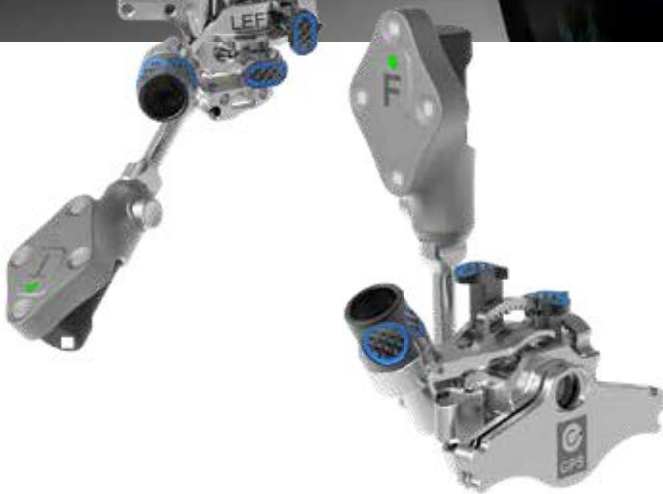


EXACTECH | KNEE

Operative Technique



GPS | KNEE

TKA Plus Application with Truliant®
Implants and Instrumentation



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INTRODUCTION

With the demand for total knee arthroplasty continuing to grow, we know you are challenged to deliver excellent clinical outcomes with ever greater efficiency. The Truliant® Knee System is a surgeon-inspired, comprehensive platform that embodies the power to achieve reproducible results in primary and revision total knee arthroplasty. Incorporating advanced design philosophies and surgical technologies, Truliant seamlessly integrates with the ExactechGPS® system for real-time guidance and data. The TKA Plus Application is designed to provide the accuracy of computer-assisted surgery without disruption of workflow or special instruments.

Note: The GPS TKA Plus is designed for use with the Truliant instruments.

The GPS system can be used with Truliant and Optetrak Logic® implants.

DETAILED OPERATIVE TECHNIQUE

SURGICAL TECHNIQUE



Figure 1
Application Screen



Figure 2
TKA Plus Screen



Figure 3
Welcome Screen

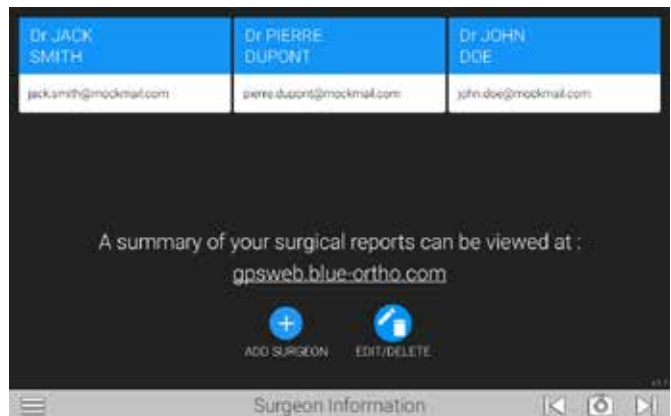


Figure 4
Surgeon Information

SYSTEM SET-UP

Application Screen

Turn the system on and when prompted to initiate the GPS Applications (*Figure 1*), select TKA Plus under Knee.

Click on the TKA Plus icon to begin the application (*Figure 2*).

Welcome Screen

The system will automatically advance to the TKA Plus Welcome screen (*Figure 3*). Select the arrow at the lower right corner of the display to advance to the Surgeon Information screen (*Figure 4*).

Surgeon Information Screen

Select from your previously entered Surgeon ID (preferred method) or create a new one.

To create a new surgeon profile, click on **+** ADD SURGEON and fill in the requested data. Once you have saved the profile, the surgeon's name will appear on the Surgeon Information Screen.



Figure 5
Patient Information

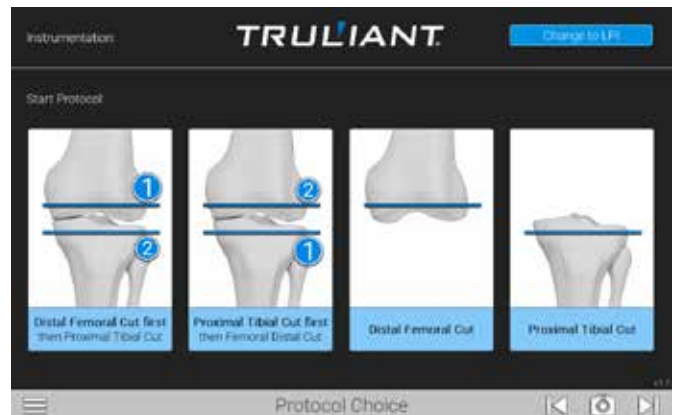


Figure 6
Protocol Choice



Figure 7
Seeking Trackers



Figure 8
Insert Batteries Positive Side First

Patient Information Screen

Advance to the Patient Information page (Figure 5). Patient identification information can be entered into the fields displayed. All fields are optional, however, you must click on either the right or left knee to continue.

Protocol Choice Screen

Advance to the Protocol Choice screen and select one of the four (4) protocol choices available. (Figure 6).

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

Connect Trackers

The Seeking Tracker screen is displayed (Figure 7). Insert batteries (positive end first) into the Probe Tracker (P), Femoral Tracker (F), Tibial Tracker (T) and the Guide Tracker (G).

Caution: Inserting negative side first or in reverse polarity may cause permanent damage to the tracker. Insert batteries positive side first (Figure 8).

DETAILED OPERATIVE TECHNIQUE

SURGICAL TECHNIQUE

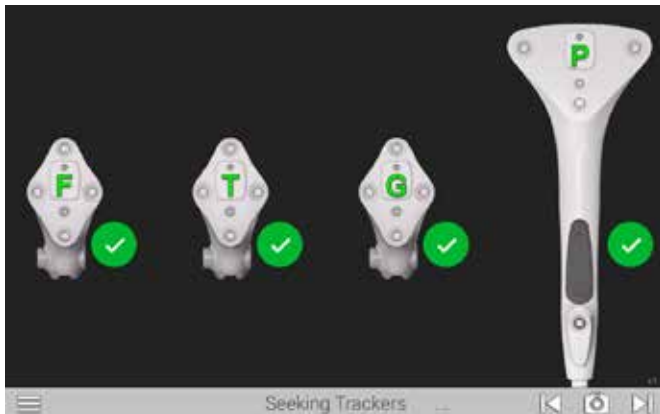


Figure 9
Start Tracking

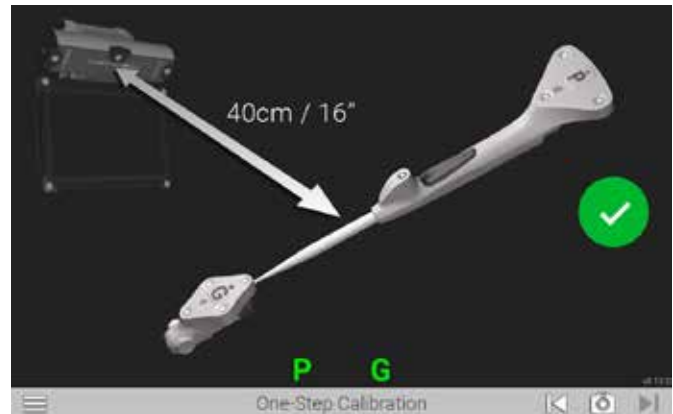


Figure 10
One-step Calibration

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 such that the LEDs face the GPS display screen. The trackers will display on the GPS display screen and a green check mark will appear to verify connection (*Figure 9*).

One-step Calibration

The One-Step calibration screen is displayed (*Figure 10*). Place the tip of the Probe Tracker (P) into the dimple node at the top of the Guide Tracker (G). Hold both together approximately 16 inches from the display unit ensuring the white diodes are facing the camera. When positioned correctly, the "G" and "P" status indicators on the display screen will appear green. Press the Forward button on the Probe to initiate calibration. The progress circle will display a green check mark to indicate a successful calibration. The system will automatically advance to the next screen.

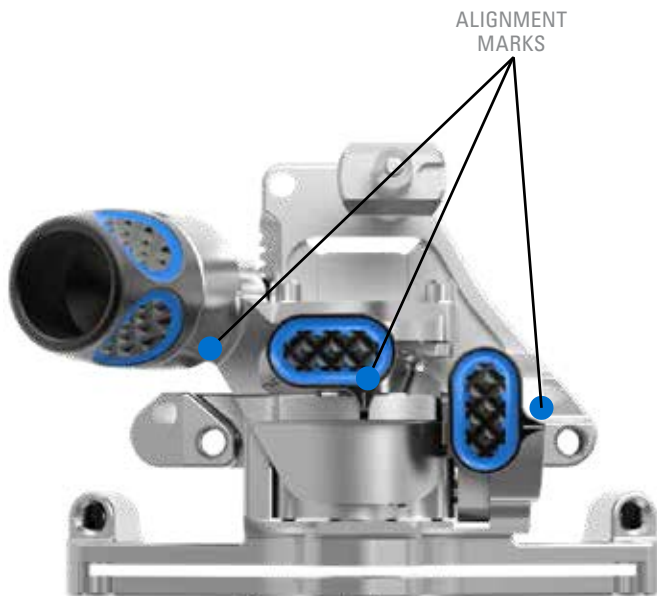


Figure 11

Align the Resection Guide



Figure 12

Assemble the Distal Femoral Block

FEMORAL PREPARATION

Before you assemble the femoral instruments, verify that the TKA Plus Distal Femoral Resection Guide is at the neutral position by aligning the varus/valgus and flexion/extension buttons with the markings on the block and by aligning the proximodistal adjustment knob neutral marking with the markings on the block (*Figure 11*).

Attach TKA Plus Distal Femoral Resection Guide

Attach the TKA Plus Distal Femoral Resection Guide to the Truliant Distal Femoral Link and Truliant Distal Femoral Alignment Guide (*Figure 12*).

DETAILED OPERATIVE TECHNIQUE

SURGICAL TECHNIQUE

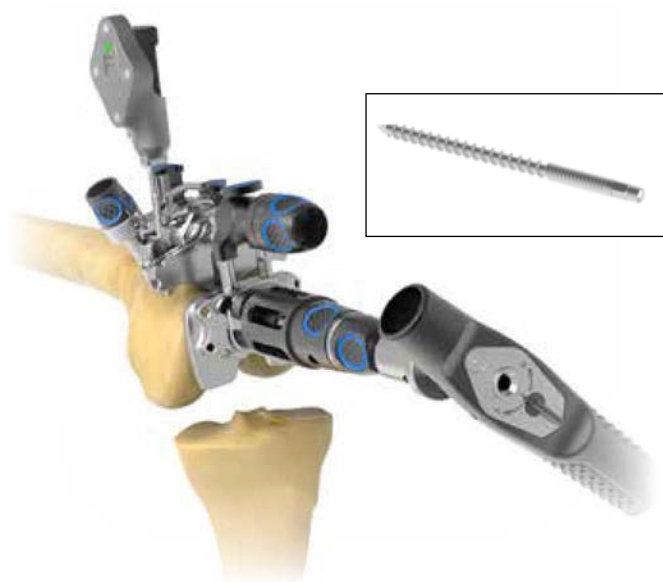


Figure 13
Femoral Assembly on Bone



Figures 14a and 14b
Attach the Femoral Tracker (F)

Pin TKA Plus Femoral Distal Resection Guide

Set your preferred parameters using the Truliant Distal Femoral Link and Truliant Distal Femoral Alignment Guide (Figure 13), and place the resection guide on the femur. Pin the TKA Plus Femoral Distal Resection Guide using threaded pins in the parallel pin holes located on the block. If additional stability is desired, remove the IM rod and pin in the angled holes adjacent to the parallel holes. It is important not to pin in the proximal hole slots at this time in order to allow for block adjustments.

The Truliant link and Distal Femoral Alignment Guide, along with the IM rod may be removed after the TKA Plus Distal Femoral Resection Guide has been successfully pinned in place.

Attach Trackers to Femur

Attach the Femoral Tracker (F) to the TKA Plus Distal Femoral Resection Guide and lock into place (Figure 14a). If desired, the optional TKA Plus Distal Femoral Tracker Extension may also be added to the TKA Plus Distal Femoral Resection Guide prior to adding the Femoral Tracker (F) (Figure 14b). Avoid contact with soft tissues and the button located on the TKA Plus Distal Femoral Tracker Extension or the tracker. Make sure the tracker is facing toward the camera.

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

Important information: If the TKA Plus Distal Femoral Tracker Extension is not used during the anatomical acquisitions on the femur, the extension may not be used later in the

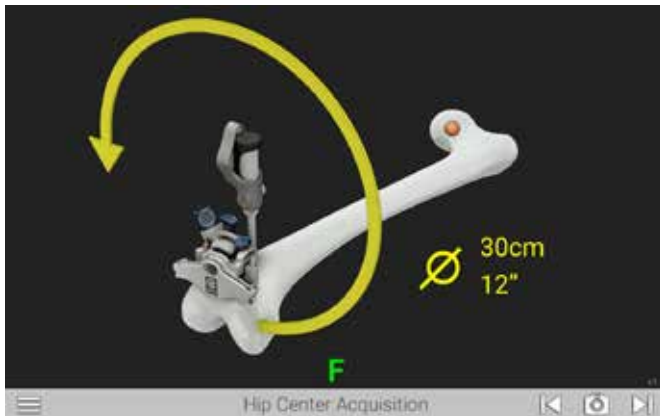


Figure 15
Hip Center Acquisition

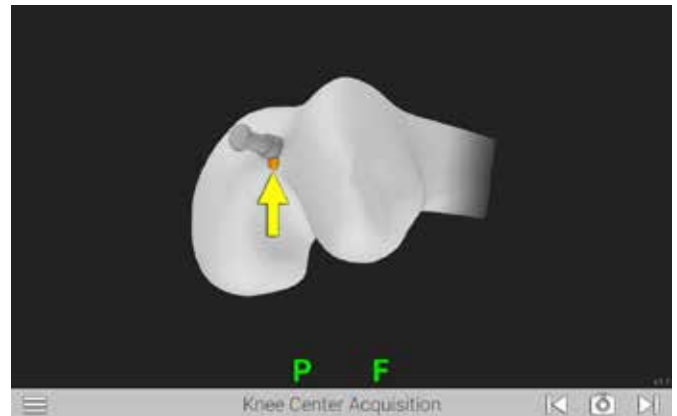


Figure 16
Knee Center Acquisition

procedure. The TKA Plus Distal Femoral Tracker Extension may only be used when the anatomical acquisitions are performed with both the extension and Femoral Tracker (F) locked in place together on the TKA Plus Distal Femoral Resection Guide.

FEMORAL IMPLANT ACQUISITIONS

Hip Center Acquisition

The Hip Center Acquisition screen is displayed (Figure 15). Movement of the bone will initiate the acquisition process (autostart). Move the knee in a 12-inch diameter circular pattern as illustrated on the display. Large diameter, slow circular motion may be more effective than rapid small radii circles. The progress bar will fill, and audible clicks will indicate successful registration of points. An audible tone will indicate registration is complete and the system will automatically advance to the next screen.

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

Knee Center Acquisition

The Knee Center Acquisition screen is displayed. Position the tip of the Probe Tracker (P) in the deepest point of the intercondylar notch (Figure 16). In most cases the posterior aspect of the previously drilled intra-medullary hole is generally used as this reference point. Press the Forward button and the system will automatically advance to the next screen.

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

DETAILED OPERATIVE TECHNIQUE

SURGICAL TECHNIQUE

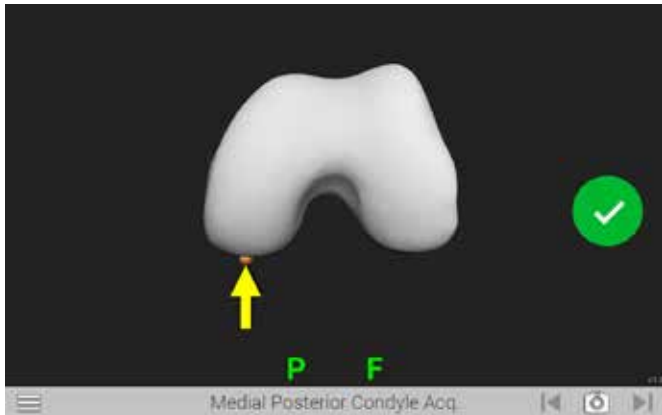


Figure 17
Medial Posterior Condyle Acquisition

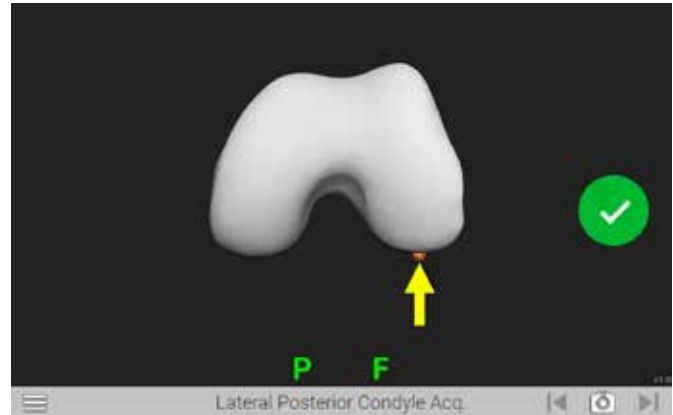


Figure 18
Lateral Posterior Condyle Acquisition

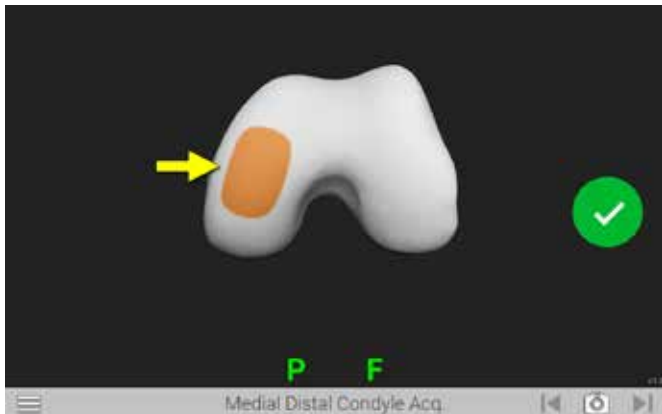


Figure 19
Medial Distal Condyle Acquisition

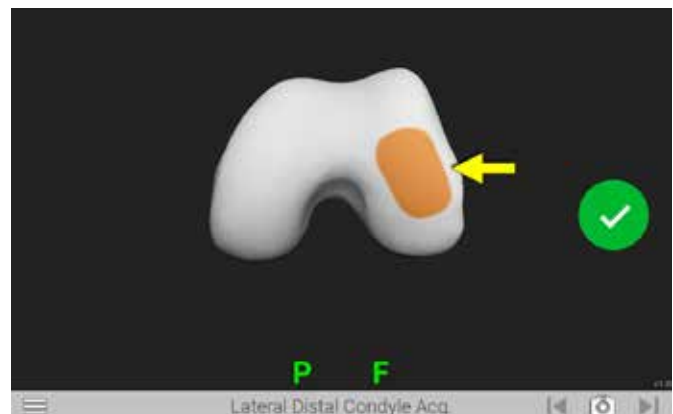


Figure 20
Lateral Distal Condyle Acquisition

Posterior Condyle Acquisition

The Medial Posterior Condyle Acquisition screen is displayed (*Figure 17*). Position the tip of the ProbeTracker (P) on the medial posterior condyle press the Forward button. Ensure the tip of the probe maintains contact with the condyle and touch a point that captures the apparent most posterior aspect of the condyle. An audible tone and a green check mark will indicate registration is complete and the system will automatically advance to the Lateral Posterior Condyle Acquisition screen (*Figure 18*). Repeat to acquire point for the lateral posterior condyle.

Distal Condyle Acquisition

The Medial Distal Condyle Acquisition screen is displayed (*Figure 19*). Position the tip of the ProbeTracker (P) on the medial distal condyle 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 Lateral Distal Condyle Acquisition screen (*Figure 20*). Repeat to acquire points on the Lateral Distal Condyle.

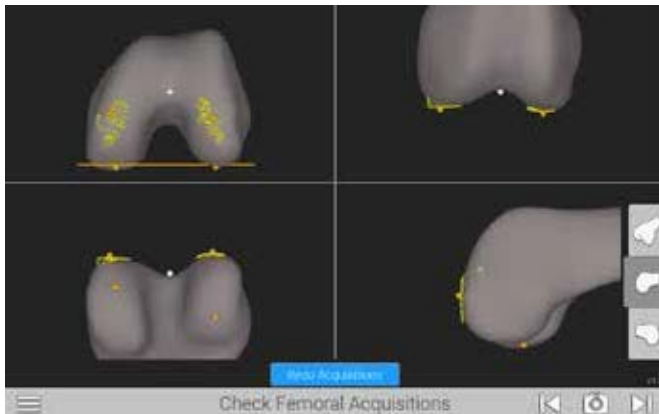


Figure 21
Check Femoral Acquisitions



Figure 22
Choose Acquisitions to Redo

Check Femoral Acquisitions

The Check Femoral Acquisition screen is displayed (Figure 21). A graphical representation of the registered points (yellow dots) is displayed. The distal orange dots represent points that will be used by the system to determine resection levels. For further review of the registered points, select one of the three options located at 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 Check Femoral Acquisitions screen. Select the acquisitions to redo (Figure 22), then select the redo button. 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.

DETAILED OPERATIVE TECHNIQUE

SURGICAL TECHNIQUE

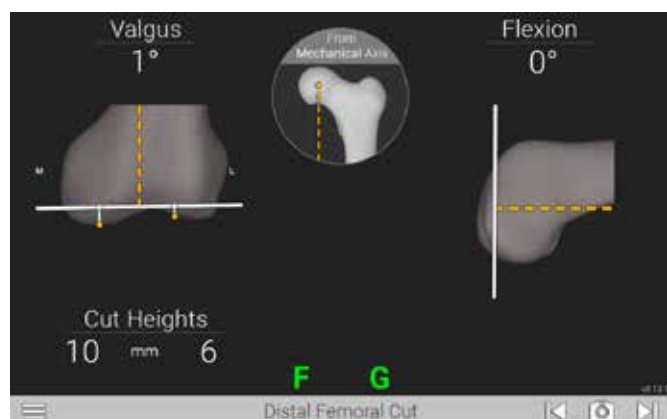


Figure 23
Distal Femoral Cut



Figure 24
Attach the Guide Tracker (G)

DISTAL FEMORAL CUT GUIDANCE

The Distal Femoral Cut screen (*Figure 23*) will be displayed.

Attach the Guide Tracker (G) to the Truliant Blade Drill Guide and lock into place (*Figure 24*). Make sure the tracker is facing toward the camera.

Place the Truliant Blade Drill Guide into the TKA Plus Distal Resection Guide cutting slot (*Figure 25*) and using the guidance provided by the GPS system, adjust the parameters on the TKA Plus Distal Femoral Resection Guide to the desired cut parameters first by using the buttons to adjust the slot orientation in term of Varus/Valgus and Flexion/Extension angles and then by using the knob to adjust the proximodistal position. The orange line displayed on the screen represents the mechanical axis. Once desired position is achieved, remove the Truliant Blade Drill Guide.

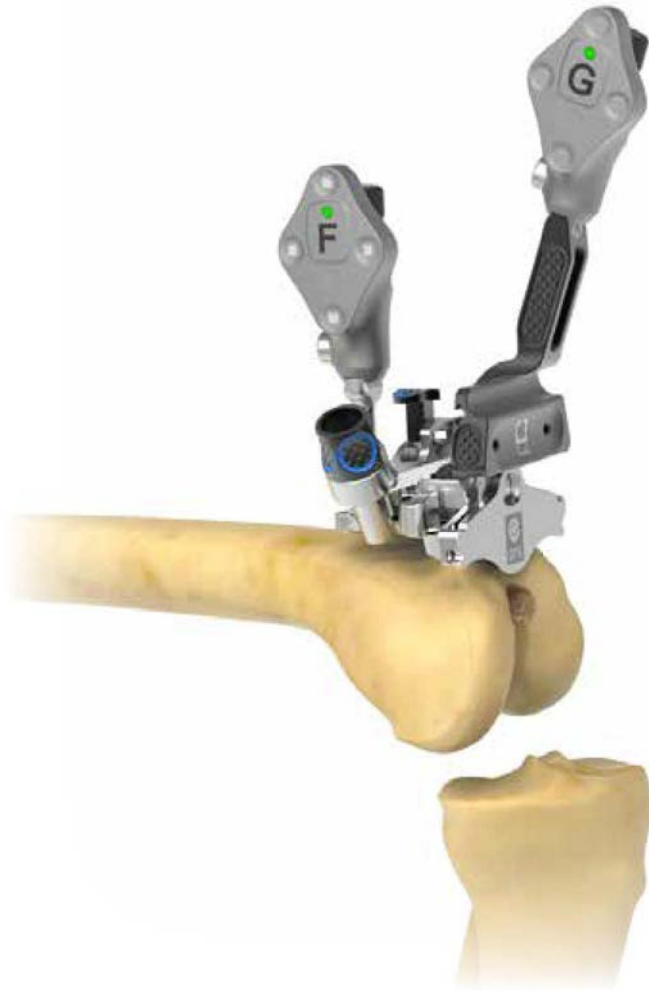


Figure 25
Distal Femoral Resection



Figure 26
Pin the Holes

Optional: If desired, after final adjustments have been made, you may pin the hole that is immediately proximal on the cutting slot of the TKA Plus Distal Resection Guide (Figure 26).

If this slot is pinned, it is recommended to place the Truliant Blade Guide back into the TKA Plus Distal Resection Guide cutting slot with the GPS GuideTracker (G) attached and verify that your selected parameters have not changed before you perform your resection.

Note: Once the femoral acquisitions have been acquired, the TKA Plus Distal Resection Guide may not be moved or removed relative to the location on the femur. If the guide is moved or removed, the anatomical acquisitions with the block fixed in place must be reacquired to maintain the accuracy of the cutting slot position and orientation.

The TKA Plus Distal Femoral Tracker Extension if used and/or the GPS Femoral Tracker (F) may be removed before femoral resection is performed, but it must be replaced before checking the cut. When replacing the Femoral Tracker (F), if the extension was used, always replace the Femoral Tracker (F) with the extension.

DETAILED OPERATIVE TECHNIQUE

SURGICAL TECHNIQUE



Figure 27
Perform Resection

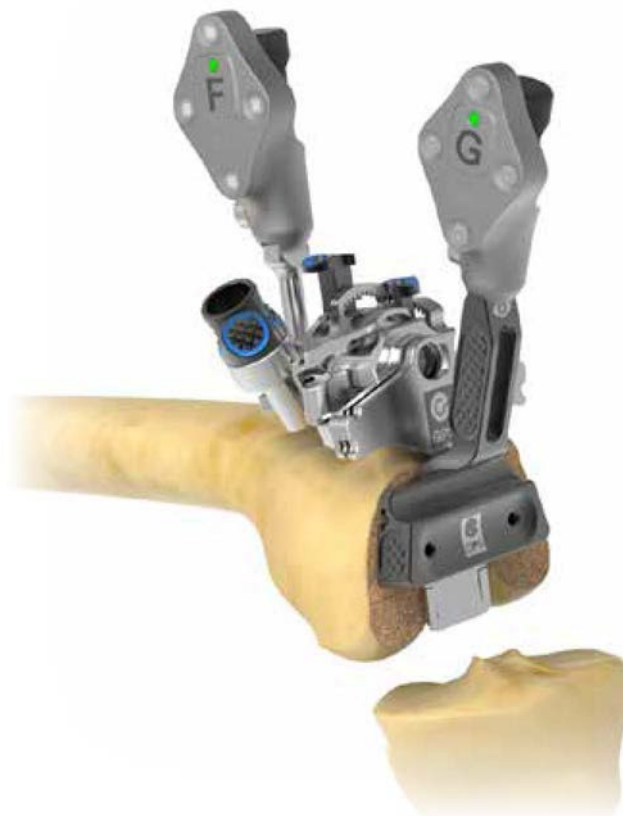


Figure 28
Validate Resection

DISTAL FEMORAL RESECTION

Perform distal resection (*Figure 27*). Invert the saw to increase access to cutting slot and avoid contact with buttons on the resection guides.

DISTAL FEMORAL RESECTION VERIFICATION

If previously removed, reattach the GPS Femoral Tracker (F) to the TKA Plus Distal Femoral Resection Guide.

Verify your resection by placing the Truliant Blade Drill Guide with the GPS Guide Tracker (G) attached on the cut surface (*Figure 28*).

The TKA Plus Distal Resection Guide should now be removed. Continue with your femoral cuts according to the protocol found in the Truliant Primary Operative Technique.

Continue with your femoral cuts according to the protocol found in the Truliant or Logic Primary Operative Technique.

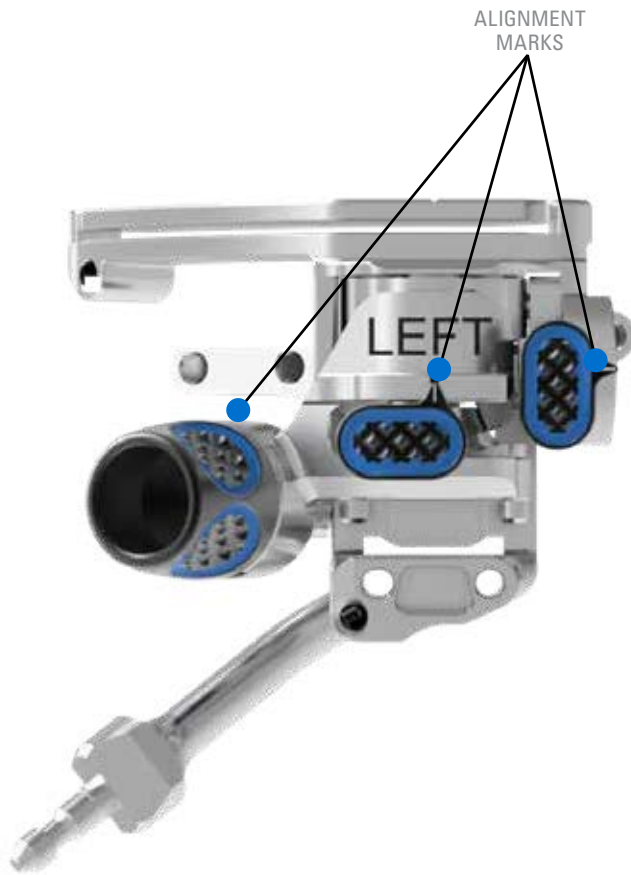


Figure 29

Align the Resection Guide



Figure 30

Attach Resection Guide

TIBIA PREPARATION

Before you assemble the tibia instruments- verify that the TKA Plus Tibial Resection Guide is at the neutral position by aligning the Varus/Valgus and Slope buttons with the markings on the block and by aligning the proximodistal adjustment knob neutral marking with the markings on the block (Figure 29).

Attach TKA Plus Tibial Resection Guide

Attach the TKA Plus Tibial Resection Guide (right or left) to the Truliant Extra-Medullary Guide (Figure 30).

DETAILED OPERATIVE TECHNIQUE

SURGICAL TECHNIQUE

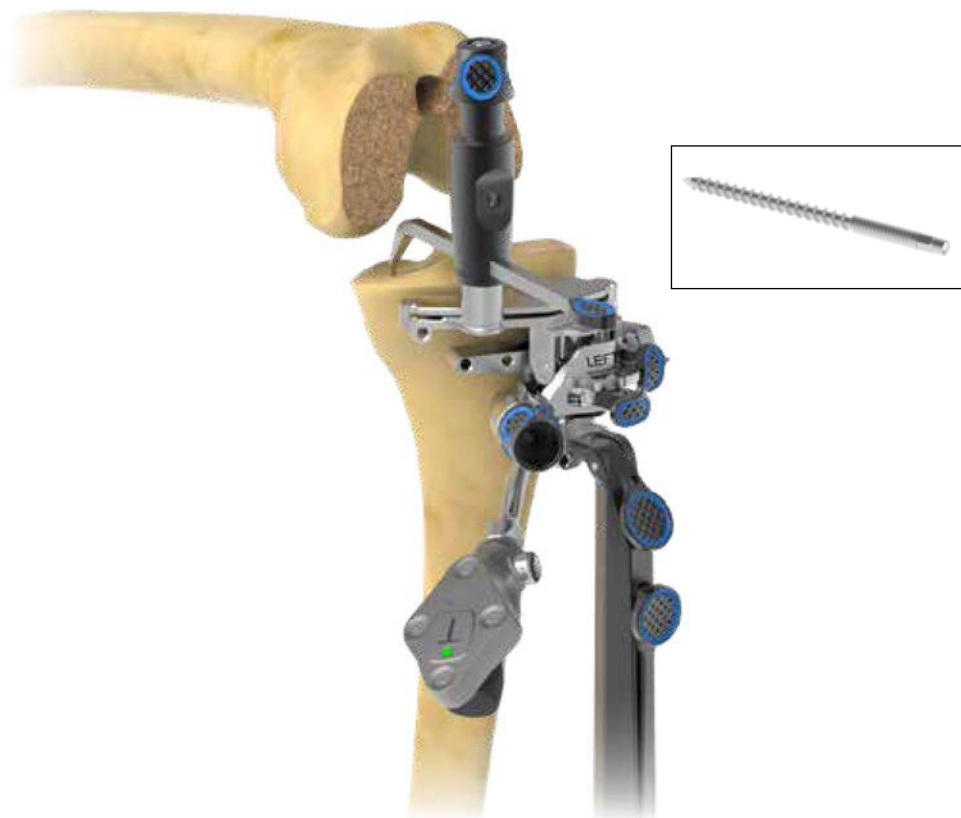


Figure 31

Place the Tibial Assembly onto Bone

Pin TKA Plus Tibial Resection Guide

Place the unit on the tibia and set your preferred slope and resection parameters using the Truliant EM Guide and the Truliant Adjustable Tibial Stylus.

To allow for later adjustments, the resection slot should not contact the bone. The tibial slope can be reduced at the level of the Truliant ankle clamp to provide additional clearance.

Pin the TKA Plus Tibial Resection Guide using threaded pins in at least one medial and one lateral pin hole. It is important not to pin in the distal hole slot at this time in order to allow for block adjustments.

Attach Trackers to Tibia

Attach the Tibial Tracker (T) to the TKA Plus Tibial Resection Guide and lock into place. (Figure 31). Make sure the tracker is facing toward the camera.

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

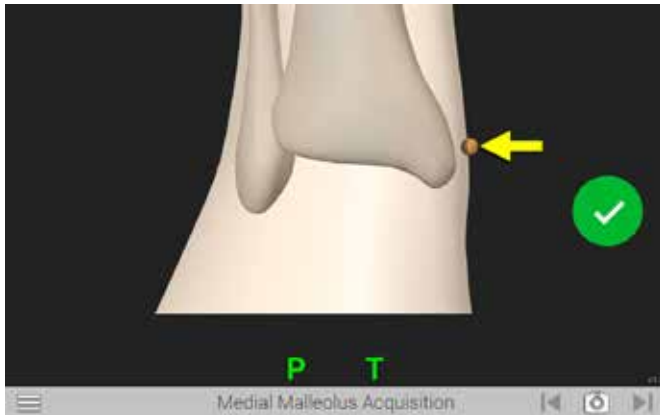


Figure 32
Medial Malleolus Acquisition

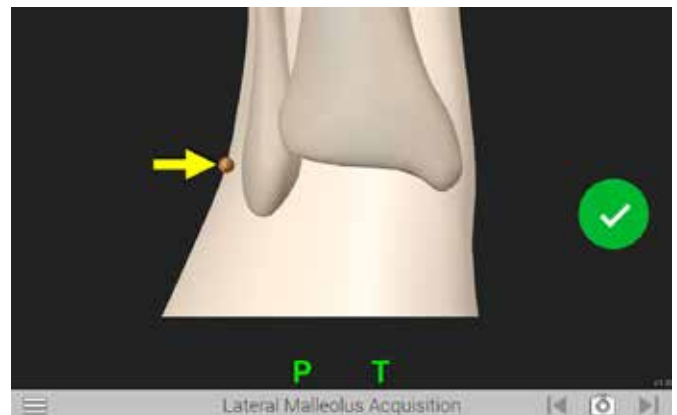


Figure 33
Lateral Malleolus Acquisition

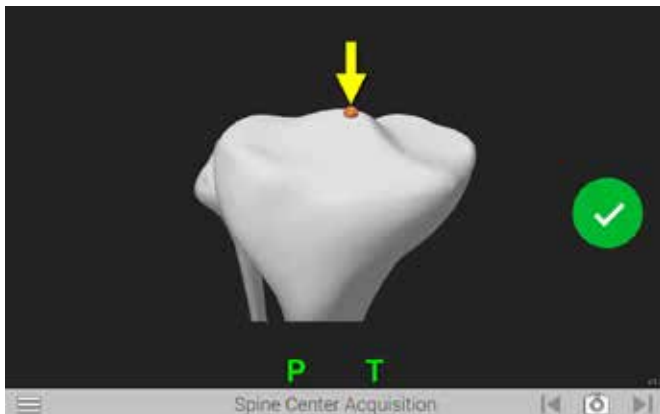


Figure 34
Spine Center Acquisition

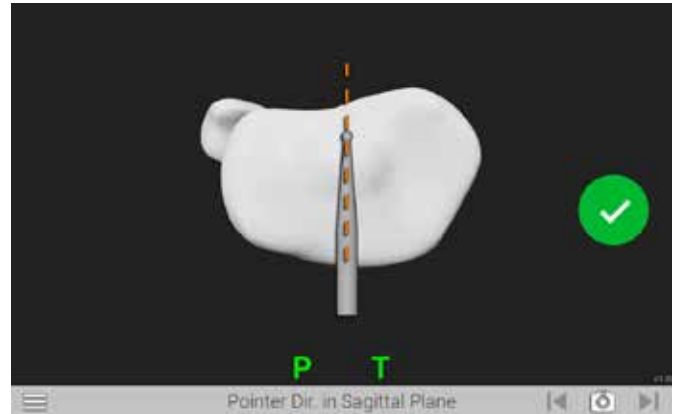


Figure 35
Pointer Direction in Sagittal Plane

TIBIA IMPLANT ACQUISITIONS

Malleolus Acquisition

Advance to the Medial Malleolus Acquisition screen (Figure 32). Position the tip of the Probe Tracker (P) on the Medial Malleolus and press the Forward button to register this point. The system automatically advances to the Lateral Malleolus Acquisition screen (Figure 33). 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.

Tibial Center Acquisition

The Tibial Center Acquisition screen is displayed (Figure 34). Position the tip of the Probe Tracker (P) on the center of the

proximal tibia and press the Forward button to register this point. The system will automatically advance to the next screen.

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

DETAILED OPERATIVE TECHNIQUE

SURGICAL TECHNIQUE

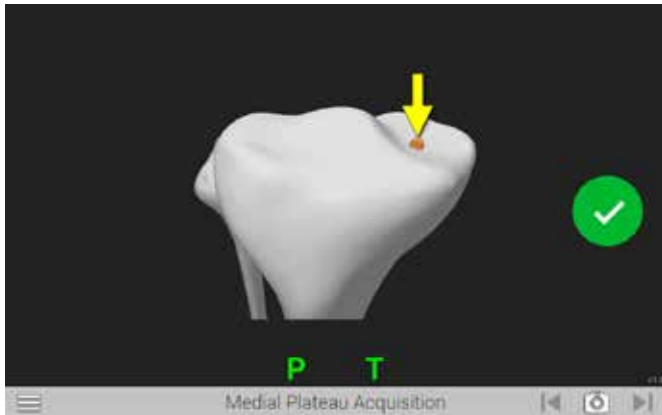


Figure 36
Medial Plateau Acquisition

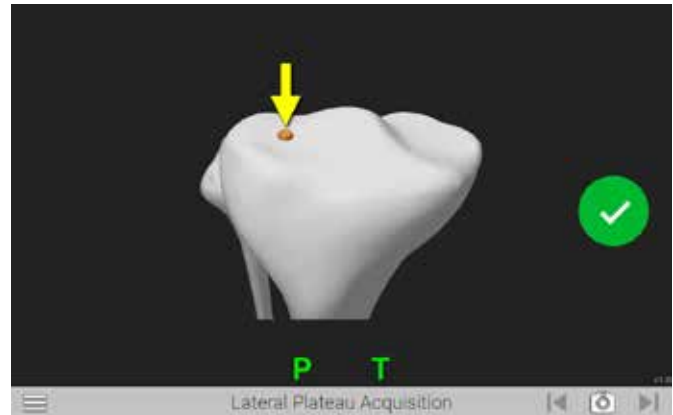


Figure 37
Lateral Plateau Acquisition

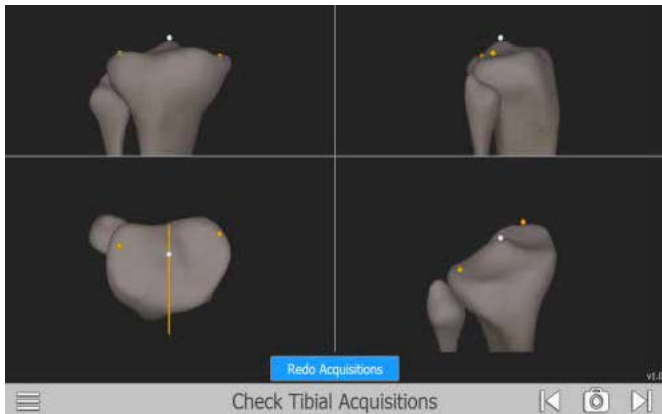


Figure 38
Check Tibial Acquisitions



Figure 39
Redo Tibial Acquisitions

Medial Plateau Acquisition

The Medial Plateau Acquisition screen is displayed (*Figure 36*). Position the tip of the Probe Tracker (P) on medial tibial plateau and press the Forward button. Ensure the tip of the tracker maintains contact with the tibial plateau and touch a point that captures 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 Lateral Plateau Acquisition screen (*Figure 37*). Repeat to acquire point for Lateral Plateau Acquisition.

Check Tibial Acquisitions

The Check Tibial Acquisition screen is displayed (*Figure 38*). If it is necessary to redo the registrations for any points, select the Redo Acquisitions button at the bottom of the Check Tibial Acquisitions Screen. Select the acquisitions to redo (*Figure 39*). Then select the redo button. 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.

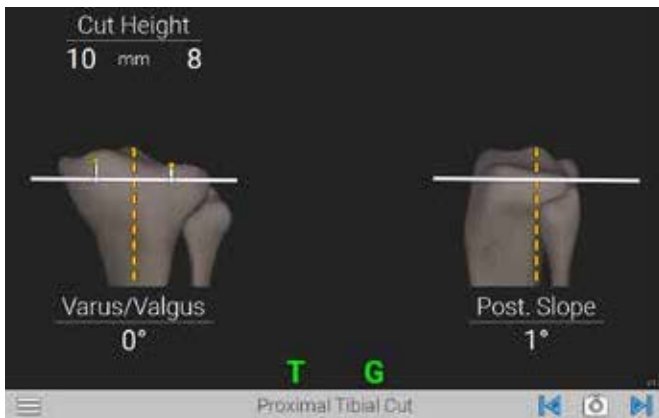


Figure 40
Proximal Tibial Cut



Figure 41
Attach Guide Tracker (G)

TIBIAL CUT GUIDANCE

The Proximal Tibial Cut screen (*Figure 40*) will be displayed.

Attach the Guide Tracker (G) to the Truliant Blade Drill Guide and lock into place (*Figure 41*). Make sure the tracker is facing toward the camera.

DETAILED OPERATIVE TECHNIQUE

SURGICAL TECHNIQUE



Figure 42

Place the Truliant Blade Drill Guide Into Slot

Place the Truliant Blade Drill Guide into the TKA Plus Tibial Resection Guide cutting slot (*Figure 42*) and using the guidance provided by the GPS system, adjust the parameters on the TKA Plus Tibial Resection Guide to the desired position by first using the buttons to adjust the slot orientation in terms of Varus/Valgus and Slope and then by using the knob to adjust the proximodistal position. The orange line displayed on the GPS screen represents the mechanical axis. Once desired position is achieved, remove the Truliant Blade Drill Guide.

Optional: If desired, after final adjustments have been made, you may pin the hole that is immediately distal on the cutting slot of the TKA Plus Tibial Resection Guide.

If the slot is pinned, it is recommended to place the Truliant Blade Guide back into the TKA Plus Tibial Resection Guide cutting slot with the GPS Guide Tracker (G) attached and verify that your selected parameters have not changed before you perform your resection.

Note: *Once the tibial acquisitions have been acquired, the TKA Plus Tibial Resection Guide may not be moved or removed relative to the location on the tibia. If the guide is moved or removed, the anatomical acquisitions with the block fixed in place must be reacquired in order to maintain the accuracy of the cutting slot position and orientation*

The Tibial Tracker (T) may be removed at this point, but it must be replaced before checking the cut.



Figure 43
Resect Tibia



Figure 44
Validate Resection

TIBIA RESECTION

Perform tibial resection (*Figure 43*). Invert the saw to increase access to cutting slot and avoid contact with buttons on the resection guides.

Optional: For additional stability, you may leave the EM guide attached to the resection guide during resection.

TIBIA RESECTION VERIFICATION

Verify your resection by placing the Truliant Blade Drill Guide with the GPS TKA Plus Guide Tracker (G) attached on the cut surface (*Figure 44*).

This concludes the use for GPS TKA Plus use during surgery.

The TKA Plus Tibial Resection Guide should now be removed. Continue with your tibial cuts according to the protocol found in the Truliant or Optetrak Logic Primary Operative Technique.

INSTRUMENT LISTING

CATALOG NUMBER PART DESCRIPTION

02-521-10-0002 TKA Plus Distal Femoral Resection Guide



02-521-10-0001 TKA Plus Distal Femoral Tracker Extension



A10003 (P) GPS Probe Tracker (P)



A10004 (F) GPS Femoral Tracker (F)



A10005 (T) GPS Tibial Tracker (T)



A10006 (G) GPS Guide Tracker (G)



I00020 GPS System



INSTRUMENT LISTING

CATALOG NUMBER PART DESCRIPTION

A10012 GPS Disposable Kit



02-521-90-1000 Truliant Blade Drill Guide*



02-521-20-1001 TKA Plus Tibial Resection Guide - Left



02-521-20-2001 TKA Plus Tibial Resection Guide - Right



521-78-2X Threaded pin Collared (multiple sizes)



521-78-3X Threaded pin Collarless (multiple sizes)



***Note:** This instrument is used to track the slot of the TKA Plus Tibial and Femoral Guides. There are additional features on this instrument that are not applicable to the TKA Plus Application.

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

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.

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