

EXACTECH | KNEE

Operative Technique

Software Version
TKA 1.13.1



Exactech GPS[®]
Guided Personalized Surgery

OpTech All-Cuts Profile

TABLE OF CONTENTS

INTRODUCTION	1
SYSTEM OVERVIEW	2
DETAILED OPERATIVE TECHNIQUE	
START EXACTECHGPS KNEE APPLICATION.....	3
FEMORAL PREPARATION	7
FEMORAL REGISTRATION.....	8
TIBIAL PREPARATION	16
TIBIAL REGISTRATION	18
INSTRUMENT LISTING	24



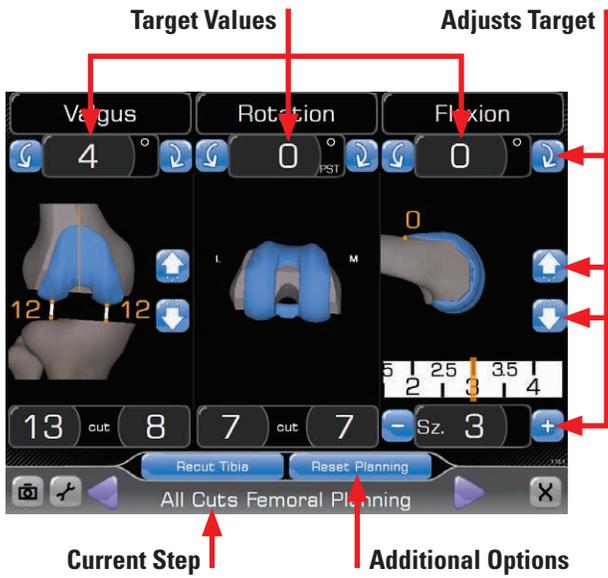
ExactechGPS® Guided Personalized Surgery is an advanced surgical technology that provides surgeons with real-time visual guidance and alignment data in total knee arthroplasty. Customized for surgeon preferences, ExactechGPS is a powerful addition to the surgical team's goals of achieving efficacy, efficiency and economics for total knee arthroplasty.

SYSTEM OVERVIEW

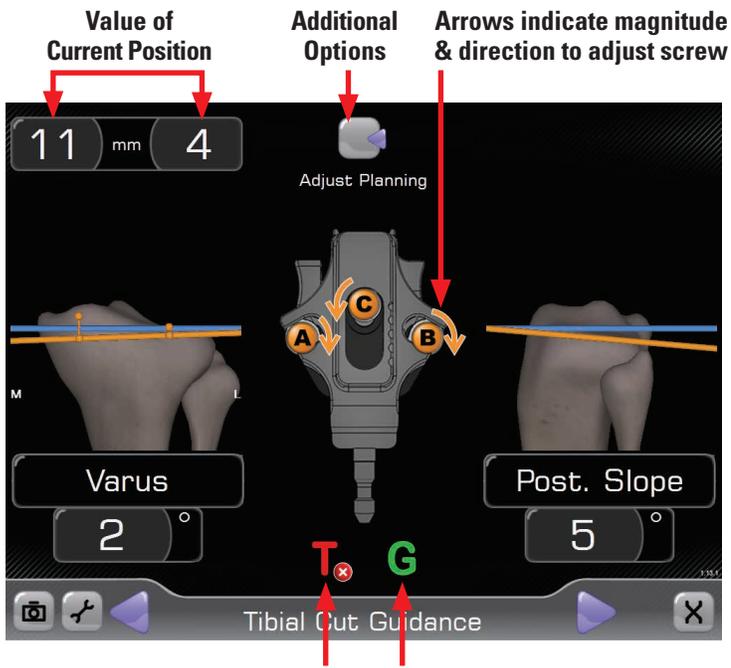
Screen Layout



Icon	Description	
	Change Language	Change the default language of the software.
	Total Knee	Access detailed options related to total knee application. (see 8.2 - Total Knee Page)
	Tools	Access maintenance options. (see 8.3 - Maintenance Page)
	Switch OFF	Switch OFF the station.
	Insert Starter Key	Insert a starter key from the disposable kit to start the total knee application.
	Home	Access the home screen



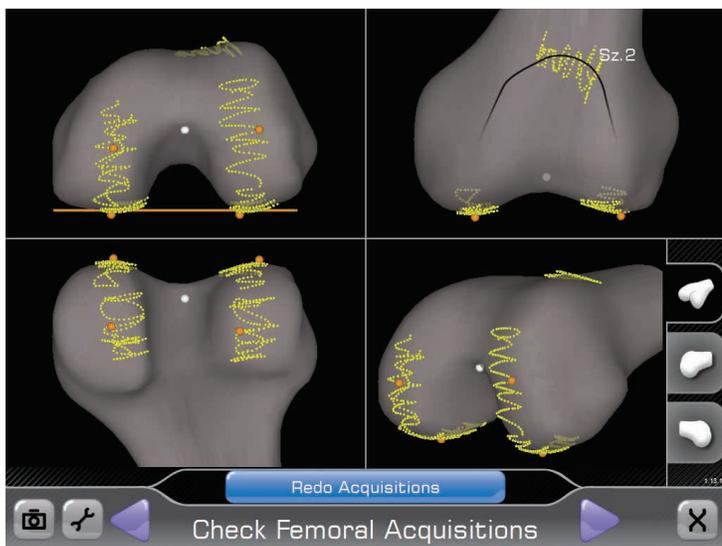
Icon	Description	
	Go Forward	Go to the next step.
	Go Backward	Go to the previous step.
	Tools	Access maintenance options.
	Screenshot	Take a screen shot of the current screen. The picture is recorded in the operative report.
	Exit	Exit the total knee application.



Identifies Tracker Required:

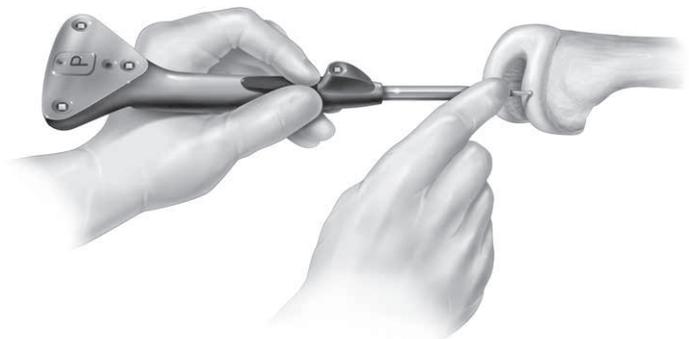
Red indicates tracker is not visible and not communicating with camera.
Green indicates tracker is visible and communicating with camera.

Icon	Description
	Red indicates tracker is not visible and not communicating with camera.
	Green indicates tracker is visible and communicating with camera.
	Blue line indicates targeted position
	Orange line indicates current position



Probe Tracker Technique

Hold the Probe Tracker (P) with the index finger on the forward button making sure not to obstruct the IR LED between the button and the probe tip. Always make sure the probe tip is on the anatomic landmark prior to pressing the forward button. For point selection, with the probe tip on the anatomic landmark press and release the forward button. For patch registration, place the probe tip on the anatomic landmark press and release the forward button and then 'paint' the anatomic reference using an S like pattern. To return to previous step or re-do an acquisition, rapidly double click the back button on the probe.



DETAILED OPERATIVE TECHNIQUE

START EXACTECHGPS KNEE APPLICATION

Note: This may be performed while system is in Docked Mode.

Insert the **Starter Key** from the ExactechGPS Knee Implant Kit into the front USB slot on the Control Unit labeled *Starter Key* when prompted (*Figure 1*) to initiate the ExactechGPS Knee Application. The system will automatically advance to the *Welcome screen* (*Figure 2*). Select the arrow at the lower right corner of the display to advance to the *Patient screen* (*Figure 3*). Patient identification information can be entered into the fields displayed. All fields are optional and this information is only stored on the Starter Key.



Figure 1
Insert Starter Key



Figure 2
Welcome Screen

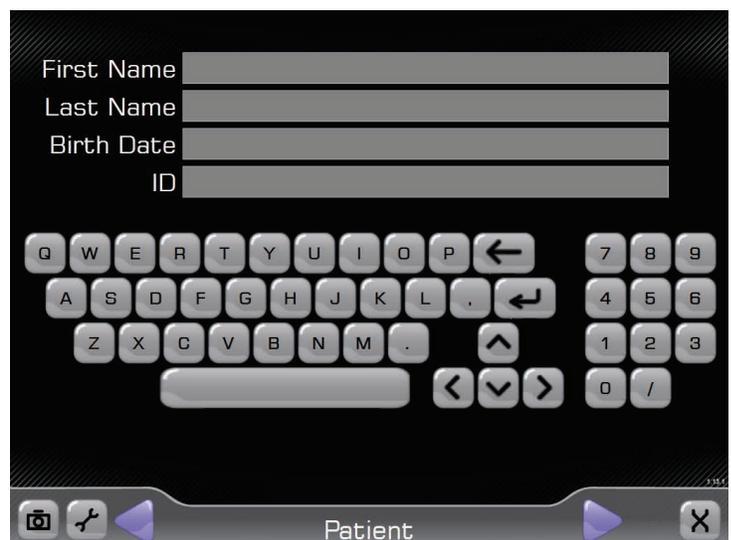


Figure 3
Complete Patient Information

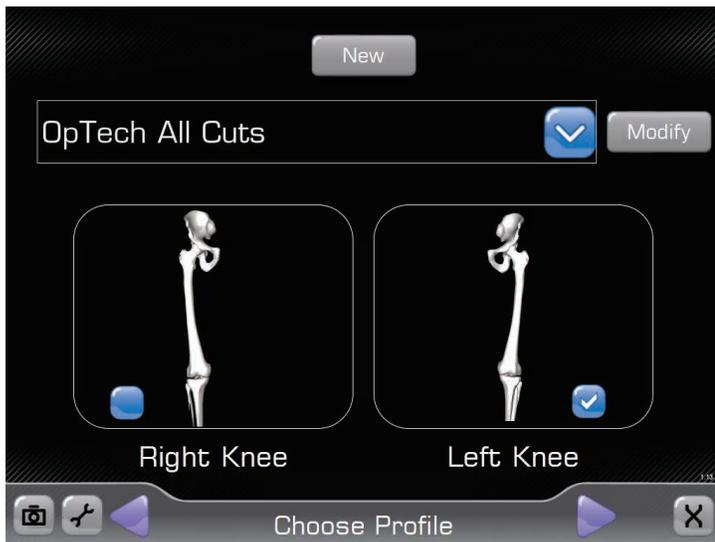


Figure 4
Select Op Tech All-Cuts Profile

Advance to the *Choose Profile* screen (Figure 4). The preferred surgeon profile can be selected from the drop-down menu. Select the Op Tech All-Cuts profile. Select the operative side and then advance to the next screen.

Note: This technique describes the OpTech All-Cuts profile. Individual operative techniques can vary based on surgeon preferences. Refer to the ExactechGPS Surgeon Profiler Manual for creating and modifying surgeon profiles.

The *Seeking Tracker* screen is displayed (Figure 5). Insert batteries, the positive side first, into the four trackers ProbeTracker (P), Femoral Tracker (F), GuideTracker (G) and TibialTracker (T) (Figure 6).

Caution: Inserting negative side first or in reverse polarity may cause permanent damage to the tracker.

When the battery is properly inserted, an LED on each tracker will illuminate solid red/orange then begin to blink green. Position the trackers such that the LEDs face the ExactechGPS Display Unit. An audible tone will indicate when each tracker connects to the ExactechGPS system. At the same time, the respective tracker is highlighted on the Display Unit, and the LED illuminates solid red/orange. After the camera and four trackers connect, the system will automatically advance to the next screen.



Figure 5
System Begins Seeking Trackers



Figure 6
Insert Batteries Positive Side First

The *One-Step Calibration* screen is displayed (Figure 7). Place the tip of the ProbeTracker (P) into the dimple node at the top of the Guide Tracker (G). Hold both together approximately 16 inches from the display unit ensuring the white diodes are facing the camera. When positioned correctly, the "G" and "P" status indicators on the display will appear green. Press the Forward button on the probe to initiate calibration. The progress bar will fill and an audible tone will indicate successful calibration. The system will automatically advance to the next screen.

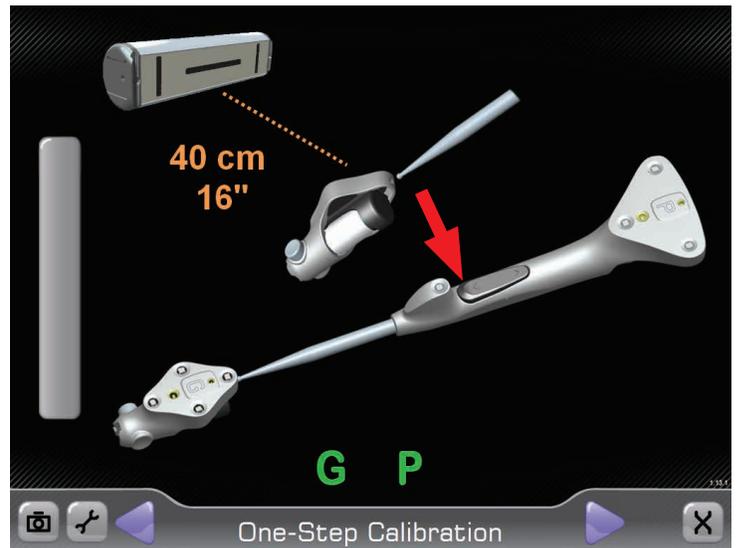


Figure 7
One-Step Calibration Screen

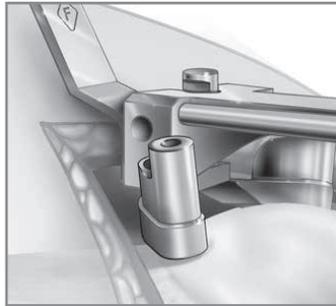


Figure 8
Assemble IM Alignment Guide, Femoral Base Template and Femoral Base

Figure 8a
Slide the Femoral Base Template on the center peg of the Femoral Base

FEMORAL PREPARATION

ExactechGPS instrumentation is designed to accommodate a surgeon's preferred incision and surgical exposure.

Assemble the **Intra-medullary Alignment Guide**, **Femoral Base Template** and **Femoral Base** (*Figure 8*).

- Press button on the Femoral Base Template
- Slide the Femoral Base Template on the center peg of the Femoral Base (*Figure 8a*)
- Release button to lock the Femoral Base Template to the Femoral Base
- Insert two shafts of the Femoral Base Template into the Intra-medullary Alignment Guide

Place the assembly on the distal femur such that the Femoral Base is positioned on the anterior femur and the Intra-medullary Alignment Guide contacts the distal femoral condyles (*Figure 9*). Ensure the assembly is not positioned in flexion or extension. A drop rod can be inserted along the anterior surface of the femur and under the soft tissues to approximate neutral flexion and extension.

Pin the Femoral Base in position using the distal holes. Press the button on the Femoral Base Template and disengage from the Femoral Base. Remove the Femoral Base Template and Intra-medullary Alignment Guide.

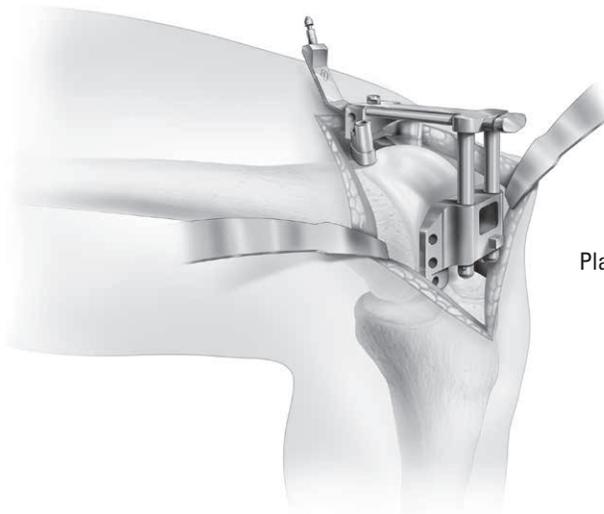


Figure 9
Place Femoral Base on Distal Femur

Assemble the Femoral Tracker (F) to the Femoral Base (Figure 10).

- Push button on Femoral Tracker
- Position tracker on Femoral Base with LED facing towards display unit.
- Release button and ensure tracker is securely locked onto base. The tracker must not rotate or move in any way.

Caution: It is important to ensure the tracker does not rotate or move in any way when connected to the base.

FEMORAL REGISTRATION

The *Hip Center Acquisition* screen is displayed (Figure 11). Press the forward button on the display unit or alternatively, press the forward button on the Probe Tracker (P) to initiate the acquisition process. Move the knee in a 12-inch diameter circular pattern as illustrated on the display.

Note: A 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 display unit and the pelvis remains stable during the hip center acquisition process.

The *Knee Center Acquisition* screen is displayed (Figure 12). Position the tip of the Probe Tracker (P) to the deepest point of the intercondylar notch, and while the probe is contacting the bone, press the Forward button. The system will automatically advance to the next screen.

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



Figure 10
Assemble Femoral Tracker to Femoral Base

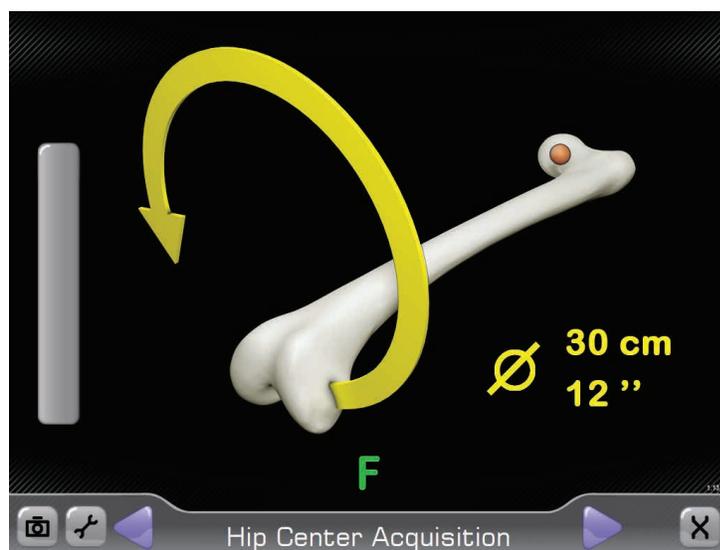


Figure 11
Perform Hip Center Acquisition

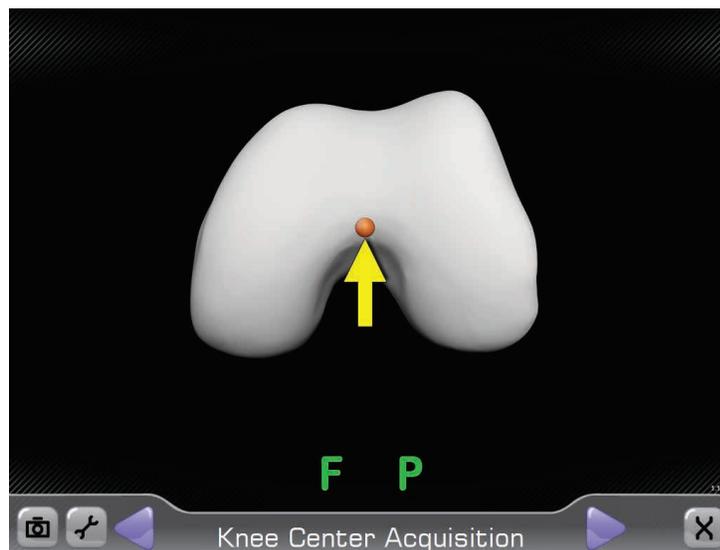


Figure 12
Perform Knee Acquisition

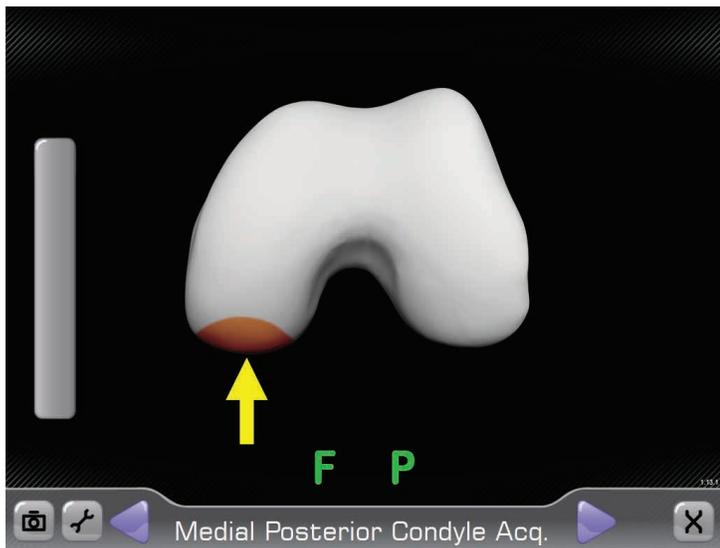


Figure 13
Perform Medial Posterior
Condyle Acquisition

The Medial Posterior Condyle Acquisition screen is displayed (*Figure 13*). Position the tip of the Probe Tracker (P) on the medial posterior condyle press the Forward button. Ensure the tip of the tracker maintains contact with the condyle and trace a patch that captures the most posterior aspect of the condyle. This is best achieved by moving the probe tip in proximal-distal in the sagittal plane.

The progress bar will fill and audible clicks will indicate successful registration points. An audible tone will indicate registration is complete and the system will automatically advance to the Lateral Posterior Condyle Acquisition screen (*Figure 14*).

Repeat to acquire points for the lateral posterior condyle.

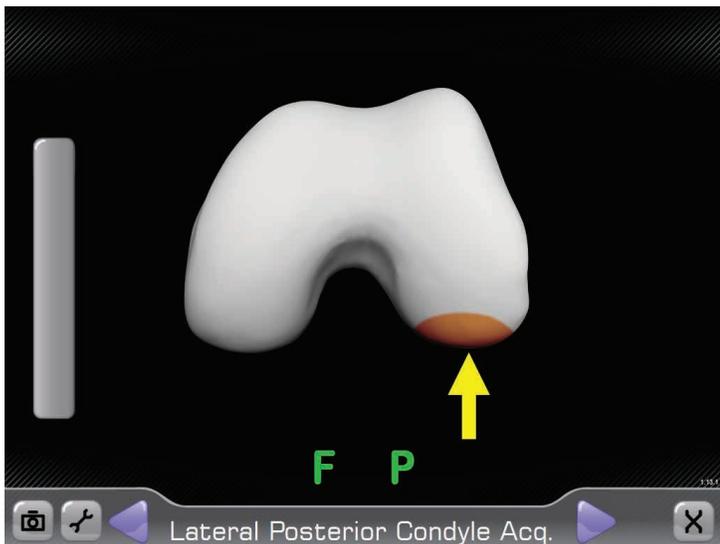


Figure 14
Perform Lateral Posterior
Condyle Acquisition

The *Medial Distal Condyle Acquisition* screen is displayed (Figure 15). Position the tip of the Probe Tracker (P) on the medial distal condyle and press the Forward button. Ensure the tip of the tracker maintains contact with the condyle and trace a patch that captures the most distal aspect of the condyle as well as the medial-lateral and anterior-posterior curve of the distal condyle.

The progress bar will fill and audible clicks will indicate successful registration points. An audible tone will indicate registration is complete and the system will automatically advance to the *Lateral Distal Condyle Acquisition* screen (Figure 16).

Repeat to acquire points on the lateral distal condyle.

The *Anterior Cortex Acquisition* screen is displayed (Figure 17). 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 Tracker (P) will be shown as an orange dot on the display. Position the tip of the Probe Tracker (P) so the dot is within the patch displayed and press the Forward button. Ensure the tip of the tracker maintains contact with the anterior cortex and trace within the patch. Ensure that points are acquired in both the medial and lateral sides of the patch area.

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.

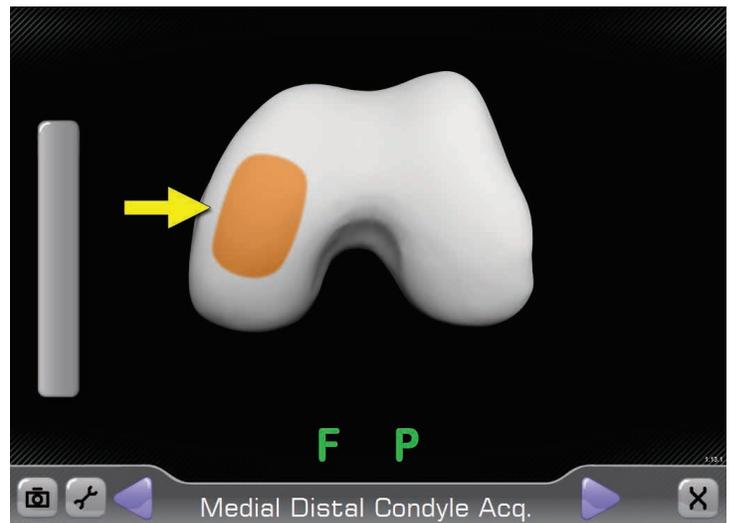


Figure 15
Perform Medial Distal Condyle Acquisition

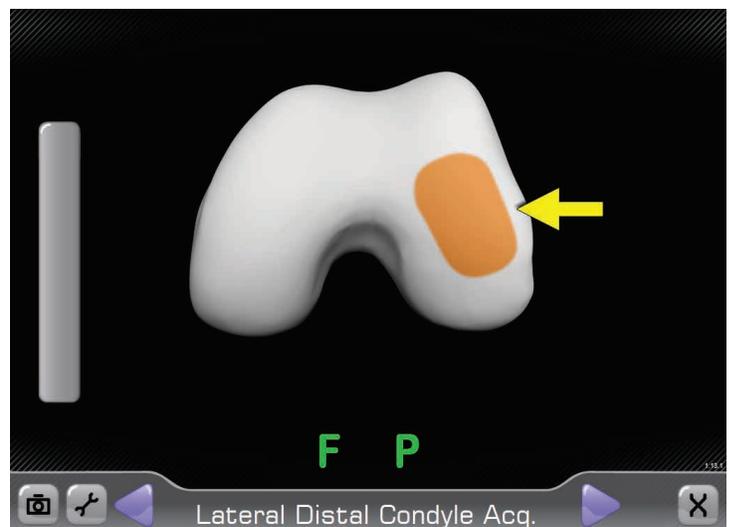


Figure 16
Perform Lateral Distal Condyle Acquisition

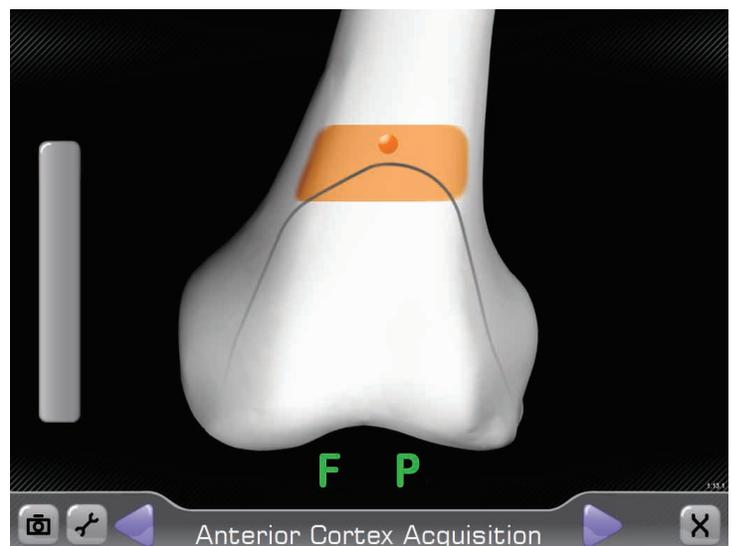


Figure 17
Perform Anterior Cortex Acquisition

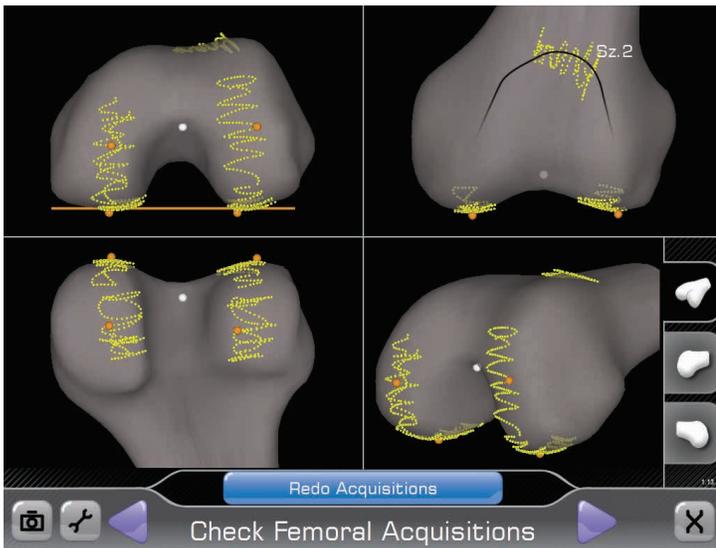


Figure 18
Check Femoral Acquisitions

The *Check Femoral Acquisitions* screen is displayed (Figure 18). A graphical representation of the registered points (yellow dots) is displayed. The orange dots represent points that will be used by the system to determine resection levels.

For further review of the registered points, the bottom-right view can be changed by selecting one of the three options located to the right. If the ProbeTracker (P) is placed on the bone, the relative position of the tip is displayed as a blue dot. This can be used as an additional aid to review the registered points.

Note: The initial femoral component size will be indicated at the top right of the *Check Femoral Acquisitions* screen.

If it is necessary to redo the registration for any or all points, select the *Redo Acquisitions* button at the bottom of the *Check Femoral Acquisitions* screen. Select the acquisitions to redo (Figure 19) then select the *Redo* button. The system will repeat the selected acquisitions.



Figure 19
Redo Acquisitions Option

Advance to the *All-Cuts Femoral Planning* screen (Figure 20). The display is divided into three panels: *V/V*, *Rotation* and *Flexion*. Varus/Valgus angle, distal resection amount, rotation and flexion are consistent with the values in the selected profile. Each of these values along with the anterior-posterior position and size of the femoral components can be adjusted intra-operatively.

Selecting the *Reset Planning* button at the bottom of the display will reset all values to the values from the profile.

- *V/V* Panel (Left) displays femoral varus/valgus angle perpendicular to the mechanical axis and the distal resection depth from each condyle (*CUT*). The arrows at the top of the panel adjust the varus/valgus angle in 1-degree increments. The arrows in the middle adjust the distal resection depth in 1mm increments. Varus/Valgus adjustments impact the distal condyle resection.

- *Rotation* Panel (Middle) displays the femoral rotation relative to the posterior condyles (*PST*) along with the resection depth of the posterior condyles (*CUT*). The arrows at the top of the panel adjust rotation angle in 1-degree increments. Rotational adjustments impact the posterior condyle resection.

- *Flexion* Panel (Right) displays femoral flexion, anterior flange position and femoral component size. The arrows at the top of the panel adjust flexion/extension angle in 1-degree increments. Flexion occurs about the anterior flange (orange dot) and impacts posterior resection and size. The arrows in the middle of the panel adjust anterior-posterior position in 1mm increments. The orange dot and number indicate the offset of the anterior flange relative to the anterior cortex of the femur. Anterior-posterior position adjustments impact posterior resection and anterior flange position. The femoral component size can be adjusted at the bottom of the panel (*Sz.*). Adjusting the component size will impact the posterior condyle resection.

Advance to the next screen when adjustments to femoral planning are complete.

Attach the **Adjustable Module** and Guide Tracker (G) to the Femoral Base.

- Press button on Adjustable Module and attach to Femoral Base (Figure 21)
- Release button and verify Adjustable Module is securely locked onto the base
- Press button on Guide Tracker (G) and attach to Adjustable Module
- Release button and verify tracker is securely locked to the module

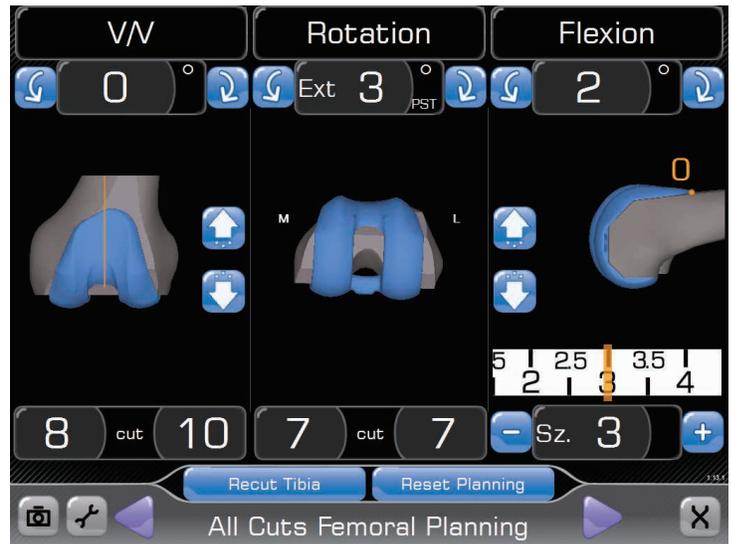


Figure 20
Review All-Cuts Femoral Planning

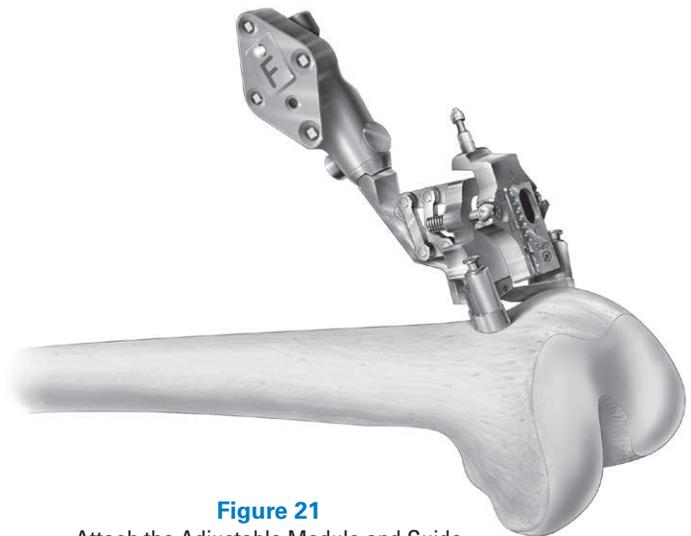


Figure 21
Attach the Adjustable Module and Guide Tracker to the Femoral Base

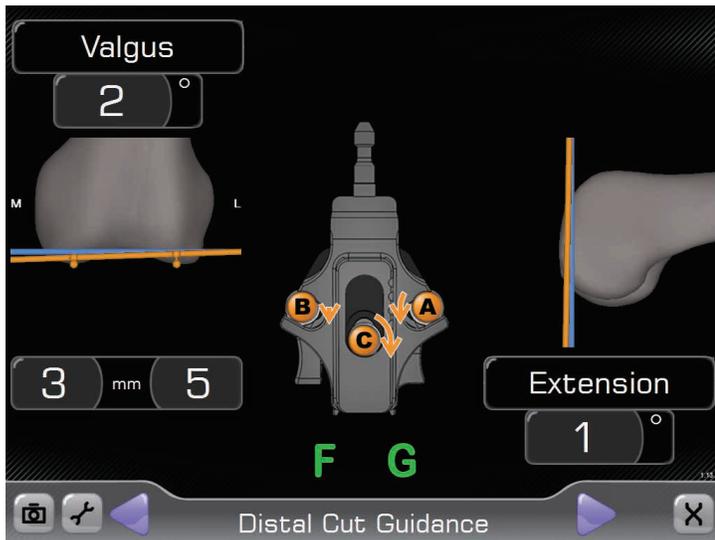


Figure 22
Prepare for Distal Resection

The Distal Cut Guidance screen is displayed (*Figure 22*). The blue lines indicate the planned distal resection. The orange lines represent the resection based on the position of the Adjustable Module. The varus/valgus degree, resection amount and flexion angle displayed are consistent with the alignment of the Adjustable Module (orange line). When the alignment of the Adjustable Module is within 1mm and 1-degree of the planned resection, the orange and blue lines align and change to green.

Use the **3.5mm Hex Driver** to adjust the three screws (*A, B, C*) on the Adjustable Module (*Figure 23*) according to the arrows displayed. The arrows indicate both magnitude and direction. Turning the screws in the direction indicated will reduce the magnitude. Adjust the three screws until the indication arrows disappear on *A, B* and *C*. This will result in a green resection line corresponding to the planned resection.

Attach the **Femoral Cutting Block** to the Adjustable Module (*Figure 24*).

- Press button on Femoral Cutting Block.
- Slide block onto the dovetail on the Adjustable Module until the block contacts the anterior femur.
- Release the button and ensure the block is securely locked in position.
- Pin the block using the proximal pin holes. Center cross-pin holes are optional.
- Remove Guide Tracker (*G*) from Adjustable Module.

Perform the distal femoral resection.

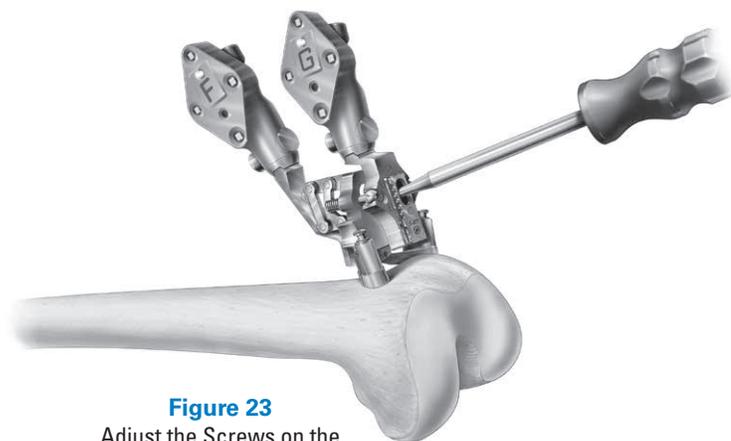


Figure 23
Adjust the Screws on the Adjustable Module

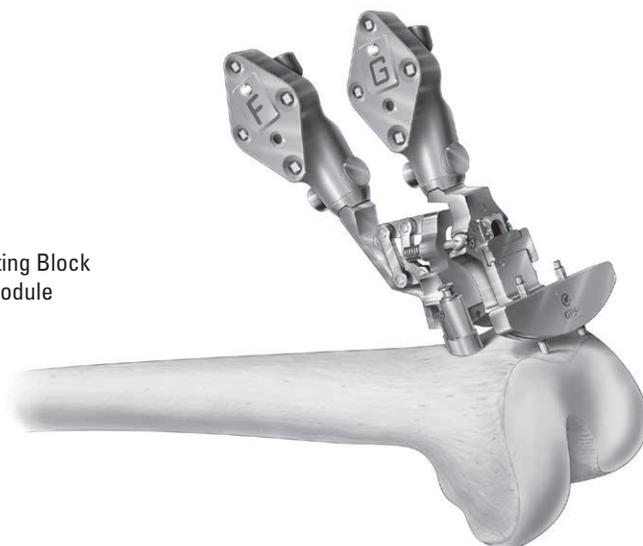


Figure 24
Attach the Femoral Cutting Block to the Adjustable Module

Advance to the Distal Cut Control screen (Figure 25).

Assemble the Guide Tracker (G) to the Blade Drill Guide such that the tracker faces the Display Unit (Figure 26). Place the Blade Drill Guide against the distal femur to verify the resection and modify as necessary. With the blade drill guide positioned against the distal femur, press the Forward button on the display unit. Alternatively, press the Forward button on the Probe Tracker (P) to advance to the next screen. The system will record the actual distal resection and update the femoral planning accordingly.

The 4-in-1 cuts Planning screen is displayed (Figure 27). The values indicate the planned position of the femoral component. The anterior-posterior offset, component size and femoral rotation values can be adjusted. Select the Forward button on the Probe Tracker (P) to advance to the next screen.

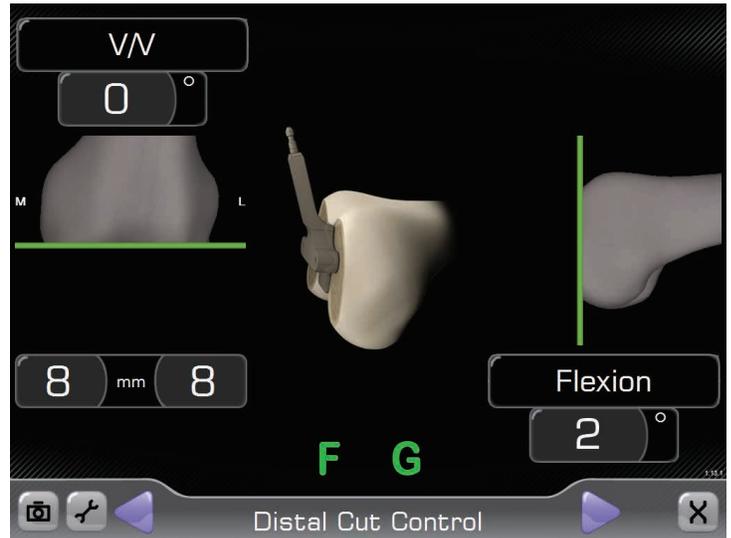


Figure 25
Verify the Distal Resection

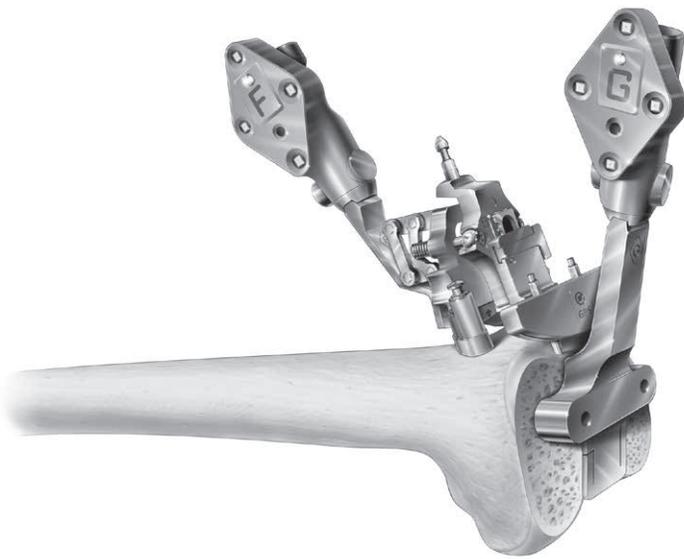


Figure 26
Assemble the Guide Tracker to
the Blade Drill Guide

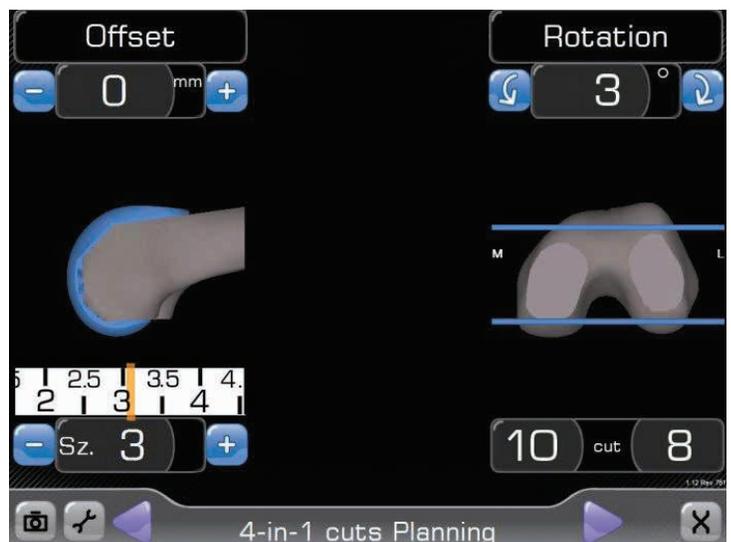


Figure 27
Plan the 4-in-1 Cuts

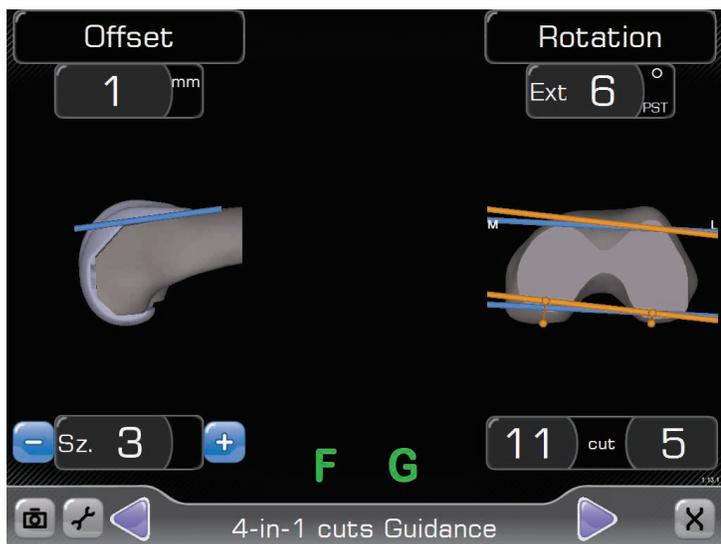


Figure 28
Review the 4-in-1 Cuts Guidance

With the GuideTracker (G) assembled to the Blade Drill Guide, position the Blade Drill Guide against the distal femur. Adjust the position of the Blade Drill Guide against the distal femur to align the orange line with the blue line on the display. The blue lines indicate the planned resections. The orange lines represent the resection based on the position of the Blade Drill Guide. When the alignment of the Blade Drill guide is within 1mm and/or 1-degree of the planned position, the orange line will change to green (Figure 28).

Hold the Blade Drill Guide in the desired position and drill the rotation holes with the Collar Drill Bit (Figure 29).

Note: After drilling the first hole, it helps to place a holding pin to help stabilize during drilling of the second hole.

Complete the femoral preparation (femoral finishing cuts, notch resection for PS) according the preferred Optetrak or Optetrak Logic distal first operative technique.

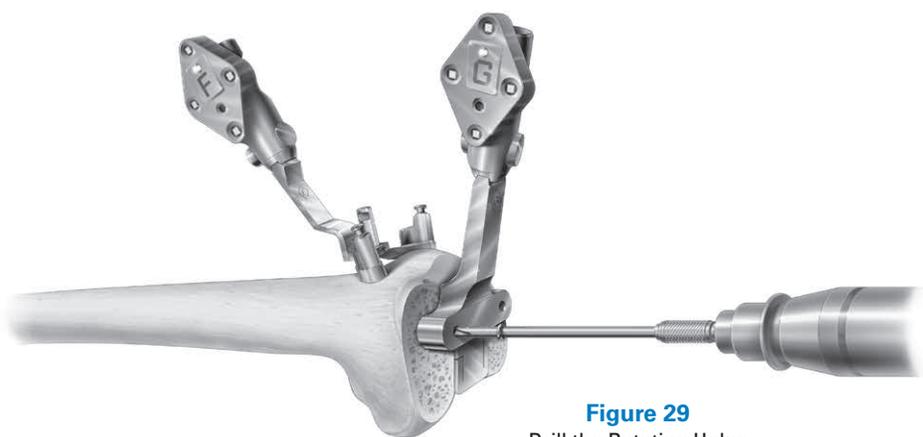


Figure 29
Drill the Rotation Holes

TIBIAL PREPARATION

Assemble Tibial Positioning Template and Tibial Base (Figure 30)

- Select the left or right Tibial Base consistent with the operative side
- Press button on Tibial Positioning Template
- Assemble Tibial Base to the Tibial Positioning Template. Left Tibial Base, identified by "L" on post, assembles to the left side of the Tibial Positioning Template, identified by "L" near button. The Right Tibial Base will assemble to the right side of the Tibial Positioning Template.
- Release button and ensure that the base is secure on the template

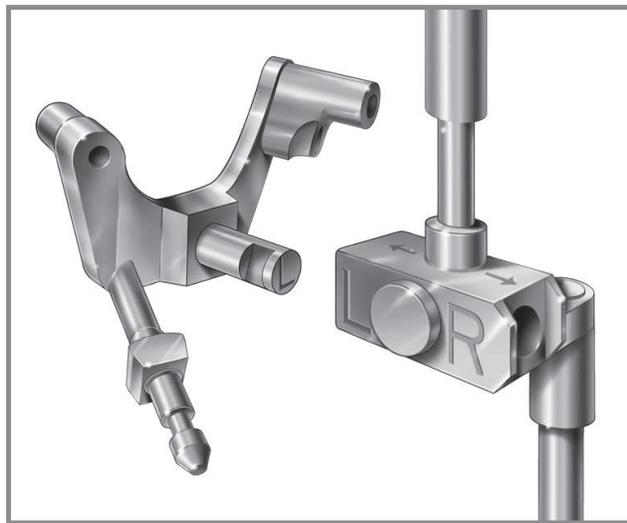


Figure 30
Assemble Tibial Positioning Template to Tibial Base



Figure 31
Position the Tibial Base Assembly



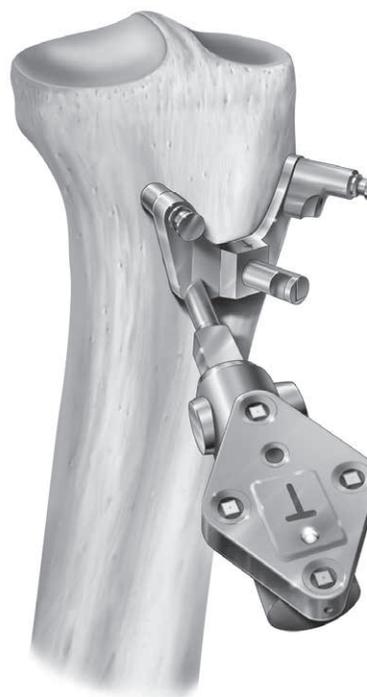
Figure 32
Assemble Tibial Tracker to Tibial Base

Position stylus on the proximal tibia. The stylus has two lengths; 1mm for the lowest point of the most affected side or 10mm for the lowest point of the least affected side. Position the assembly against the tibia. The Tibial Base is designed to be positioned just medial to the tubercle. Adjust the lower end of the Tibial Positioning Template such that the shaft of the template is parallel with the tibia (*Figure 31*).

Pin the Tibial Base in position. Press the button on the Tibial Positioning Template and disengage from the Tibia Base.

Assemble the Tibial Tracker (T) to the Tibial Base (*Figure 32*)

- Push button on Tibial Tracker (T)
- Position on medial post of the Tibial Base with LED facing towards display unit.
- Release button and ensure tracker is securely locked onto base. The tracker must not rotate or move in any way.



TIBIAL REGISTRATION

Advance to the Medial Malleolus Acquisition screen (Figure 33). Position the tip of the Probe Tracker (P) on the medial malleolus and press the Forward button to register this point. The system will automatically advance to the Lateral Malleolus Acquisition screen (Figure 34).

Repeat to acquire point for lateral malleolus.

The Tibial Center Acquisition screen is displayed (Figure 35). Position the tip of the Probe Tracker (P) on the center of the proximal tibia and press the Forward button to register this point. The system will automatically advance to the next screen.

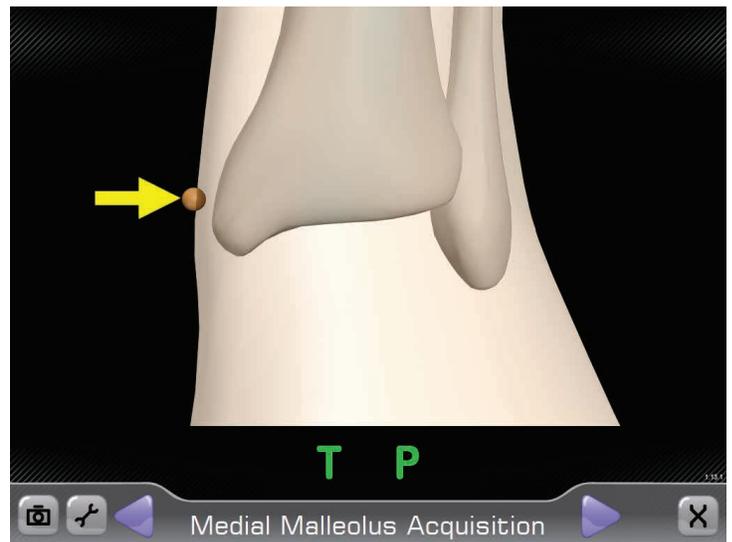


Figure 33
Perform Medial Malleolus Acquisition

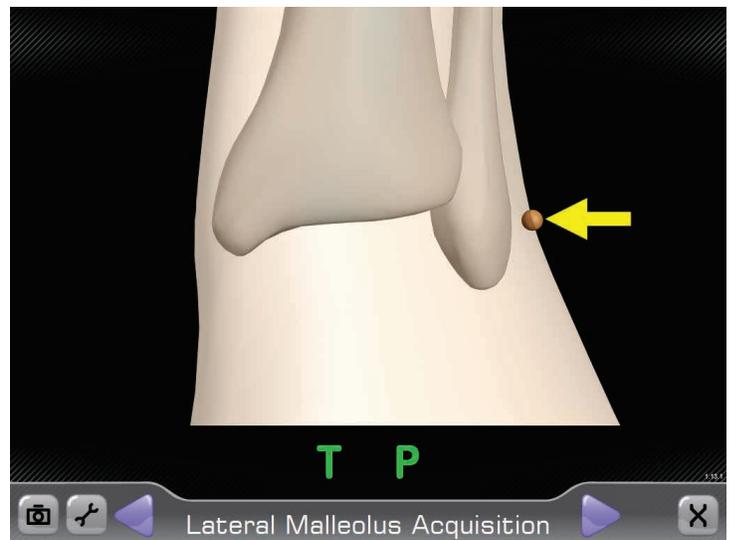


Figure 34
Perform Lateral Malleolus Acquisition

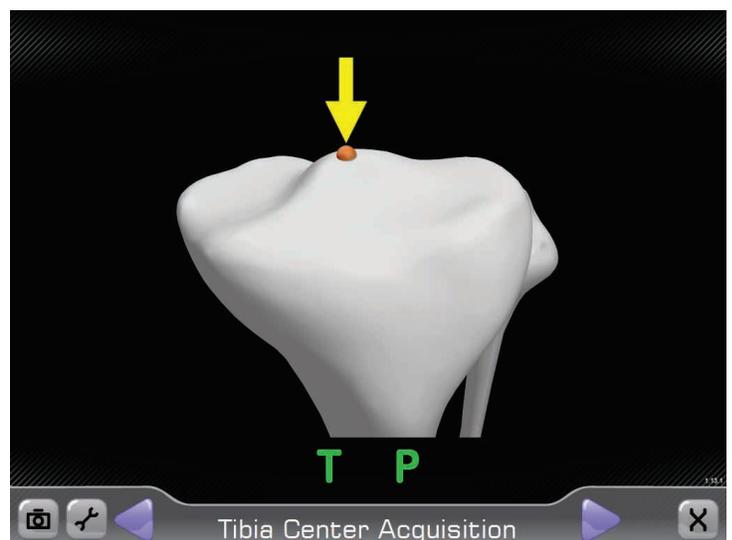


Figure 35
Perform Tibial Center Acquisition

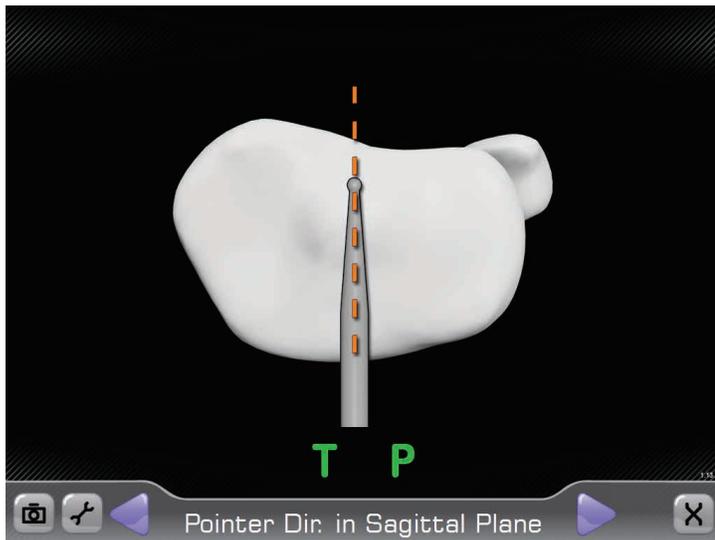


Figure 36
Perform the Pointer Dir in the Sagittal Plane

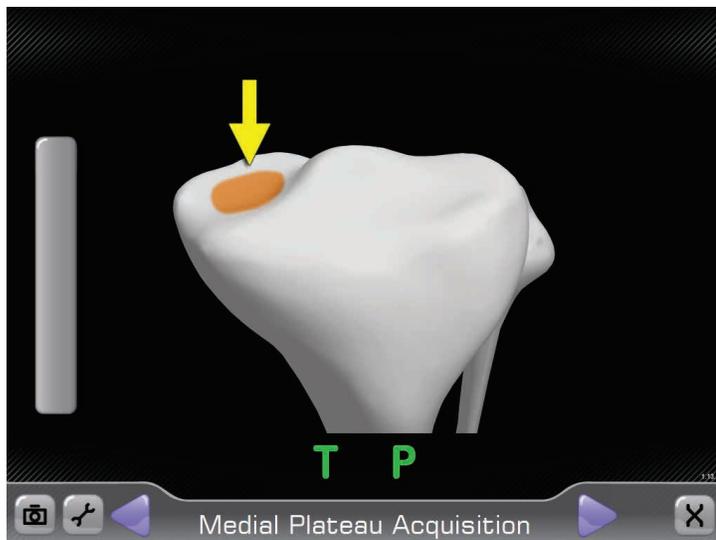


Figure 37
Perform Medial Plateau Acquisition

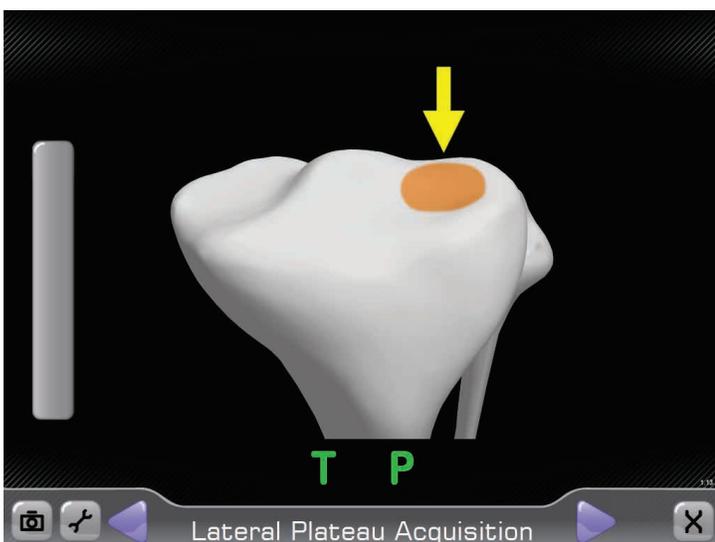


Figure 38
Perform Lateral Plateau Acquisition

The Pointer Dir. in Sagittal Plane screen is displayed (Figure 36). Position the tip of the Probe Tracker (P) at the posterior center (PCL insertion) and the shaft of the Probe Tracker (P) on the proximal tibia along a line connecting the center of the tibia and the medial-third of the tibia tubercle. Press the Forward button to register this orientation. The system will automatically advance to the next screen.

The Medial Plateau Acquisition screen is displayed (Figure 37). Position the tip of the Probe Tracker (P) on medial tibial plateau and press the Forward button. Ensure the tip of the tracker maintains contact with the plateau and trace a patch that captures the lowest point on the medial tibia plateau.

The progress bar will fill and audible clicks will indicate successful registration points. An audible tone will indicate registration is complete and the system will automatically advance to the Lateral Plateau Acquisition screen (Figure 38).

Repeat to acquire points for lateral plateau.

The Check Tibial Acquisitions screen is displayed (Figure 39). A graphical representation of the registered points (yellow dots) is displayed. The orange dots represent points that will be used by the system to determine resection levels.

If the Probe Tracker (P) is placed on the bone, the relative position of the tip is displayed as a blue dot. This can be used as an additional aid to review the registered points.

If it is necessary to redo the registration for any or all points, select the Redo Acquisitions button at the bottom of the Check Tibial Acquisitions screen (Figure 40). Select the acquisition(s) to redo from the Choose Acquisition(s) to redo prompt then select the Redo button. The system will repeat only the selected acquisitions.

Attach the Adjustable Module and Guide Tracker (G) to the Tibial Base (Figure 41)

- Press button on Adjustable Module and attach Tibial Base
- Release button and verify Adjustable Module is securely locked onto the base
- Press button on Guide Tracker (G) and attach to Adjustable Module
- Release button and verify tracker is securely locked to the module

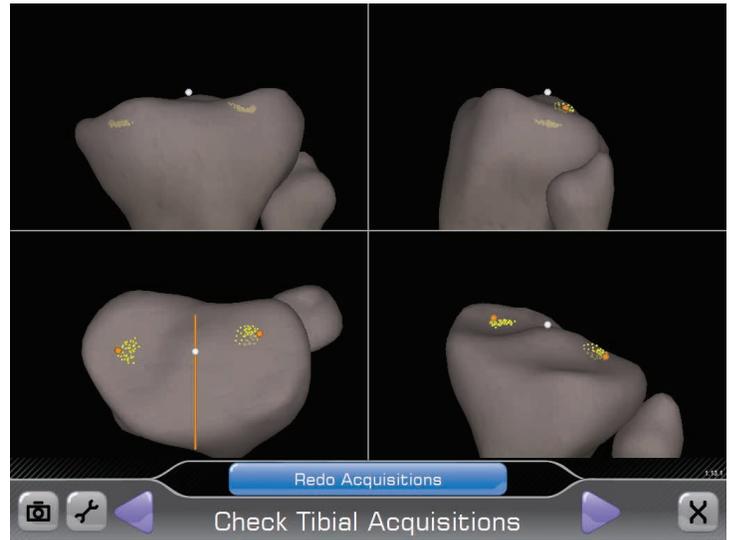


Figure 39
Check Tibial Acquisitions

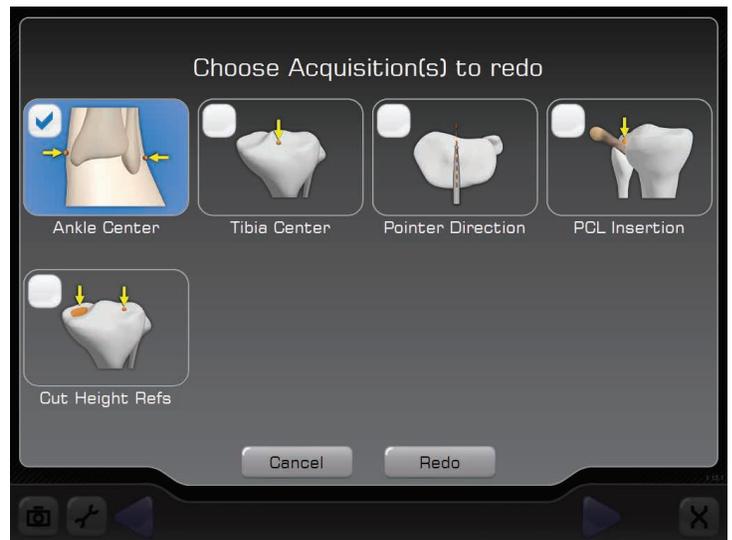


Figure 40
Option to Select Acquisitions to Redo

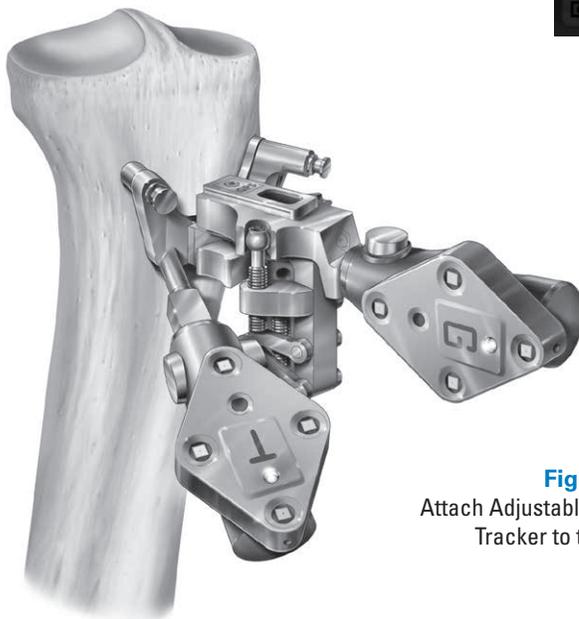


Figure 41
Attach Adjustable Module and Guide Tracker to the Tibial Base

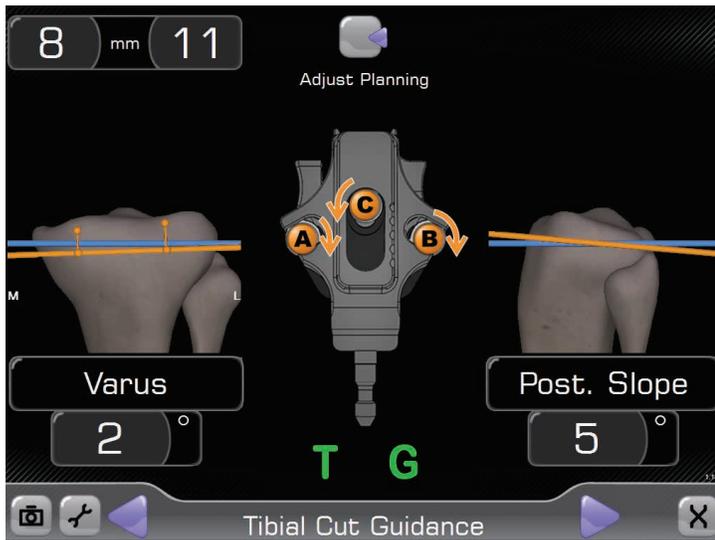


Figure 42
Prepare Tibial Cut Guidance



Figure 43
Turn the Screws on the Adjustable Module

Advance to the Tibia Cut Guidance screen (*Figure 42*). The blue lines indicate the planned tibial resection. The orange lines represent the resection based on the position of the Adjustable Module. The medial and lateral resection depth, varus/valgus angle and posterior slope angle displayed are consistent with the alignment of the Adjustable Module (orange line).

Use the 3.5mm Hex Driver to turn the A, B and C screws (*Figure 43*) on the Adjustable Module. The arrows indicate both magnitude and direction each screw needs to be turned for planned alignment. The A, B and C indicators, the arrows and orange lines will change to green when the Adjustable Module is within 1mm and/or 1-degree of the planned resection. As the position gets closer to 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 (*Figure 44*) where resection depth, varus/valgus angle and tibial slope angle can be modified. Select Resume Guidance to return to the Tibial Cut Guidance screen.

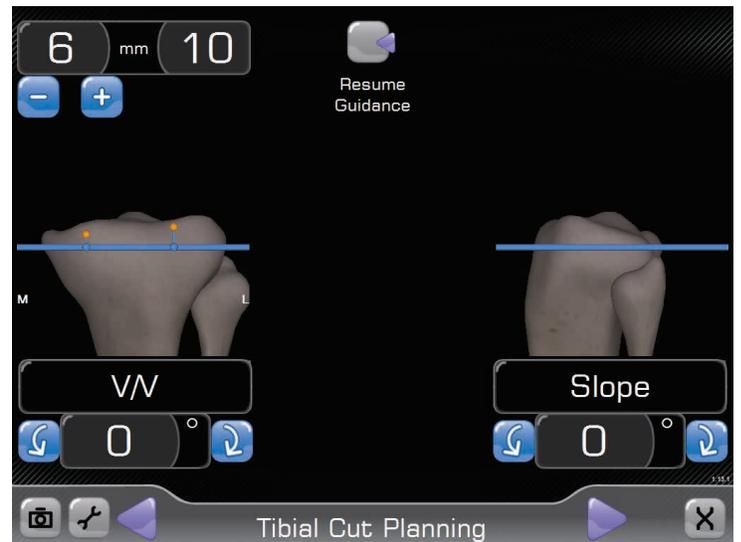


Figure 44
Option to Select Adjust Planning

Assemble the Tibial Cutting Block to the Adjustable Module (*Figure 45*).

- Press the button on the Tibial Cutting Block.
- Slide block onto the dovetail track on the Adjustable Module until it contacts the anterior tibia.
- Release the button and ensure the block is securely locked in position.
- Pin the guide using the lowest (distal) pin holes. Center cross-pin holes are optional.
- Advance to the Tibial Cut Control screen (*Figure 46*).
- Remove Guide Tracker (G) from Adjustable Module.

Perform tibial resection.

Assemble the Guide Tracker (G) to the Blade Drill Guide. Verify the tibial resection by placing the blade drill guide against the proximal tibial resection (*Figure 47*). Press Forward button on Probe Tracker (P) to advance to the next screen.

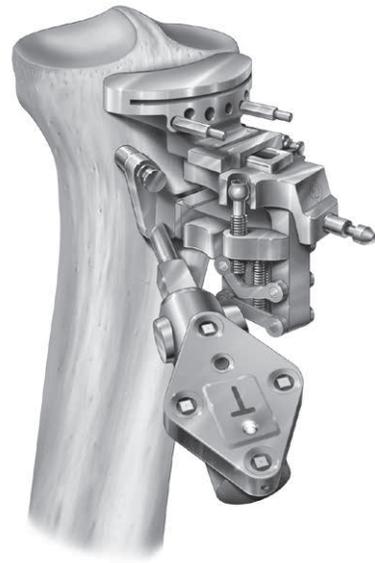


Figure 45

Assemble Tibial Cutting Block to Adjustable Module

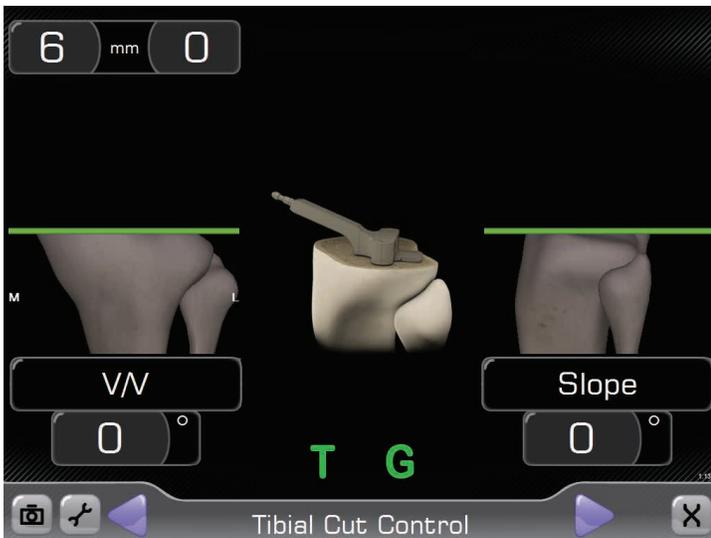


Figure 46

Advance to Tibial Cut Guidance

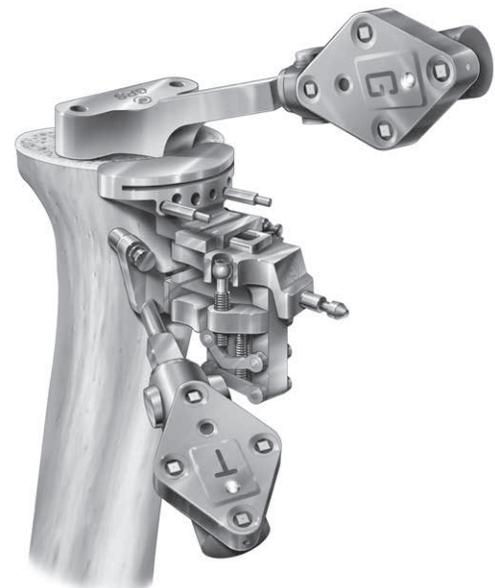
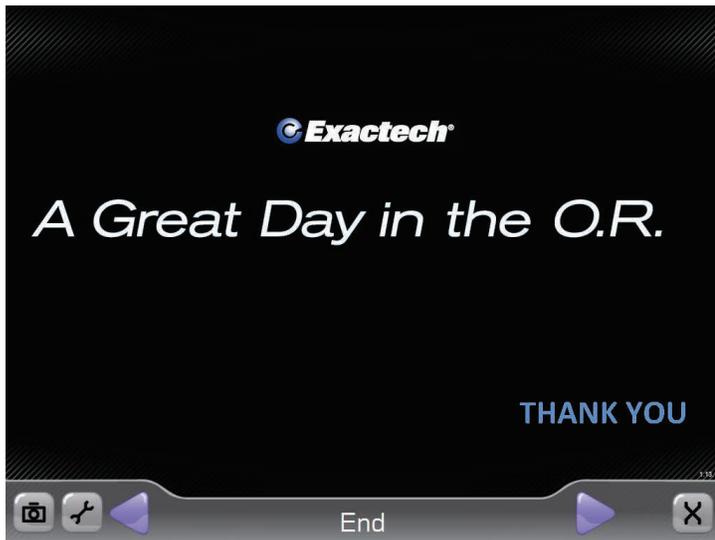


Figure 47

Verify Tibial Resection



This concludes the use for ExactechGPS use during surgery with the All-Cuts Profile. Select the Forward button to save the data to the Starter Key. Complete the surgical procedure according to the preferred Optetrak® or Optetrak Logic® operative technique.

INSTRUMENT LISTING

Catalog No. **Part Description**

A10007 ExactechGPS Knee Implant Kit

I00008 Control Unit



I00007 Display Unit



A10003 Probe Tracker (P)



A10004 Femoral Tracker (F)



A10005 Tibial Tracker (T)



A10005 Guide Tracker (G)



213-03-00 Intra-medullary Alignment Guide



521-40-13 Femoral Base Template



Catalog No.

Part Description

521-40-11 Femoral Base



521-11-10 Adjustable Module



521-11-04 Hex Driver (3.5mm)



521-40-12 Femoral Cutting Block



521-11-02 Blade Drill Guide



213-49-00 Collar Drill, 4mm (LPI)
201-50-00 Collar Drill, 4mm (Classic)



207-50-01 Holding Pin (Stabilizing Bullet)



521-30-03 Tibial Positioning Template



521-30-01 Tibial Base Left
521-30-02 Tibial Base Right



521-30-05 Tibial Cutting Block



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For additional device information, refer to the Exactech Knee System—Instructions for Use for a device description, indications, contraindications, precautions and warnings. For further product information, please contact Customer Service, Exactech, 2320 NW 66th Court, Gainesville, Florida 32653-1630, USA. (352) 377-1140, (800) 392-2832 or FAX (352) 378-2617.

Exactech does not practice medicine, and is not responsible for recommending the appropriate surgical technique for use on a particular patient. 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 comprehensive warnings, precautions, indications for use, contraindications and adverse effects.

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