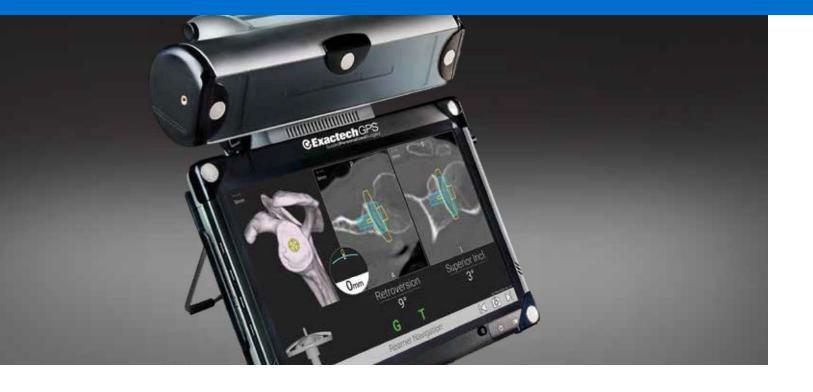
EXACTECHIEXTREMITIES

Operative Technique





ExactechGPS® Shoulder Application



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ExactechGPS[®] computer-assisted surgical technology provides surgeons with real-time visual guidance and alignment data in shoulder arthroplasty. Customized for surgeon preferences, ExactechGPS is a powerful addition to the surgical team's goals of achieving efficacy, efficiency and economics for shoulder arthroplasty.

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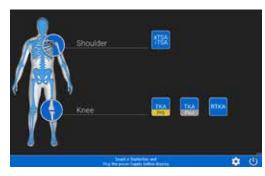
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SYSTEM OVERVIEW EXACTECHGPS® SHOULDER APPLICATION

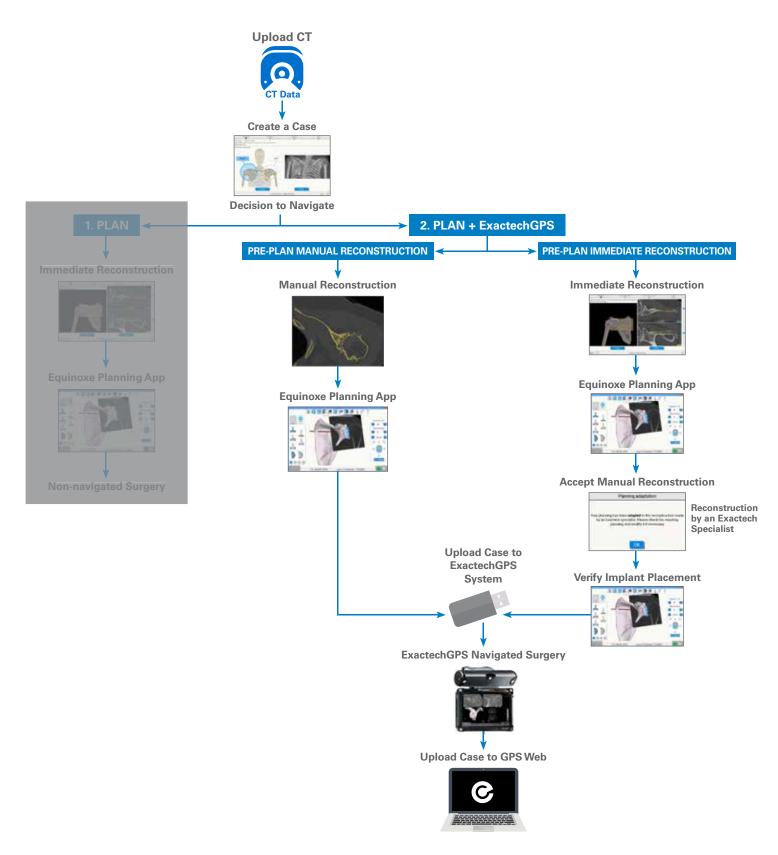


Screen Layout

lcon		Description
U	Switch OFF	Switch OFF the station.
ক্ট	Tools	Access maintenance options.
→ ﷺ	Change Language	Change the default language of the software.
aTSA rTSA	Total Shoulder	Access detailed options related to total shoulder application.
ê	Screenshot	Take a screen shot of the current screen. The
\odot		picture is recorded in the operative report.
\triangleright	Go Forward	Go to the next step.
[<]	Go Backward	Go to the previous step.
- 110	Menu	Access to options (exit, reconnect trackers)
→ ()	Exit	Exit the shoulder application.

EXACTECHGPS SHOULDER APPLICATION WORKFLOW OVERVIEW

Workflow: Preoperative Planning and ExactechGPS Surgery



SURGICAL TECHNIQUE

Patient Positioning

The patient should be placed on an operating table in a supine position. The head of the operating table should be elevated approximately 30° in a modified beach chair position. A small bolster should be placed laterally behind the involved shoulder. The patient should be moved to the side of the table so that the upper extremity can be placed into maximum extension without obstruction by the operating table. Alternatively, a Captain's chair or similar positioning device can be used for proper patient positioning. The patient should be secured to the operating table to minimize any changes in position intraoperatively.

Once the patient is secure, the extremity is examined to assess the range of motion, with particular attention to external rotation with the arm at the side. If external rotation is restricted (i.e. internal rotation contracture) the need for more extensive subscapularis mobilization or lengthening procedures may be necessary. The entire upper extremity should be prepped to allow complete access to the operative area and full mobility during the procedure.

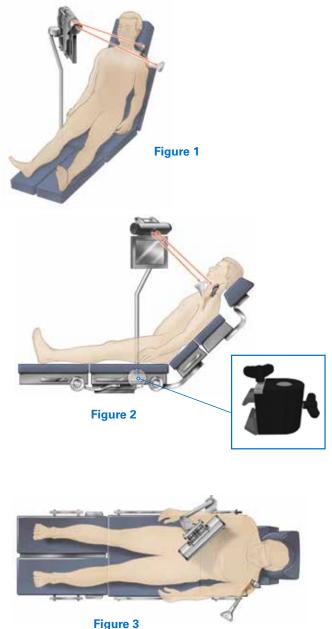
Station Positioning

With the patient in place, the ExactechGPS station may be set up. The station should be placed near the patient's opposite hip where visibility is optimal. Attach the GPS clamp to the bed rail under the patient's hips on the contralateral side, assuming there is one rail under the back, one rail under the hips, and one rail under the lower legs. Bring the clamp all the way up to the edge of the bed rail under the hips, toward the patient's head.

If patient positioning is too flat or supine, Tracker visibility with the station could be impeded. If the surgeon prefers not to adjust the patient position to a beach chair angle, the station should be adjusted on the table closer and superior to the hip. The arm holder/pad for the non-operative arm should be positioned toward the head (elbow pulled back) so the station can sit higher on the rail for better line of sight to the tracker.

Drape the patient once the station is in the optimal position (GPS station and arm are attached to bed rail). Connect all cables and the USB key before draping. Once the GPS station is draped, connectors are not accessible. Take the sterile drape by the two tabs and place it on the GPS Station from the top, with the transparent sheet on the screen side. Unroll the drape all along the mounting arm (if using the cart, unroll along the cart). Position the transparent sheet in front of the screen; exact positioning will then be done automatically. Remove the open windows protection and throw it away immediately.

Alternatively, the surgeon may choose to use the mobile cart, which provides flexibility for height adjustments and mobility between cases. The cart's offset arm allows the ExactechGPS station to remain in the sterile field. Draping application and removal can be performed quickly.



Note: When draping, it is helpful to adjust the head holder all the way back, and turn the patient's head to the contralateral side if possible. This helps to keep the drapes and intubation away from obstructing the view of the trackers. It can also be helpful to tape down the drapes around the patient's head.

Ensure the camera and station have line-of-sight to the incision to guarantee visibility throughout the technique (*Figures 1-3*).

Note: In a cold room or climate, start the station 30-45 min. in advance to ensure proper Tracker/camera visibility. When plugging in the station, first screw the power cable into the back of the station, then plug the other end of the power cable into the wall, and finally turn on the unit.

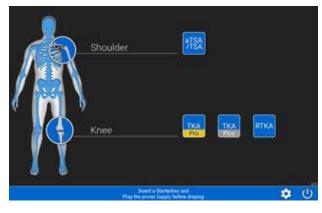
START EXACTECHGPS SHOULDER APPLICATION

START EXACTECHGPS SHOULDER APPLICATION

Insert the USB with the case when prompted to initiate the ExactechGPS Shoulder Application (*Figure 4*). Press the Shoulder Application icon. The Shoulder Application screen will appear (*Figure 5*). Select the arrow at the lower right corner of the display to advance to the Patient screen.

On the ExactechGPS unit, import the case from the USB drive used in the preoperative planning tool by selecting Import Cases and selecting the proper case. Select the drop down menu to choose this case, making sure to verify proper shoulder side and correct orientation of the upper mounting arm (*Figure 6*) and patient ID number. Choose Anatomical Procedure or Reverse Procedure based on the type of procedure, and select the option for either pilot tip or cannulated instrumentation. The surgeon may also select/ unselect the rotation and impaction steps (*Figure 7*).

Patient identification information can be entered into the fields displayed (*Figure 8*).









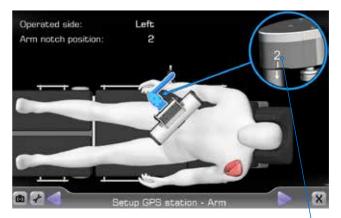
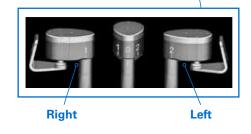


Figure 6



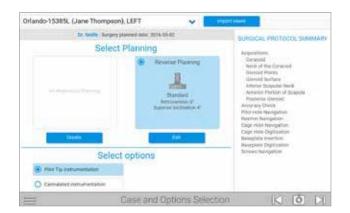
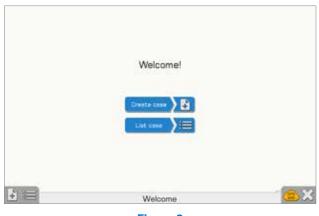


Figure 7





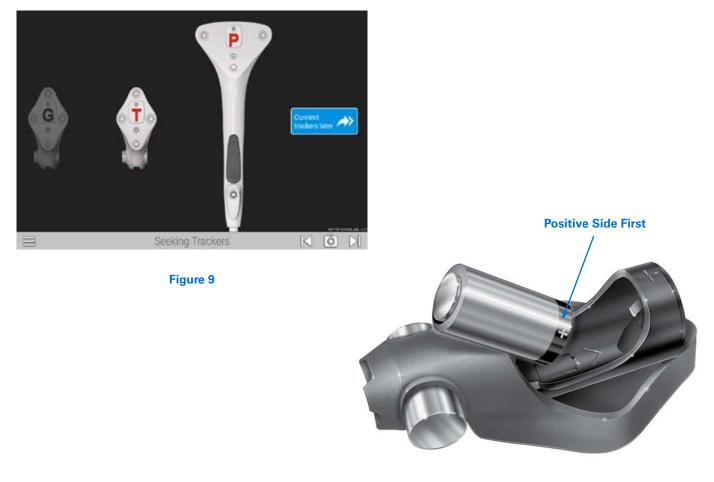


Figure 10

BATTERY INSERTION

The Seeking Tracker screen is displayed. Insert batteries, the positive side first, into the three Trackers **Probe Tracker (P)**, **Glenoid Tracker (G)**, and **Tool Tracker (T)** (*Figure 9*).

Caution: Inserting negative side first or in reverse polarity may cause permanent damage to the Tracker *(Figure 10)*.

Note: Use only the dedicated sterile batteries provided in the GPS kit. Do not reuse or sterilize the batteries. Additional sterile batteries are provided in the GPS kit if needed.

Discard all used and unused batteries after completing the procedure. When the battery is properly inserted, an LED on each Tracker will illuminate solid red/orange then begin to blink green. Position the Trackers such that the LEDs face the ExactechGPS Unit. An audible tone will indicate when each Tracker connects to the ExactechGPS system. At the same time, the respective Tracker is highlighted on the Unit, and the LED illuminates solid orange. After the camera and three Trackers connect, the system will automatically advance to the next screen.

Note: In a cold room or climate, start the station 30-45 min. in advance to ensure proper Tracker/camera visibility.

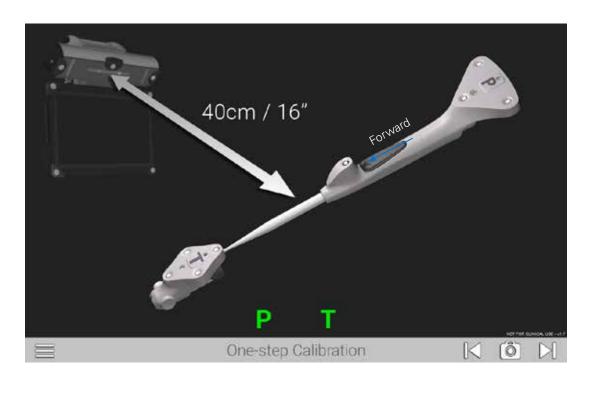


Figure 11

Follow the onscreen prompts for calibrating the probe and Tracker. This step confirms that the probe's readings are accurate.

The One-Step Calibration screen is displayed (*Figure 11*). Place the tip of the Probe Tracker (P) into the dimple node at the top of the T Tracker. Hold both together no more than 16 inches from the display unit ensuring the white diodes are facing the camera. When positioned correctly, the T 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.

Note: Attach the T Tracker to the Modular Driver at this point. At any point in the procedure where a Tracker is attached to an instrument, test the physical connection every time by firmly tugging on the Tracker once it is attached. The Tracker will remain in place if it is properly attached.

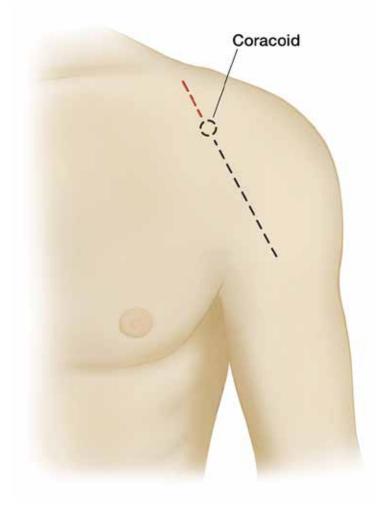


Figure 12

An anterior deltopectoral incision is made beginning inferior to the clavicle and passing over the coracoid process and extending distally toward the deltoid insertion (*Figure 12*). Medial and lateral subcutaneous flaps are created, and the deltopectoral interval is identified. The position of the Tracker on the coracoid requires exposure of the coracoid bone. The incision should start 10mm proximal to the tip of the coracoid to guarantee exposure and minimize tissue tension throughout the case. The extended incision is required to minimize soft tissue force on the Tracker fixation throughout the case.

SURGICAL STEPS

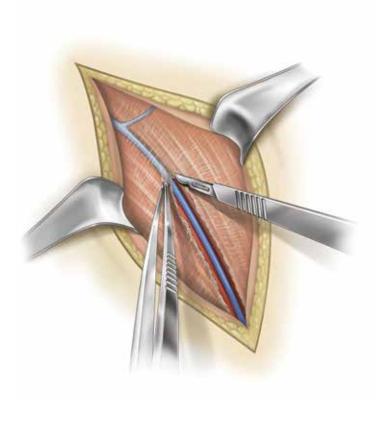


Figure 13

A thin fat stripe is usually located over the cephalic vein; the interval can be developed laterally depending on the surgeon's preference *(Figure 13)*. Branches of the cephalic vein on the approach side are cauterized, and the interval is developed inferior to superior to expose the clavipectoral fascia. The advantage of retracting the cephalic vein with the deltoid is the majority of the branches come from the deltoid. The disadvantage is the vein is more exposed to injury from the retractor as it crosses the superior aspect of the interval.

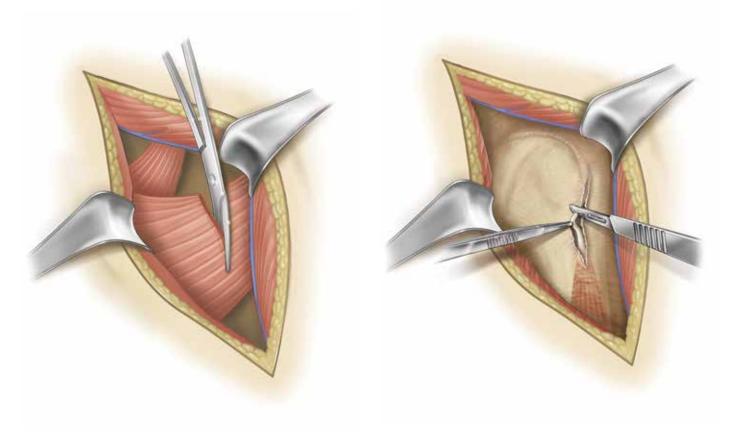


Figure 14

Figure 15

Resect the upper 1/3 of pectoralis tendon (Figure 14).

Tenodese the biceps tendon (Figure 15).

SURGICAL STEPS

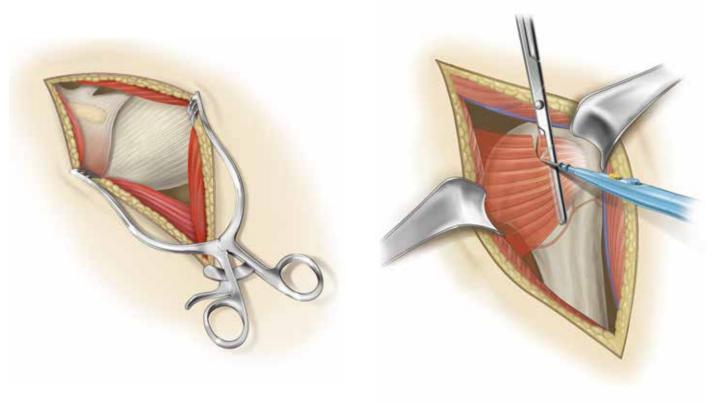


Figure 16

Figure 17

The subdeltoid space is mobilized with a blunt elevator. The clavipectoral fascia is incised longitudinally up to the coracoacromial ligament (which is spared), and the conjoined tendon is mobilized. A self-retaining retractor is placed with care to avoid excessive traction on the conjoined tendon (*Figure 16*). The coracoacromial ligament is identified and the subacromial space is mobilized with a blunt elevator. The subscapularis tendon insertion on the lesser tuberosity is identified along with the rotator interval. The anterior humeral circumflex vessels along the inferior border of the subscapularis muscle, the "three sisters", are cauterized extensively, and the biceps tendon is palpated in its groove *(Figure 17)*. The subscapularis tendon and the capsule are tenotomized 1cm medial to the lesser tuberosity and tagged with #1 sutures.

An alternative approach is to elevate the subscapularis directly off the bone or elevate its insertion with a thin wafer of bone (1-2mm thick) using an osteotome. The choice is based on surgeon preference.

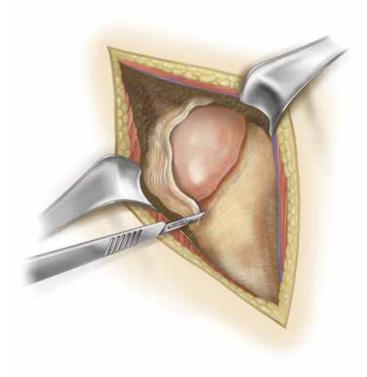


Figure 18

Figure 19

The rotator interval is divided in a lateral to medial direction up to the superior glenoid rim (*Figure 18*). With the humerus extended, adducted and externally rotated, the capsule is carefully dissected off the inferior humeral neck, protecting the axillary nerve inferiorly with a small blunt retractor placed just inferior to the capsule. The capsular releases should be performed to allow 90° of external rotation. The self-retaining retractor is then repositioned to retract the subscapularis. At this point, the humeral head can be dislocated. Make the appropriate humeral head resection (Figure 19).

SURGICAL STEPS

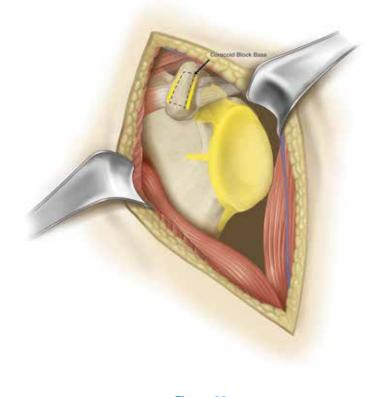
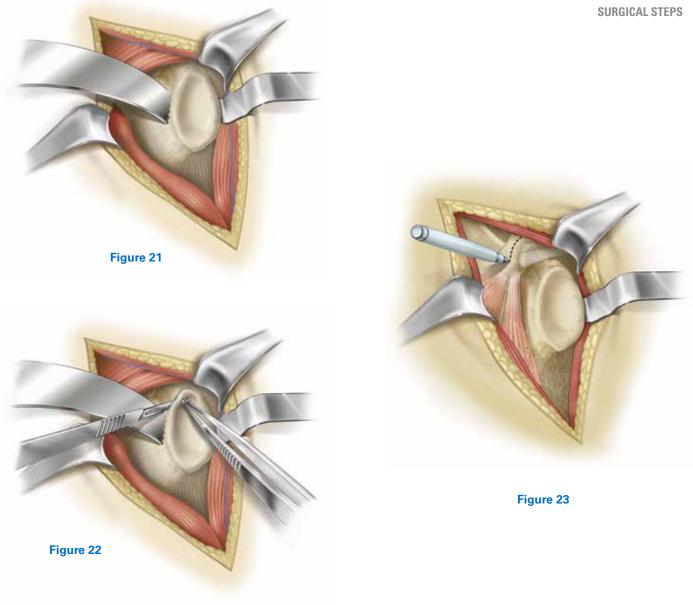


Figure 20

All areas in yellow must be exposed for acquisitions. All soft tissues and cartilage must be removed *(Figure 20)*. Removal of the coracoacromial ligament is not required for acquisitions.

Note: Do not remove osteophytes or other bony landmarks before taking acquisitions, as these are necessary for proper use of the GPS system.



Place a retractor along the posterior border of the glenoid face (*Figure 21*) and retract the humeral head to expose the anterior glenoid edge. Dissect the anterior labrum (*Figure 22*).

Remove anterior labrum and capsule and clear soft tissue from glenoid face (*Figure 23*).

Carefully remove the hyaline cartilage from the glenoid surface using a Cobb elevator, ring curette, or comparable removal tool.

Note: It is critical to perform all the prep work on the humeral side (e.g. head resection) and extra glenoid exposure needed for the acquisition points before pinning the **Coracoid Block**. This is to minimize joint movement and risk of block fixation movement once the Coracoid Block has been pinned.

Continue exposing the glenoid by placing a blunt elevator under the subscapularis and releasing soft tissues attached to the anterior glenoid face. This will allow for better registration of the anterior glenoid border.

Some key steps to adequate glenoid exposure are as follows:

- 1. Fully mobilize subdeltoid space.
- 2. Release inferior capsule completely off the humerus while externally rotating the humerus.
- 3. Release anterior capsule and subscapularis from glenoid.
- 4. Excise labrum and release anterior and inferior capsule (protect axillary nerve).

SURGICAL STEPS

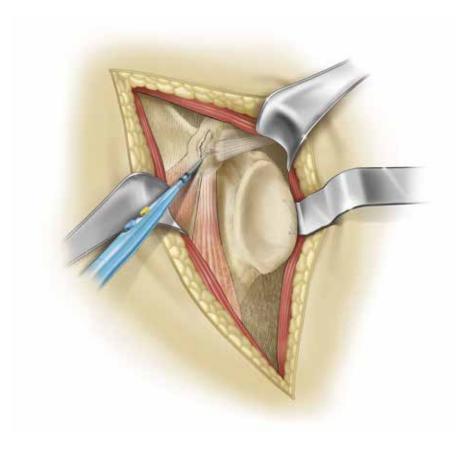


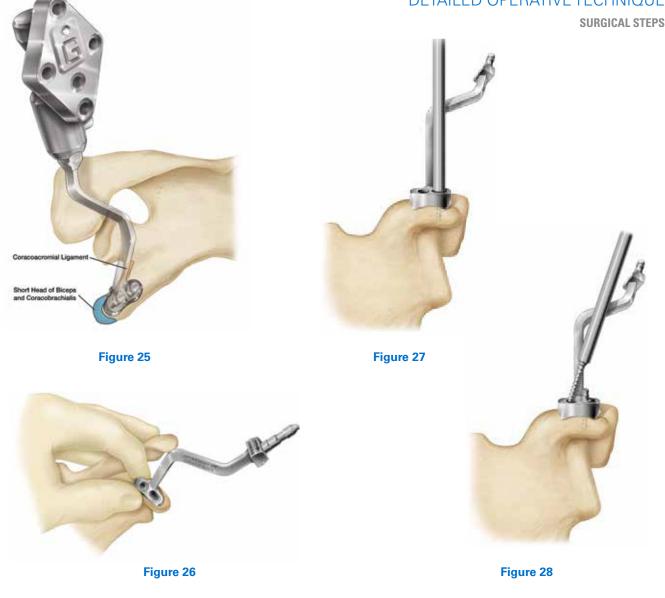
Figure 24

- 5. Resect adequate amount of humerus.
- 6. Stretch posterior capsule with humeral head retractor pushing humerus posterior to the glenoid.
- 7. If exposure is not adequate after steps 1-7, release posterior inferior capsule and triceps origin (must isolate and retract axillary nerve for this procedure).
- 8. If still poor exposure (very rare), then a posterior capsule release should be performed.

Clear fascia on superior coracoid using an electrocautery or blade (*Figure 24*). Using a marking pen or cautery, identify the axis of the coracoid.

It is important to note the short head of the biceps inserts near the tip of the coracoid and the pectoralis minor can wrap over the bone from the anterior side. Portions of these tissues may need to be removed to gain access to the bone.

Identify any soft tissue on the inferior portion of the coracoid and around the coracoid base. Remove this soft tissue.



Once the coracoid is exposed, the Tracker block should be affixed to the bone ensuring the Tracker post is oriented toward the camera (Figure 25). Note the camera can maintain visibility up to 160°, but more direct focus leads to better signal strength.

Note: For the first cases, extend the incision above the coracoid until it is determined how much exposure is needed for block placement.

Note: Before pinning the Coracoid Block, attach the G Tracker and hold the block up to where it will be pinned to the coracoid. This ensures Tracker visibility to the station before pinning, as it will not be able to be moved afterwards.

Coracoid anatomy can vary so make sure that the threaded coracoid pins have solid bone purchase with the first try. This can be achieved by palpating or aiming with a small K-wire through the posterior angled pin hole.

Step 1: Position the block on top of the coracoid so it is in line with the axis of the coracoid and the trajectory of the screws will have good bone purchase, taking special care to ensure the posterior 30 degree angled pin will shoot down the base of the coracoid (Figure 26).

Step 2: Insert the short pin into the lateral slot in the block until hand tight. Aim for the middle of the slot so the block can self-adjust when the long pin is inserted (Figure 27).

Step 3: Insert the long pin into the medial hole of the block down the neck of the coracoid until hand tight. Carefully retighten pins, if necessary (Figure 28).

DETAILED OPERATIVE TECHNIQUE **SURGICAL STEPS** Figure 30 Figure 29 Figure 31

The block is now fixated and ready for Tracker attachment (*Figures 29-31*).

Note: If the bone quality is dense, it can help to pierce the top cortex on the coracoid through the block holes with a small 1.6mm K-wire (no larger) before inserting the threaded pins.

Note: Screws should be tightened by hand (to confirm the G Tracker fixation).

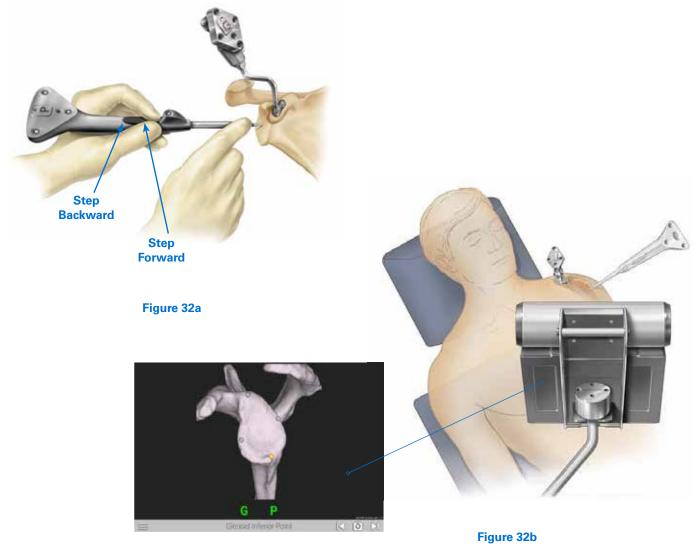
Note: It is imperative to keep the coracoid block free of soft tissue tension throughout the case, and to keep a retractor behind it at all times. If there are assistants holding retractors, it is important to not let the tissue encroach on the base of

the block. It is a good idea to gently feel the fixation of the block throughout each navigated step, to ensure it is still robust.

Use a gelpi, or similar self-retaining retractor, vertically to keep the coracoid block free of soft tissue tension. The retractor can be clamped to the patient's head drapes to enable hands-free retraction.

Note: If robust fixation is not achieved the first time pinning the Coracoid Block to the bone, it is not advised to attempt repinning the block, creating additional holes in the bone.

SURGICAL STEPS



PROBE TRACKER TECHNIQUE

Trackers may be paired before or after selecting the patient information. Before begining registration, ensure that the G Tracker is completely seated on the coracoid block. Hold the Probe Tracker (P) with the index finger on the forward buttom making sure not to obstruct the IR LED between the button and the probe tip *(Figure 32a)*.

Always make sure the probe tip is on the anatomic landmark press and release the Forward button (*Figure 32b*).

For patch registration, place the probe tip on the anatomic landmark, **press and release** the forward button, then paint the anatomic reference shown on the screen using an S-like pattern. The button does not need to be held down for acquisitions. To return to previous step or re-do an acquisition, rapidly double click the back button on the probe. The probe must be visible in order for the buttons to be selected.

SURGICAL STEPS

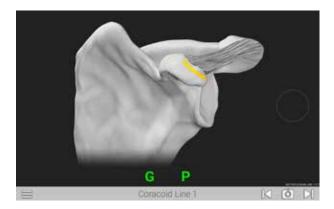


Figure 33a: Line anterior of coracoid block

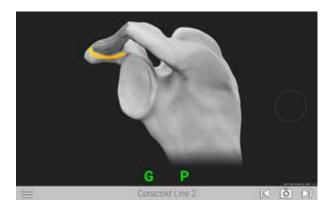


Figure 33b: Line posterior of coracoid block

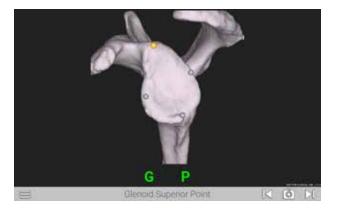


Figure 33c: Four points on glenoid face: superior, inferior, anterior, posterior

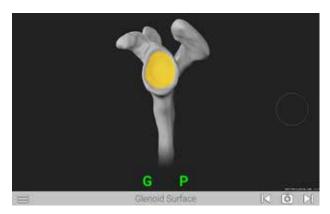


Figure 33d: Paint glenoid surface

ACQUISITIONS

Using a two handed approach, probe the acquisition points listed on each screen as guided by the system (*Figures 33a-d*). When the probe tip is in contact with the bony area to be acquired, press the Forward button on the probe handle. The system will begin to acquire points as soon as the button is pressed. The button does not need to be held down to continue acquiring points, it only needs to be pressed once per step. Move the probe tip across the bony surface until the system has acquired enough points and moves to the next step. Take care to keep the probe in contact with bone the entirety of the acquisition process. If the probe tip is lifted off or if incorrect points are acquired, the surgeon can re-do the acquisitions by clicking the backwards button on the probe handle twice in succession.

On all points on the side walls of the glenoid face (inferior scapular neck, anterior lines), probe as medial on the bone as possible to aid in registration.

SURGICAL STEPS

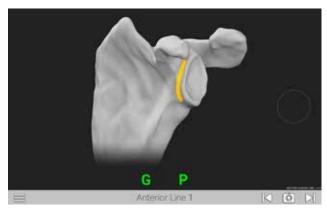


Figure 33f: Superior/Inferior line on scapular wall anterior of glenoid face

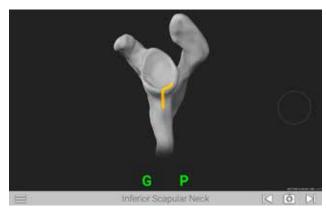


Figure 33e: Inferior glenoid neck

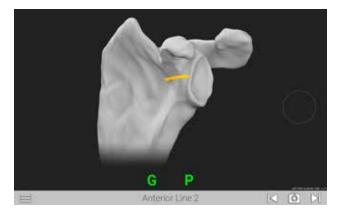


Figure 33g: Medial/Lateral line on scapular wall anterior of glenoid face

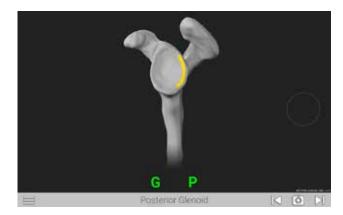


Figure 33h: Line on posterior face of glenoid

Note: Take care to sufficiently expose each acquisition area of all soft tissue and cartilage before probing points, so only bone is exposed and probed. Do not trim any osteophytes before taking acquisitions, even if they are a part of a specific acquisition area. The CT scan and 3D scapula model see only bone, so the surgeon must probe only bone for an accurate registration.

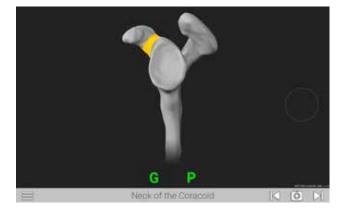


Figure 33i: Base of coracoid

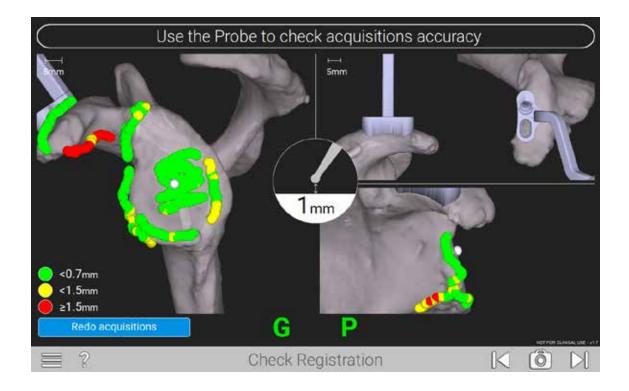


Figure 34

The system will digitize the acquisitions and generate a color map of the points for verification (*Figure 34*).

Green points signify that acquired points match digital reconstruction within .7mm or less.

Yellow points signify that acquired points vary from .7 to 1.5mm from digital reconstruction. Red points signify that acquired points vary more than 1.5mm from the digital reconstruction.

Surgeons should strive for all green points in the digitization. It is important to identify which acquisition areas may be inaccurate based on the color and locations of the points. For example, if there is a trail of yellow and red dots at the end of an acquisition area that extends off the surface of the bone, assume that the probe tip was lifted off of the bone surface before all points were acquired, and points were acquired in empty space.

Once all acquisitions obtained are green, the surgeon needs to verify accuracy as described below.

On this screen, the scapula can be spun around by touching the screen and rotating the finger, or using the mouse and clicking and rotating. Use the probe tip to touch different surfaces on the scapula to see the probe tip show up on the screen; this will verify the probe is registering where the user is physically touching the bone.





If any acquisition regions look inaccurate or include any red points, they should be repeated by selecting Redo Acquisitions at the bottom of the screen, and select only the acquisition regions the surgeon would like to re-do (*Figure 35*).

Note: Use the Select All button to re-do all acquisitions.

PRIMARY SHOULDER

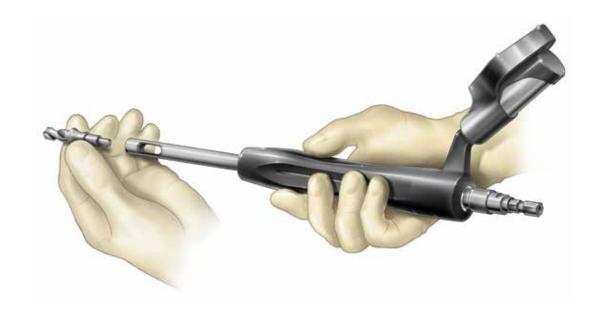


Figure 36

PRIMARY SHOULDER

Once registration is completed, attach the ExactechGPS center drill to prep the central peg for the glenoid hole *(Figure 36).*

Figure 37c

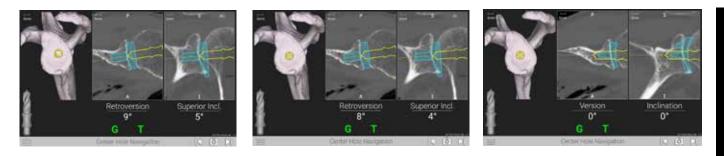


Figure 37a

Figure 37b



Figure 38

For positioning of the drill, the tip of the drill is indicated by a yellow dot (*Figures 37a and 37b*).

The planned position is indicated by a blue dot (Figure 37a).

Note: Avoid applying a bending force to the modular driver or using the modular driver to retract the humeral head as this may cause fracture of the 2mm K-wire or pilot tip reamer.

The orientation is guided by the circular cross-hair indicator. When the target is perfectly aligned, the screen will display the the cross-hair superimposed on the yellow dot *(Figure 37b).*



Figure 39

Note: The numbers shown for version and inclination are displayed according to the preoperative plan.

The plan may not necessarily read 0° version and 0° inclination. The surgeon may deviate from this plan if desired. This screen includes an image of the orientation that is synchronized with the CT scan slices to visualize the cortices. Follow the on-screen guidance to drill the center hole.

DRILL DIGITIZATION

Hold the Modular Handle still over the drilled axis to capture the position of the future implant. The system will adjust the original plan to where the drill was actually placed. The system will advance to the next step once accurately recording the drill axis position (*Figure 39*).

SURGICAL STEPS

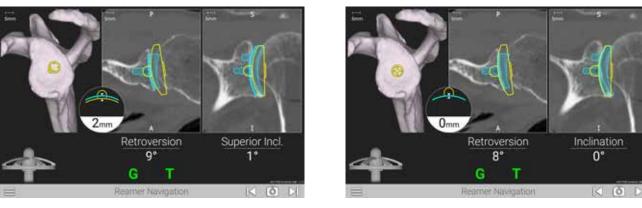


Figure 40a

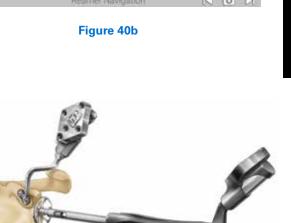


Figure 41a

Figure 41b

Select a Primary Nubbed Reamer per Equinoxe® surgical technique 718-01-30 and attach to the Reamer Handle (Figure 41).

Follow the on-screen guidance to ream the proper orientation according to the plan (Figure 40). The reaming screen is guided in a similar fashion with realtime feedback on the position of the reamer head relative to the planned depth. Press Next arrow to proceed.

Note: When preparing for augmented glenoid components, be aware that the drilling axis is different from the reaming axis. The system accounts for this; the surgeon does not need to adjust for this mismatch.

SURGICAL STEPS

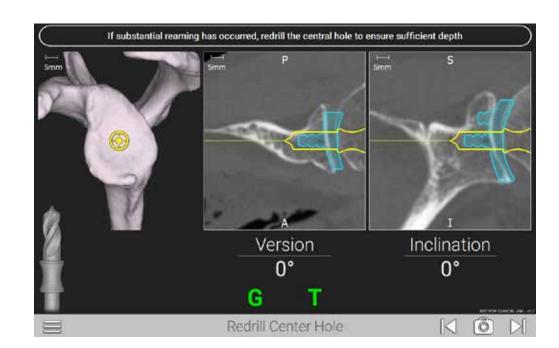
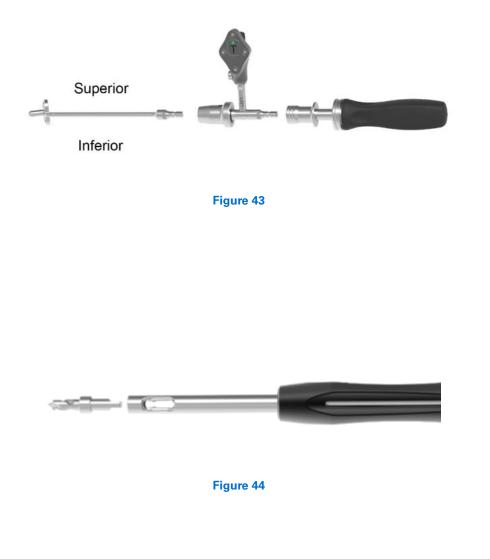


Figure 42

VERIFY DRILL DEPTH

If the surgeon reams more than 2mm of glenoid bone, re-attach the center drill to the Modular Driver and re-drill the center hole to ensure proper depth for implant seating *(Figure 42)*.



PRIMARY SHOULDER

PERIPHERAL PEG DRILL

Remove the T Tracker from the Modular Driver and attach it to the Zimmer-Hudson adapter. Ensure the Tracker is facing the direction of the indicated shoulder with the laser marking on the post under the Tracker (i.e. left for left, right for right). Attach the male end of the Zimmer-Hudson adapter to the Zimmer-Hudson handle, and the female end of the Zimmer-Hudson adapter to the appropriate Peripheral Peg Drill Guide for the planned anatomic glenoid implant, with the drill guide size marking reading right side up in the direction of the Tracker. Ensure that the drill guide bottoms out and fully engages with the Zimmer-Hudson adapter, and that the collar of the Zimmer-Hudson adapter fully deploys over the male end of the Zimmer-Hudson drill guide (*Figure 43*).

Next, attach the Peripheral Peg Drill (315-27-63 in the Equinoxe kit) to the Modular Driver *(Figure 44)*.

SURGICAL STEPS

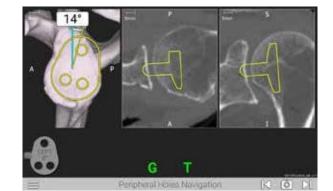


Figure 45a

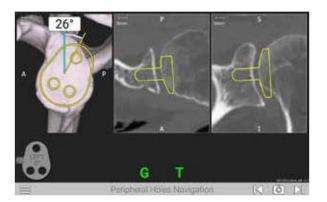


Figure 45b



With one hand, hold the Drill Guide with the TTracker. With the other hand, use the GPS handle to insert the Peripheral Peg Drill into the Peripheral Peg Drill Guide *(Figures 45a and 46a)*.

Use the angle measurement on the screen to adjust the Peripheral Peg Drill Guide to the plan (*Figures 45b and 46b*).

When finished drilling peripheral peg holes, remove the tools and advance the screen.

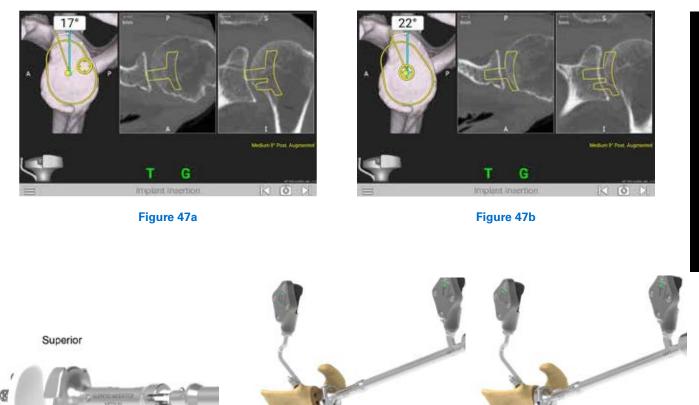


Figure 48b

IMPLANT INSERTION

Inferior

Figure 48a

Attach the appropriate anatomic Glenoid Inserter Impactor Tip to the ExactechGPS Impactor Handle. Attach the TTracker to the Handle (again ensuring left for left, right for right).

Note: Make sure the superior portion of the implant is always being handled in the same direction as the Tracker (Figure 48a).

Use the onscreen prompts to place and impact the implant properly according to the plan (*Figures 47 and 48*).

Figure 48c

Note: Only Equinoxe Ergo Impactor Tips are compatible (315-54-02/03/04/05 and 315-55-02/03/04/05).

REVERSE SHOULDER

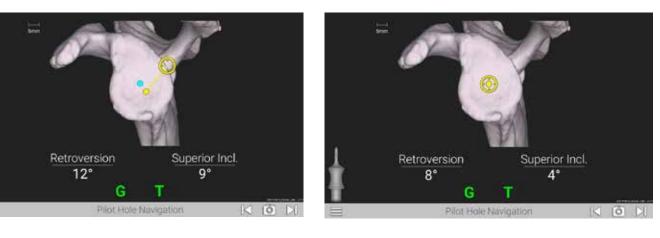


Figure 49a

Figure 49b



Figure 50

REVERSE SHOULDER

Once registration is completed, attach the **2.0mm Drill** to create the pilot hole for reaming *(Figure 50)*.

Follow on-screen guidance to position the Drill and create pilot hole.

For positioning of the Drill, the tip of the Drill is indicated by a yellow dot (*Figures 49 and 50*). The planned position is indicated by a blue dot (*Figure 49a*).

Note: Avoid applying a bending force to the modular driver or using the modular driver to retract the humeral head as this may cause fracture of the 2mm *K*-wire or pilot tip reamer.

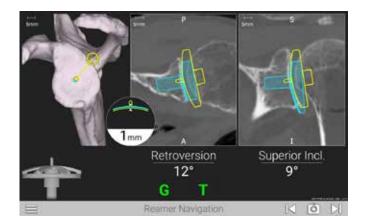
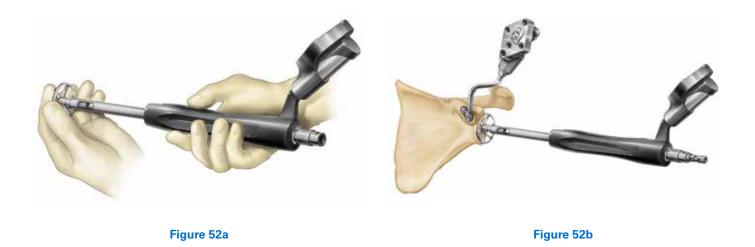


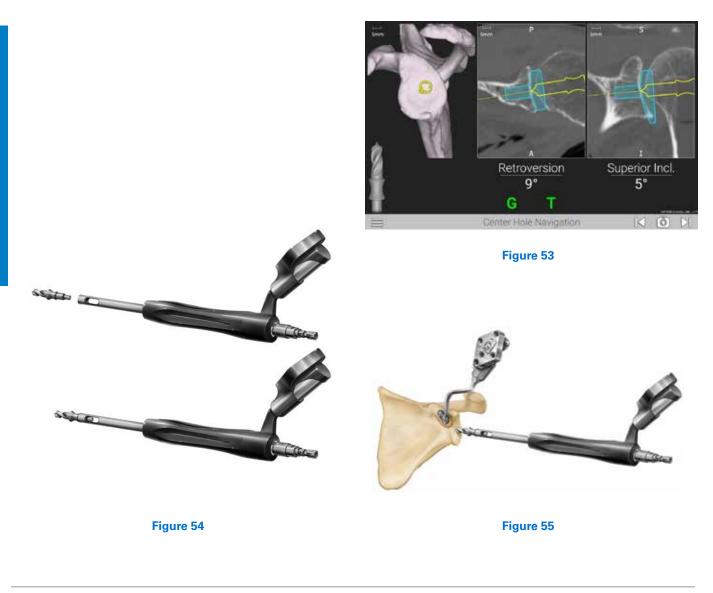
Figure 51



Select a **Reverse Pilot Tip Reamer** per Equinoxe surgical technique 718-01-30 and attach to the Reamer Handle *(Figure 52a).*

Follow the on-screen guidance to ream the proper orientation according to the plan (*Figures 51 and 52*).

SURGICAL STEPS



Attach the Center Cage Drill Bit to the Driver (Figure 54).

Drill the center cage hole for the **Reverse Glenoid Plate** (*Figures 53 and 55*).



Figure 56

DRILL DIGITIZATION

Hold the Modular Handle still over the drilled axis to capture the position of the future implant. The system will adjust the original plan to where the drill was actually placed. The system will advance to the next step once accurately recording the drill axis position (*Figure 56*).

SURGICAL STEPS

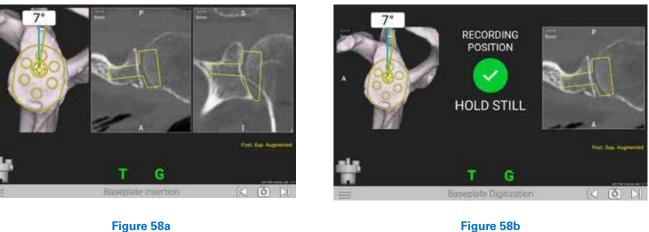
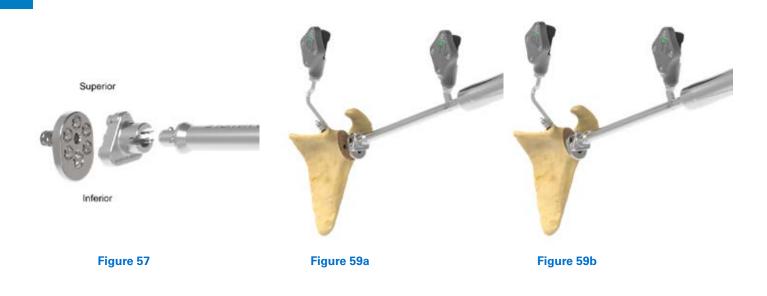


Figure 58b



IMPLANT INSERTION

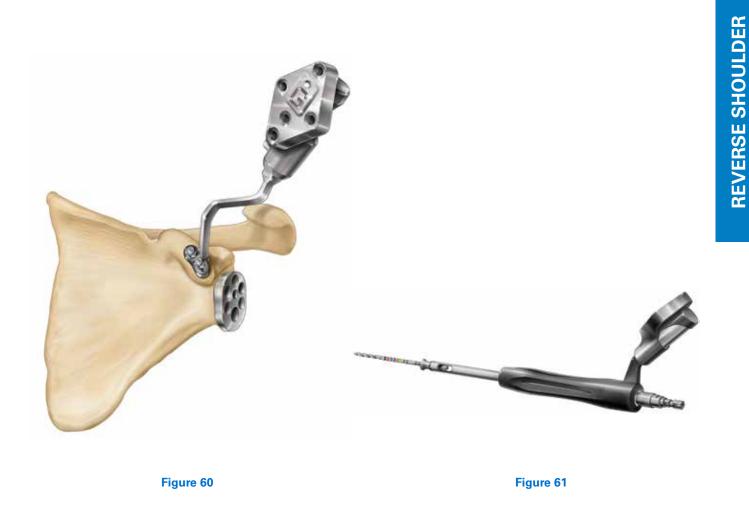
Attach the appropriate corresponding reverse baseplate Impactor Tip to the GPS Impactor Handle. Attach the T Tracker to the Handle (ensuring left for left, right for right).

Note: Ensure the superior portion of the implant is always oriented in the same direction as the Tracker (Figure 57).

Align the blue and yellow dots as done previously, while referencing the angular measurements, to impact the implant based on the plan (Figures 58a, 59a and b).

IMPLANT DIGITIZATION

After implanting, hold the Impactor Handle and Inserter still and flush against the implant face. Press the Next button on the screen to capture the position of the implant placement, which will adjust the original plan to where the surgeon placed the implant (Figure 58b).



Attach the **3.2mm GPS Drill** to the Driver *(Figure 60).* The 3.2 GPS Drill is sterile packed specifically for use with ExactechGPS. **Note:** Since the reamer handle uses a snap fit connection, the surgeon must drill in reverse upon removal of the drill bit from the bone.

SURGICAL STEPS

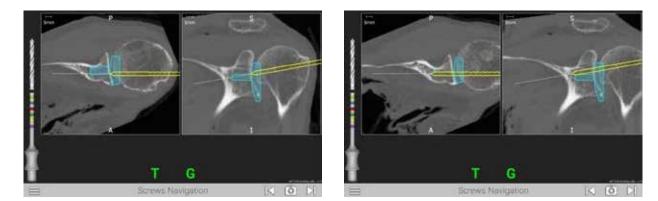
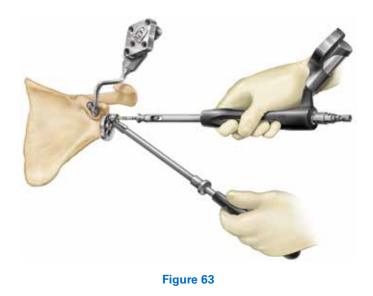


Figure 62a

Figure 62b



Place the **Drill Guide** into the preferred hole of the Glenoid Plate and insert the Drill through the Guide (*Figure 63*).

The navigation screen will display the trajectory of the 3.2mm Drill Bit (*Figures 62a-b*).

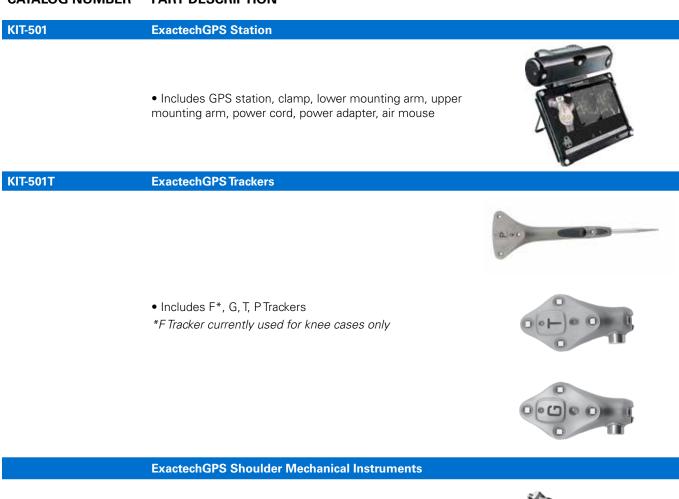
The screen will display the trajectory of the Drill to allow for aiming for bicortical fixation, for example.

Once the GPS technique is complete, remove the G Tracker and Coracoid Block before Glenosphere insertion.

Complete remaining surgical steps per Equinoxe surgical technique 718-01-30. At the end of the case, the Exactech representative will run GetStationLog on the GPS system to upload the case to the passkey. Make sure to upload all the cases to GPS Web.

INSTRUMENT LISTING

CATALOG NUMBER PART DESCRIPTION



531-01-03 531-01-04	Coracoid Block Left Coracoid Block Right	
531-25-00	Modular Driver	
531-27-60	Center Drill Bit	
531-27-63	Cannulated Center Drill Bit	
1RL3-C01	Zimmer-Hudson Ratchet Handle	E=;-(
521-78-11	Pin Driver, Short Low Profile	

CATALOG NUMBER PART DESCRIPTION

	ExactechGPS Shoulder Mechanical Instruments	
531-27-04	Peripheral Peg Drill Guide, Left	
531-27-05	Peripheral Peg Drill Guide, Right	
531-27-14	8 Degree Posterior Augment Peripheral Peg Drill Guide, Left	
531-27-15	8 Degree Posterior Augment Peripheral Peg Drill Guide, Right	
531-29-14	16 Degree Posterior Augment Peripheral Peg Drill Guide, Left	
531-29-15	16 Degree Posterior Augment Peripheral Peg Drill Guide, Left	<u></u>
531-07-05	Impactor Handle	
531-07-50	Zimmer Hudson Adapter	
315-54-02 or 315-55-02	ATSA Glenoid Impactor, Small	
315-54-03 or 315-55-03	ATSA Glenoid Impactor, Medium	=
315-54-04 or 315-55-04	ATSA Glenoid Impactor, Large	3
315-54-05 or 315-55-05	ATSA Glenoid Impactor, Extra Large	=
321-19-13	Standard Inserter (Reverse)	

CATALOG NUMBER PART DESCRIPTION

	ExactechGPS Coracoid Pins	
531-78-20	Disposable Hex Pins Kit	
OPT- 531DB	ExactechGPS Reverse Drill Bit Kit	
531-20-00	Disposable Reverse Drill Kit (2.0, 3.2mm drill bits)	
A10012	ExactechGPS Disposable Kit	
A10012	ExactechGPS Disposable Kit • Includes sterile drape, batteries and cleaning wipe	<u>G</u>

Planning software minimum requirements:

- TSA planning software is qualified for MacOS, Windows 7, Windows 8.1 and Windows 10 environments.
- It is recommended to have 8GB or more of RAM, and a screen resolution of at least 1280x800 pixels.
- It is mandatory to have the Administrator rights during software installation.
- If network security measures are implemented (Web filtering, firewall, proxy...), it may be necessary to ask the surgeon's IT department to ensure communication is possible.
- Graphical hardware must support at least OpenGL v2.1. Graphics cards and chipsets made after 2010, with up-to-date drivers, should satisfy this condition.

INDICATIONS FOR USE

The ExactechGPS is intended for use during preoperative planning and during stereotaxic surgery to aid the surgeon in locating anatomical structures and aligning the endoprosthesis with the anatomical structures provided that the required anatomical landmarks can be identified on the patient's preoperative CT scan.

The ExactechGPS Total Shoulder Application is specifically indicated for Total Shoulder Arthroplasty using the Equinoxe system to aid the surgeon in locating anatomical structures and aligning the glenoid component with the anatomical structures.

CONTRAINDICATIONS

The ExactechGPS Total Shoulder Application is designed to function only with the Equinoxe Shoulder System implants. All indications and contraindications for those implants should be followed when using the ExactechGPS Total Shoulder Application.

The use of the ExactechGPS Total Shoulder Application is also contraindicated in patients who have inadequate coracoid bone for tracker fixation.

The surgeon has to determine whether the patient's conditions are appropriate for this kind of procedure or not. A pathological condition against the use of this system could be in some cases:

- Advanced osteoporosis,
- Crack or break of coracoid process.

The system requires a computed tomography (CT) scan of the patient's scapula for planning and registration purposes, and is contraindicated if the imported scan does not contain the required bony anatomy.

The ExactechGPS Total Shoulder Application as well as the Equinoxe Shoulder System are available for prescription use only.

NOTES	

ExactechGPS® is manufactured by Blue Ortho and distributed by Exactech, Inc.

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 manufacturer's 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 distributor of this device, does not practice medicine, and is not responsible for recommending the appropriate surgical technique for use on a particular patient. These 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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