EXACTECH | **KNEE**

Operative Technique
Addendum

TRULIANT®

ExactechGPS® TKA Pro Application

Exactech®

TABLE OF CONTENTS

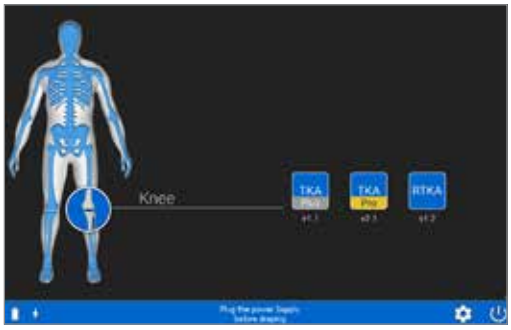
INTRODUCTION

ExactechGPS® is a dynamic computer-assisted technology that enhances the surgical experience with active intraoperative feedback for real-time execution in a compact and mobile system within the sterile field. Seamlessly integrated with the Truliant® Total Knee System, ExactechGPS provides a reproducible, efficient and personalized experience.

The ExactechGPS TKA Pro Application offers three levels of personalization through the RAPID, SMART and CUSTOM profile options, which are designed for ease of use, intra-operative flexibility and integration into your preferred surgical workflow.

The ExactechGPS TKA Pro Application provides a fully customizable surgical experience with advanced options, including planning, component sizing, rotation guidance, anatomical acquisitions, resection validation and integrated ligament balancing options. The ExactechGPS technology was developed in conjunction with:

Jeffrey Ginther, MD
James Huddleston III, MD
Raul Marquez, MD



Screen Layout

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.

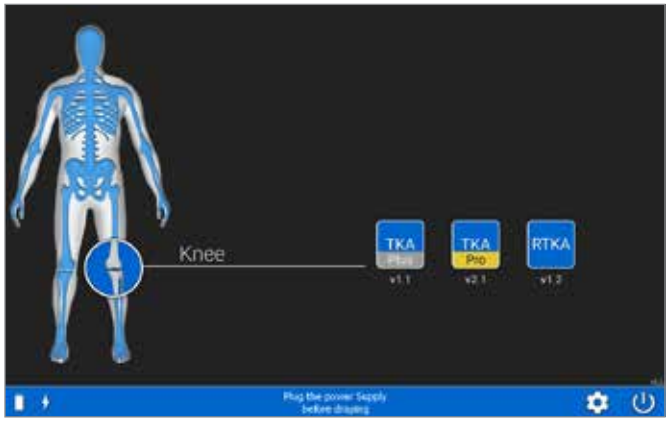


Figure 1
Start Application Screen

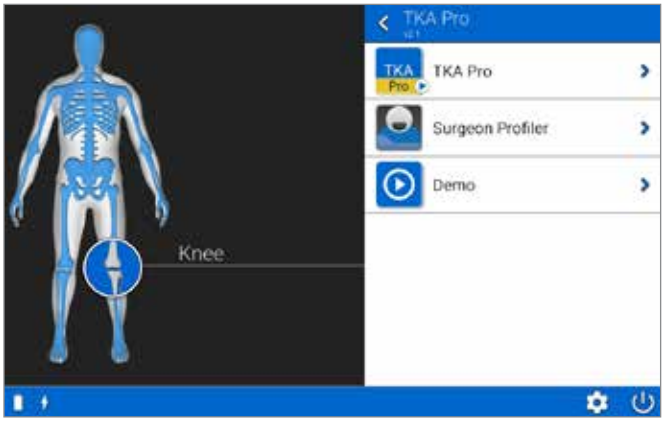


Figure 2
Confirmation Screen

SYSTEM SETUP

Application Screen

Turn on the ExactechGPS system. When prompted select the ExactechGPS 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

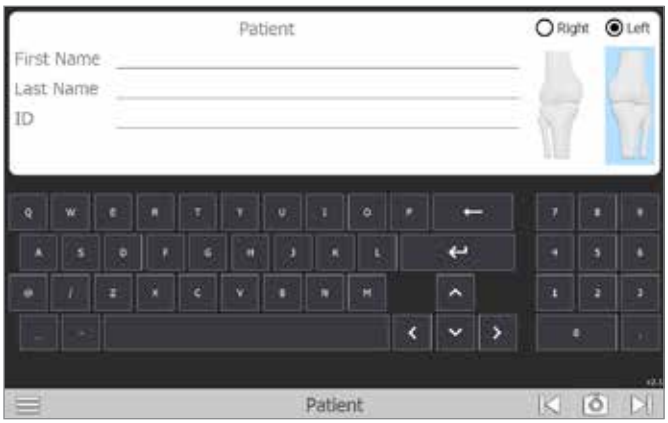


Figure 4
Patient Information Screen

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

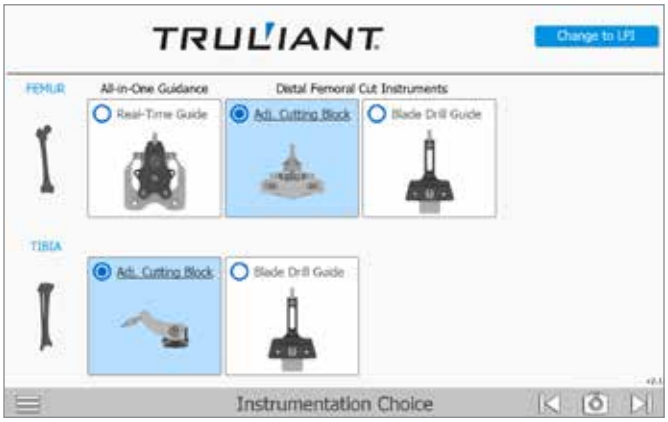


Figure 6
Instrument Choice Screen

Surgeon Information Screen

Surgeons registered on the ExactechGPS 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 ExactechGPS 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.

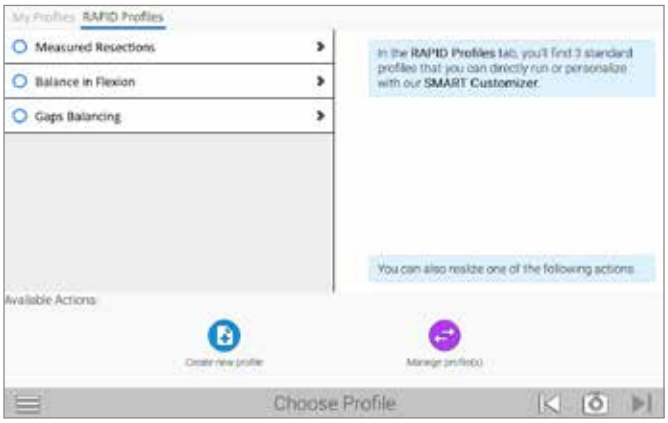


Figure 7
Profile List Screen

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).

If no changes are desired, click on the START SURGERY icon. Detailed profile descriptions can be found in the Appendix.

Note: *The Adjustable Cutting Block and the Measured Resections profile are detailed in this operative technique.*

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 negative side first or in reverse polarity may cause permanent damage to the tracker. Insert batteries positive side first (Figure 9).*

Figure 10
Verify Connection

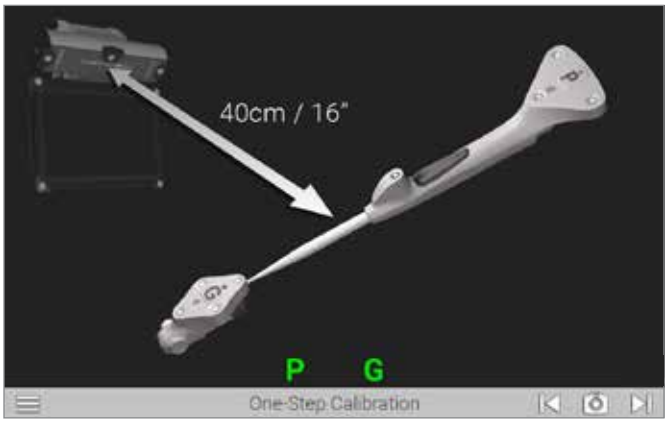


Figure 11
One-Step Calibration

Once batteries are in place and within visibility of the camera, the status LED on each tracker will illuminate solid red/orange and begin to blink green. Position the trackers with the LEDs facing the display unit. The trackers will display on the display unit and a green check mark will appear to verify connection *(Figure 10)*.

One-Step Calibration

Place the tip of the Probe into the dimple node at the top of the G Tracker *(Figure 11)*. 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 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 FIXATOR
for use with the Real-Time Guide and Adjustable Cutting Block

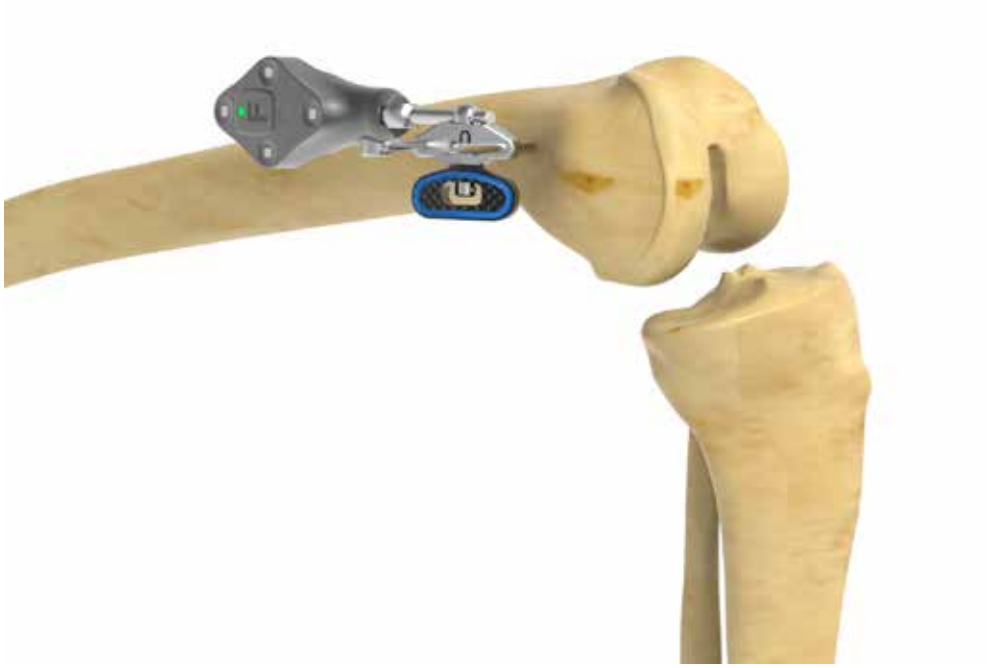


Figure 12
Place the External Fixator

FEMORAL PREPARATION

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. Using either the 0-degree External Tracker Fixator or the 30-Degree 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.

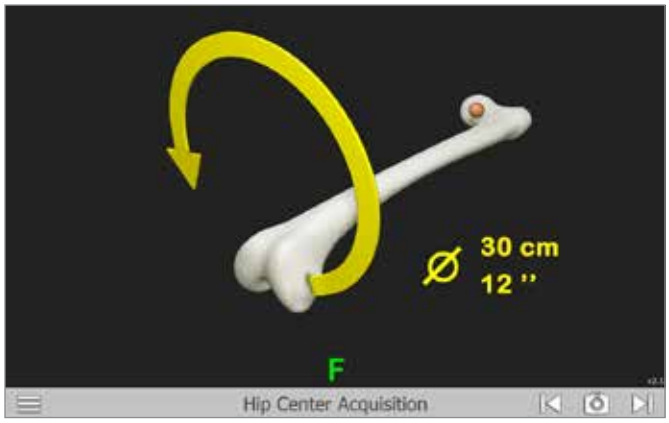


Figure 13
Hip Center Acquisition Screen

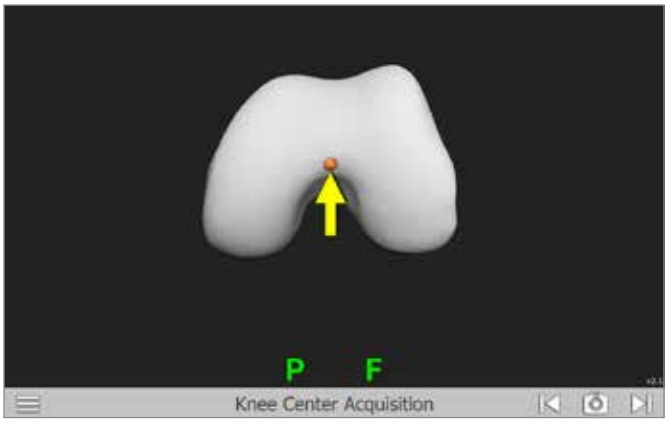


Figure 14
Knee Center Acquisition Screen

FEMORAL ACQUISITIONS

Hip Center Acquisition

Movement of the bone will initiate the acquisition process *(Figure 13)*. 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 14)*.

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

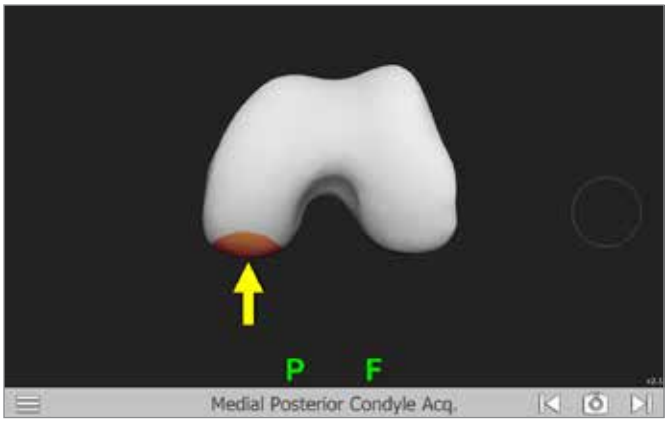


Figure 15
Medial Posterior Condyle Acquisition Screen

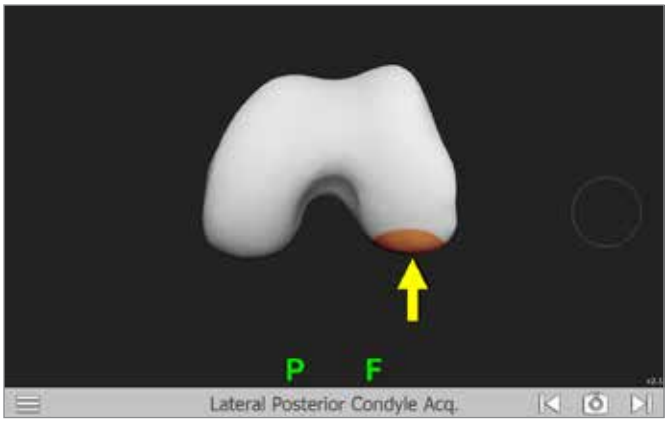


Figure 16
Lateral Posterior Condyle Acquisition Screen

Posterior Condyle Acquisition

Position the tip of the Probe on the medial posterior condyle press the Forward button *(Figure 15)*. Ensure the tip of the probe maintains contact with the condyle and trace a patch that captures the apparent most posterior aspect of the condyle. This is best achieved by moving the probe tip in proximal-distal direction in the sagittal plane.

An audible tone and a green check mark will indicate registration is complete and the system will automatically advance to the next screen *(Figure 16)*. Repeat to acquire data for the lateral posterior condyle.

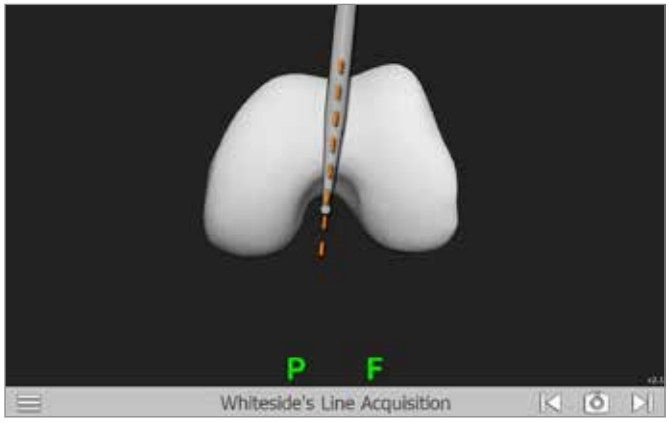


Figure 17
Whiteside's Line Acquisition Screen (optional)

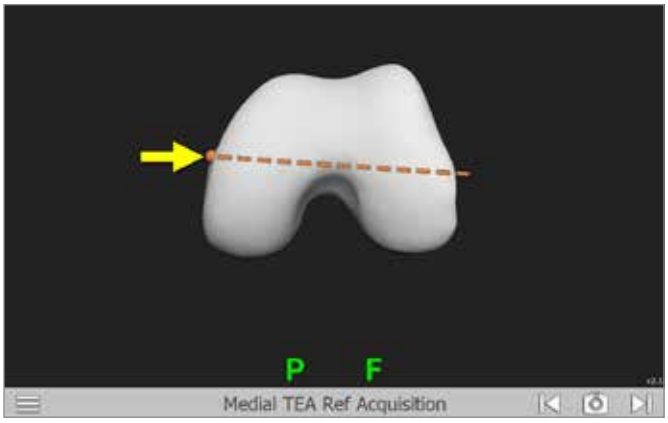


Figure 18
TEA Medial and Lateral Points Acquisition Screen (optional)

Whiteside's Line and TEA (Optional Acquisitions)

If Whiteside's line *(Figure 17)* or Trans-Epicondyle Axis (TEA) are selected in the surgeon profile, you can now perform the acquisitions. *(Figure 18)*.

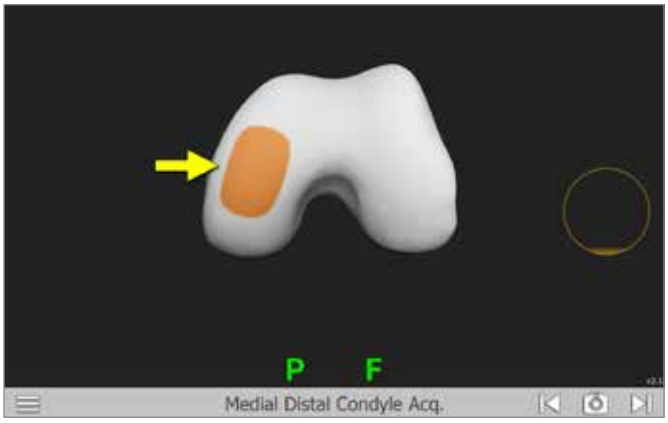


Figure 19
Medial Distal Condyle Acquisition Screen

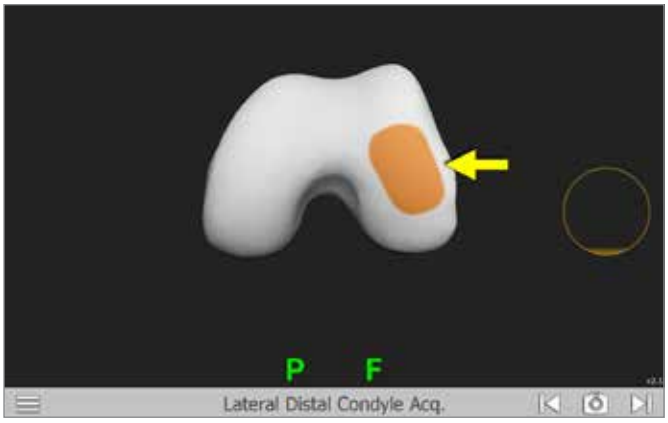


Figure 20
Lateral Distal Condyle Acquisition Screen

Distal Condyle Acquisition

Position the tip of the Probe on the medial distal condyle *(Figure 19)* and press the Forward button. Ensure the tip of the probe 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.

An audible tone and a green check mark will indicate registration is complete and the system will automatically advance to the next screen *(Figure 20)*. Repeat to acquire data on the lateral distal condyle.

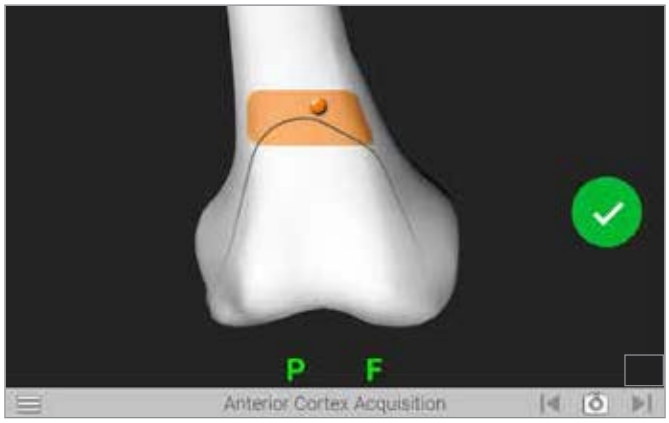


Figure 21
Anterior Cortex Acquisition Screen

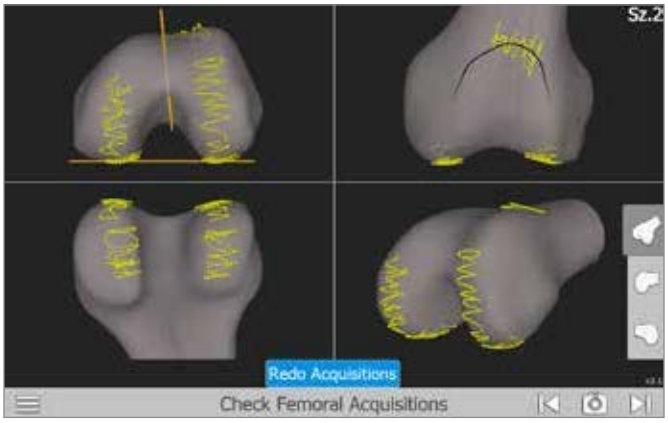


Figure 22
Check Femoral Acquisition Screen

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 *(Figure 21)*. Ensure the tip of the tracker maintains contact with the anterior cortex and trace within the patch in both the medial and lateral sides.

Check Femoral Acquisitions

A graphical representation of the registered points (yellow dots) will be displayed *(Figure 22)*. The orange dots represent 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. If it is necessary to redo the registration for any points, select the "REDO ACQUISITIONS" button at the bottom of the screen *(Figure 22)*. Select the acquisitions to redo *(Figure 23)*. Select the redo button and the system will repeat the selected acquisitions. Once completed, a summary screen will appear and if no other changes are desired, advance to the next screen.

All Cuts Femoral Planning

The screen will be displayed based on the specific surgeon profile you have created. It will be divided into panels and will have some or all parameters provided: varus/valgus, distal resection depth, rotation and flexion. Each of these values along with the anterior-posterior position and size of

Figure 23
Redo Femoral Acquisition Screen

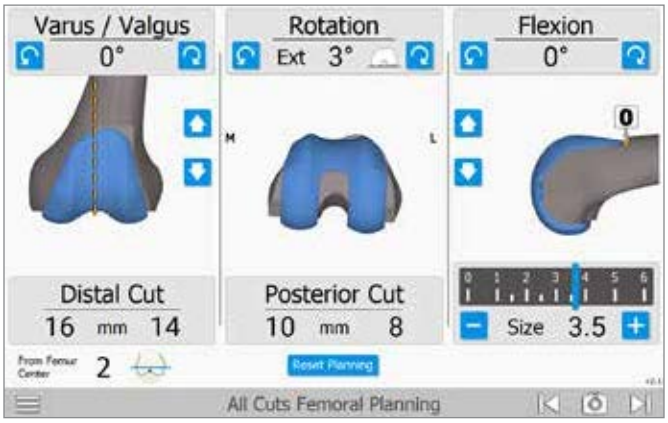


Figure 24
All Cuts Femoral Planning Screen
(Panels vary depending on your profile selection)

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 *(Figure 24)*.

- **V/V Panel (Left)** displays femoral varus/valgus angle perpendicular to the mechanical axis and the distal resection depth from each condyle. Varus/Valgus adjustments can be made in 1-mm increments and impact the distal condyle resection.
- **Rotation Panel (Middle)** displays the femoral rotation relative to the posterior condyles along with the resection depth of the posterior condyles. Rotational adjustments can be made in 1-mm increments and impact the posterior condyle resection.
- **Flexion Panel (Right)** 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. Changing the flexion parameter impacts the posterior resection. The arrows in the middle of the panel adjust anterior-posterior position in 1-mm increments and impact 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. The femoral component size can be adjusted at the bottom of the panel. Adjusting the component size will impact the posterior condyle resection.

REAL-TIME GUIDE
Placement and Adjustments

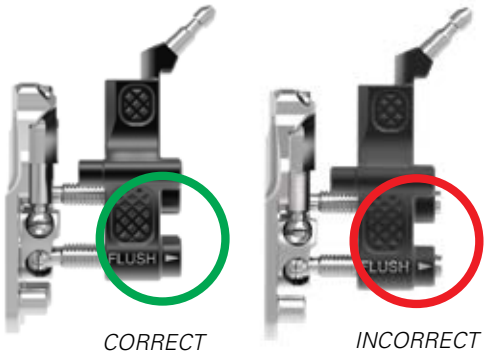


Figure 25
Neutralize screws to FLUSH position

Figure 26
Assemble the Real-Time Guide

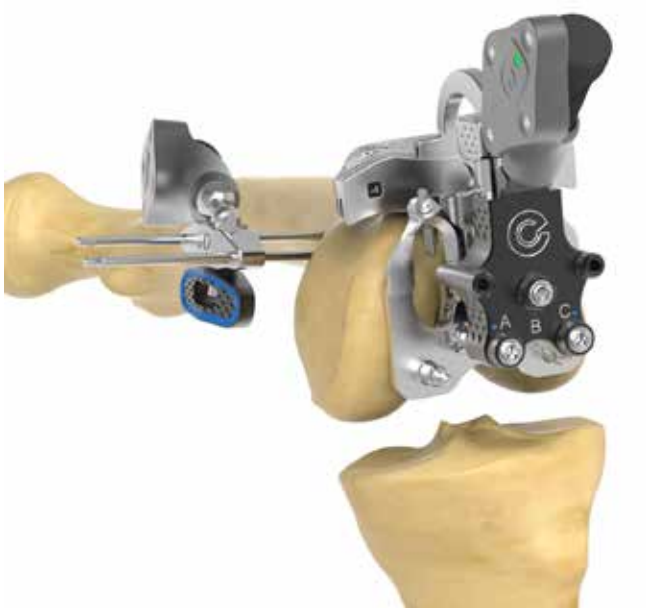


Figure 27
Place the Real-Time Guide

FEMORAL ADJUSTMENTS

Real-Time Guide

Prior to this step, neutralize the Real-Time Guide by aligning the screw ends FLUSH to the instrument body *(Figure 25)*.

Insert the Real-Time Guide Coupler into the Truliant Distal Femoral Resection Guide and connect assembly to the Real-Time Guide *(Figure 26)*. Place the coupler so that the ball detent rests on the instrument.

Attach the G Tracker on the Real-Time Guide to face the camera. Verify the tracker is securely locked.

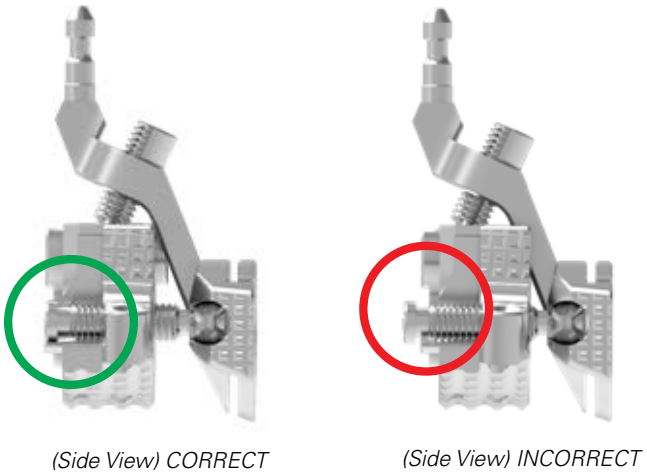
To position the block on the femur, hold the Real-Time Guide with the G Tracker facing the camera and place on the femur. Minimize the distance between the blue and white line displayed on the display screen. This will reduce the amount of adjustments needed to get to your planned parameters.

Pin the Real-Time Guide to the femur using at least two pins *(Figure 27)*.

Note: *When two pins are used, one pin should be at the top of the instrument and the other should be in the bottom of the instrument to enhance stability.*

Do not pin the Truliant Distal Femoral Resection Block at this time.

ADJUSTABLE CUTTING BLOCK
Placement and Adjustments



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

Figure 28
Neutralize the Block

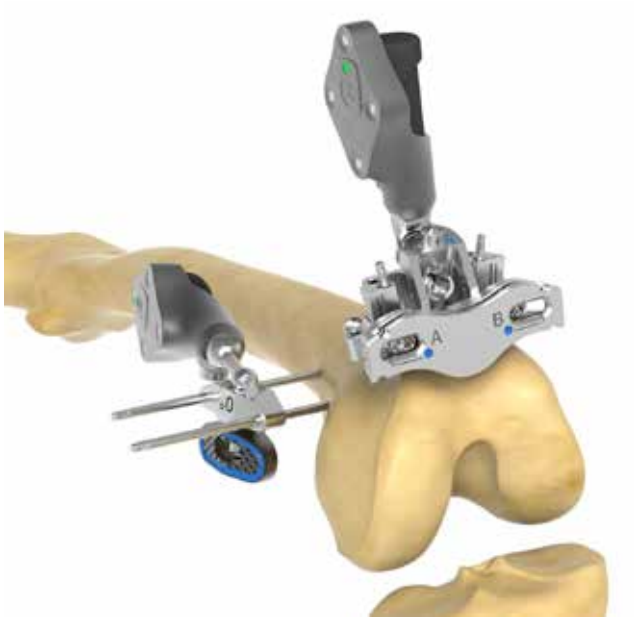


Figure 29
Place the Adjustable Cutting Block

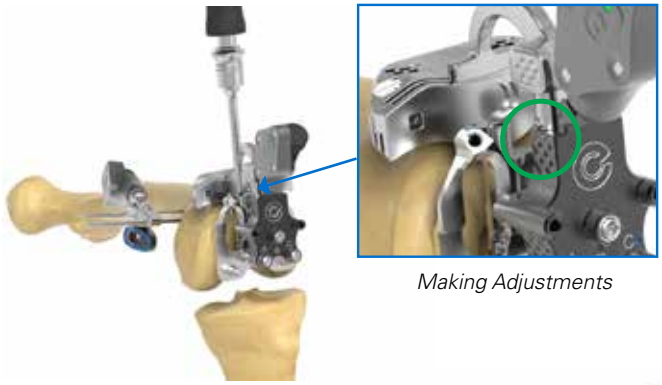
Adjustable Cutting Block

Prior to this step, neutralize the Femoral Adjustable Cutting Block by aligning the screw ends FLUSH to the instrument body *(Figure 28)*.

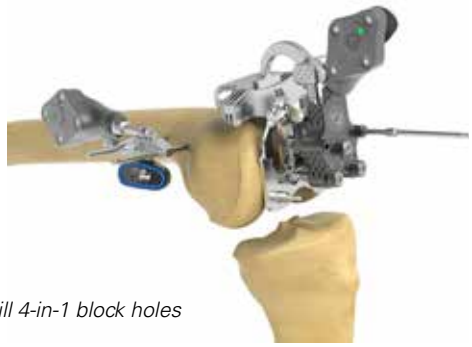
Place the G Tracker on the Adjustable Cutting Block facing the camera and verify the tracker is securely locked into place. To position the block on the femur, hold the Adjustable Cutting Block with the G Tracker facing the camera and place on the anterior femur. Minimize the distance between the blue and the white line displayed on the display screen. This will reduce the amount of adjustments needed to get to the planned parameters.

Pin the TKA Adjustable Cutting Block to the femur using at least two pins, one on each side *(Figure 29)*.

REAL-TIME GUIDE
Parameter Adjustments



Making Adjustments



Drill 4-in-1 block holes

Figure 30
Distal Femoral Cut Guidance Screen with Real-Time Guide

Figure 31
Pin Truliant Femoral Resection Guide

Real-Time Guide *(Figure 30)*: On the display screen the blue lines indicate the planned distal resection. White lines represent the resection based on the position of the selected block. The varus/valgus, resection and flexion angle parameters displayed are consistent with the alignment of the white line. When the alignment of the block is within 1mm or 1-degree of the planned resection, white lines change to green.

Use the 3.5mm Hex Driver to adjust the screws in alphabetical order (A, B, C, D, E) 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 screws until the indication arrows disappear. This will result in a green resection line corresponding to the planned resection.

Note: *If there is increased resistance or tension while turning the screws, switch to the next screw and continue or you may proceed to screw E and adjust and work back to screw A until all arrows are reduced as much as possible. To maximize the ability for adjustments, lift the coupler slightly upward off the bone with the Truliant Distal Femoral Resection Guide attached. Make adjustments, then slide the Truliant Distal Femoral Resection Guide close to the bone.*

Drill the rotation holes using the Collared 3.2mm Drill Bit before pinning the Truliant Distal Femoral Resection Guide to avoid potential movement of the Real-Time Guide.

Pin the Truliant Distal Femoral Resection Block in the neutral holes *(Figure 31)*. Remove the Coupler and the Real-Time Guide from the bone.

ADJUSTABLE CUTTING BLOCK
Parameter Adjustments

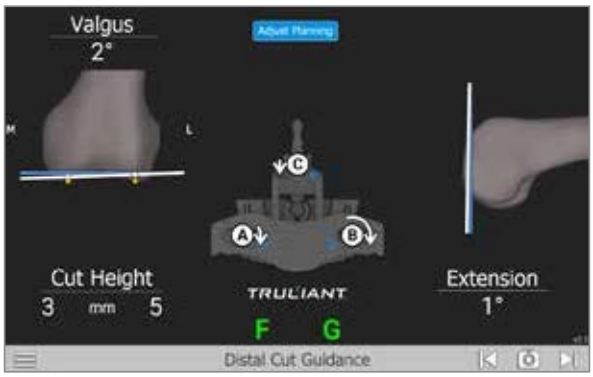


Figure 32
Distal Femoral Cut Guidance Screen
with Adjustable Cutting Block

Adjustable Cutting Block *(Figure 32)*: Use the 3.5mm Hex Driver to adjust the screws in alphabetical order (A, B, C) 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 screws until the indication arrows disappear and the Adjustable Cutting Block display on the screen turns green. Green indicates the alignment of the block is within 1mm or 1-degree of the planned resection values.

REAL-TIME GUIDE
Distal Femoral Resection

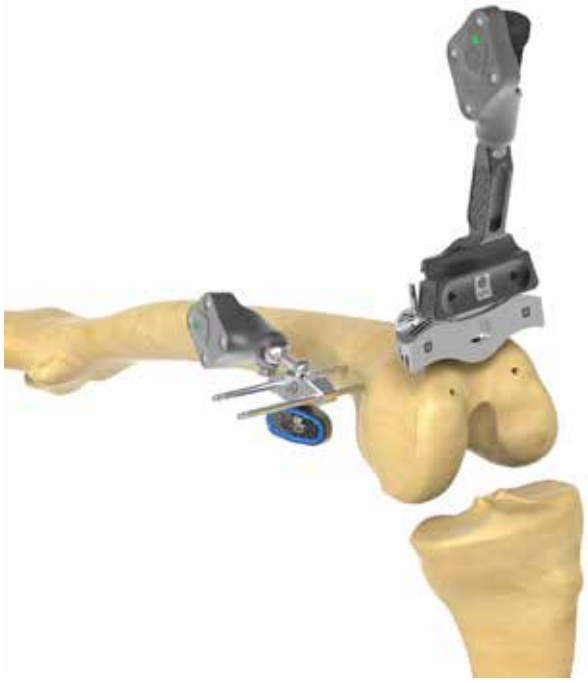


Figure 33
Check Distal Resection

FEMORAL RESECTION

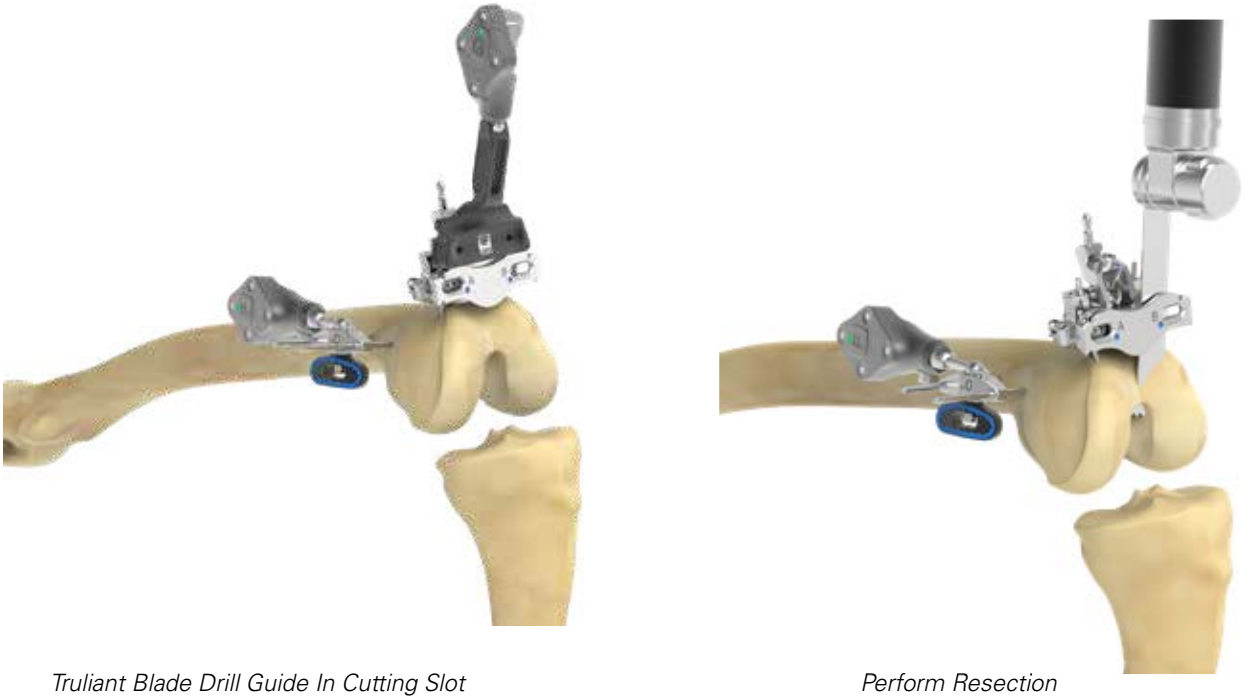
Distal Femoral Resection

Using the Truliant Blade Drill Guide with the attached G Tracker, place in the resection cutting slot. Verify the tracker is securely locked in place.

Review the display screen to confirm the planned placement of the Truliant Distal Femoral Resection Block *(Figure 33)*. An additional pin may be added for increased stability in the cross pin hole location.

Perform the distal resection. Remove block and pins after resection.

ADJUSTABLE CUTTING BLOCK
Distal Femoral Resection



Truliant Blade Drill Guide In Cutting Slot

Perform Resection

Figure 34
Perform Distal Resection

Adjustable Cutting Block

Using the Truliant Blade Drill Guide with the attached G Tracker, place in the resection cutting slot *(Figure 34)*. Verify the G Tracker is securely locked into place. Review the display screen to confirm the planned placement of the Adjustable Cutting Block.

Perform the distal resection through the Adjustable Cutting Block slot. Remove block and pins after resection.

REAL-TIME GUIDE
Distal Femoral Finishing Block

Figure 35
Validate Distal Resection

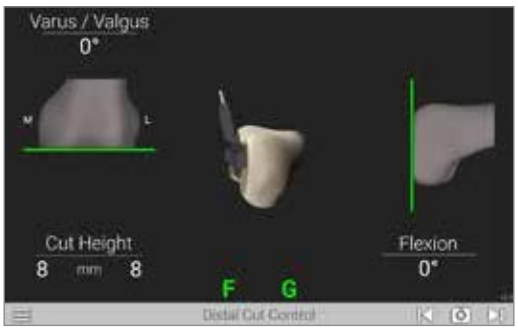


Figure 37
Pin Distal Femoral Finishing Guide

Figure 36
Assemble Finishing Adaptor Pin to Distal Femoral Finishing Guide

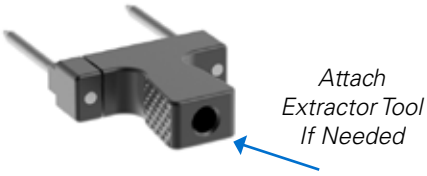


Figure 38
Remove Adaptor Pin

Distal Cut Control and Remaining Femoral Preparation

With the Truliant Blade Drill Guide positioned against the distal femur *(Figure 35)*, view the display screen to review your cuts and press the Forward button on the Probe to advance to the next screen.

Assemble the Truliant Finishing Pin Adpator to the size specific Truliant Femoral Finishing Guide recommended by the ExactechGPS system by placing the Truliant Finishing Pin Adpator in the zero hole position *(Figure 36)*. Place on the femur by inserting the pins into the holes previously drilled in the distal femur.

Once the Truliant Femoral Finishing Guide is properly positioned, secure it by inserting two headed pins into the cross pinholes on the side *(Figure 37)*. Ensure the Truliant Femoral Finishing Guide is securely fixed and stays flush against the distal femur.

Remove the Truliant Finishing Pin Adpator. An extractor attachment can be attached for removal if necessary *(Figure 38)*.

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

Continue with the femoral preparation according to the protocol found in the Truliant Primary Operative Technique.

ADJUSTABLE CUTTING BLOCK
Distal Femoral Finishing Block

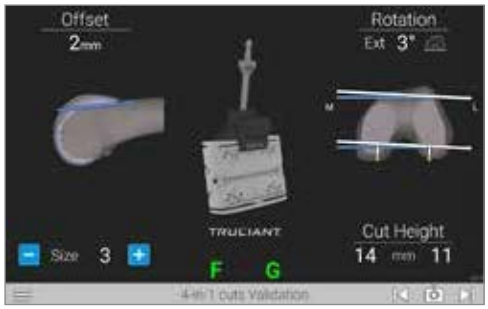


Figure 39
Validate Distal Resection

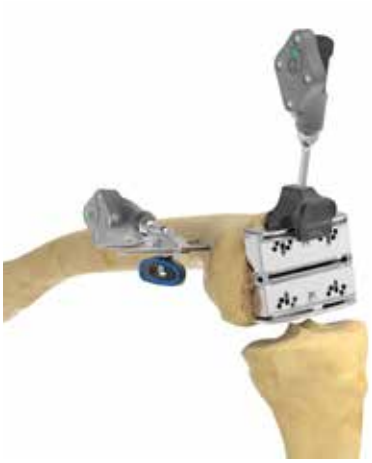


Figure 40a and 40b
Adjust and Pin Distal Femoral Finishing Block

4-in-1 Cut Guidance and Remaining Femoral Preparation

With the Truliant Blade Drill Guide positioned against the distal femur, *(Figure 39)* view the display screen to review your cuts and press the Forward button on the Probe to advance to the next screen.

Attach the Femoral Finishing Guide Tracker to the size-specific Truliant Femoral Finishing Guide recommended by the ExactechGPS system. Verify the tracker is securely locked in place.

Place the assembled component on the distal femoral resection previously completed. Adjust the rotation of the block until the blue and white lines merge and the green lines appear. Green indicates the alignment of the block is within 1mm or 1 degree of the planned values.

Once the Truliant Femoral Finishing Guide is properly positioned, secure by inserting two headed pins into the cross pinholes on the side (*Figure 40a and 40b*). Ensure the Truliant Femoral Finishing Guide is securely fixed and stays flush against the distal femur.

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.

Continue with the femoral preparation according to the protocol found in the Truliant Primary Operative Technique.

DETAILED OPERATIVE TECHNIQUE

TIBIA PREPARATION

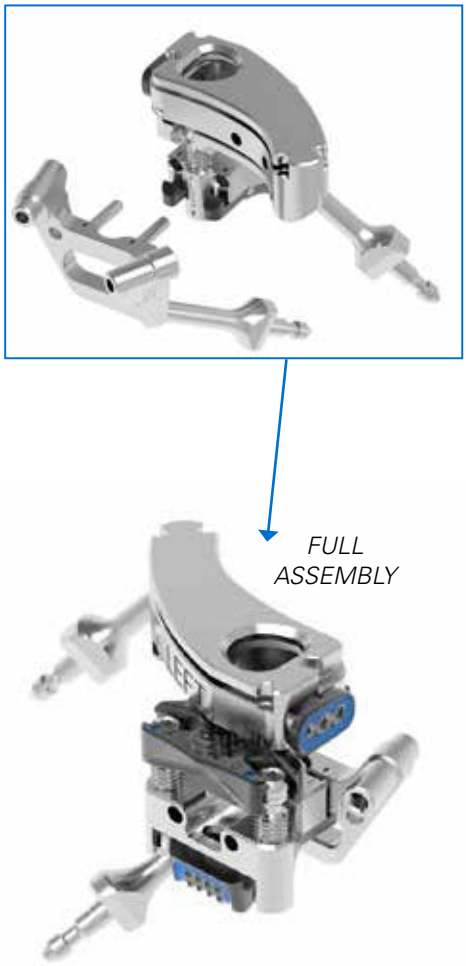


Figure 41
Assemble Tibial Resection Guide to Tibial Base

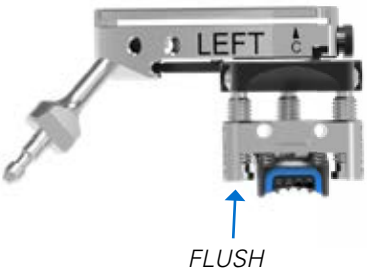


Figure 42
Neutralize Block

Figure 43
Position Template to Tibial Base

TIBIA PREPARATION

Attach the right or left Tibial Resection Guide to a side-specific Tibial Base *(Figure 41)*.

Neutralize the Tibial Resection Guide by aligning the screw ends flush to the instrument body *(Figure 42)*.

Assemble the Truliant Extra-Medullary (EM) Tibial Alignment Guide to the Ankle Clamp. Connect the Tibial Resection Guide (right or left) with the Truliant Adjustable Tibial Stylus and position the assembly against the tibia just medial to the tibial tubercle *(Figure 43)*. Adjust your varus/valgus, slope and resection height using the Truliant instruments per your standard surgical preference.

Attach Trackers to Tibia

Attach the T Tracker to the Tibial Base of the instrument and lock into place. Be sure the tracker is facing toward the camera.

Note: *It is important to ensure the tracker is locked into place and does not rotate or move when connected to the instrument.*

Pin the Tibial Base.

Note: *You may leave the EM Guide attached to the assembly to provide stability of the base and cutting block.*

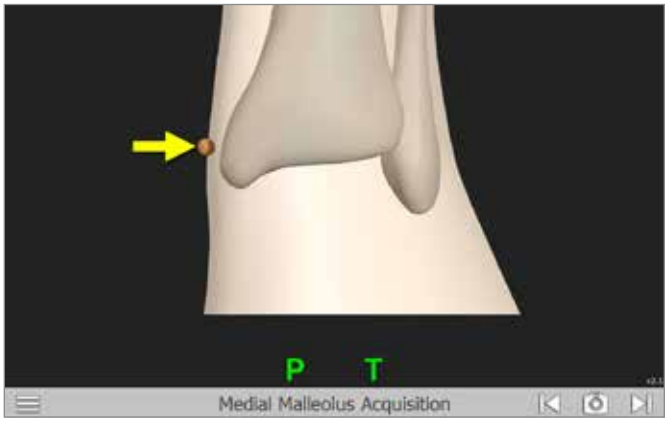


Figure 44
Medial Malleolus Acquisition Screen

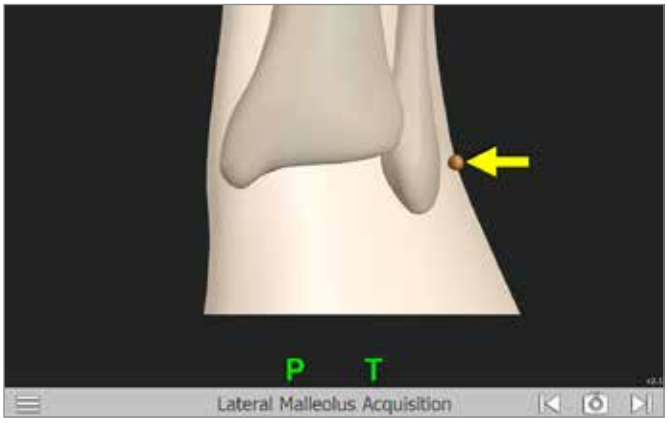


Figure 45
Lateral Malleolus Acquisition Screen

TIBIA ACQUISITIONS

Malleolus Acquisition

Position the tip of the Probe on the medial malleolus and press the Forward button to register this point *(Figure 44)*.

The system automatically advances to the next screen *(Figure 45)*. Repeat to acquire point for lateral malleolus acquisition.

Note: *It may be helpful to position the knee in mid-flexion or full extension to easily acquire the lateral malleolus.*

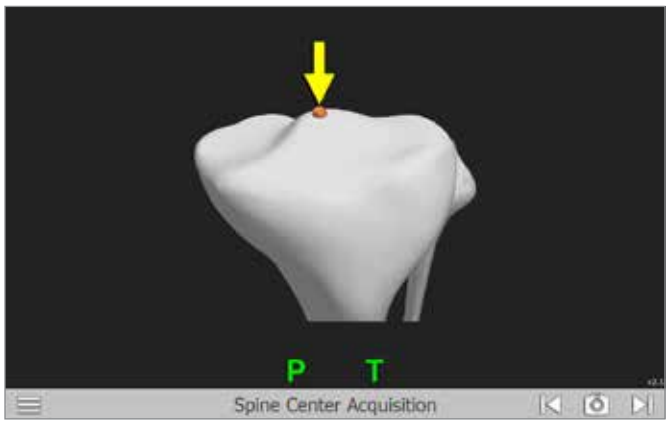


Figure 46
Tibia Center Acquisition Screen

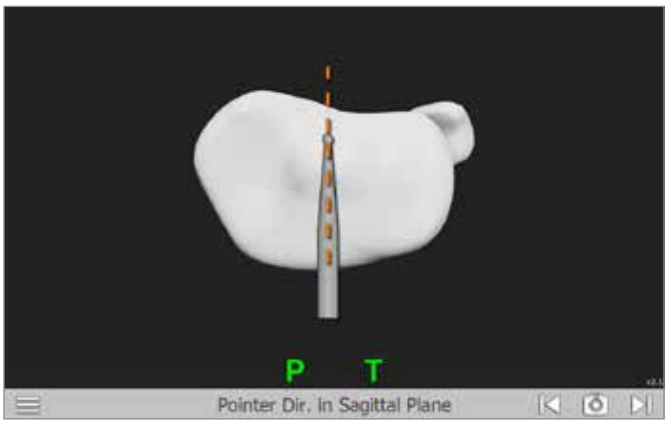


Figure 47
Pointer Direction in Sagittal Plane Acquisition Screen

Tibial Center Acquisition

Position the tip of the Probe on the center of the proximal tibia and press the Forward button to register this point *(Figure 46)*. The system will automatically advance to the next screen.

Note: *This point is used to determine the mechanical axis of the tibia.*

Sagittal 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 47)*. Press the Forward button to register this orientation. The system will automatically advance to the next screen.

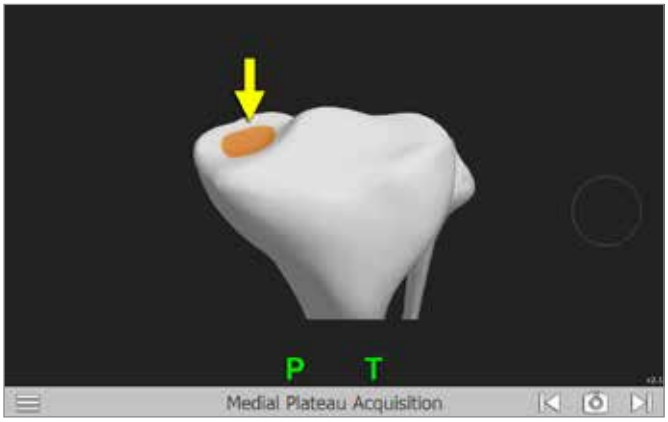


Figure 48
Medial Plateau Acquisition Screen

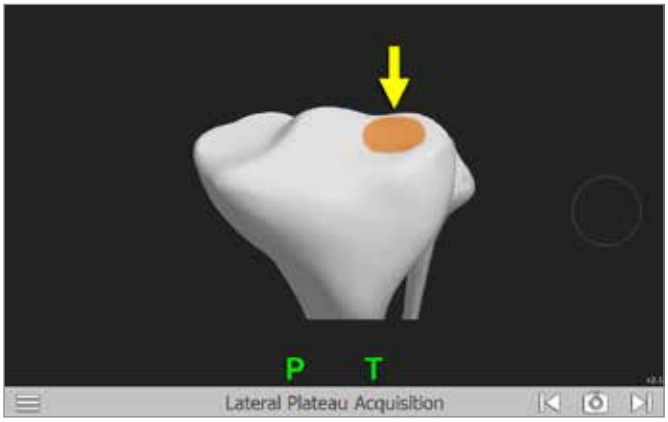


Figure 49
Lateral Plateau Acquisition Screen

Medial Plateau Acquisition

Position the tip of the Probe on medial tibial plateau and press the Forward button *(Figure 48)*. Ensure the tip of the tracker maintains contact with the tibial plateau and trace a patch that captures the lowest point on the medial tibial plateau.

An audible tone and a green check mark will indicate registration is complete and the system will automatically advance to the next screen *(Figure 49)*. Repeat to acquire points for lateral plateau acquisition.

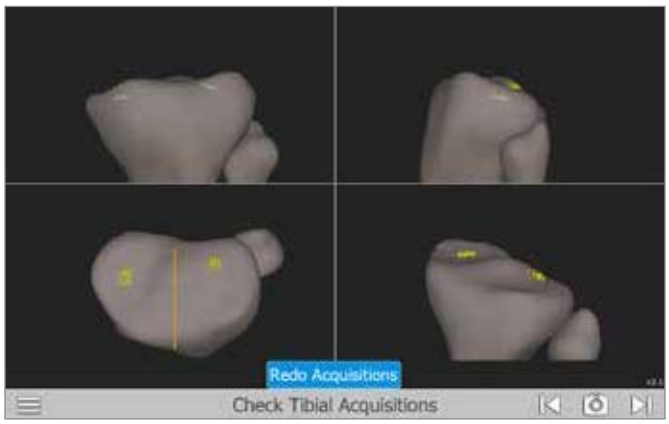


Figure 50
Check Tibial Acquisition Screen

Figure 51
Redo Tibial Acquisition Screen

Check Tibial Acquisitions

A graphical representation of the registered points (yellow dots) is displayed *(Figure 50)*. The orange dots represent points that will be used by the system to determine resection levels. If it is necessary to redo the registrations for any points, select the REDO ACQUISITIONS button at the bottom of the screen.

Select the acquisitions to redo *(Figure 51)*. Select the REDO button and the system will repeat the selected acquisitions. Once complete, a summary screen will appear and if no other changes are desired, advance to the next screen.

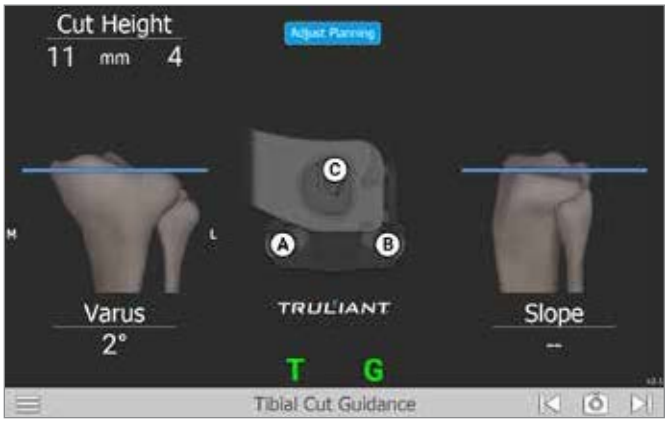


Figure 53
Tibial Cut Guidance Screen

Figure 52
Attach G Tracker to Tibial Resection Guide

Figure 54
Adjust Tibial Resection Guide

TIBIAL ADJUSTMENTS

Attach the G Tracker to the tracker post to the cutting slot *(Figure 52)*. Verify tracker is securely locked to the cutting slot and is facing the camera.

Tibial Cut Guidance

The blue lines indicate the planned tibial resection *(Figure 53)*. The white lines represent the resection based on the position of the Tibial Resection Guide.

Use the 3.5mm Hex Driver to turn the A, B and C screws in alphabetical order *(Figure 54)* on the Tibial Resection Guide. 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 white lines will change to green when the Tibial Resection Guide 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.*

▲ *AWAY FROM THE BONE*

CLOSE TO THE BONE ▼

Figure 55
Slide Tibial Block

Figure 56
Invert Saw for Increased Access to Cutting Slot

TIBIAL RESECTION

Optional: After your adjustments, you may check the position of the cutting slot by placing the Truliant Blade Guide into the cutting slot and verify parameters have not changed.

Prior to resection, press the button on the side of the Resection Guide and place your finger in the open area (same location as the C adjustment screw) to slide the slot located in the Tibial Resection Guide forward as close as possible to the bone *(Figure 55)*.

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

Perform tibial resection. Invert the saw to increase access to cutting slot and avoid touching the EM Guide during resection *(Figure 56)*.

Figure 57
Tibial Cut Control Screen

Figure 58
Final Screen

Tibial Cut Control Screen

Advance to the next screen *(Figure 57)*. After the resection has been completed, assemble the G Tracker to the Truliant Blade Drill Guide. Verify tracker is securley locked into place.

Verify the tibial resection by placing the Truliant Blade Drill Guide against the proximal tibial resection.

Press Forward button on the Probe to advance to the next screen and save your data. This is the end of ExactechGPS TKA Pro Application *(Figure 58)*.

The Tibial Resection Guide can now be removed. Completely open the Truliant ankle clamp. Press the trigger to release the Tibial Resection Guide, Tibial EM Guide and ankle clamp from the tibia.

Note: *If performing post-implant kinematics, pull the EM Guide straight out from the bone to avoid disturbing the tibial base stability on the bone. Once post-implant kinematics has been completed, remove pins and tibial baseplate. Continue with your tibial cuts according to the protocol found in the Truliant Primary Operative Technique.*

APPENDIX

FEMORAL INSTRUMENT GUIDE OPTIONS

Approach	Key Points	Instruments	
ADJUSTABLE CUTTING BLOCK	• Distal femoral cuts and rotation using two instruments • Three adjustments • Real-time guidance	Adjustable Cutting Block	
		Truliant Finishing Guide Tracker	
		External Fixator 0° or 30°	
REAL-TIME GUIDE	• Position all distal femoral cuts and rotation at one time with same instrument • Five adjustments • Real-time guidance • Pre- and postoperative kinematics	Real-Time Guide	
		External Fixator 0° or 30°	
		Truliant Distal Femoral Resection Guide	

Exactech offers you three profile options to align with your preferred surgical workflow.

RAPID PROFILE

Offers three pre-defined profiles options:

- Measured Resection Profile includes femoral planning, distal cut, 4-in-1 femoral cuts and tibial cut
- Balance in Flexion Profile includes distal cut, tibial cut, balance in flexion, femoral planning and 4-in-1 femoral cuts
- Gap Balancing Profile includes pre-operative kinematics, tibial cut, balance in extension, balance in flexion, femoral planning, distal cut, 4-in-1 femoral cuts and post-operative kinematics

SMART PROFILE

- Allows the flexibility to personalize your preferred surgical technique, make changes to resection depths, resection orientation, anatomical reference points, femoral rotational references and pre/post-operative kinematics.

CUSTOM PROFILE

- In addition to all of the parameters options available in the SMART profile, this section offers advanced options for anatomical reference points, implant sizing and a wide variety of acquisition options.

Your Exactech sales representative will be able to help you create your personalized surgeon profile. Multiple profiles can be created, modified and transferred via a PC or on the ExactechGPS station.

Figure A
Surgeon Information Screen

EXACTECHGPS PROFILE OPTIONS

This section will provide information on how to create a new surgeon profile, to find an existing surgeon profile and how to transfer an existing profile from a pass key to the ExactechGPS system.

Surgeon Profiler Setup

A new surgeon profile can be set up one of two ways:

- directly on the ExactechGPS system (no pass key necessary), or
- on a Windows-based computer (pass key required).

This manual provides instruction on surgeon profile setup using a computer with a pass key.

Creating a New Surgeon Profile

Pass keys will be provided to ExactechGPS sales representatives. If a computer is used, the profile can be saved on a USB drive and exported to the ExactechGPS system.

Step 1: Insert ExactechGPS Pass Key into a USB port on your computer.

Step 2: Open folder to view files

Step 3: Double click on the Pass Key folder to open

Step 5: Double click on the Surgeon Profiler folder to open

Step 6: Double click on SurgeonProfiler.exe to launch

Once the Surgeon Profiler application is launched, the Surgeon Information screen will be displayed *(Figure A)*:

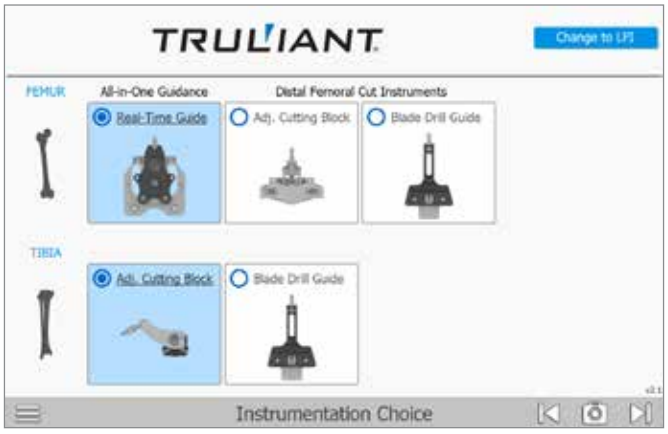


Figure B
Instrument Screen

To create a profile, click on the +ADD SURGEON icon .

Type in your First and Last Name, along with your email address. Your email address is recognized as your unique identifier for ExactechGPS Web where your reports can be accessed.

The screen will revert back to the Surgeon Information screen and you are ready to begin to develop a profile. Click on your name to begin.

Instrument Screen

Select your preferred instrument for both the femur and the tibia and press the Forward arrow *(Figure B)*.

You may choose the Real-Time Guide or the Adjustable Cutting Block or the Truliant Blade Guide for the femur. For the tibia, you may select the Adjustable Cutting Block or the Blade Guide.

Note: *This system defaults to Truliant Instrumentation. If you are using the ExactechGPS TKA Pro LPI Instrumentation, you can change the default to LPI Instrumentation by selecting the Change to LPI button.*

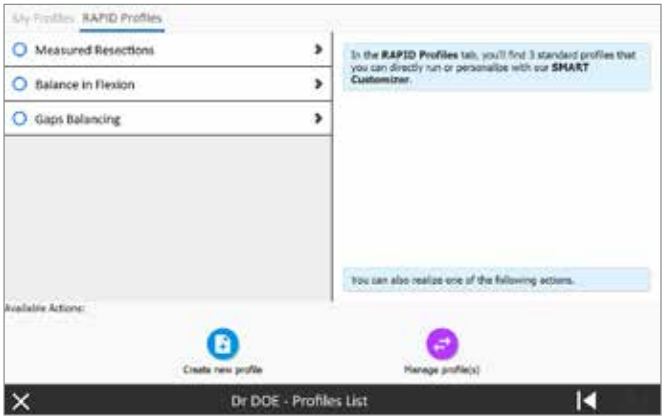


Figure C
Rapid Profile Screen

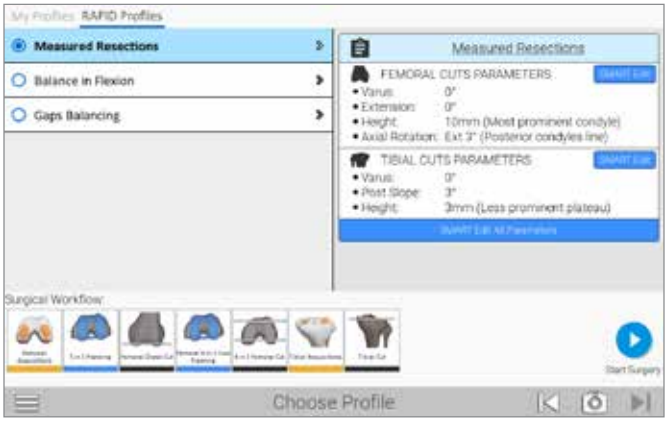


Figure D(a)
Rapid Profile Screen-Measure Resections

Profile List Screen

A Rapid Profile screen will be displayed. Based on your previously selected femoral instrument, your profile options will be displayed. The three options are: Measured Resection, Balance in Flexion or Gap Balancing *(Figure C)*.

Click on the option your prefer. The predefined parameters will be displayed on the right side of the screen *(Figure Da,b c)*. There are two ways to make parameter changes.

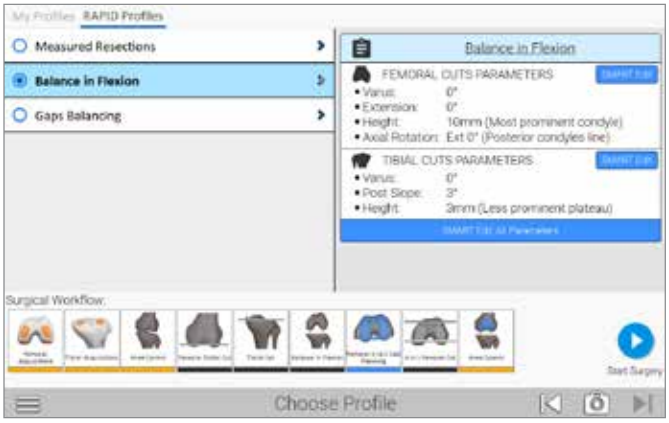


Figure D(b)
Rapid Profile Screen-Balance in Flexion

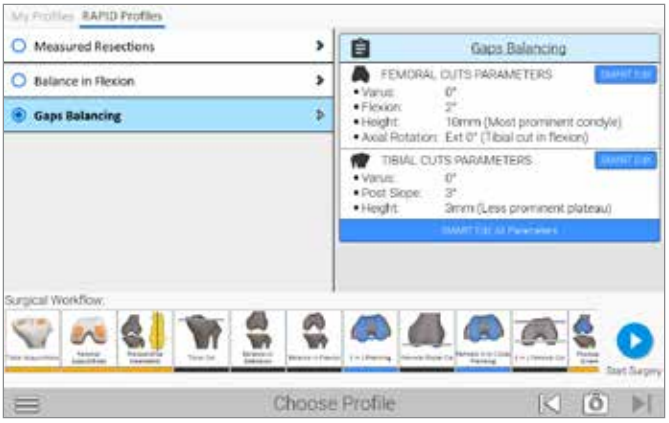


Figure D(c)
Rapid Profile Screen-Gap Balance

After reviewing the predefined parameters, should you wish to edit either the femoral or the tibial parameters, select the SMART Edit button in the designated section. You may make changes by pressing the . As you make changes, you will visualize the change on the screen.

To modify your workflow, kinematics, or additional parameters, select the SMART Edit All Parameters button and make your changes as prompted. The surgical workflow will be visualized in the images at the bottom of the screen.

APPENDIX

SURGEON PROFILER

Figure E
Smart Cut Order

Figure F
Smart Knee Control

Depending on what profile option you selected, you may be asked to define your surgical workflow *(Figure E)*.

You will be asked to select your preferences for the following:

Kinematics

If pre-operative and/or postoperative kinematics were selected, you may also select to control the knee HKA before any cuts, or with trial implants. You can also record the kinematic envelope of the knee *(Figure F)*.

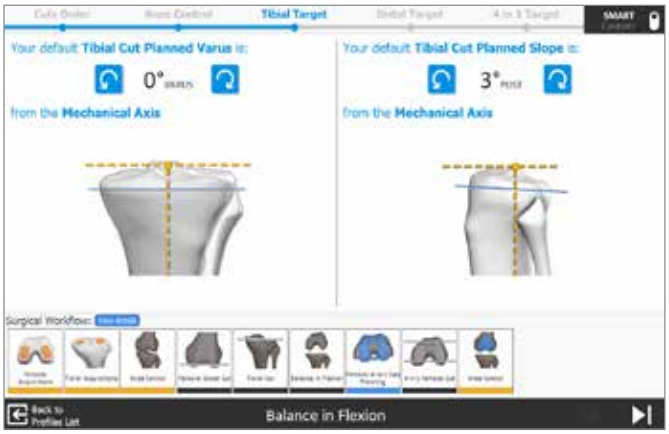


Figure G
Smart Tibia Varus and Slope

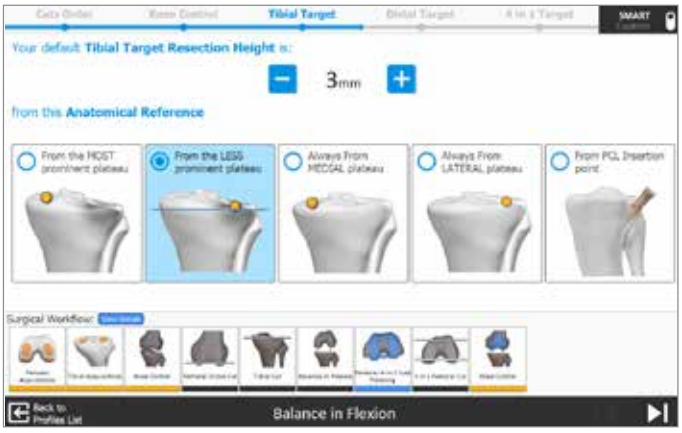


Figure H
Smart Tibia Height

Tibia

Select both the default Tibial Cut Plan Varus parameter from your Mechanical Axis and the default Tibial Cut Planned Slope parameter from the Mechanical Axis *(Figure G)*.

Next, select the default Tibial Target Resection Height parameter from your preferred Anatomical reference *(Figure H)*.

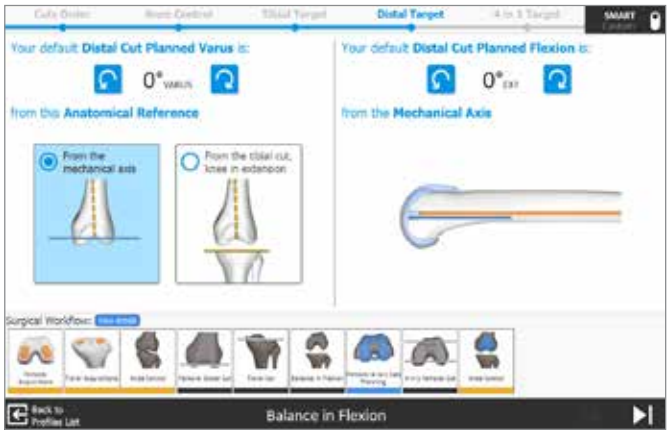


Figure I
Smart Distal Target

Figure J
SmartFemur Height

Femur

Select both default Distal Cut Plan Varus parameters from the preferred Anatomical reference and the default Distal Cut Plan Flexion parameter from the Mechanical Axis *(Figure I)*.

Select the default Distal Target Resection Height parameter from the preferred Anatomical reference *(Figure J)*.

Figure K
Smart Rotation

Figure L
Smart Femoral Implant

Select the default Femoral Axis Rotational reference from a primary and secondary reference point *(Figure K)*.

Select the Exactech Knee implant of choice *(Figure L)*.

When complete, you will be asked to save your profile. The system will provide a suggested profile with the date. You may personalize for easier identification. Select the save button when you made all of your changes.

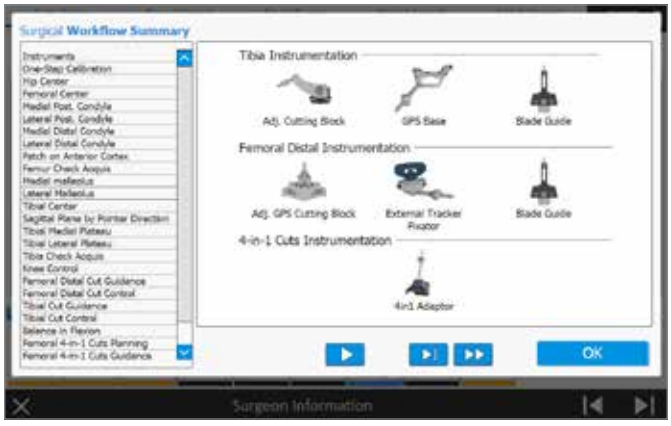


Figure M
Summary Tab

Workflow Summary

The surgeon can preview/visualize a summary of the surgical technique steps at any time before surgery. To view your summary, go to the Profile page and click on the eyeglass icon View details Surgical Workflow. This will provide a full summary of your workflow *(Figure M)*.

Advance to the end, or quit the modifications screen. You will be prompted to enter a profile name to save your newly create profile on the passkey.

OVERVIEW AND UPLOADING THE PROFILE

Finding and Opening an Existing Profile on a Pass Key

To find and open an existing profile on your Pass Key, click on Manage Profiles icon from the Profiles List screen. Profiles of identified surgeons are displayed first. Highlight a profile to view options, including Load, Rename, Duplicate, Delete and Explore. Select the Explore option to view the current profile or to make change to that specific profile.

Transferring a Profile with a Pass Key

When a pass key is plugged into an ExactechGPS system and the system is turned on, from the Surgeon Information screen or the Profiles List screen, click on "Manage Profiles". Pass Key profiles are displayed on the right panel; station profiles are displayed on the left panel.

From either the station profiles on the left or the pass key profiles located on the right side of the screen, highlight the profile you wish to be moved, then click on the corresponding arrow to transfer it to the desired location. If you transfer a surgeon profile from PassKey to Station, the "Profiles List" screen will display the transferred profile if and only if you are registered as this surgeon.

If you transfer a profile from an unregistered surgeon, surgeon will automaticcally be registered on the station.

Note: *Some profiles are not compatble with the Real-Time Guide, and will not be displayed on Profiles List screen if Real-Time Guide is selected.*

CATALOG NUMBER	PART DESCRIPTION	
I00020	ExactechGPS System	
A10003 (P)	ExactechGPS Probe (P) Tracker	
A10004 (F)	ExactechGPS Femoral (F) Tracker	
A10005 (T)	ExactechGPS Tibial (T) Tracker	
A10006 (G)	ExactechGPS Guide (G) Tracker	
A10012	ExactechGPS Disposable Kit	

**Special Order Only*

CATALOG NUMBER	PART DESCRIPTION	
02-521-90-0000	External Tracker Fixator 0 Deg	
02-521-90-0030	External Tracker Fixator 30 Deg	
02-521-10-0003	Femoral Adjustable Resection Guide	
02-521-10-0008	Truliant Finishing Guide Tracker	
02-521-10-0004	Truliant Real-Time Guide	
02-521-10-0006	Truliant Real-Time Guide Coupler	
02-521-10-0007	Truliant Finishing Guide Pin Adaptor	
02-521-78-0000	ExactechGPS Collared 3.2mm Drill Bit	

CATALOG NUMBER	PART DESCRIPTION	
02-521-20-1002	Left Tibial Adjustable Resection Guide	
02-521-20-1003 or 02-521-20-1004	Left Tibial Base	
02-521-20-2002	Right Tibial Adjustable Resection Guide	
02-521-20-2003 or 02-521-20-2004	Right Tibial Base	
02-521-90-0001	Truliant 3.5mm Ball Hex Driver	
02-521-90-0002	Truliant Hex Driver Handle	
02-521-90-1000	Truliant Blade Drill Guide	

NOTES

NOTES

Exactech, Inc. is proud to have offices and distributors around the globe. For more information about Exactech products available in your country, please visit www.exac.com

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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, Inc., 2320 NW 66th Court, Gainesville, Florida 32653-1630, USA. (352) 377-1140, (800) 392-2832 or FAX (352) 378-2617.

Exactech, 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. 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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