and ACCUBALANCE™ Graph Recording screen

See <u>Initial Leg Alignment and ACCUBALANCE™ Graph Recording</u> for the description of the Implant Toolbar and <u>Recuts (If Necessary)</u> for the use of the Resection Toolbar.

> ■ **Note:**
> After the "Alignment and Graph" button 🦵 was used to go to the Leg Alignment and ACCUBALANCE™ Graph Recording screen, when tapping the blue foot pedal or the "Next" button ❯, the final screen (Export of Case Report and Exit) will appear. Similarly, after the "Planning" button 🗂 was used to go to the PROADJUST™ Surgical Planning screen, the Checkpoint Verification screen corresponding to the first resection will appear next.

There are three status options for the acquisition and resection buttons:

		White	Acquisition or resection not completed
		Black	Current acquisition or resection
		Green	Acquisition or resection completed

Introduction

Status Indicator

The Status Indicator light is located between the Robotic-Assisted Device and the Planar Articulation.
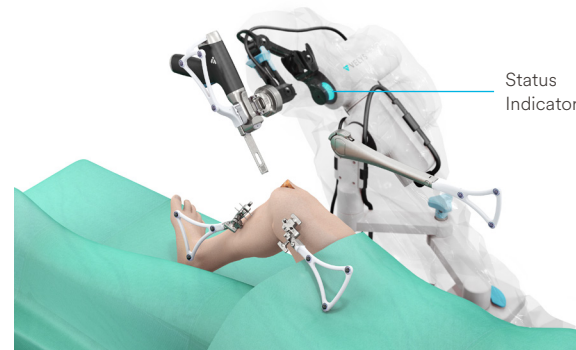
Status Indicator

The Status Indicator can display different options:

Color	State	Description	Example of Situation
Blue	Fixed	Robotic-Assisted Device is on, passive	During acquisitions or planning
Blue	Blinking	Robotic-Assisted Device is connecting	Connecting to Base Station
Blue	Circling	Robotic-Assisted Device is moving	Robotic-Assisted Device is moving to next resection plane
Green	Fixed	Robotic-Assisted Device is ready for resection	Bone resection with all conditions met
Orange	Blinking	Robotic-Assisted Device cannot complete step	Bone or Saw Array not visible during resection Foot pedal released before end of Robotic-Assisted Device movement

Footswitch

The Footswitch is placed on the floor next to the operating table.

Blue foot pedal: Execute the requested action, acknowledge the information on the current screen, or advance to next screen.

Yellow foot pedal: Cancel the ongoing action or go back to previous screen.
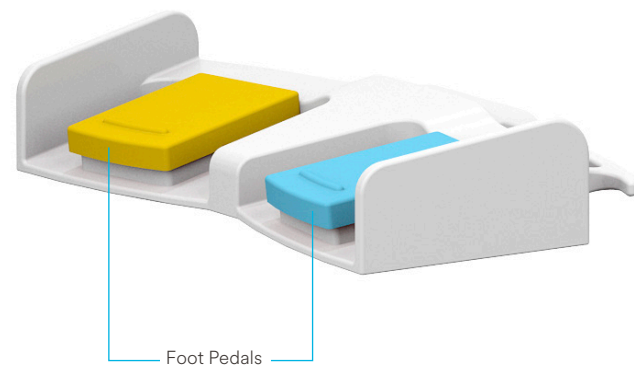
Foot Pedals

> ■ **Note:**
> Throughout this surgical technique:
> - "Tap foot pedal" or "Press foot pedal" means a short tap
> - "Press and hold foot pedal" means continue holding until the action is complete

OR Pre-Op Setup

The system and the instruments must be set up according to the instructions from the VELYS™ Robotic-Assisted Solution for Total Knee User Guide.

Stations Positioning and Connection of Stations

Start

Workflow Selection : Total Knee Tibia First

Connections Check

Each surgeon must have a Surgeon Account. See Appendix 2 for creating a Surgeon Account.

Select the surgeon's name from the list.

Select a surgeon account to continue

Dr Karl Andersen | Dr Gabriela Martinez | Dr Lisa Schneider | Dr Ichiro Takahashi | Dr Ja Willia
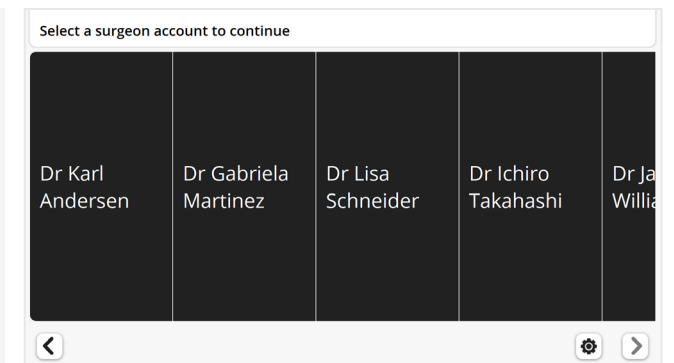
Enter the surgeon's password.
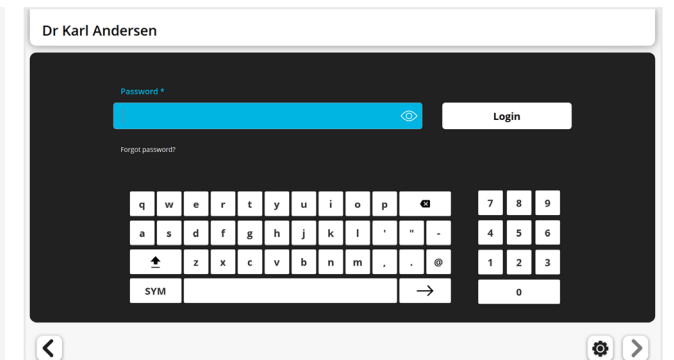
Dr Karl Andersen

OR Pre-Op Setup
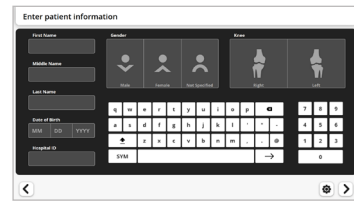
Patient Information

Robotic-Assisted
Device Initialization

Saw Array Assembly

Saw Blade Attachment
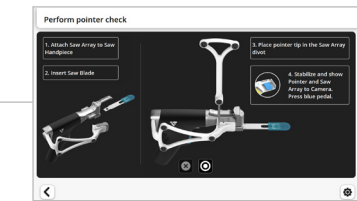
Pointer Check
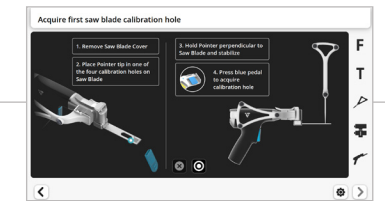
Saw Blade Calibration

Robotic-Assisted Device and
Satellite Station Draping
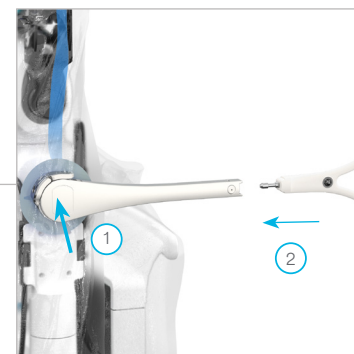
Attachment of Robotic-Assisted
Device Array Interface and
Robotic-Assisted Device Array
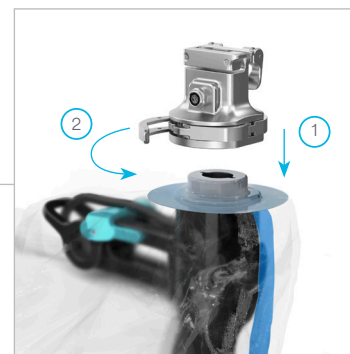
Attachment of Saw Interface
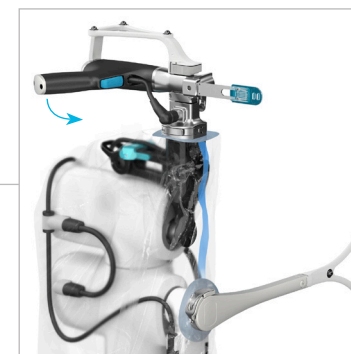
Attachment of Saw and
Connection of Saw Cable
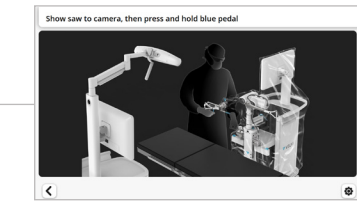
Robotic-Assisted Device
Check

Patient Positioning
Patient Draping
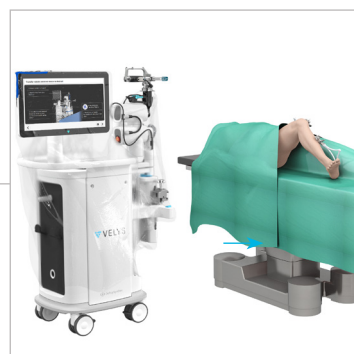
Robotic-Assisted Device
Transfer to Table
Robotic-Assisted Device
Attachment to Table

180 cm
6 ft
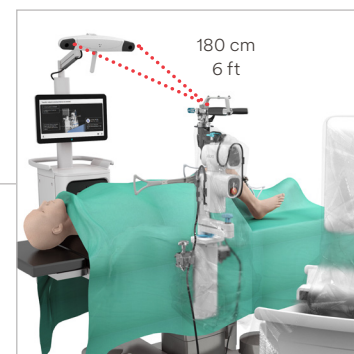
Base Station Positioning

Surgical Profile Selection

The Surgical Profile defines the anatomical references, implant type, and the settings used for implant positioning during the planning stage.

Each surgeon can define and store different Surgical Profiles depending on specific clinical scenarios. See Appendix 3 for the Creation of Surgical Profiles and the description of the default values.

Select a Surgical Profile for the procedure.

> **▲ Caution:**
> The surgeon should review the Surgical Profile summary at this stage of the procedure to ensure the selected settings are appropriate for the specific patient.

Either Tap the blue foot pedal or tap the "Next" button ❯ to proceed with the settings displayed,

or Tap "Edit Planning" to make changes (optional).

When editing the planning, modify the settings to ensure they are appropriate for the specific patient.

"Reset" will cancel the edits. "Delete" will delete the Surgical Profile.
Optional: Tap "Save" to permanently store the Surgical Profile edits.
If "Save" is not tapped, the modified settings will apply to the current procedure only and will not be stored.

Tap the "Next" button ❯ to proceed.
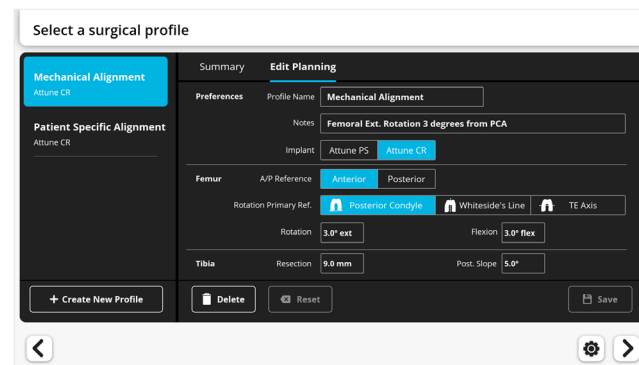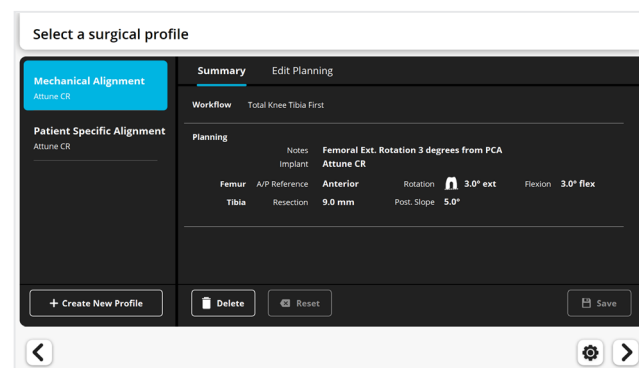
Surgical Exposure and Creation of Bone Checkpoints

Perform surgical exposure using the surgeon's preferred technique.

Checkpoints are small bone indentations created by the surgeon on the femur and tibia that are used as fixed reference points during the procedure to confirm that the Bone Arrays have not moved. They should be distinct, clear of soft tissue, and easily located.

> **▲ Caution:**
> Position each Checkpoint at a site where the bone will not be resected, e.g., below the anticipated tibial resection plane.
>
> Create each Checkpoint cautiously with the appropriate instrument and into the cortical bone.

Place the sharp tip of the Array Drill Pin on the tibial bone, below the tibial resection and adjacent to the tibial tubercle.

Tap gently on the Array Drill Pin with a mallet to create the small bone indentation.

Do not use the drill. Do not make the indentation too deep, as low density of cancellous bone may introduce inconstancies later when verifying the bone Checkpoints.

Repeat on the femoral bone in the region anterior to the medial epicondyle.

> **▲ Caution:**
> The Checkpoints must be easily identifiable later during the procedure. Marking the Checkpoints with a surgical pen will facilitate finding their location.

> **■ Note:**
> The surgeon can select another method to create appropriate Checkpoints.

Anticipated Resection

Checkpoint

Checkpoint

Anticipated Resection
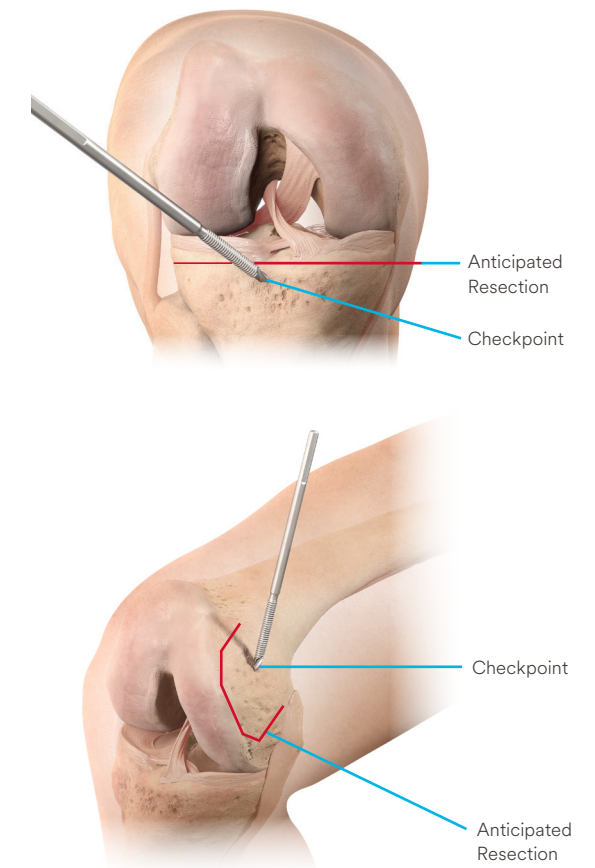
Bone Arrays Setup

The Femur and Tibia Arrays are the fixed reference points used to create an accurate frame of reference for the system. The Camera tracks the orientation of these Arrays throughout the procedure — it is how the system "sees" the knee. The Arrays are attached to an Array Clamp that is rigidly fixed to Array Drill Pins that are fixed to the femur and tibia at the beginning of the procedure.

It is critical that:

1. The Array Drill Pins and Array Clamps are securely fixed to the femur and tibia; any loss of fixation will result in loss of accuracy of the system, which could lead to inability to complete the procedure using the Robotic-Assisted Device.

2. The Arrays are positioned such that:
   a. Clear line of sight with the Camera can be maintained at all times.
   b. Surgeon access to the knee is not compromised.
   c. Saw access to the knee will not be impeded.

Instruments Description

Array Drill Pins
The 4 mm diameter single use Array Drill Pins are available in different lengths to accommodate for variations in patient anatomy, BMI, or surgical technique.

Typical Use:

Length	Bone	Location
100 mm	Tibia	Outside incision (recommended)
125 mm	Femur	Inside incision (recommended)
175 mm	Femur	Outside incision

Array Clamps
The Array Clamp slides over the Array Drill Pins and is secured by tightening the Pin Wingnut. The Arrow should be pointing toward the Camera (medially). When tightened, the Array Wingnut locks the orientation of the Bone Array to the Array Clamp.

> ■ **Note:**
> The Array Clamp is disassembled into two components prior to sterilization by unscrewing the Array Wingnut. The Array Clamp must be assembled prior to use.

Tibia Array — Array Drill Pins — Femur Array — Array Clamps

Pin Hole
Pin Wingnut
Pin Hole
Button
Arrow
Wedge
Array Wingnut
Array Clasp
Bone Array
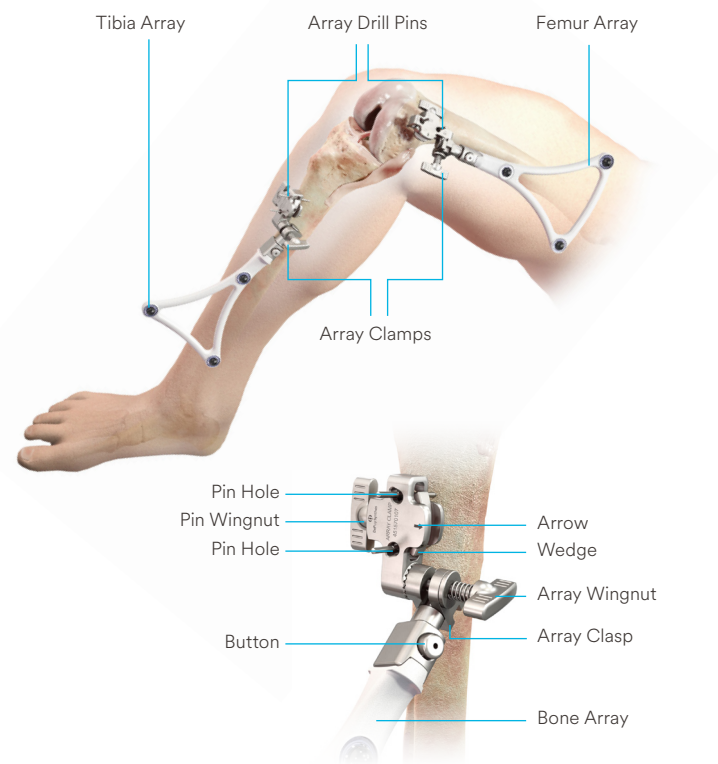
Bone Arrays
There are two unique Bone Arrays: The Femur Array and the Tibia Array, which are attached to the Femur and Tibia, respectively. Each Bone Array is fastened to the Array Clamp by pressing the button on the Array Clamp and engaging.

Femur Array (Convex)   Tibia Array (Concave)
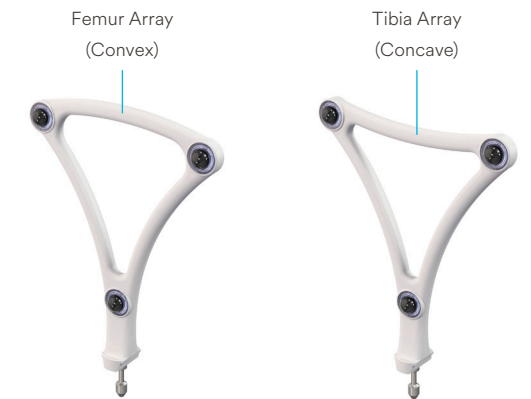
Array Drill Pins and Array Clamp Placement: Tibia

Position the Array Drill Pin into a special Array Drill Pin Inserter attached to the Hudson adapter of a drill.

Array Drill Pin
Array Drill Pin Inserter
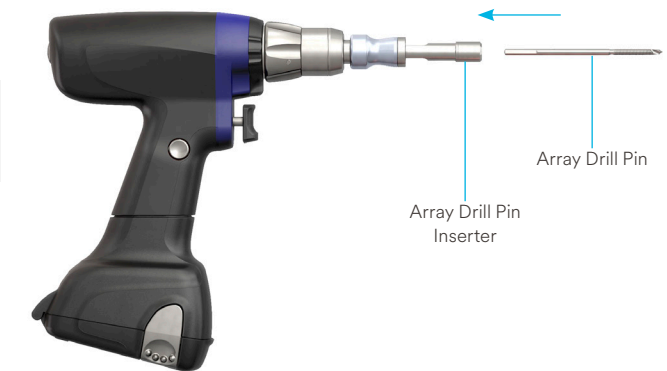
The Array Drill Pins are inserted three to four fingers below the incision and medial to the tibial crest.

> ■ **Note:**
> This position should be:
> - Distal enough to avoid conflict with the Saw Handpiece during tibial resection
> - Proximal enough to avoid conflict with the Pointer visualization during malleoli acquisition

Recommended positioning for the array outside incision

30° — 40°
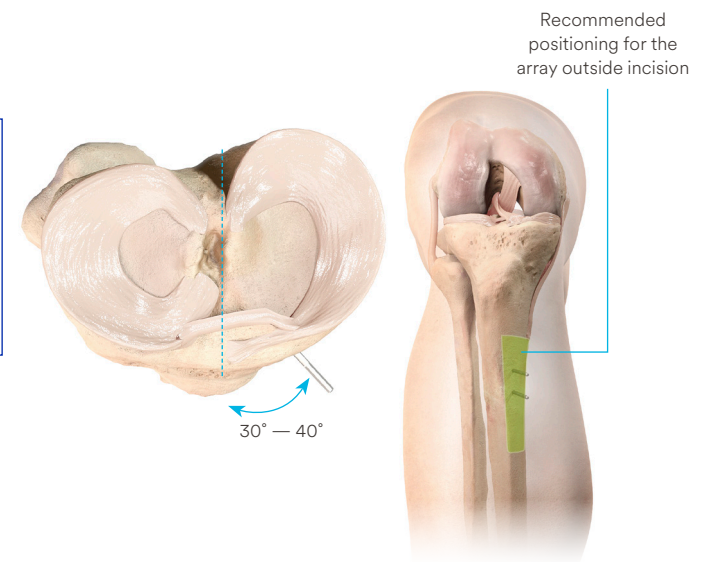
Bone Arrays Setup

Array Drill Pins and Array Clamp Placement: Tibia

Perform a small stab incision into the skin at the intended location of the **proximal** Array Drill Pin.

Drill the first Array Drill Pin perpendicular to the flat antero-medial tibial surface through the cortex to engage the postero-lateral cortex. Drill through the center of the bone to avoid a purely cortical pin position. Care should be taken to avoid overpenetration of the postero-lateral tibial cortex.

> **▲ Caution:**
> Ensure the Array Drill Pins are rigidly attached to the bone. Avoid fixation into sclerotic bone.

The pins should be positioned in the bone such that:
1. Array line of sight with the Camera can be maintained at all times.
2. Surgeon, Robotic-Assisted Device, and Saw access to the knee is not compromised.

> **▲ Caution:**
> The length and positioning of the Array Drill Pins should avoid:
> - Conflict with the surgical instruments including Saw Handpiece and retractors
> - Bone resections: Posterior condyles, box for PS implant, or tibial keel
> - Stresses from adjacent soft tissues during knee flexion and extension

Place the Array Clamp over the first Array Drill Pin, using the proximal Pin Hole.

- The **Button** on the Array Clamp should be **pointing away from the joint**
- The **Arrow should be pointing toward the Camera** and the **Pins Wingnut pointing opposite the Camera**. If not, flip the Array Clamp over

Correct

Incorrect   Incorrect

1st Array Drill Pin
Pin Wingnut
2nd Array Drill Pin
Arrow pointing towards Camera
2nd Array Drill Pins aligned with Tibial Long Axis
Button away from joint
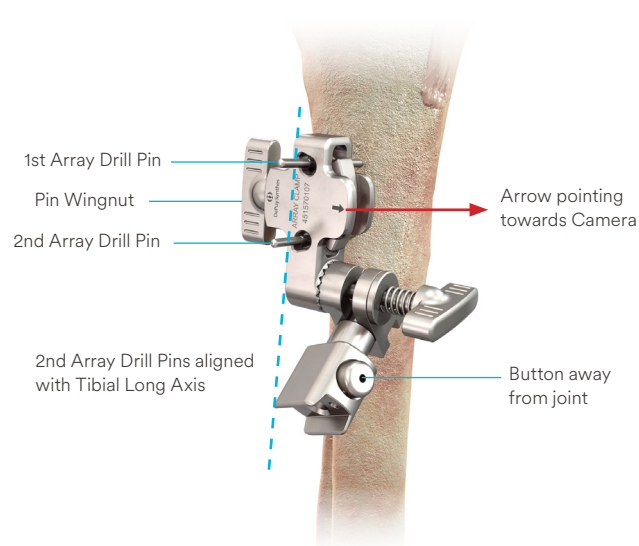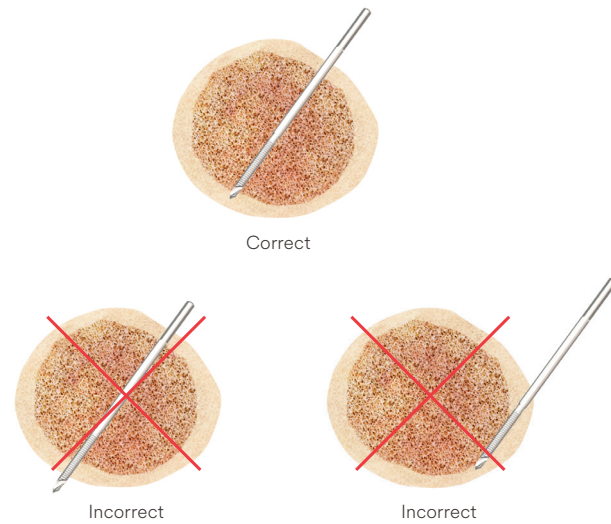
Perform a stab incision at the intended location of the distal Array Drill Pin.

Use the distal Pin Hole as a guide to drill the second Array Drill Pin parallel to the first Array Drill Pin, to avoid stress on the bone when adjusting the Array Clamp position. The two Array Drill Pins should be in line with the long bone axis.

Fix the Array Clamp on the Array Drill Pins by tightening the Pin Wingnut.

> **▲ Caution:**
> Ensure there is 1 to 2 cm of clearance between the Array Clamp and the skin surface to avoid potential movement of the Array during the procedure.

Array Drill Pins and Array Clamp Placement: Femur

The same procedure is used on the femur. The same cautions apply.

Inside incision technique — recommended
The Array Drill Pins are inserted proximal and anterior to the medial epicondyle, angling medially toward the Camera at 30 to 50 degrees relative to the sagittal plane.

Drill first the **distal** Array Drill Pin.

Place the Array Clamp over the Array Drill Pin, using the distal Pin Hole. The Button on the Array Clamp should be pointing away from the joint.

Use the proximal Pin Hole as a guide to drill the second Array Drill Pin parallel to the first Array Drill Pin.

Fix the Array Clamp.

Recommended positioning for the Array Drill Pins inside the incision

30° — 50°

2nd Array Drill Pins aligned with Femoral Long Axis
2nd Array Drill Pin
Pin Wingnut
Button away from joint
Arrow pointing towards Camera
1st Array Drill Pin
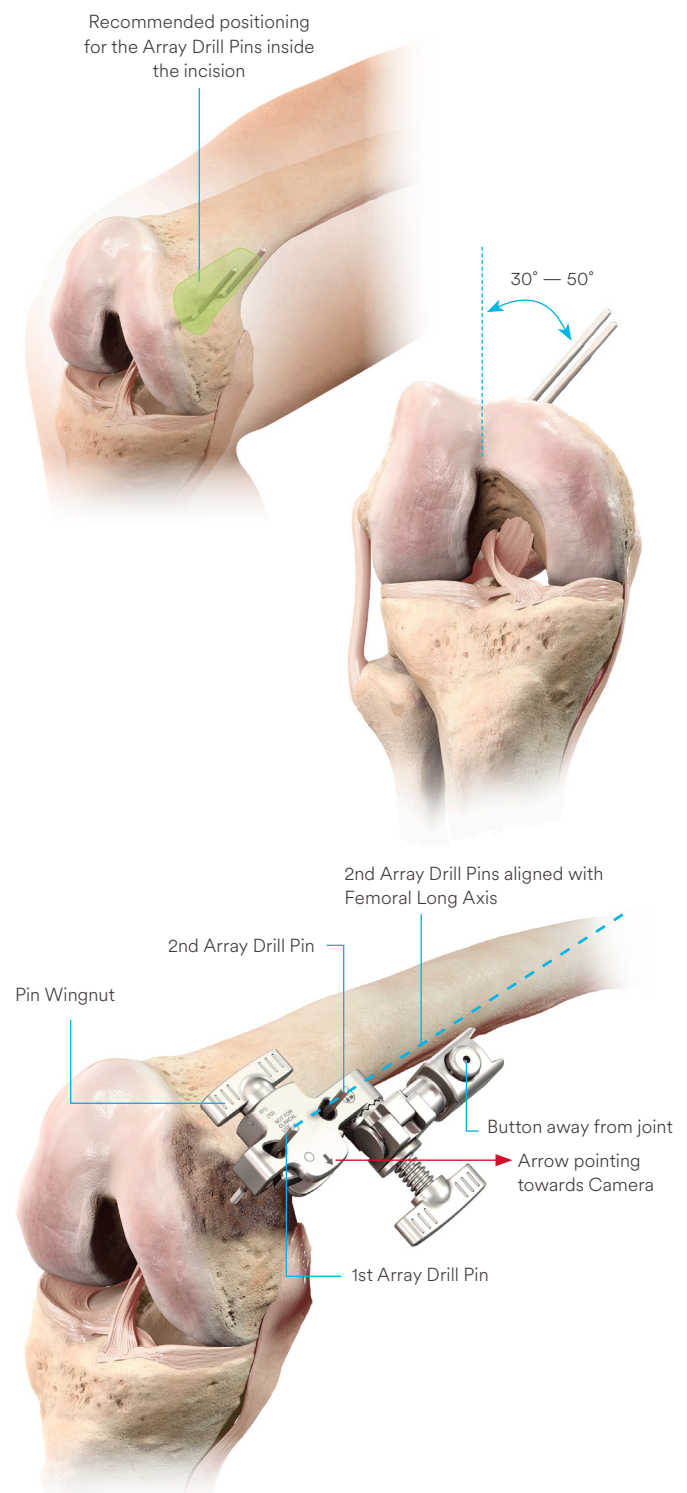
Bone Arrays Setup

Bone Array Fixation to Tibia and Femur

Attaching the Bone Array to the Array Clamp

Select the appropriate Bone Array: Tibia Array or Femur Array.

Align the Bone Array Tip with the Array Clamp Tip Hole.

Press and hold the Array Clamp button.

Insert the Bone Array Tip into the Array Clamp.

Release the button and check that the Bone Array is rigidly fixed. The Bone Array should point away from the joint.

Align the axis of the Bone Array parallel to the respective bone axis.
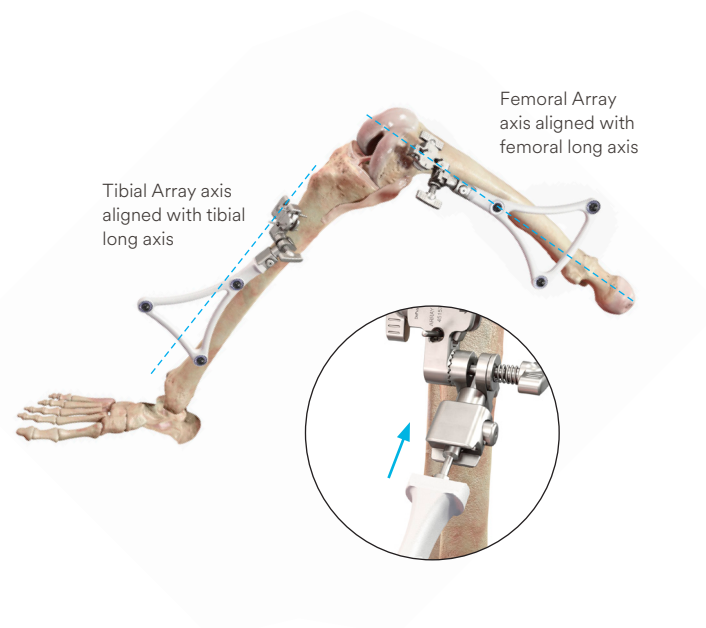
> **▲ Caution:**
> Orient the Bone Array by adjusting the Array Clamp only. Do not grasp the Bone Array itself.
>
> The position of the Bone Arrays must not move during the surgical procedure, as this will result in inaccurate information.
>
> Ensure the two Wingnuts on each Array Clamp are securely tightened.
>
> Hand tighten the Wingnuts only — do not use tools because over-tightening may damage the clamp.

Orient the plane of the Bone Array toward the Camera.

Check that the Array remains orientated toward the Camera throughout knee ROM, and line of sight between the Arrays and the Camera is maintained.

Tighten the Bone Array on to the Array Clamp using the Array Wingnut.

Repeat for the other Bone Array.

Tibial Array axis aligned with tibial long axis

Femoral Array axis aligned with femoral long axis

Point towards Camera
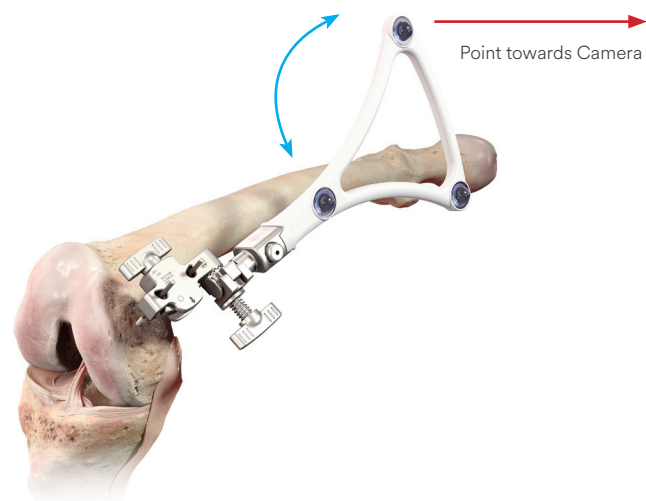
> **▲ Caution:**
> Prior to fully tightening the Array Wingnut, ensure:
> - There is no impingement between the Array Clasp and Wedge
> - The teeth are properly engaged to avoid a non-stable "teeth-on-teeth" positioning
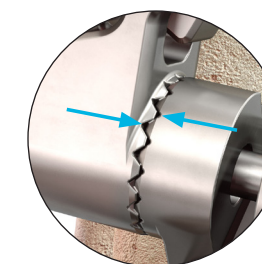
Correct
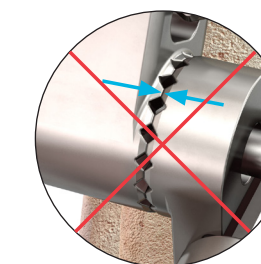
Incorrect
"teeth-on-teeth" positioning

Perform a full leg flexion-extension and a rotation of the leg around the hip joint to check that the Bone Arrays will not touch the skin or the drapes later during the procedure. Adjust the array position and orientation if needed.
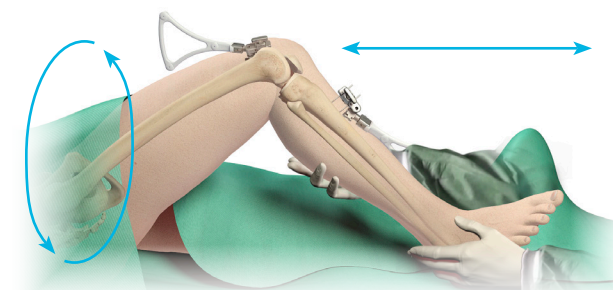
Camera Adjustment

Adjust the Camera orientation so the Bone Arrays remain clearly visible at all likely leg positions during the case. This is achieved by matching both the alignment and diameter of the blue and white circles on the Screen.

Place the knee in 90 degrees of flexion.

Move the Camera to align the blue circle with the white target on the Screen.

The white target represents the midpoint of a line connecting the Tibia and Femur Arrays. The blue circle indicates the center of the field of vision of the Camera.

The blue circle will move on the screen when the Camera orientation is adjusted. Align the center of the blue circle with the center of the white target to ensure the Camera is pointing toward the center of the Bone Arrays.

⚠ Caution:
Use the handle to avoid damaging the lenses. Touching the Camera lenses may lead to inaccurate tracking.

Adjust the distance between the Camera and the two Bone Arrays to *equalize the size* of the circles.

The diameter of the blue circle will increase when the Camera is moved closer to the two Bone Arrays and decrease when the Camera is moved away.

The Camera has reached a correct position once the blue circle and white targets are aligned and have the same diameter. This will be confirmed by the Header on the screen turning green.

■ Note:
The Camera distance to the operative leg can be modified by moving the Base Station or by repositioning the articulated arm holding the Camera. Keep in mind the desired position of the surgical assistant when positioning the Base Station.

■ Note:
Instruments and reference arrays equipped with PURESIGHT™ Reflectors must have an unobstructed line of sight to the Camera in order to be tracked.

To minimize interference with the Camera, keep bright light sources (certain OR lights, direct sunlight) or highly reflective objects out of the Camera's field of view.

Check the visibility of the Bone Arrays in both flexion and extension. Ensure the two Bone Arrays always remain visible through a full knee range of motion, i.e. the blue circle remains continuously visible on the screen. Adjust the Camera orientation and position as required to satisfy this condition before proceeding.

When ready, tap the blue foot pedal tap or the "Next" button ❯ to proceed.

⚠ Caution:
It is critical to have optimally placed and rigidly fixed Bone Arrays. Movement of the Arrays or loosening of the Array Drill Pins will compromise the accuracy of the system. Adjustments to the position of the Bone Arrays can be made:
- Prior to landmark acquisition
- Following landmarks acquisition but prior to the first bone resection. This will require new acquisition of all landmarks for the bone where the Array was adjusted and new PROADJUST™ Surgical Planning

Adjustments are not permitted after the first bone resection: If Bone Array movement occurs the reference frame becomes inaccurate. The Robotic-Assisted procedure must be aborted, and the procedure must be completed using conventional manual instruments (see Appendix 5).

Bone Checkpoints Acquisition

To acquire the Tibia Checkpoint, place the tip of the Pointer into the Tibia Checkpoint and then tap the "Start" button ◉ or tap the blue foot pedal.

Ensure tibia checkpoint is created then acquire checkpoint with pointer
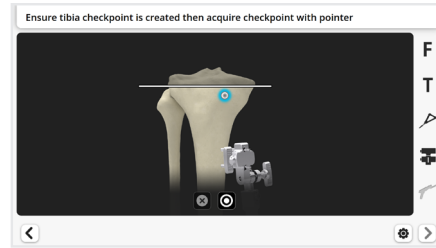
Checkpoint

To acquire the Femur Checkpoint, place the tip of the Pointer into the Femur Checkpoint and then tap the blue foot pedal or tap the "Start" button ◉ .

Ensure femur checkpoint is created then acquire checkpoint with pointer
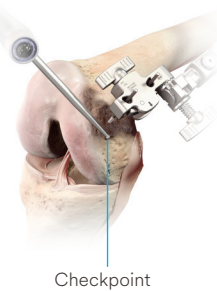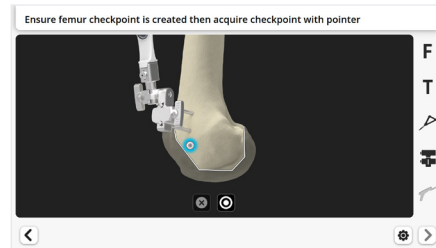
Checkpoint

> **⚠ Caution:**
> Ensure the tip of the Pointer fully seats at the bottom of the Checkpoint. For this, ensure the Checkpoint indentation contains no debris. Place the Pointer approximately perpendicular to the surface of the bone.
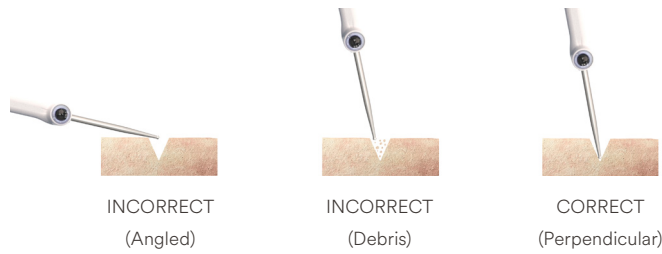
> **■ Note:**
> "Verify Tibia/Femur Checkpoint" may be accessed in the Toolbox to confirm that the Checkpoints can be verified repeatedly.

INCORRECT
(Angled)

INCORRECT
(Debris)

CORRECT
(Perpendicular)

Landmarks Acquisition

The goal of this step is to acquire the anatomical landmarks and axes which will be used by the system for surgical planning.

Access to the Landmarks

Prior to starting landmarks acquisition remove accessible osteophytes including posterior osteophytes, menisci, and the ACL. The PCL may be removed when using a PS implant or a CR implant with a CS application. Secure sufficient access to the medial and lateral compartments to register the distal and posterior condyles and the tibial plateau.

Mechanical Axes Definition

Acquisition of the required landmarks will enable the software to define the femoral and tibial mechanical axes.

Proximal Point
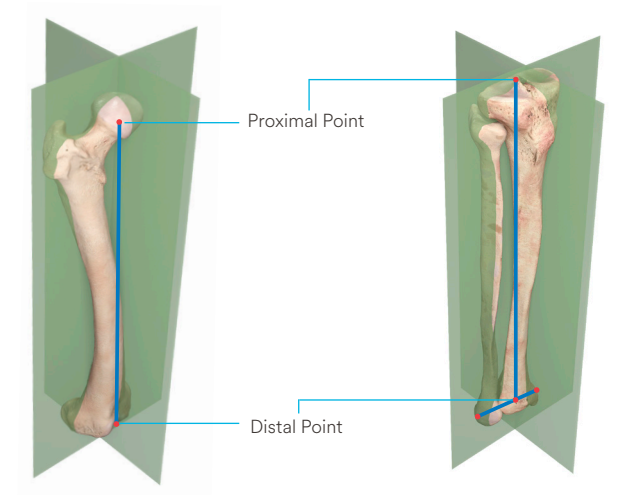
Distal Point

To define these axes, a proximal and distal point will be registered on each bone using the following landmarks:

Mechanical Axis	Axis Point	Landmark
Femoral	Proximal	Femoral Head Center — acquired by hip circumduction
	Distal	Femoral Knee Center — acquisition of a single point
Tibial	Proximal	Tibial Knee Center — acquisition of a single point
	Distal	Midpoint of the Malleoli — calculated following acquisition of two single points: the medial and lateral Malleoli

Landmarks Acquisition

Acquisition Process

During acquisition of a landmark, progress is shown on the Header of the Screen.

When a landmark has been successfully acquired:
- An audible "beep" will sound
- The software will automatically proceed to the next acquisition

> **▲ Caution:**
> Careful acquisition of landmarks is essential for the system to assess the joint, plan implant position, balance and alignment; and execute accurately.
>
> The landmarks acquired should be representative.
>
> Small anatomical defects or protruding osteophytes that are not representative should not be acquired as they may falsely represent the landmark needed.

Femoral Head Center

Gently flex the knee and the hip to approximately 30 degrees.

Ensure the Femur Array is visible to the Camera.
- The Femur Array icon should be black on the Array Sidebar of the Screen

To start the acquisition, tap the blue foot pedal or tap the "Start" button ◉ .

Start rotating leg and press blue pedal to acquire femoral head center
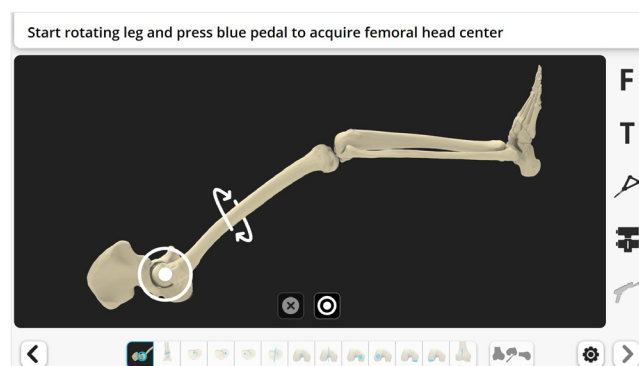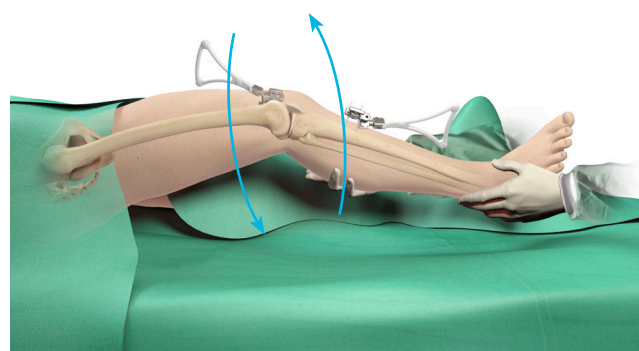
Perform smooth circumduction of the thigh taking care to avoid any movement of the pelvis.

This maneuver creates a "cone" with its tip at the center of the hip joint and its base (at least 30 cm diameter) at the level of the knee.

An audible "beep" will sound when the Femoral Head Center has been registered.

The software uses this information to compute the rotational center of the femoral head, which defines the Femoral Head Center.

> **▲ Caution:**
> During acquisition of the Femoral Head Center, it is critical that:
> - The pelvis remains stable
> - The Camera is not moved

Any movement of the pelvis, or the Camera, during acquisition will result in inaccurate calculation of the Femoral Head Center. This is most likely in patients with a high BMI or a stiff hip. Options include:
- Have the assistant secure the pelvis by applying pressure to one or both ASIS
- Temporary release of the lateral side leg support to allow free motion of the leg
- Decrease the arc of motion of the leg to not move the pelvis

Malleoli

The acquisition of the two malleoli enables the software to calculate the center of these two points, which defines the distal end of the tibial mechanical axis.

The most prominent points of the malleoli can usually be located by palpation, before acquiring the landmarks.
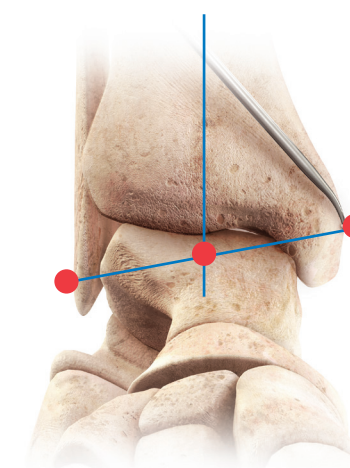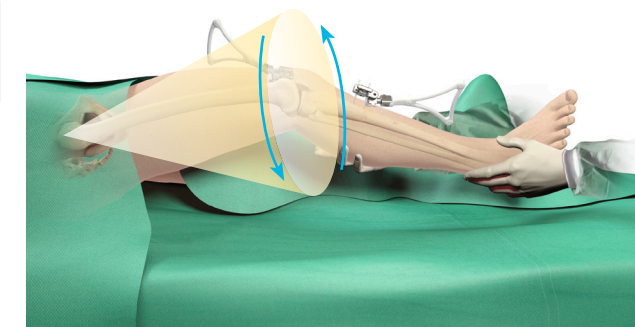
Landmarks Acquisition

Place the tip of the Pointer on the most prominent medial point of the *medial* malleolus. This is *not* the tip of malleolus, but its most prominent protuberance.

Tap the blue foot pedal or tap the "Start" button ◉ .

Acquire medial malleolus
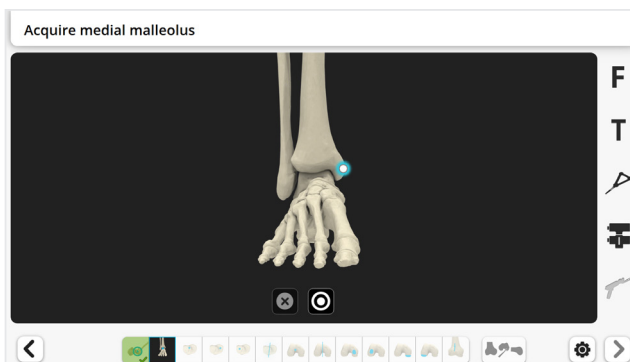
Place the tip of the Pointer on the most prominent *lateral* point of the lateral malleolus.

Tap the blue foot pedal or tap the "Start" button ◉ .

Acquire lateral malleolus
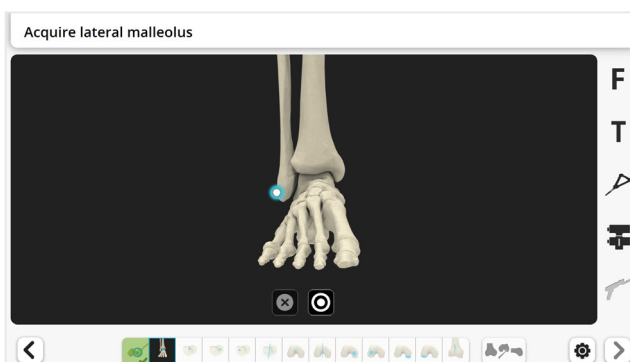
> **▲ Caution:**
> These points should be precisely collected in both the proximal-distal and anterior-posterior directions in order for the system to accurately calculate tibial slope.
>
> Don't acquire malleoli over a thick wrap.
>
> Care should be taken for patients with severe ankle deformity, where the malleoli may not represent accurate landmarks for defining the tibial mechanical axis.

Tibial Knee Center

Place the tip of the Pointer at the posterior aspect of the ACL tibial insertion footprint.

This point will define the intersection of the coronal and sagittal planes of the tibia (center of the proximal tibia).
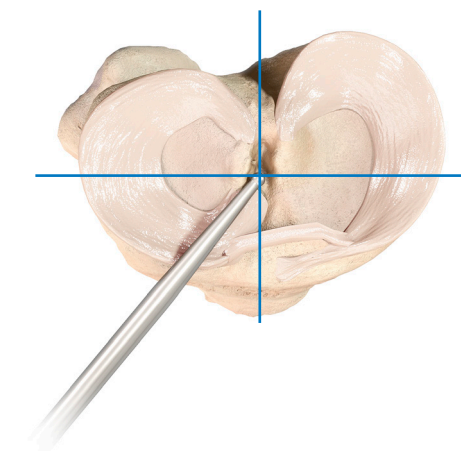
Tap the blue foot pedal or tap the "Start" button ◉ .

Acquire tibia knee center
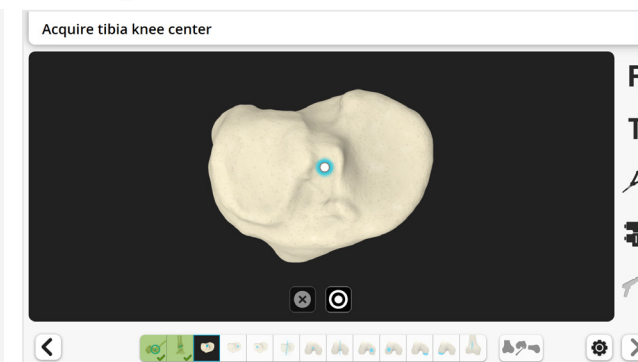
> **▲ Caution:**
> This point should be precisely collected in anterior-posterior direction in order for the system to accurately calculate tibial slope.

Landmarks Acquisition

Tibial Plateau

The goal of acquisition of a single point on each plateau (medial and lateral) is to define the tibial resection level. Each point should be representative of the resection reference the surgeon desires on each side.

Ensure that the Pointer is centered in the A/P plane, as failure to do this this may lead to incorrect resection thickness.

The initial resection height is measured from the highest of these two points. The default value for this height is 9 mm. It can be modified in the Surgical Profile Selection and adjusted for each patient in the PROADJUST™ Surgical Planning.

The Initial Surgical Planning, based on a mechanical alignment, will ensure a minimum of 2 mm resection on the lowest of these 2 points. For example, if the plan resulted in a 9 mm lateral and 1 mm medial resection, the initial plan will be modified to 10 mm lateral and 2 mm medial.

A combination of the following techniques can be used to provide greater access to the tibial plateau:
- Resect the anterior horns of the menisci
- Resect anterior fat pad
- Increase the knee flexion
- Sublux the tibia anteriorly
- Apply Varus or Valgus stress to the knee joint
- Rotate the tibia internally or externally

Place the tip of the Pointer at the **lowest** part of the **medial** plateau.

Highest
9 mm — Lowest Min. 2 mm

Highest
9 mm — Lowest 1 mm

Modified

Highest
10 mm — Lowest 2 mm

Lowest part of the medial plateau

Highest part of the lateral plateau

Tap the blue foot pedal or tap the "Start" button ⊚.

Acquire medial plateau

F
T
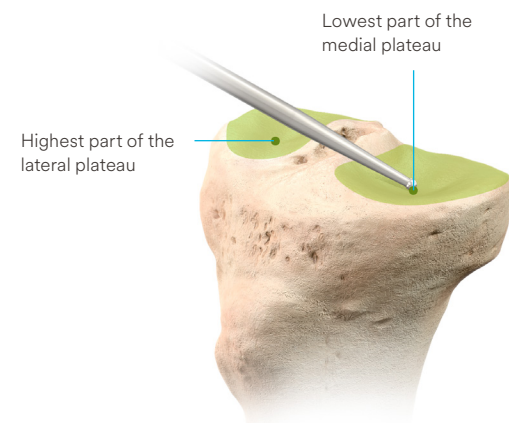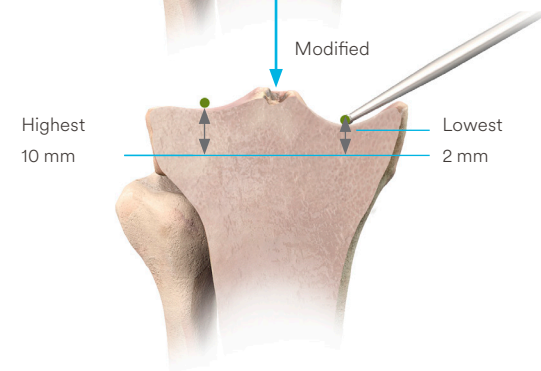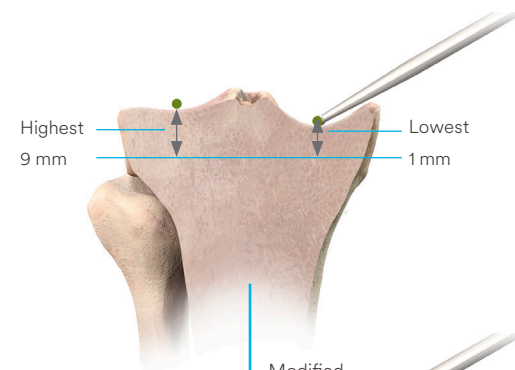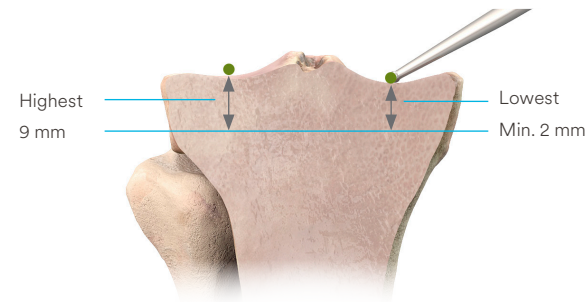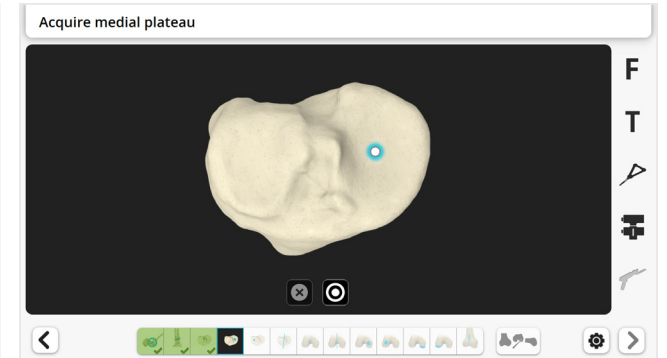
Repeat for **lateral** plateau on the **highest** point, which should be in the center of plateau.

Acquire lateral plateau

F
T
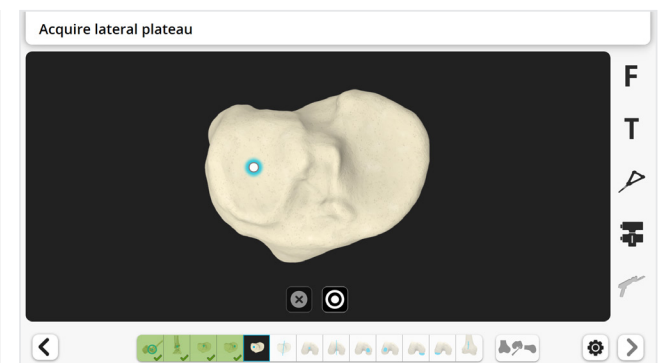
In some cases, e.g. cartilage or bone wear, the highest point found and acquired on the lateral plateau might be lower than the native highest point. In this case, during PROADJUST™ Surgical Planning, the surgeon may need to reduce the resection depth to avoid over-resection of the proximal tibia.

■ **Note:**
The resection level is set using the same rationale as for manual instrumentation. The tip of the Pointer should be placed at the same position that the Pointer of the Adjustable Tibial Stylus from the INTUITION™ Instruments would be resting.

Acquire both points carefully and ensure representative landmarks are acquired.
- If a defect appears to be the deepest point on the medial plateau, register the bottom of this defect, unless this defect is very deep
- Avoid registering prominent features such as osteophytes

Landmarks Acquisition

Tibial Sagittal Axis

The acquisition of the Tibial Sagittal Axis will define the direction of the sagittal plane.

> **■ Note:**
> The system uses the Tibial Sagittal Axis to calculate the direction of the sagittal plane only. The *degree of slope* is determined during PROADJUST™ Surgical Planning.

Sagittal Plane

Coronal Plane

Tibial Knee Center

Medial Third of the Tibial Tubercle

Tibial Slope

Coronal Plane
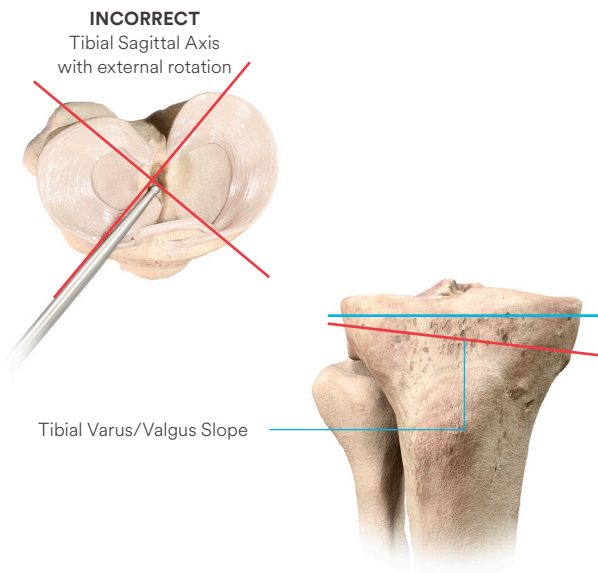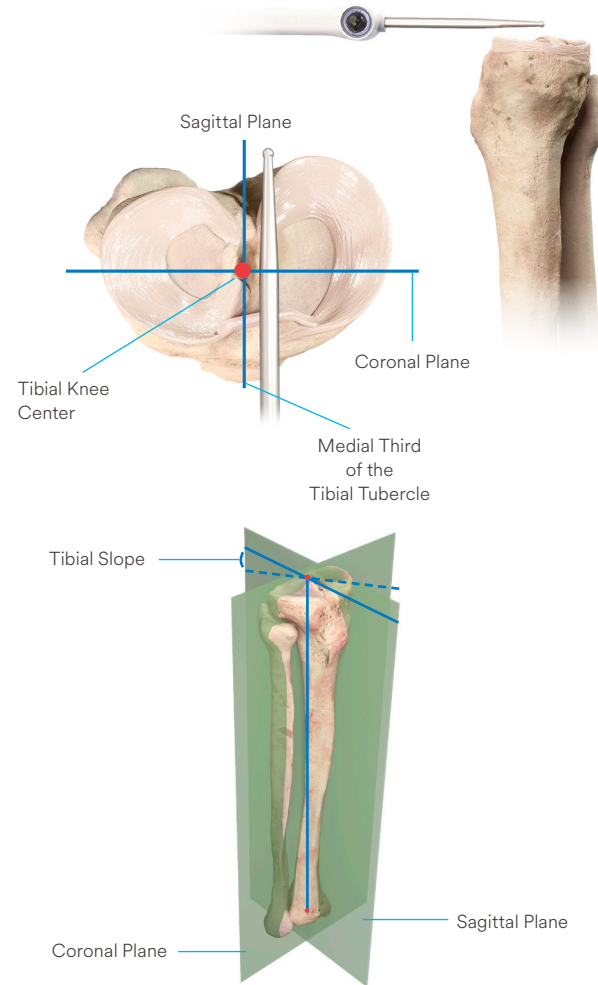
Sagittal Plane

The tibial slope is calculated within the sagittal plane. Thus, while this sagittal axis acquisition does not set the tibial slope directly, **internal or external rotation of the Pointer will result in an oblique slope (Varus/Valgus)** as shown in the adjacent image.

INCORRECT
Tibial Sagittal Axis with external rotation

Tibial Varus/Valgus Slope

Place the Pointer horizontally in the A/P direction, so it lies on the tibial eminence. Be sure the Pointer is in line with the medial third of the tibial tubercle.

Tap the blue foot pedal or tap the "Start" button ⊙ .

Acquire tibia sagittal axis

Medial third of the tibial tubercle
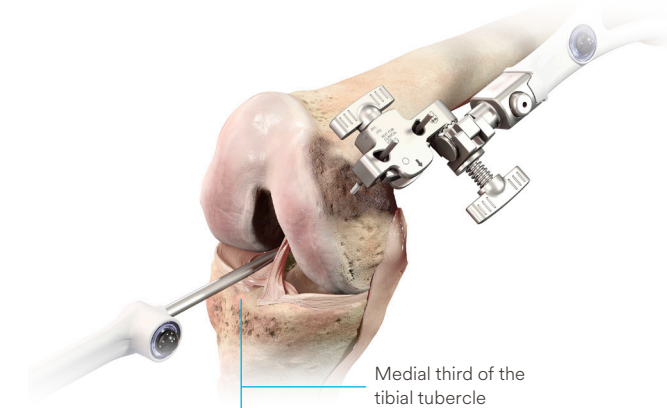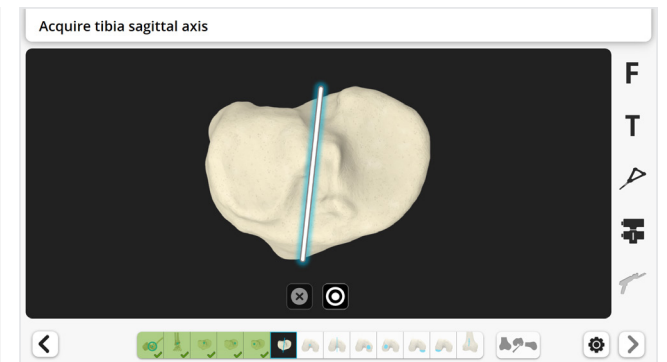
Femoral Knee Center

The Pointer should be placed 2-3 mm anterior and 2-3 mm medial to the apex of the notch (close to the entry point of the femoral canal).

Tap the blue foot pedal or tap the "Start" button ⊙ .

> **⚠ Caution:**
> This point should be precisely collected in anterior-posterior direction for the system to accurately calculate femoral component flexion.

Acquire femur knee center
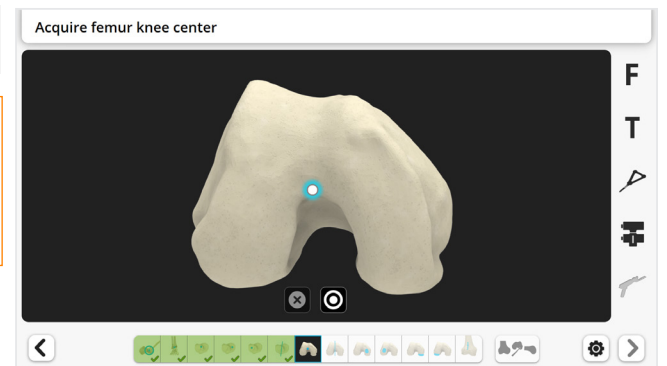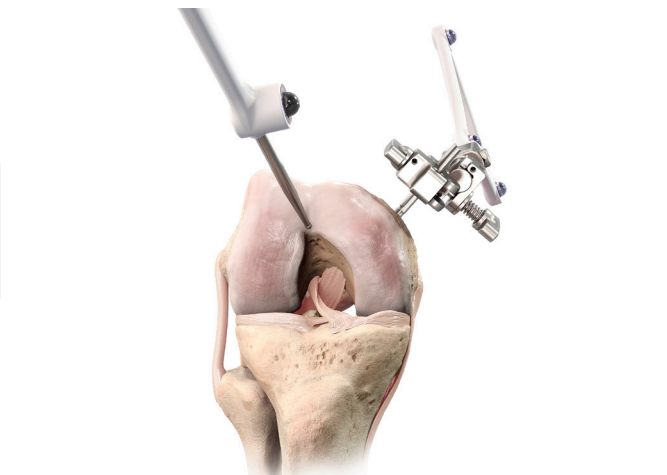
Landmarks Acquisition

Femoral Component Rotation Reference

For femoral component rotation, three axes may be used depending on surgeon preference:
1. Whiteside's Line
2. Transepicondylar axis (TEA) — Optional
3. Posterior condylar axis (PCA)

The primary femoral rotation reference axis is defined by the surgeon in the Surgical Profile. In all cases, Whiteside's Line and the PCA will be acquired and used as primary or secondary reference axis. The TEA will only be acquired if it is selected as the primary rotation reference axis.

Lateral Epicondyle

Medial Epicondyle

Transepicondylar Axis

Whiteside's Line

Posterior Condylar Axis

Lateral Most Posterior Point

Medial Most Posterior Point
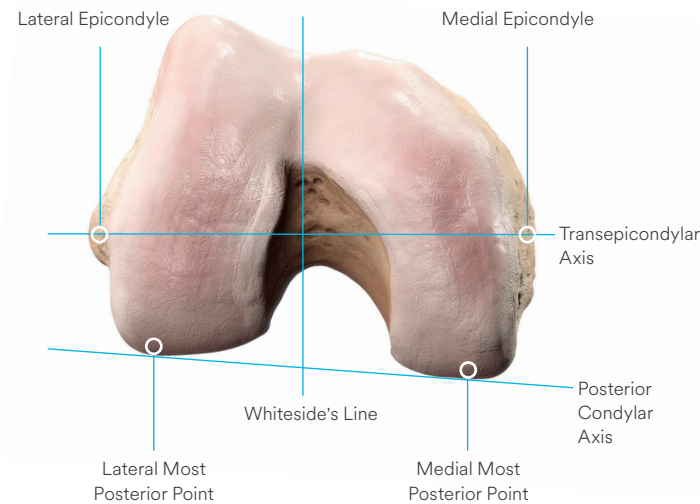
Whiteside's Line (Anteroposterior Axis)

Place the Pointer along Whiteside's Line — the line created by connecting thepoints in the deepest part of the trochlear groove.

■ Note:
Initially marking this line using electrocautery or a sterile pen may help in aligning the Pointer with Whiteside's Line.

Tap the blue foot pedal or tap the "Start" button ⊚ .

Whiteside's Line

Acquire Whiteside's line
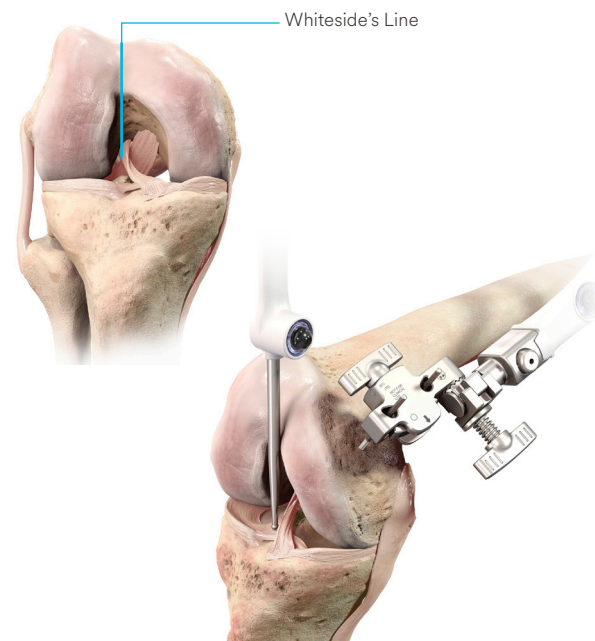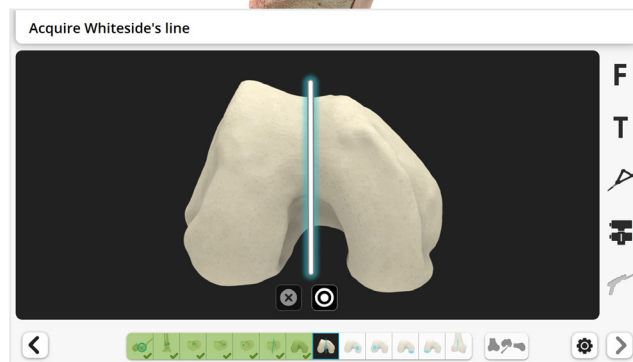
Transepicondylar Axis (Optional)

The two femoral epicondyles define the surgical transepicondylar axis (TEA). The acquisition of these two landmarks is only performed if the TEA was selected in the surgical profile as primary reference for the femoral rotation.

▲ Caution:
The two femoral epicondyles may be difficult to locate. Therefore, when the TEA is used as primary reference, the positioning of the femoral implant should be checked against the secondary references (posterior condylar axis and Whiteside's Line) during Surgical Planning.

Place the tip of the Pointer on the medial sulcus which sits in the depression posterior to the *medial* epicondyle.

Tap the blue foot pedal or tap the "Start" button ⊚ .

Acquire medial epicondyle
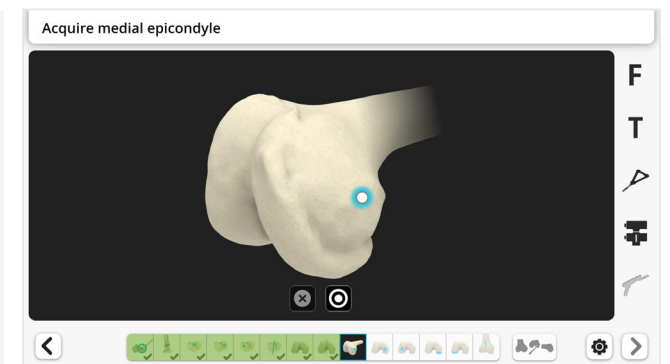
Repeat for the *lateral* epicondyle, placing the tip of the Pointer at the center of the lateral epicondylar prominence.

Acquire lateral epicondyle
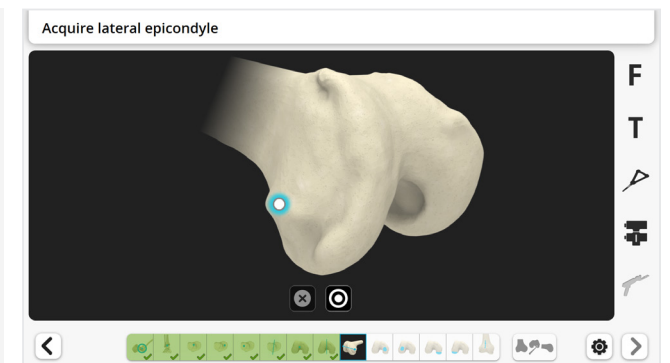
Landmarks Acquisition

Distal Femoral Condyles

Distal femoral condyle acquisition will identify the most distal point of the medial and lateral femoral condyles. These points are used for measuring the distal resection depth.

This is achieved by mapping the surface of both distal condyles with the Pointer. The software will then automatically determine for each condyle the most distal point in the direction of the femur mechanical axis.

> **⚠ Caution:**
> Ensure the entire area around the most distal condyles is mapped.
>
> Avoid mapping osteophytes, which may protrude from the condyles.
>
> While mapping, ensure the Pointer tip is kept in contact with the surface of the femoral condyle at all times.

To avoid the tip of the Pointer lifting off the bone, one technique is to use two hands — one to hold the Pointer and the second to support and guide the tip smoothly across the surface of the bone. If such lift off occurs, repeat the acquisition.

Correct
Most Distal point (green) is included in cloud of blue points acquired by the surgeon (green patch)

Incorrect
Most Distal point (orange) is NOT included in cloud of blue points acquired by the surgeon. Green will be selected, but it is not the most distal point

Place the Pointer tip on the distal aspect of the *medial* condyle.
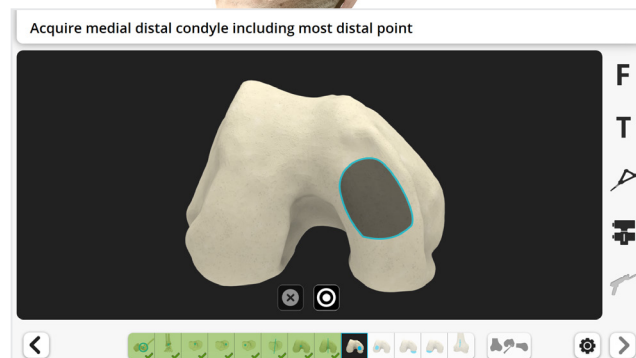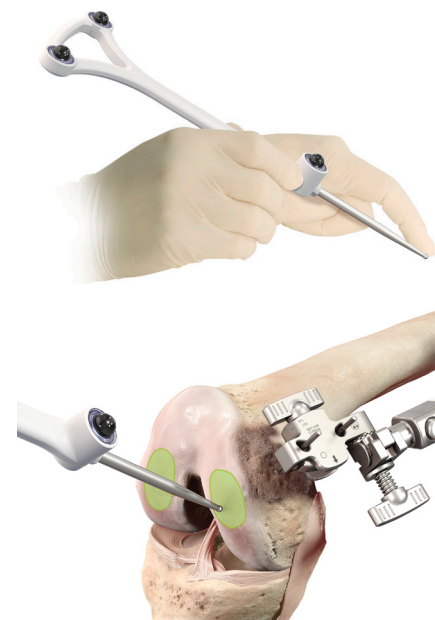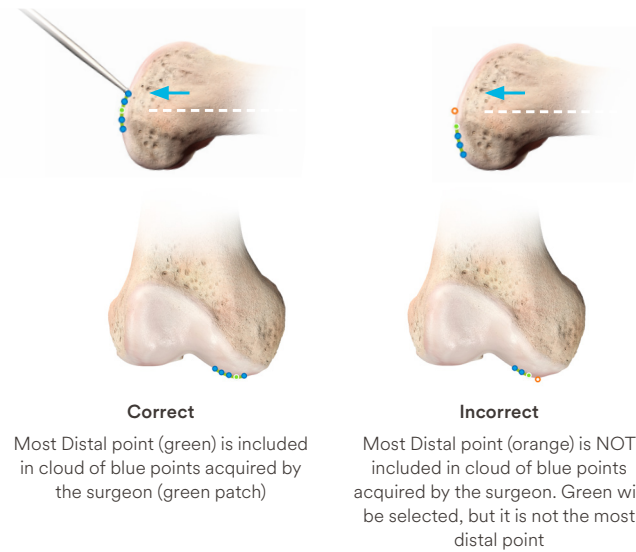
Tap the blue foot pedal or tap the "Start" button ⊙.

Acquire medial distal condyle including most distal point

Move the Pointer in a zig-zag motion to digitally "paint" the entire surface.

A "beep" will sound when the system has acquired the required number of points on the surface.
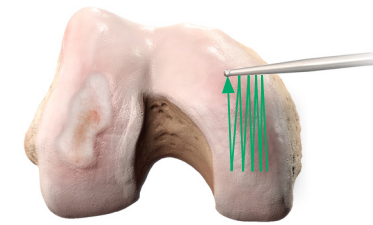
Repeat the above steps to acquire points on the distal aspect of the *lateral* condyle.

Acquire lateral distal condyle including most distal point
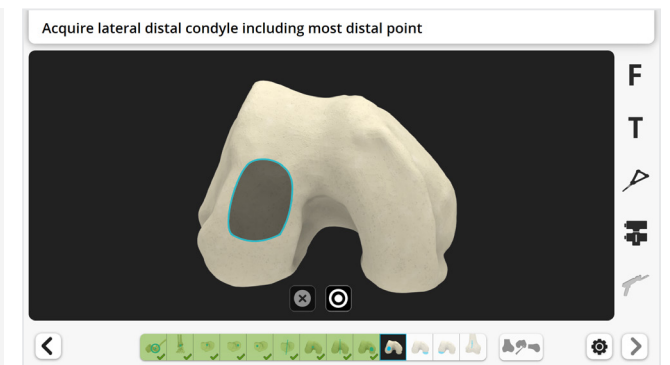
In some cases, e.g. cartilage or bone wear, the most distal points **determined** on the distal condyles might be less distal than the **native** most distal point. In this case, during PROADJUST™ Surgical Planning, the surgeon may need to reduce the distal condyle resection to avoid over-resection of the femur.

Posterior Femoral Condyles

Posterior femoral condyle acquisition will identify the most posterior points of the medial and lateral points. These points are used for:
- Measuring posterior condylar resection depths, used by the surgeon to guide
  a. Femoral sizing
  b. Flexion gap adjustments
- Defining the Posterior Condylar Axis (PCA) which is used to set the femoral component rotation

> **■ Note:**
> The PCA defines the coronal and sagittal planes of the femur. Therefore correct landmark acquisition is also required for appropriate Femoral Varus/Valgus and Flexion adjustments.

As with the distal condyles, this acquisition is achieved by mapping the surface of both posterior condyles with the Pointer. The software will then automatically determine for each condyle the most posterior point in the A/P direction of the femur, which is perpendicular to the femur mechanical axis.

Correct
Most posterior point (green) is included in cloud of white points acquired by the surgeon

Incorrect
Most posterior point (orange) is NOT included in cloud of white points acquired by the surgeon. Green will be selected, it is not the most posterior point
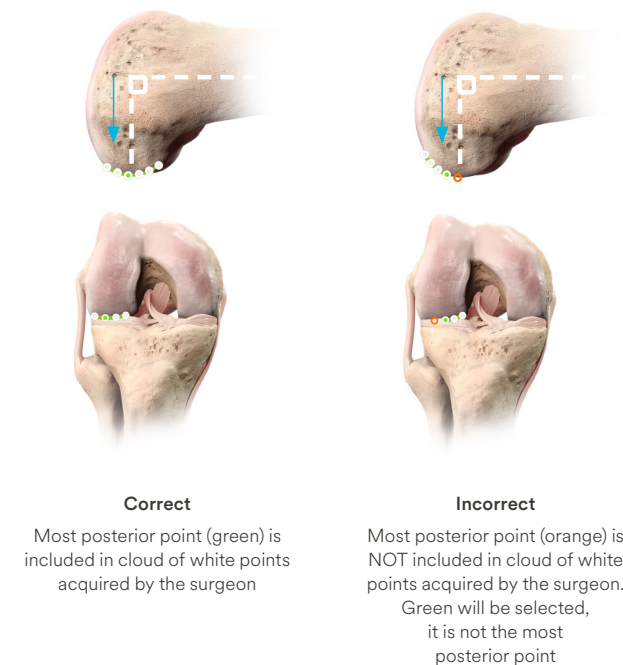
Landmarks Acquisition

> **⚠ Caution:**
> The same cautions as for the distal condyles acquisition apply. Be aware of common pitfalls:
> - Difficulty of accessing the posterior condyle
> - Difficulty keeping the tip of the Pointer in contact with the bone, potentially leading to the acquisition of points too posterior

> **■ Note:**
> Tips for reaching the posterior condyle in a tight compartment:
> - Maximally flex the knee
> - Ensure removal of the anterior horn of the meniscus
> - Distract the relevant compartment by applying a Varus or Valgus force to the tibia

Correct

Incorrect
Acquisition of points
too posterior
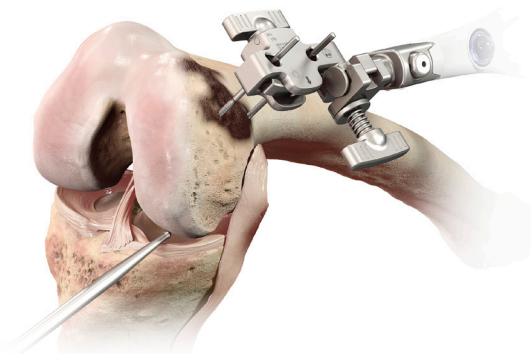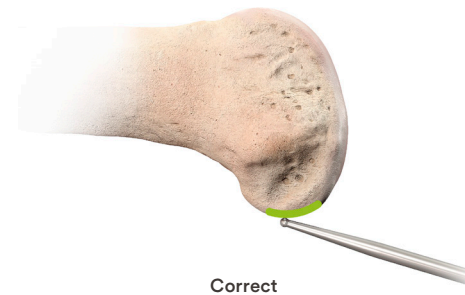
Place the Pointer tip on the posterior aspect of the *medial* condyle.
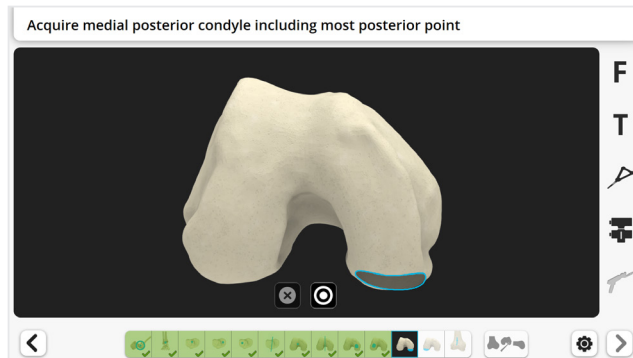
Tap the blue foot pedal or tap the "Start" button ⊙ .

Acquire medial posterior condyle including most posterior point

---

Move the Pointer in a zig-zag motion to digitally "paint" the entire surface.

A "beep" will sound when the system has acquired the required number of points on the surface.
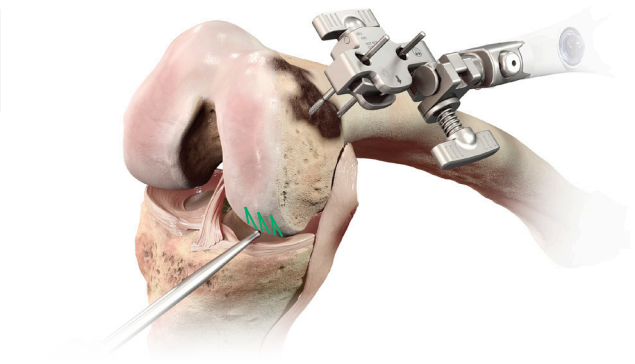
Repeat the above steps to acquire points on the posterior aspect of the *lateral* condyle.

Acquire lateral posterior condyle including most posterior point
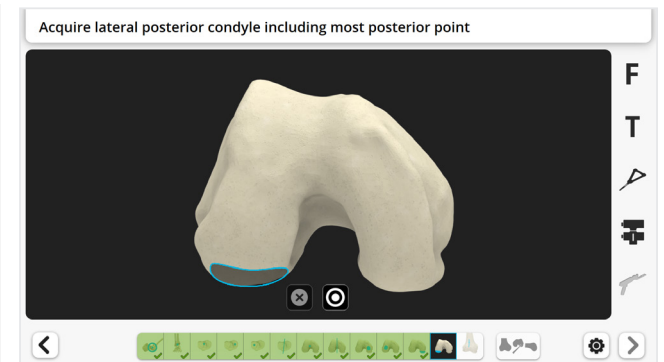
Anterior Cortex

The anterior cortex acquisition will be used to:
- Calculate the femoral implant size
- Determine the initial A/P position of the femoral implant
- Quantify the position of the implant anterior flange relative to the anterior cortex (notching or gap)

A smooth line (green on the adjacent figure) must be acquired with the Pointer along the lateral surface of the anterior cortex. This line will later be used to calculate the Anterior Reference Point (white dot on the adjacent figure) which is where this line crosses the exit of the anterior cut plane when A/P shift = 0 mm.

10 mm min.

L   M   P
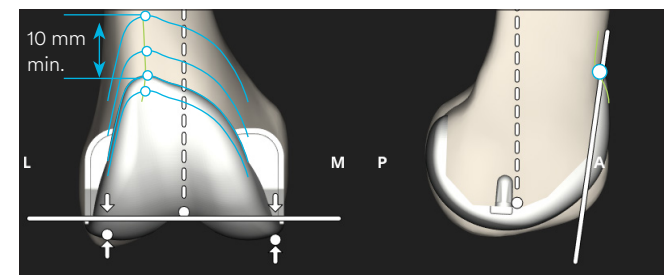
Landmarks Acquisition

Remove any prominent surface defects or soft tissue that will prevent accurately registering the bony surfaces.

A blade may be used to score a path within the soft tissue, to guide the Pointer during the acquisition.

Start acquiring the line proximally enough to permit adjustments to larger implant sizes later during Surgical Planning, i.e. at least 10 mm proximally from the anticipated most proximal aspect of the anterior flange of the implant.

Place the Pointer tip on the proximal lateral anterior femoral cortex.

Tap the blue foot pedal or tap the "Start" button ◉ to start the acquisition.
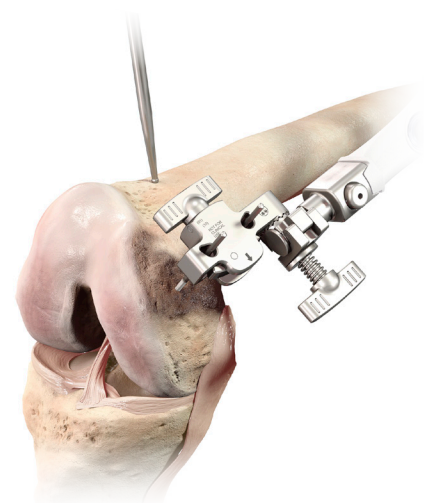
Acquire anterior cortex
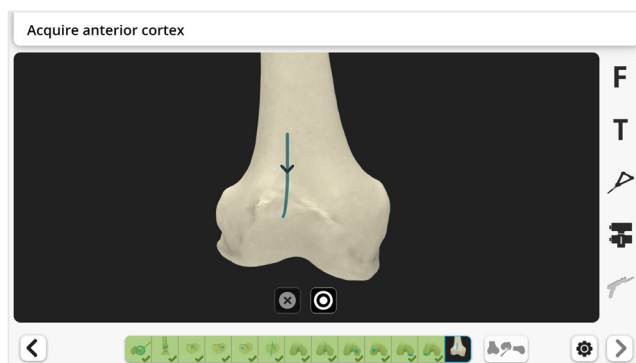
Slide the Pointer distally over the lateral anterior cortex.

A "beep" will sound when the surface has been registered. The system will automatically proceed to the next screen.

■ Note:
Draw a single and continuous line in the distal direction. If drawing is interrupted, delete the acquisition and draw the full line again.
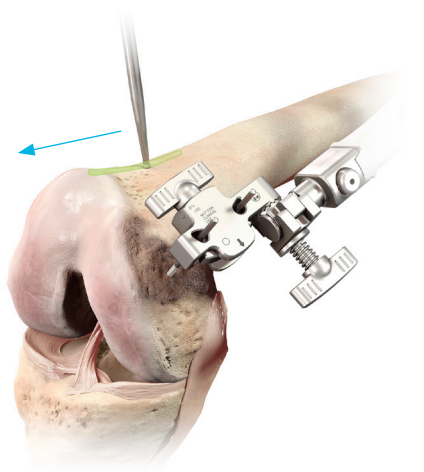
Confirmation of Acquired Landmarks

The confirmation screen displays the 5 landmarks that have been extracted from the four "painted" areas and the line to allow a visual check of each acquired landmark (represented on screen by a green dot outlined in white). The 5 landmarks can be checked in any order.

The distal points acquired are shown in two clouds of blue dots, the posterior and the anterior points in clouds of white dots.

▲ Caution:
The confirmation process requires extra care. The most distal and posterior femoral landmarks as well as the Anterior Reference Point are the basis for implant positioning and sizing.

Any inaccuracy should be corrected by repeating acquisition of the relevant landmark.

Prior to confirming the location of the acquired landmarks, check on the screen that:
- The green dots are centered in the cloud. A green dot shown on a cloud border indicates the adjacent area was not acquired and may contain points possibly more distal or posterior. Check this missing area with the Pointer (see adjacent figure)
- The patches are homogeneous. Green dots away from the main cloud indicate potential Pointer tip lift-off during acquisition. Acquire this patch again (see end of the section)

Validate the landmarks selected by the system

Offset from landmark

Dot is on the cloud border   Pointer tip lift-off during acquisition

Incorrect
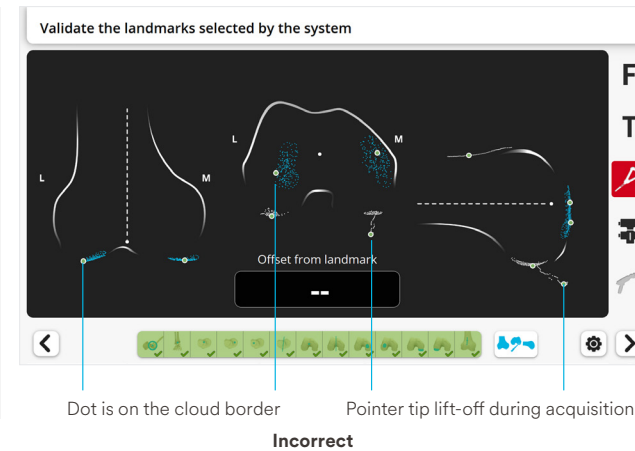
Landmarks Acquisition

Step A: Distal Condyles

This step confirms that the medial and lateral distal points determined during the distal femoral condyle acquisition are the most distal anatomical points.

The system will measure the "offset" which is the difference in the distal-proximal direction between:
- The tip of the Pointer and
- The point determined by the system during acquisition (green dot)

A distal offset between +/- 0.5 mm will be displayed in green along with a positive sound.

On the adjacent example, the tip of the Pointer is 0.4 mm more **proximal** to the green dot.

On this condyle, if the tip of the Pointer remains **more proximal at every point**, then the distal point determined by the system **is the most distal point** and the acquisition is acceptable for this condyle.

A distal offset greater than 0.5 mm will be displayed in red along with a negative sound.

On the adjacent example, the tip of the Pointer (orange) is 1.0 mm **distal** to the green dot.

The tip of the Pointer identified a position more distal than the green dot. Provided the Pointer is in contact with representative bone, **the distal point determined by the system is actually not the most distal on the bone**, and repeating acquisition of this distal condyle is suggested (see page 47).

Place the Pointer tip on the bone at the location identified by the surgeon as the most distal when viewed from the lateral side.

Compare on the screen with the location of the most distal point determined by the system, represented by a green dot.

Move the Pointer tip on the surface of the bone to include the green dot.

0.4 mm

Validate the landmarks selected by the system

Offset from landmark

-0.4 mm

1 mm

Validate the landmarks selected by the system

Offset from landmark

⚠ **1.0** mm
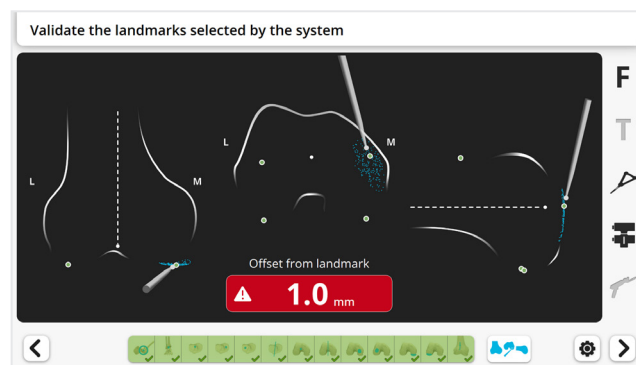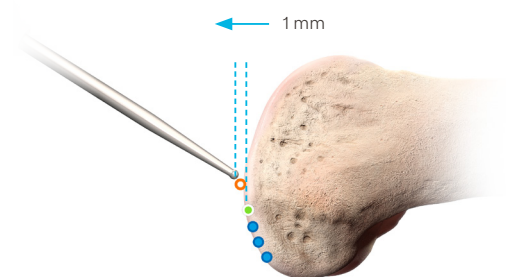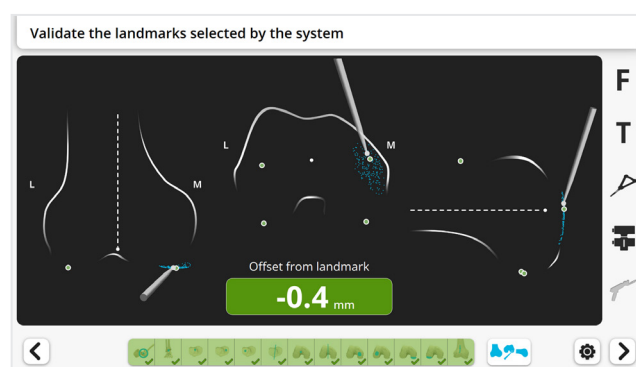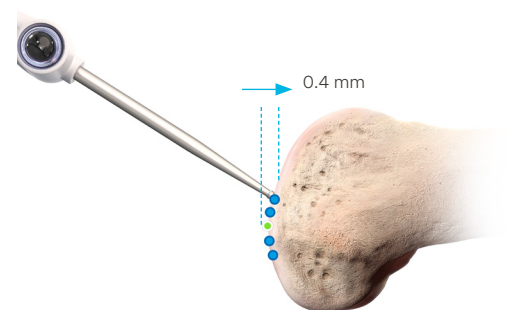
If the distal offset is greater than 0.5 mm as signaled by the negative sound, check if the tip of the Pointer is in contact with representative bone. If so, assess if repeat of acquisition for this distal condyle is required.

Repeat for the other distal green dot.

> ■ **Note:**
> At this step there is no point to acquire. Tap the blue foot pedal only to move to the next step once all five landmarks have been confirmed.

Step B: Posterior Condyles

Similarly, confirm that the medial and lateral posterior points determined during the posterior femoral condyle acquisition are the most posterior anatomical points. The system will measure the offset in the anterior-posterior direction.

A posterior offset greater than 0.5 mm will indicate that the tip of the Pointer found a position more posterior than the posterior green dot being assessed. In this case, assess if repeating acquisition of this posterior condyle is required.
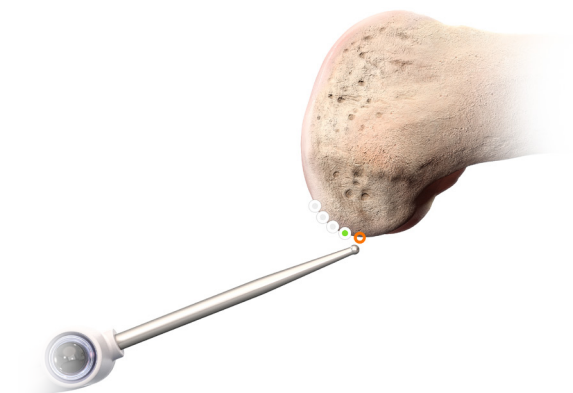
Landmarks Acquisition

Step C: Anterior Cortex

Once the landmarks acquisition is complete, the initial position and size of the femoral implant are automatically calculated by the software. This Initial Surgical Planning is based on a measured resection technique (see PROADJUST™ Surgical Planning for more information) with anterior referencing or posterior referencing as per surgeon's selection in the surgical profile.

It is important to confirm the Anterior Reference Point defined by the system is at the appropriate location on the anterior cortex (see Anterior Cortex acquisition). This point is a critical reference for indication of notching, implant A/P positioning adjustments, and gap balancing during the Surgical Planning phase.

Position the Pointer tip on the bone at the location of the Anterior Reference Point indicated on the screen by the green dot.

Move the Pointer tip on the surface of the bone around this green dot. The screen will indicate the antero-posterior offset between the tip of the Pointer and the Anterior Reference Point.

Confirm that the Anterior Reference Point location corresponds to the anticipated exit of the anterior cut plane with the default plan. If this is not the case, consider acquiring the Anterior Cortex again at the previous step, avoiding any defect or cavity.

Tap the blue foot pedal or tap the "Next" button ⓘ to proceed.

Validate the landmarks selected by the system
Offset from landmark
-0.4 mm

■ Note:

Changing the size of the femoral implant during Surgical Planning will change the location of the Anterior Reference Point.

The antero-posterior offset value is always displayed with the black background.
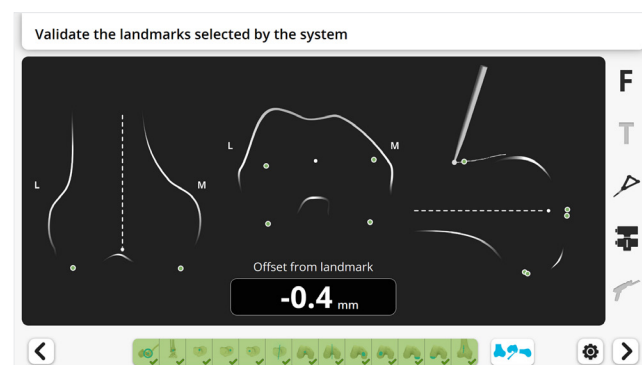
Repeat Landmarks Acquisition

If the surgeon is not satisfied with the confirmation of landmarks, repeat the acquisition of the relevant landmarks before proceeding to the next step.

In the Acquisition Toolbar (1), tap the icon corresponding to the landmark to acquire again.

Tap the blue foot pedal or tap the "Start" button ⓞ to start the acquisition.

Repeat if the next landmark must be acquired again. If not, tap the "Next" button ⓘ or the "Confirmation of Landmarks" button 🔖 (2).

Repeat the confirmation step for the re-acquired landmark.

Tap the blue foot pedal or tap the "Next" button ⓘ to proceed.

Validate the landmarks selected by the system
Offset from landmark
--

■ Note:

Do not tap the blue foot pedal at a landmark acquisition step where the acquisition does not need to be repeated, as this will start a new acquisition.
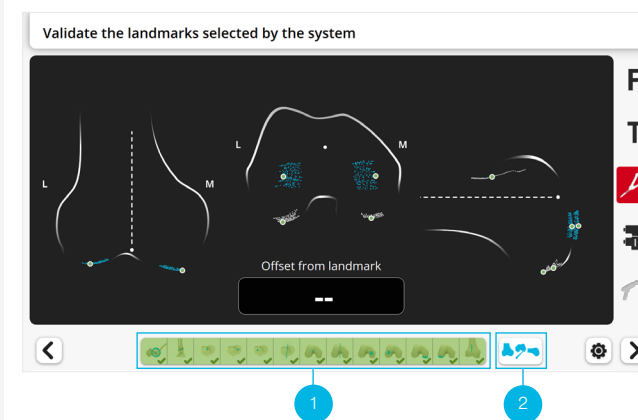
Initial Leg Alignment and ACCUBALANCE™ Graph Recording

The goal of this step is to assess leg alignment and knee balance. Combined with the information acquired during landmarks acquisition, the data recorded during this step creates the ACCUBALANCE™ Graph, a soft tissue stability graph, which is modified during PROADJUST™ Surgical Planning to create the desired final alignment and balance of the knee.

Screen Display

The screen shows the current coronal alignment (Hip Knee Ankle [HKA] angle) and sagittal alignment of the knee (1), the type of implant (2), the calculated size of the femoral component (3), and the insert thickness (4), initially 5 mm. These can be adjusted with a corresponding change in the ACCUBALANCE™ Graph (5).

The tibial resection (6) and femoral implant (not displayed) are positioned according to the Initial Surgical Planning. The right-hand side of the screen shows the ACCUBALANCE™ Graph, which displays the expected gap throughout the range of motion (ROM). This gap is measured between:
- **Femoral implant** (thus not the femoral bone)
- **Tibial resection** or **tibial insert** depending on the position of the Switch (7)
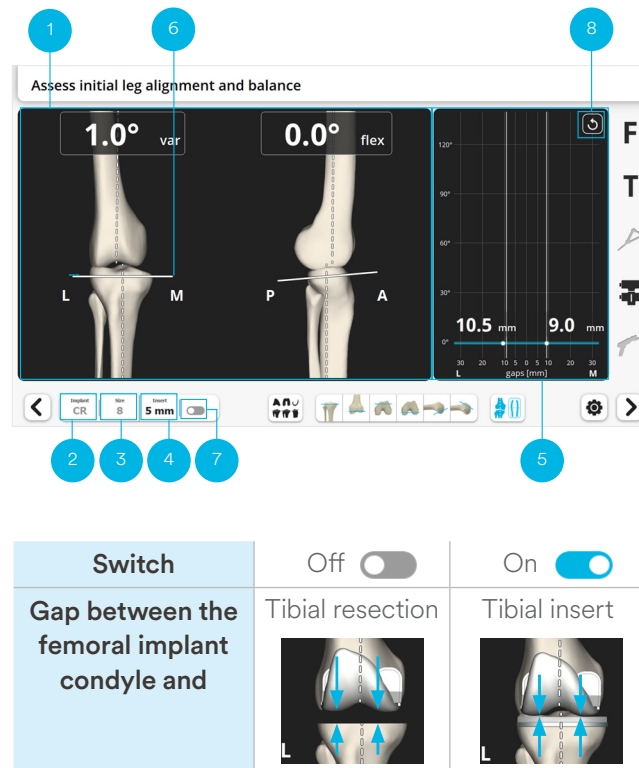
Assessment of Initial Range of Motion and Alignment

Before assessing Range of Motion (ROM) and alignment, remove any tissue that may affect soft tissue balancing. This includes:
- Osteophytes
- ACL
- PCL when using a PS implant or a CR implant with a CS application

Prior to creating the ACCUBALANCE™ Graph, the system will provide quantitative information on ROM and alignment for assessment of the stability and correctability of the alignment in the coronal plane. Correctability indicates if the HKA is likely to be corrected without soft tissue releases.

Assess initial leg alignment and balance

1.0° var   0.0° flex

10.5 mm   9.0 mm

Switch	Off ⬤	On ⬤
Gap between the femoral implant condyle and	Tibial resection	Tibial insert

Initial Range of Motion

Bring the leg into full flexion.

Bring the leg into full extension.

Assess knee ROM in the sagittal plane including presence of fixed flexion deformity (FFD) or hyperextension.
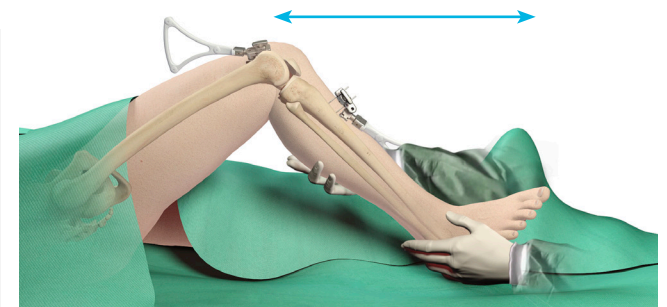
The software will record the maximum flexion and extension for documentation in the case report.

Initial Alignment, Stability and Correctability

In extension perform a Varus and Valgus stress.

Assess the stability and correctability in the coronal plane.
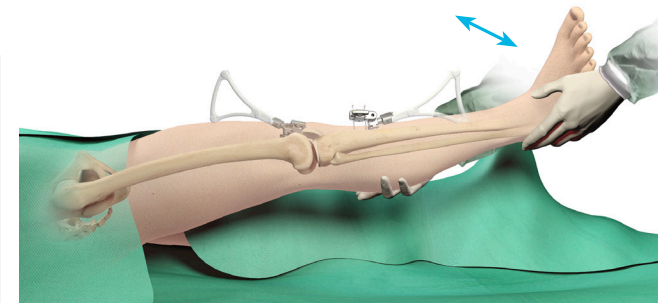
It is recommended to also assess the MCL and LCL function at 10-15 degrees flexion where the posterior capsule will not be fully tensioned.

Initial soft tissue releases, if needed, should be done prior to recording the ACCUBALANCE™ Graph.

Initial Leg Alignment and ACCUBALANCE™ Graph Recording

Recording of the ACCUBALANCE™ Graph

The ACCUBALANCE™ Graph is intended to represent the relationship between the tibial and femoral implants through flexion and extension **with the soft tissues in the intended tension**. There are two possible options for recording the graph:
A. Through the full ROM, or
B. Only in full extension and 90 degrees of flexion

In both techniques, the amount of Varus and Valgus stress applied should represent the surgeon's intended final tension in the lateral and medial collateral ligaments, respectively.

> **▲ Caution:**
> The ACCUBALANCE™ Graph should be recorded with the intended *postoperative ligament tension*. The surgeon **must not try to adjust or equalize the gaps at this step** by overstretching the ligaments in Varus or Valgus or by distracting the joint. Gaps can be adjusted during the following PROADJUST™ Surgical Planning step.

Tap the "Reset" button 🔁 (8). This will erase data recorded previously with possibly excessive tension.

The graph is automatically recorded. The user does not need to tap the blue pedal to begin recording.

> **▲ Caution:**
> On the Leg Alignment and ACCUBALANCE™ Graph recording screens, the Graph is continuously updated to record the largest medial and lateral gap found at each flexion angle. Reset the Graph if it does not reflect the intended tension in the soft tissues, i.e. if some ligaments were overstretched in Varus or Valgus.

8

120°

90°

60°

30°

0°

10.5 mm   **9.0** mm

30 20 10 5 0 5 10   20   30
L   gaps [mm]   M
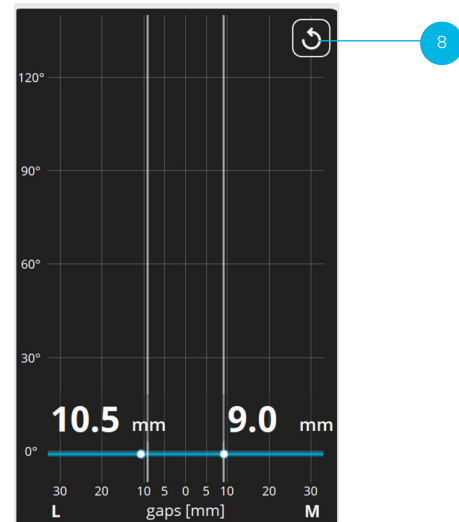
Option A: Recording Along the Full Range of Motion

In extension, apply a Varus force to stress the lateral side of the knee with the intended soft tissues tension.
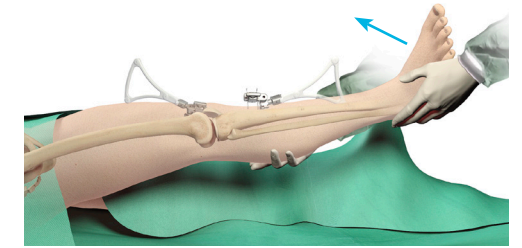
Smoothly flex the knee while maintaining the Varus force and the intended lateral soft tissues tension. **Avoid external hip rotation** as flexion increases to ensure applied force is transmitted to the collateral ligaments and not lost in rotation, and that the arrays remain visible to the Camera.

Once maximum flexion angle is reached, release the Varus force and bring the knee back into extension.
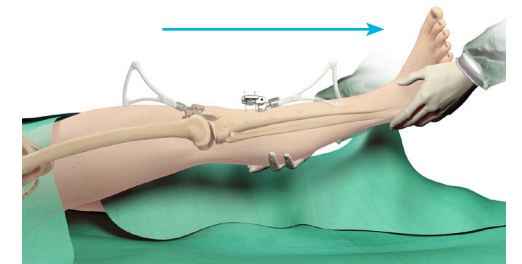
Repeat the process for the medial side: Apply a Valgus force to stress the medial side with the intended soft tissues tension.
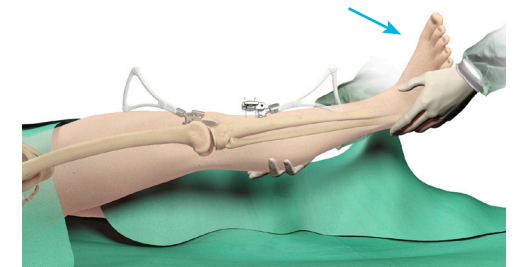
Smoothly flex the knee while maintaining the Valgus force and the intended medial soft tissues tension.
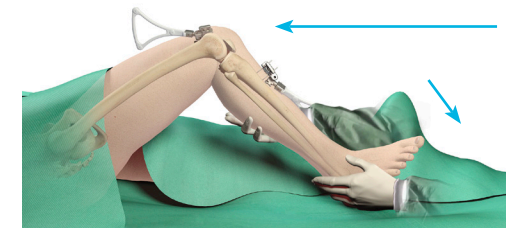
Once maximum flexion angle is reached, release the Valgus force and bring the knee back into extension.
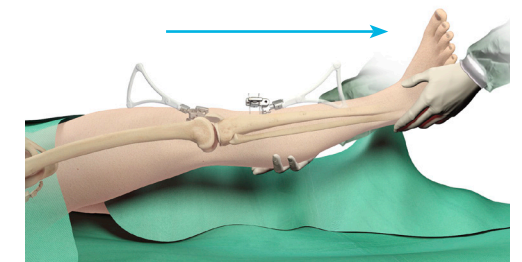
Initial Leg Alignment and ACCUBALANCE™ Graph Recording

Option B: Recording in Flexion-Extension Only

In extension:
- Apply a Varus force to stress the lateral side of the knee with the intended soft tissues tension
- Apply a Valgus force to stress the medial side of the knee with the intended soft tissues tension
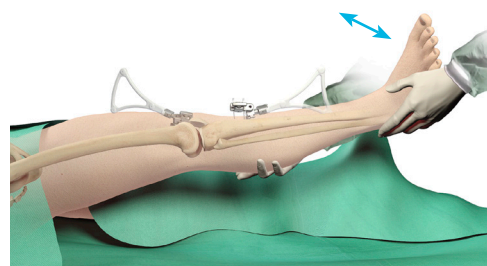
At 90 degrees of knee flexion:
- Apply a Varus force to stress the lateral side of the knee with the intended soft tissues tension, **while avoiding hip rotation**
- Apply a Valgus force to stress the medial side of the knee with the intended soft tissues tension
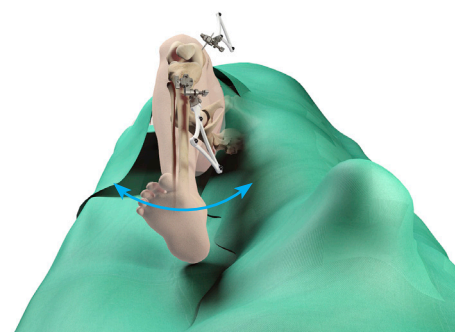
Gap Angle Adjustment (Optional)

The ACCUBALANCE™ Graph now shows the calculated gaps between the femoral implant and the tibial resection (or tibial insert) as positioned in the Initial Surgical Planning and with the soft tissues in the intended tension.

The gap values in mm are displayed for:
- The angle closest to 0 degree flexion next to the Extension Gap Window (9) and
- The angle closest to 90 degrees flexion next to the Flexion Gap Window (10)

The position of the two Gap Windows can be adjusted to display the gap values at different angles. For instance, the Extension Gap Window can be positioned at 10 degrees or 15 degrees flexion to display gaps:
- Where the posterior capsule may not be fully tensioned,
- Or in the presence of fixed flexion deformity (FFD)

Tap the Window (9) or (10).

Tap the up or down arrows to adjust the angle.

> ■ **Note:**
> Adjustments to the Gap Windows at this step will be maintained at the PROADJUST™ Surgical Planning screen. The same adjustments can be made at the PROADJUST™ Surgical Planning screen.
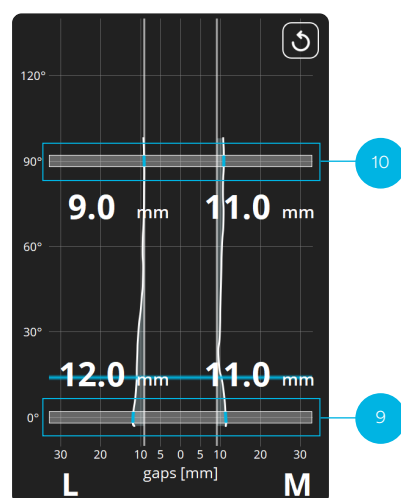
Range of adjustments

Gap Window	Min	Initial	Max
Extension	-5° (hyperextension)	0°	20°
Flexion	70°	90°	95°

ACCUBALANCE™ Graph Assessment

The surgeon may now use this assessment of the soft tissue envelope to accurately achieve the desired balance by choosing **one** of the options below:
- Modifying the position of the components (bone resection) during next step, "PROADJUST™ Surgical Planning"
- Selectively releasing soft tissue followed by repeating the Graph acquisition
- A combination of the above

> ▲ **Caution:**
> Any bone resection or implant size modification during PROADJUST™ Surgical Planning will automatically update the Graph.
>
> Soft tissue changes will **not** be captured automatically. It is important to **reset the Graph and record again after any adjustments to the soft tissue envelope** are made.

At any time later in the procedure, a new ACCUBALANCE™ Graph can be recorded by tapping the "Alignment and Graph" button ⏸ .

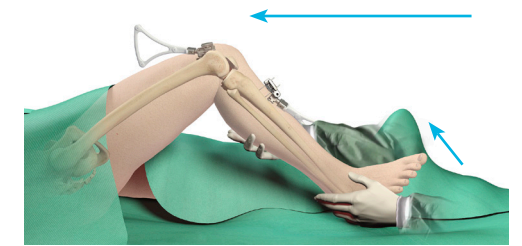> ▲ **Caution:**
> If the Leg Alignment and ACCUBALANCE™ Graph Recording screen is accessed *via* the "Alignment and Graph" button ⏸ , return the Robotic-Assisted Device to its Home Position before manipulating the leg. In the toolbox select "Return to home" and refer to Tibial Resection - Return Robotic Device to Home Position.

Coronal Leg Alignment Recording

Finally, the software will record the initial coronal leg alignment (HKA angle) for documentation in the case report.

Hold the leg in extension with no Varus/Valgus stress.
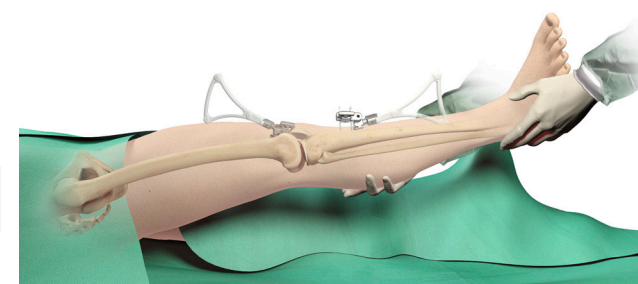
To record the initial coronal leg alignment and proceed, tap the blue foot pedal or tap the "Next" button ❯ .
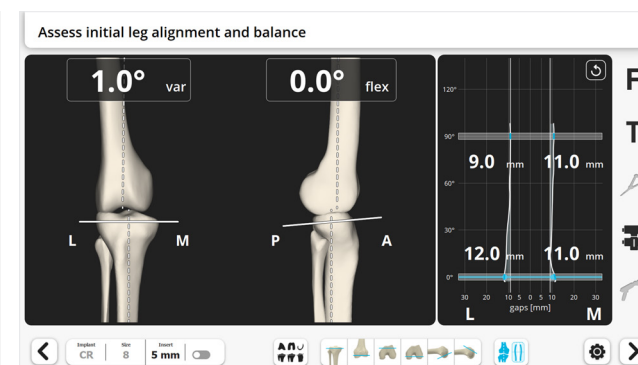
PROADJUST™ Planning Software

The goal of the PROADJUST™ Surgical Planning is to plan the size and position of both femur and tibia implants simultaneously by adjusting the bone resections.

The parameters are adjusted on either of the two Touchscreens. Movement of either component will be reflected on the ACCUBALANCE™ Graph.

Any adjustment may affect:
- Bone resection
- Alignment
- Balance and gaps
- Joint line

Initial Surgical Planning

Initial implant size and position is determined automatically based on the landmarks acquired and the parameters set by the surgeon in the Surgical Profile.

1.	Femur Coronal Alignment	8.	Tibia Coronal Alignment
2.	Distal Femoral Resection	9.	HKA Angle
3.	Femoral Rotation	10.	Tibial Resection Height
4.	Femoral Flexion	11.	Tibial Slope
5.	A/P Shift	12.	Reset Femur Parameters
6.	Posterior Resections	13.	Reset Tibia Parameters
7.	Femoral Component Size		
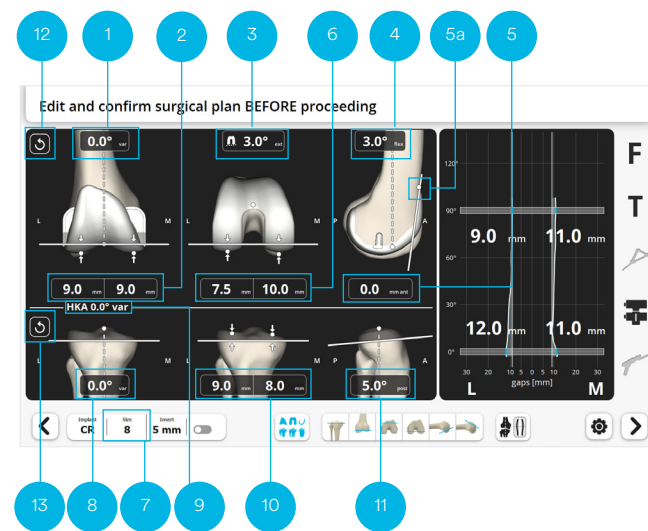
⚠ Caution:
Adjustments on one parameter may affect other parameters.

The surgeon must review all component position parameters and resulting alignment and gap balancing at planning completion to ensure they meet values that the surgeon finds acceptable.

The following primary default settings are used in the Robotic-Assisted System.

Femur Coronal Alignment (1)
- 0 degrees Varus/Valgus relative to the mechanical axis of the femur

Distal Femoral Resection (2)
- 9 mm resection from the most distal point of the most distal condyle
- The medial or lateral side with the highest initial resection value becomes the "Varus/Valgus pivot point", i.e. the highest resection value remains constant when adjusting the femur coronal alignment

Clinical judgment is required to determine the appropriate resection amount on both distal condyles, especially in cases of wear or severe deformity. Adjust the distal femoral resection and/or the coronal alignment of the resection as required.

Femoral Rotation (3)
- Three reference axes can be used for femoral component rotational axis
  - Posterior condylar axis (PCA)
  - Whiteside's Line
  - Transepicondylar axis (TEA)
- One of these axes is set as the primary axis (3a) in the Surgical Profile
- The default rotation relative to the primary axis is also set in the Surgical Profile
- When making rotation adjustments, the resulting position of the implant relative to the secondary axes will be displayed (3b)
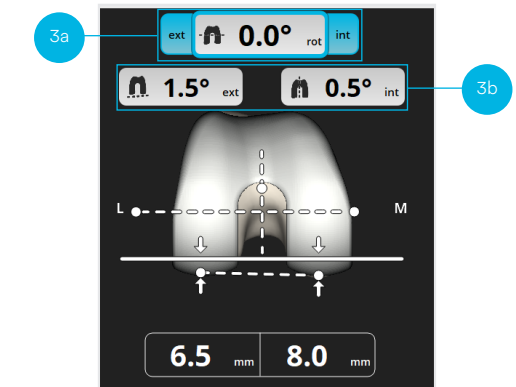
Surgical Profile Setting	Acquisitions	Surgical Planning	
Primary Reference Selection	Epicondyles Required	Symbol	Secondary Reference Displayed
Posterior condylar axis	No		Whiteside's Line
Whiteside's Line	No		Posterior condylar axis
Transepicondylar axis	Yes		Posterior condylar axis Whiteside's Line

PROADJUST™ Planning Software

Femoral Flexion (4)
- As chosen in the Surgical Profile

> ▲ **Caution:**
> The femoral component flexion is measured in the sagittal plane and set relative to the mechanical axis. Conventional IM manual instrumentation utilizes the anatomical axis. In the sagittal plane there is on average a 3 degrees difference between the anatomical and mechanical axis due to the distal femur bow and the anteversion of the femoral neck. Therefore, with this system, the femoral component should be flexed on average at 3 degrees to the mechanical axis to reproduce native femoral sagittal bowing.
>
> Reducing native femoral bowing generally results in an upsized femoral component to avoid notching.

Mechanical axis
Anatomic axis
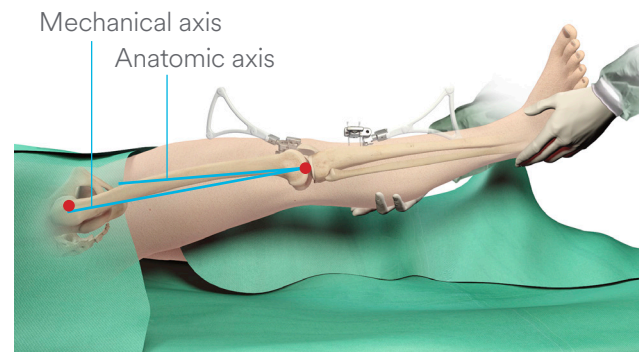
A/P Shift (5)
- 0 mm if Anterior Referencing was selected in the Surgical Profile
- The A/P shift is the distance between the anterior cut plane and the Anterior Reference Point (5a) (see Anterior Cortex acquisition)
- The A/P will be modified when the posterior resections (6) are adjusted, and reciprocally

> ▲ **Caution:**
> When translating the femoral implant in A/P, notching will be indicated by a negative A/P shift and gap by a positive A/P shift.
>
> On the ATTUNE™ Primary Knee System, there is a 3 mm difference in A/P between each implant size. A shift smaller than 0 mm or larger than 3 mm will be indicated in red. In this situation, consider either:
> - Changing the implant flexion
> - Changing the implant size

Posterior Resections (6)
- Set so that posterior lateral resection is 8 mm when femoral external rotation is 3 degrees relative to the posterior condylar axis, if Posterior Referencing was selected in the Surgical Profile

Femoral Component Size (7)
- Size is based on A/P dimensions of the femur (anterior cortex and most posterior landmark)

When the size is increased by 1 increment:
- In Anterior Referencing, posterior resections translate posteriorly by 3 mm while maintaining anterior resection plane
- In Posterior Referencing, anterior resection plane translates anteriorly by 3 mm while maintaining posterior resections plane

When the implant size is decreased by 1 increment, the adjustments are inverted.

> ▲ **Caution:**
> Ensure the software selected a femoral component size consistent with the surgeon's pre-operative planning.

> ▲ **Caution:**
> On the ATTUNE™ Primary Knee System, **the amount of posterior condyle resection is the same for both CR and PS implants,** with a recommended 8 mm resection in a posterior referencing technique.
>
> However, the femoral *implant posterior condyle thickness* is 8 mm on CR implants and 9 mm on PS implants. Thus, changing the type of implant CR or PS will impact the gaps in flexion, which can be observed on the ACCUBALANCE™ Graph.

Tibia Coronal Alignment (8)
- 0 degrees Varus/Valgus relative to the mechanical axis of the tibia
- 0 degree calculated HKA angle (9)

8 mm CR
9 mm PS

9 mm

Construct
minimum 9 mm

Tibial Resection Height (10)
- Resection from the high side as chosen in the Surgical Profile
- Minimum of 2 mm from the low side (see diagram in Tibial Plateau Acquisition section)
- The medial or lateral side with the highest initial resection value becomes the "Varus/Valgus pivot point", i.e. the highest resection height remains constant when adjusting the tibia coronal alignment
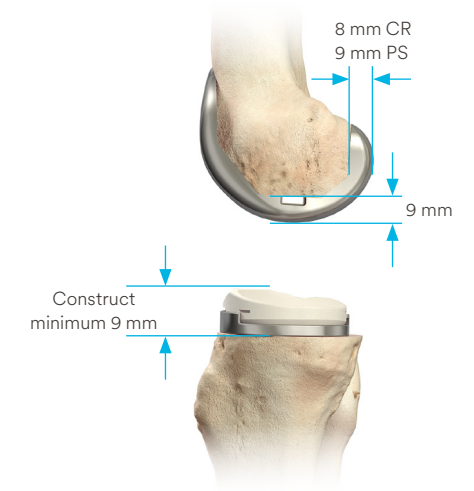
Clinical judgment is required to determine the appropriate resection amount on both plateaus, especially in cases of wear or severe deformity. Adjust the height and/or the coronal alignment of the resection as required.

Tibial Slope (11)
- As chosen in the Surgical Profile
The plan can be reset to the initial values using the buttons (12) for the femur parameters (including size and implant type) and (13) for the tibia parameters.

> ▲ **Caution:**
> When using a ATTUNE™ Revision Tibial Base with a Stem: The construct is longer, therefore the surgeons should pre-operatively template a stemmed tibial construct to assess the impact of **coronal alignment** and **slope** upon Stem orientation and fit within the canal. Tibial stems are not recommended for Patient Specific Alignment techniques.

PROADJUST™ Planning Software

Gaps Balancing

During the ACCUBALANCE™ Graph Recording, the intended medial and lateral ligament tension in flexion and in extension were recorded. Changes can be made to the Initial Surgical Plan and the Graph will update automatically.

The goal of balancing with the PROADJUST™ surgical planning is to adjust the tibial and femoral components position to modify the flexion and extension gaps to obtain the intended ligament tension.

> **▲ Caution:**
> Proper soft tissue balance is important for successful Knee Replacement. It is especially important for Rotating Platform (RP) knee construct to reduce the risk of spin out of the tibial insert.

Coronal Gap Balancing
Differences between the medial and lateral gaps need to be addressed with the following options:

1. In extension:
- Adjusting the femur coronal alignment
- Adjusting the tibia coronal alignment

2. In flexion:
- Adjusting the tibia coronal alignment. Note this changes the medial and lateral gaps BOTH in extension and flexion
- Adjusting the femoral rotation. Care should be taken:
  - Avoid excessive internal rotation as it may compromise patella tracking
  - Rotation changes may change the A/P Shift on the anterior femoral cortex with a risk of notching or gapping
  - When adjusting rotation around the primary axis, monitor the resulting rotation around the secondary axes and ensure all stay within the surgeon's acceptable limits

Sagittal Gap Balancing
For flexion and extension gap discrepancies, multiple options exist:

1. Femoral sizing (in anterior referencing mode)
- Downsizing the femoral component will increase the flexion gap
- Upsizing the femoral component will decrease the flexion gap

Neither will change the extension gap.

2. Femoral component A/P translation
- Translating the femoral component anteriorly will increase the flexion gap
- Translating the femoral component posteriorly will decrease the flexion gap

Neither will change the extension gap. Any A/P translation will affect the relationship of the anterior flange of the component to the femoral cortex.

3. Femoral component flexion (in anterior referencing mode)
- Reducing the femoral component flexion will increase the flexion gap
- Increasing the femoral component flexion will decrease the flexion gap

4. Distal femoral resection level
- Shifting the femoral component proximally (increased femoral resection) will increase the extension gap
- Shifting the femoral component distally (less distal resection) will decrease the extension gap

Neither will change the flexion gap.

> **■ Note:**
> In the software, the following parameters aim to preserve the joint line when being adjusted, and therefore are not used for sagittal gap balancing:
>
> Tibial slope:
> - Low impact on extension and flexion gaps
>
> Femoral flexion:
> - Low impact on flexion gap in posterior referencing mode
> - Low impact on extension gap in anterior and posterior referencing modes
>
> Modifying the amount of tibial resection will change BOTH flexion and extension gaps, i.e. it will not resolve gap discrepancies.

> **■ Note:**
> The goal of sagittal balancing is to create a knee that achieves full extension without hyperextension in combination with a balanced flexion gap. This is dependent upon many factors including component balancing, but also on initial ROM (presence or absence of FFD or hyperextension), and final adjustment may be needed after the trial stage to achieve this goal.

Boundaries
The ATTUNE™ Primary Knee System has been validated for use within the below stated boundaries.

	Maximum Valgus	Maximum Varus
Tibia	0°	3°
HKA	3°	3°

PROADJUST™ Planning Software

Pointer Verification

As an extra check prior to resection, the Pointer can be placed on the bone surface near a resection plane and used to verify the position of the resection planes. The Pointer tip will appear at the same point on the PROADJUST™ Surgical Planning screen. This is particularly useful on the anterior aspect of the distal femur to ensure the component position will not result in notching.
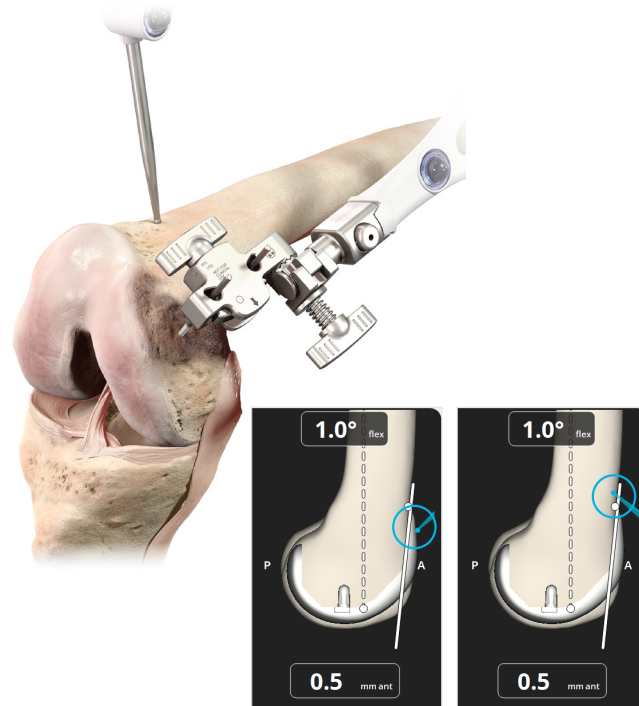
Pointer tip anterior to resection plane: bone will be resected

Pointer tip posterior to resection plane: bone will not be resected

Tap the blue foot pedal or tap the "Next" button ▷ to proceed.

Edit and confirm surgical plan BEFORE proceeding

Tibia Checkpoint Verification
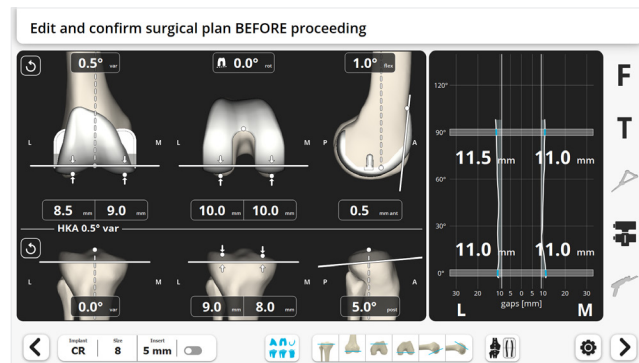
To confirm the Tibia Array has not moved since landmarks acquisition, the tip of the Pointer is placed in the Tibia Checkpoint and the distance between this measured point and the previously registered point is displayed. Deviation suggests possible movement of the Tibia Array, and confirmation by the surgeon may be required to proceed.

Place the Pointer tip on the Tibia Checkpoint.

Do not tap the blue foot pedal during the measurement. The system will automatically proceed to the next step if the distance is acceptable.

Place pointer on checkpoint to verify that tibia array has not moved

Distance 0.6 mm
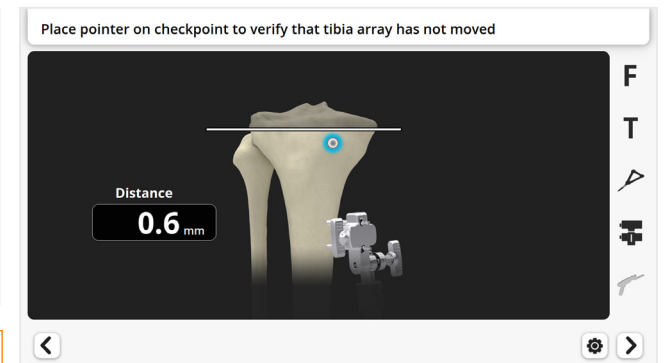
⚠ Caution:
If the measured distance displayed on the screen is different from the distance between the tip of the Pointer and the original Checkpoint, the Tibia Array has moved, and the surgeon must not proceed with the femur resections.

⚠ Caution:
If the system does not automatically proceed:
- Confirm the tip of the Pointer is at the acquired Tibia Checkpoint position and well-seated in the indentation created
- Ensure the base of the Checkpoint is clear of soft tissue or debris
- Confirm the Pointer and the Tibia Array are visible to the Camera

The surgeon may consider the deviation in position is representative of the distance between the tip of the Pointer and the original Checkpoint and decide to proceed by tapping the blue foot pedal.
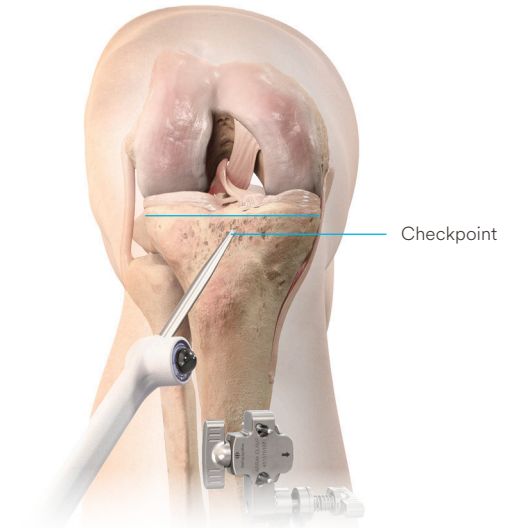
Checkpoint

If the deviation is unacceptable, the Tibia Array must be re-stabilized, and all tibial landmark acquisition and subsequent steps repeated:
- Check Tibia Array connections and tighten where needed
- Re-acquire Tibia Checkpoint, tibial landmarks
- Record the alignment and the ACCUBALANCE™ Graph
- Repeat Surgical Planning
- Verify Tibia Checkpoint

⚠ Caution:
When using the Resection Toolbar, the Checkpoint verification screen will not automatically be displayed, so the Checkpoint must be verified at least once for each bone by using the toolbox (see Appendix 1).

Robotic-Assisted Device Positioning

The goal of this step is to manually position the Robotic-Assisted Device so that:
- It is best positioned to reach the first resection plane
- The need for subsequent repositioning is minimized

The screen will guide the placement of the Robotic-Assisted Device to this Recommended Position.

Initial Manual Positioning

Attachment to Table
Attach the Robotic-Assisted Device to the bedrail adjacent to the hip center if the Robotic-Assisted Device has not already been attached during OR Pre-Op Setup.

Robotic-Assisted Device Positioning

Place the knee in a stable position, flexed between 90 degrees and 110 degrees.

Press the Holding Arm Vertical Adjustment button for vertical adjustment.

Horizontal Adjustment Locking Mechanism

Vertical Adjustment Button

90 - 110°
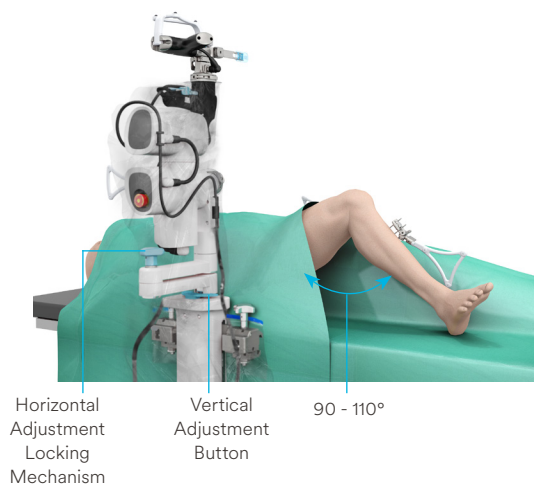
Unlock the Holding Arm Horizontal Adjustment for horizontal movements.

Position the center of the Device Array Interface at 25 mm (1 inch) below the femoral epicondyles.

Array Interface

25 mm - 1"

90 - 110°
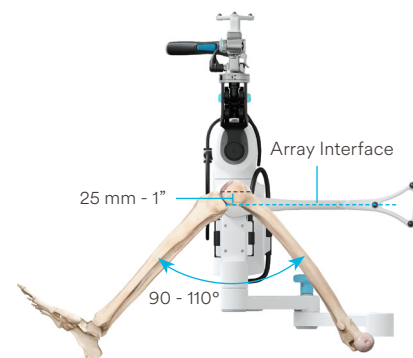
Position the center of the knee at approx. 180 mm (7") from the Device Array Interface.

180 mm 7"
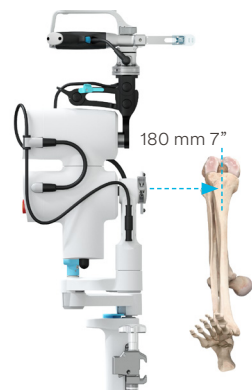
Common Pitfalls
Ensure the leg and the Holding Arm are both vertically aligned.
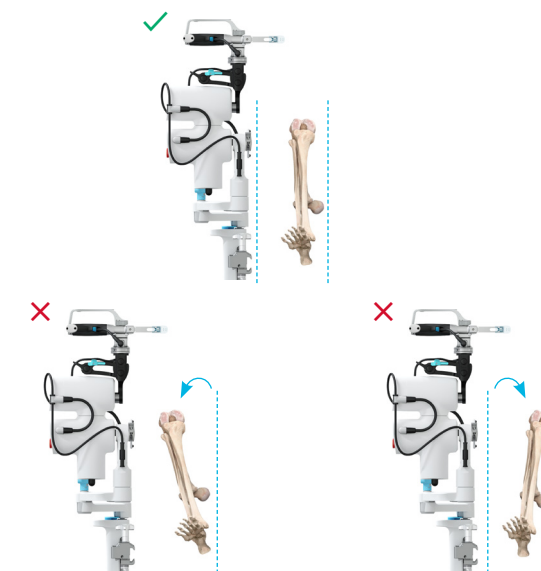
Ensure the planned implant axis (and not the bone axis) is aligned with the Device axis. In case a significant femoral component rotation is planned, the femoral bone may need to be first manually rotated prior to Device positioning.
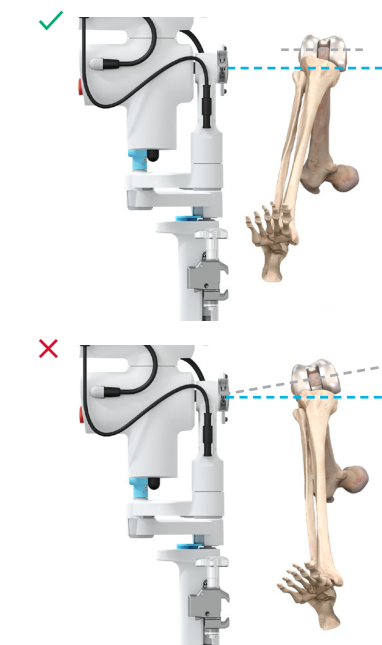
Ensure the elbow of the horizontal adjustment, when flexed, is pointing away from the patient.
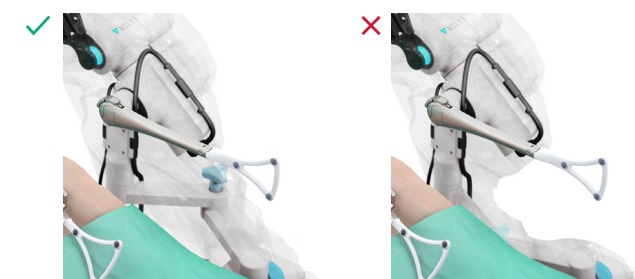
Robotic-Assisted Device Positioning

Positioning Adjustment

Test of Robotic-Assisted Device Position

Tap the blue foot pedal or tap the "Next" button ⊙ to test if the Robotic-Assisted Device is in a position where it can reach the distal femur resection plane.

Press and hold blue pedal to reach tibial plane
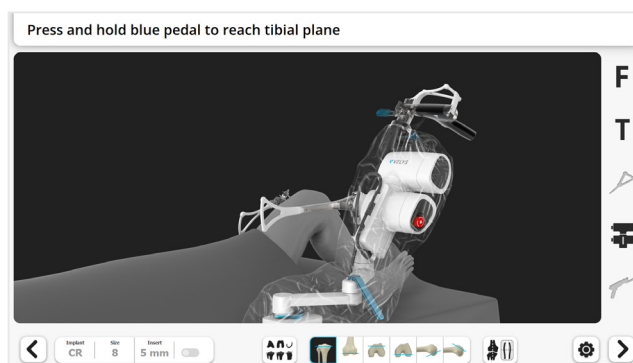
- If the Robotic-Assisted Device is well positioned to reach all resection planes, the Device will directly move to the next resection plane as described in the next section.
- If the Robotic-Assisted Device position needs to be adjusted to perform the next resection, the Robotic-Assisted Device Positioning screen described below will appear. This is generally for the first resection.

Adjustments

The blue circle on the screen indicates the position of the Robotic-Assisted Device and will move when the Robotic-Assisted Device position is adjusted.
Move the articulating arm to position the Robotic-Assisted Device until the screen displays the blue circle centered on the white target.

Tibial plane not reachable

Adjust the distance between the Robotic-Assisted Device and the knee. Match the diameter of the blue circle to the diameter of the white target. The diameter of the blue circle will increase when the Robotic-Assisted Device is moved closer to the knee and will decrease when the Robotic-Assisted Device is moved away from the knee.
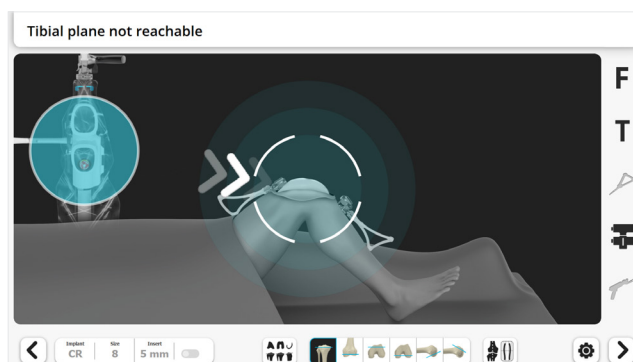
Optimum position is reached when the check mark appears and the Header is green.

To proceed, lock the Holding Arm Horizontal Adjustment and tap the blue foot pedal or tap the "Next" button ⊙ .

Tibial plane reachable   Press blue pedal

> ⚠ **Caution:**
> Ensure the Holding Arm Horizontal Adjustment is locked after positioning of the Robotic-Assisted Device during and between resections.
>
> When manipulating the Horizontal Adjustment Locking Mechanism, ensure there is some slack in the Device Drape to avoid perforation of the Drape.

> ▪ **Note:**
> The green Header may appear at a different time than the check mark.
>
> If the *Header is green* but the *check mark not visible*: The first resection will be possible but not all subsequent resection planes may be accessible. The Robotic-Assisted Device position will need to be adjusted for the subsequent resections. Continuing to adjust the position to reach the Recommended Position is advised but not mandatory.
>
> If the *check mark is visible* but the *Header is not green*: The first resection will not be possible. Continue to adjust the Robotic-Assisted Device position. Check if instructions on the right of the Header are suggesting any leg position adjustment.
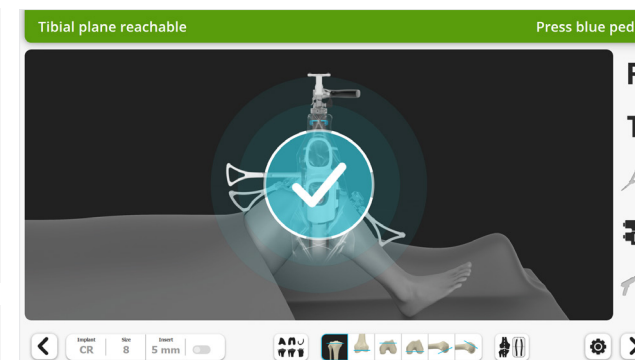
Tibial Resection

The Tibial Resection will be performed in two steps.

1. Position the leg and retractors, then move the Robotic-Assisted Device to the precise resection plane.
2. Resection of the bone.

The system will display a specific screen for each step.

Device Movement

> **⚠ Caution:**
> Prior to each resection, ensure the leg is stabilized in the desired position.

Step 1 — Move the Robotic-Assisted Device to the Resection Plane

Position leg and retractors.
- Place retractors to protect soft tissues during the bone resections. The retractors must be placed so they can be held by the assistant without blocking the line of sight between the Arrays and the Camera
- Appendix 4 outlines options for positioning of surgical assistants and retractors to avoid interference with the Camera and Robotic-Assisted Device

Ensure visibility of the Tibia Array and Device Array. These are indicated by the arrays being highlighted black on the screen.

Press and hold blue pedal to reach tibial plane

To move the Robotic-Assisted Device to the resection plane, press and hold the blue foot pedal.

Moving to tibial plane — Keep blue pedal pressed

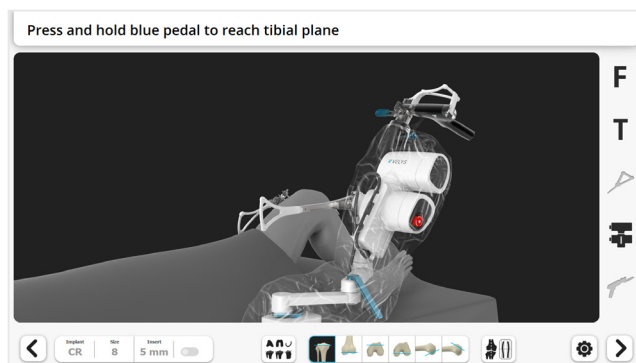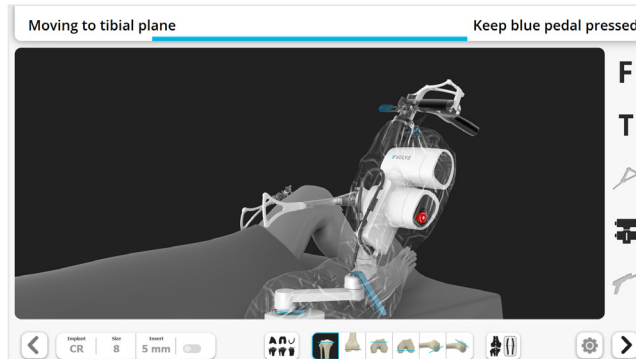The Robotic-Assisted Device will stop when the resection plane is reached.

Release the blue foot pedal. The system will then automatically proceed to the resection screen.

Final position reached — Release blue pedal
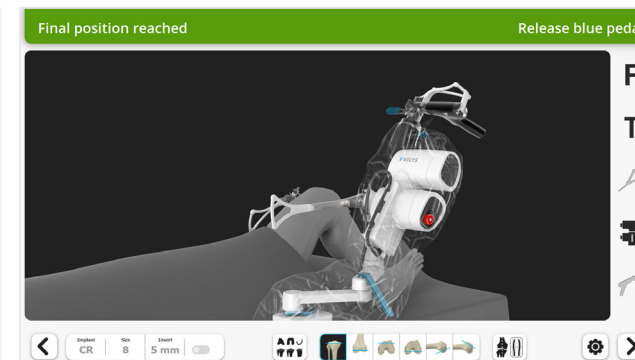
If the Robotic-Assisted Device appears to have reached the resection plane, but the green header is not maintained, the Robotic-Assisted Device may not be in an optimal position for the resection. Adjust the leg flexion or the position of the Robotic-Assisted Device on the Holding Arm.

> **⚠ Caution:**
> Between two resections:
> - Do not hold the Saw Handpiece, leave it locked on the Robotic-Assisted Device
> - Ensure the Saw Blade is covered by the Saw Blade Cover
> - Movement between resection planes can be stopped at any point by releasing the blue foot pedal

> **■ Note:**
> It is recommended to position the leg and the lateral retractor prior to positioning the Robotic-Assisted Device. Otherwise, if the leg is moved excessively after Device movement, the system will request to stabilize the knee and to move again the Robotic-Assisted Device to the resection plane.

Tibial Resection

Performing Resections

Step 2 — Tibial Resection

> **⚠ Caution:**
> There are no mechanical boundaries on the Saw Blade. Therefore, it must be controlled at all times by the surgeon. Prior to each resection, ensure the leg is stabilized in the desired position, and retractors are suitably placed.
>
> - Any large leg movement will require a rapid adjustment by the Robotic-Assisted Device and can potentially introduce inaccuracy
> - Incomplete retractor placement exposes soft tissues to potential damage
> - Ensure the Holding Arm Horizontal Adjustment is fully locked after positioning of the Robotic-Assisted Device during and between resections

> **■ Note:**
> During Robotic-Assisted Device movement to the resection plane in step 1, the Device Array must be visible to the Camera.
>
> In step 2, once the Robotic-Assisted Device is positioned and the Saw is released from the Robotic-Assisted Device, visibility of the Device Array is needed only once at the beginning and then no longer required. This provides space for assistant positioning and retraction. Conversely, in step 2 it is essential to maintain direct line of sight between the Saw Array and the Camera.

Ensure the retractors are ready for resection.
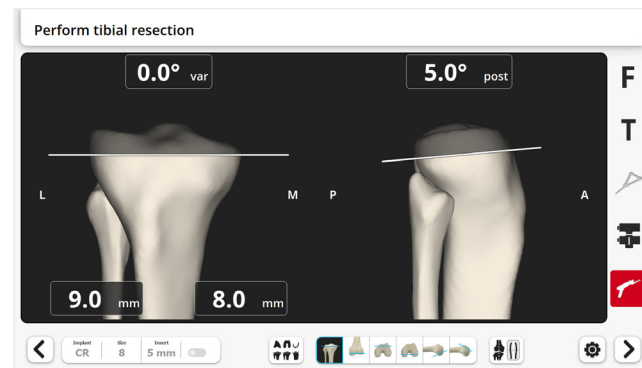
Hold the Saw Handpiece and unlock the Planar Articulation. Slide the blue Planar Articulation Lock on the Planar Articulation to release the Saw.

> **⚠ Caution:**
> Manipulate the Planar Articulation Lock through the reinforced region of the drape to not tear the Device Drape.
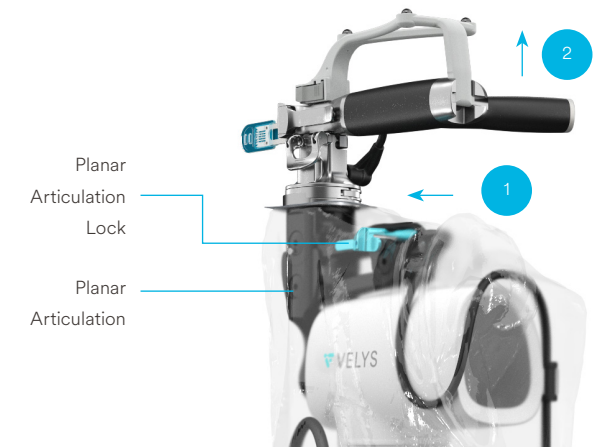
Position the Saw adjacent to the tibial bone.

Confirm the visibility of the Tibia Array and the Saw Array on the screen. The Status Indicator will turn green when both Arrays are visible and when the Saw is adjacent to the bone.
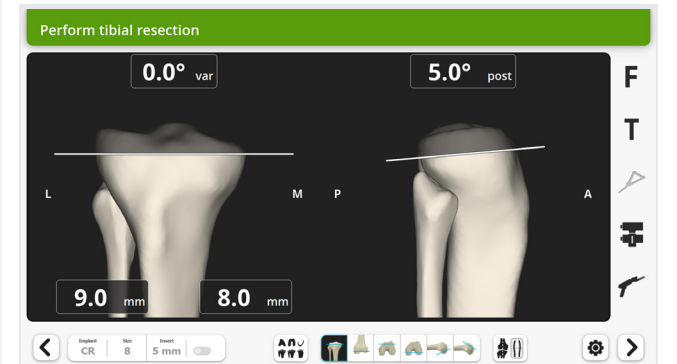
Tibial Resection

Remove the Saw Blade Cover on the Saw Blade.

Execute the resection.
- Activate the Saw by pressing the trigger

- Carefully advance and direct the Saw Blade to perform the resection without damaging the surrounding soft tissue
  - There is NO mechanical boundary control of the Saw Blade
  - The Robotic-Assisted Device positions the Saw into the cutting plane, but the surgeon is in full control of the Saw Blade movements

- Take care to apply force on the Saw Handpiece only into the resection plane
  - Application of force out of the resection plane will cause the Robotic-Assisted Device to immediately stop both the Robotic-Assisted Device adjustment and the Saw
  - Should this occur, to restart the resection, and before restarting the Saw, release pressure on the Saw Handpiece, validate the error pop-up on the Screen, and keep the blue foot pedal pressed to reposition the Robotic-Assisted Device back on to the precise resection plane

Once resection is complete, stop the Saw.

▲ Warning:
During a resection, as per a manual technique, the surgeon is in control of the movement of the Saw within the resection plane. This is similar to using a Saw Blade positioned in the slot of a cutting block.

The surgeon is also in control of starting and stopping the Saw.

The surgeon should make sure that the soft tissues are not damaged by the Saw Blade by 1) using retractors to protect the soft tissues when needed, 2) not penetrating the soft tissues with the Saw Blade, and 3) stopping the Saw when necessary.

▲ Caution:
Assess the flatness of the resected surface and run the Saw again if needed. To ensure flat resection surfaces:
- Wait for the motor of the Saw to reach full speed prior to engaging the bone
- Hold gently the Saw Handpiece to allow the Robotic-Assisted Device to adjust the resection plane
- While cutting, advance or retract the Saw Blade, avoiding mediolateral movements. This will ensure the sharp end of the Saw Blade is used to resect bone, not the sides of the Saw Blade

Replace the Saw Blade Cover on the Saw Blade.

Dock the Saw back in its rest position. The blue Planar Lock on the Planar Articulation will slide automatically and emit a "click" sound when the Saw is fully seated and locked in its rest position.

▲ Caution:
Be careful to not tear the drape while performing resection and when manipulating the Planar Articulation mechanism.

▲ Caution:
Ensure the Saw Blade is safely positioned away from the knee and Saw Blade Cover is replaced before initiating any Robotic-Assisted Device movement.

The Saw should never be left free to move and instead should always be held by the surgeon or docked on the Robotic-Assisted Device prior to moving to the next resection plane.

Saw is docked back on the Planar Articulation in its rest position

Tibial Resection

Resection Check (Optional)

> ⚠ **Caution:**
> Remove debris from the resected surface.

Place and hold the Pointer on the resected surface to compare the resected bone surface to the planned resection plane.

The screen will display in blue the distance between the Pointer tip and the planned resection.

> ⚠ **Caution:**
> Avoid potential cavities in cancellous bone.
> Check different locations to evaluate uniformity and identify potential areas with incomplete bone resection.

> ◼ **Note:**
> The Pointer can also be positioned on the bone surface prior to the resection, to check the position of the resection.

Use pointer on bone to check tibial resection
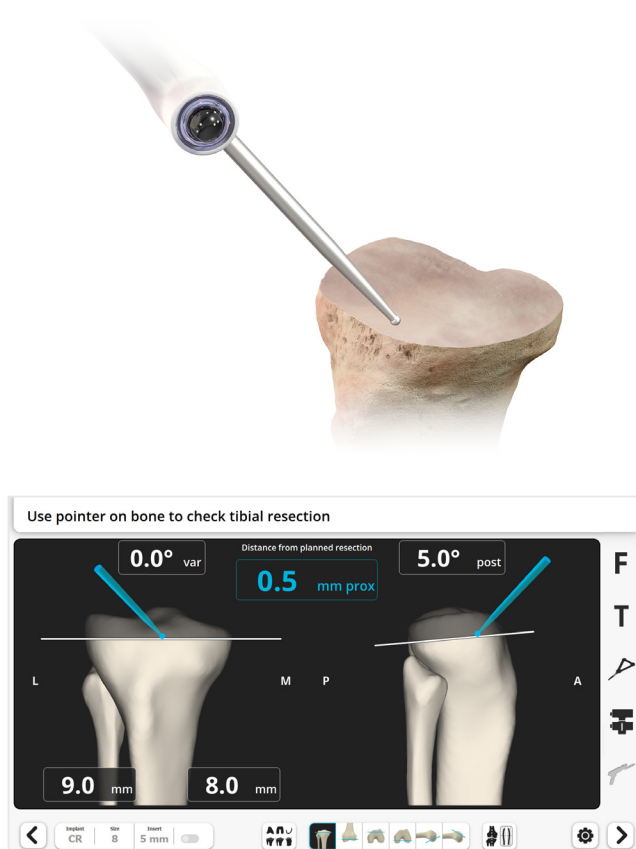
Next steps

Deviations can be corrected by running the Saw again following all steps described in Performing Resections. When finished, tap the blue foot pedal or tap the "Next" button ❯ .

> ⚠ **Caution:**
> The system will NOT update the Surgical Planning and the ACCUBALANCE™ Graph to compensate for any measured deviations in the actual versus planned resection plane.
>
> The planned plane remains the basis for further resections.

> ⚠ **Caution:**
> If the procedure cannot be completed with the Robotic-Assisted Device, see Appendix 5 for instructions to proceed with the manual instrumentation.

Check at a later stage

If the **Tibial Resection** needs to be checked again later, tap **Tibia** button 🔲 in the Resection Toolbar.

The screen now displays the Device Movement page. Do NOT tap the blue foot pedal.

Place and hold the Pointer on the resected tibial surface to check the resection.

Tap the blue foot pedal only if the tibial resection needs to be repeated, as this will position the Saw for this resection.

Otherwise tap on the button in the Resection Toolbar corresponding to the next desired step, or tap the "Next" button ❯ .

> ◼ **Note:**
> The other resections, once performed, can be similarly checked at a later stage.

Return Robotic-Device to Home Position

Once the tibial resection is complete, the Robotic-Assisted Device can be returned to its Initial Home Position and moved away from the operating field.

To move the Robotic-Assisted Device to Home Position, press and hold the blue foot pedal.

The Robotic-Assisted Device will stop when the Home Position is reached.

Release the blue foot pedal. The system will then automatically proceed to the next screen.

Unlock the Holding Arm Horizontal Adjustment to permit horizontal movements.

Move the Robotic-Assisted Device proximally along the bed.

Lock the Holding Arm Horizontal Adjustment.

Press and hold blue pedal to move device to home position
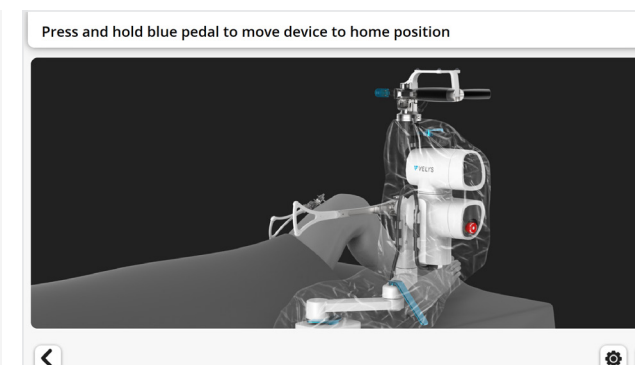
ACCUBALANCE™ Graph Update

The goal of this step is to record again the ACCUBALANCE™ Graph after the resection of the tibia and possibly further removal of osteophytes which may both impact the soft tissues tension.

The new ACCUBALANCE™ Graph created will permit to adjust, if needed, the femoral component position during the PROADJUST™ Surgical Planning update.

ACCUBALANCE™ Graph

Initially, the ACCUBALANCE™ Graph shows the calculated gaps between the femoral implant and the tibial resection (or tibial insert):
- As sized and positioned in the PROADJUST™ Surgical Planning (see PROADJUST™ Surgical Planning for more information)
- With the relationship between the tibia and femur defined during the last ACCUBALANCE™ Graph recording (see Initial Leg Alignment and ACCUBALANCE™ Graph Recording for more information)

Assess post-tibial resection leg alignment and balance

2.0° var   0.0° flex

11.5 mm   11.0 mm

11.0 mm   11.0 mm
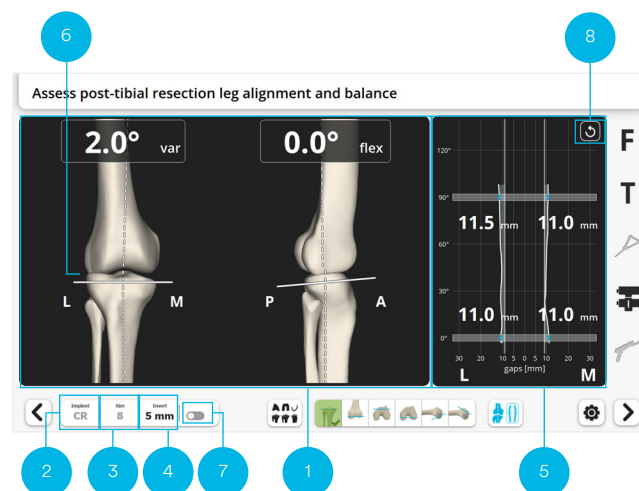
Ligament Tensor

Use the Ligament Tensor to tension the knee.
The Ligament Tensor allows for easy movement of the leg throughout the ROM, while constantly maintaining tension in the medial and lateral compartments.

> ▲ **Caution:**
> Prior to inserting the Ligament Tensor, it is imperative that the joint space is cleared of any loose tissue or debris and that the tibial cut is completed.
>
> Medial osteophytes that may tent the medial collateral ligament need to be resected.
>
> Posterior osteophytes will tent the posterior capsule. Gap measurement with the posterior osteophytes still in place will lead to a smaller gap measurement. This will result in too much distal femur and posterior femoral condyle resection, which may cause instability.

Ligament Tensor Assembly

The Ligament Tensor is available in sizes 2 and 4:
- Size 2 is used for a Size 5 ATTUNE™ Primary Knee System Tibial Base Plate or smaller
- Size 4 is used for a Size 6 ATTUNE™ Primary Knee System Tibial Base Plate or larger

Select the Ligament Tensor size that most closely matches the size of the planned tibial implant (If between sizes, use the smaller size to avoid soft tissue impingement).

Attach the chosen Ligament Tensor to the Handle Instrument. The Ligament Tensor can be attached to the Handle Instrument on either the right or the left side to accommodate variations in surgical exposure.

Use the right arm for a left knee

Use the left arm for a right knee
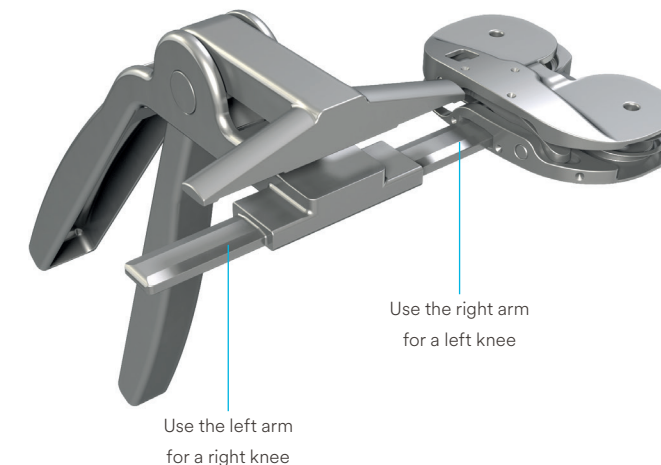
Ligament Tensor Insertion

Distract the knee in flexion with a bone hook to open the joint space to make enough room to insert the Ligament Tensor (the minimum height of the Ligament Tensor is approximately 6.5 mm when fully compressed with the handle).

Squeeze the Ligament Tensor Handle to compress the assembly and introduce the device into the joint space, ensuring the base plate is centered over and covers the tibial plateau.

Ensure the joint is distracted by the Ligament Tensor, then detach and remove the Ligament Tensor Handle.

Reduce the patella and bring the knee into full extension.

> ▲ **Caution:**
> The patella should be reduced as lateral patella eversion or subluxation may put too much tension on the lateral side, resulting in inaccurate lateral gap measurements.
>
> The reduced patella will also prevent the Ligament Tensor from shifting anteriorly during subsequent ROM steps.
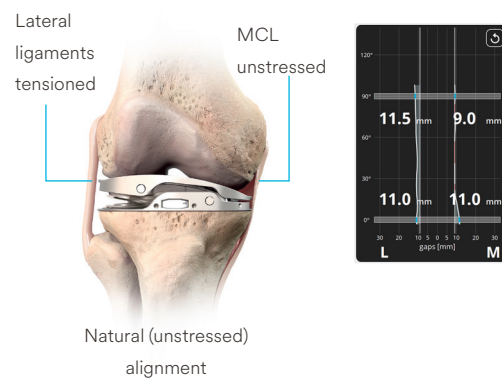
ACCUBALANCE™ Graph Update
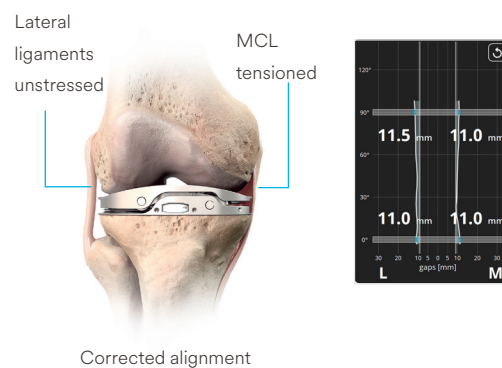
ACCUBALANCE™ Graph Update

Tap the "Reset" button ⟲ (8).
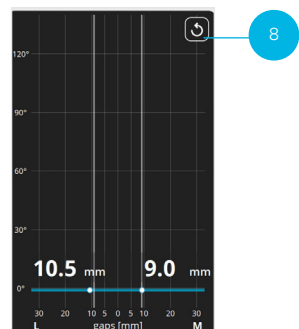
Take the leg through a first full ROM from extension-flexion-extension by applying a Varus force to stress the Lateral ligaments with the intended tension.

Lateral ligaments tensioned — MCL unstressed

Natural (unstressed) alignment

Take the leg through a second ROM by applying a Valgus force to stress the Medial Collateral Ligament with the intended tension.

Lateral ligaments unstressed — MCL tensioned

Corrected alignment

Recording the ACCUBALANCE™ Graph

⚠ Caution:
While performing the ROM movements:

Ensure that the tibia is held near 0 degrees of internal/external rotation in relation to the femoral axis.

Focus on the knee during this activity and not the screen to ensure the Ligament Tensor remains in the correct location and orientation throughout the ROM assessment.

PROADJUST™ Surgical Planning Update - Femur

The goal of this step is to update the position of the resections on the femoral component to balance the knee. The PROADJUST™ Surgical Planning for the femur should be thoroughly checked and adjusted as necessary to ensure correct resections, knee flexion, implant size, joint line, and gaps.

Adjustments on Femur

Initially, the ACCUBALANCE™ Graph shows the calculated gaps between the femoral implant and the tibial resection (or tibial insert) based on:
- The updated ACCUBALANCE™ Graph
- The last PROADJUST™ Surgical Planning

Adjust the femoral component position to modify the flexion and extension gaps to obtain the intended ligament tension. Use the following parameters:
- Femur coronal alignment (1)
- Distal femoral resection (2)
- Femoral rotation (3)
- Femoral flexion (4)
- A/P shift (5)
- Posterior resections (6)
- Femoral component size (7)

For more information, see "Gap Balancing" in PROADJUST™ Surgical Planning.
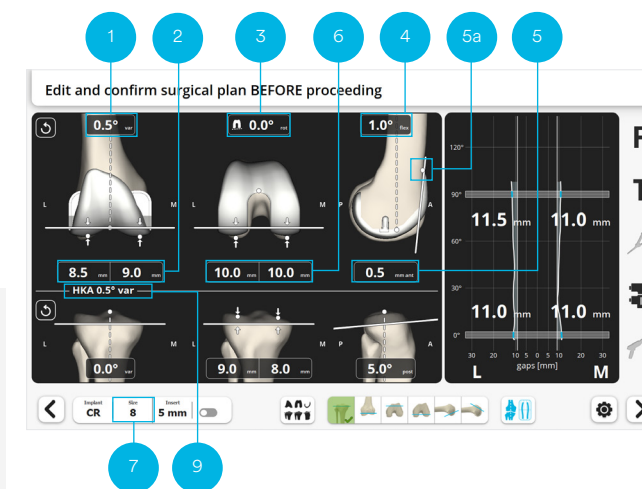
Femoral Resections

Femur Checkpoint Verification

The goal of this step is to verify that the Femur Array has not moved.

> **⚠ Caution:**
> Confirmation of the position of the Femur Array relative to the Femur Checkpoint is obtained in the same way as on the tibia and the same cautions apply.

Place the Pointer tip on the Femur Checkpoint.

Place pointer on checkpoint to verify that femur array has not moved
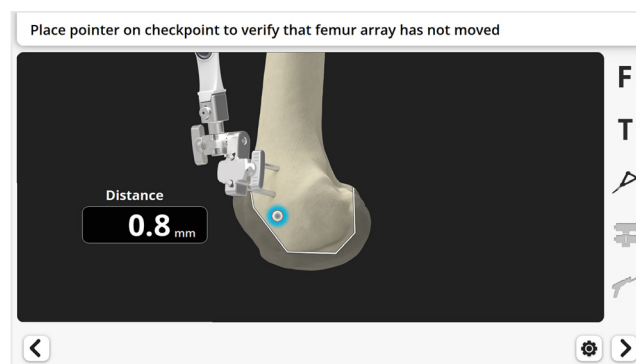
Distance
0.8 mm

The system will automatically proceed to the next step if the distance is acceptable.

If the deviation is unacceptable, the Robotic-Assisted procedure must be aborted, and the procedure must be completed using conventional manual instruments (see Appendix 5).

Checkpoint
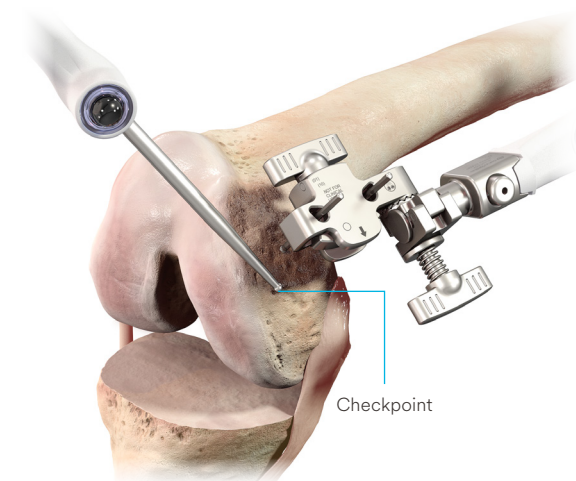
Distal Femur

For all femoral resections the steps are similar to the tibial resection.

> **⚠ Caution:**
> For the distal femur resection and all following resections, the same cautions as for the tibial resection apply.
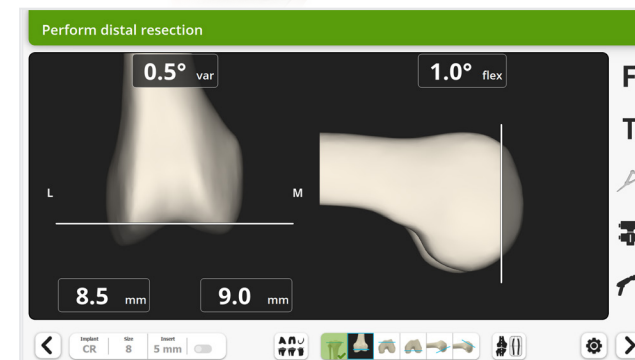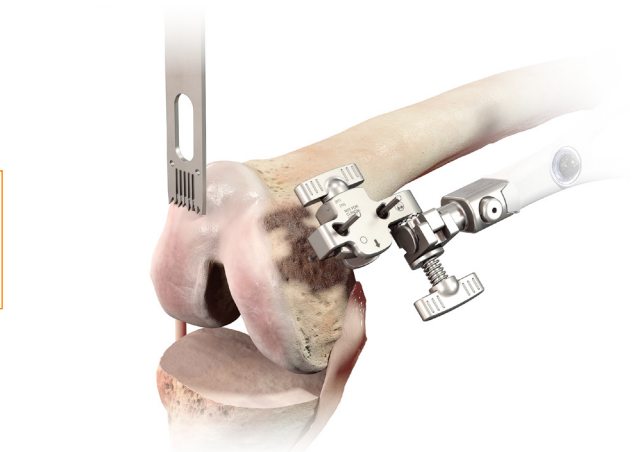
To move the Robotic-Assisted Device to the distal femur resection plane, press and hold the blue foot pedal.

Unlock the Planar Articulation, position the Saw, ensure visibility of the Femur Array and Saw Array, and perform the resection.

Dock the Saw back in its rest position.

Verify the resection with the Pointer (optional).

When finished, tap the blue foot pedal or tap the "Next" button ⟩.

Perform distal resection

0.5° var   1.0° flex

L   M

8.5 mm   9.0 mm

CR   8   5 mm

Anterior Femur

> **⚠ Caution:**
> Before performing the anterior femoral resection, check the Saw position is at the intended A/P level.
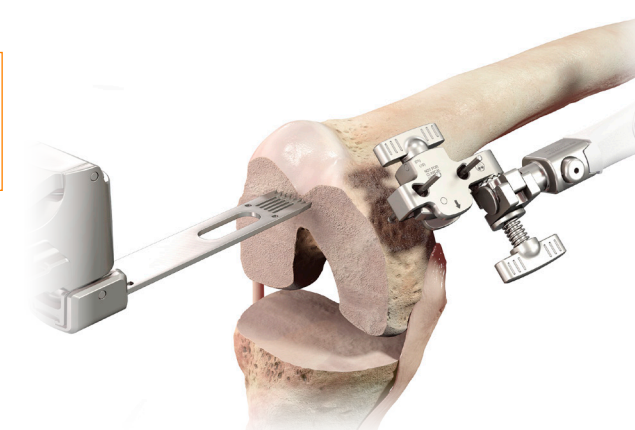
To move the Robotic-Assisted Device to the anterior femur resection plane, press and hold the blue foot pedal.

Unlock the Planar Articulation, position the Saw, ensure visibility of the Femur Array and Saw Array, and perform the resection.

Dock the Saw back in its rest position.

Verify the resection with the Pointer (optional).

When finished, tap the blue foot pedal or tap the "Next" button ⟩.

Perform anterior resection

0.0° rot   0.5 mm ant

L   M

10.0 mm   10.0 mm

CR   8   5 mm

Femoral Resections

Posterior Femur

To move the Robotic-Assisted Device to the posterior femur resection plane, press and hold the blue foot pedal.

Unlock the Planar Articulation, position the Saw, reconfirm appropriate retractor placement to assure protection of the soft tissues, ensure visibility of the Femur Array and Saw Array, and perform the resection.
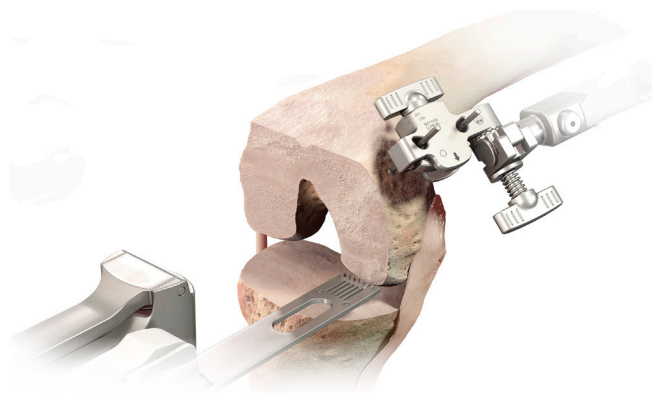
Dock the Saw back in its rest position.

Verify the resection with the Pointer (optional).

When finished, tap the blue foot pedal or tap the "Next" button ⊙ .

> ⚠ **Caution:**
> Visually confirm the resection. If needed, run the Saw Blade through the resection plane again.

Perform posterior resection

Posterior Chamfer

To move the Robotic-Assisted Device to the posterior chamfer resection plane, press and hold the blue foot pedal.

Unlock the Planar Articulation, position the Saw, reconfirm appropriate retractor placement to assure protection of the soft tissues, ensure visibility of the Femur Array and Saw Array, and perform the resection.

Dock the Saw back in its rest position.

Verify the resection with the Pointer (optional).

When finished, tap the blue foot pedal or tap the "Next" button ⊙ .

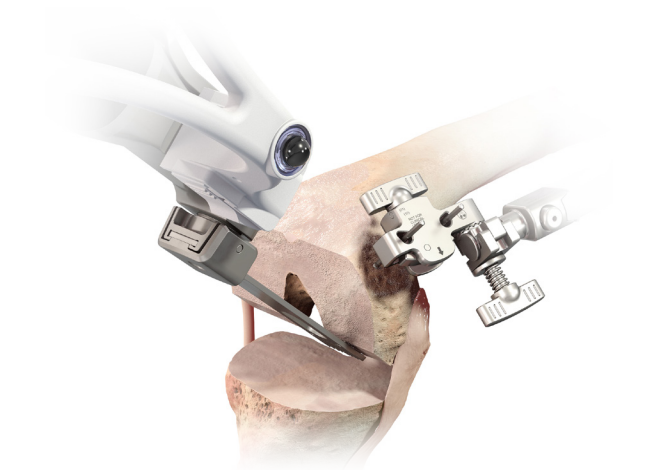
Perform posterior chamfer resection

Anterior Chamfer

To move the Robotic-Assisted Device to the anterior chamfer resection plane, press and hold the blue foot pedal.

Unlock the Planar Articulation, position the Saw, ensure visibility of the Femur Array and Saw Array, and perform the resection.

Dock the Saw back in its rest position.

Verify the resection with the Pointer (optional).

When finished, tap the blue foot pedal or tap the "Next" button ⊙ .

When implanting an ATTUNE™ Primary Knee System CR component, use the Femoral Finishing Guide to perform the sulcus cut per the manual surgical technique. The Robotic-Assisted Device will not perform this resection.

Perform anterior chamfer resection
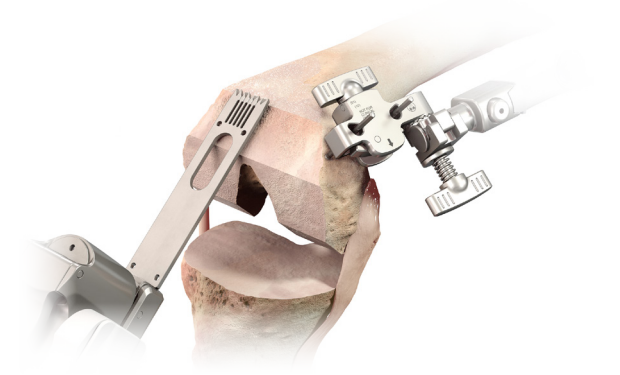
Femoral Resections

Completion of Resections

Return Robotic-Device to Home Position
Once all resections are complete, the Robotic-Assisted Device can be returned to its Initial Home Position and moved away from the operating field.

To move the Robotic-Assisted Device to Home Position, press and hold the blue foot pedal.

The Robotic-Assisted Device will stop when the Home Position is reached.

Release the blue foot pedal. The system will then automatically proceed to the next screen.
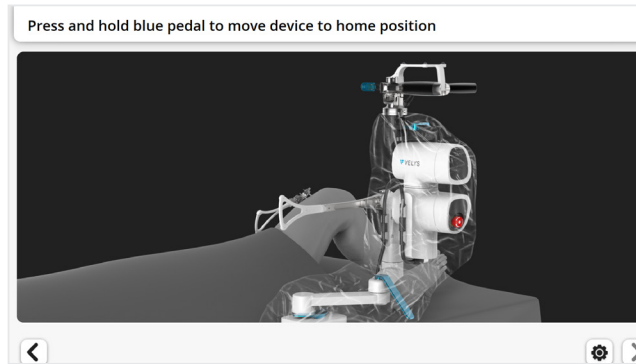
Unlock the Holding Arm Horizontal Adjustment to permit horizontal movements.

Move the Robotic-Assisted Device proximally along the bed.

Lock the Holding Arm Horizontal Adjustment.

Finishing
Complete the femur, tibia, and patella preparation and place the implant trials.

Press and hold blue pedal to move device to home position

Leg Alignment and ACCUBALANCE™ Graph Recording with Trial Implants

Ensure the femur component type (1) and size (2) and insert thickness (3) used are selected on the screen. If different trial tibial inserts are used, change the selection on the screen.

Assess final leg alignment and balance
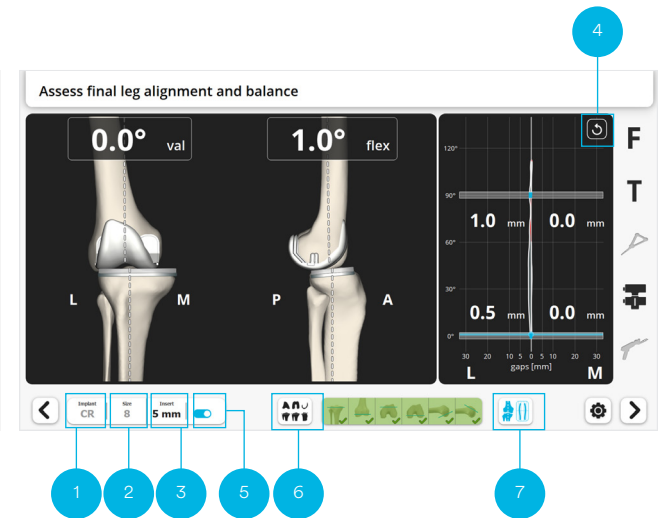
Bring the leg into full extension and full flexion. Assess the final knee range of motion. The software will automatically record the maximum extension and flexion for documentation in the case report.
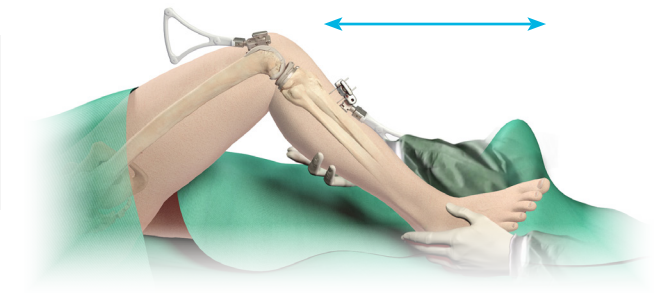
Record the new ACCUBALANCE™ Graph

Tap the "Reset" button (4) to clear the ACCUBALANCE™ Graph.

Starting in full extension place a Varus force on the knee and smoothly flex the knee into full flexion, tensioning the lateral ligament complex.

Repeat this step with Valgus force.

Assess laxity on the Graph and adjust insert thickness (3) if needed.

Assess final leg alignment and balance
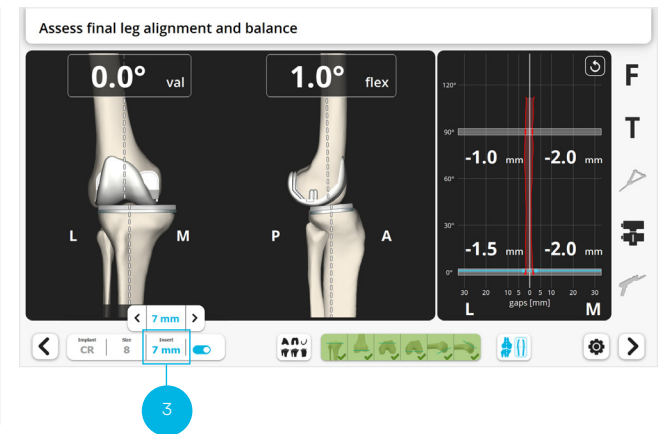
The ACCUBALANCE™ Graph displays the gap measured between the planned positions for the femoral implant and the planned surface of the tibial insert.

Negative numbers (red line) describe a measured gap between the planed femoral implant and tibial resection smaller than the tibial construct (tibial plateau + insert thickness selected). The tissues could be under excessive tension to accommodate for that insert thickness.

> ■ **Note:**
> Bone under-resection may increase the measured gap between the femur and tibia, reflected by a positive gap on the graph. Conversely, bone over-resection may lead to a display of a negative gap.
>
> The gap between the femoral implant and the tibial resection can be measured by shifting the Switch (5).

Next Step Options
A. Finish the Robotic-Assisted procedure.

Hold the leg in extension with no Varus/Valgus stress.

To record the final coronal leg alignment for documentation in the case report, and to proceed, tap the blue foot pedal or tap the "Next" button ⊙.

or

B. Make adjustments if necessary.
If final alignment or balance are not satisfactory, adjustments can be made to either:
- Implant position. See Recuts (If Necessary)
- Soft tissue tension *via* soft tissue releases

Both maneuvers will change alignment and balance, therefore, after execution of the adjustments a final ACCUBALANCE™ Graph should be recorded again as described above.

or

C. Perform an optional final leg balance after insertion of the implants. See Leg Alignment and ACCUBALANCE™ Graph Recording with Final Implants (Optional).

Recuts (If Necessary)
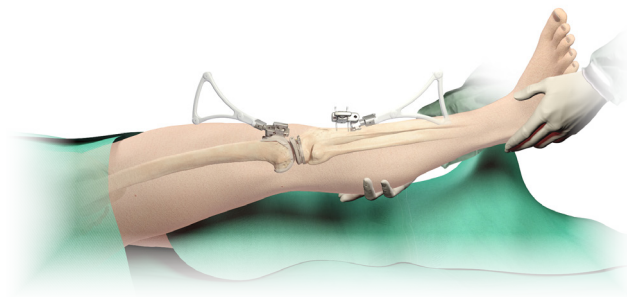
Recut Planning

On the ACCUBALANCE™ Graph Recording screen tap the "Planning" button ⊞ (6).

On the PROADJUST™ Surgical Planning screen, the implant position can be adjusted as required.

Edit and confirm surgical plan BEFORE proceeding
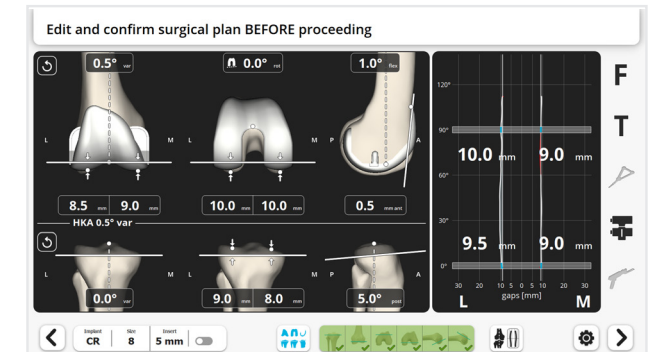
The screen displays:
- The last plan and implant size defined by the surgeon
- The last ACCUBALANCE™ Graph recorded during trialing

> ⚠ **Caution:**
> When tapping the "Reset" button ⟲, the values of all parameters are set back to the Surgical Planning settings used for the resections already performed, not to the Initial Surgical Planning settings.

The knee tension may have changed after the first resections were made, e.g. due to removal of osteophytes during the resections, so the graph may no longer represent the gaps with the intended tension.

> ⚠ **Caution:**
> When planning a recut, the graph must be up to date. If no ACCUBALANCE™ Graph has been recorded with Trial Implants, record a new graph prior to updating the surgical planning.

For this, tap the "Alignment and Graph" button ⧩ (7). Select the preferred method of ligament tensioning, including the use of trial implants if possible.
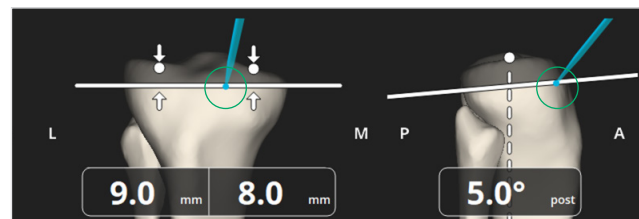
Recuts (If Necessary)

> ⚠️ **Caution:**
> When planning a recut, make sure the new resection will be a complete and single plane cut, i.e. not a "facetted", "multiplanar" or incomplete recut.

When planning a recut on the tibia, the pivot point for the tibial resection plane is moved anteriorly when increasing the tibial slope and posteriorly when reducing the slope.

To ensure a non-facetted cut, run the tip of the Pointer over initial cut surface, especially on the most anterior aspect. Check simultaneously on the screen that the tip of the Pointer is above (proximal to) the new cut plane, i.e. the new cut plane is entirely through new bone.

The same principle applies to recuts on the femur, e.g. when increasing the distal resection in the case of residual flexion contracture.

Facetted Recut

Initial Planning:
Pivot on Tibia Center

Recut:
Increasing Slope

Recut:
Decreasing Slope

9.0 mm 8.0 mm   5.0° post

Prior to adjustments.
Tip of pointer in contact with the bone, at level of initial resection.

10.5 mm 9.0 mm   post 8.0° post ant
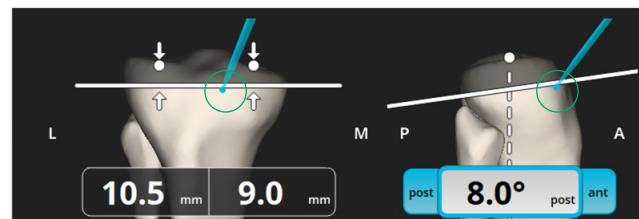
Tip of pointer in contact with the bone but below new resection.
Anterior portion will not be recut. « Facetted » or incomplete recut.

dist 11.5 mm 10.5 mm prox   8.0° post
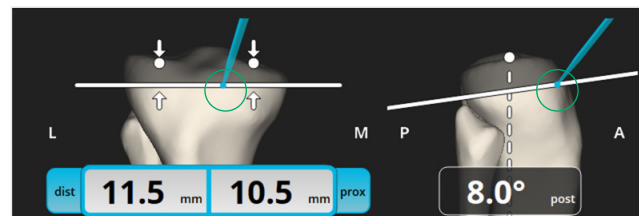
Tip of pointer in contact with the bone and above new resection.
Complete recut.

Recuts Execution

When the changes to the Surgical Planning are complete, tap either:
- The distal femur resection button 🦴 if changes were made to the femoral component
- Or the tibia resection button 🦴 if changes were made only to the tibial component
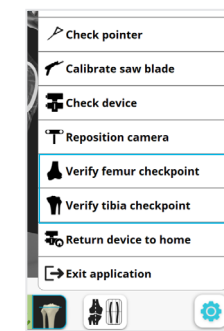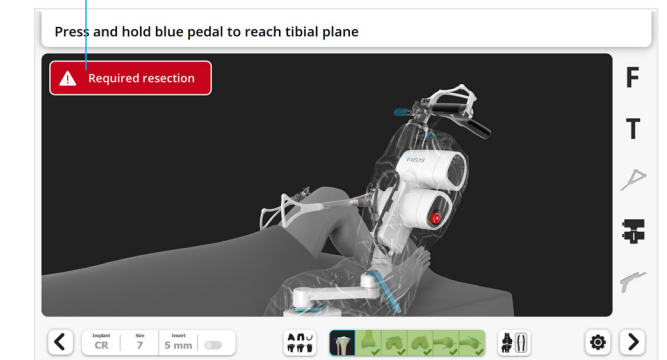
> ⚠️ **Caution:**
> Check on the Resection Toolbar which resections require a recut.

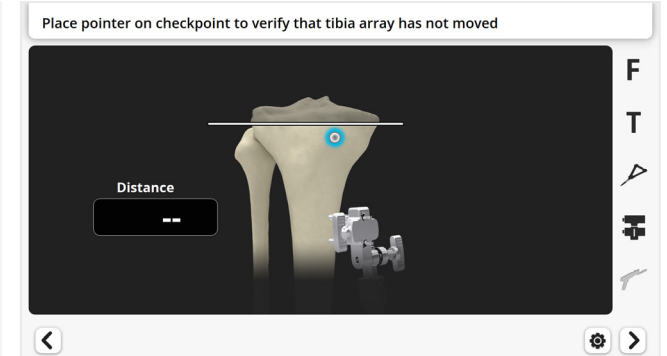|		
🦴	White	Resection must be redone
🦴	Black	Current resection
🦴	Green	Resection doesn't need to be redone

On the Device Movement screen, an information prompt indicates when a recut is required for this resection.

In the toolbox, select Verify Checkpoint for this bone (tibia or femur, see Appendix 1).

Recut required

Press and hold blue pedal to reach tibial plane

⚠️ Required resection

F T

Check pointer
Calibrate saw blade
Check device
Reposition camera
Verify femur checkpoint
Verify tibia checkpoint
Return device to home
Exit application

Verify the Bone Checkpoint.

Place pointer on checkpoint to verify that tibia array has not moved

F T

Distance
--

Position the knee ready for resection as described in Robotic-Assisted Device Positioning:
- Position the flexed knee in a stable position
- Position the center of the Device Array Interface at 25 mm (1 inch) below the femoral epicondyles

Array Interface

25 mm - 1"

90 - 110°
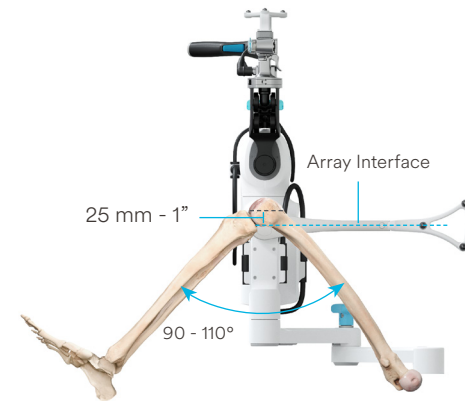
▲ Caution:
Ensure the Holding Arm Horizontal Adjustment is locked after positioning of the Robotic-Assisted Device during and between resections.

To position the Robotic-Assisted Device to the new resection plane, press and hold the blue foot pedal.

Moving to tibial plane   Keep blue pedal pressed

F
T

▲ Caution:
For the recuts, the same cautions as for the first resection apply.

For making and verifying the recut, follow the steps previously described for the distal femoral resection.

Repeat for each resection step that requires a recut.

If the two bones are recut, verify the Checkpoint on the other bone prior to its first recut.
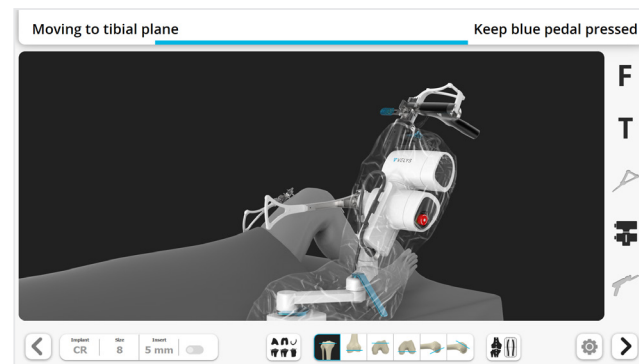
Perform a Balance Assessment with Trial Implants as described in Leg Alignment and ACCUBALANCE™ Graph Recording with Trial Implants.

Alternatively to the use of the Resection Toolbar, the "Next" and "Back" buttons can be used. All Device Movement screens for the femur and tibia will be displayed and the Checkpoint verification screens will automatically be displayed.

■ Note:
At device movement screens where no recut is required, tap the "Next" button ❯ on the screen to proceed to the next Device Movement screen. Do not tap the blue foot pedal as this will position the Device for this resection.

Leg Alignment and ACCUBALANCE™ Graph Recording with Final Implants (Optional)

Measurement of final limb alignment after insertion of the definitive implants is optional. Retraction during insertion, cement mantle and impaction may all modify the final component position and knee balance so the surgeon may decide to record again the ACCUBALANCE™ Graph acquired during ACCUBALANCE™ Graph Recording with Trial Implants. The final measurements will be documented in the case report.

▲ Caution:
The surgeon must first verify the position of the Checkpoints to confirm the Bone Arrays have not moved during insertion of the implants.

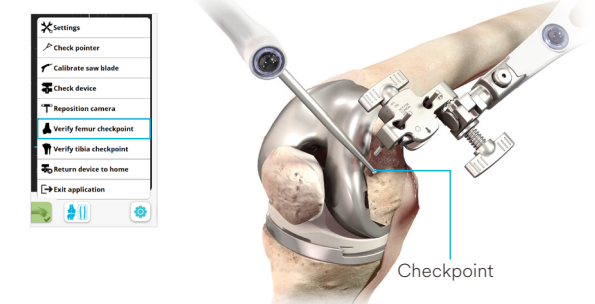In the toolbox, select Verify Tibia Checkpoint (see Appendix 1).

Verify the Tibia Checkpoint.
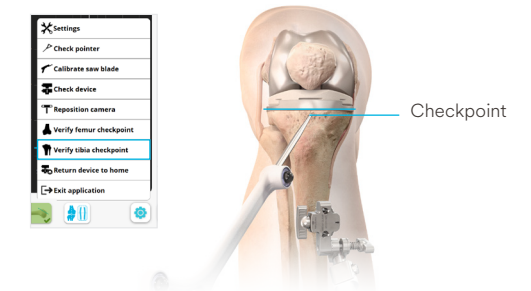
Checkpoint

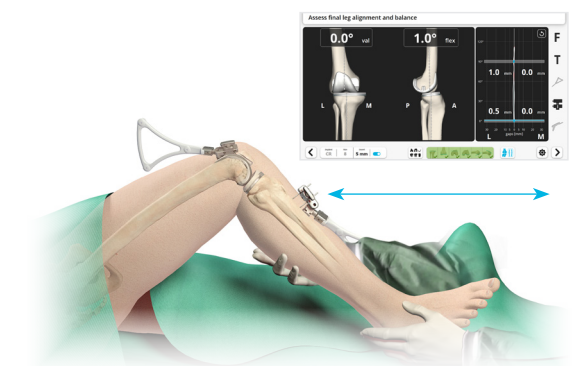In the toolbox, select Verify Femur Checkpoint.

Verify the Femur Checkpoint.

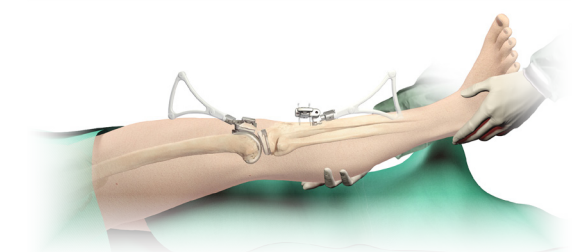To clear the Graph, tap the "Reset" button ⟳ .

Checkpoint

Assess the final stability, alignment, and range of motion.

The Graph will now reflect the latest information.

To record the final coronal alignment and finish the Robotic-Assisted procedure hold the leg in extension with no Varus/Valgus stress and tap the blue foot pedal or the "Next" button ❯ .

End of the Procedure
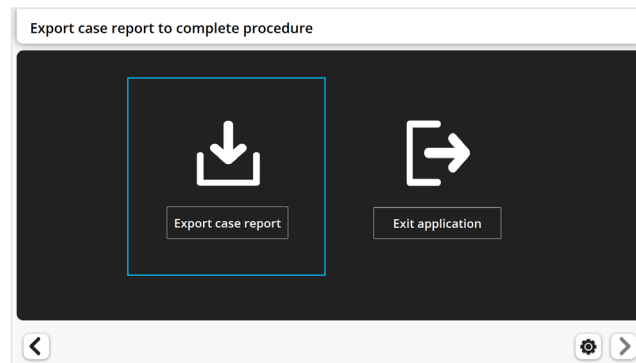
Removal of Instruments

Prior to closure of the knee:
- Detach the Femur and Tibia Arrays, detach the Array Clamps
- Unscrew the Array Drill Pins
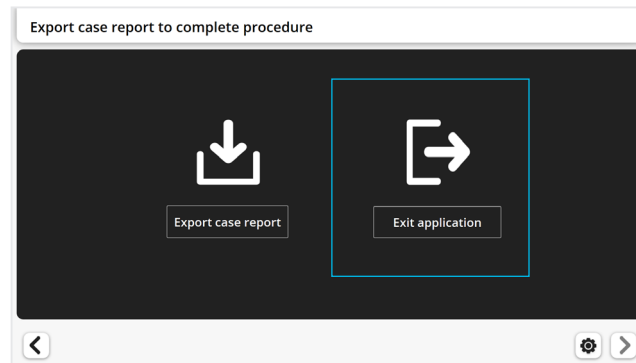
Then proceed with the closure of the knee.

Export of Case Report (Optional)

A case report can be exported on a USB drive inserted at the front of the Main Station. Tap "Export Case Report".

Exit the Application

To exit the application, tap the blue foot pedal or the "Exit" button ⏏ on the Touchscreen.

> ■ **Note:**
> The case reports are also stored on the system and can alternatively be exported later from the Surgeon Account (see Appendix 2).

Appendix 1: Toolbox

During the procedure, the "Toolbox" button ⚙ provides a shortcut to different tools used at a predefined step during the standard workflow. For detailed instructions on how to use each tool, refer to the description of the standard workflow in this surgical technique or to the VELYS™ Robotic-Assisted Solution for Total Knee User Guide.
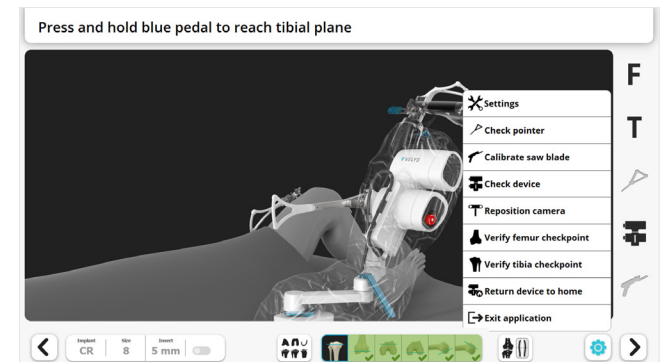
Device Settings
Use the slider to adjust Volume and Brightness to the desired level.

Check Pointer Calibration
Verify that the tip of the Pointer is well positioned relative to the array of the Pointer.

Calibrate Saw Blade
Calibrate the Saw Blade again if needed, e.g., if the Saw Blade must be changed during the procedure.

Check Robotic-Assisted Device Calibration
The Robotic-Assisted Device will move the Saw Handpiece according to a predefined trajectory to verify that the movement is correct.

Reposition Camera
Position the Camera in case the Bone Arrays are not visible in a specific patient leg position.

Verify Tibia or Femur Checkpoints
Verify the position of the Femur or Tibia Checkpoints, to confirm that the Femur Array or the Tibia Array have not moved.

Home Robotic-Assisted Device
Return the Robotic-Assisted Device to its Home Position in case the Robotic-Assisted procedure is stopped before this step is reached in the standard workflow. This enables the transfer of the Robotic-Assisted Device back to the Satellite Cart after the surgical procedure is complete.

Exit Application
Exit the application in case the Robotic-Assisted procedure is stopped before the closing step is reached with the standard workflow.

Appendix 2: Surgeon Account

The surgeon must have an account to use the system. The Surgeon Account function allows for account creation and deletion, password changes, and other personal data updates. The Surgeon Account will also permit the export of the case reports stored on the system.
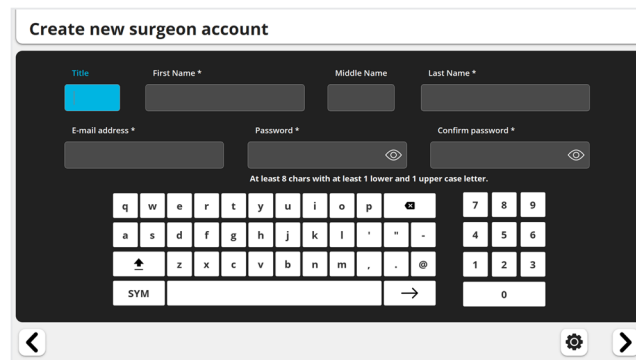
Surgeon Account Creation

On the Home Screen tap the User Icon 👤 and then "Surgeon".
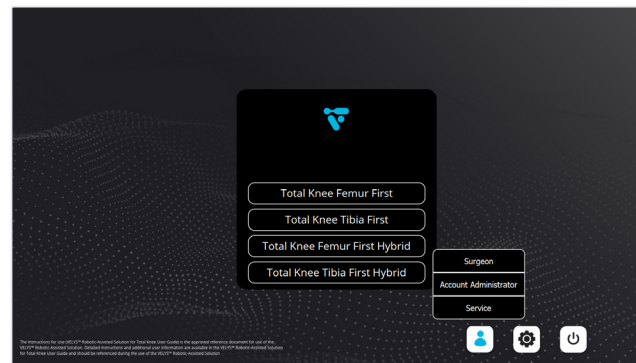
Tap "Create Surgeon Account" at bottom of the screen.
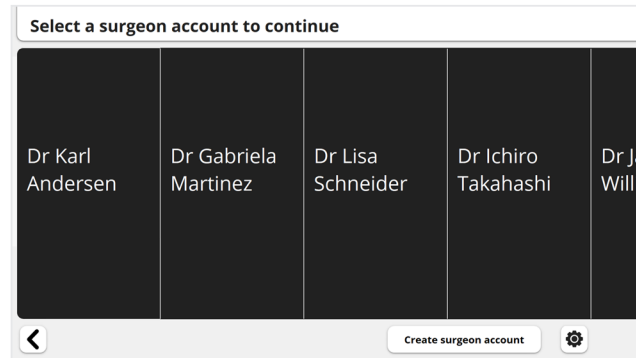
Enter the surgeon information.

When finished, tap the "Next " button ❯ or tap the blue foot pedal to save the information and access the Surgeon Account screen.
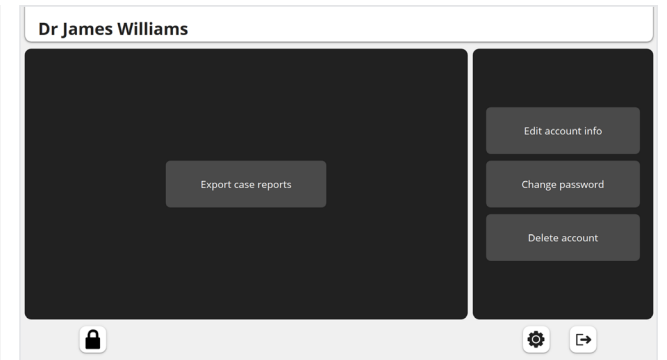
Tap 🠖 to exit and return to the Home Screen.

Account Login

On the Home Screen tap the User Icon 👤 and then "Surgeon".

Select the surgeon and enter the password.

To reset the password, contact the hospital Account Administrator of the system.

Appendix 2: Surgeon Account
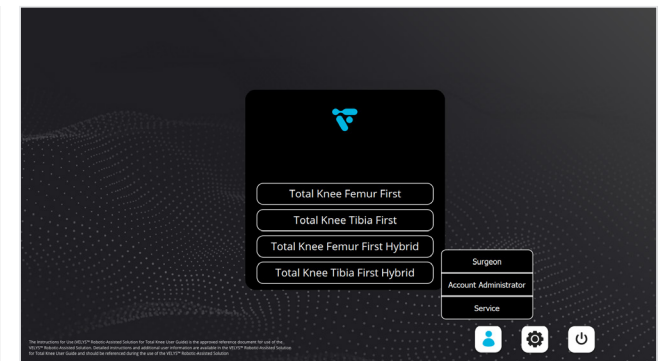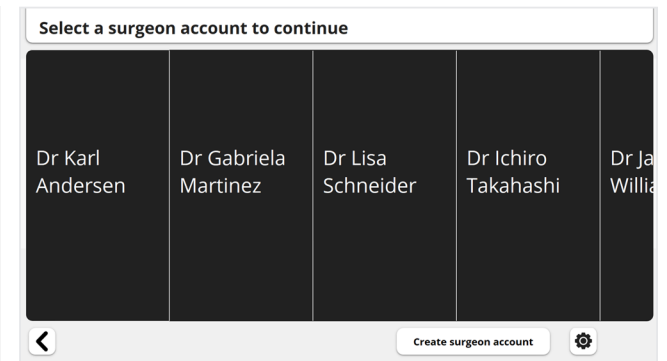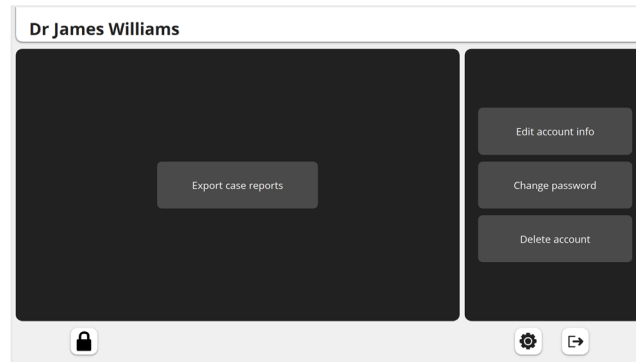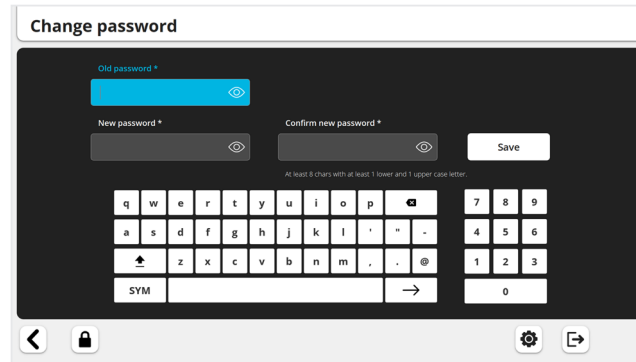
Change Password

On the Surgeon Account screen, select "Change Password".

Dr James Williams

Export case reports

Edit account info

Change password

Delete account

Enter the old password and then the new password.

Change password

Old password *

New password *

Confirm new password *

Save

At least 8 chars with at least 1 lower and 1 upper case letter.

q w e r t y u i o p ⌫ 7 8 9

a s d f g h j k l ' " 4 5 6

⇧ z x c v b n m . , @ 1 2 3

SYM → 0

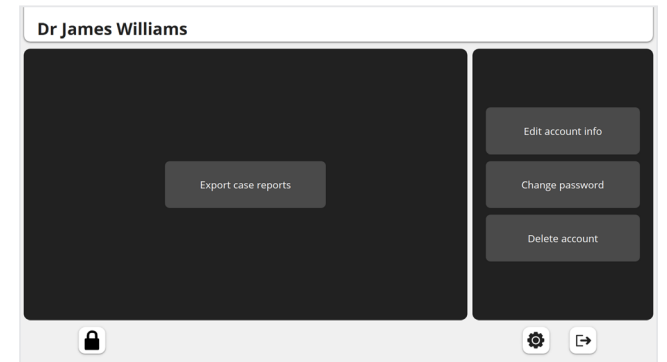Tap "Save" and ⏏ to exit the Surgeon Account.

Personal Data Update, Account Deletion and Other Functions
Editing of account information and account deletion are performed in a similar fashion as password change. Refer to the System User Guide for a more detailed description of these functionalities and of other functionalities accessible from the Home Screen such as administrator and maintenance accounts and settings.

Case Report Export

Case reports are stored and can be exported individually or in batches. Each file is a table of data (CSV format) and permits detailed analysis and statistics.

On the surgeon account screen, select "Export Individual Case Reports".

Dr James Williams

Export case reports

Edit account info

Change password

Delete account

Select the report(s) to be exported.

Insert a USB drive into the USB port at the front of the Base Station.

Tap "Export Case Reports".

Select case reports to export

Select all	Hospital ID	Last Name	Date	Application	Case ID
☑	423643748	Johnson	14 JAN 2021	Total Knee Tibia First	0000000003
☐	125374889	Johnson	14 JAN 2021	Total Knee Femur First	0000000002
☐	4263748	Johnson	13 JAN 2021	Total Knee Tibia First	0000000001

Export Case Reports

Other functions available:

🗑 Delete selected cases

‹ Back to Previous screen

Tap ⏏ to exit the Surgeon Account.

> ■ **Note:**
> Exporting a case will not delete it from the system.

Appendix 3: Creation of Surgical Profiles

The system recognizes that each Surgeon has his or her own individual approach to TKA. Surgical profiles are important for setting the default planning options for each individual surgeon. The Surgical Profiles relate to the initial values and primary axes each surgeon desires for the initial implant positioning.

A surgeon can create and store several Surgical Profiles for different clinical scenarios, e.g., CR, PS, neutral knee, Varus knee, Valgus knee, large fixed flexion deformity. Once the procedure has begun, these settings can be modified during Surgical Planning (except the primary femoral rotation reference).

At the screen "Select a surgical profile", tap "Create new profile".
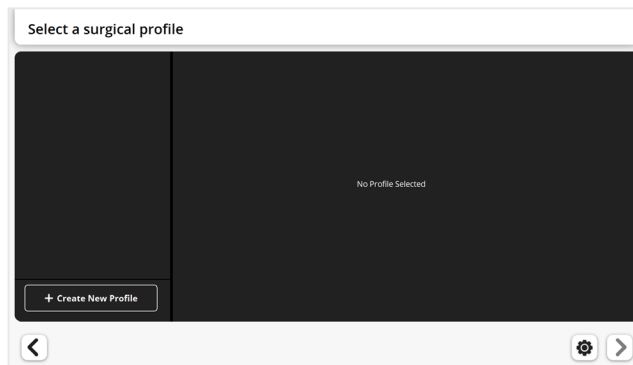
Choose and enter a name for the Surgical Profile. Adding notes to describe and help differentiate each Surgical Profile is optional.
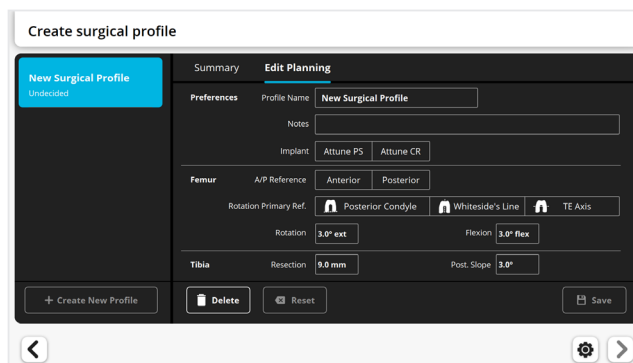
Select the type of implant: CR or PS to populate the surgical profile with manufacturer default settings used for initial ATTUNE™ Primary Knee Implant position.

Select the femur A/P reference: Anterior or Posterior

Select the femur rotation primary reference.

Edit all other settings as desired by selecting each value.

Set the desired posterior slope for the Tibia.
The recommended manufacturer tibial posterior slope for ATTUNE™ Primary or Revision Knee Systems is:
- For Posterior Stabilized (PS) configurations: 3 degrees
- For Cruciate Retaining (CR) configurations:
  - Fixed Bearing:
    - When the PCL is retained, a range of 5-7 degrees, attempting to match the patient's slope. In PCL retaining TKA, not adding adequate slope may limit the postoperative flexion
    - When the PCL is sacrificed: 3 degrees
  - Rotating Platform: Irrespective of whether the PCL has been retained or sacrificed, 5-7 degrees, attempting to match the patient's slope

Tap "Save", and the surgical profile will now appear in the Surgical Profile list.
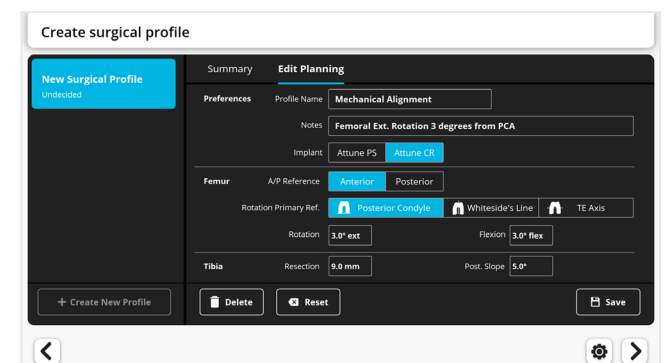
	Setting	Reference	Default
Femur	Rotation	Post. condylar axis	3° ext.
		Whiteside's Line	0°
		Transepicondylar axis	0°
	Flexion	Femur mech. axis	3°
Tibia	Resection	Highest plateau	9 mm
	Post. Slope	Tibia mech. axis	PS: 3° CR: 5°

Appendix 4: Staff Positioning and Retractors

To accommodate the Robotic-Assisted technique, some modifications of staff positioning and retractor placement may be necessary.
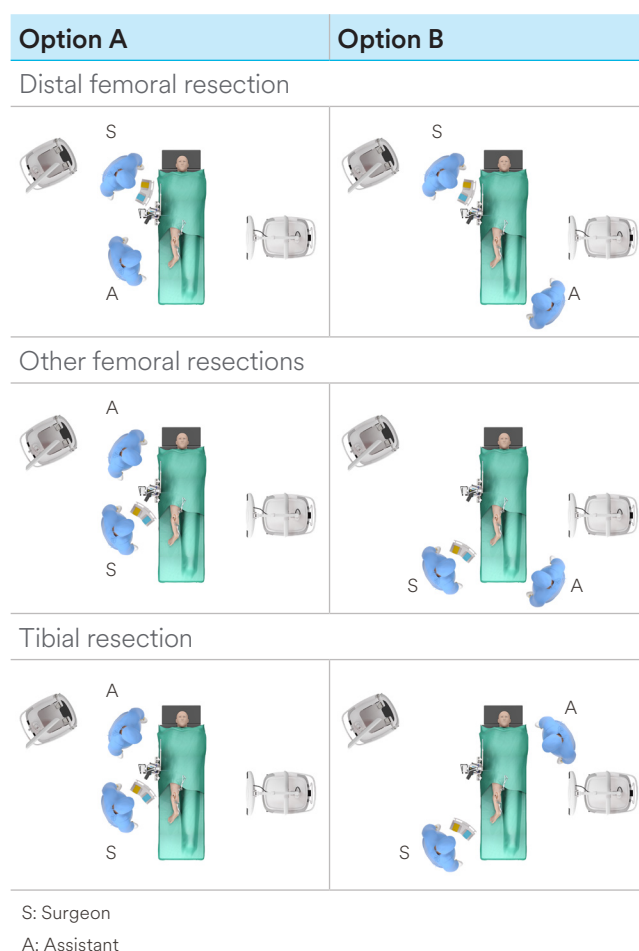
Staff positioning
This section presents options for surgeon and assistant positioning to maintain the required line of sight for the Bone Arrays and the Saw. This positioning should be adapted to the organization of the surgical team and to the patient requirements.

Two sets of options are shown:
**Option A:** Surgeon and assistant on the side of the operative knee.
Option B: Surgeon on the side of the operative knee and assistant on the opposite side of the operative knee.

Option A	Option B
Distal femoral resection	
Other femoral resections	
Tibial resection	

S: Surgeon
A: Assistant

Retractors
The Robotic-Assisted Device defines a cutting plane but does not limit Saw movement within this plane. Therefore, the surgeon must control the Saw Blade excursion at all times, and retractors must be used during the resection to protect the soft tissues from damage by the Saw Blade. The retractors should be placed so they protect the soft-tissues at risk from the oscillating Saw, along the line of the cutting plane.

Place the retractors and the assistant so they do not interfere with the line of sight between the Saw and Bone Arrays and the Camera.
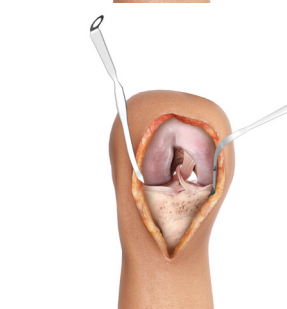

Central Axis of Retractor
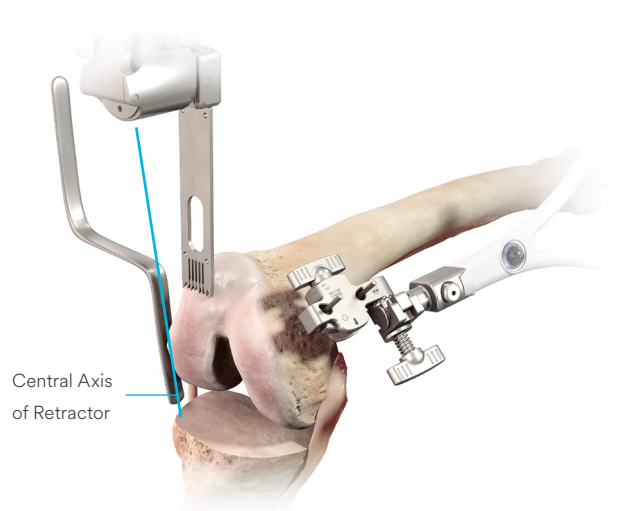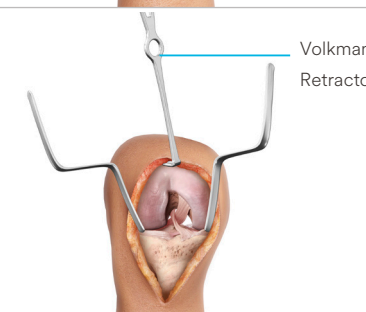
Distal femur and chamfers

Adapt the position of the retractors for each resection.

Example 1: Use a "Z" Retractor on each side.

Example 2: Use a bent Hohmann Retractor medially and a Hohmann Retractor laterally.

Anterior femur: Protect the anterior tissues using a Volkmann or Kocher Retractor.
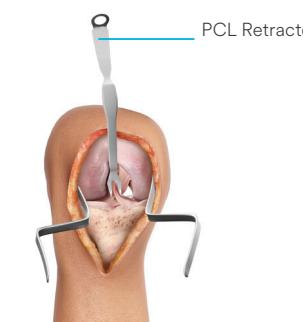
Posterior femur: Protect the popliteal tendon.

Tibia: Protect the medial and lateral collateral ligaments and the posterior tissues.

Bringing the tibia forward will provide additional safety on the posterior soft tissues.

L   M

Volkmann Retractor

PCL Retractor

Appendix 5: Completing the Case using a Conventional Manual Procedure

If the case cannot be completed with the Robotic-Assisted Device, the procedure can be completed with the manual instrumentation.
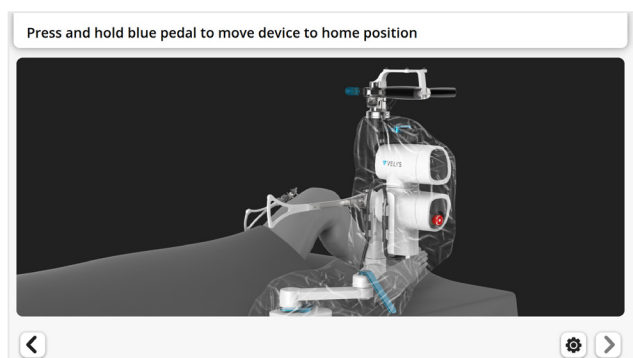
Return Robotic-Assisted Device to Home Position
Return the Robotic-Assisted Device to its Initial Home Position to enable the transfer of the Robotic-Assisted Device back to the Satellite Cart after the surgical procedure.

In the Toolbox, tap "Return Device to Home".
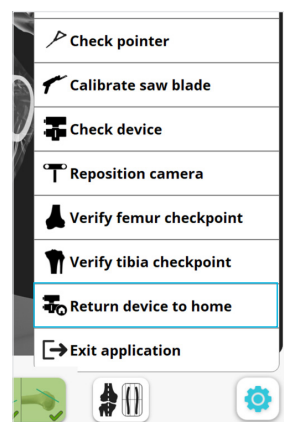
Press and hold the blue foot pedal.

When finished, tap the blue foot pedal or tap the "Next" button ➤ .

**Repositioning of the Robotic-Assisted Device**
The Robotic-Assisted Device can be moved away from the joint to provide more working space.
- Unlock the Holding Arm Horizontal Adjustment to permit horizontal movements.
- Move the Robotic-Assisted Device proximally along the bed.
- Lock the Holding Arm Horizontal Adjustment.

Exit Application

In the Toolbox, tap "Exit application".
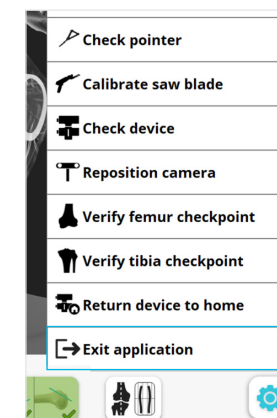
Removal of Instruments
- Detach the Femur and Tibia Arrays, detach the Array Clamps.
- Remove the Array Drill Pins.

Refer to the System User Guide for the system tear-down and system troubleshooting instructions.

Complete the Case using Manual Instruments
The case can be completed with either the INTUITION™ Instruments, or the INTUITION™ Essential Instruments. Perform the remaining resections as described in the ATTUNE™ Primary Knee System INTUITION™ Instruments Surgical Technique.

Ask a DePuy Synthes representative for more information, or visit VELYSDigitalSurgery.com

Please refer to the instructions for use for a complete list of indications, contraindications, warnings and precautions.

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