# KNEE

**Operative Technique**

# GPS Knee Newton™ Balancing Operative Technique

advita ORTHO

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The following table describes the pictorial icons commonly used in the GPS system.

| Icon | | Description |
|---|---|---|
| | Screenshot | Take a screenshot. The picture is recorded in the operative report. |
| | Exit | Exit the knee application. |
| | Go Forward | Go to the next step. |
| | Go Backward | Go to the previous step. |
| | Switch OFF | Switch OFF the station. |
| | Information | A regulatory label is displayed to provide data for labeling and CE Marks. |
| | Menu | Provides various options throughout the procedure. |
| | Open Profile | Open an existing profile. |
| | Increase or Decrease | Increase/decrease a parameter. |
| | Increase or Decrease | Increase/decrease a parameter. |
| | Edit/Delete | Edit or delete a profile. |
| | Manage Profiles | Transfer, edit or manage surgeon profiles. |
| | Add Surgeon | Create a surgeon profile. |

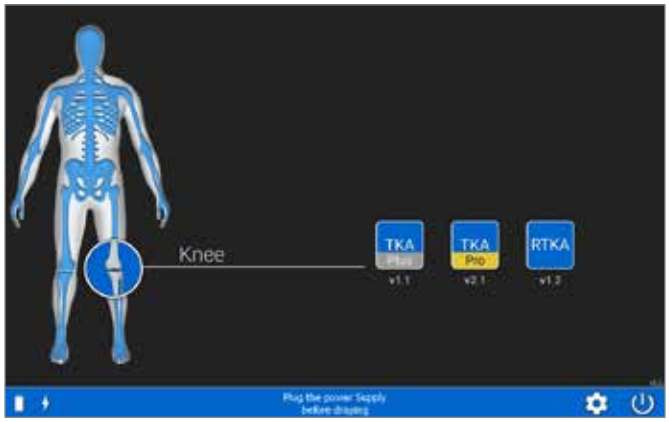


**Figure 1**
Start Application Screen

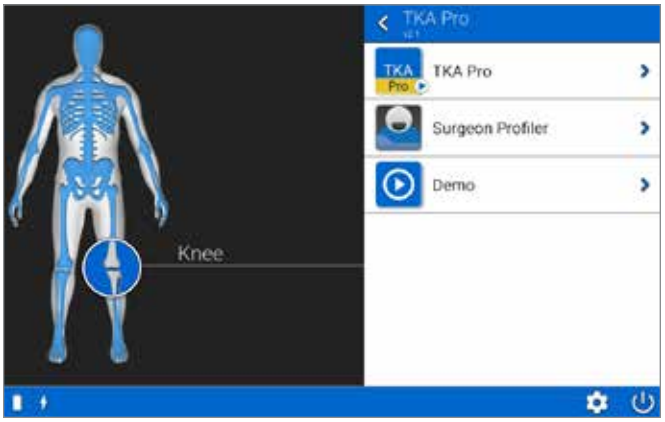


**Figure 2**
Confirmation Screen

## SYSTEM SETUP

### Application Screen

Turn on the GPS system. When prompted select the GPS TKA Pro Application *(Figure 1)*.

### Confirmation Screen

You may select to either begin the TKA Pro Application or create/edit a profile through the Surgeon Profiler *(Figure 2)*. Select the TKA Pro icon, and the system will automatically advance to the TKA Pro Welcome Screen.

**Figure 3**
Welcome Screen

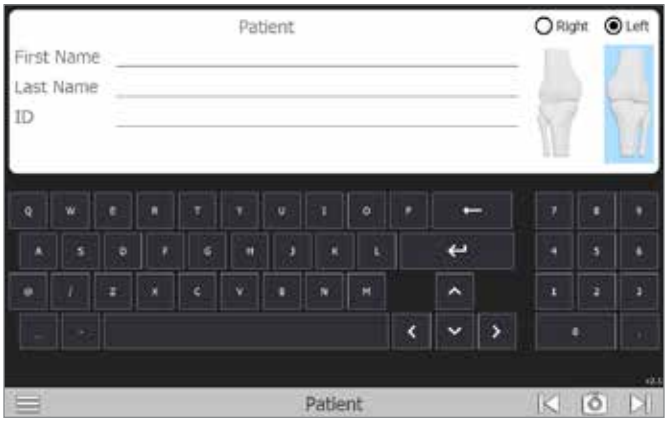


**Figure 4**
Patient Information Screen

**Welcome Screen**

Select the arrow at the lower right corner of the display to advance to the next screen *(Figure 3)*.

**Patient Information Screen**

Patient identification information may be entered in the fields displayed. You must select either the right or left knee to continue *(Figure 4)*.

**Figure 5**
Surgeon Screen

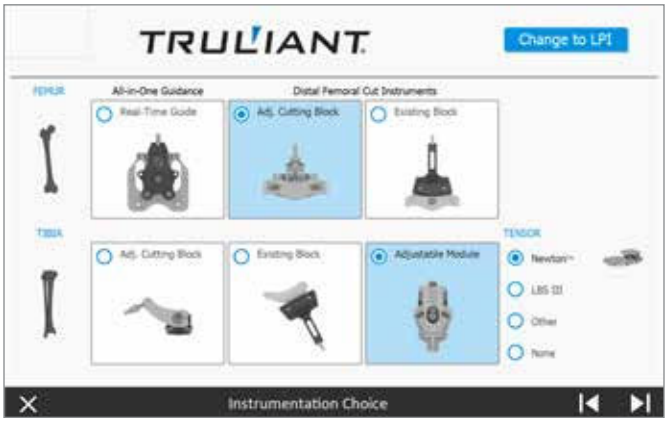


**Figure 6**
Instrument Choice Screen

**Surgeon Information Screen**

Surgeons registered on the GPS station will be displayed on the screen *(Figure 5)*. From here, you can create, edit or delete a surgeon. If you are registered on the GPS Station, click on your name and it will advance to the Instrument Choice screen.

- To register a surgeon, click on the ADD SURGEON icon and complete the requested information. Select the CREATE button. Your profile will now be displayed on the Surgeon Information Screen.
- To EDIT/DELETE registered surgeons, click on the EDIT/DELETE icon. All surgeons will be displayed. Click on the surgeon to be edited and then the edit icon to make your changes.

**Instrument Choice**

Select or change your preferred instruments *(Figure 6)*. Please note, you must select both a femoral and tibial instrument. Click the forward arrow to proceed.

**Figure 7**
Profile List Screen

**Figure 8**
Seeking Trackers Screen

**Figure 9**
Tracker Battery Position

**Profile List Screen**

All RAPID and personalized profiles are displayed *(Figure 7)*. Select your preferred profile. You may independently edit either the femoral or tibial parameters (SMART Edit) or you may modify the entire current profile (SMART Edit All Parameters).

For a comprehensive guide to editing the surgeon profiles, refer to main GPS TKA Pro Operative Technique.

If no changes are desired, click on the START SURGERY icon.

***Note:*** *Surgeon profile set up will be default upon log in next time.*

**Select Trackers**

Insert batteries (positive end first) into the Probe (P) Tracker, Femoral (F) Tracker, Tibial (T) Tracker and the Guide (G) Tracker *(Figure 8)*.

***Caution:*** *Inserting the batteries incorrectly may cause permanent damage to the tracker. Be sure to insert the batteries with positive side to positive first (Figure 9).*

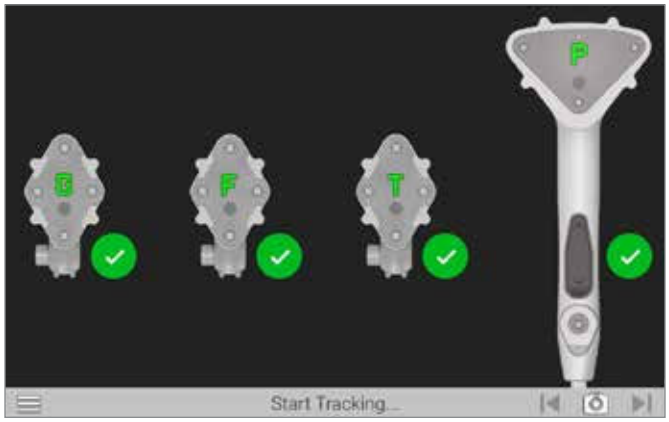


**Figure 10**
Verify Connection

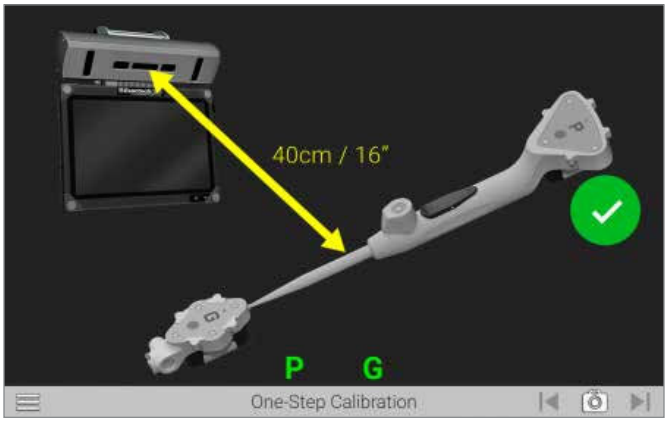


**Figure 11**
One-Step Calibration

Once the batteries are installed and the trackers are visible to the camera, a status LED on each tracker will illuminate solid red/orange and begin to blink green.

Position the trackers with the LEDs facing the camera of GPS Unit approximately 16 inches away. The trackers will display on the screen and a green check mark will appear to verify connection *(Figure 10)*.

**One-Step Calibration**

Place the tip of the Probe into the dimple at the top of the G Tracker *(Figure 11)*.

Hold both together approximately 16 inches from the camera of the GPS Unit ensuring the trackers are facing the camera. When positioned correctly, the "G" and "P" status indicators on the display will appear green.

Press and release the Forward button on the Probe to initiate calibration. The progress circle will fill and once filled, a green check mark appears to indicate a successful calibration.

The system will automatically advance to the next screen.

## EXTERNAL TRACKER FIXATOR

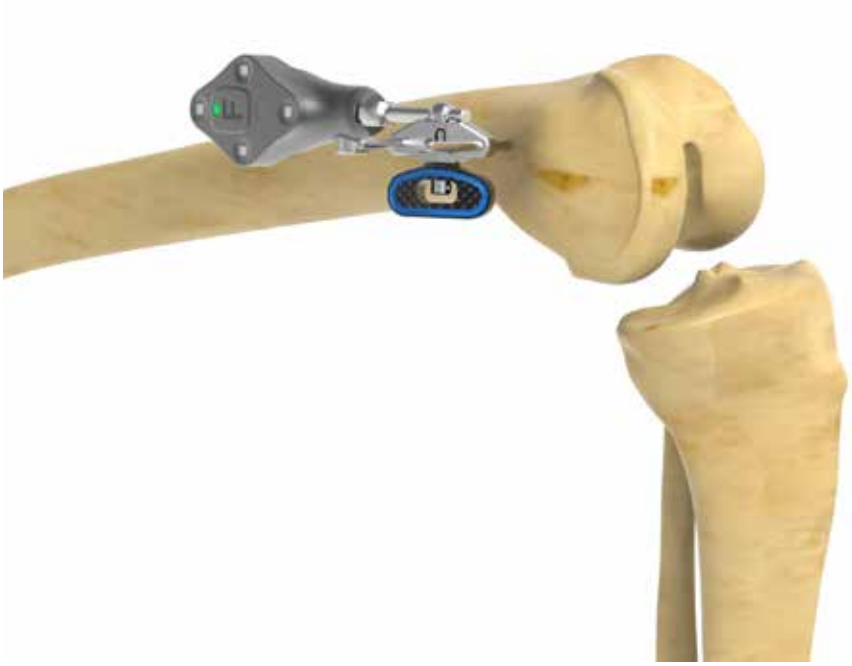

**Figure 12**
Place the External Tracker Fixator

### APPROACH AND EXPOSURE

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

### FEMORAL PLACEMENT OF THE EXTERNAL FIXATOR AND FEMORAL TRACKER

Drill the first 5.1-inch Schanz Pin slightly anterior and proximal to the medial epicondyle. This should be done at an angle approximately 20 degrees anterior from the coronal plane. Recommend distal pin placement 1cm anterior and Proximal to the MCL insertion point.

Using an External Fixator, guide the position of the second 5.1-inch Schanz Pin to be pinned proximally to the first.

Next, place the F Tracker onto the External Tracker Fixator and lock into place *(Figure 12)*. Verify the F Tracker is securely locked to the External Tracker Fixator.

Be sure the F Tracker is pointing at the camera prior to tightening the External Tracker Fixator. The 3.5mm Hex Screw Driver may be used if additional tightening of the External Tracker Fixator is needed.

***Note:*** *It is critically important to assure that the fixator is tightened before moving on to the next step. An inadequately tight fixator can cause tracker movement leading to inaccurate assessment and measurement of the surgical plan.*

**Figure 13**
Assemble Tibial Template to Tibial Base

**Figure 14**
Assemble Tibial Stylus to Tibial Template

### TIBIA BASE AND TRACKER PLACEMENT

Attach the Pro Tibial Template to the side-specific (left and right) Truliant Pro Tibial Base *(Figure 13)* using 3.2mm Collared pins.

Place the foot of the Truliant Adjustable Tibial Stylus into the stylus slot of the Tibial Template *(Figure 14)*.

**Figure 15a**
Position Assembly Against Tibia

**Figure 15b**
Pin the Tibial Base and Remove the Rest of the Assembly

**Figure 15c**
Attach T Tracker to Tibial Base

Position the assembly against the tibia, just medial to the tibial tubercle. Adjust the lower end of the Tibial Template so the shaft of the Template is parallel with the tibia *(Figure 15a)*. The tibial resection level can be adjusted by turning the dial on the top of the Tibial Stylus to the desired depth (ranging from 0 to 14mm) from the tip of the stylus.

***Note:*** *To ensure that the instruments will have enough range to perform the desired resection, it is important to match the stylus resection amount to the plan within the GPS software.*

Pin the Tibial Base in position and remove the Tibial Template and Tibial Stylus *(Figure 15b)*.

Attach the T Tracker to the Tibial Base *(Figure 15c)*.

***Note:*** *It is important to ensure the tracker is locked into place and does not rotate or move when connected to the instrument. Perform a pull test on the tracker to ensure connection.*

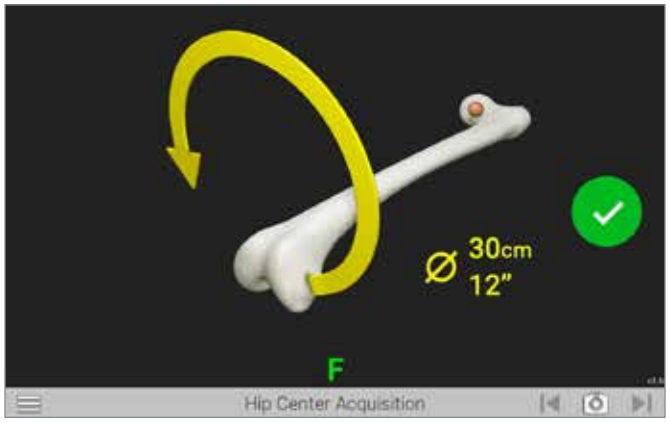


**Figure 16**
Hip Center Acquisition Screen

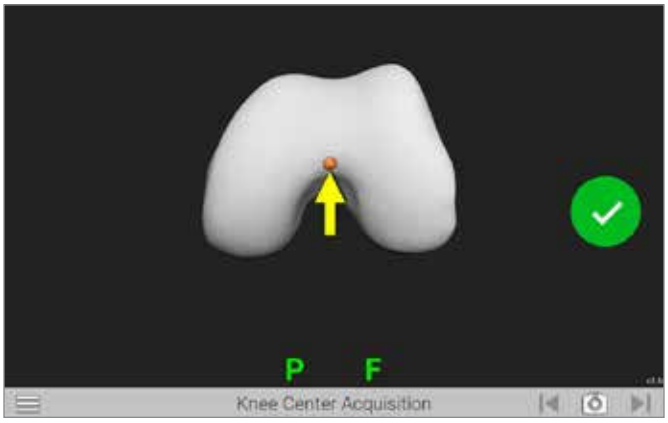


**Figure 17**
Knee Center Acquisition Screen

## HIP AND KNEE CENTER ACQUISITIONS

### Hip Center Acquisition

Movement of the bone will initiate the acquisition process *(Figure 16)*. Move the knee in a 12-inch diameter circular pattern as illustrated on the display.

***Note:*** *Large diameter, slow circular motion may be more effective than rapid small radii circles. The progress bar will fill, and audible clicks will indicate successful registration of points. An audible tone will indicate registration is complete and the system will automatically advance to the next screen.*

***Caution:*** *It is important to ensure the pelvis remains stable during the hip center acquisition process.*

### Knee Center Acquisition

Position the tip of the Probe in the deepest point of the intercondylar notch *(Figure 17)*.

***Note:*** *The hip and knee centers are used to define the mechanical axis of the femur.*

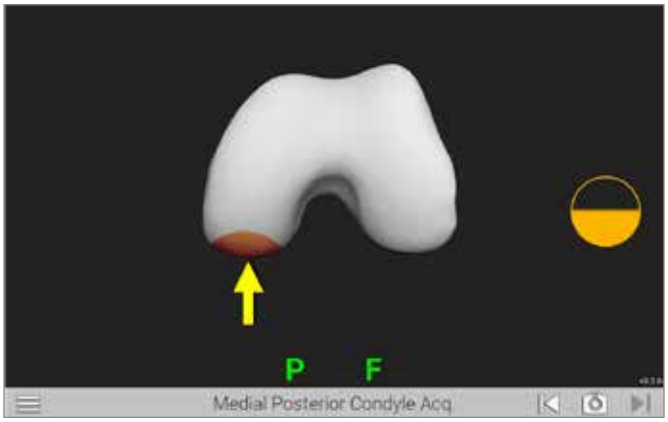


**Figure 18**
Medial Posterior Condyle Acquisition Screen

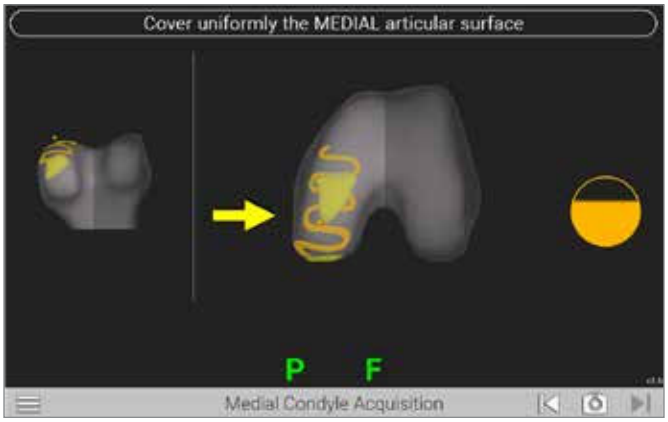


**Figure 19**
Medial Distal Condyle Acquisition Screen

**Acquisition of the Femoral Condyles**

GPS does not require any pre-operative imaging. In order to provide the most accurate representation of the patient anatomy, acquisition of the native femur must occur.

In order to acquire adequate data, the user will be guided to gather points in specific areas represented by orange patches *(Figures 18 and 19)*.

Femoral registration will occur in the following order:
1. Posterior Medial Condyle
2. Posterior Lateral Condyle
3. Distal Medial Condyle
4. Distal Lateral Condyle

***Note:*** *During the acquisition phase, it is important to be sure that the probe always maintains contact with the femur.*

Begin the registration process by positioning the tip of the Probe on the medial posterior condyle press the Forward button *(Figure 18)*.

Assure that the probe captures the most posterior aspect of the condyle, start posteriorly inside yellow patch and move anteriorly and continue registration until the orange indicator fills, changes to a green checkmark, and an audible tone is heard *(Figure 19)*.

The system will automatically advance to the next step. Follow the onscreen prompts to complete the remaining condylar acquisitions.

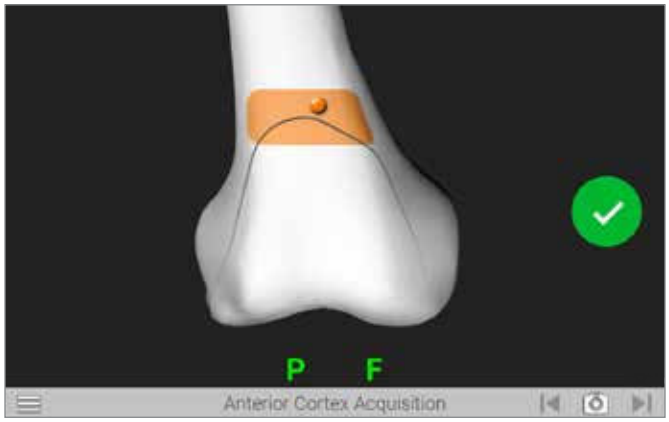


**Figure 20**
Anterior Cortex Acquisition Screen

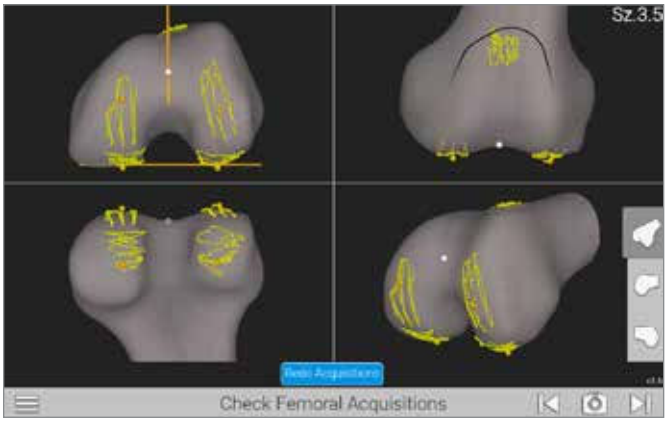


**Figure 21**
Verify Femoral Acquisition Screen

**Anterior Cortex Acquisition**

Based on the previous registrations, the system determines the approximate femoral component size and requires registration of points within the patch displayed. The relative location of the tip of the Probe will be shown as an orange dot on the display.

Position the tip of the Probe so the dot is within the patch displayed and press the Forward button to begin acquisition *(Figure 20)*. To maintain accuracy, please be sure to register the medial and lateral aspects of the anterior cortex.

**Check Femoral Acquisitions**

After the femoral acquisitions have been completed, the accuracy of the registration can be verified.

A graphical representation of the registered points (yellow dots) will be displayed *(Figure 21)* with orange dots representing the points that will be used by the system to determine resection levels.

For additional views of the registered points, select one of the three options located on the bottom right of the screen.

***Note:*** *If re-registration is required, press the "REDO ACQUISITIONS" button at the bottom of the screen (Figure 21).*

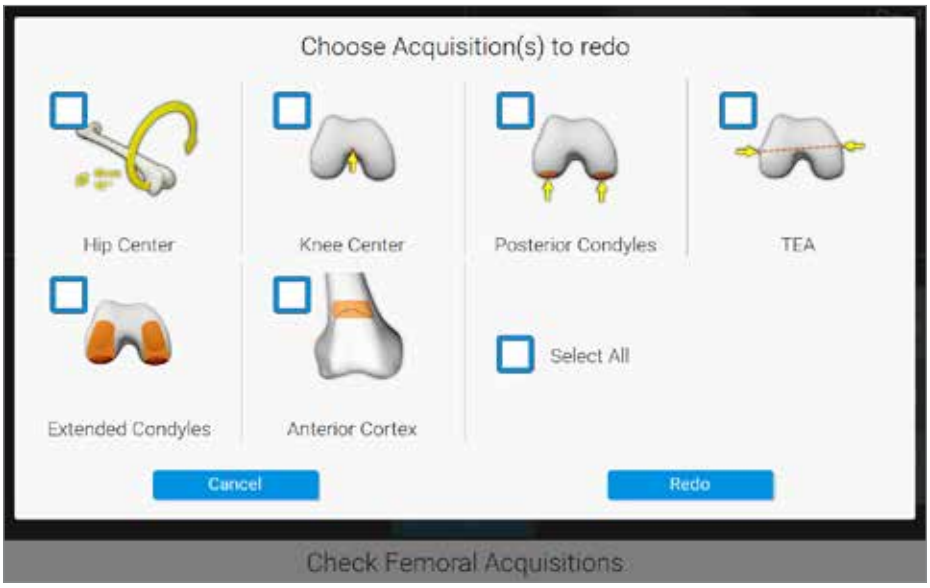


**Figure 22**
Redo Femoral Acquisition Screen

*The user will now be prompted to select which acquisitions to repeat and will move forward by pressing the "Redo" button (Figure 22).*

*Once completed, a summary screen will appear and if no other changes are desired, advance to the next screen.*

### TIBIA ACQUISITIONS

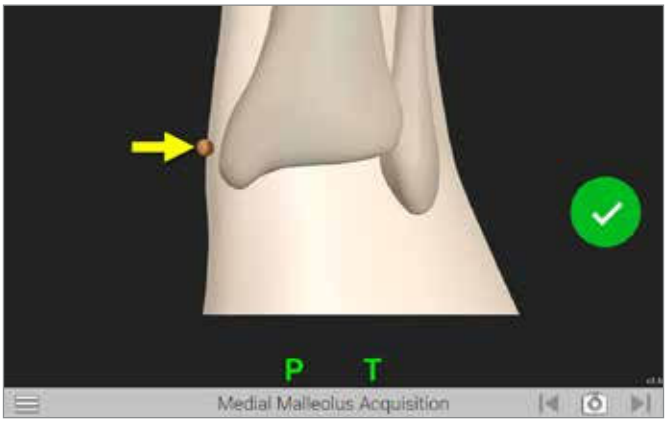


**Figure 23a**
Medial Malleolus Acquisition Screen

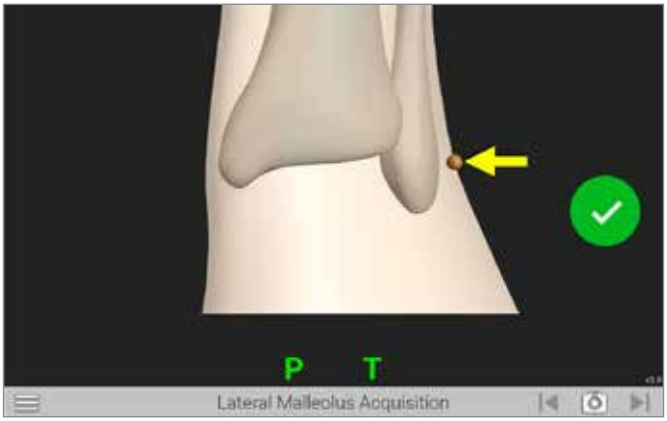


**Figure 23b**
Lateral Malleolus Acquisition Screen

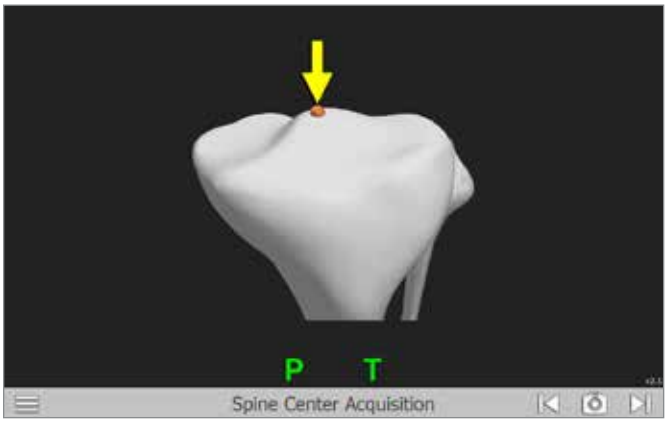


**Figure 24**
Tibia Center Acquisition Screen

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### TIBIA ACQUISITIONS

Once the femoral anatomy has been registered, a similar process will be followed to acquire the tibial points.

Tibia registration will occur in the following order:
1. Medial Malleolus
2. Lateral Malleolus
3. Tibia spine center
4. Sagittal (Slope) Plane
5. Medial Plateau
6. Lateral Plateau

**Mechanical Axis Acquisition**

The process will begin with determining the mechanical axis of the tibia by acquiring the medial and lateral malleolus, and the center of the tibia spine.

Position the tip of the Probe on the medial malleolus and press the Forward button to register this point *(Figure 23a)*. Follow the onscreen prompts to capture points for the lateral malleolus *(Figure 23b)* and the center of the tibia spine *(Figure 24)*

***Note:*** *The tibia center point is best represented by the most anterior point of the insertion point of the PCL. This point combined with the ankle center, will establish the mechanical axis of the tibia.*

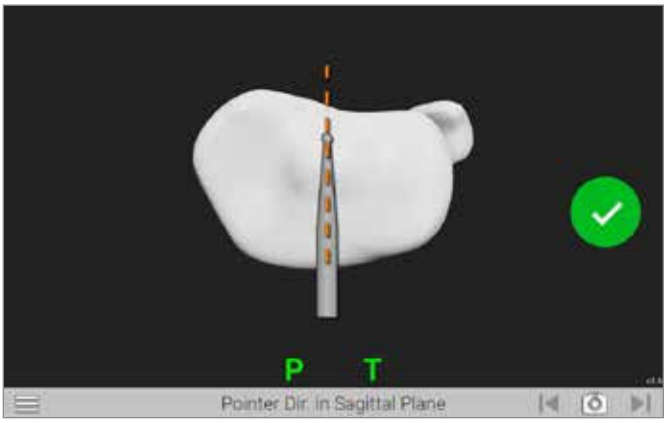



**Figure 25**
Pointer Direction in Sagittal Plane Acquisition Screen

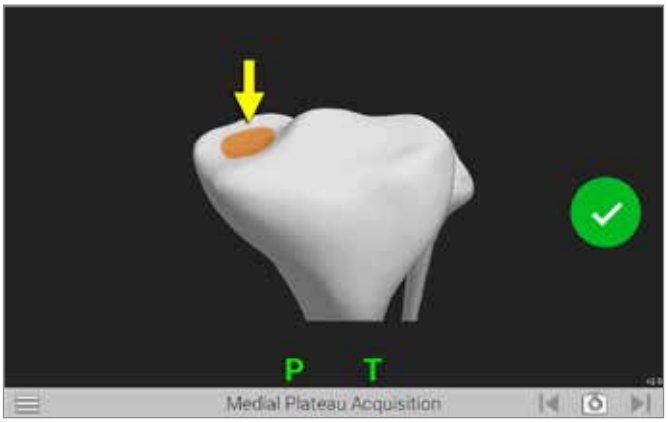



**Figure 26**
Medial Plateau Acquisition Screen

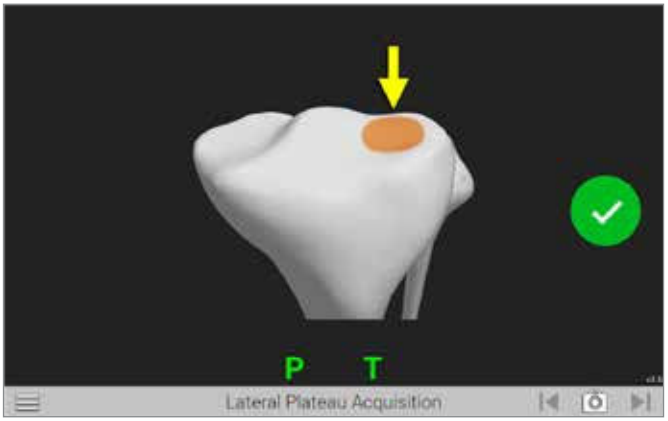



**Figure 27**
Lateral Plateau Acquisition Screen

**Sagittal (slope) Plane Acquisition**

Position the tip of the Probe at the posterior center (PCL insertion) and the shaft of the Probe on the proximal tibia along a line connecting the center of the tibia and the medial-third of the tibia tubercle *(Figure 25)*. Press the Forward button to register this orientation. The system will automatically advance to the next screen.

**Tibia Plateau Acquisition**

Position the tip of the Probe on medial tibial plateau and press the Forward button *(Figure 26)*. Ensure the probe maintains contact with the tibial plateau and trace a patch that captures the lowest point on the medial tibial plateau.

Once complete, follow the onscreen prompts to complete registration for the lateral plateau *(Figure 27)*.

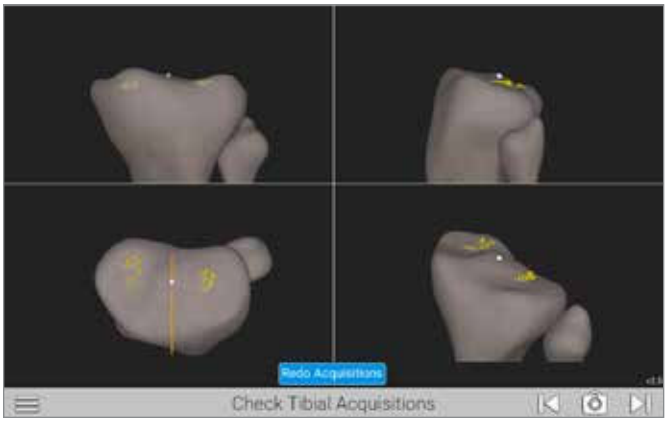



**Figure 28**
Verify Tibial Acquisition Screen

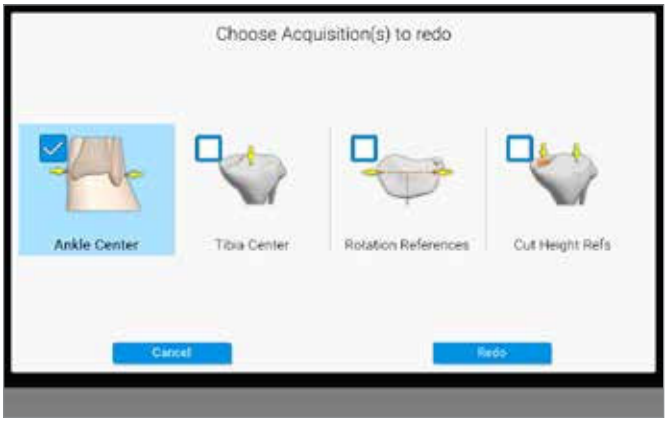



**Figure 29**
Redo Tibial Acquisition Screen

**Check Tibial Acquisitions**

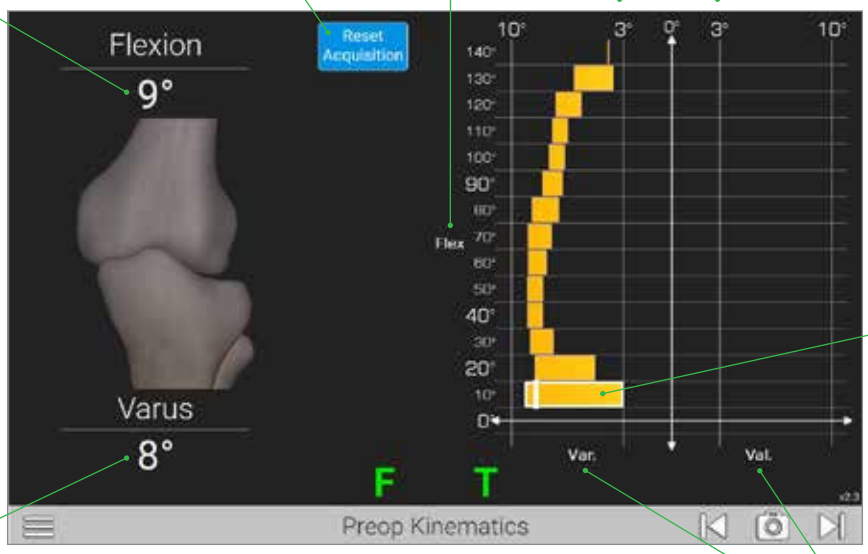
A graphical representation of the registered points is displayed *(Figure 28)*. The yellow dots show the areas where the points were registered. Additionally, orange dots are shown to represent the points from which the resection levels will be calculated.

If the orange dots do not accurately represent the deepest part of the articular surface, the acquisitions can be redone.

***Note:*** *If it is necessary to redo the registrations for any points, select the REDO ACQUISITIONS button at the bottom of the screen.*

If necessary, the user be prompted to select which acquisitions to repeat and will move forward by pressing the "Redo" button *(Figure 29)*.

Once completed, a summary screen will appear. If no other changes are desired, advance to the next screen.




**Reset Acquisition:** Clears the graph

**3° lines:** The two vertical white lines at +/- 3° of mechanical alignment serve as a visual indicator of acceptable mechanical alignment as stated in the literature.

**Flexion:** Live measure of the patient's flexion angle

**Flex:** Indicates flexion angle at which data is captured

**Yellow bars:** The width of the yellow bars indicates measured laxity of the joint at the given flexion angle as varus/valgus stress is applied. The white line represents the live alignment of the joint.

**Varus:** Depicted as "Varus" in this image, the value represents overall alignment, and will shift between Varus & Valgus depending on patient anatomy.

**Var. & Val.:** Indicates captured patient alignment at each 10° of range of motion.

**Figure 30**
Pre-op Kinematic Screen

## UNDERSTANDING AND REVIEWING PRE-OP KINEMATICS

### Pre-op Kinematic Screen

A live graphical representation of the presurgical knee provides live data to inform the surgeon of laxity and alignment at a given flexion angle to inform surgical decision making *(Figure 30)*.

The range of motion, laxity of the joint, and native alignment of the knee can be used to make an informed decision regarding the depth, slope and angle of the tibial resection.

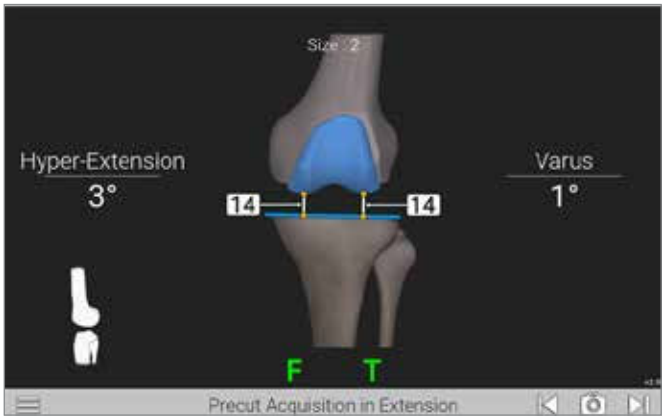



**Figure 31**
Acquiring the Extension Gaps

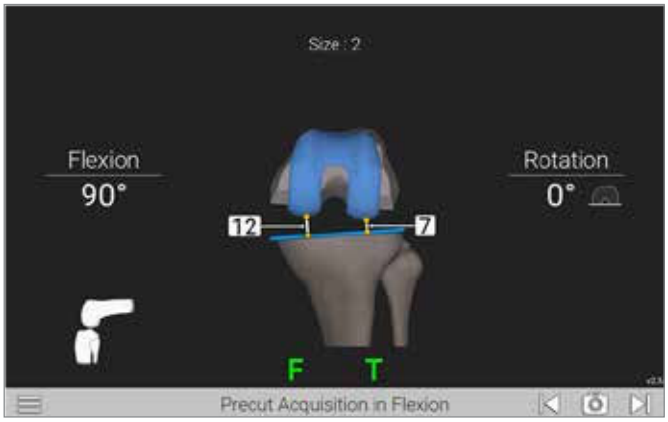



**Figure 32**
Acquiring the Flexion Gaps

After the pre-op kinematics have been captured, the software will advance to the PreCut acquisition screens. The software will guide the surgeon through the acquisition of the medial and lateral gaps in both flexion and extension providing data required to plan the Tibia resection.

**Acquiring Pre-Resection Gaps**

To acquire the anatomic pre-resection gaps, static poses will be captured in two positions: flexion and extension. To begin the acquisition process, assure that the knee is in full extension and apply stress until the appropriate native, natural, resting ligament tension is achieved both, medially and laterally *(Figure 31)*. Advance to the next screen by pressing the forward arrow to capture the extension gap data.

Repeat this process with the knee in 90° of flexion to complete the Pre-Cut acquisitions *(Figure 32)*. Capture the gap data by pressing the forward arrow to advance to the next screen.

***Note:*** *If desired, a distraction tool (e.g. osteotome or spacer/ spoon) can be placed between the unaffected tibia and femoral condyle to assist in capturing natural, resting ligament tension.*

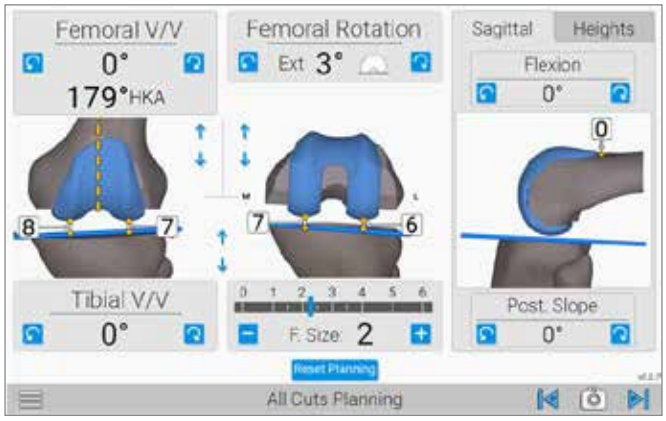



**Figure 33**
Femur and Tibia Cut Planning Screen: Flexion

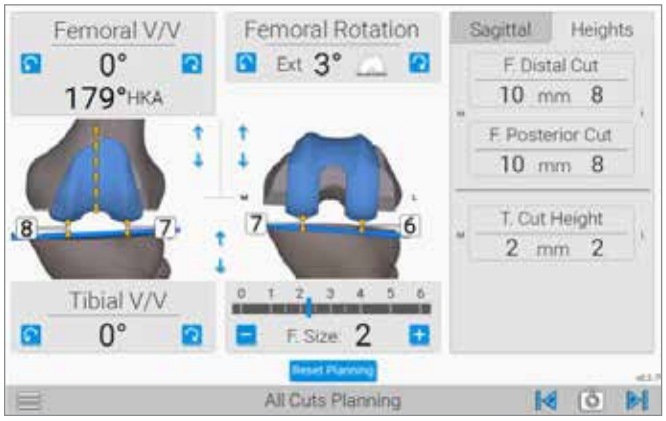



**Figure 34**
Femur and Tibia Cut Planning Screen: Heights

### RESECTION REVIEW

This screen allows the user to plan Tibial resections *(Figure 33)*. Preliminary femoral resection amounts are shown; however, the femoral plan will be recalculated during the subsequent full range of motion acquisition and plan.

It is important to know that the resection levels have been moved from the primary screen to the "Heights" tab.

By Selecting the "Heights" tab, you will gain visibility to the resection depths of the Tibia Cut *(Figure 34)*.

Switching back to the "Sagittal" tab will return to the sagittal view and access to the Flexion and Tibia Slope adjustments *(Figure 33)*.

Adjust Tibia resection cut height by considering Extension (HKA) and Flexion gaps (Middle Panel) shown on *Figure 33*.

***Note:*** *The full range of motion Tensioner's collapsed minimum thickness is 7.25mm. Be sure to allow for at least 8mm of space between the resected tibia surface and the native femur for effective operation of the tensioner.*

Once the tibia plan has been completed, advance to the next screen by pressing the forward button.

# DETAILED OPERATIVE TECHNIQUE

## TIBIA RESECTION

**Figure 35**
Attach Adjustable Module and G Tracker to Tibial Base

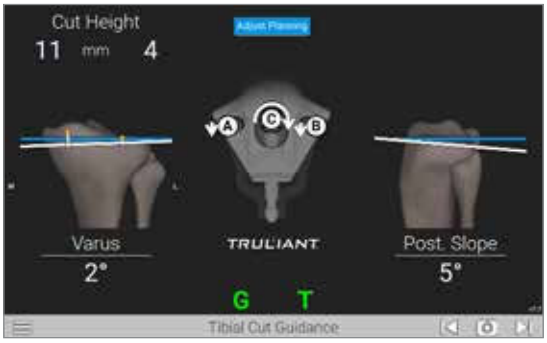



**Figure 36**
Tibial Cut Guidance Screen

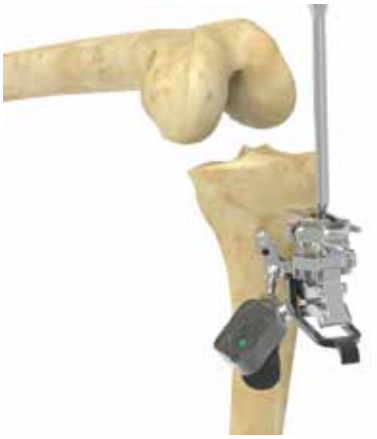


**Figure 37**
Adjust the Adjustable Module

### PLANNING THE TIBIAL RESECTION

Attach the TKA Pro Adjustable Module and G Tracker to the Tibial Base *(Figure 35)*.

Verify that the Adjustable Module is securely locked onto the Tibial Base and that the G Tracker is securely locked to the module and facing the camera of the GPS Unit.

***Note:*** *It is important to ensure the tracker is locked into place and does not rotate or move when connected to the instrument. Perform a pull test on the tracker to ensure connection.*

The Tibial cut guidance screen will be displayed. The blue lines indicate the planned tibial resection *(Figure 36)*. The white lines represent the resection based on the position of the Adjustable Module. The medial and lateral resection depth, varus/valgus and posterior slope parameters displayed are consistent with the alignment of the Adjustable Module.

Use the 3.5mm Hew Driver to turn the A, B and C screws in alphabetical order *(Figure 37)* on the Adjustable Module. The arrows displayed on the GPS screen indicate both magnitude and direction each screw needs to be turned for planned alignment. The A, B and C indicators, the arrows and white lines will change to green when the Adjustable Module is within 1mm or 1 degree of the planned resection. As the position approaches the target, the arrow will disappear. Advance to the next screen when adjustments are complete.

***Note:*** *Select ADJUST PLANNING to change to Tibial Cut Planning screen where resection depth, varus/valgus angle and tibial slope angle can be modified. Select RESUME GUIDANCE to return to the Tibial Cut Guidance screen.*

**Figure 38**
Attach Tibial Resection Guide

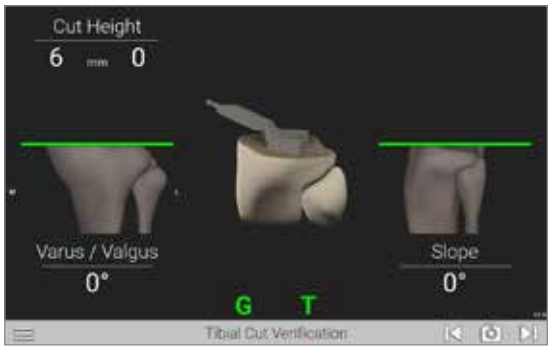



**Figure 39a**
Tibial Cut Verification Screen

**Figure 39b**
Verify Tibial Resection

### PERFORMING THE TIBIAL RESECTION

Attach the Pro Tibial Resection Guide to the Adjustable Module *(Figure 38)* by pressing the button on the Tibial Resection Guide and sliding the Guide onto the dovetail track of the Adjustable Module. Ensure the Guide contacts the tibia and is securely locked in position. Pin the Resection Guide using the lowest (distal) pin holes. A center divergent pin hole is available and optional.

***Note:*** *The G Tracker may be removed at this time to further enhance saw blade access.*

Perform the tibial resection. If desired, the saw may be inverted to increase access to cutting slot.

Advance to the Tibial Cut Verification screen *(Figure 39a)*. After the resection has been completed, assemble the G Tracker to the Truliant Blade Drill Guide.

Verify the tibial resection by placing the Truliant Blade Drill Guide against the proximal tibial resection *(Figure 39b)*.

Press Forward button on Probe to advance to the next screen and save your data.

The Tibial Resection Guide and the Pro Adjustable Module can now be removed.

Continue with the primary tibial preparation according to the protocol found in the Truliant Primary Knee System operative technique (OPTECH-000189).

***Note:*** *After completion of the proximal tibial resection, ensure osteophytes have been cleared from the femur/tibia. In addition, if a PCL sacrificing component is to be used, the PCL should be removed prior to advancing to gap acquisitions.*

**Figure 40a and 40b**
Assemble the Tensioner with the Inserter Handle

**Figure 41**
Insert Assembly into Joint and
Remove the Inserter from the Tensioner

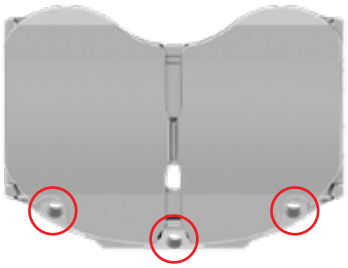


**Figure 42**
Pin the Tensioner to the Tibia Using
Any of the Three Anterior Pin Holes

### PERFORMING THE FULL RANGE OF MOTION ACQUISITION

Attach the unlocked, open Inserter to the Tensioner *(Figure 40a)*.

Squeeze the Inserter handle to compress the Tensioner and then switch the lever to LOCK *(Figure 40b)*.

Insert the Tensioner into between the resected tibia, and native unresected femur.

Unlock and remove the Inserter leaving the Tensioner between the tibia and femur *(Figure 41)*.

If desired, Tensioner may be pinned to the tibia using the three anterior pin holes (see *Figure 42)*.

***Note:*** *After completion of the proximal tibial resection, ensure osteophytes have been cleared from the femur/ tibia. In addition, if a PCL sacrificing component is to be used, the PCL should be removed prior to advancing to gap acquisitions.*

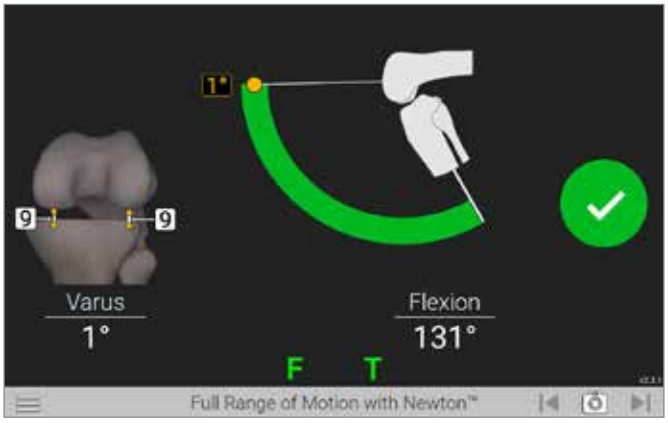



**Figure 43**
Perform the Full Range of Motion Acquisition

**Figure 44**
Overall Femoral Planning Screen

***Note:*** *To reduce creep of the soft tissue, it is recommended to run the leg through range of motion with the Newton Tensioner in place 2-3 times prior to the final acquisition.*

Starting with the knee in extension, confirm your varus valgus alignment and perform soft tissue releases as needed. Press the forward button on the probe or the screen to start the recording of the acquisition. Support the femur and allow the tibia to follow without any varus or valgus stress through the full range of motion *(Figure 43)*. A green check mark will appear and audible tone is heard when acquisition is compete.

### PLANNING THE FEMORAL RESECTIONS

Once the gap acquisitions have been performed, the software will advance to the Femoral Planning screen *(Figure 44)*.

The femoral planning screen allows the user to select the appropriate component placement based on gaps assessed using the Tensioner.

The component's starting location will be determined by the surgeon profile selected.

**Left Panel** displays femoral varus/valgus angle perpendicular to the mechanical axis and the distal resection depth from each condyle.

Varus/Valgus adjustments can be made impacting distal resection, and soft tissue balance in extension.

The up and down arrows adjust the distal resection and can be used to open/close soft tissue gaps equally in extension *(Figure 45a)*.

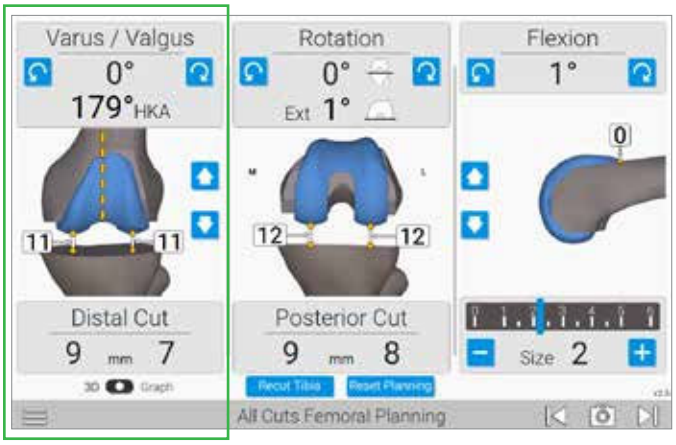



**Figure 45a**
Varus /Valgus

**Middle Panel** displays the femoral rotation relative to the posterior condyles along with the resection depth of the posterior condyles.

Rotational adjustments can be made impacting posterior resections, and soft tissue balance in flexion *(Figure 45b)*.

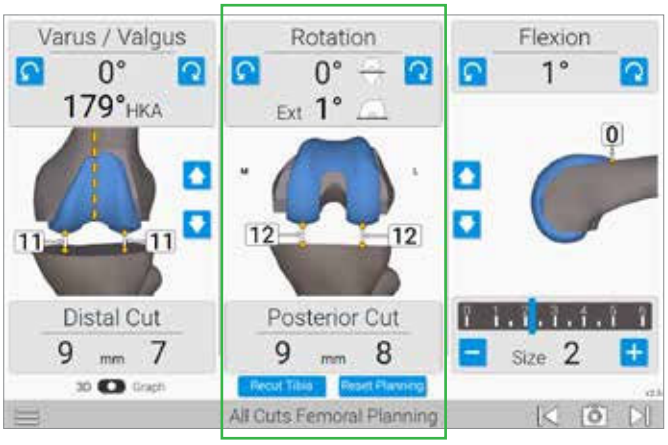



**Figure 45b**
Rotation

**Right Panel** displays femoral flexion, anterior flange position and femoral component size. The femoral component rotates about the tip of the anterior flange (orange dot) to generate the desired flexion angle. Flexion angle can be used to close or open the posterior gaps equally.

***Note:*** *When the flexion angle is adjusted, the component pivots around the tip of the anterior flange to avoid notching of the anterior femur.*

The arrows in the middle of the panel adjust anterior-posterior position impacting the posterior resection and anterior flange position. The orange dot and number indicate the offset of the anterior flange relative to the anterior cortex of the femur.

Additionally, the femoral component size can be adjusted at the bottom of the panel effecting the posterior resection *(Figure 45c)*.

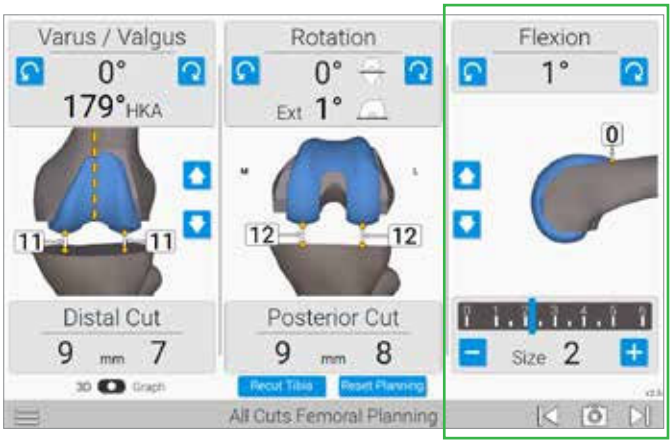



**Figure 45c**
Flexion

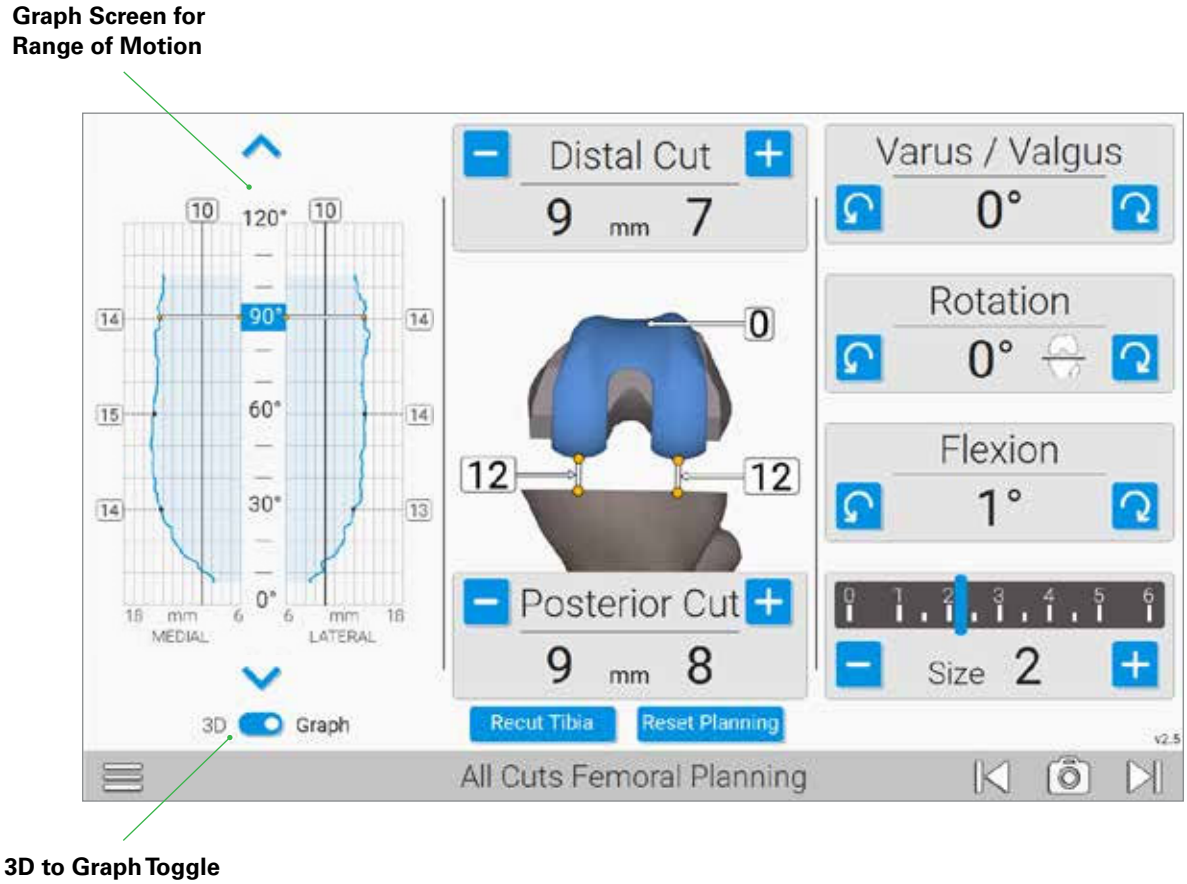



**Figure 46**
All-Cuts Femoral Planning Screen
(panels vary depending on your profile selection)

Additional gap information can be reviewed by switching to "Graph" located on the lower left corner of the screen *(Figure 46)*.

### UNDERSTANDING THE GAP GRAPH

**3D to Graph Toggle (bottom left)** changes the all cuts femoral planning view to include a graphical representation of the soft tissue gaps.

The blue shaded area is a visual representation of the predicted post-operative soft tissue balance based on planned position of the implant. As adjustments are made to the femoral plan, the graph will update in real time to reflect the new predicted gaps.

Additionally, when "Graph" is toggled, adjustments for V/V, rotation, flexion, and size shift to the right panel.

The 3D representation of the femur in the middle panel will show the gaps of the selected angle represented by a blue square in the center column of the graph; in this example 90-degrees *(Figure 46)*.

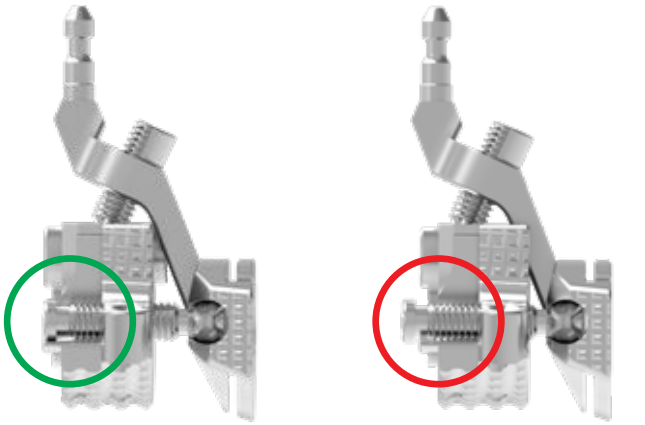
**Graph:** The graph shown displays the gap between the resected tibia surface and the planned femoral component throughout range of motion *(Figure 46)*.

The blue line represents the gaps (mm) for both M/L compartments. The black line serves as a reference point for a 10mm gap.

The circles show numerical gap values at fixed point with additional angles available by selecting the arrows at the top and bottom of the graph. Additionally, any angle can be chosen by touching the desired angle position.

Once an appropriate plan has been selected, press the button to move on to the femoral resections.

## ADJUSTABLE CUTTING BLOCK
Placement and Adjustments



*(Side View) CORRECT* *(Side View) INCORRECT*

**Figure 47**
Neutralize the Block

**Figure 48**
Place the Adjustable Cutting Block

### PERFORMING THE FEMORAL RESECTIONS

**Neutralizing the Cutting Block**

Prior to executing the femoral resections, the Femoral Adjustable Cutting block needs to be set to the Neutral position.

As shown, neutralize the block by aligning the screw ends flush to the instrument body *(Figure 47)*.

**Placing the Cutting Block**

Place the G Tracker on the Adjustable Cutting Block facing the camera of the GPS Unit and verify the tracker is securely locked into place.

To position the block on the femur, hold the Adjustable Cutting Block with the G Tracker facing the camera and place on the anterior femur.

Minimize the distance between the blue and the white line displayed to reduce the number of adjustments needed.

Pin the TKA Adjustable Cutting Block to the femur using at least two pins, one on each side *(Figure 48)*. It is recommended to use 3 threaded pins to ensure stability of the block.

## ADJUSTABLE CUTTING BLOCK
Parameter Adjustments

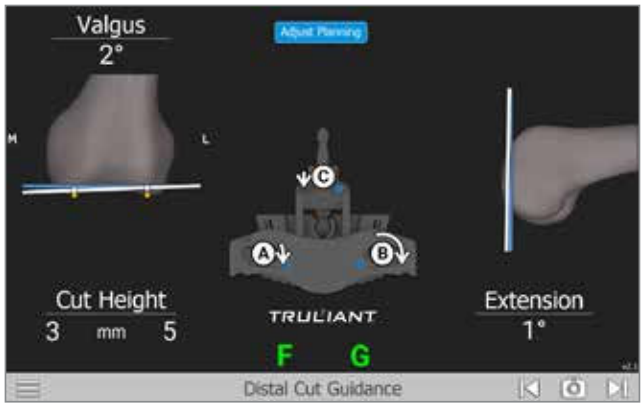



**Figure 49a**
Distal Femoral Cut Guidance Screen

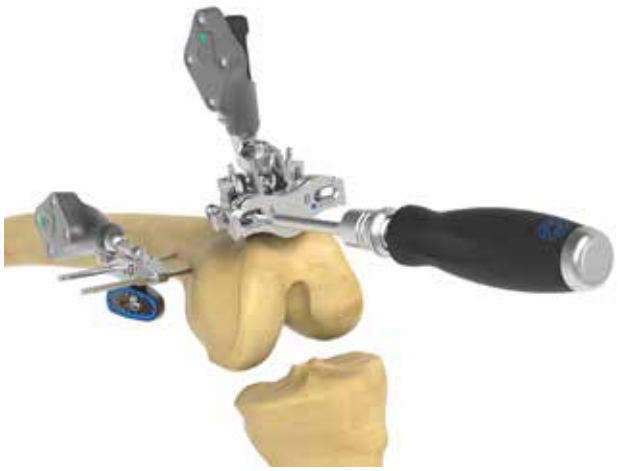


**Figure 49b**
Adjustable Cutting Block

**Distal Cut Guidance**
Once the adjustable cutting block has been secured to the femur, the Distal Cut Guidance screen will instruct the surgeon on how to finalize block adjustment.

The screws on the Adjustable Cutting Block are labeled "A", "B", & "C" and should be adjusted in alphabetical order according to the arrows displayed.

The arrows represent both direction and magnitude of the adjustment and will change as the block is adjusted *(Figure 49a)*.

**Adjusting the Block**
Use the 3.5mm Hex Driver to adjust the screws in alphabetical order (A, B, C) according to the arrows displayed until they disappear. *(Figure 49b)*

The lines on the screen will turn green once the alignment of the block is within an acceptable range of the planned resection values.

***Note:*** *The lines will turn green as the block enters the acceptable range, but it is recommended to continue adjusting the screws until the arrows disappear to assure maximum accuracy.*

## ADJUSTABLE CUTTING BLOCK
Distal Femoral Resection and Verification

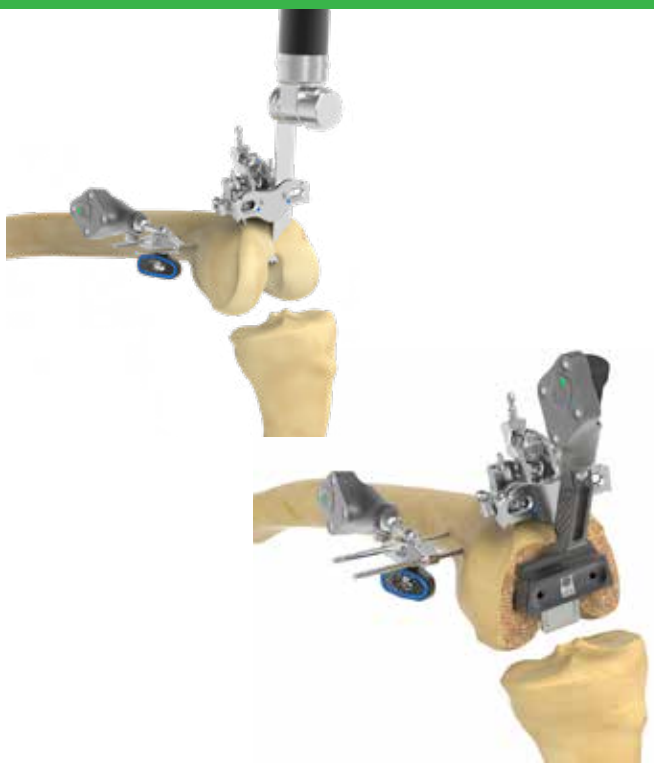


**Figure 50**
Distal Femoral Condyle Resection

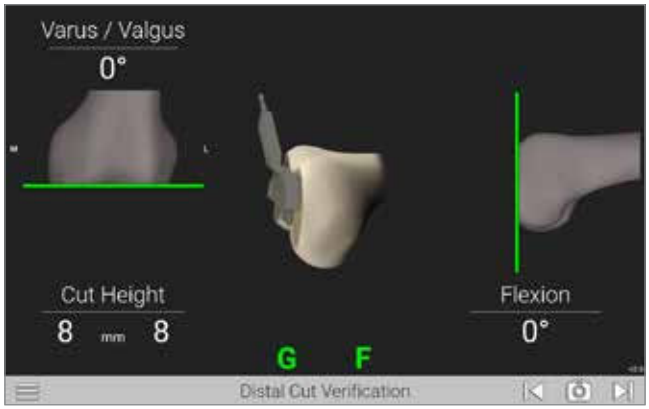



**Figure 51**
Verify Distal Resection

Remove the G Tracker for the Adjustable Cut Block for easy saw blade access.

**Performing the Distal Resection**

The distal resection can now be performed through the cutting slot of the Adjustable Cutting Block *(Figure 50)*.

***Note:*** *If additional stability is required due to poor bone quality, additional pins can be placed in the outer holes in the base of the Adjustable Cutting block prior to making the distal resection.*

**Verifying and Recording the Distal Cut**

With the Truliant Blade Drill Guide positioned flush against the distal femur *(Figure 51)*, view the display screen to review your cuts and press the Forward button on the Probe to advance to the next screen.

The adjustable cutting block and pins may now be removed.

***Note:*** *Verifying the resections properly is critical to the accuracy of the post operative assessment. Verification is used to record actual cut values and provide an accurate representation of soft tissue balance in case additional releases or resections are to be performed.*

## 4-IN-1 CUT GUIDANCE
Femoral Finishing Guide

**Figure 52a**
Assemble the Finishing Guide Tracker

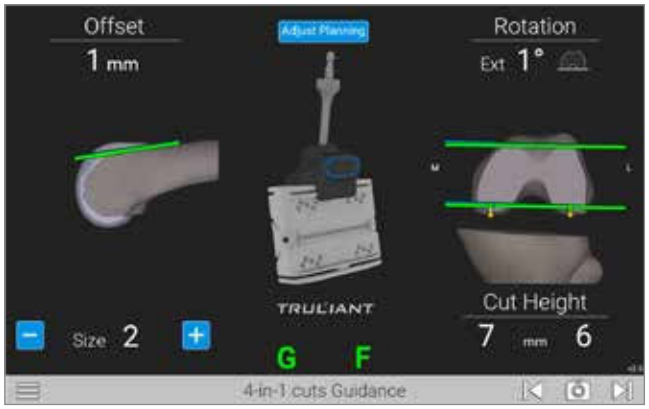



**Figure 52b**
Guiding the Truliant Finishing Block

**4-in-1 Cut Guidance**

The preferred method of locating the Truliant Femoral Finishing guide is by using the Femoral Finishing Guide Tracker. This procedure assures maximum stability during the guidance process.

Alternatively, the Drill Guide may be used and can be selected via the menu during the procedure.

Attach the Femoral Finishing Guide Tracker to the size specific Truliant Femoral Finishing Guide selected in the previous planning step. Verify the tracker is securely locked in place *(Figure 52a)*.

**Adjust and Pin Femoral Finishing Block**

Place the assembled component on the distal femoral resection previously completed. Adjust the rotation of the Truliant Femoral Finishing Guide until the blue and white lines merge and the green lines appear. Green indicates the alignment of the block is within 1mm of an acceptable range of the planned values *(Figure 52b)*.

Once the Truliant Femoral Finishing Guide is properly positioned, secure by inserting two collarless pins into the "0mm" pin holes first and then the cross pinholes on the side. Ensure the Truliant Femoral Finishing Guide is securely fixed and stays flush against the distal femur.

## 4-IN-1 CUT GUIDANCE
Using the Drill Guide

**Figure 52c**
Using the Drill Guide

**Using the Drill Guide**

Place the drill guide against the resected distal femur *(Figure 52c)* and follow the on-screen guidance to place it into position where the lines turn green, and the resection/rotation values match the intended plan *(Figure 52b)*.

Once the drill guide is properly positioned, collarless pins can be driven through the holes while assuring the guide does not move.

Remove the drill guide and place the Truliant Femoral Finishing Guide onto the resected distal bone with the pins through the "0mm" pin holes.

## 4-IN-1 CUT GUIDANCE

Anterior and Posterior Femoral Resection and Verification

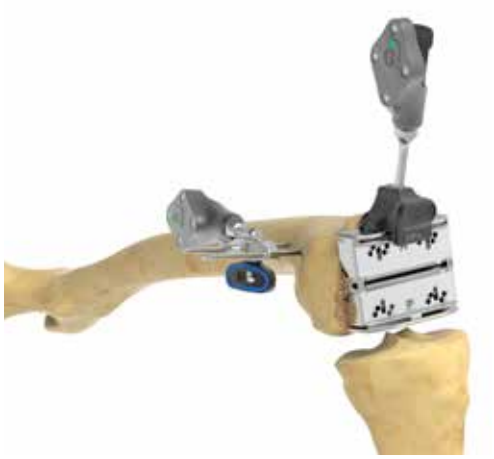


**Figure 53**
Cutting Anterior/Posterior

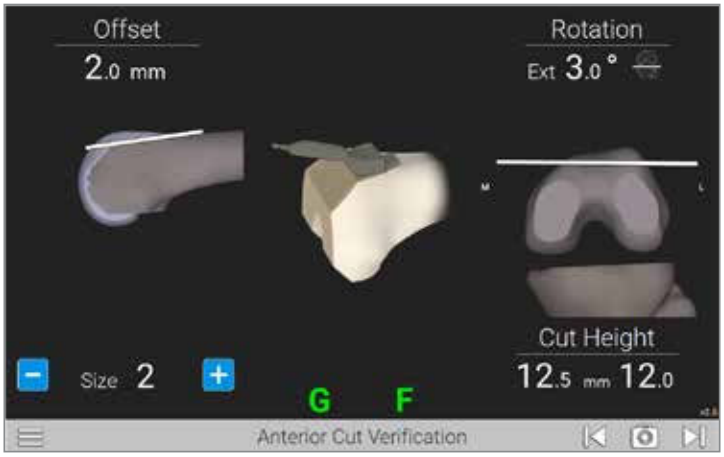



**Figure 54**
Recording the Anterior Cut

**Complete the Femoral Resections**

Remove the Femoral Finishing Guide Tracker from the Femoral Finishing Guide.

Perform the anterior and posterior cut, followed by the chamfer cuts. Once all cuts have been completed, the Truliant Distal Femoral Finishing Guide and pins can be removed.

**Recording the Anterior Cut**

With the Truliant Blade Drill Guide positioned against the anterior Femur, view the display screen to review the cuts and press the Forward button on the Probe to advance to the next screen *(Figure 54)*.

***Note:*** *Verifying the anterior resection properly is critical to the accuracy of the post operative assessment. Verification is used to record actual cut values and provide an accurate representation post resection component placement.*

**Figure 55**
Re-insert Tensioner

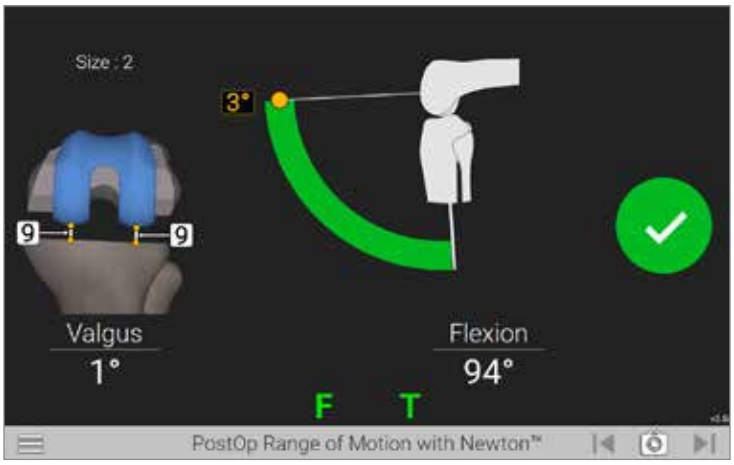



**Figure 56**
Postop Range of Motion Screen

**Femoral Trial**

Once the anterior cut has been recorded, and values deemed acceptable, continue to place the femoral trial according to the protocol found in the Truliant Primary Operative Technique (OPTECH-000189).

**Assessing the Post Operative Soft Tissue Balance**

Once the appropriate femur trial has been placed, re-insert the Tensioner with Inserter Handle as described previously to prepare to record the post operative joint gaps *(Figure 55)*.

**Postoperative Range of Motion With Newton**

Starting with the knee in extension, confirm your varus valgus alignment and perform soft tissue releases as needed. Press the forward button on the probe or the screen to start the recording of the acquisition. Support the femur and allow the tibia to follow without any varus or valgus stress through the full range of motion *(Figure 56)*. A green check mark will appear and audible tone is heard when acquisition is compete.

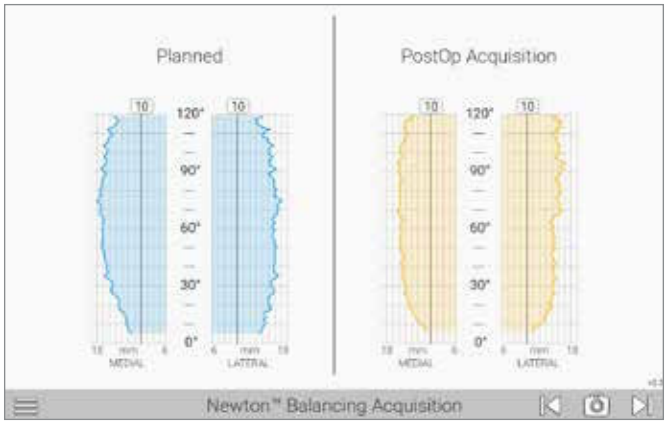



**Figure 57**
Postop Range of Motion Planned vs Postop Graph Screen

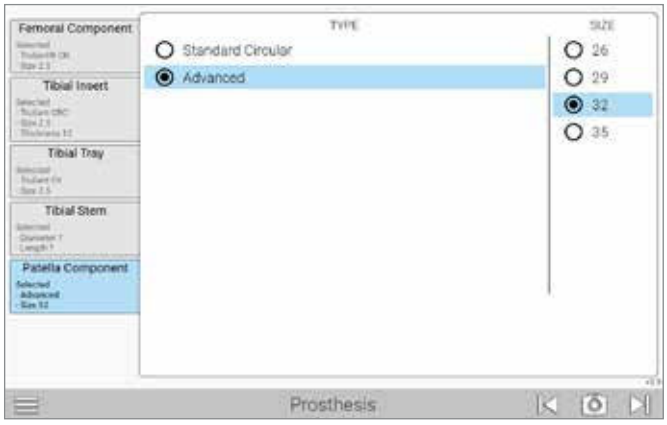



**Figure 58**
Prosthesis Screen

**Newton Knee Balancing Acquisition**

Once the ROM check has been completed, press the forward button to review a graphical representation on screen showing planned gaps and the postop acquisition gaps *(Figure 57)*.

***Note:*** *After soft tissue release is performed, reacquire gap data with Range of motion screen with implant trial in place.*

**Prothesis Information**

The prothesis screen should be used to enter in the final implants chosen *(Figure 58)*. This information will be carried through to the case reports accessible through the AI One user portal.

# APPENDIX A

## FLEX FEMUR FIRST BALANCE PLANNING TECHNIQUE

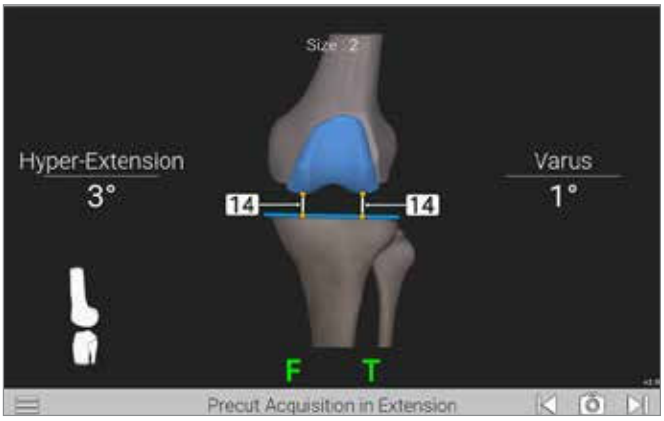



**Figure 59**
Acquiring the Extension Gaps

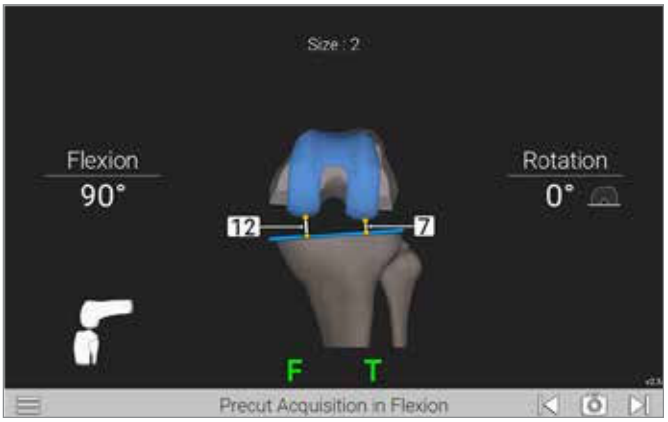



**Figure 60**
Acquiring the Flexion Gaps

### PRE-CUT ACQUISITIONS

**Introduction**

TKA Pro Application 2.6 allows surgeons to perform a femur-first procedure and plan all cuts prior to resections.

**PreCut Acquisitions**

After the pre-op kinematics have been captured, the software will advance to the PreCut acquisition screens. The software will guide the surgeon through the acquisition of the medial and lateral gaps in both flexion and extension providing data required to plan the Tibia and Femur positioning at the same time.

**Acquiring Pre-Resection Gaps**

To acquire the anatomic pre-resection gaps, static poses will be captured in two positions: flexion and extension. To begin the acquisition process, assure that the knee is in full extension and apply stress until the appropriate native, natural resting ligament tension is achieved both, medially and laterally *(Figure 59)*. Advance to the next screen by pressing the forward arrow to capture the extension gap data.

Repeat this process with the knee in 90° of flexion to complete the Pre-Cut acquisitions *(Figure 60)*. Capture the gap data by pressing the forward arrow to advance to the next screen.

***Note:*** *If desired, a distraction tool (e.g. osteotome or spacer/ spoon) can be placed between the unaffected tibia and femoral condyle to assist in capturing natural, resting ligament tension.*

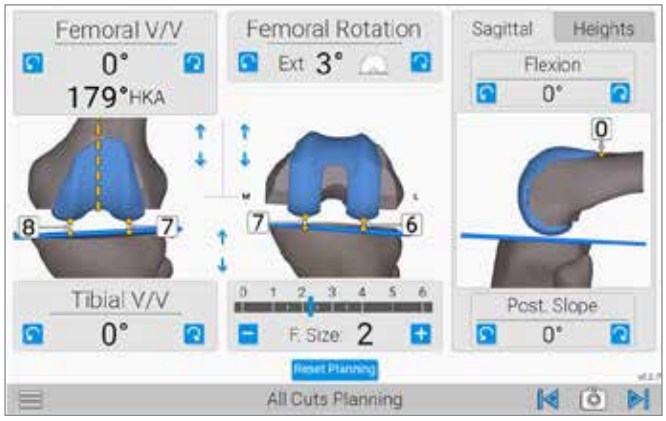



**Figure 61**
Femur and Tibia Cut Planning Screen: Flexion

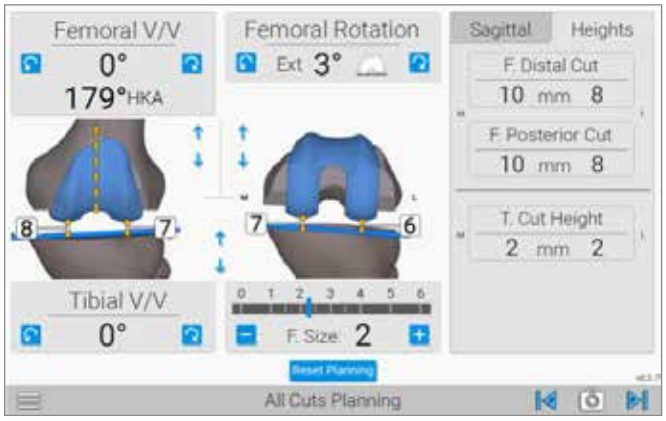



**Figure 62**
Femur and Tibia Cut Planning Screen: Heights

## COMBINED ALL-CUTS PLANNING

This screen allows the user to plan both Femoral and Tibial resections at the same time *(Figure 61)*.

**Resection Review**

The resection levels are reported under the "Heights" tab.

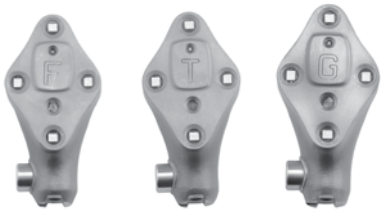
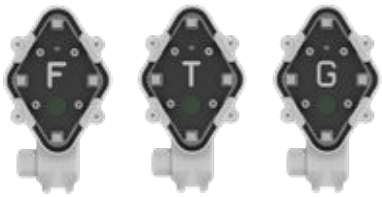
By Selecting the "Heights" tab, you will gain visibility to the resection depths of the Femoral Distal Cut, Femoral Posterior Cut, and Tibia Cut *(Figure 62)*.

Switching back to the "Sagittal" tab will return to the sagittal view and access to the Flexion and Tibia Slope adjustments *(Figure 60)*.

Once the combined femur and tibia plan has been completed, advance to the next screen by pressing the forward button.

The procedure will continue as depicted in the Optetrak Logic or Truliant primary operative technique.

## INSTRUMENT LISTING

| CATALOG NUMBER | PART DESCRIPTION | |
|---|---|---|
| I00020 | GPS System | |
| A10003 (P)<br>A00203 (P) | GPS Probe (P) Tracker<br>P Tracker 2* | |
| A10004 (F)<br>A10005 (T)<br>A10006 (G) | GPS Femoral (F) Tracker<br>GPS Tibial (T) Tracker<br>GPS Guide (G) Tracker |  |
| A00204<br>A00205<br>A00206 | GPS Femoral (F) Tracker 2*<br>GPS Tibial (T) Tracker 2*<br>GPS Guide (G) Tracker 2* |  |
| 02-521-90-0100 | Truliant external tracker fixator 0 degree, Pro | |
| 02-521-90-0130 | Truliant external tracker fixator 30 degree, Pro | |

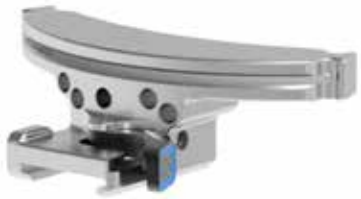
**Special Order Only*

*****Note:** A comprehensive overview of the Truliant primary knee system can be found in the Truliant Operative Technique #712-35-41*

******Note:** Alternatively, KIT-521_XO1.5 can be used as a substitute*

| CATALOG NUMBER | PART DESCRIPTION | |
|---|---|---|
| 02-521-10-0003 | Femoral Adjustable Resection Guide | |
| 02-521-10-0008 | Truliant Finishing Guide Tracker | |
| 02-521-20-1005 | Left Tibial Base, Pro | |
| 02-521-20-2005 | Right Tibial Base, Pro | |
| 02-521-90-1002 | Truliant Adjustable Module, Pro | |
| 02-521-20-3000 | Tibial Template, Pro | |

## INSTRUMENT LISTING

| CATALOG NUMBER | PART DESCRIPTION | |
|---|---|---|
| 02-521-20-3004 | Left Tibial Resection Guide, Pro | |
| 02-521-20-3005 | Right Tibial Resection Guide, Pro | |
| 02-521-20-3003 | Wide Non-slotted Tibial Resection Guide, Pro* | |
| 02-521-20-3002 | Wide Symmetrical Tibial Resection Guide, Pro* |  |
| 02-521-20-3001 | Symmetrical tibial resection guide, Pro* | |
| 02-521-20-3006 | Left Tibial Resection Guide, Non-slotted, Pro* | |
| 02-521-20-3007 | Right Tibial Resection Guide, Non-slotted, Pro* | |

**Special Order Only*

| CATALOG NUMBER | PART DESCRIPTION | |
|---|---|---|
| 02-521-90-0000 | External Tracker Fixator 0 Deg* | |
| 02-521-90-0001 | Truliant 3.5mm Ball Hex Driver Zhudson | |
| 02-521-90-0002 | Truliant Hex Driver Handle | |
| 02-521-90-0030 | External Tracker Fixator 30 Deg* | |
| 02-521-90-1000 | Truliant Blade Drill Guide | |
| 02-521-90-2003 | Newton Inserter | |
| 02-521-90-2000 | Newton Tensioner | |
| 02-521-90-2001 | Newton Handle* | |
| 02-521-90-2002 | Newton 8mm Spacer* | |
| Kit-521Pins | GPS Single Use Pins Kit | |
| KIT-501T | GPS Active Trackers Kit | |
| | Truliant Instrument Set** | |
| KIT-521_Newton | GPS Newton Mechanicals Kit*** | |

**Special Order Only*

*****Note:** A comprehensive overview of the Truliant primary knee system can be found in the Truliant Operative Technique #712-35-41*

******Note:** Alternatively, KIT-521_XO1.5 can be used as a substitute*

# INSTRUMENT LISTING

| CATALOG NUMBER | PART DESCRIPTION |
|---|---|
| KIT-521PRO_TRU | ProTruliant GPS Instruments |
| A10012 | GPS Disposable Kit |

NOTES

GPS is manufactured by Blue Ortho SAS, an Advita Ortho subsidiary, and distributed by Advita Ortho, LLC.

For additional device information, refer to the manufacturer's Instructions for Use for information including, but not limited to, a device description, indications, contraindications, precautions and warnings. For further product information, please contact Customer Service, Advita Ortho, LLC. 2320 NW 66th Court, Gainesville, Florida 32653-1630, USA. (833) 4-ADVITA.

Blue Ortho, as the manufacturer of this device, does not practice medicine and is not responsible for recommending the appropriate surgical technique for use on a particular patient. Because this information does not purport to constitute any diagnostic or therapeutic statement with regard to any individual medical case, each patient must be examined and advised individually, and this document does not replace the need for such examination and/or advice in whole or in part. These guidelines are intended to be solely informational, and each surgeon must evaluate the appropriateness of these guidelines based on his or her personal medical training and experience. Prior to use of this system, the surgeon should refer to the product package insert for information including, but not limited to, comprehensive warnings, precautions, indications for use, contraindications and adverse effects.

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