EXACTECH | KNEE

Operative Technique
Addendum

TRULIANT®

ExactechGPS® RTKA 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 RTKA Application provides a fully customizable surgical experience for complex primary and revision total knee arthroplasty with advanced options, including bone defect management and integrated ligament balancing options. The ExactechGPS technology was developed in conjunction with:

Gérard Giordano, MD

James Huddleston, MD

Bernard Stulberg, MD

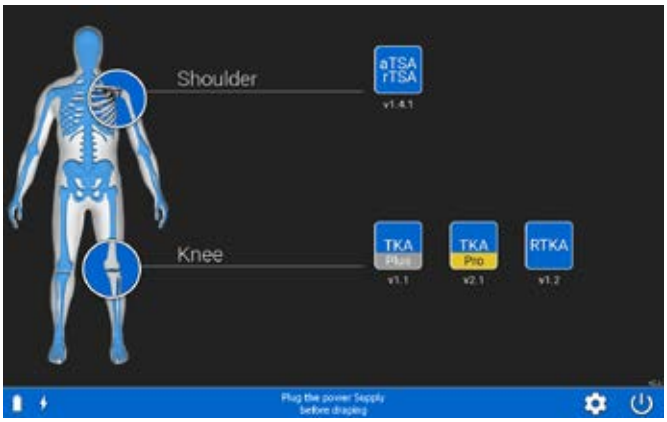


Figure 1
Start Application Screen

Figure 2
Welcome Screen

Figure 3
Patient Information Screen

SYSTEM SET-UP

Welcome Screen

Select RTKA under Knee *(Figure 1)*. The system will automatically advance to the Welcome Screen. Select the arrow at the lower right corner of the display to advance to the Patient Screen *(Figure 2)*.

Patient Information Screen

Patient identification information can be entered into the fields displayed *(Figure 3)*. All fields are optional and this information is only stored on the Starter Key. You must select either the left or right knee to continue. Advance to the Choose Profile Screen.

Figure 4
Choose Profile Screen

Figure 5
Seeking Trackers Screen

Figure 6
Tracker Battery Position

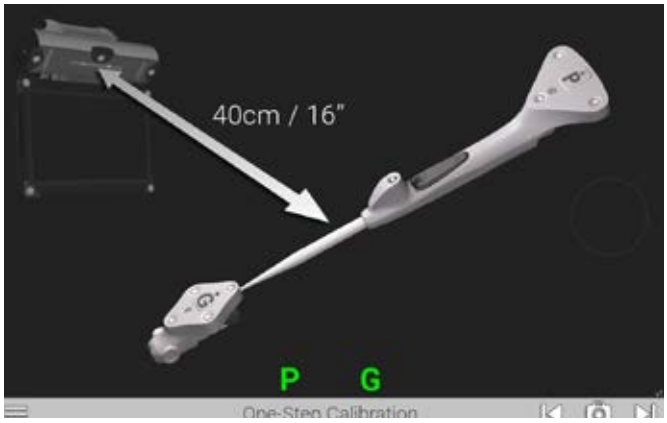


Figure 7
Verify Connection

Choose Profile

The preferred surgeon profile can be selected from the drop-down menu. Select either the "Standard Cuts" or "Full Balance" profile *(Figure 4)*. The profiles can be edited based on surgeon preference.

This operative technique will follow the full balance technique, as it includes the steps for standard cuts as well. Select "Start" on the desired profile to advance to the next screen.

Select Trackers

The Seeking Tracker screen is displayed *(Figure 5)*. Insert batteries (positive end first) into the trackers and Probe (P) Tracker, Femoral (F) Tracker, Tibial (T) Tracker and the Guide (G) Tracker.

Caution: *Inserting negative side first or in reverse polarity may cause permanent damage to the tracker. Insert batteries positive side first (Figure 6). Once trackers are synced with the system, the screen will advance to the one-step calibration step automatically.*

One-Step Calibration

The One-Step Calibration screen is displayed. *(Figure 7)*.

Figure 8
Pin the Diaphysis

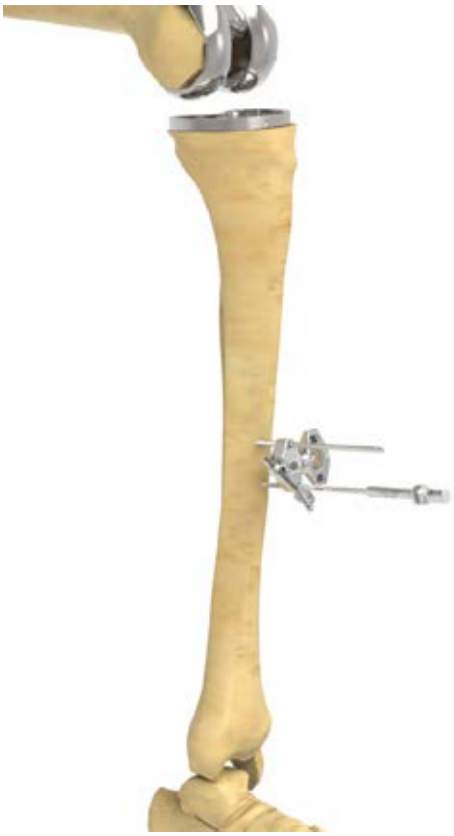


Figure 9
Attach the External Tracker Fixator

Place the tip of the Probe into the dimple node at the top of the G Tracker. 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.

Attach Trackers to Tibia

Attach the T Tracker to the tibia by pinning in the tibial diaphysis using the 5.1 inch pins *(Figure 8)*. The 30 degree external Tracker Fixator for the tibial tracker should be placed approximately 20 cm below the joint line to accommodate reamers and/or stems. Position the tracker to aim directly at the station.

An intramedullary reamer may be used to assist in determining the best position for the most proximal pin. The pin is placed from antero-medial to postero-lateral with contact but not perforation of the postero-lateral cortex *(Figure 9)*.

Figure 10
Attach theT Tracker

Figure 11
8cm reference on the Femoral Clamp

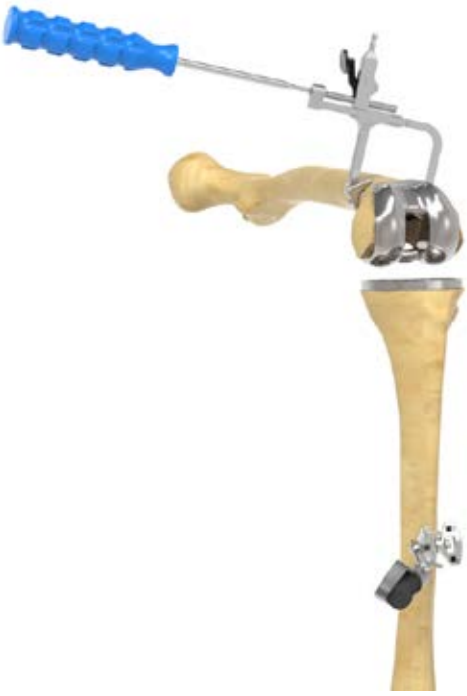


Figure 12
Attach the Femoral Clamp

Attach theT Tracker to the External Tracker Fixator *(Figure 10)*.

Attach Trackers to Femur

Using the 3.5mm Hex Screwdriver attach the Femoral Clamp to the femur at least two finger breadths above the existing femoral component *(Figure 11)* using the 8cm mark on the Femoral Clamp as a reference for placement *(Figure 12)*.

Figure 13
Attach F Tracker to Femoral Clamp

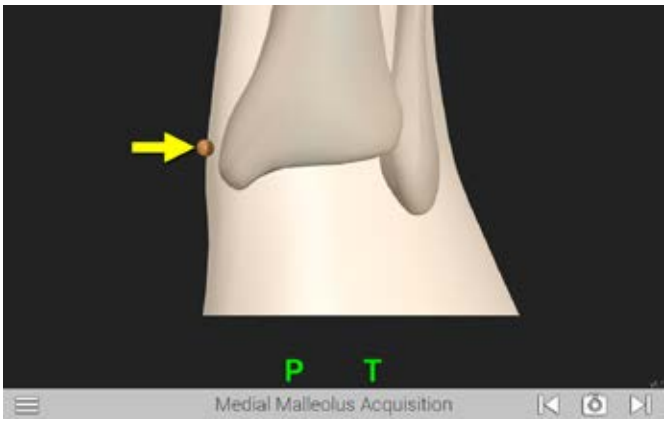


Figure 14
Medial and Lateral Malleolus Acquisitions Screen

The clamp should be rotated externally and placed on the distal femoral diaphysis just proximal to the metaphyseal flare (approximately 8cm from the distal femoral condyle of the retained implant). Attach the F Tracker to the Femoral Clamp *(Figure 13)*. In case of soft-tissue contact, increase the length of the incision in the proximal direction. Should it be difficult to anchor the Femoral Clamp to the bone, check the quality of the bone and change the Femoral Clamp position to fix more proximally on cortical bone.

PRIMARY TIBIAL IMPLANT ACQUISITIONS

Malleolus Acquisition

Advance to the Medial Malleolus Acquisition screen *(Figure 14)*. Position the tip of the Probe on the medial malleolus and press the Forward button to register this point. The system will automatically advance to the Lateral Malleolus Acquisition screen. Repeat to acquire point for lateral malleolus.

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

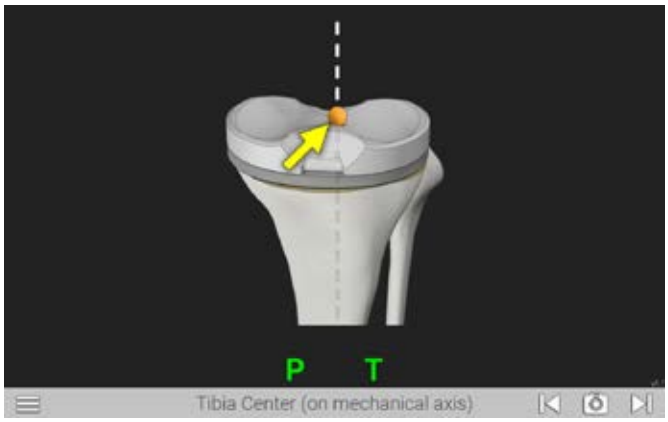


Figure 15
Tibial Center Acquisition Screen

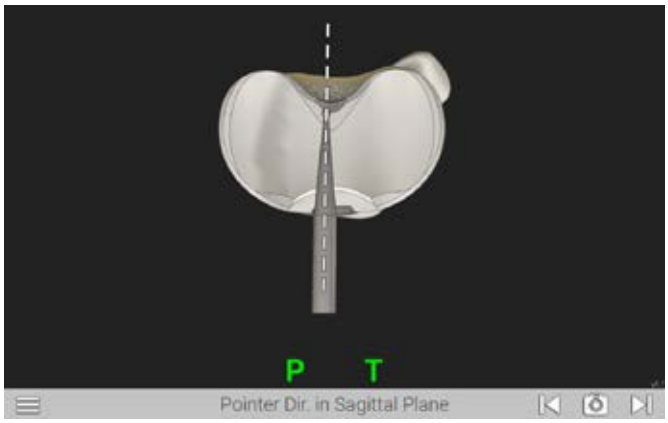


Figure 16
Pointer Direction in Sagittal Plane Screen

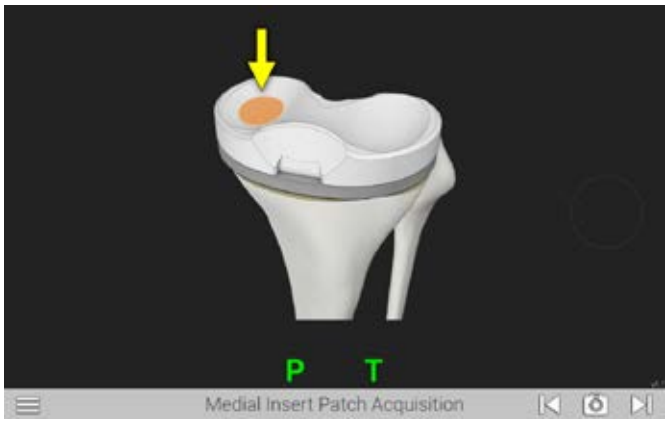


Figure 17
Medial & Lateral Insert Patch Acquisition Screen

Tibia Center Acquisition

Position the tip of the Probe on the center of the tibial insert in the same axis as the stem extension reamer and press the Forward button to register this point *(Figure 15)*. 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

The Pointer Direction in Sagittal Plane screen is displayed *(Figure 16)*. Position the tip of the Probe at the posterior center (PCL insertion) and the shaft of the Probe on the insert along a line connecting the center of the tibial insert and the medial-third of the tibial tubercle.

Please Note: *If the primary implant is in mal-rotation this acquisition may differ from current implant rotation. Press the Forward button to register the orientation. The system will automatically advance to the next screen.*

Insert Plateau Acquisition

Position the tip of the Probe on the medial tibial insert plateau and press the Forward button *(Figure 17)*. Ensure the tip of the tracker maintains contact with the tibial insert plateau and trace a patch that captures the entire medial tibial insert 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. Repeat to acquire points for lateral insert plateau.

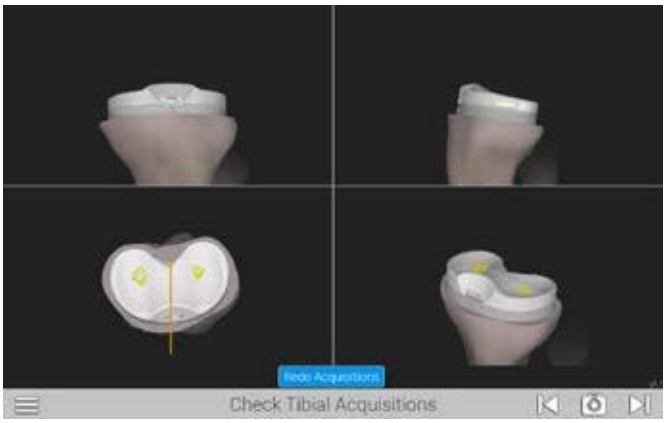


Figure 18
Check Tibial Acquisitions Screen

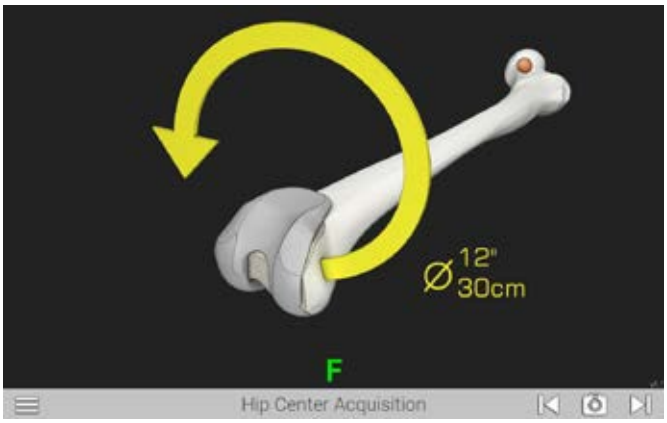


Figure 19
Hip Center Acquisition Screen

Check Tibial Acquisitions

A graphical representation of the registered points (yellow dots) is displayed *(Figure 18)*. If it is necessary to redo the registration for any points, select the redo acquisitions button at the bottom of the screen. Select the acquisitions to redo then select the redo button. The system will repeat the selected acquisitions.

PRIMARY FEMORAL IMPLANT ACQUISITIONS

Hip Center Acquisition

Move the knee in a 12-inch diameter circular pattern as illustrated on the display *(Figure 19)*. Large diameter, slow circular motion may be more effective than rapid small radii circles.

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

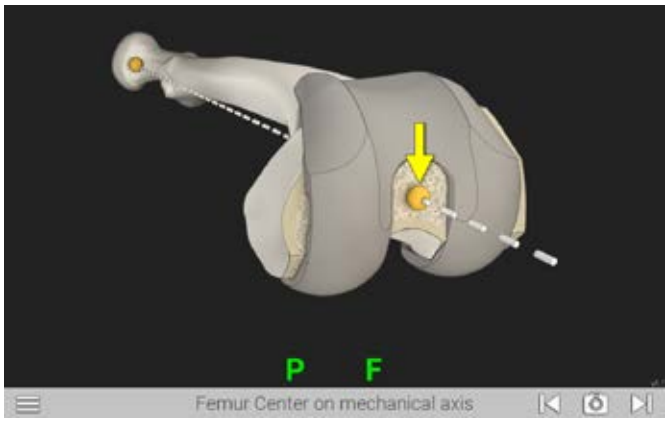


Figure 20
Femur Center Acquisition Screen

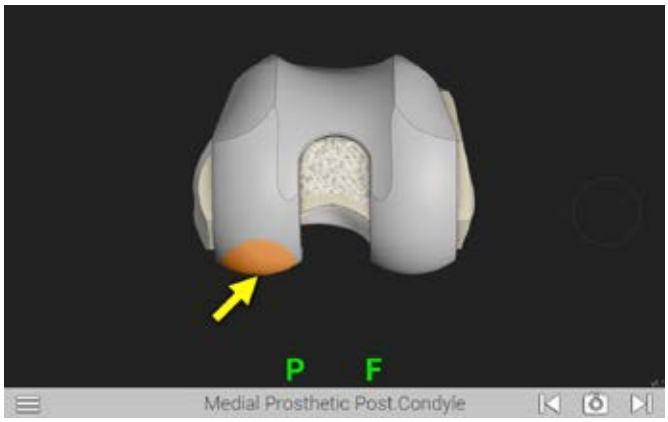


Figure 21
Medial & Lateral Posterior Condyle Acquisition Screen

Femur Center Acquisition

Position the tip of the Probe to the femoral center (using the mechanical axis) within the intercondylar notch, and while the probe is contacting the bone, press the Forward button *(Figure 20)*. The system will automatically advance to the next screen.

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

Posterior Condyle Acquisition

Position the tip of the Probe on the medial prosthetic posterior condyle and press the forward button *(Figure 21)*. Ensure the tip of the probe tracker maintains contact with the prosthetic condyle and trace a patch that captures the most posterior aspect of the prosthetic condyle. This is best achieved by moving the probe tip proximal-distal in the sagittal plane.

Repeat to acquire points for the lateral prosthetic posterior condyle.

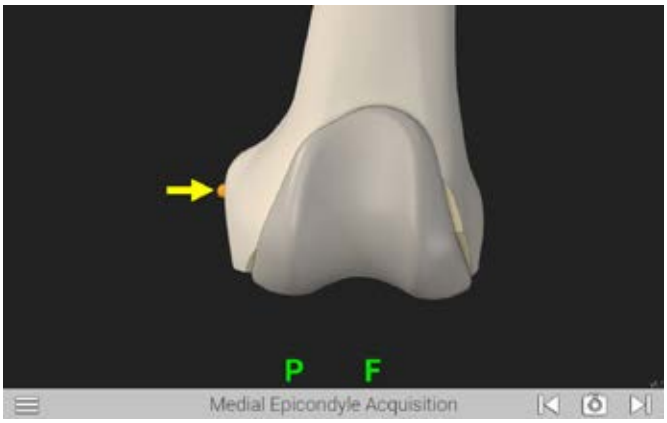


Figure 22
Medial & Lateral Epicondyle Acquisition Screen

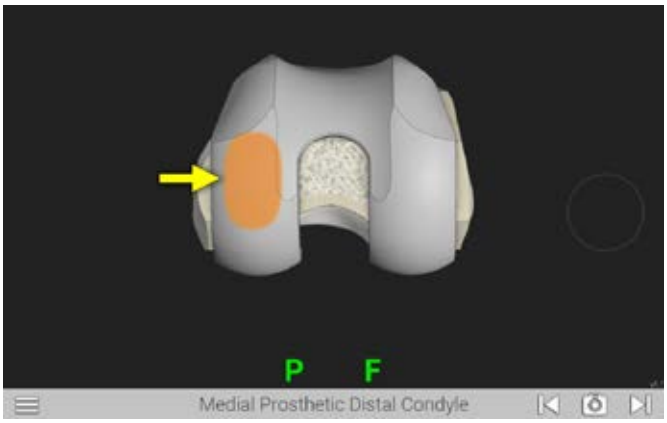


Figure 23
Medial & Lateral Distal Condyle Acquisition Screen

Epicondyle Acquisition

Position the tip of the Probe on the medial epicondyle and press the Forward button to register this point *(Figure 22)*. Repeat to acquire the lateral epicondyle.

Distal Condyle Acquisition

Position the tip of the Probe on the medial prosthetic distal condyle and press the Forward button *(Figure 23)*. Ensure the tip of the tracker maintains contact with the prosthetic condyle and trace a patch that captures the most distal aspect of the prosthetic condyle as well as the medial-lateral and anterior–posterior curve of the distal condyle. Repeat to acquire points on the lateral prosthetic distal condyle.

Figure 24
Anterior Cortex Acquisition Screen

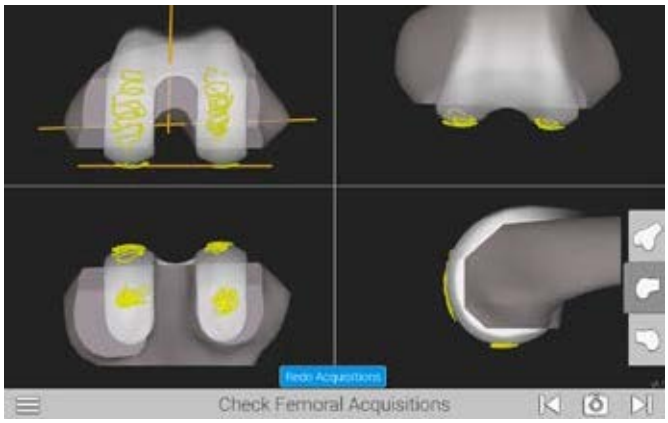


Figure 25
Check Femoral Acquisitions Screen

Anterior Cortex Acquistion

Position the tip of the Probe on the anterior cortex of the bone and press the forward button *(Figure 24)*. Ensure the tip of the tracker maintains contact with the femoral bone (not the implant) and trace a patch that remains inside the orange box on the screen.

Check Femoral Acquisitions

A graphical representation of the registered points (yellow dots) is displayed *(Figure 25)*. 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 it is necessary to redo the registration for any points, select the redo acquisitions button at the bottom of the screen. Select the acquisitions to redo then select the redo button. The system will repeat the selected acquisitions.

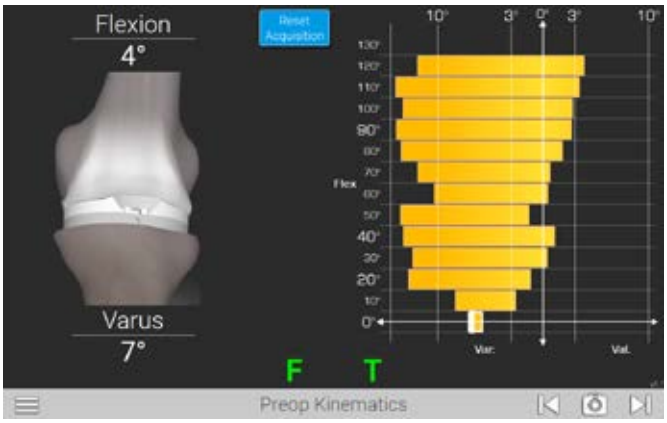


Figure 26
Preop Kinematics Screen

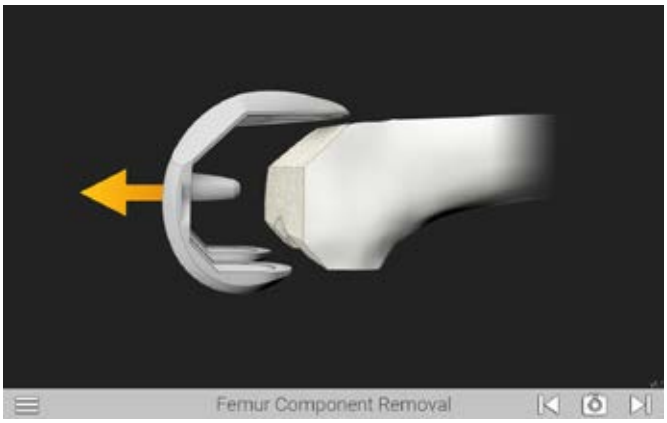


Figure 27
Femoral Component Removal Screen

Perform Preoperative Kinematics

The Preoperative Kinematics screen is displayed *(Figure 26)*. With the primary implants still in place perform a range of motion with the knee to review the maximum flexion and extension and varus/valgus angles. The screen will show the instability present in the knee at various degrees of flexion. For example, *Figure 26* shows more than 10 degrees of instability at 90 degrees of flexion.

Remove Primary Implants

The existing femoral and tibial components should be removed and debridement of the distal femur should be performed *(Figure 27)*.

Figure 28
Tibial Component Removal Screen

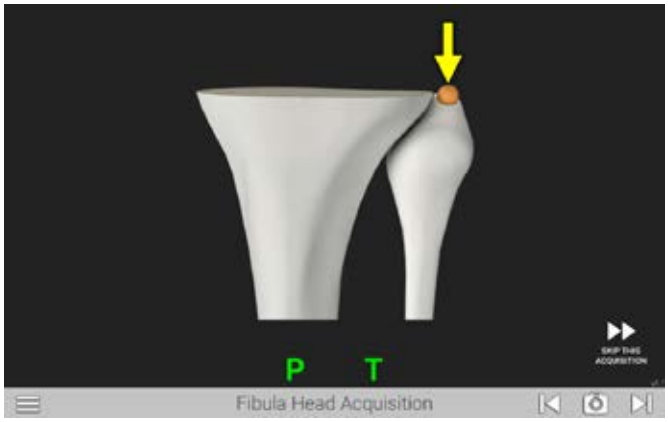


Figure 29
Fibular Head Acquisition Screen

The AcuDriver® Automated Osteotome System can be used to loosen and remove the femoral and tibial components. Once the femoral component is removed, press the forward button and perform the same process for the tibial component *(Figure 28)*. Be careful to avoid disturbing the femoral and tibial trackers during component removal.

Fibula Head Registration

The Fibula Head Acquisition screen is displayed *(Figure 29)*. Position the tip of the Probe on the fibula head and press the Forward button to register this point. If desired, the double arrow above the next button can be selected to skip this acquisition.

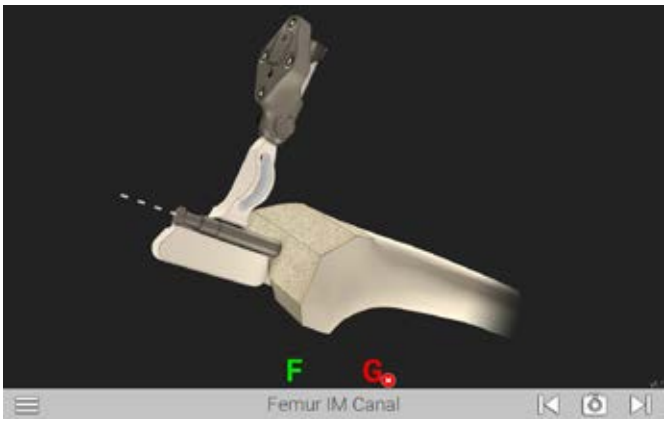


Figure 30
Femoral IM Canal Acquisition Screen

Figure 31
Position Blade Drill Guide on Reamer

DISTAL FEMORAL RESECTION

IM Canal Acquisition(Femur)

Assemble the Ratcheting T-Handle to the 10mm Intra-Medullary Pilot Drill *(Figure 30)*. Insert the IM Pilot Drill into the intra-medullary canal. Progressively ream without power using the stem extension reamers until cortical chatter is obtained and a sufficient depth is achieved in order to assure neutral alignment and a stable reamer. Although not required at this step, it is important to ream deep enough to accommodate the selected stem extension length (i.e. the depth marking should be flush with the distal femur). If using an offset coupler, the reamer depth must be adjusted for the additional 30mm in length. Instead of reaming to the depth marking,ream to the beginning of the black box outlining the next measurement (i.e. for an 80mm stem with an offset coupler, ream to the beginning of the 120mm box).

When reamer stability is established, the reamer should be left in place and disconnected from the t-handle. Attach the G Tracker to the Truliant Blade Drill Guide and position on the Stem Extension Reamer *(Figure 31)*. Press the Forward button to register the location of the femoral IM Canal. If needed, move the knee into flexion to improve tracker visibility.

Note: *These steps allow judgments of IM canal alignment (anatomic alignment) versus mechanical axis alignment.*

Distal Femoral Planning

The orange line represents the mechanical axis, the white line is the IM canal (anatomical axis) and the blue stem represents

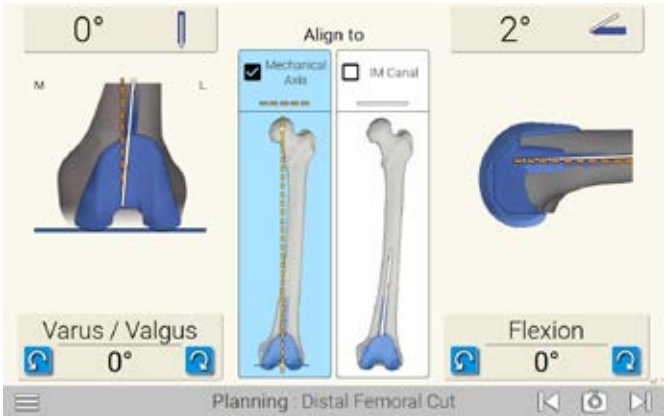


Figure 32
Distal Femoral Cut Planning Screen

Figure 33
Assemble the Distal Cut Guide

the stem extension implant *(Figure 32)*. Select to align the femur to the mechanical axis or the IM Canal using the options in the center of the screen based on their desired technique. Selection of the IM Canal or Mechanical Axis alignment options adjust the varus/valgus angle and flexion/extension angle. A custom plan may also be selected by using the varus/valgus angle and slope buttons to select values between the true mechanical and IM alignment. When choosing mechanical axis that doesn't align with the IM canal, there may be a discrepancy between the stem extension and the reamer cavity. A smaller stem may be needed to allow the femur to sit flush on the mechanically aligned distal femoral cut.

The CC femoral component's stem boss is fixed at a 5-degree valgus angle. The RTKA software incorporates this angle into the distal femoral plan. Advance to the next screen.

Distal Femoral Cut Guidance

Note: *Prior to this step make sure all screws are set to their neutral position on the RTKA Femoral Adjustable Guide. The ends of the three screws should be flush with the instrument when at the neutral position.*

Assemble the Truliant Femoral link to the Valgus Alignment Guide by verifying the proper left or right designation on the Valgus Alignment Guide is pointing anteriorly, and slide the coupler pegs into the holes. The Valgus Alignment Guide is fixed at 5 degrees valgus. The black knobs on both instruments should be aligned in the same plane when assembled correctly. Attach RTKA Femoral Adjustable Guide to the Adjustable Distal Resection Coupler via the central peg. Lastly, attach the G Tracker to the Guide *(Figure 33)*.

Figure 34
Position the Distal Cut Guide on the Bone and Pin Through the "0" Holes

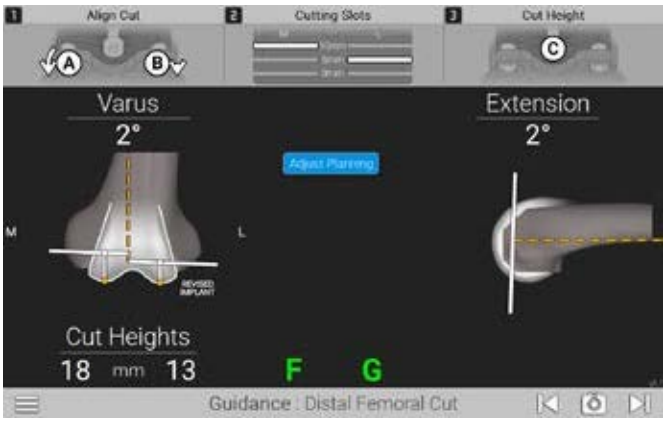


Figure 35
Distal Femoral Cut Guidance Screen

The black knob on the Truliant Femoral Link can be adjusted from 1-14mm, which determines the distal femoral resection amount. Each "click" of the knob changes the distal resection amount by 1mm and adjusts the joint line location. Additionally, the resection amount can still be adjusted by using the various pin holes in the resection guide as well as the C screw after the guide is pinned.

Place the assembly onto the reamer with the RTKA Femoral Adjustable Guide raised to clear the anterior bone. Leave the dial at 1mm and slide the distal femoral valgus alignment guide against the distal femoral bone for a cleanup cut. If desired, adjust the resection depth by turning the knob. When the assembly is positioned correctly, the black knob on the Valgus Alignment Guide can be turned to lock to the reamer. The RTKA Femoral Adjustable Guide is pinned to the bone through the "0" holes *(Figure 34)*. Headless pins can be used to provide the most flexibility/adjustments, but if additional stability is required, headed pins are available. Remove the Adjustable Distal Resection Coupler and Valgus Alignment Guide.

The orange points on the guidance screen represent the existing implant/joint line *(Figure 35)*. The white line represents the resection based on the current position of the guide on the bone.

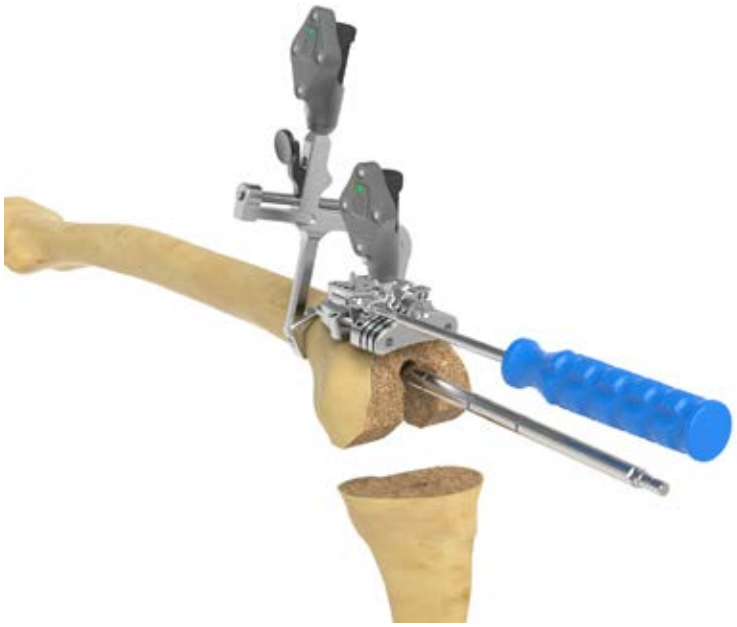


Figure 36
Turn the A and B Screws

Figure 37
Perform Distal Resection

The medial and lateral resection depth, varus/valgus angle and flexion angle displayed are consistent with the alignment of the RTKA Femoral Adjustable Guide (white line). Use the 3.5mm Hex Driver to turn the A and B screws on the Guide *(Figure 36)*.

The arrows indicate both the magnitude and direction each screw needs to be turned for the planned alignment. The white lines will change to green when the Guide is within 1 degree of the planned orientation. Initially, align the cut by turning the A and B screws until the planned varus/valgus and flexion/extension amounts are achieved. Next, select the appropriate resection guide slots in step 2. Lastly, turn the C screw to fine tune the resection amount based on the bone stock available. Advance to the next screen when adjustments are complete.

Note: *The C screw is not guided by ExactechGPS; therefore, the approporiate resection amount is chosen based on the surgical preference and bone loss.*

Distal Femoral Resection

Perform distal resection and advance to the next screen *(Figure 37)*.

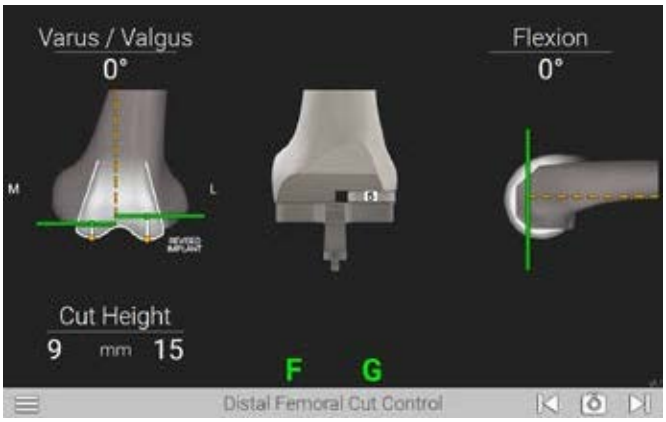


Figure 38
Distal Femoral Cut Control Screen

Figure 39
Verify Distal Resection

Distal Femoral Cut Control

Assemble the G Tracker to the Truliant Blade Drill Guide with the augments attached (if necessary) *(Figure 38)*.

For larger femurs, the Truliant Blade Drill Guide Extension can be attached if preferred. Verify the distal resection by placing the Truliant Blade Drill Guide against the distal femur resection *(Figure 39)*. The cut height amount represents the distance from the previous joint line to the planned cut. Press Forward button on the Probe to advance to the next screen.

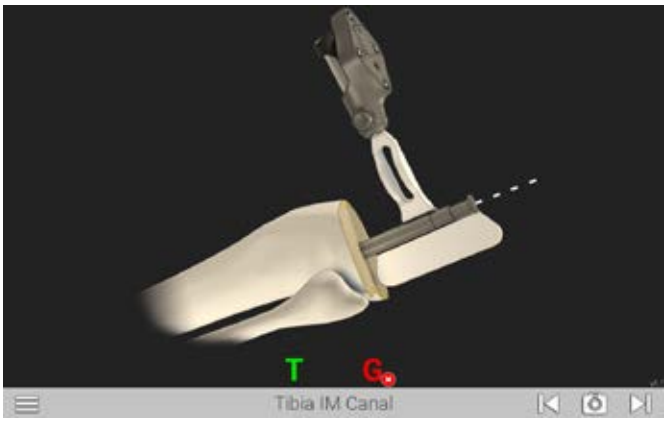


Figure 40
Tibial IM Canal Acquisition Screen

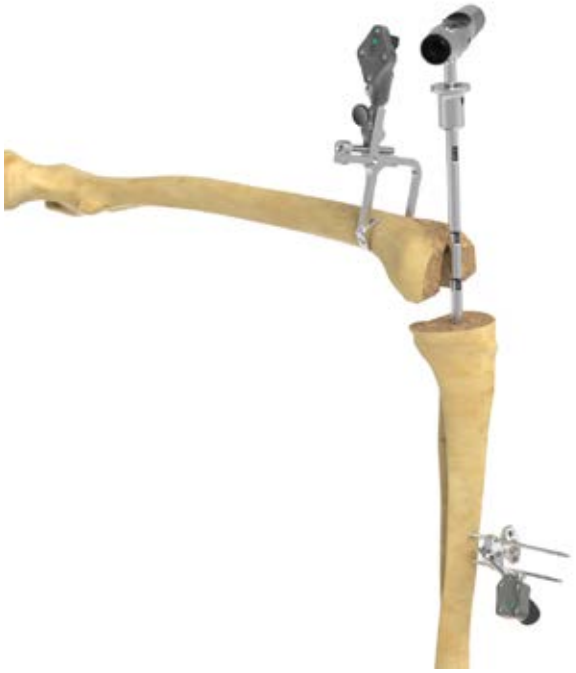


Figure 41
Ream the IM Canal

PROXIMAL TIBIAL RESECTIONL RESECTION

IM Canal Acquisition(Tibia)

Assemble the Ratcheting T-Handle to the 10mm Intra-Medullary Pilot Drill. Insert the IM Pilot Drill into the intra-medullary canal *(Figure 40)*.

Progressively ream without power using the stem extension reamers until cortical chatter is obtained and a sufficient depth is achieved in order to assure neutral alignment and a stable reamer *(Figure 41)*.

Although not required at this step, it is important to ream deep enough to accommodate the selected stem extension length (i.e. the depth marking should be flush with the proximal tibia). If using an offset coupler, the reamer depth must be adjusted for the additional 30mm in length. Instead of reaming to the depth marking, ream to the beginning of the black box outlining the next measurement (i.e. for an 80mm stem with an offset coupler, ream to the beginning of the 120mm box). When reamer stability is established, the reamer should be left in place and disconnected from the T-Handle.

Figure 42
Position Blade Drill Guide on Reamer

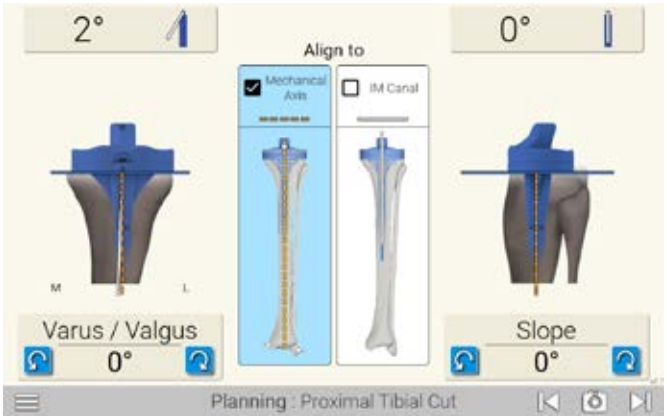


Figure 43
Proximal Tibial Cut Planning Screen

Attach the G Tracker on the Truliant Blade Drill Guide and position on the Stem Extension Reamer *(Figure 42)*. Press the Forward button to register the location of the tibial IM Canal.

Proximal Tibial Planning

The orange line represents the mechanical axis, the white line is the IM canal (anatomical axis) and the blue stem represents the stem extension implant *(Figure 43)*. Select to align the tibia to the mechanical axis or the IM Canal using the options in the center of the screen based on the desired technique. Selection of the IM Canal or Mechanical Axis alignment options adjust the varus/valgus angle and slope. A custom plan may also be selected by using the varus/valgus angle and slope buttons.

When choosing mechanical axis that doesn't align with the IM canal, there may be a discrepancy between the stem extension and the reamer cavity. A smaller stem may be needed to allow the tibia to sit flush on the mechanically aligned proximal tibial cut.

Figure 44
Assemble the Proximal Tibial Cut Guide

Proximal Tibial Cut Guidance

Advance to the Proximal Tibial Cut Guidance screen.

Note: *Prior to this step make sure all screws are set to their middle position on the RTKA Tibial Adjustable Guide. The ends of the three screws should be flush with the instrument when at the neutral position.*

The CC Fixed Intramedullary (IM) Tibial Guide is used to initially position the RTKA Tibial Adjustable Guide. The reference point for this guide is the IM canal and reamer left in place from the previous step. Therefore, the proximal tibial cut should be perpendicular to the reamer.

Attach the RTKA Tibial Adjustable Guide to the Fixed IM Tibial Guide by pressing the black push-button guide attachment *(Figure 44)*.

Next, attach the G Tracker to the Guide. Slide the Cut Line Predictor or the CC Tibial Stylus into the tibial resection guide slot. Place the assembly over the Stem Extension Reamer and lower it until the tibial stylus contacts the least affected tibial plateau. Position the Tibial Stylus at a point where a cleanup cut will provide a smooth, flat surface for the tibial implant. Typically 1 or 2-mm is a sufficient cleanup cut. The stylus allows the resection depth to be adjusted from 1 to 10mm depending on surgeon preference. If a bone defect is present on one side, do not position the stylus on the defect since it will remove the additional bone stock on the other least affected side. Tighten the macro proximal/distal depth adjustment knob around the reamer to lock the position. Move the RTKA Tibial Adjustable Guide posteriorly until it is touching the anterior tibia. Tighten the A/P adjustment small black knob to lock the A/P position of the Tibial Resection Guide.

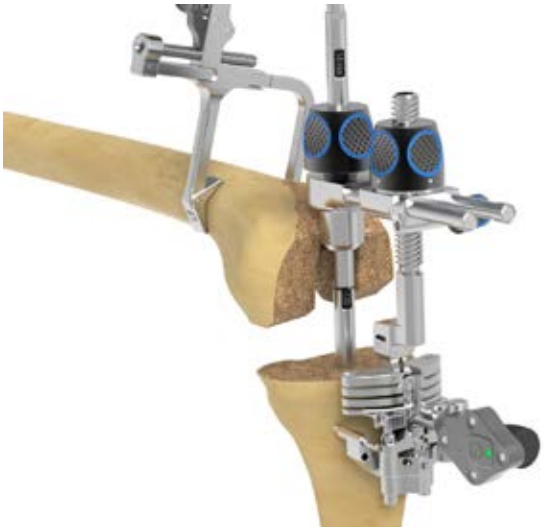


Figure 45
Pin the Tibial Cut Guide

Figure 46
Proximal Tibial Cut Guidance Screen

Micro proximal/distal depth adjustments can be made by turning the black knob on the threaded shaft of the IM Tibial Guide. Once the correct position is established, use the pins to secure the guide to the tibia through the top pin holes *(Figure 45)*. Additional pin holes are available if needed. The central distal holes may not be used unless the reamer is removed.

The resection amount can be adjusted by using the various pin holes in the resection guide, as well as the A, B, and C screws after the guide is pinned.The orange points on the guidance screen represent the existing implant/joint line *(Figure 46)*. The white line represents the resection based on the current position of the guide on the bone.

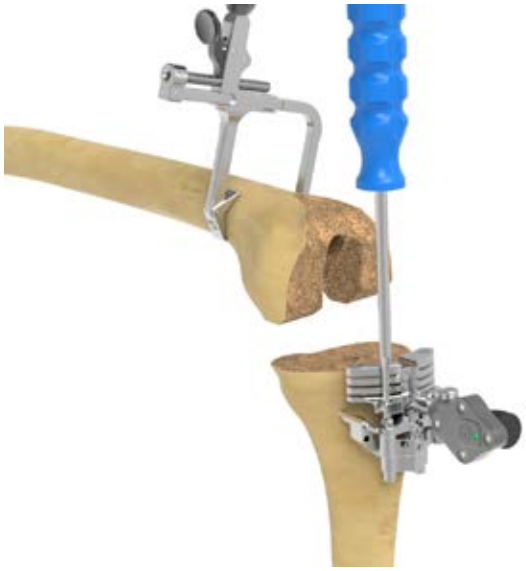


Figure 47
Turn the A and B Screws

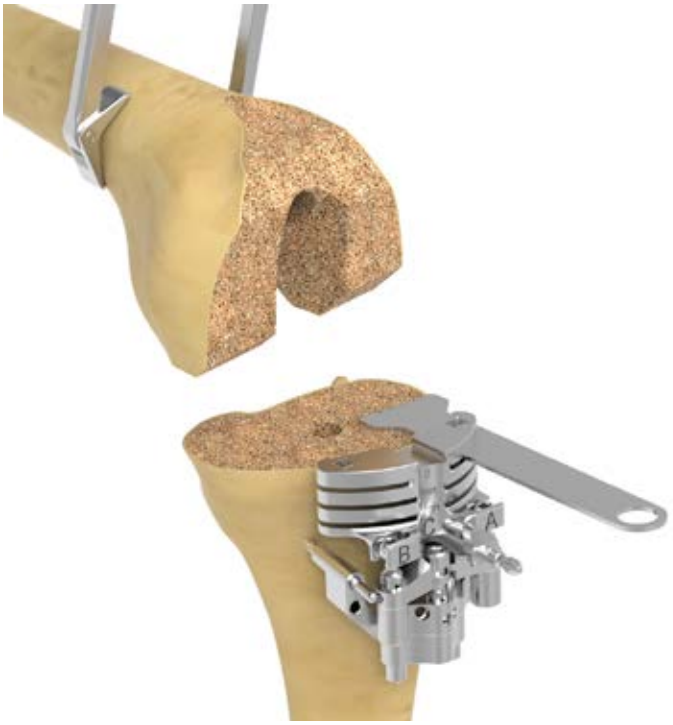


Figure 48
Perform Tibial Resection

The medial and lateral resection depth, varus/valgus angle and slope displayed are consistent with the alignment of the RTKA Tibial Adjustable Guide (white line). Use the 3.5mm Hex Driver to turn the A and B screws on the Guide *(Figure 47)*. The arrows indicate both the magnitude and direction each screw needs to be turned for the planned alignment. The white lines will change to green when the Guide is within 1 degree of the planned resection. Initially, align the cut by turning the A and B screws until the planned varus/valgus and slope amounts are achieved. Next, select the appropriate resection guide slots in step 2. Lastly, turn the C screw to adjust the resection amount based on the bone stock available. Advance to the next screen when adjustments are complete.

Note: *The C screw is not guided by ExactechGPS; therefore, the approporiate resection amount is chosen based on the surgical preference.*

Proximal Tibial Resection

Perform proximal tibial resection and advance to the next screen *(Figure 48)*.

Figure 49
Proximal Tibial Cut Control Screen

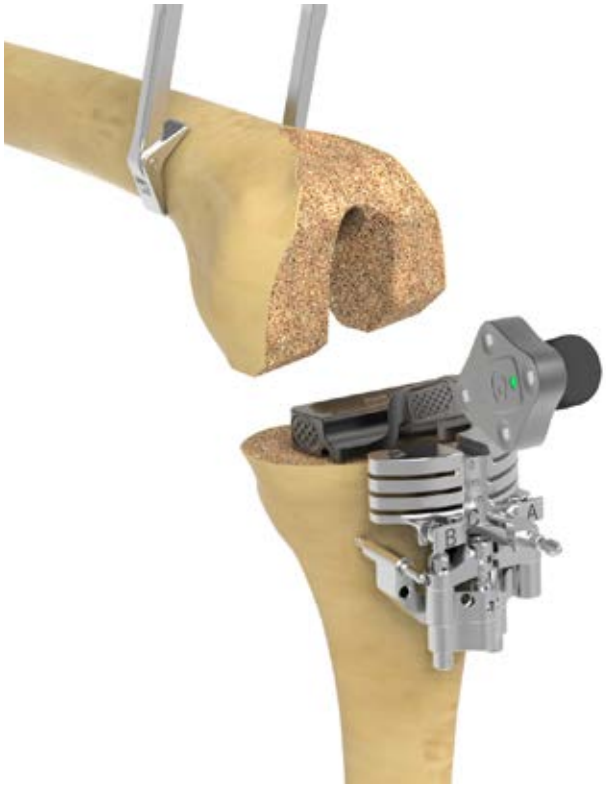


Figure 50
Verify the Proximal Tibial Cut

Proximal Tibial Cut Control

Assemble the G Tracker to the Truliant Blade Drill Guide *(Figure 49)*.

Verify the tibial resection by placing the Blade Drill Guide against the proximal tibial resection with the augment trial attached to the Truliant Blade Drill Guide, if necessary *(Figure 50)*. Press Forward button on Probe to advance to the next screen.

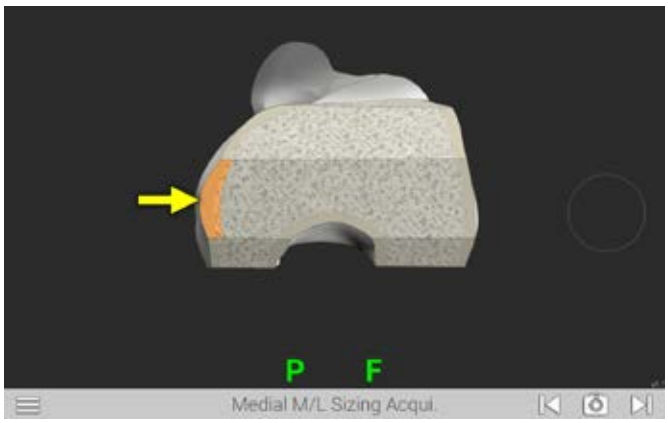


Figure 51
Medial & Lateral M/L Sizing Acquisition Screen

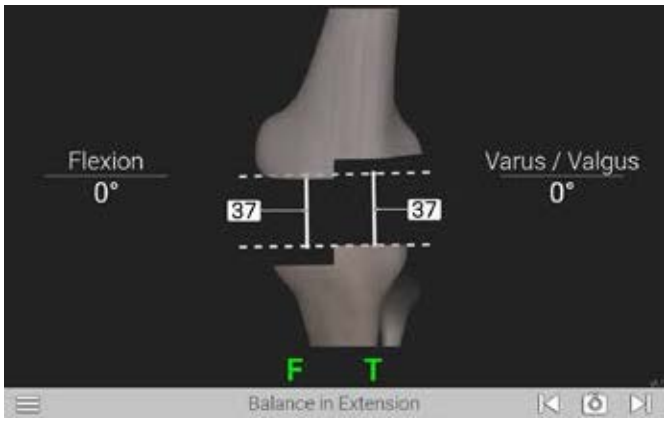


Figure 52
Balance in Extension Screen

Medial M/L Sizing Acquisition

Position the tip of the Probe on the medial edge of the resected distal condyle and press the Forward button *(Figure 51)*. Ensure the tip of the tracker maintains contact with the medial edge and trace a patch that captures the most medial aspect of the resected distal condyle. Repeat to acquire points on the lateral distal condyle.

Balance in Extension

The Ligament Balancing in Extension screen is displayed *(Figure 52)*. Place the Augmentable LBSIII with the tibial and distal femoral augment trials attached. The tibial and distal femoral augment trials should match the discrepancy between the medial and lateral cuts (femur and tibia), but may not correspond directly with final augment implant selected. If tibial augments are needed, Size 1 tibial augment trials must be attached to the balancer. Place the knee in full extension to verify the actual degrees of flexion/extension and varus/valgus. The knee should be placed as close as possible to full extension. Distract the knee joint to the desired tension being careful to avoid over-tensing the ligaments.

A similar tension level should be used for flexion and extension balancing steps. Press the Probe to advance to the next screen.

Figure 53
Balance in Flexion Screen

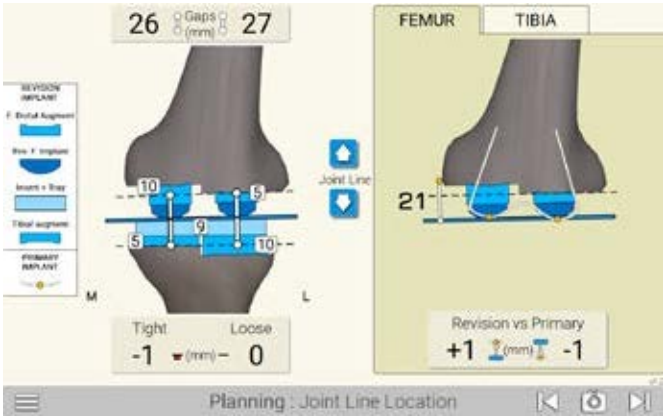


Figure 54
Joint Line Location Planning Screen

Balance in Flexion

Remove previously attached distal femoral augment trials (if any), and attach posterior augment trials if needed *(Figure 53)*. The posterior femoral augments chosen at this step may not correspond to the final selected augments since the new posterior resection has not been completed. Place the LBS with the augment trials attached. Place the knee in flexion to verify the actual amount of flexion and varus/valgus angle. The knee should be placed as close as possible to 90 degrees of flexion. Distract the knee joint up to the tension level used for the balance in extension.The posterior gaps are not shown, since the bone has not been resected.Press the Probe to advance to the next screen.

Joint Line Location Planning

The left side of this screen provides a detailed view of the required poly thickness and augments for the femur and tibia *(Figure 54)*.The total gap at the top of the screen must be a minimum of 17mm to accommodate a femoral component, tibial component, and 9mm poly. The tight/loose at the bottom of the screen highlights any discrepancy between the selected implants and the joint space.

The right side shows the revision femoral implant relative to the primary. The orange dots and white outline represent the primary implant. The blue line represents the joint line for the new implants.

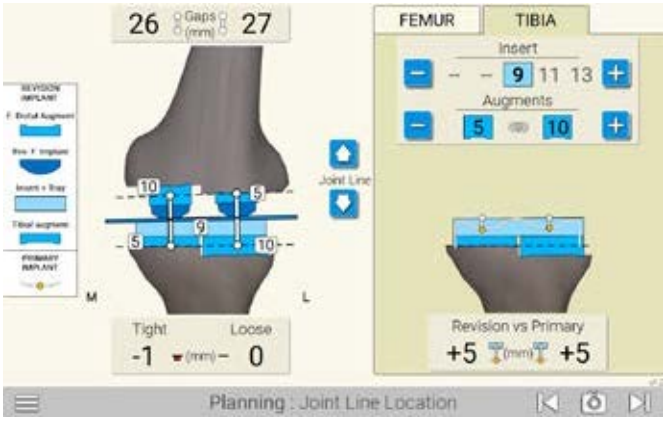


Figure 55
Joint Line Location Planning Screen

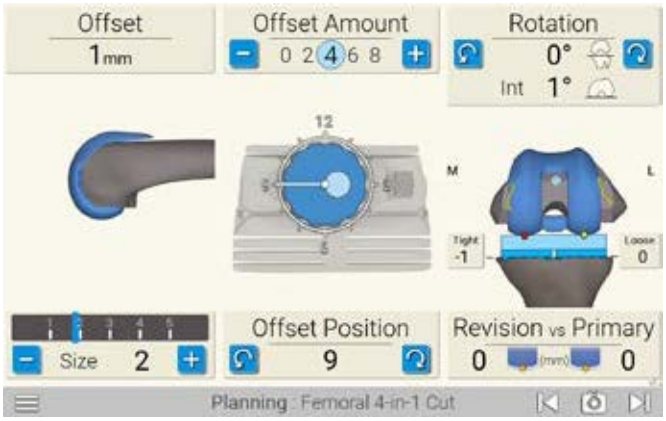


Figure 56
Femoral 4-in-1 Cut Planning Screen

Select tibia to view the joint line planning screen for the tibia *(Figure 55)*. The insert thickness and tibial augment thickness can be adjusted on this screen.

4-IN-1 CUTS PLANNING

The 4-in-1 Cuts Planning Screen is displayed *(Figure 56)*. The values indicate the planned position of the femoral component. The anterior-posterior offset, component size, femoral rotation values, offset bushing size and rotation are all displayed. The size of the component, as well as the offset amount, offset position and rotation, can be adjusted if needed.

Select the Forward button on the Probe to advance to the next screen.

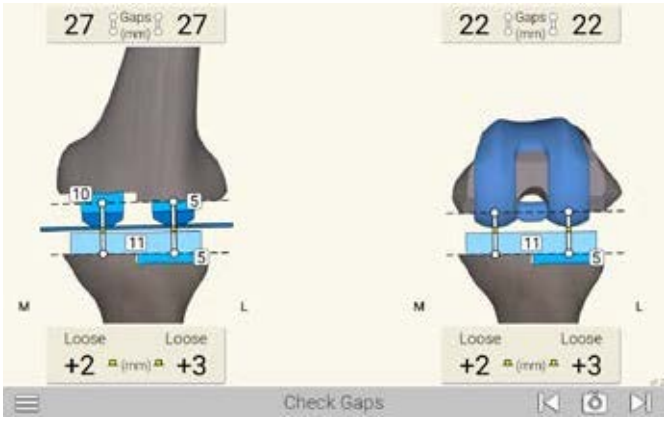


Figure 57
Check Gaps Screen

Figure 58
Attach Distal Augments

Check Gaps

Review the tight/loose at the bottom of the screen and note if there are any discrepancies between the selected implants and the joint space *(Figure 57)*.

Femoral 4 in 1 Resection

The system allows for either anatomical (IM alignment), mechanical (or custom) alignments. Please proceed to the appropriate section.

Anatomical (IM Canal) Alignment

If removed, insert the reamer back into the femoral IM canal. The CC Femoral Finishing Guide uses the Stem Extension Reamer as the reference point for the proper M/L and A/P position. Markings on the anterior and posterior sides of the Femoral Finishing Guide correspond to the M/L width of the femoral implant. Rotation of the femoral component is determined by the rotation of the CC Femoral Finishing Guide. If distal augments are required, attach the appropriate CC Distal Femoral Augment Trial to the distal side of the CC Femoral Finishing Guide *(Figure 58)*.

Distal Femoral Augment Trials are grouped by femoral sizes 1-2 and 3-5 and are available in 5, 10 and 15mm thicknesses. Augment trials are stackable for distal augments greater than 15mm. A Cut Line Predictor may be used to assess the remaining bone anteriorly and posteriorly. Augments can be stacked both distally and posteriorly. Whenever a 15mm or larger augment trial is used, the adjacent posterior or distal aspect of the femoral component will only accept a 5mm augment (i.e. 15mm posterior augment and 5mm distal or 15mm distal augment and 5mm posterior).

Figure 59
Assemble 4-in-1 Cut Guide

Figure 61
Lock Position

Figure 60
Release Position

Figure 62
Rotate Position

Assemble the appropriate CC Offset Bushing (0, 2, 4, 6, or 8mm) to the CC Femoral Offset Bushing Guide with the lever in the "release" position *(Figures 59-60)*.

Because the offset bushing guide is designed with 5 degrees of valgus, the appropriate "left" or "right" marking on the offset bushing guide should face anteriorly. Attach the assembly to the appropriate CC Femoral Finishing Guide and verify its orientation.

Three orientations are designated on the lever as follows:

1) "Release" is the open position that allows for the bushing to be taken in or out. Pull the lever to release the bushing *(Figure 60)*.

2) "Lock" position is when the lever arrow is pointing toward the center of the bushing *(Figure 61)*.

3) "Rotate" allows you to determine the correct offset position. The lever can either be turned up or down 90 degrees *(Figure 62)*.

Rotate the bushing within the guide until at the desired location as determined in Femoral 4-in-1 Planning step. Once the proper position is achieved, move the lever to the "lock" position to secure the orientation *(Figure 61)*.

If using an offset coupler, the reamer depth must be adjusted for the additional 30mm in length. Instead of reaming to the depth marking, ream to the beginning of the black box outlining the next measurement (i.e. for an 80mm stem with an offset coupler, ream to the beginning of the 120mm box).

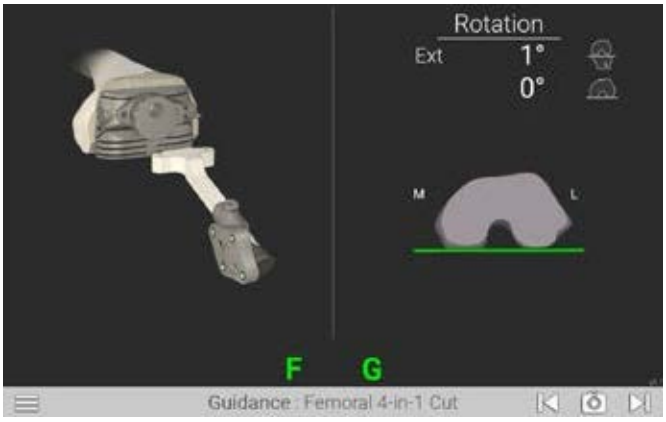


Figure 63
Femoral 4-in-1 Cut Guidance Screen

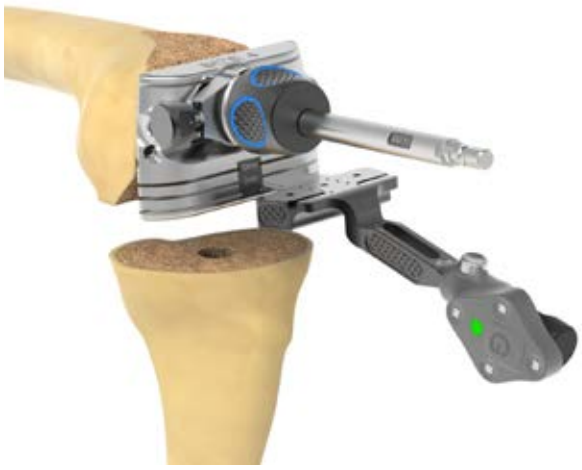


Figure 64
Set 4-in-1 Guide Rotation

Mechanical Alignnment

If mechanical alignment was chosen, the reamer should be downsized in the IM canal until the FFG can be placed flush with the distal femoral bone cut. Please follow the anatomical alignment section above after downsizing the reamer.

Femoral 4-in-1 Cuts Guidance

Place the Knee Blade Drill Guide in the cutting slot with the G tracker attached and rotate the FFG using the screen as guidance *(Figures 63 & 64)*. Adjust the position of the FFG 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 FFG. When the alignment of the FFG is within 1mm and/or 1 degree of the planned position, the orange line will change to green. Pin the guide in place. Select the Forward button on the Probe to advance to the next screen.

In the case of mechanical alignment where a downsized reamer was selected, the scribe marks on the femoral finishing guide may be used to set the M/L position. The scribe marks correspond to the width of the implant.

Perform Femoral 4-in-1 Resection

Cuts should be made through the anterior, anterior chamfer and posterior chamfer slots. For easier saw access, removing the offset bushing and femoral offset bushing guide prior to making the resections is suggested. If the femoral component requires distal augments, there may not be any chamfer bone to resect. Posterior bone loss should be evaluated on the medial and lateral posterior condyles. The bone should be resected through the slots that provide a minimal cut and maximum bone contact independently on the medial and lateral posterior condyles. The CC Femoral Finishing Guides have resection slots to prepare the bone for

Figure 65
Ream for Femoral Boss

0, 5 and 10mm CC Posterior Femoral Augment Trials. After all resections have been made, remove the reamer from the CC Femoral Finishing Guide.

Note: *When stacking distal augment trials (>15mm augments), the CC Femoral Finishing Guide can not be pinned on the stacked side. Leave the CC Offset Bushing and CC Femoral Offset Bushing Guide over the reamer and pin the side without stacked trials to stabilize the femoral finishing guide. Anterior and posterior resections can be performed with the bushing attached. Chamfer resections can not be completed, but these are typically not required when using distal augments greater than 15mm. Alternatively, femoral finishing guide handles are available in the set.*

The system provides flexibility by offering various offset positions and reamer diameters. However, it is important to verify that the combination of offset and diameter chosen does not penetrate the cortex of the femoral bone when preparing the femoral boss in the next step.

The stem boss on the constrained femoral prosthesis is 16mm in diameter. If the femur was prepared without offset, additional reaming is required if the canal has been reamed less than 16mm. If the femur is prepared with offset, additional reaming is required regardless of the size. To accommodate the boss in the canal, the CC Femoral Boss Prep Reamer should be used to ream the distal canal 2cm deep to the distal cut. Attach the CC Femoral Boss Prep Guide to the CC Femoral Finishing Guide and use the Femoral Boss Prep Reamer to prepare the bone *(Figure 65)*. The Femoral Boss Prep Reamer should be advanced into the femur until the depth stop is engaged. Remove the CC Femoral Finishing Guide and the reamer from the femur.

Figure 66
Attach Femoral Augments

Figure 67
Femoral Trial Assembly

Note: *If the combination of the Stem Extension Reamer diameter and desired offset does not easily allow the femoral boss to be prepared through the Femoral Finishing Guide, it can be prepared through the CC Notch Guide. Attach the CC Femoral Boss Prep Guide to the Notch Guide. With this approach, the distal pin holes on the Femoral Base Trial can not be used. Proceed with the Femoral Boss Prep Reamer.*

FEMORAL BASE TRIAL ASSEMBLY

Select the appropriate size Femoral Base Trial that corresponds to the previously determined femoralcomponent size. If distal or posterior femoral augments are needed, the appropriate trial should be attached to the distal or posterior side of the Femoral Base Trial *(Figures 66-67)*. Augment Trials are grouped by femoral sizes 1-2 and 3-5 and available in 5, 10, and 15mm thicknesses. Augment Trials are stackable for augments greater than 15mm.

If additional bone cuts are required for augments, the bone can be prepared directly through the femoral trial.

Note: *The Femoral Base Trial is symmetric but has cutouts on the anterior flange that represent the profile of the left and right implants.*

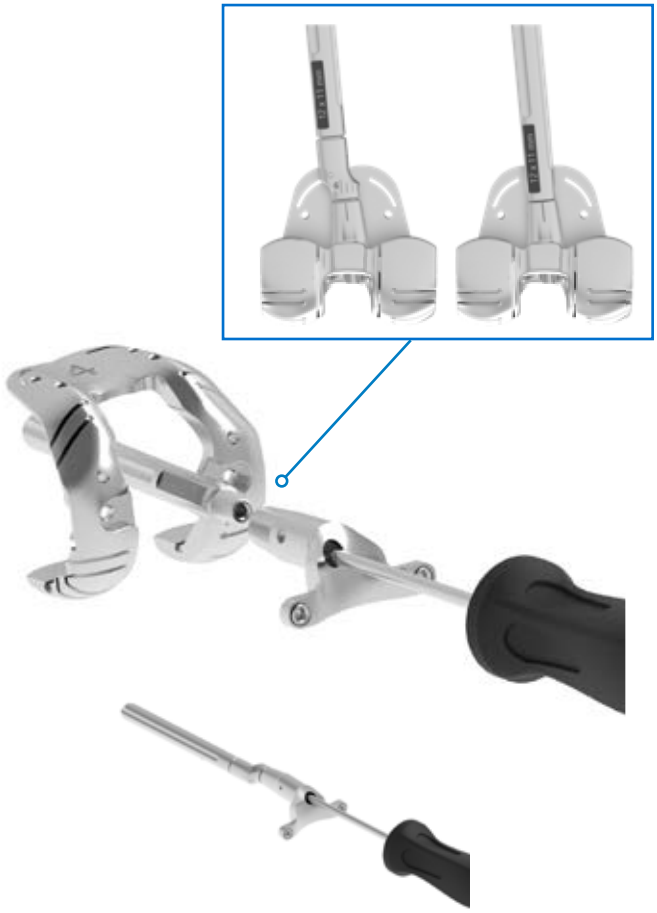


Figure 68
Stem Adaptor Assembly

Figure 69
Secure the Femoral Base Trial

Femoral Trialing: Stem Extension Only

After preparing the A/P femoral cuts with the Femoral Finishing Guide, assemble the Femoral Base Trial with the CC Femoral Stem Adaptor and appropriate Stem Extension Trial and Offset Coupler Trial (if required) to assess the fit of the components prior to preparing the notch resection. Insert the Stem Extension Trial taper into the CC Femoral Stem Adaptor and tighten the captured screw using the 3.5mm Hex Driver and Torque-Limiting Screwdriver Handle. If an Offset Coupler Trial is required, align the appropriate number on the offset coupler trial with the line on the femoral stem adaptor. The location (number) of the offset was determined previously. The stem extension trial is then attached to the coupler trial. The stem extension assembly is attached to the femoral base trial and the screws are tightened. Place the assembly on the bone and pin it in place using either the distal or anterior flange pin holes *(Figures 68-69)*.

Caution: *Do not engage the breakaway torque feature to tighten the screws. Overtightening the screws may damage the instruments.*

Note: *The offset couplers add 30mm of additional length to astraight stem extension. Ensure reamer depth is sufficient.*

It is critical to securely pin the femoral base trial prior to removing the stem trial and adaptor *(Figure 69)*. If the femoral base trial moves after it is removed, the stem trial must be re-inserted and reattached to the femoral trial to reestablish the femoral position relative to the canal. Pin the femoral trial securely prior to moving to the femoral notch resection step.

Once the femoral base trial is pinned, use the hex driver to loosen the screws by attaching the femoral stem adaptor to the femoral base trial. Attach the CC Trial Extractor to the

Figure 70
Stem Extension Trial Removal

Figure 71
Assemble CC Notch Guide

Slaphammer and insert the extractor into the stem adaptor. Turn it 90 degrees until the lock symbol is facing anteriorly and then remove the femoral stem adaptor and stem extension trial *(Figure 70)*.

Femoral Notch Resection

Assemble the CC Notch Guide to the Femoral Base Trial using the 3.5mm Hex Driver to tighten both screws *(Figure 71)*.

Caution: *Do not engage the breakaway torque feature to tighten the screws. Overtightening the screws may damage the instruments.*

Figure 72
Perform Notch Resection

Figure 73
Trim the Notch

Attach the Notch Cutter to a power drill. With the knee in flexion, introduce the Notch Cutter into the Notch Guide, making sure that the drill is set on the "drill" setting. Once the teeth on the Notch Cutter have cleared the black bushing and before the teeth contact the bone, activate the drill. Apply pressure to the Notch Cutter as it travels posteriorly and ream until the Notch Guide prevents the Notch Cutter from further travel *(Figure 72)*.

Turn the power drill off and remove the Notch Cutter from the Notch Guide. Do not activate the drill while removing the Notch Cutter to prevent the cutting teeth from scoring the black bushing.

Due to the cylindrical shape of the Notch Cutter, it is necessary to remove any existing bone remnants from the distal femur. It is recommended to use a sagittal saw to remove the bone remnants, aligning the saw to the inner surfaces of the Notch Guide and trim the medial and lateral sides of the notch *(Figure 73)*. Remove the Notch Guide after all cuts are performed.

Preparation for the CC femoral component is complete.

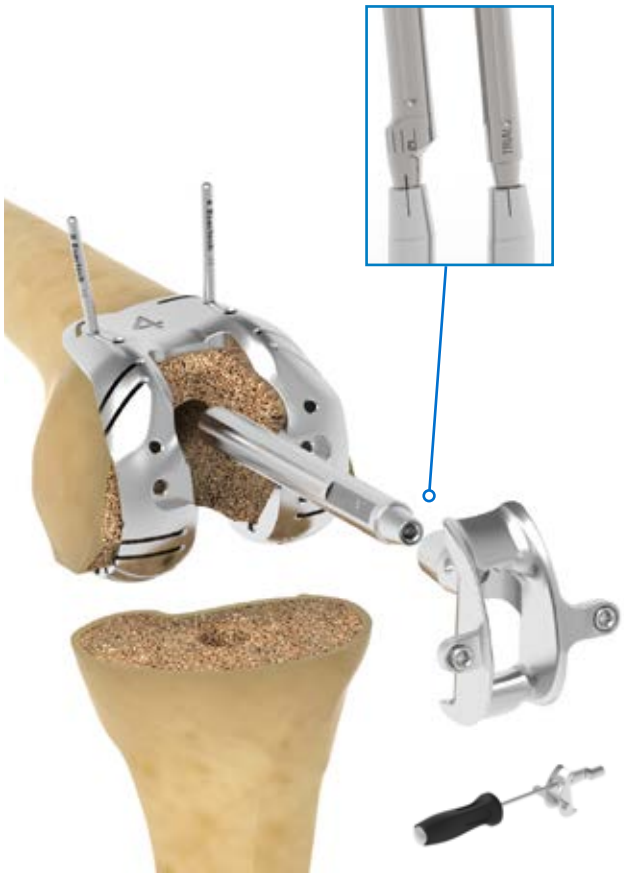


Figure 74
Attach Stem Extension Trial

Figure 75
Attach Modular Femoral Box Trial

Femoral Trial Assembly

Select the CC Modular Femoral Box Trial corresponding to the appropriate size and orientation (left or right) Femoral Base Trial. Attach the appropriate length and diameter stem extension trial to the Modular Femoral Box Trial. If an Offset Coupler Trial is required, align the appropriate number on the offset coupler trial with the line on the modular femoral box trial. The location (number) of the offset should have been determined previously. The stem extension trial is then attached to the coupler trial *(Figures 74-75)*.

Attach the Modular Femoral Box Trial and Stem Extension Trial to the Femoral Base Trial using the 3.5mm hex driver and two screws on the distal surface.

Trial Reduction (Optional)

If desired, a trial reduction can be done prior to determining the final tibial rotation and preparation.

The Truliant Tibial Tray Trial should be selected as the largest tray that fits within the borders of the resected tibial surface without any overhang. The tray trial selected must be within one whole size up or down of the selected femoral component size.

Figure 76
Attach Tibial Augment Trial

Figure 77
Match the Trial Shim and Top

If cuts have been made for tibial augmentation, the appropriate FIT Augment Trial(s) should be attached to the underside of the tibial tray trial. The augment trials are side specific (left/right) and each have a captured screw. Select the appropriate augment trial and match it with the profile of the tibial tray trial. Using the 3.5mm hex driver, tighten both screws *(Figure 76)*. Place the tibial tray trial on the resected proximal tibial surface.

Next, the appropriate thickness of Truliant Tibial Insert Trial Shim should be assembled to the desired Truliant Tibial Insert Trial Top (PS, PSC, or CC). The Tibial Insert Trial Shims and Top should match the selected femoral component size *(Figure 77)*.

Figure 78
Exchange Tibial Insert Trials

Figure 79
Assess in Flexion and Extension

The Truliant Tibial Trial Handle should then be inserted into the Shim/Top combination and placed on the Tibial Tray Trial *(Figure 78)*. To adjust the thickness of the Tibial Insert Trial Assembly, the Shim can be exchanged as needed using the Tibial Trial Handle until a "best fit" is achieved.

Assess the knee in both flexion and extension *(Figure 79)*. Once the desired result is achieved, the trials can be removed from the bone.

Remove the Modular Tibial Insert Trial using the Insert Trial Handle. At this point the femoral base trial can be removed from the bone.

Figure 80
Remove the Trial

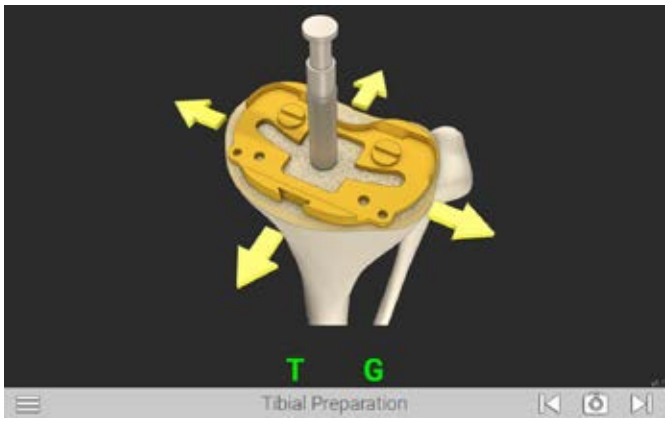


Figure 81
Offset Tibial Preparation Screen

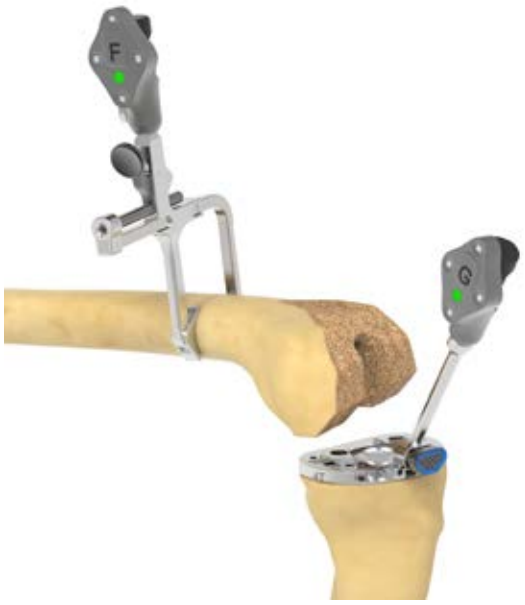


Figure 82
Attach the G Tracker to the Trial and Pin the Trial

Attach the CC Trial Extractor to the Slaphammer and insert the extractor into the modular femoral box trial. Turn it 90 degrees until the lock symbol is facing anteriorly and then remove the box trial and stem extension trial *(Figure 80)*.

TIBIAL PREPARATION

Attach the Tray Tracker attachment to the tibial tray *(Figure 81)*. When the FIT Tibial Tray and stem assembly is introduced into the canal, the M/L and A/P positions will be influenced by the stem fit in the canal. Additionally, the stem of the FIT tray must be prepared with the appropriate tamp. Select the CC Tibial Tray Trial size that provides the desired tibial coverage by placing the compatible sizes onto the resected tibial surface. The system allows the tibia to be same size, up-size or down-size from the selected femoral size. Pin the tray trial with two short headed pins. If a tibial augment is needed, the tray must be pinned through the posterior holes *(Figure 82)*.

Note: *When using the syringe pin puller (02-029-90-4100) avoid bending the instrument off-axis during manipulation as such off-axis bending may damage the instrument.*

Select the Forward button on the Probe to advance to the next screen.

Figure 84
FIT Tibial Drill Guides

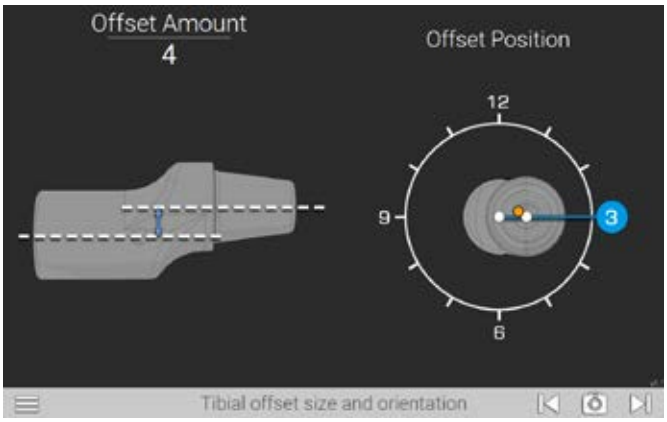


Figure 83
Tibial Offset Size and Orientation Screen

Figure 85
Tibial Tamp Adaptor Bar Assembly

Tibial Offset Management

The values indicate the planned position of the tibial component based on where it is positioned on the proximal tibia *(Figure 83)*. The offset amount and offset position are displayed.

If the tibia was prepared with offset, additional reaming is required. To accommodate the offset coupler in the canal, the CC Tibial Boss Prep Reamer should be used to prepare the proximal portion of the tibial canal for the offset coupler.

Place the 14mm FIT Tibial Drill Guide on the Tibial Tray Trial and use the Tibial Boss Prep Reamer to prepare the bone *(Figure 84)*. The Tibial Boss Prep Reamer should be advanced into the tibia until the line on the reamer matches the line in the window of the appropriate tibial tray size. Remove the FIT Tibial Drill Guide and the reamer from the bone.

Tibial Tamping

Attach the Tibial Tamp Adaptor Bar to the tamp guide *(Figure 85)*.

Figure 86
Assemble Tibial Tamp

Figure 87
Push Tamp into Tibia Until Plate Contacts Handle

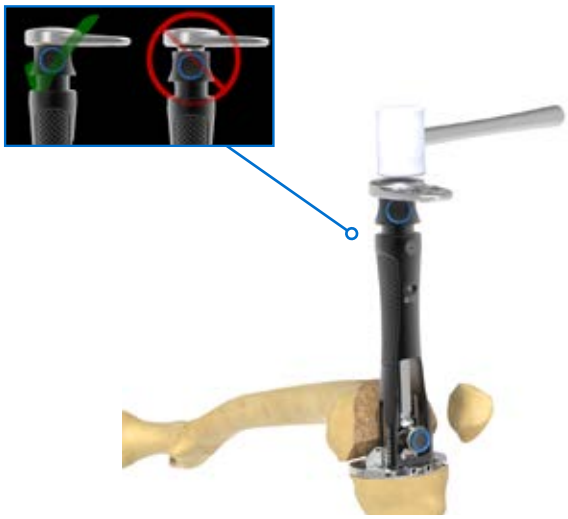


Figure 88
Impact the FIT Tamp

Figure 89
Remove the FIT Tamp

Assemble the Truliant Fit Tibial Tamp Head to the Truliant Tibial Tamp Guide by pressing the button on the anterior distal end of the Tamp Guide *(Figure 86)*. Set the size on the Tamp Guide that corresponds to the previously determined tibial tray size by rotating the dial at the proximal end until the desired size is viewed in the window.

Align the pegs on the bottom of the Tamp Guide with the holes on the Tibial Tray Trial and seat the Tamp Guide flush and stable against the Tibial Tray Trial *(Figure 87)*. The Tamp Head is driven into the tibia until the impaction plate contacts the handle on the Tamp Guide. Complete impaction can also be confirmed using the size markings on the distal end of the Tamp Guide *(Figure 88)*.

Note: *Be sure to hold the Tamp Guide steady during impaction to avoid tilt or lift-off.*

The Tamp Guide and Tamp Head should be removed from the proximal tibia by retrograde impaction of the impaction plate with a mallet *(Figure 89)*.

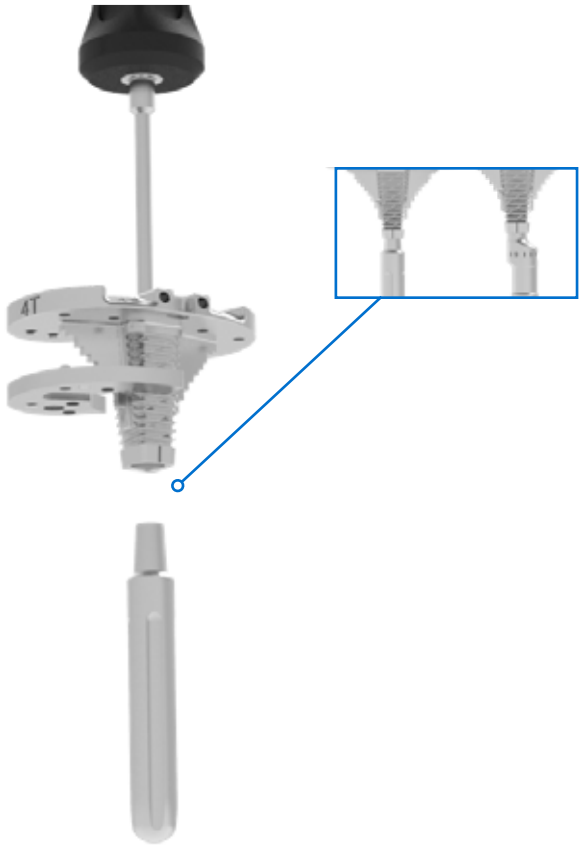


Figure 90
Assemble Tibial Trials

Figure 91
Assemble Tibial Trials

Tibial Trial Assembly

The FIT Tibial Tray Trial provides an opportunity to evaluate fit and function of the tibial tray, stem extension and any tibial augments prior to selecting the actual components. Select the appropriate Stem Extension Trial and Offset Coupler Trial (if required) that corresponds with the depth and diameter of the last reamer used. If mechanical alignment was chosen in the planning step, the stem extension diameter should be downsized in the IM canal until the FIT Tibial Tray Trial can be placed flush with the proximal tibial bone.

The Stem Extension Trial should be screwed into the base of the FIT Tibial Tray Trial using the 3.5mm Hex Driver. If an Offset Coupler Trial is required, align the appropriate number on the offset coupler trial with the line on the FIT Tibial Tray Trial. The location (number) of the offset was determined previously. The stem extension trial is then attached to the coupler trial. The Tibial Augmentation Block Trial(s), if required, should now be transferred to the FIT Tibial Tray Trial *(Figure 90, 91)*.

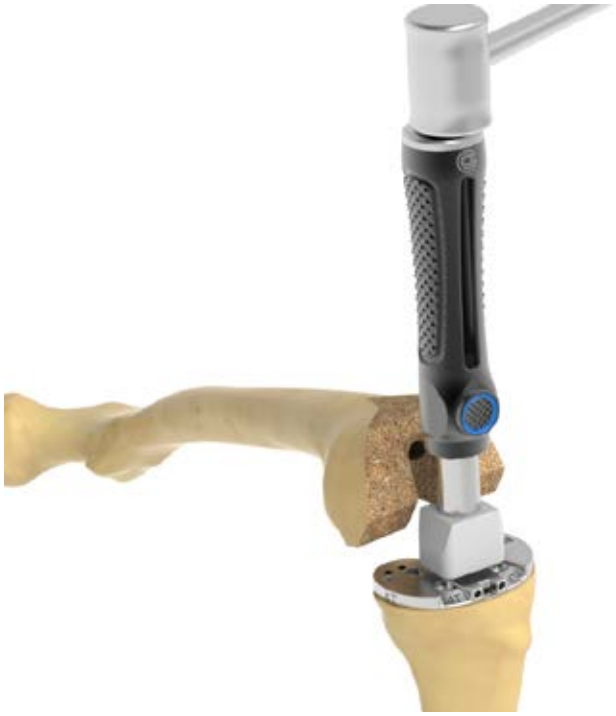


Figure 92
Impact the Trial

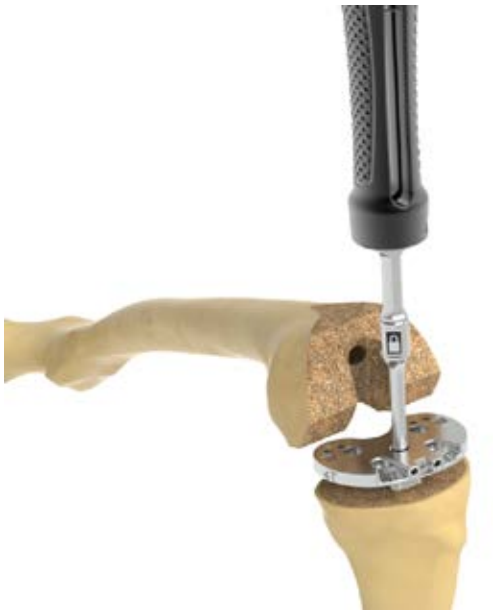


Figure 93
Remove the Trials

Impact the fully assembled trial into the bone to assess the fit as shown in *(Figure 92)*.

Once fit of the trial is assessed, attach the CC Trial Extractor to the Slaphammer and insert the extractor into the FIT Tibial Tray Trial. Turn it 90 degrees until the lock symbol is facing anteriorly and then remove the tibial tray trial and stem extension trial *(Figure 93)*.

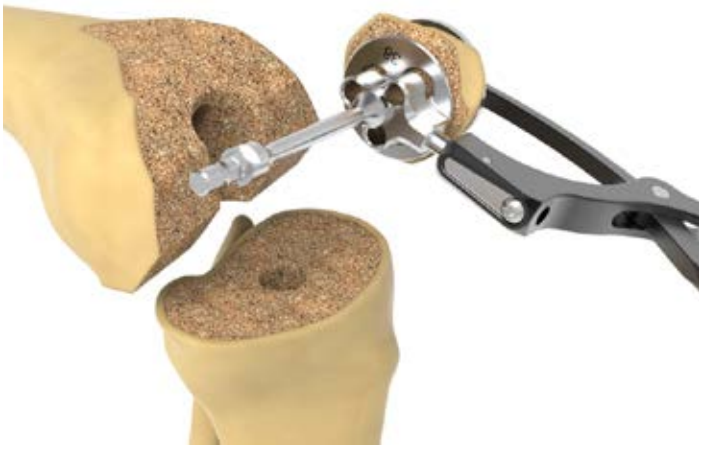


Figure 94
Size Patella and Drill Peg Holes

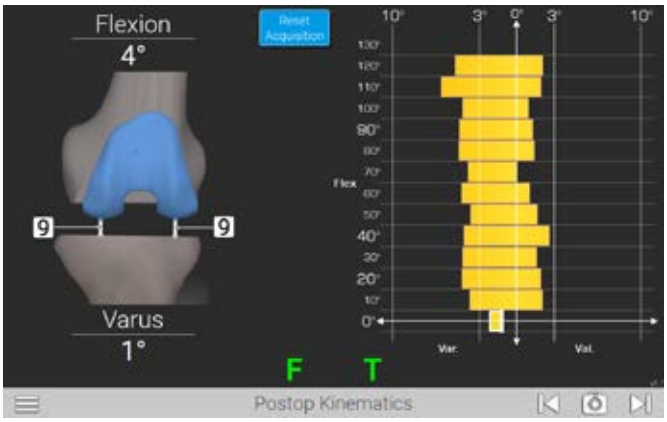


Figure 95
Post-operative Kinematics Screen

PATELLA RESECTION

It is not always necessary to revise the patellar component. A well-fixed component from the Optetrak system may be left. If the component is loose or found to be incompatible, determine if there is enough bone remaining to implant a new patellar component. Sufficient bone must remain to ensure the pegs from the new prosthesis do not protrude through the anterior surface.If the decision is made to replace the primary patellar component with an Optetrak patellar component, final determination of patellar size (diameter) and hole preparation should be performed using the Patellar Universal Drill Guide assembled to the Patella Preparation Handle.

With the handle completely open, position the Drill Guide on the patella to determine the patellar diameter. The pattern and size of the Drill Guide holes are universal for all three-peg patella components. Clamp the patella and secure the handle by turning the knob. Holes should be drilled through the patellar universal drill guide in either the three-hole or the single-hole configuration using the appropriate Patellar Drill. After the holes are drilled, loosen the knob and remove the handle and Drill Guide from the patella. The appropriate size One-Peg Patella Trial or Three-Peg Patella Trial should be placed on the patella *(Figure 94)*.

IMPLANT ASSEMBLY

Assemble and implant the implants per the Optetrak Logic CC Total Knee System with Truliant CC Instrumetation Op Tech (712-35-33).

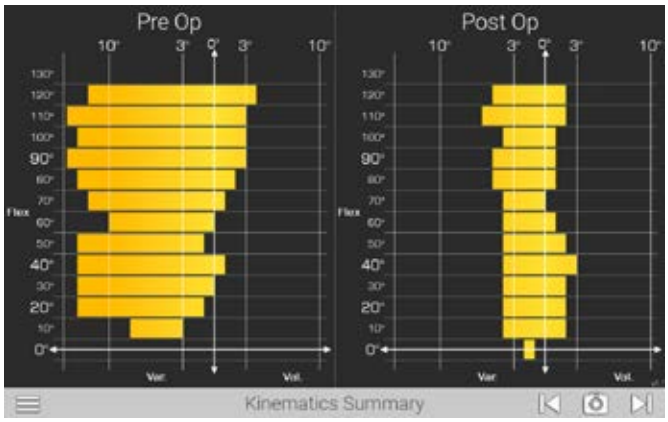


Figure 96
Kinematics Summary Screen

Figure 97
Preparation Complete

POSTOP KINEMATICS

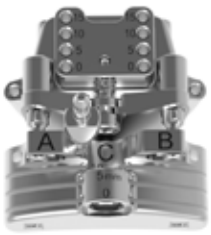
With the Femoral Clamp attached run the knee through a ROM *(Figure 95)*. Select the Forward button on the Probe to advance to the next screen.

This screen displays both the preop and postop kinematic values *(Figure 96)*. Select the Forward button on the Probe to advance to the next screen.

PROCEDURE COMPLETE

The final screen of the RTKA application is displayed *(Figure 97)*. Select the exit button to save the data to the starter key.

INSTRUMENT LISTING

CATALOG NUMBER	PART DESCRIPTION	
02-521-50-0000	RTKA Femoral Adjustable Guide	
02-521-70-0000	RTKA Tibial Adjustable Guide	
02-521-70-0001	RTKA Tibial Tray Tracker	
02-521-90-1000	Truliant Blade Drill Guide	
02-521-90-1001	Truliant Blade Drill Guide Extension	

For additional instrumentation, please reference the Truliant CC Operative Technique (712-35-33).

CATALOG NUMBER	PART DESCRIPTION	
521-10-00	0-Degree External Tracker Fixator	
521-10-30	30-Degree External Tracker Fixator	
521-50-03	Femoral Clamp Fixator	
521-50-08	Augmentable LBS III	

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For additional device information, refer to the Truliant 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.

 712-32-30 Rev. B 0621

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