



VELYS™ Robotic-Assisted Solution for Total Knee Surgical Technique

Femur First Approach

Version 1.3

1.0	Introduction	3	Overview and Objectives	9.0	Initial Leg Alignment and ACCUBALANCE™ Graph Recording	38	Screen Display
		3	Surgical Technique Workflow			39	Assessment of Initial Alignment and Joint Stability
		4	Key Surgical Steps Summary			39	Recording of the ACCUBALANCE™ Graph
		5	System Overview			41	Coronal Leg Alignment Recording
		7	Interactions with the Display Screen				
		9	Interaction with the Robotic-Assisted Device	10.0	PROADJUST™ Surgical Planning	42	Initial Surgical Planning
		9	Interaction with the Footswitch			45	Extension and Flexion Gaps Balancing
2.0	OR Pre-Op Setup	10	OR Pre-Op Setup Summary			46	Pointer Verification
		11	OR Pre-Op Setup				
3.0	Surgical Profile Selection	12	Surgical Profile Overview	11.0	Femur Checkpoint Verification	47	Femur Checkpoint Verification
		13	Edit Surgical Profile				
4.0	Surgical Exposure and Creation of Bone Checkpoints	14	Surgical Exposure and Creation of Bone Checkpoints	12.0	Robotic-Assisted Device Positioning	48	Positioning
5.0	Bone Arrays Setup	15	Instruments Description				
		16	Location and Orientation of Array Drill Pins	13.0	Distal Femur Resection	50	Device Movement
		17	Array Drill Pins and Array Clamp Placement Workflow			51	Performing Resections
		19	Bone Array Fixation to Tibia and Femur			53	Plane Verification
6.0	Camera Adjustment	20	Camera Adjustment	14.0	Next Resections	54	Anterior Femur
7.0	Bone Checkpoints Registration	22	Bone Checkpoints Registration			55	Posterior Femur
8.0	Registration	23	Acquisition Methods			55	Posterior Chamfer
		25	Mechanical Axes Definition			56	Anterior Chamfer
		25	Femoral Head Center			56	Tibia Checkpoint Verification
		26	Tibial Mechanical Axis - Distal			57	Tibial Resection
		27	Tibial Knee Center			57	Completion of Resections
		27	Tibial Plateau	15.0	ACCUBALANCE™ Graph Recording with Trial Implants	58	ACCUBALANCE™ Graph Recording with Trial Implants
		29	Tibial Sagittal Axis				
		30	Femoral Knee Center	16.0	Recuts (If Necessary)	60	Recut Planning
		30	Femoral Component Rotation Reference			61	Recuts Execution
		31	Whiteside's Line (Anteroposterior Axis)	17.0	ACCUBALANCE™ Graph Recording with Final Implants (optional)	62	ACCUBALANCE™ Graph Recording with Final Implants (optional)
		31	Transepicondylar Axis				
		32	Distal Femoral Condyles	18.0	End of the Procedure	63	Removal of Instruments
		33	Posterior Femoral Condyles			63	Export of Case Report (optional)
		34	Anterior Cortex	19.0	Appendices	65	Appendix 1: Toolbox
		35	Confirmation of Acquired Landmarks			66	Appendix 2: Surgeon Account
		37	Repeat Landmark Registration			68	Appendix 3: Creation of Surgical Profiles
						69	Appendix 4: Staff Positioning and Retractors
						71	Appendix 5: Completing the Case using a Conventional Manual Procedure

1.0 Introduction

Overview and Objectives

The following VELYS™ Robotic-Assisted Solution for Total Knee Surgical Technique – Femur First Approach provides a guideline for the implantation of the ATTUNE® Primary Knee System using the VELYS™ Robotic-Assisted Solution from DePuy Synthes, and either the INTUITION™ Instruments, or the INTUITION™ Essential Instruments, or the INTUITION SOLO™ Single Use Instruments.

The surgical procedure follows a “Femur First” workflow.

This surgical technique must be used in conjunction with: **Either** the ATTUNE® Primary Knee System INTUITION™ Instruments Surgical Technique, **or** the ATTUNE® Knee System INTUITION SOLO™ Single Use Instruments Surgical Technique, **and** the VELYS™ Robotic-Assisted Solution for Total Knee User Guide which describes in detail the functionalities of the system.

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

Surgical Technique Workflow

The VELYS™ Robotic-Assisted Solution Application for Total Knee follows a predefined surgical workflow that includes the following steps:

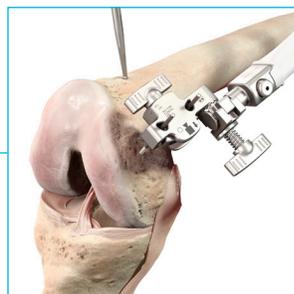
- Registration of bony landmarks
- Initial leg alignment and balance assessment
- Surgical Planning
- Robotic resections – femur (distal, anterior, posterior and chamfers)
- Robotic resection – tibia
- Final leg alignment and balance assessment with trial implants

All Surgical Planning values displayed are calculated using the bony landmarks acquired by the surgeon during Registration. The Surgical Planning can be modified at any time.

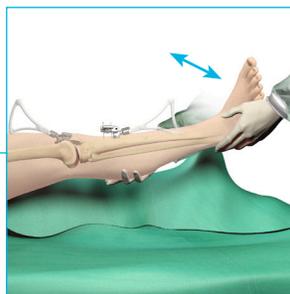
Key Surgical Steps Summary



Incision, Exposure and Removal of Osteophytes



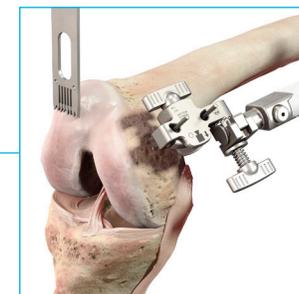
Bony Landmarks Acquisitions



Initial Leg Alignment and Balance Assessment



Surgical Planning



Distal Femoral Robotic Resection



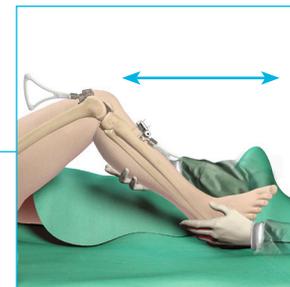
Anterior, Posterior, and Chamfer Femoral Robotic Resections



Tibial Robotic Resection



Trial Reduction*



Leg Alignment and Balance Assessment with Trial Implants



Tibial Preparation*



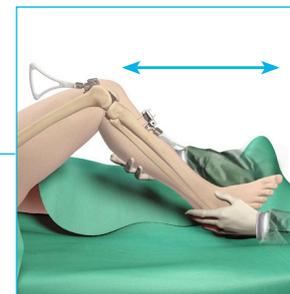
Femoral Lug Hole Preparation*



Patella Resection and Final Patella Preparation*



Final Component Implantation*



Leg Alignment and Balance Assessment with Final Implants (optional)

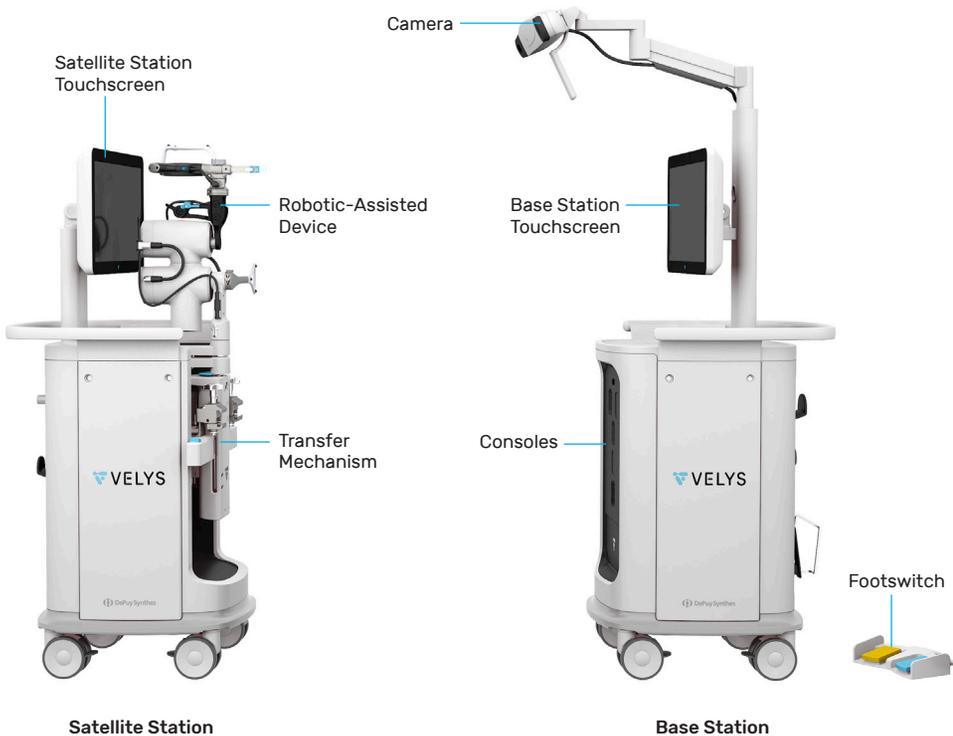
* This step can be performed using either the INTUITION™ Instruments, or the INTUITION™ Essential Instruments, or the INTUITION SOLO™ Single Use Instruments

System Overview

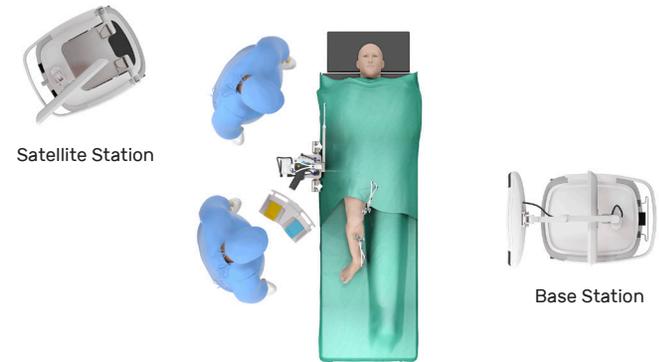
The VELYS™ Robotic-Assisted Solution's Operating Platform includes two stations:

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

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

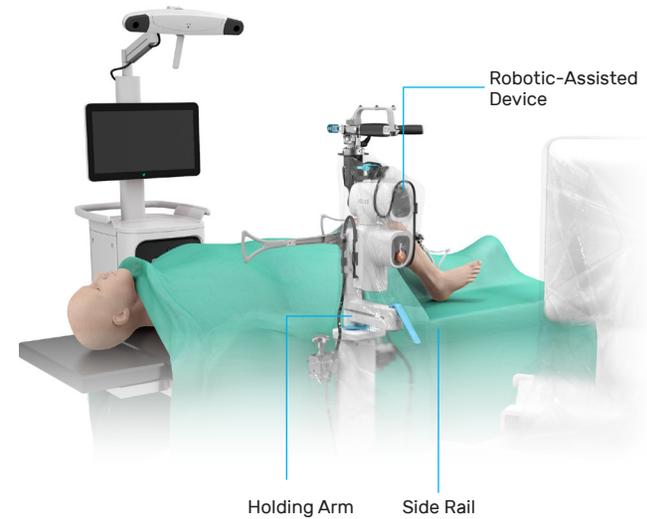


- Key:**
-  Warning Box
 -  Caution Box
 -  Information Box



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.

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.



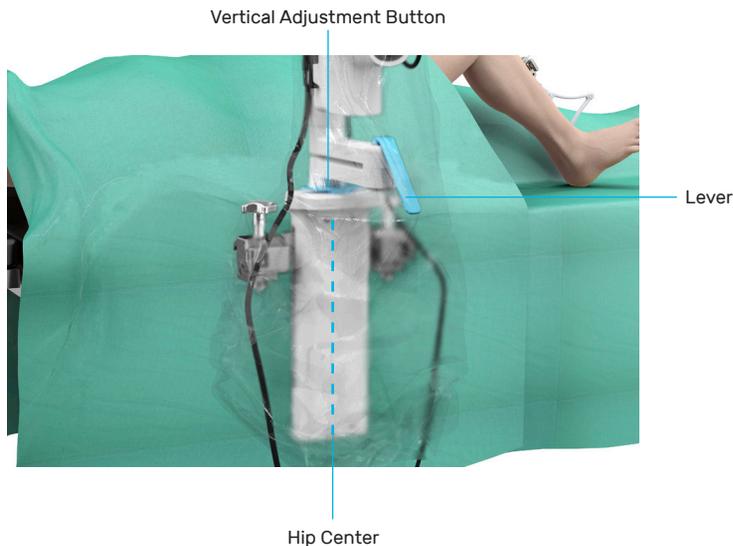
 The Robotic-Assisted Device may be transferred to the OR table before or after surgical exposure or after PROADJUST™ Surgical Planning, depending on surgeon preference (see Section 12, "Robotic-Assisted Device Positioning").

System Overview

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

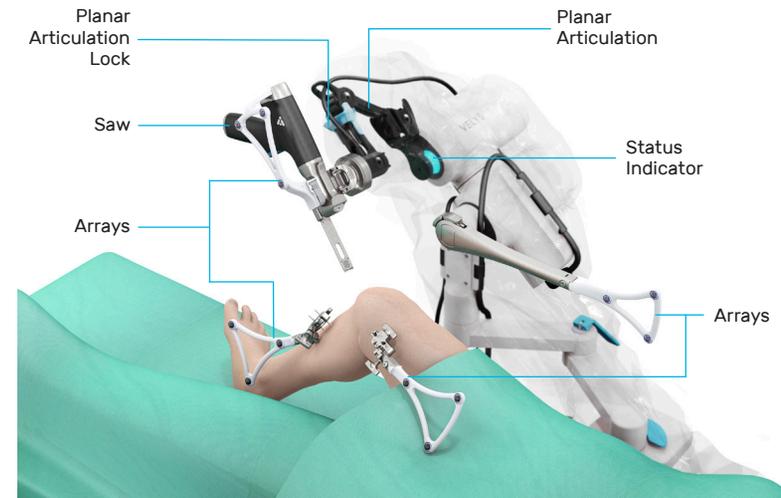
i The user should not rotate the screen of the Satellite Station once the satellite station is draped. This could change the position of the slit in the drape at the back of the Satellite Station, which may inhibit access to the crank at the back. Adjusting the orientation of the screen slightly is acceptable.

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 Lever (position up). See Section 12, "Robotic-Assisted Device Positioning" for the recommended position for execution of the resections.



The Saw is attached to the Planar Articulation of the Robotic-Assisted Device. The Planar Articulation enables the free movement of the Saw within the resection plane set by the Robotic-Assisted Device.

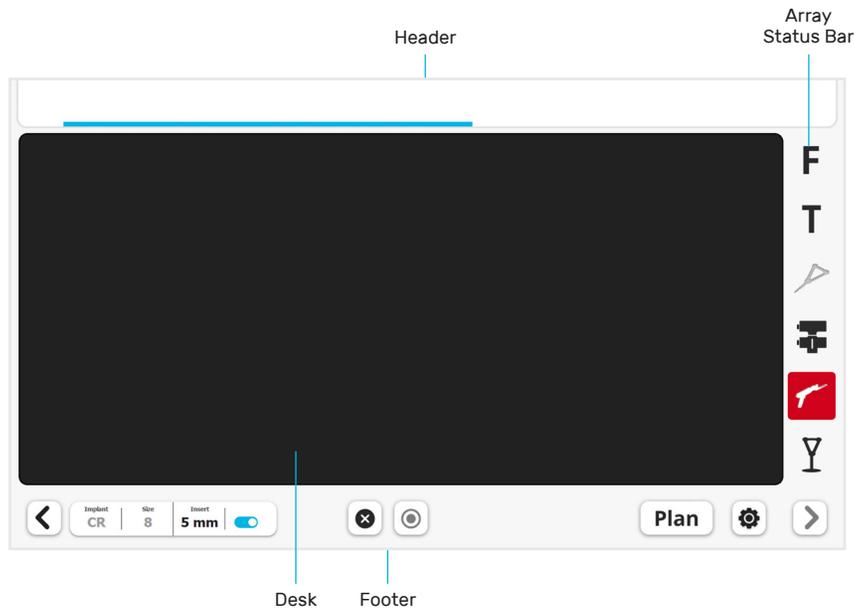
When not in use, the Saw is maintained and locked on the folded Planar Articulation. When ready to use, the Saw is unlocked by sliding the blue Planar Articulation Lock on the Planar Articulation.



The Camera, on the Base Station, tracks the position and orientation of bones (tibia and femur), instruments (Pointer, Plane Tool), Robotic-Assisted Device, and Saw *via* the PURESIGHT™ hydrophobic optical reflectors attached to the Arrays. The system requires a clear line of sight between the Camera and the PURESIGHT™ reflectors.

i To minimize interference with the Camera, keep bright light sources or highly reflective objects out of the Camera's field of view.

Interactions with the Display Screen



Each screen will display the following content:

Desk

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

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 six arrays. Each icon corresponds to its respective array as shown:

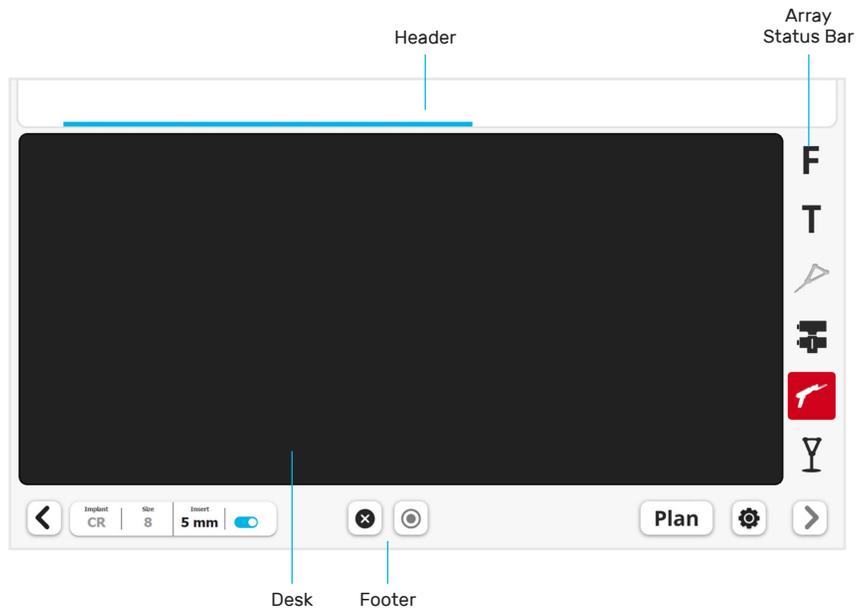
-  Femur
-  Tibia
-  Pointer
-  Robotic-Assisted Device
-  Saw
-  Plane Tool

 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

Interactions with the Display Screen



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 |
|  | Start | Execute the registration |
|  | Stop | Cancel the registration |
|  | Toolbox | Access the Toolbox |
|  | Plan | Access the PROADJUST™ Surgical Planning screen |

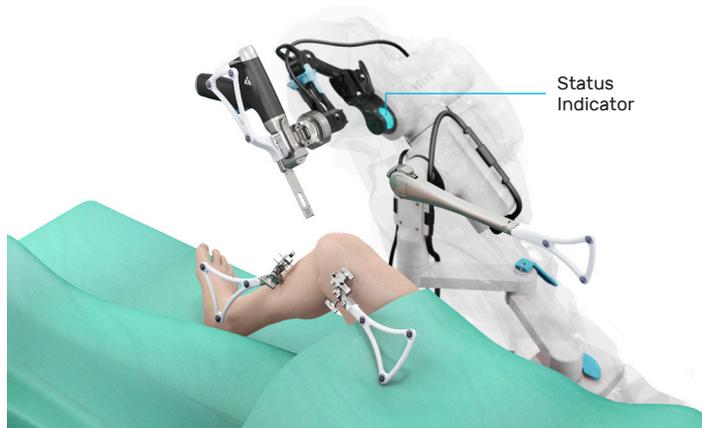
There are two status options for the buttons:

- | | | |
|---|-------|---|
|  | Black | Button is active |
|  | Grey | Button is inactive or more action is required |

Interaction with the Robotic-Assisted Device

Robotic-Assisted Device Status Indicator

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



The Status Indicator can display different options:

Color	State	Description	Example of Situation
Blue	Fixed	Robotic-Assisted Device is on, passive	During registration 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

Interaction with the Footswitch

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

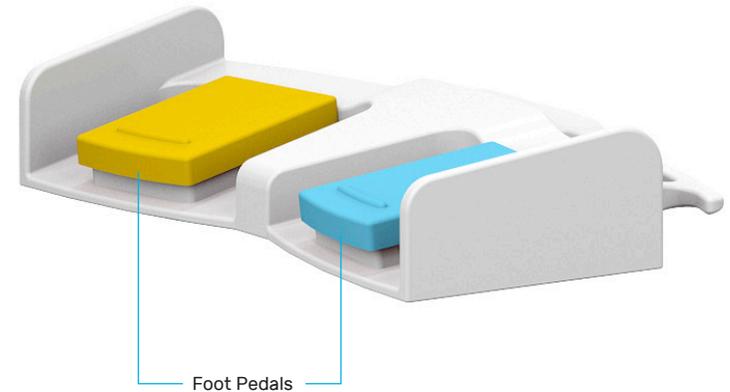
Blue foot pedal: Execute the requested action, acknowledge the information on the current screen, or advance to next screen.

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



Throughout this surgical technique:

- "Tap foot pedal" means a short tap
- "Hold foot pedal" means press and hold until the action is complete



2.0 OR Pre-Op Setup

OR Pre-Op Setup Summary

This section summarizes the pre-operative 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.



OR Pre-Op Setup



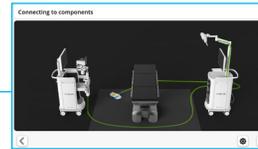
Stations Positioning and Connection of Stations



Start



Workflow Selection :
Total Knee Femur First



Connections Check



Patient Information



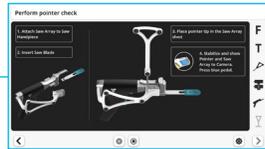
Robotic-Assisted Device Initialization



Saw Array Assembly



Saw Blade Attachment



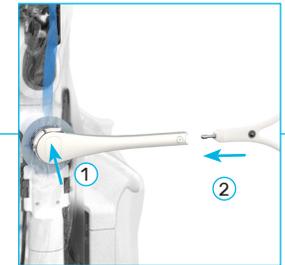
Pointer Check



Saw Blade Calibration



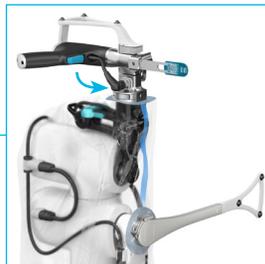
Robotic-Assisted Device and Satellite Station Draping



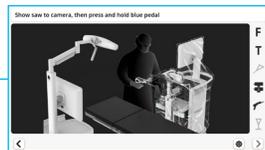
Attachment of Robotic-Assisted Device Array Interface and Robotic-Assisted Device Array



Attachment of Saw Interface



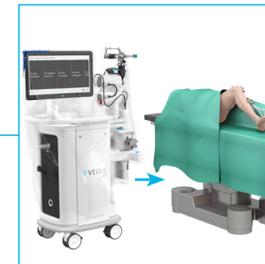
Attachment of Saw



Robotic-Assisted Device Check



Patient Positioning
Patient Draping



Robotic-Assisted Device Transfer to Table
Robotic-Assisted Device Attachment to Table



Base Station Positioning

Key:
Actions performed by sterile scrub team
 Actions performed by non-sterile team

3.0 Surgical Profile Selection

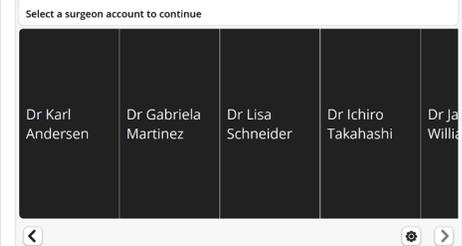
Surgical Profile Overview

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

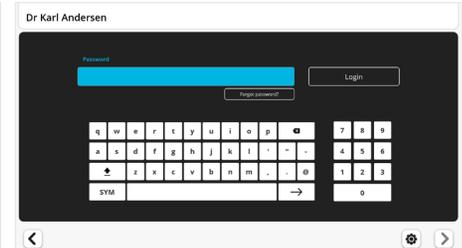
i Each surgeon must have a Surgeon Account. See Appendix 2 for creating a Surgeon Account.

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.

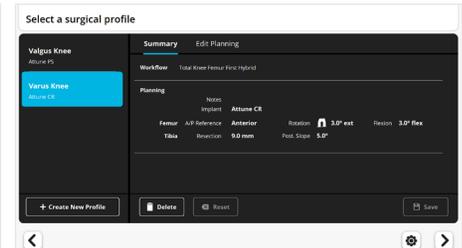
Select the surgeon's name from the list.



Enter the surgeon's password.



Select a Surgical Profile for the procedure.



! 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.

Edit Surgical Profile

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

or Tap “Edit Planning” to make changes.

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.

Select a surgical profile

Valgus Knee
Attune CR

Varus Knee
Attune CR

Summary **Edit Planning**

Preferences Profile Name:

Notes:

Implant:

Femur A/P Reference:

Rotation Primary Ref.:

Rotation: Flexion:

Tibia Resection: Post. Slope:

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.

4.0 Surgical Exposure and Creation of Bone Checkpoints

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.

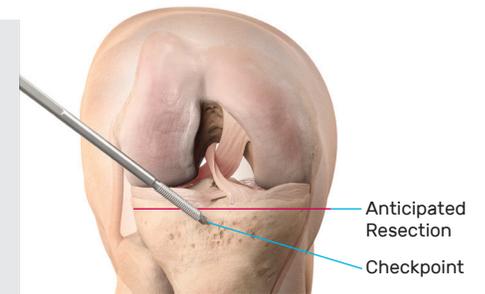
! Position each Checkpoint at a site where the bone will not be resected, e.g., below the anticipated tibial resection plane.

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.



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



! The Checkpoints must be easily identifiable later during the procedure. Marking the Checkpoints with a surgical pen will facilitate finding their location.

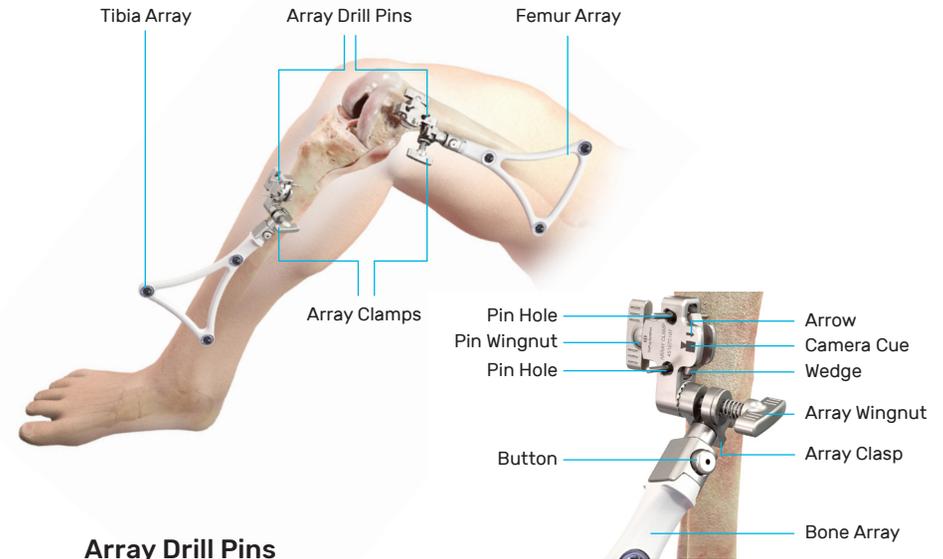
5.0 Bone Arrays Setup

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.

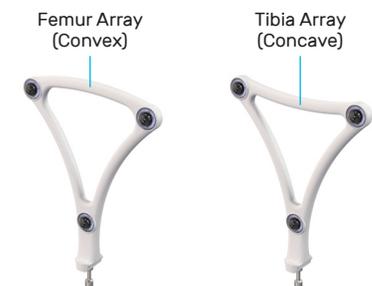
Array Clamps

The Array Clamp slides over the Array Drill Pins and is secured by tightening the Pin Wingnut. A Camera cue etched on the clamp (top and bottom) indicates the direction the clamp should be facing, with the cue pointing toward the Camera (medially). When tightened, the Array Wingnut locks the orientation of the Bone Array to the Array Clamp.

i 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.

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.



Location and Orientation of Array Drill Pins

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.

! The length and positioning of the Array Drill Pins should avoid:

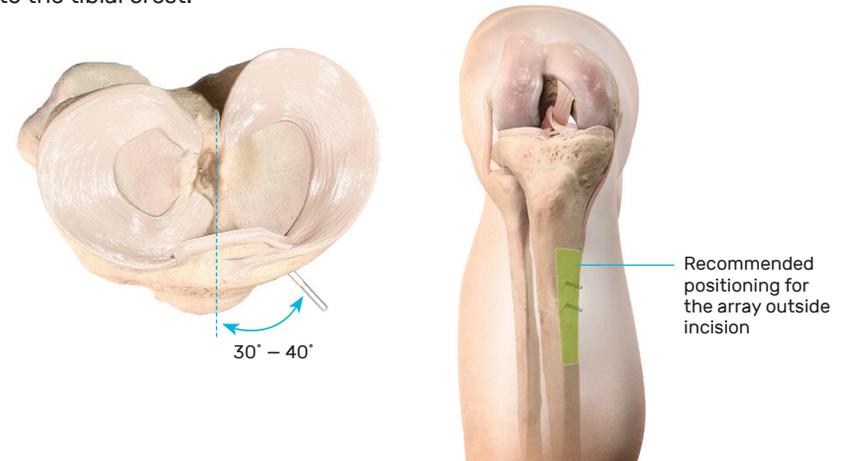
- Conflict with the surgical instruments including Saw Handpiece and retractors
- Bone resections: Posterior condyles, box for PS implant, or tibial keel
- Stresses from adjacent soft tissues during knee flexion and extension

Typical Use:

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

Tibia

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



- i** 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 registration

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

Drill the Array Drill Pins 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.



Location and Orientation of Array Drill Pins

! Ensure the Array Drill Pins are rigidly attached to the bone. Avoid fixation into sclerotic bone.

Femur (inside incision technique – recommended)

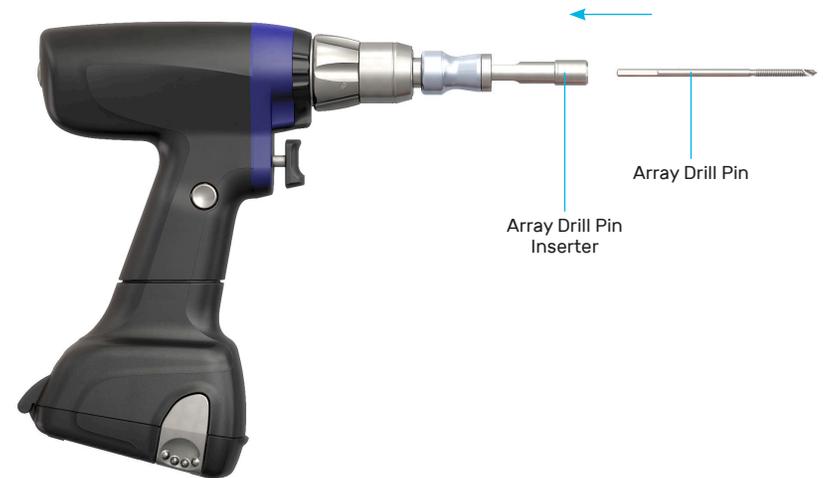
The Array Drill Pins are inserted proximal and anterior to the medial epicondyle, angling medially toward the Camera at 30 to 50 degrees relative to the sagittal plane.



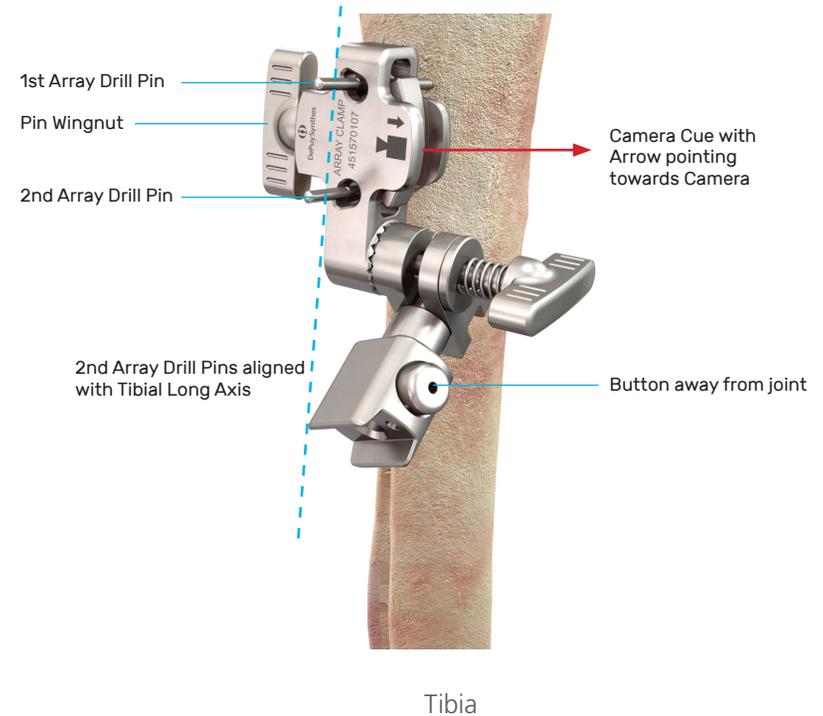
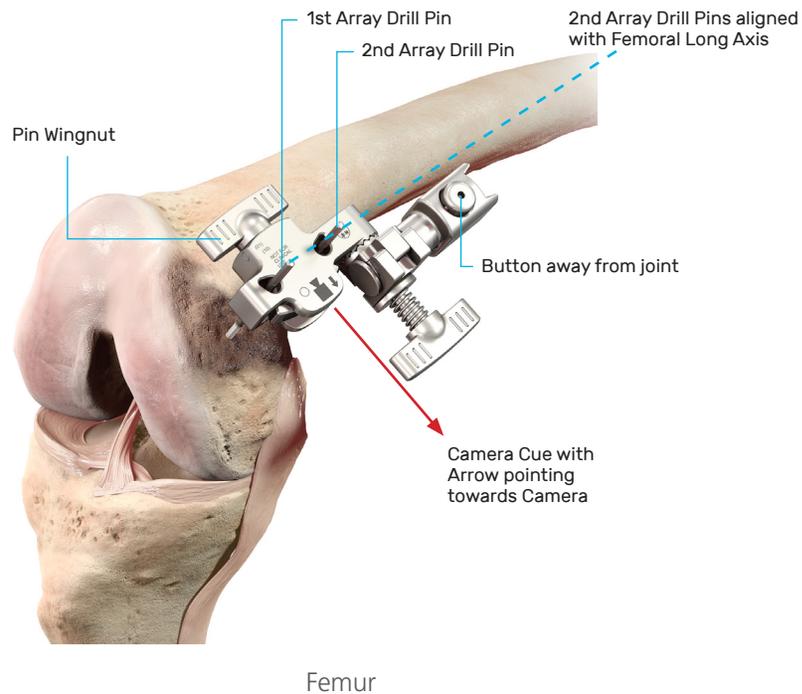
! When placing the Array Drill Pins outside of the incision, Pin insertion is best performed in flexion. Avoid tethering the quadriceps tendon and injuring neurovascular structures.

Array Drill Pins and Array Clamp Placement Workflow

The Array Drill Pin is positioned into a special Array Drill Pin Inserter attached to the Hudson adapter of a drill.



Array Drill Pins and Array Clamp Placement Workflow



First insert the Array Drill Pin closest to the joint.

Place the Array Clamp over the first Array Drill Pin, using the Pin Hole closest to the joint.

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

Use the other 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. Repeat for the other bone.

! 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.

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.

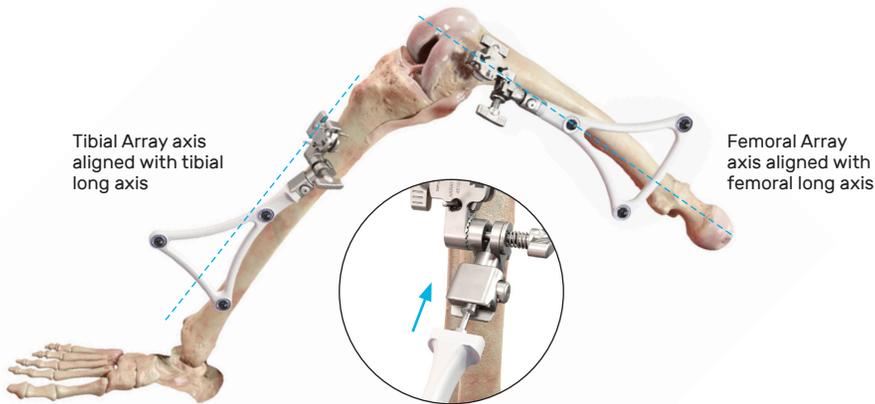
Align the Bone Array Tip with the Array Clamp Tip Hole.

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.

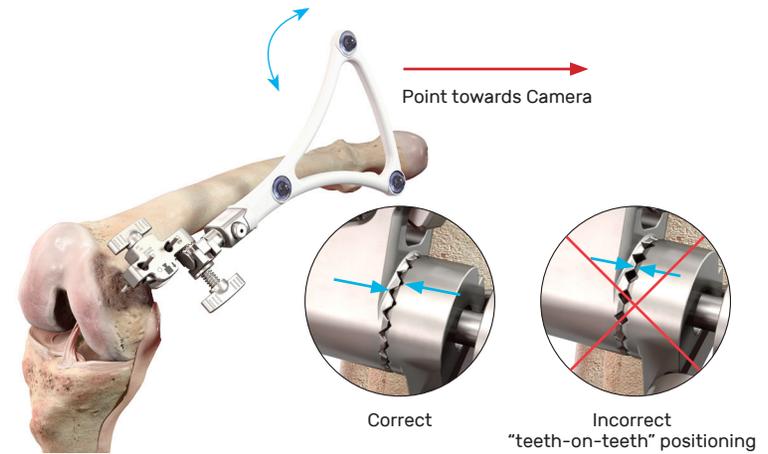


! Orient the Bone Array by adjusting the Array Clamp only. Do not grasp the Bone Array itself.

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.

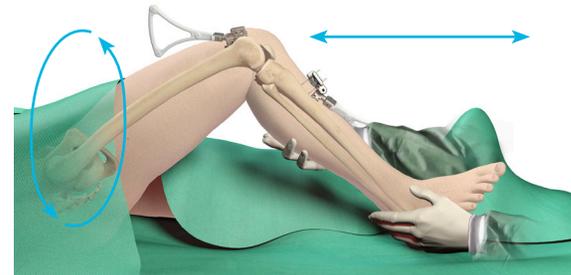
Check that the Array remains orientated toward the Camera throughout knee ROM, and line of sight between the Arrays and the Camera is maintained.

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

Repeat for the other Bone Array.

! Prior to tightening the Array Wingnut, ensure there is no impingement between the Array Clasp and Wedge.

Ensure the teeth are properly engaged before fully tightening the Array Wingnut to avoid a non-stable "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.

6.0 Camera Adjustment

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.

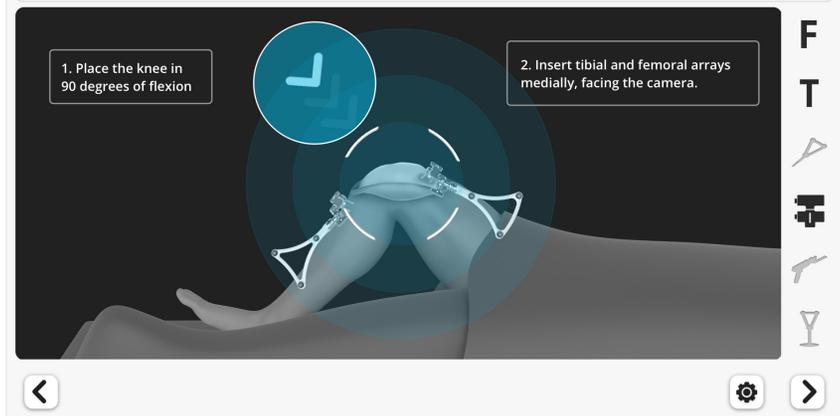
Place the knee in 90 degrees of flexion.

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.

Adjust camera position to reach target on the screen



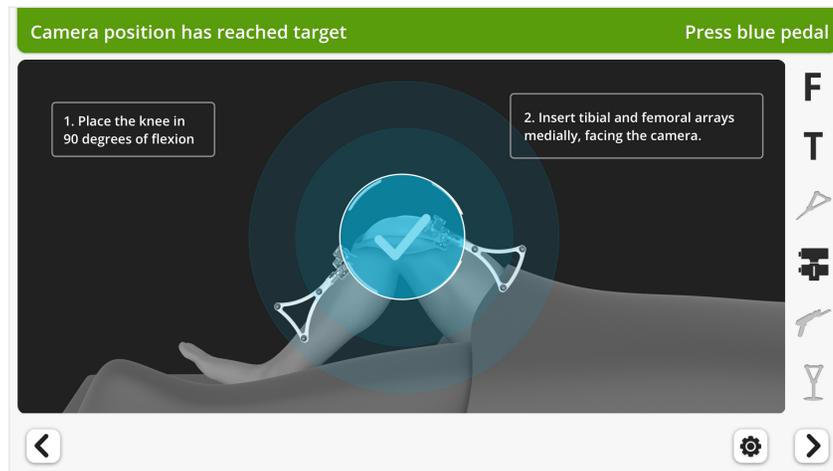
! Use the handle to avoid damaging the lenses. Touching the Camera lenses may lead to inaccurate tracking.

Camera Adjustment

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.



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.

! 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 registration
- Following registration but prior to bone resection. This will require new registration 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).

i 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.

i Instruments and reference arrays equipped with spheres must have an unobstructed line of sight to the Camera in order to be tracked.

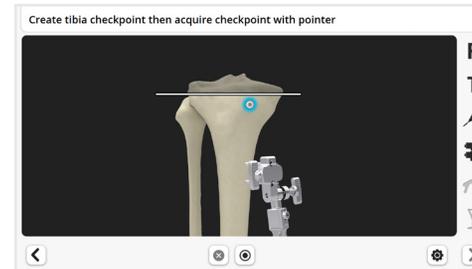
To minimize interference with the Camera, keep bright light sources (certain OR lights, direct sunlight) or highly reflective objects out of the Camera's field of view

7.0 Bone Checkpoints Registration

The Pointer will be used to acquire the location of the Checkpoint on each bone.

Bone Checkpoints Registration

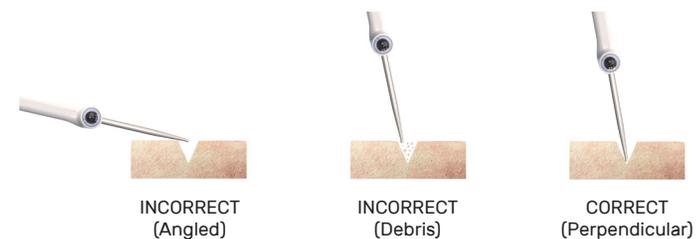
To acquire the Tibia Checkpoint, place the tip of the Pointer into the Tibia Checkpoint and then tap the "Start" button  or tap the blue foot pedal.



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 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.



8.0 Registration

The goal of the registration process 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 registration 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 condyles and the tibial plateau.

Acquisition Methods

Acquisition Methods

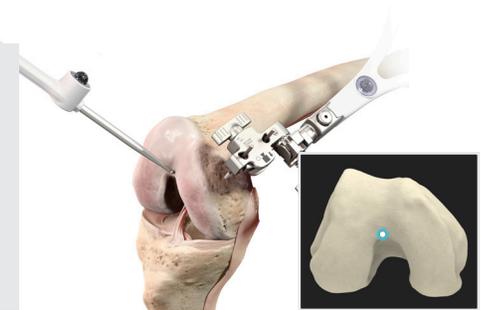
Four types of landmarks will be acquired: point, axis, line and area.

Point Acquisition

Key single point landmarks are acquired by touching the appropriate bony landmarks (or cartilage or soft tissue covering the bone structure) with the tip of the Pointer.

Touch the landmark with the tip of the Pointer.

To acquire the position of a landmark, tap the blue foot pedal or tap the “Start” button .



The following point landmarks will be acquired:

- Malleoli (medial and lateral)
- Tibia center
- Tibia plateaus (medial and lateral)
- Femur center
- Epicondyles (medial and lateral – optional)

Axes Acquisition

Axes and directions are acquired by positioning the Pointer in a specific alignment.

Position the Pointer in the specified alignment.

To acquire the direction, tap the blue foot pedal or the “Start” button .



The following axis directions will be acquired:

- Tibial Sagittal Axis
- Whiteside’s Line

Acquisition Methods

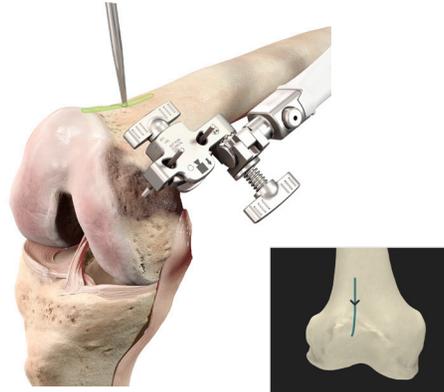
Line Acquisition

This method is used to acquire multiple points along a line.

Place the Pointer tip at the beginning of the line.

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

Slide the tip of the Pointer along the desired line.



The following line will be acquired:

- Anterior Cortex (femur)

Area Acquisition

This method is used to acquire the surface of a bone area. The software can then determine the highest or lowest point of that surface.

Touch a bone landmark within the area to be acquired with the tip of the Pointer.

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

Move the tip of the Pointer over the bone surface to map, or digitally "paint", the desired area.



The following areas will be acquired using the area acquisition method :

- Distal Femoral Condyles (medial and lateral)
- Posterior Femoral Condyles (medial and lateral)

The acquisition progress is shown on the Header of the Screen.

To obtain an accurate registration the tip of the Pointer should remain in direct contact with the surface being acquired during the entire painting process. 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.



In case the tip of the Pointer lifts off the bone during the acquisition, repeat this step

All Acquisition Steps

When a point, axis or area has been successfully acquired:

- An audible "beep" will sound
- The software will automatically proceed to the next acquisition

! Careful registration is essential for the system to plan and execute accurately.

The landmarks acquired should be representative.

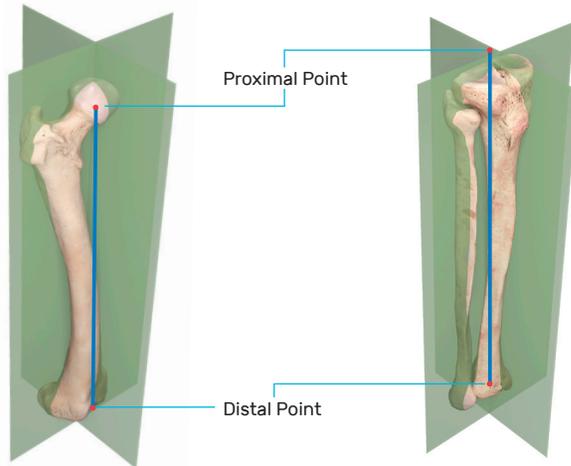
Small anatomical defects or protruding osteophytes that are not representative should not be acquired as they may falsely represent the landmark needed.

! The reflective spheres must remain visible to the Camera during the registration steps.

- Any debris (blood or tissue) on the reflective spheres obscure their visibility to the Camera. Minimize touching the spheres directly and wipe any debris from them
- Maintain a clear line of sight between the Pointer or Bone Arrays and the Camera

Mechanical Axes Definition

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



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 – acquired by single point registration
Tibial	Proximal	Tibial Knee Center – acquired by single point registration
	Distal	Midpoint of the Malleoli – calculated following single point registration of the medial and lateral Malleoli

! Accurate registration of these landmarks is critical for subsequent software calculations of implant position, balance, and alignment.

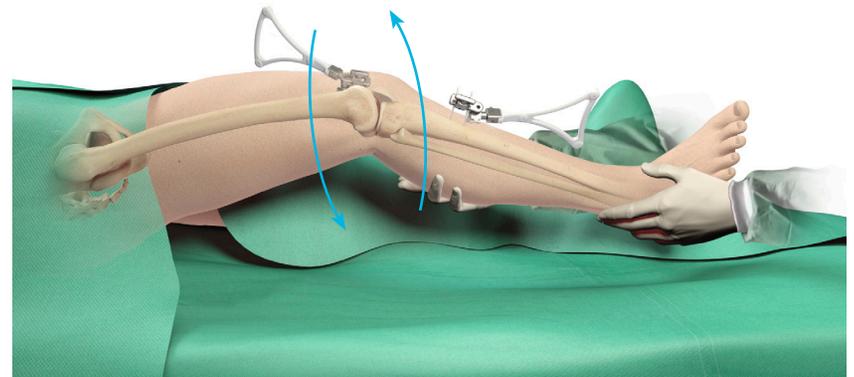
Femoral Head Center

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

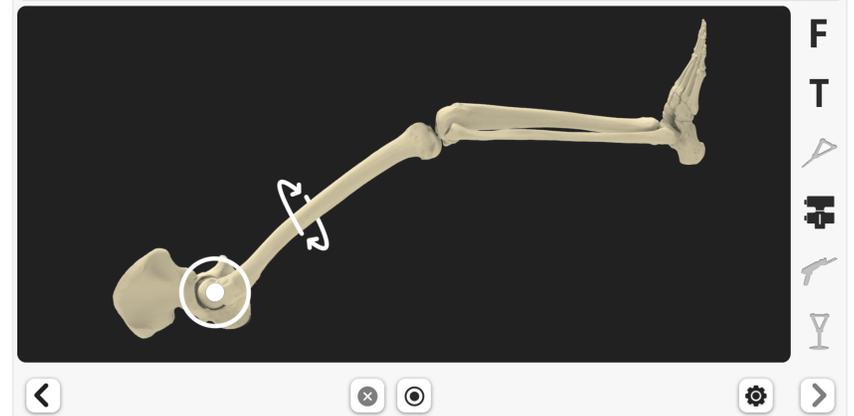
Ensure the Femur Array is visible to the Camera.

- 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 .

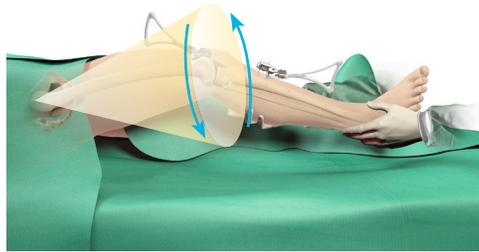


Start rotating leg and press blue pedal to acquire hip center



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.

! 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

Tibial Mechanical Axis - Distal

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.

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  .



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  .



! 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.

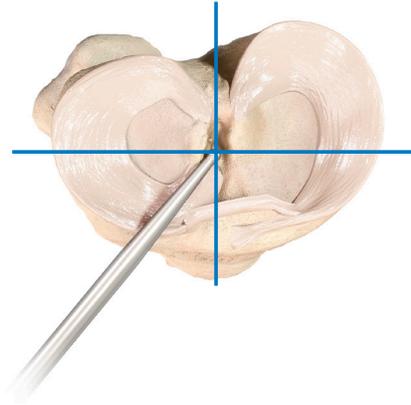
Don't acquire malleoli over a thick wrap.

Care should be taken for patients with severe ankle deformity, where the malleoli may not represent accurate landmarks for defining the tibial mechanical axis.

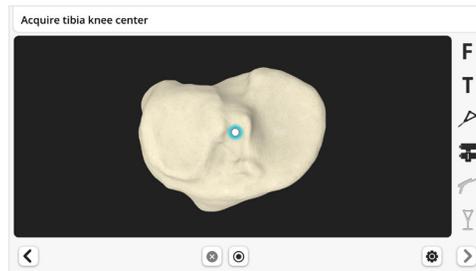
Tibial Knee Center

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

This point will define the intersection of the mid-coronal and mid-sagittal planes of the tibia (center of the proximal tibia).



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

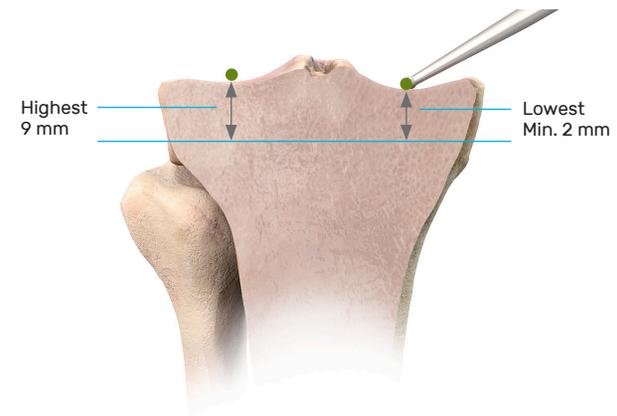


! This point should be precisely collected in anterior-posterior direction in order for the system to accurately calculate tibial slope.

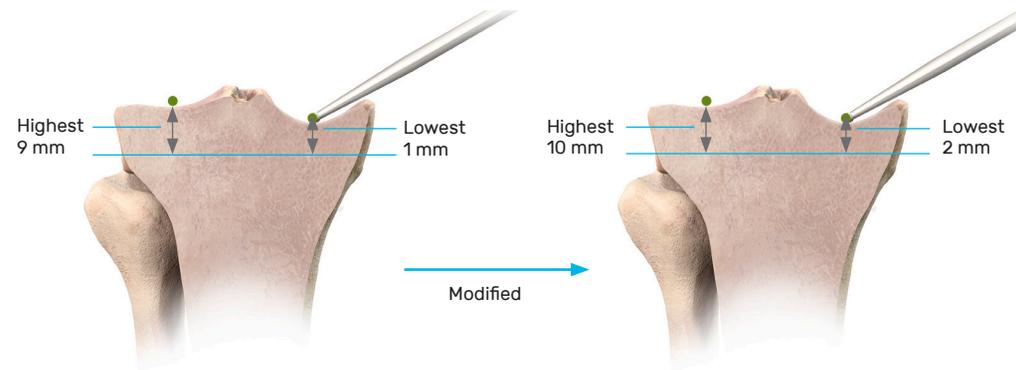
Tibial Plateau

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.

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 (Section 3) and adjusted for each patient in the PROADJUST™ Surgical Planning (Section 10).



The Initial Surgical Planning will set the resection from the highest point by the amount defined in the Surgical Profile (by default 9 mm), with a minimum of 2 mm from the lowest point. For example, if the plan resulted in a 9 mm lateral and 1 mm medial resection, the plan would be modified to 10 mm lateral and 2 mm medial.

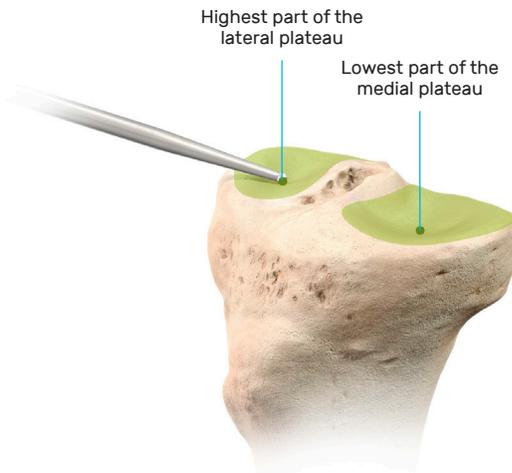


Tibial Plateau

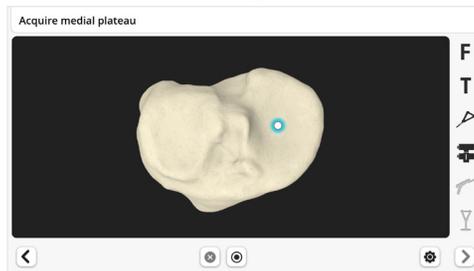
A combination of the following techniques can be used to provide greater access to the tibial plateau:

- Resect the anterior horns of the menisci
- 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.



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



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



In some cases, 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 overresection of the proximal tibia.

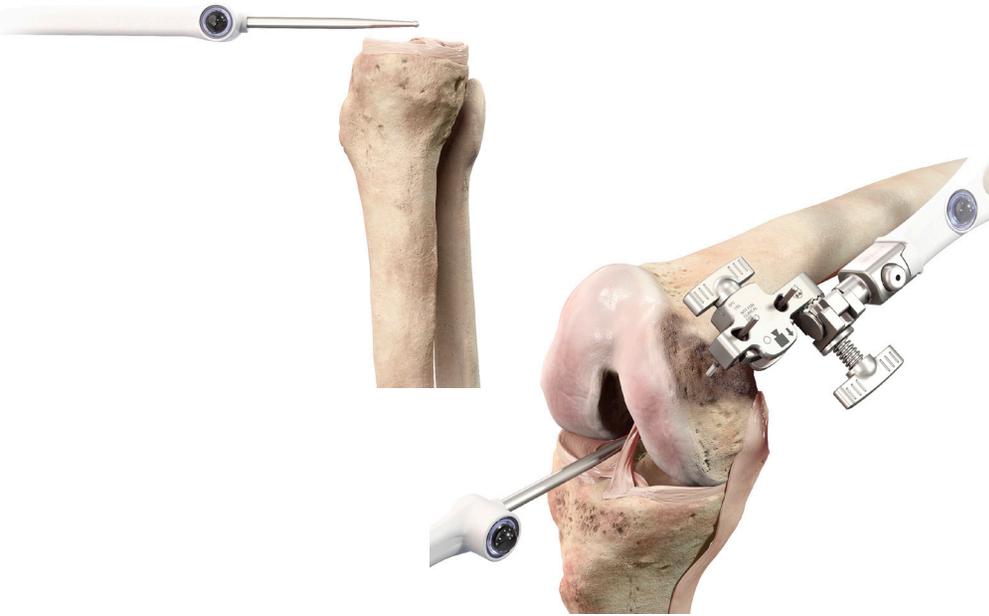
i The resection level is set using the same rationale as for manual instrumentation. The tip of the Pointer should be placed at the same position that the Pointer of the Adjustable Tibial Stylus from the INTUITION™ Instruments would be resting.

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

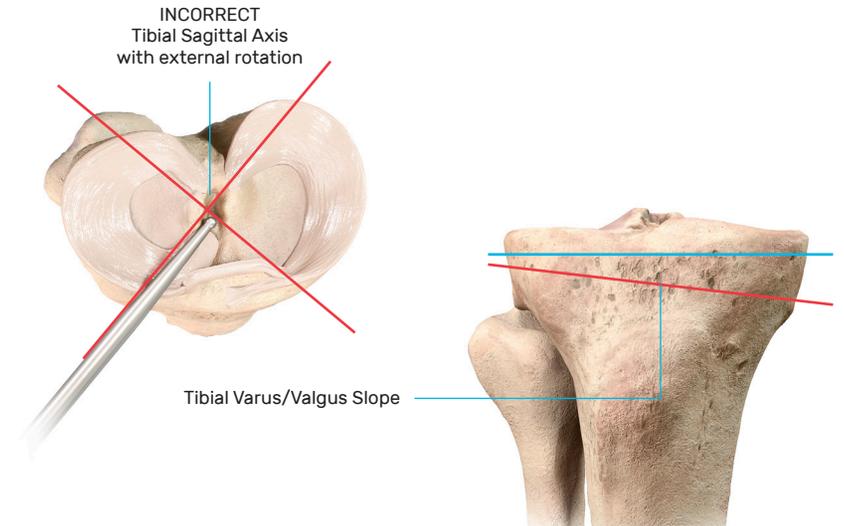
Tibial Sagittal Axis

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

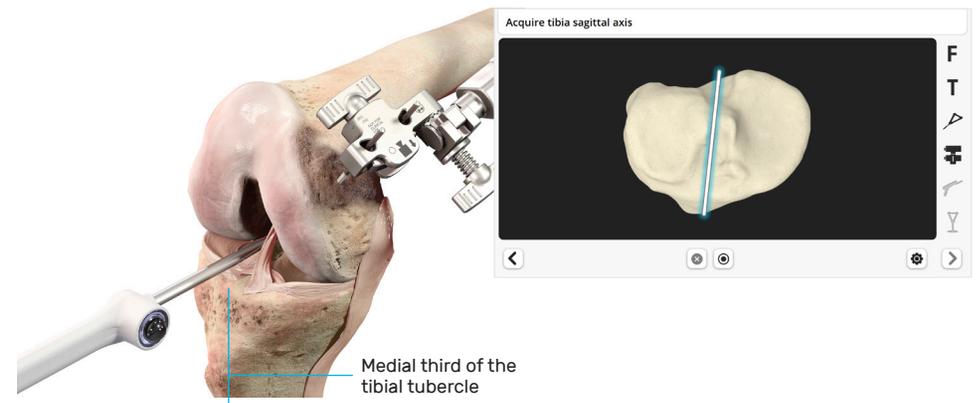


It is important that this direction is set in neutral rotation, through the center of the tibia. Failure to do so can result in inaccuracies both in the sagittal and coronal planes when defining the tibial resection.

The tibial slope is calculated within the sagittal plane. Thus, while this sagittal axis acquisition does not set the tibial slope directly, it will influence the slope indirectly by changing the sagittal plane position. **Internal or external rotation will result in an oblique slope** as shown in the image.



i 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.

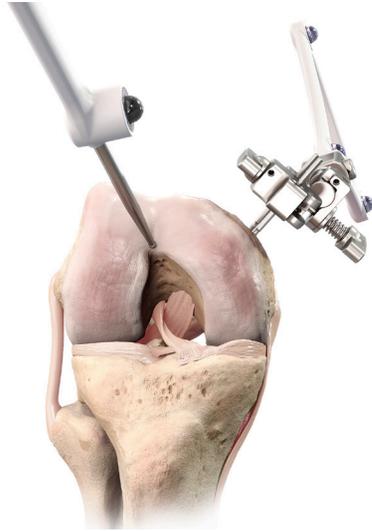


Place the Pointer horizontally in the A/P direction, so it lies on the tibial eminence. Be sure the Pointer is in line with the medial third of the tibial tubercle.

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

Femoral Knee Center

Place the tip of the Pointer at the intercondylar notch apex.



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



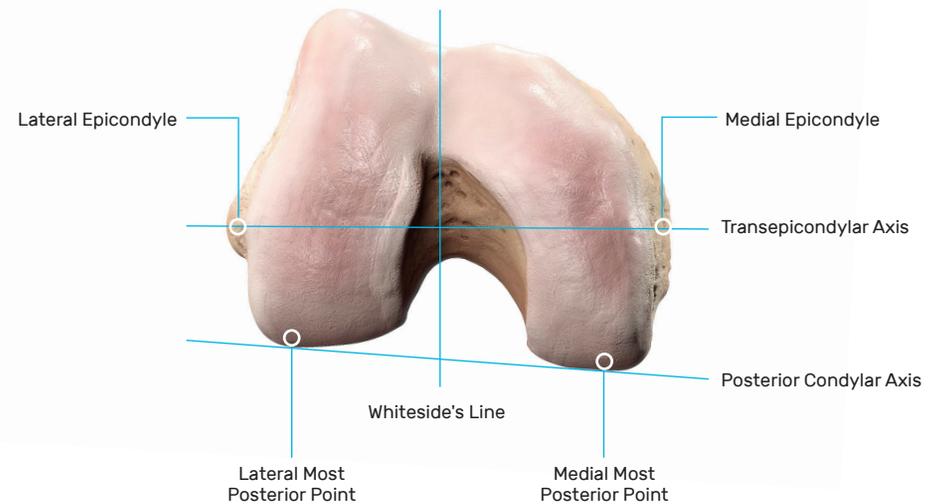
This point should be precisely collected in anterior-posterior direction for the system to accurately calculate femoral component flexion.

Femoral Component Rotation Reference

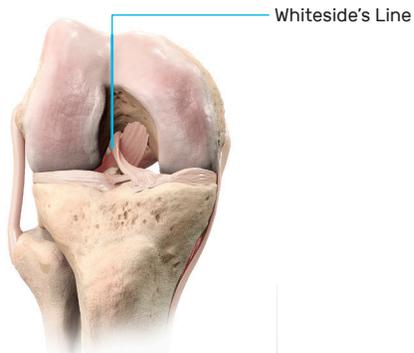
For femoral component rotation, three axes may be used depending on surgeon preference:

1. Whiteside's Line
2. Transepicondylar axis (TEA)
3. Posterior condylar axis (PCA)

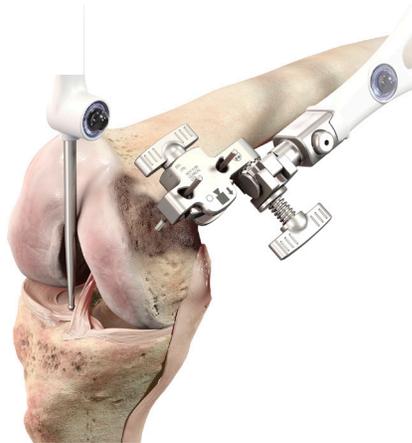
The primary femoral rotation reference axis is defined by the surgeon in the Surgical Profile. In all cases, Whiteside's Line and the PCA will be registered and used as primary or secondary reference axis. The TEA will only require registration if it is selected as the primary reference axis.



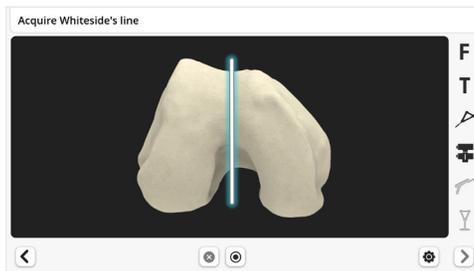
Whiteside's Line (Anteroposterior Axis)



Place the Pointer along Whiteside's Line – the line created by connecting the points in the deepest part of the trochlea groove.



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



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

Transepicondylar Axis

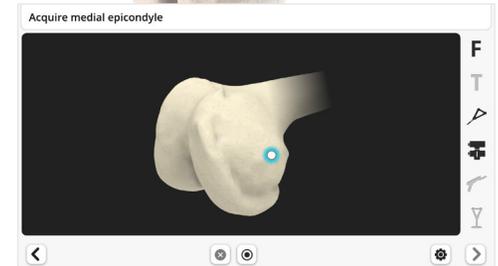
The two femoral epicondyles define the surgical transepicondylar axis (TEA). The acquisition of these two landmarks is only performed if the TEA was selected in the surgical profile as primary reference for the femoral rotation.

! The two femoral epicondyles may be difficult to locate. During Surgical Planning, the TEA should be used only as reference for femoral component rotation and in combination with the other references available (posterior condylar axis and Whiteside's Line).

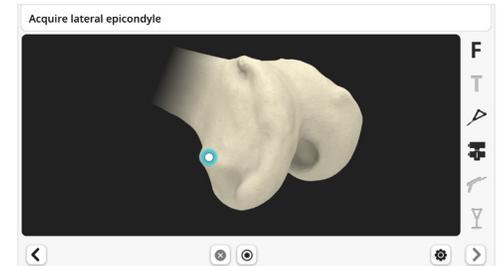
Place the tip of the Pointer on the medial sulcus which sits in the depression posterior to the *medial* epicondyle.



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



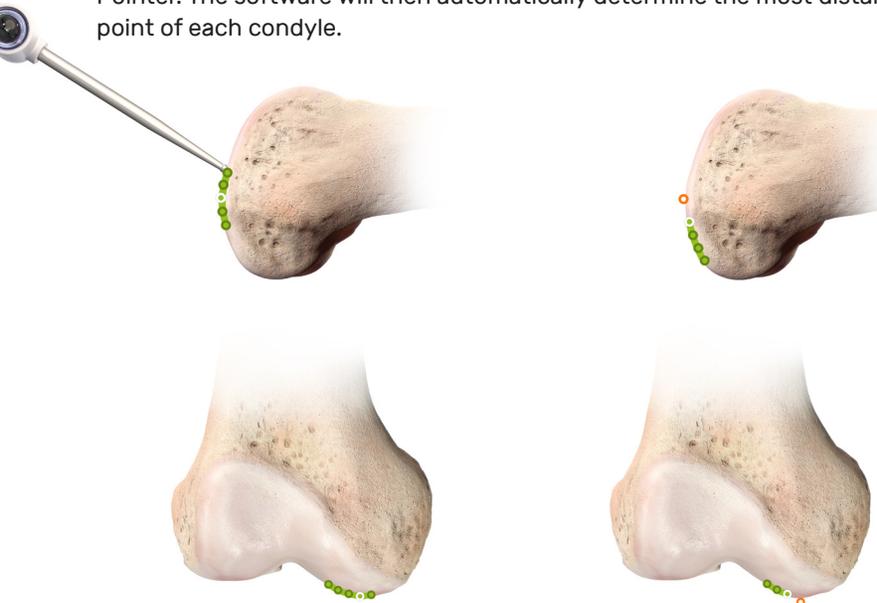
Repeat for the *lateral* epicondyle, placing the tip of the Pointer at the center of the lateral epicondylar prominence.



Distal Femoral Condyles

Distal femoral condyle registration 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 the most distal point of each condyle.



Correct

Most Distal point (white) is included in points acquired by the surgeon (Green patch)

Incorrect

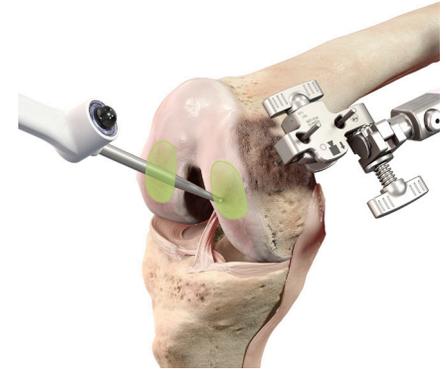
Most Distal point (orange) is NOT included in points acquired by the surgeon (Green patch). White will be selected, but it is not the most distal point

! While mapping, ensure the Pointer tip is kept in contact with the surface of the femoral condyle at all times.

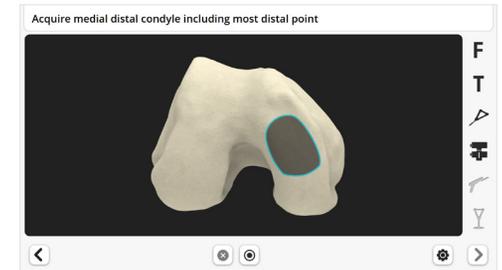
Ensure the entire area around the most distal condyles is mapped.

Avoid mapping osteophytes, which may protrude from the condyles.

Place the Pointer tip on the distal aspect of the *medial* condyle.



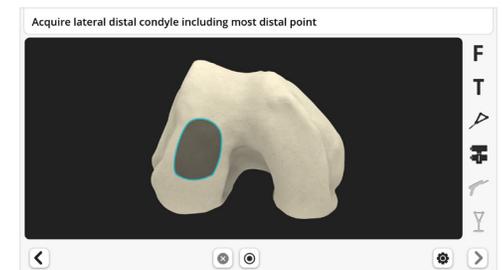
Tap the blue foot pedal or tap the "Start" button .



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

A "beep" will sound when the surface has been registered.

Repeat the above steps to acquire points on the distal aspect of the *lateral* condyle.



Posterior Femoral Condyles

Posterior femoral condyle registration 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 and setting the femoral component rotation

As with the distal condyles, this is achieved by mapping the surface of both posterior condyles with the Pointer. The software will then automatically determine the most posterior point of each condyle.



Correct

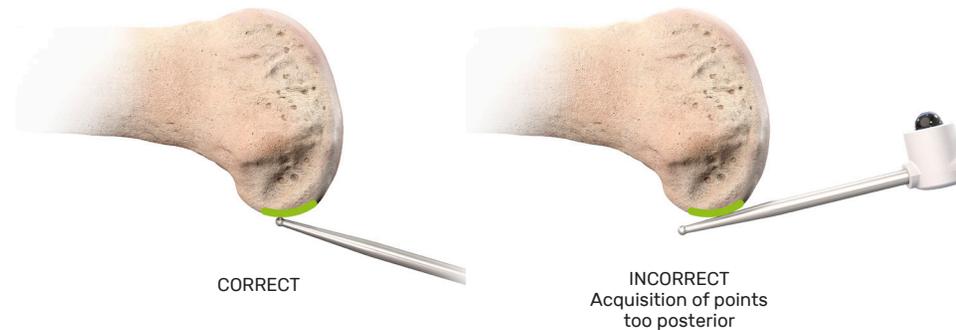
Most posterior point (white) is included in points acquired by the surgeon (Green patch)

Incorrect

Most posterior point (orange) is NOT included in points acquired by the surgeon (Green patch). White will be selected, it is not the most posterior point

! The same cautions as for the distal condyles registration 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



i Tips for reaching the posterior condyle in a tight compartment:

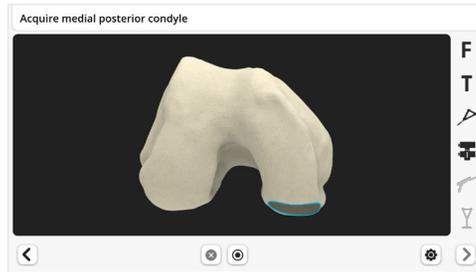
- Maximally flex the knee
- Ensure removal of the anterior horn of the meniscus
- Distract the relevant compartment by applying a varus or valgus force to the tibia

Place the Pointer tip on the posterior aspect of the *medial* condyle.



Posterior Femoral Condyles

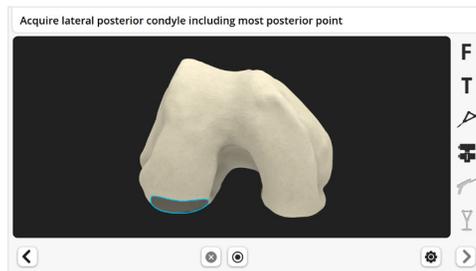
Tap the blue foot pedal or tap the "Start" button .



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

A "beep" will sound when the surface has been registered.

Repeat the above steps to acquire points on the posterior aspect of the *lateral* condyle.

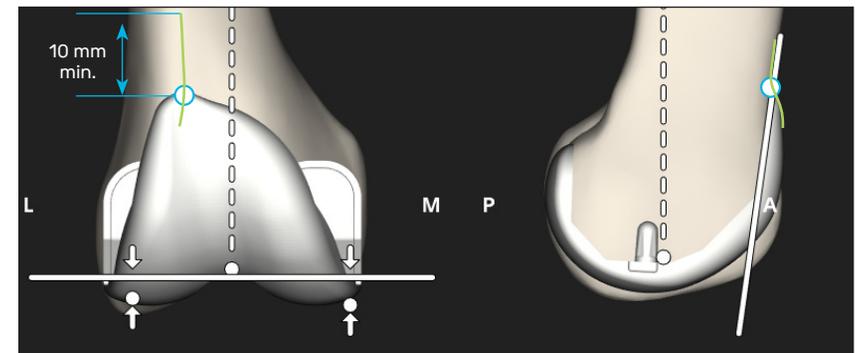


Anterior Cortex

The anterior cortex registration 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)

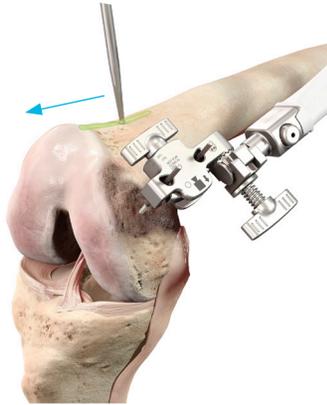
A smooth line (green on the figure below) must be acquired with the Pointer along the lateral surface of the anterior cortex. This line will later be used to calculate the Anterior Reference Point (white dot on the figure below) which is where this line crosses the exit of the anterior cut plane in an anterior referencing technique.



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

Anterior Cortex

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.



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.

Confirmation of Acquired Landmarks

This step is a validation process to confirm that the significant landmarks extracted by the software from the registration process are accurate and representative of the surgeons' desired landmarking.

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

! 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.

Step A: Distal Condyles

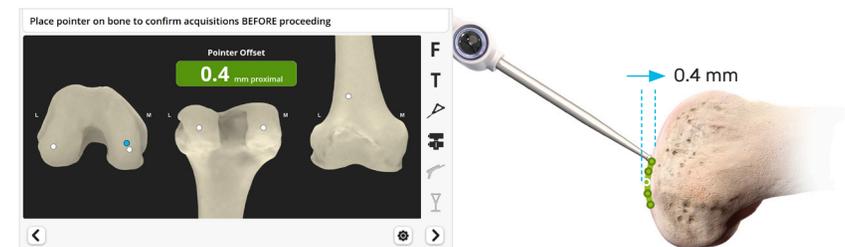
This step confirms that the medial and lateral distal points determined during the distal femoral condyle registration are the most distal anatomical points.

The system will measure the "offset" which is the difference in the distal-proximal direction between:

- The observed point (tip of the Pointer – blue dot) and
- The point determined by the system during registration (white dot)

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

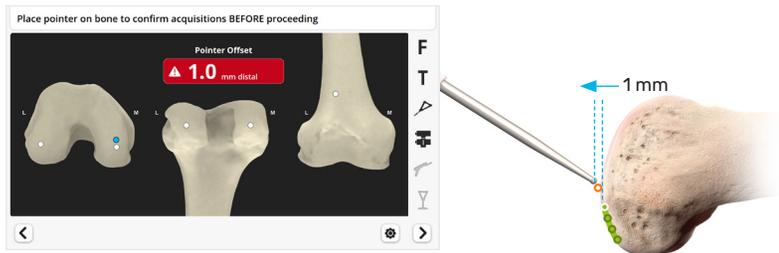
On this condyle, if the tip of the Pointer remains **more proximal at every point**, then the distal point determined by the system (white dot) is **the most distal point** and the registration is acceptable for this condyle.



Confirmation of Acquired Landmarks

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

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



Position the Pointer tip on the bone at the location of a distal white dot indicated on the screen.

Move the Pointer tip on the surface of the bone around this white dot.

Observe on the screen the Pointer offset value for each Pointer tip location.

A distal offset greater than 0.5 mm will be displayed in red. In this case, check if the tip of the Pointer is in contact with representative bone and assess if repeat of registration for this distal condyle is required.

Repeat for the other distal white dot.

Step B: Posterior Condyles

Similarly, confirm that the medial and lateral posterior points determined during the posterior femoral condyle registration 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 white dot being assessed. In this case, assess if repeating registration of this posterior condyle is required.



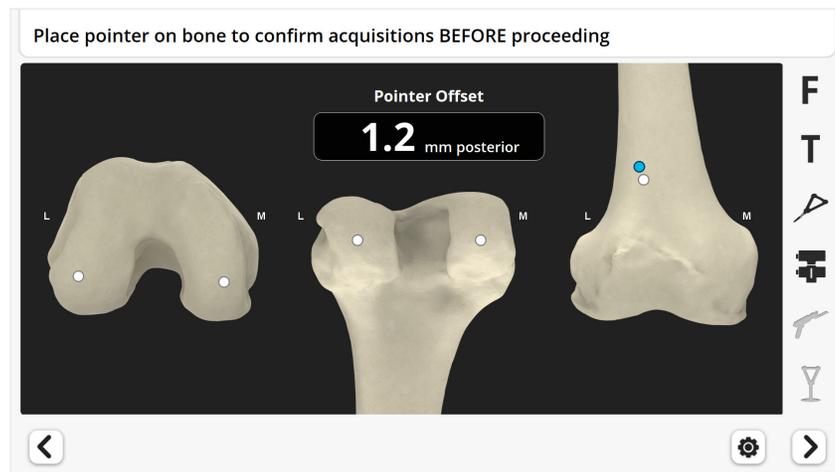
Step C: Anterior Cortex

Once registration 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 Section 10, "PROADJUST™ Surgical Planning" for more information).

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 Registration). This point is a critical reference for indication of notching, for implant A/P positioning adjustments, and gap balancing during the Surgical Planning phase.

i 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.

Confirmation of Acquired Landmarks



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

Move the Pointer tip on the surface of the bone around this white 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.

 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 Landmark Registration

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

Tap the "Back" button  and repeat until the corresponding step is reached.

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

Tap the "Next" button  and repeat until the Confirmation of Acquired Landmarks screen is reached. Do not press the blue foot pedal on the screens where the acquisition does not need to be repeated, as this will start a new acquisition.

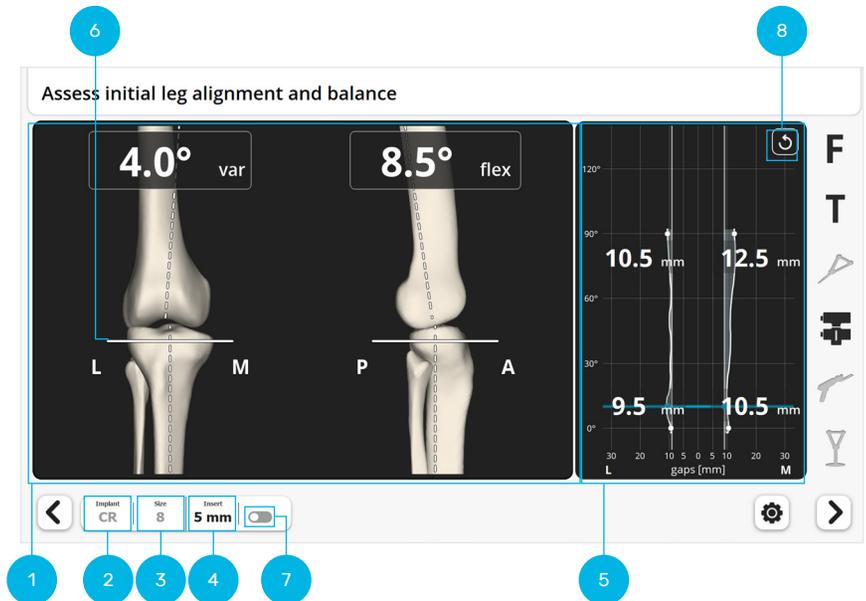
Repeat the confirmation step for the re-registered landmark.

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

9.0 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 registration, the data recorded during this step creates the ACCUBALANCE™ Graph, a soft tissue stability graph, which is modified during Surgical Planning to create the desired final alignment and balance of the knee.

Screen Display



The screen shows the current coronal and sagittal alignment (Hip Knee Ankle [HKA] angle) of the knee (1), the type of implant (2), the calculated size of the femoral component (3), and the insert size (4).

- The initial insert size is 5 mm
- The insert size can be modified with a corresponding change in the ACCUBALANCE™ Graph (5)

Although no resections have been performed, the screen displays the tibial resection (6) 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** positioned according to the Initial Surgical Planning; (thus not the femoral bone)
- **Tibial resection** or **tibial insert** depending on the position of the Switch (7)

Switch	Off <input type="checkbox"/>	On <input checked="" type="checkbox"/>
Gap between the femoral implant condyle and	Tibial resection 	Tibial insert

Assessment of Initial Alignment and Joint Stability

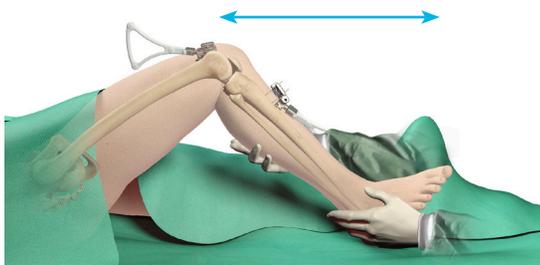
Before assessing alignment and joint stability, remove any tissue that may affect soft tissue balancing. This includes:

- Osteophytes
- ACL
- PCL when using a PS implant or a CR implant with a CS application

Starting ROM and Alignment

Prior to creating the ACCUBALANCE™ Graph, the system will provide quantitative information on ROM and alignment. This data will not be part of the ACCUBALANCE™ Graph but may be useful for assessment and initial soft tissue releases, which should be done prior to recording the ACCUBALANCE™ Graph, if needed.

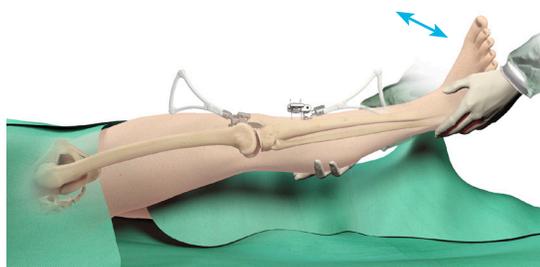
Bring the leg into full extension and full flexion. Assess knee ROM in the sagittal plane including presence of fixed flexion deformity (FFD) or hyperextension.



The software will record the maximum extension and flexion for documentation in the case report.

Bring the leg into extension and perform a varus and valgus stress.

Assess the stability in the coronal plane.



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 desired tension. There are two possible options for recording the Balance Graph:

1. Through the full ROM, **or**
2. Only in full extension and 90 degrees of flexion

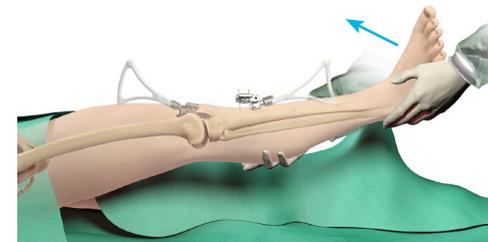
In both techniques, the amount of varus and valgus stress applied should represent the surgeon's desired final tension in the medial and lateral collateral ligaments, respectively.

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

To delete the data recorded on the graph during the initial assessment of the range of motion and stability, tap the "Reset" button (Ⓢ) (8). This will erase data possibly recorded with excessive tension, and allow a new Graph to be recorded

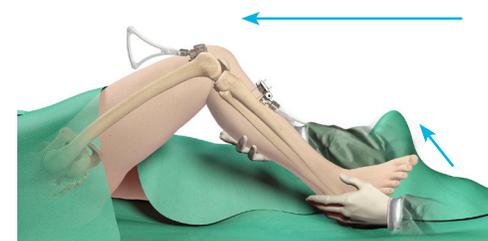
Option A: Recording Along the Full Range of Motion

In extension, apply a desired varus force to tension the lateral side.



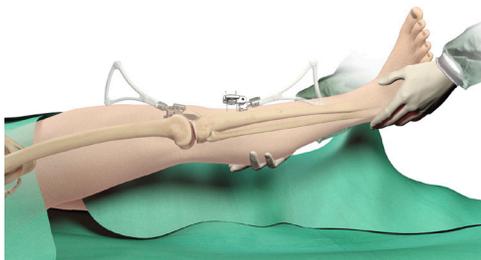
Smoothly flex the knee while maintaining the desired varus stress and lateral tension.

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.

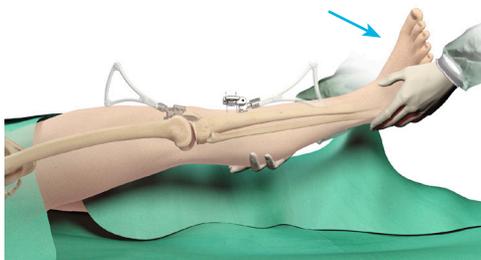


Recording of the ACCUBALANCE™ Graph

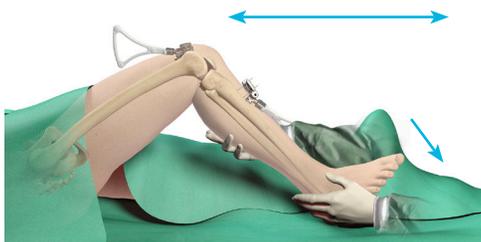
Once maximum flexion angle is reached, release the varus force and bring the knee back into extension.



Repeat the process for the medial side: Apply a valgus force to suitably tension the medial side.



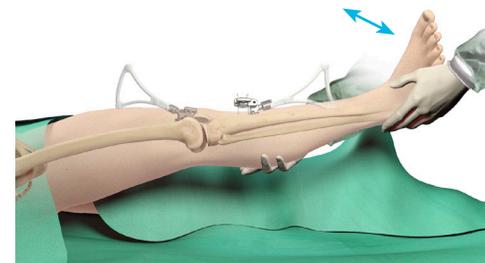
Move the knee through full ROM. When the maximum flexion angle is reached, release the force applied on the leg.



Option B: Recording in Flexion-Extension Only

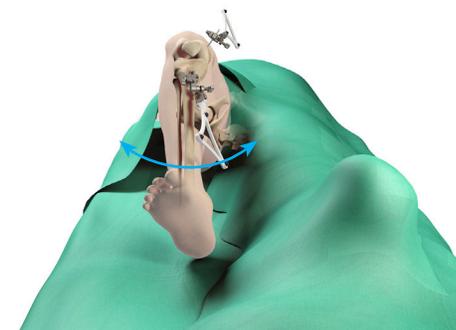
In extension:

- Apply a varus force to stress the lateral side of the knee with the intended tissue tension.
- Apply a valgus force to stress the medial side of the knee with the intended tissue tension.



At 90 degrees of knee flexion:

- Apply a varus force to stress the lateral side of the knee with the intended tissue tension, taking care to apply tension to the Lateral Ligament Complex **while avoiding hip rotation.**
- Apply a valgus force to stress the medial side of the knee with the intended tissue tension.



Recording of the ACCUBALANCE™ Graph

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 desired tension.

! On the Leg Alignment and Balance screens, the ACCUBALANCE™ 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.

At any time later in the procedure, a new ACCUBALANCE™ Graph can be recorded by returning to this screen using the “Back” ⏪ and “Next” ⏩ buttons.

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

! The ACCUBALANCE™ Graph should be recorded with the *intended post-operative ligament tension*. The surgeon **must not try to adjust or equalize the gaps at this step** by overstressing the ligaments in varus or valgus or by distracting the joint. Gaps can be adjusted during the following PROADJUST™ Surgical Planning step.

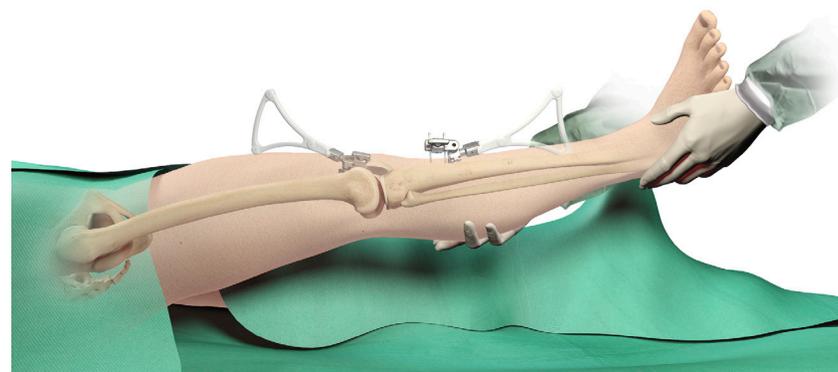
! Any changes in bony resection, soft tissue (releases), or implant size will alter the ACCUBALANCE™ Graph.

Any bone resection modification during PROADJUST™ Surgical Planning will be automatically reflected on the Graph (the Graph will self-update).

Soft tissue changes will not be captured automatically. It is important to **delete the Graph and record again after any adjustments to the soft tissue envelope** are made.

Coronal Leg Alignment Recording

Finally, the software will record the initial coronal leg alignment, i.e., the HKA angle at this stage, and this information will be documented 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 ⏩.

10.0 PROADJUST™ Surgical Planning

The goal of this step is to plan the position of both femur and tibia implants simultaneously by adjusting the bone resections.

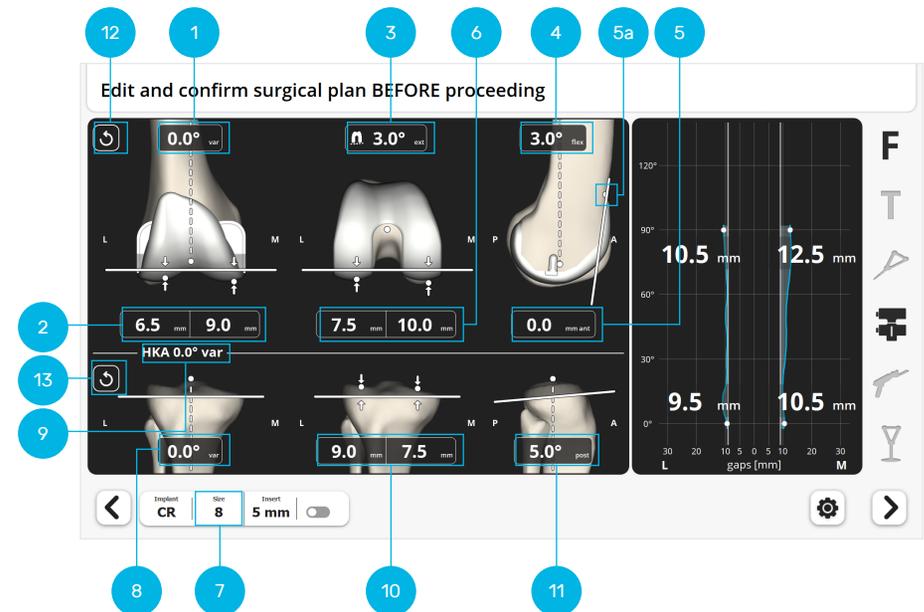
The component positioning can be adjusted by pressing the parameter value on either of the two Touchscreens. Movement of either component will be reflected on the ACCUBALANCE™ Graph. Any adjustment may affect:

- Size
- Bone resection
- Alignment
- Balance and gaps
- Joint line

The goal of the PROADJUST™ Surgical Planning is to virtually achieve the surgeon's desired component position, knee balance, and leg alignment before engaging the Robotic-Assisted Device to perform bone resections.

Initial Surgical Planning

Initial implant size and position is determined automatically based on the data registration 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		

! 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.

Initial Surgical Planning

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

Femur Coronal Alignment (1)

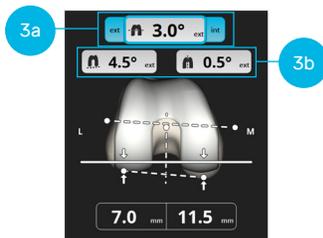
- 0 degrees varus/valgus relative to the mechanical axis of the femur

Distal Femoral Resection (2)

- 9 mm resection from the most distal point of the most distal condyle
- The highest initial resection value remains constant when adjusting the femur coronal alignment

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)



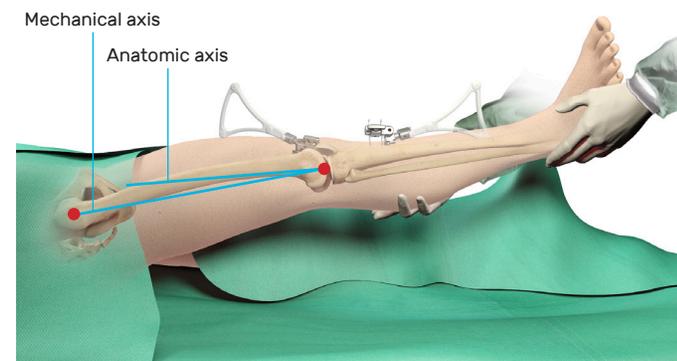
Surgical Profile	Registration	Surgical Planning	
		Symbol	Secondary Reference Displayed
Posterior condylar axis	No		Whiteside's Line
Whiteside's Line	No		Posterior condylar axis
Transepicondylar axis	Yes		Posterior condylar axis Whiteside's Line

Femoral Flexion (4)

- As chosen in the Surgical Profile

! The femoral component flexion is displayed relative to the sagittal 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 3 degrees to the mechanical axis to reproduce conventional position.

Failure to do this generally results in an upsized femoral component to avoid notching.



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 registration)
- The A/P will be modified when the posterior resections (6) are adjusted, and reciprocally

! 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

Initial Surgical Planning

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.

! Ensure the software selected a femoral component size consistent with the surgeon's pre-operative planning.

! 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)

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 Registration section)
- The highest initial resection value remains constant when adjusting the tibia coronal alignment

Clinical judgment is required to determinate the appropriate resection amount on both plateaus, especially in cases of 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.

Extension and Flexion Gaps Balancing

During Initial Leg Balance and ACCUBALANCE™ Graph Recording, the intended medial and lateral ligament tension in flexion and in extension were recorded.

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

There are two aspects to balancing the knee:

1. Coronal balance – adjust the difference between medial and lateral gap for the extension gap and the flexion gap.
2. Sagittal balance – equalize the difference between the flexion and extension gaps.

Coronal Gap Balancing

Adjusting the tibial resection varus/valgus will change the medial and lateral gaps BOTH in flexion and extension.

Adjusting the femoral component varus/valgus will change the medial and lateral gaps in extension.

Adjusting the femoral component rotation will change the medial and lateral gaps in flexion. When adjusting rotation around the primary axis, monitor the resulting rotation around the two secondary axes and ensure all stay within the surgeon's acceptable limits.



Changing the tibial or femoral varus/valgus will result in a corresponding change of the overall mechanical alignment of the leg.

Sagittal Gap Balancing

Modifying the amount of tibial resection will change BOTH flexion and extension gaps

For flexion and extension gap inequality, multiple options exist:

1. The distal femoral resection level can be adjusted
 - Shifting the femoral component distally (less distal resection) will decrease the extension gap
 - Shifting the femoral component proximally (increased femoral resection) will increase the extension gap

Neither will change the flexion gap.

2. Tibial slope can be adjusted
 - Increasing the tibial slope will increase the flexion gap
 - Reducing the tibial slope will tighten the flexion gap

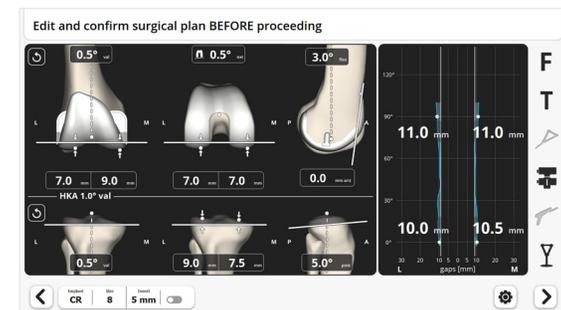
Neither will change the extension gap.

3. 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.

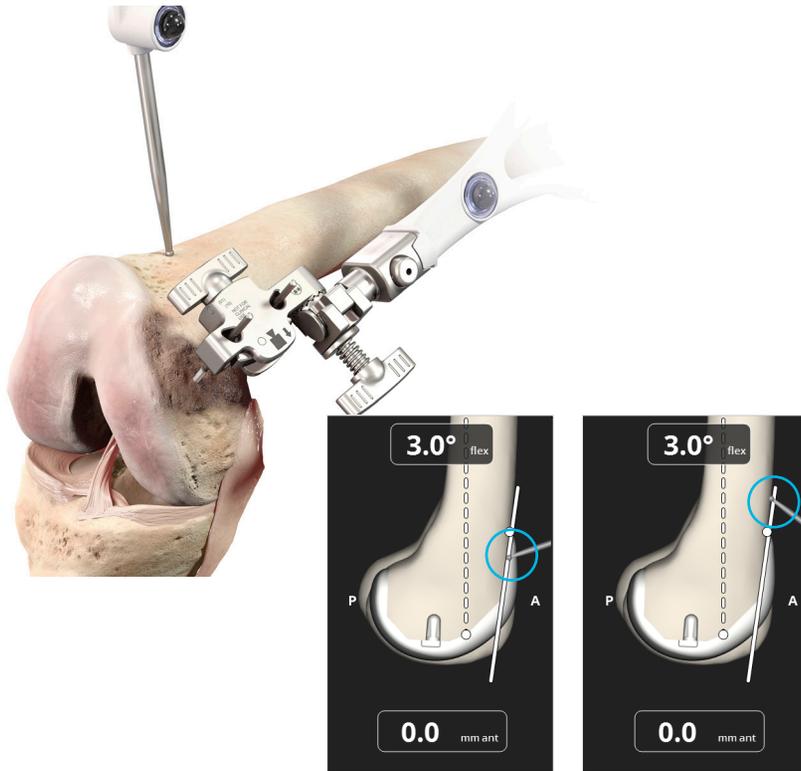
4. Femoral component A/P translation
 - Translating the femoral component anteriorly will increase the flexion gap
 - Translating the femoral component posteriorly will decrease the flexion gap

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



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.



11.0 Femur Checkpoint Verification

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

Femur Checkpoint Verification

! If the measured distance displayed on the screen does not match the distance between the tip of the Pointer and the original Checkpoint, the Femur Array has moved, and the surgeon must not proceed with the femur resections. See below for next step options.

Place the Pointer tip on the Femur 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.



! Confirmation that the Femur Array has not moved is required prior to bony resections. If the system does not automatically proceed:

Confirm the tip of the Pointer is at the acquired Femur Checkpoint position and well-seated in the indentation created.

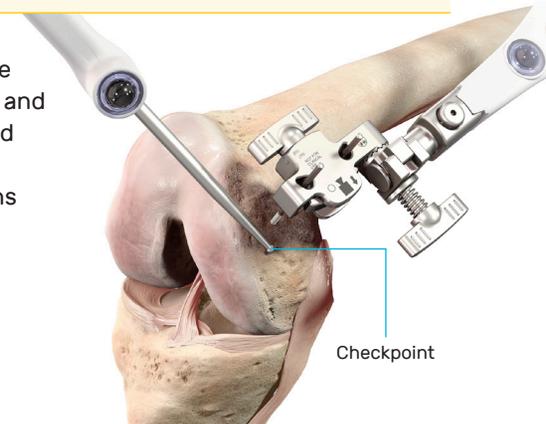
Ensure the base of the Checkpoint is clear of soft-tissue or debris.

Confirm the Pointer and the Femur 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.

If the deviation is unacceptable, the Femur Array must be re-stabilized, and all femoral landmark acquisition and subsequent steps repeated:

- Check Femur Array connections and tighten where needed
- Re-acquire Femur Checkpoint, femoral landmarks
- Record the alignment and the ACCUBALANCE™ Graph
- Repeat Surgical Planning
- Verify Femur Checkpoint



12.0 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.

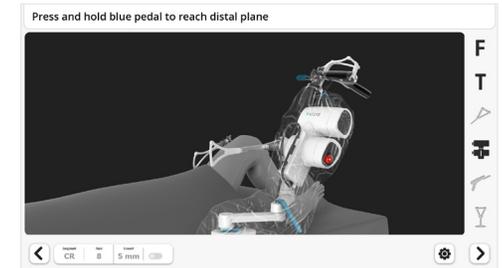
Positioning

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.

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.

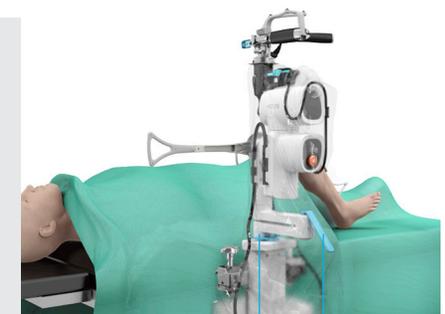


- If the Robotic-Assisted Device position needs to be adjusted to perform the next resection, the Robotic-Assisted Device Positioning screen described on the next page will appear. This is generally for the first resection.
- Otherwise, the Robotic-Assisted Device will directly move to the next resection plane as described in the next section.

Robotic-Assisted Device Positioning

Place the knee in a stable, flexed position.

Align the Status Indicator on the Robotic-Assisted Device with the epicondylar axis. Press the Holding Arm Vertical Adjustment button if vertical adjustment is required.



Lever
Vertical Adjustment Button

Positioning

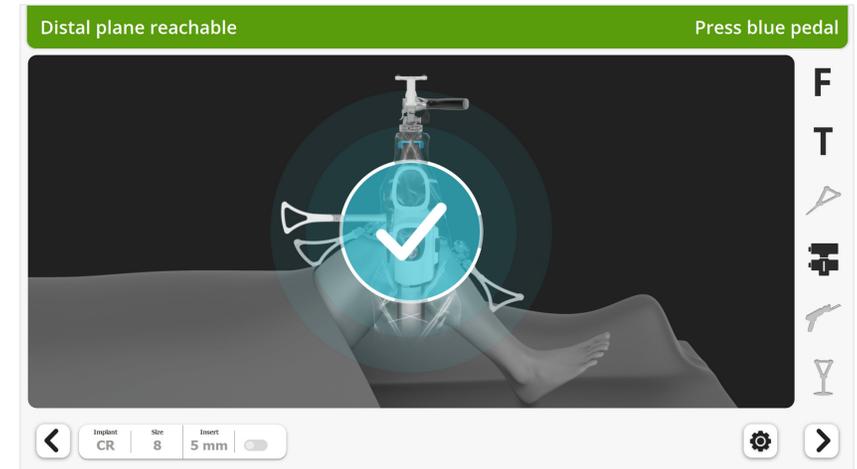
Unlock the Holding Arm Lever (up) to permit horizontal movements. The articulated arm will allow the Robotic-Assisted Device to swing in a horizontal plane. By adjusting the position of the elbow of the articulation and the Robotic-Assisted Device itself, adjustment of both horizontal position of the Robotic-Assisted Device and distance from the knee is possible.

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.



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 Lever (down) and tap the blue foot pedal or tap the "Next" button .

! Ensure the Holding Arm Lever is locked after positioning of the Robotic-Assisted Device during and between resections.

When manipulating the holding arm lever, ensure there is some slack in the Device Drape to avoid perforation of the Drape.

i 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 have 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.

13.0 Distal Femur Resection

The Distal Femur 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

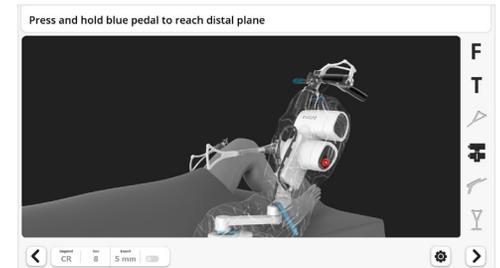
! Prior to each resection, ensure the leg is stabilized in the desired position.

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

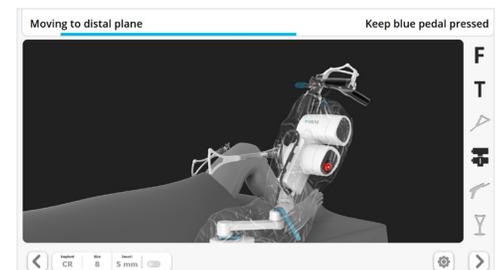
Position leg and retractors.

- 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 Femur Array and Device Array. These are indicated by the arrays being highlighted black on the screen.



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



Device Movement

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.



! When the Robotic-Assisted Device moves from one resection plane to the next:

- 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

i 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.

Performing Resections

Step 2 – Distal Femur Resection

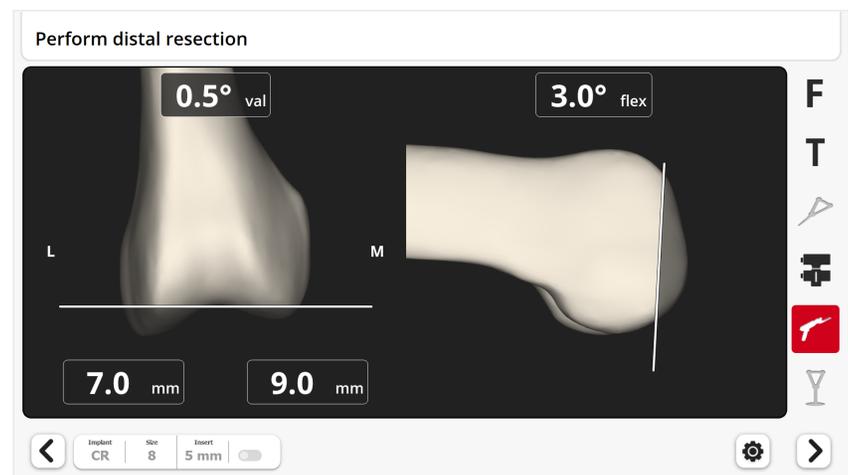
! There are no mechanical boundaries on the Saw Blade. Therefore, it must be controlled at all times by the surgeon. Prior to each resection, ensure the leg is stabilized in the desired position, and retractors are suitably placed.

- Any 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

i During Robotic-Assisted Device movement to the resection plane in step 1, the Device Array must be visible to the Camera.

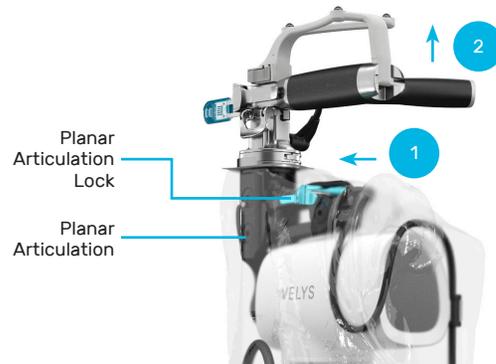
In step 2, once the Robotic-Assisted Device is positioned and the Saw is released from the Robotic-Assisted Device, visibility of the Device Array is needed only once at the beginning and then no longer required. This provides space for assistant positioning and retraction. Conversely, in step 2 it is essential to maintain direct line of sight between the Saw Array and the Camera.

Ensure the retractors are ready for resection.



Performing Resections

Hold the Saw Handpiece and unlock the Planar Articulation. Slide the blue Planar Articulation Lock on the Planar Articulation to release the Saw.



! Manipulate the Planar Articulation Lock through the reinforced region of the drape to not tear the Device Drape.

Position the Saw adjacent to the femoral bone.



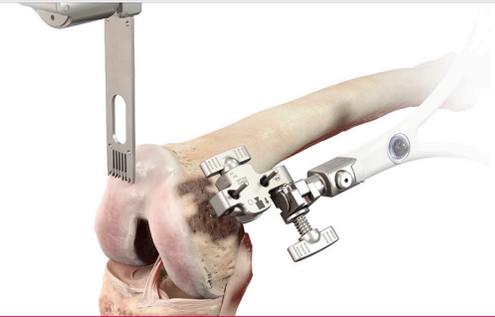
Confirm the visibility of the Femur Array and the Saw Array on the screen. The Status Indicator will turn green when both Arrays are visible and when the Saw is adjacent to the bone.

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.



! 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.

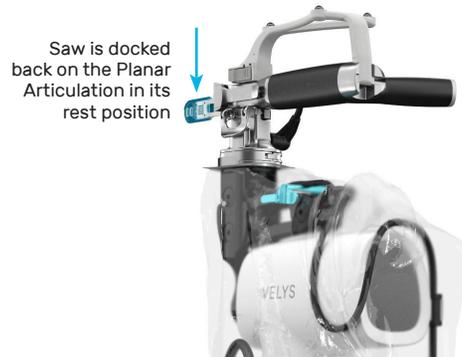
Performing Resections

! Wait for the motor of the Saw to reach full speed prior to engaging the bone.

Assess the flatness of the resected surface and run the Saw again if needed.

Be careful not to tear the Device Drape.

i Use the sharp end of the Saw Blade to resect bone, not the sides of the Saw Blade. While cutting, advance or retract the Saw Blade, avoiding mediolateral movements.



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.

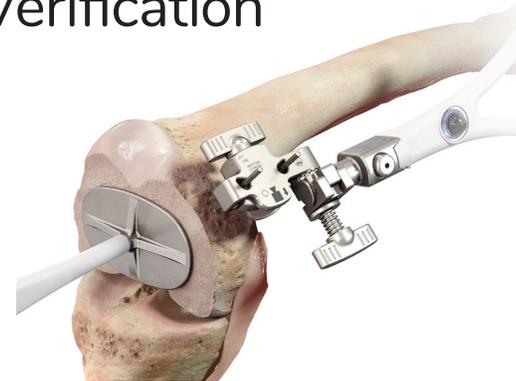
! To not tear the Device Drape, ensure it is not caught in the Planar Articulation mechanism.

! 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 be held by the surgeon or docked on the Robotic-Assisted Device.

The Saw should always be docked prior to moving to the next resection plane.

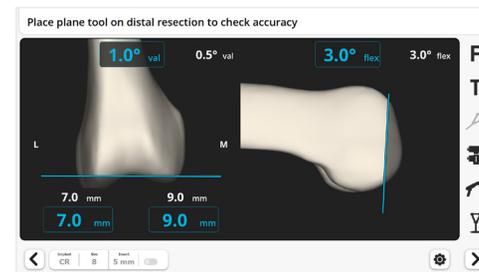
Plane Verification



Verify the resection (optional).

Place and hold the Plane Tool on the resected surface.

The screen will display the measured parameter values for the resection plane in blue and the planned values in white.



Deviations can be corrected by running the Saw again following all steps described in the sub-section “Performing Resections”. When finished, tap the blue foot pedal or tap the “Next” button > .

! The system will NOT update the Surgical Planning and the ACCUBALANCE™ Graph to compensate for any deviations in the actual *versus* planned resection plane.

The planned plane remains the basis for further resections, not the measured resection plane.

Remove debris from the resected surface.

! If the case cannot be completed with the Robotic-Assisted Device, see Appendix 5 for instructions to proceed with the manual instrumentation.

14.0 Next Resections

For all remaining resections (anterior, posterior, chamfers, and tibia), the steps are similar to the distal femoral resection.

! For the Anterior femur resection and all following resections, the same cautions as for the distal femoral resection apply.

Anterior Femur

! 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.

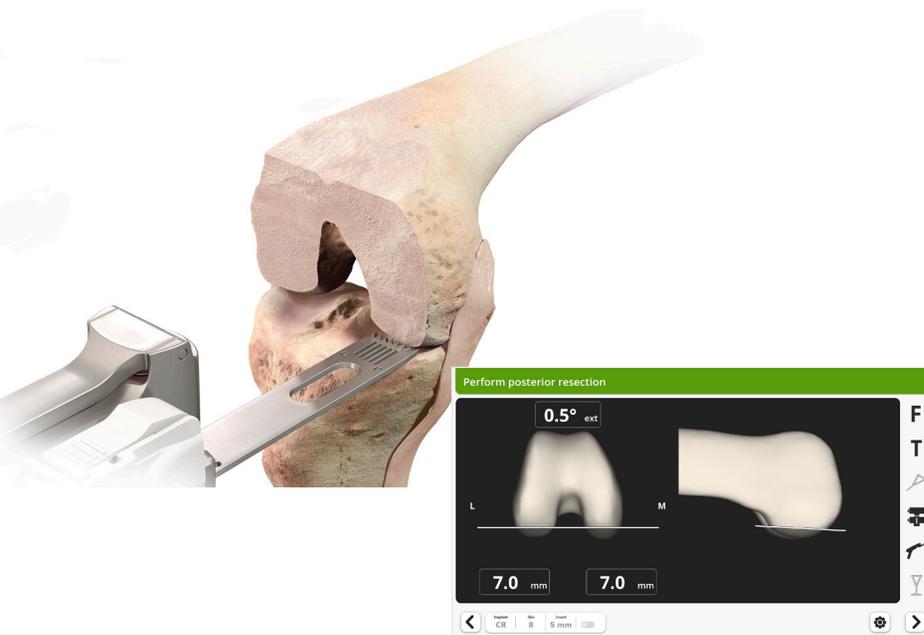
Unlock the Planar Articulation, position the Saw, ensure visibility of the Femur Array and Saw Array, and perform the resection.

Dock the Saw back in its rest position.

Verify the resection with the plane tool (optional).

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

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.

When finished, tap the blue foot pedal or tap the “Next” button .

 Visually confirm the resection. If needed, run the Saw Blade through the resection plane again.

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.

When finished, tap the blue foot pedal or tap the “Next” button .

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.

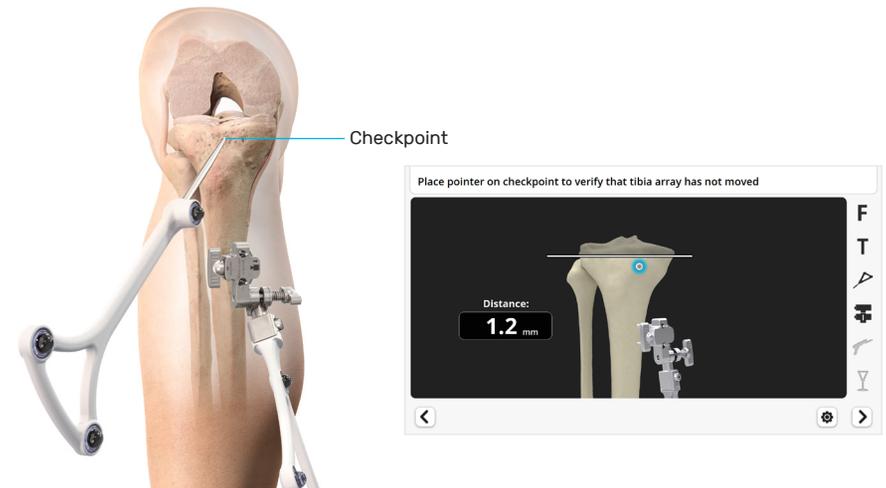
When finished, tap the blue foot pedal or tap the “Next” button .

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.

Tibia Checkpoint Verification

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

! Confirmation of the position of the Tibia Array relative to the Tibia Checkpoint is obtained in the same way as on the femur and the same cautions apply.



Place the Pointer tip on the Tibia Checkpoint.

The system will automatically proceed to the next step if the distance is acceptable. If the deviation is unacceptable, the Tibia Array must be re-stabilized, and all tibia landmark acquisition and subsequent steps repeated:

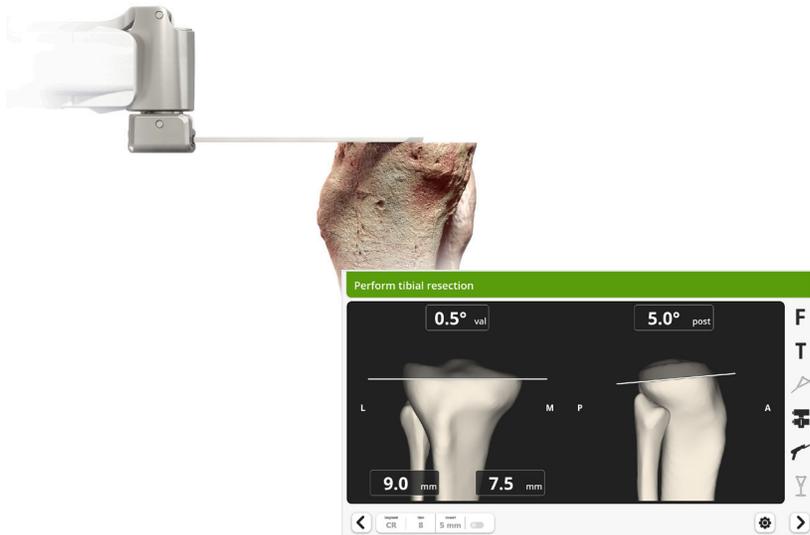
- Check Tibia Array connections and tighten where needed
- Re-acquire Tibia Checkpoint, tibial landmarks
- Finish the preparation of the femur and place the Femoral Trial Implant
- Record again the ACCUBALANCE™ Graph and remove the Femoral Trial Implant
- Repeat Surgical Planning for the tibial component
- Verify Tibia Checkpoint

Tibial Resection

! 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.

Incomplete retractor placement exposes soft tissues to potential damage.

i Increased knee flexion improves the joint surface visualization and lowers the Saw position. Flexion of 110 to 120 degrees is recommended.



To move the Robotic-Assisted Device to the tibia resection plane, tap the blue foot pedal.

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

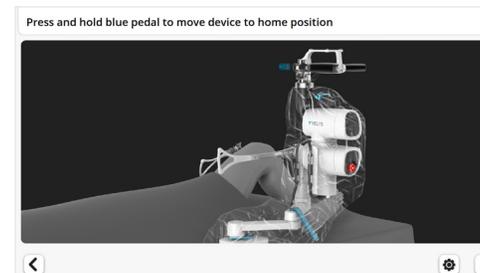
Dock the Saw back in its rest position.

Verify the resection with the plane tool (optional).

Completion of Resections

Return Robotic-Assisted 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.

Unlock the Holding Arm Lever (up) to permit horizontal movements.

Move the Robotic-Assisted Device proximally along the bed, e.g., at the level of the patient's chest.

Lock the Holding Arm Lever (down).

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

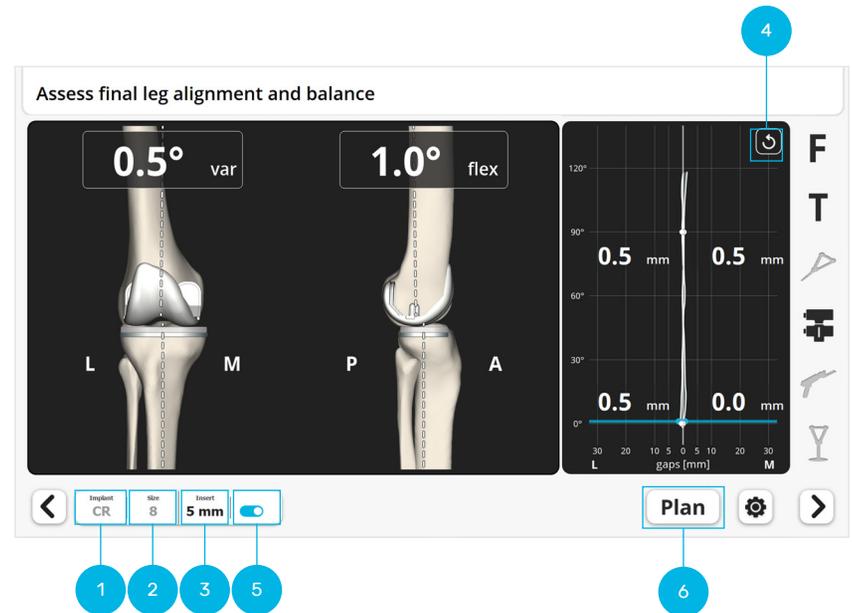
Release the blue foot pedal. The system will then automatically proceed to the next screen.

Finishing

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

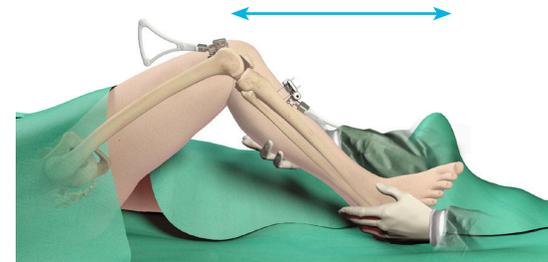
15.0 ACCUBALANCE™ Graph Recording with Trial Implants

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 tested, change the selection on the screen.

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.



ACCUBALANCE™ Graph Recording with Trial Implants

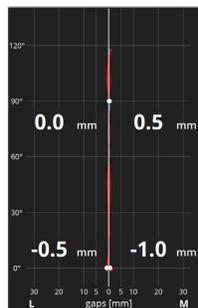
Record the new ACCUBALANCE™ Graph

Press 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.

- The Lateral line (L) on the Graph represents the gap generated between the femoral and tibial *components* due to this lateral tension.
- Repeat this step with valgus force. A similar Medial line (M) will represent medial laxity.

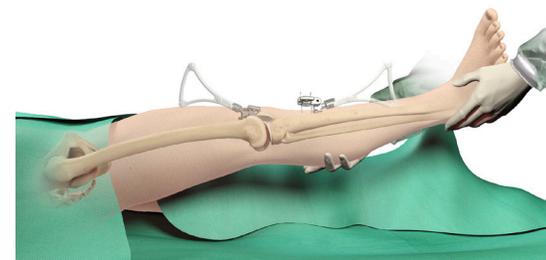
Assess laxity on the Graph and adjust insert thickness (3) if needed. When trialing a different implant thickness, the curve displayed on the screen will turn red and gaps will be represented by negative numbers if the *insert thickness* is greater than the recorded gap between the *femoral component* and the *tibial resection*, i.e. the tissues could be under excessive tension to accommodate for that insert thickness.



 The gap between the femoral implant and the tibial *resection* can be measured by shifting the Switch (5).

Next Step Options

A. To record the final HKA 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 .



or

B. Make adjustments if necessary.

If final alignment or balance are not satisfactory, adjustments can be made to either :

- Implant position. See section 16, “Recuts”.
- 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 section 17, “ACCUBALANCE™ Graph Recording with Final Implants (optional)”.

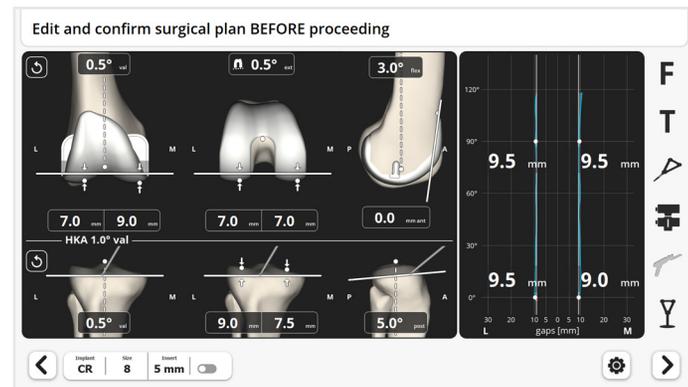
16.0 Recuts (If Necessary)

Recut Planning

On the Final Leg Balance screen press the “Plan” button  (6).

On the Planning Screen, the implant position can be adjusted as required. The screen displays:

- The last plan and implant size defined by the surgeon
- The last ACCUBALANCE™ Graph recorded during trialing



! When pressing 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.

i If a recut is planned prior to the ACCUBALANCE™ Graph Recording with Trial Implants step, consider recording a new graph by going back to the Initial Leg Alignment and ACCUBALANCE™ Graph Recording step.

This is important because the knee tension may have changed after the first resections were made, e.g. due to removal of osteophytes during the resections. Select the preferred method of ligament tensioning, including the use of trial implants if possible.

Recut Planning

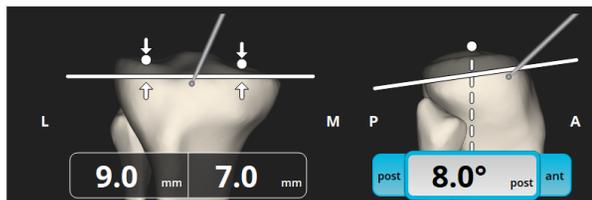
! When planning a recut, make sure the new resection will be a complete and single plane cut, i.e. not a “facetted”, “multiplanar” or incomplete recut.

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.

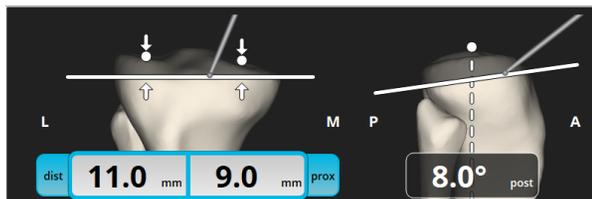
To ensure a non-facetted cut, run the tip of the Pointer over initial cut surface, especially on the most anterior aspect. Check simultaneously on the screen that the tip of the Pointer is above (proximal to) the new cut plane, i.e. the new cut plane is entirely through new bone.



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



Tip of pointer in contact with the bone but below new resection. Anterior portion will not be recut. « Facetted » or incomplete recut.



Tip of pointer in contact with the bone and above new resection. Complete recut.

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

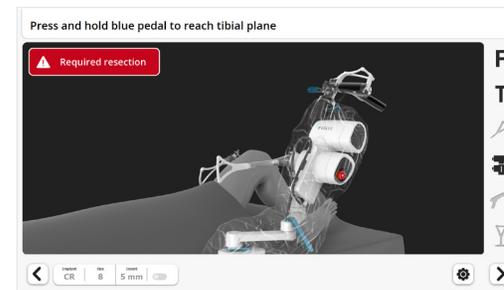
When the changes to the Surgical Planning are complete, press the blue foot pedal or tap the “Next” button  to proceed.

Recuts Execution

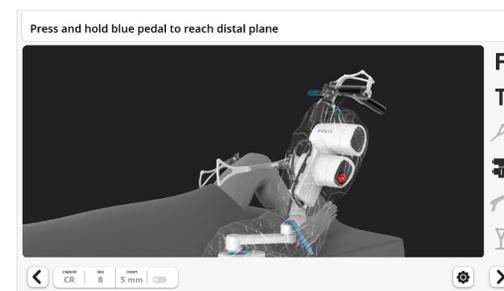
When pressing next, the successive Device Movement screens will appear. There are two options for each screen:

Option A. A text indicates a recut is required for the corresponding resection. To position the Robotic-Assisted Device to the new resection plane, press and hold the blue foot pedal.

Follow the previously described steps for making the resection and verify the recut.



Option B. No text indicates a recut is required. Tap the “Next” button  to proceed to the next Device Movement screen.



Repeat for each resection step.

Perform a Balance Assessment with Trial Implants as described in section 15, “ACCUBALANCE™ Graph Recording with Trial Implants”.

! Check on all Robotic-Assisted Device Movement screens if a recut is required.

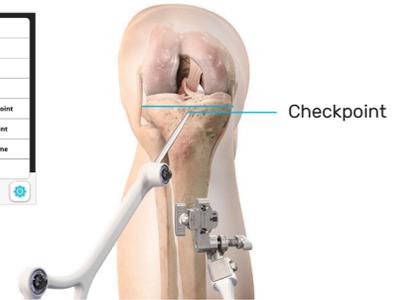
17.0 ACCUBALANCE™ Graph Recording with Final Implants (optional)

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.

! 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).

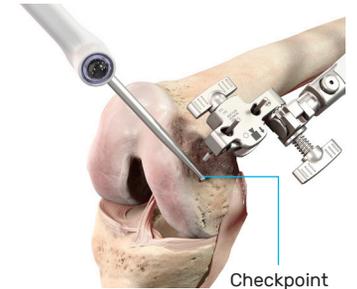
Verify the Tibia Checkpoint.



In the toolbox, select Verify Femur Checkpoint.

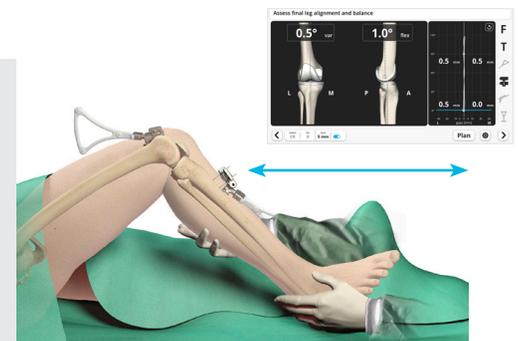
Verify the Femur Checkpoint.

To clear the Graph, tap the “Reset” button .

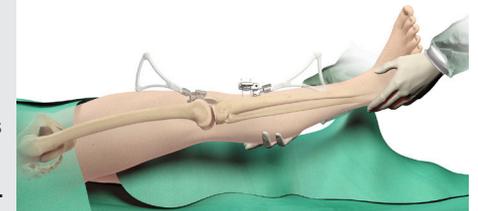


Assess the final stability, alignment, and range of motion.

The Graph will now reflect the latest information.



To record the final HKA 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 .



18.0 End of the Procedure

Removal of Instruments

Prior to closure of the knee:

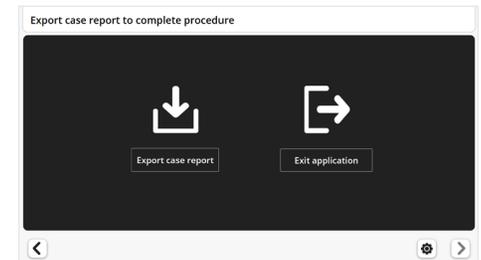
- Detach the Femur and Tibia Arrays, detach the Array Clamps
- Unscrew the Array Drill Pins

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. Press "Export Case Report".

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



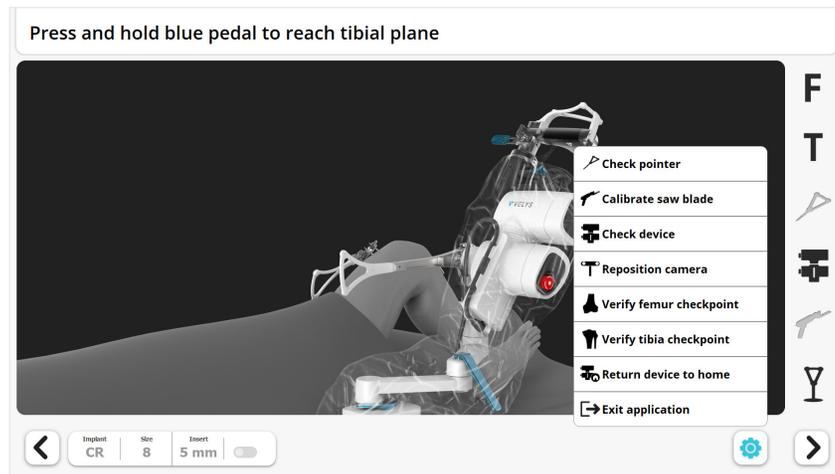
The case reports are also stored on the system and can alternatively be exported later from the Surgeon Account (see Appendix 2, "Surgeon Account").

19.0 Appendices



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.



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

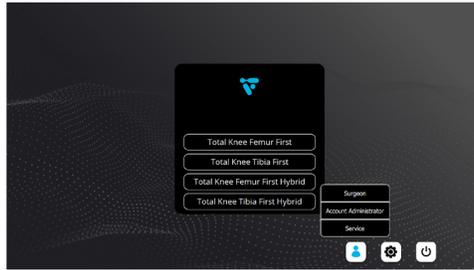
Exit the application in case the Robotic-Assisted procedure is stopped before the closing step is reached with the standard workflow.

Appendix 2: Surgeon Account

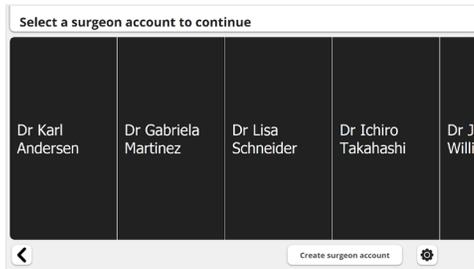
The surgeon must have an account to use the system. The Surgeon Account function allows for account creation and deletion, password changes, and other personal data updates. The Surgeon Account will also permit the export of the case reports stored on the system.

Surgeon Account Creation

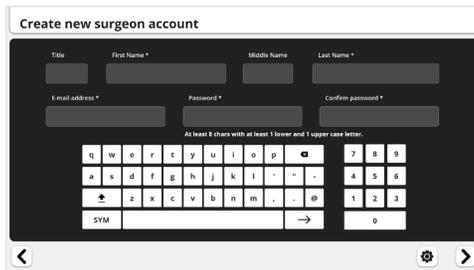
On the Home Screen press the User Icon  and then "Surgeon".



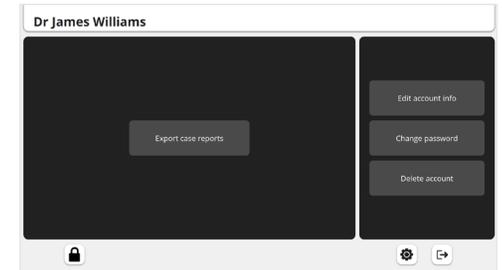
Press "Create Surgeon Account" at bottom of the screen.



Enter the surgeon information.



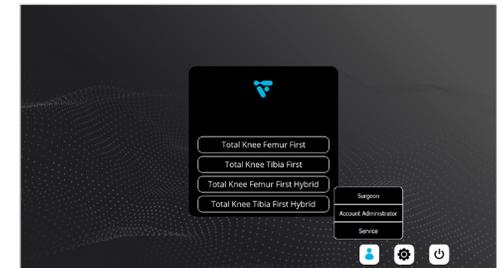
When finished, tap the "Next" button  or press the blue foot pedal to save the information and access the Surgeon Account screen.



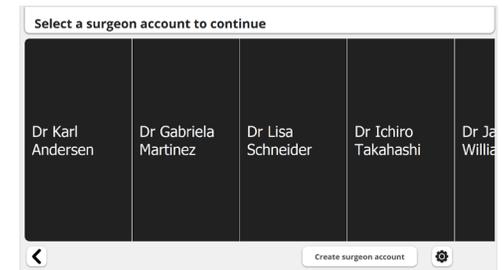
Tap  to exit and return to the Home Screen.

Account Login

On the Home Screen press the User Icon  and then "Surgeon".



Select the surgeon and enter the password.

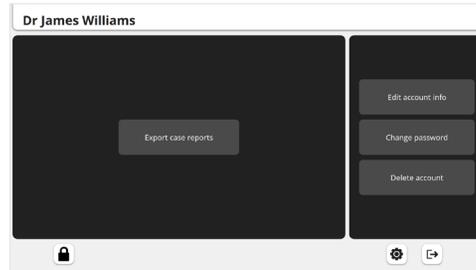


To reset the password, contact the hospital Account Administrator of the system.

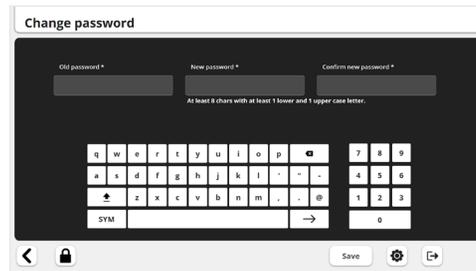
Appendix 2: Surgeon Account

Change Password

On the Surgeon Account screen, select “Change Password”.



Enter the old password and then the new password.



Press “Save” and  to exit the Surgeon Account.

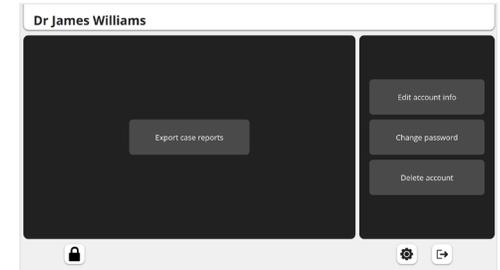
Personal Data Update, Account Deletion and Other Functions

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.

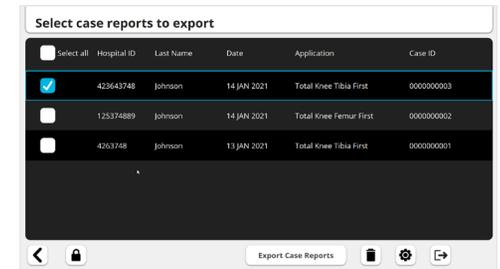
On the surgeon account screen, select “Export Individual Case Reports.”



Select the report(s) to be exported.

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

Press “Export Case Reports”.



Other functions available:

-  Delete selected cases
-  Back to Previous screen

Press  to exit the Surgeon Account.

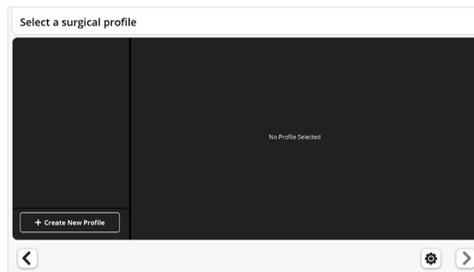
 Exporting a case will not delete it from the system.

Appendix 3: Creation of Surgical Profiles

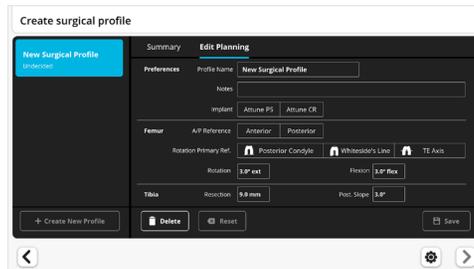
The system recognizes that each Surgeon has his or her own individual approach to TKA. Surgical profiles are important for setting the default planning options for each individual surgeon. The Surgical Profiles relate to the initial values and primary axes each surgeon desires for the initial implant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

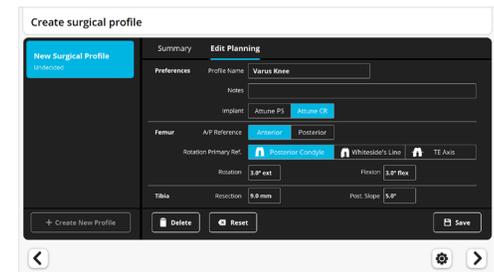
Select the femur A/P reference: Anterior or Posterior

Select the femur rotation primary reference.

Edit all other settings as desired by pressing each value.

Set the desired posterior slope for the Tibia. The recommended manufacturer posterior slope for initial ATTUNE® Primary Knee System positioning is 3 degrees for PS and 5 degrees for CR.

Press “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°
Tibia	Flexion	Femur mech. axis	3°
	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.

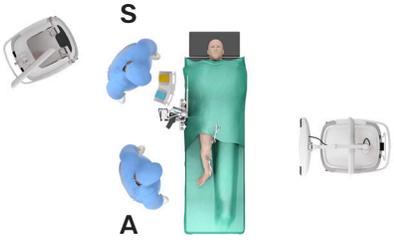
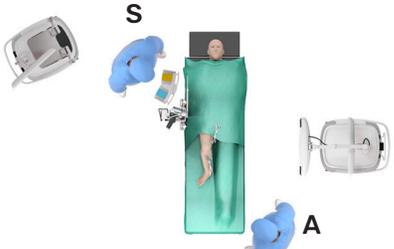
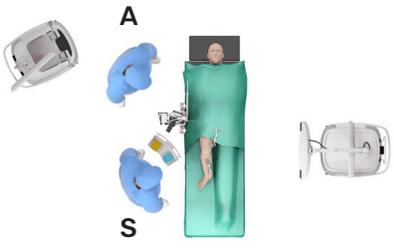
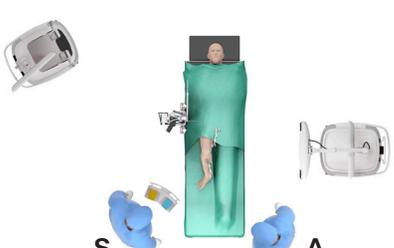
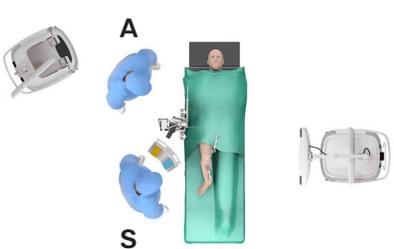
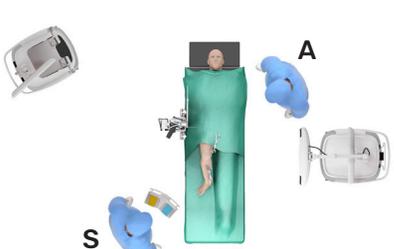
Staff positioning

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.

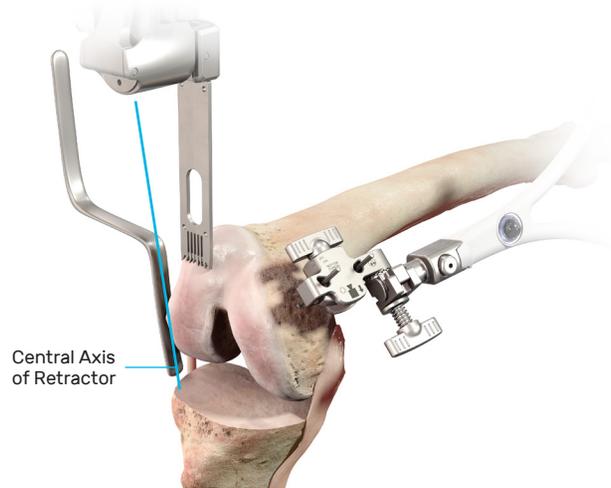
Option A	Option B
Distal femoral resection	
	
Other femoral resections	
	
Tibial resection	
	

Appendix 4: Staff Positioning and Retractors

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.



<p>Distal femur and chamfers</p> <p>Adapt the position of the retractors for each resection.</p> <p>Example 1: Use a "Z" Retractor on each side.</p> <p>Example 2: Use a bent Hohmann Retractor medially and a Hohmann Retractor laterally.</p>	<p style="text-align: center;">L M</p>
<p>Anterior femur: Protect the anterior tissues using a Volkmann or Kocher Retractor.</p>	
<p>Posterior femur: Protect the popliteal tendon.</p>	
<p>Tibia: Protect the medial and lateral collateral ligaments and the posterior tissues.</p> <p>Bringing the tibia forward will provide additional safety on the posterior soft tissues.</p>	

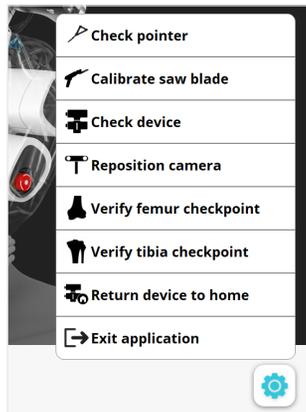
Appendix 5: Completing the Case using a Conventional Manual Procedure

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

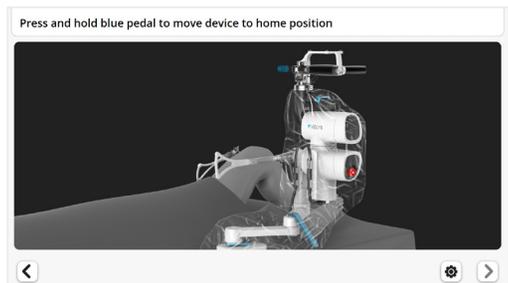
Return the Robotic-Assisted Device to its Initial Home Position to enable the transfer of the Robotic-Assisted Device back to the Satellite Cart after the surgical procedure.

In the Toolbox, press “Return Device to Home”.



Press and hold the blue foot pedal.

When finished, tap the blue foot pedal or tap the “Next” button >.



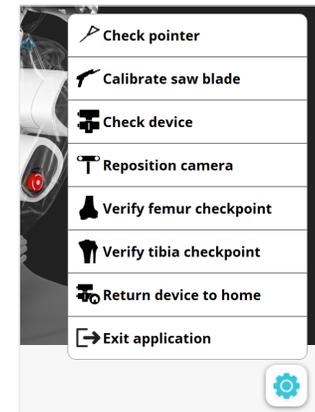
Repositioning of the Robotic-Assisted Device

The Robotic-Assisted Device can be moved away from the joint to provide more working space.

- Unlock the Holding Arm Lever (up) to permit horizontal movements.
- Move the Robotic-Assisted Device proximally along the bed, i.e., at the level of the patient’s chest.
- Lock the Holding Arm Lever (down).

Exit Application

In the Toolbox, press “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, or the INTUITION SOLO™ Single Use Instruments. Proceed as described in the ATTUNE® Primary Knee System INTUITION™ Instruments Surgical Technique for each remaining resection.

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



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