CORE Shoulder

Surgical Technique Manual

for use in

Anatomic or Reverse Total Shoulder Arthroplasty (TSA)

This IFU is available online; either scan the QR Code or go to:
https://coreifu.com/shld

Only available in English.

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1. INTRODUCTION

The durability of implants in Anatomic or Reverse TSA (total shoulder arthroplasty) depends, among other factors, on the stability of the glenoid component. Exact implant placement is one of the most important elements for achieving stability.

CORE Shoulder is designed to reproduce the preoperative plan with precise execution intraoperatively. It aids in targeting the K-wire used to drive the glenoid implant by providing live feedback, by referencing anatomical landmarks of the shoulder that are identifiable on preoperative CT imaging scans. The system includes a Workstation and a smart handheld instrument, the COREmote, connected wirelessly to each other.

2. INDICATIONS

The CORE Shoulder medical device system is a handheld surgical instrument with computer navigational assistance and is intended to assist the surgeon with placement of the K-wire (central guide pin) used in the preparation of the glenoid and the positioning of the glenoid component during primary Anatomic or Reverse total shoulder arthroplasty.

The CORE Shoulder system is designed for use with the following LINK Implant systems:

LINK Embrace Shoulder System – Reverse Configuration
LINK Embrace Shoulder System – Anatomic Configuration

The indications for use of the LINK Implant systems with which the CORE Shoulder system may be used are the same as those described in the labeling for these shoulder implant systems, except where the contraindications listed below apply.

3. CONTRAINDICATIONS

The CORE Shoulder System is not intended to be used with instruments or implants made by manufacturers other than LinkBio Corp. or Waldemar Link GmbH & Co KG. The CORE Shoulder system is not designed for use in the following situations:

- Revision Shoulder Arthroplasty
- Cases where the following are identified: Axillary nerve damage, a non-functioning deltoid muscle, glenoid vault deficiency precluding baseplate fixation, infection, and neuropathic joints.
- If anatomical landmarks cannot be identified or registered.
- Skeletal immaturity

4. USE ENVIRONMENT AND TRAINING

Rx Only: Caution: Federal law restricts this device to sale by or on the order of a physician.

The CORE Shoulder system is intended for use by orthopaedic surgeon(s) in an Operating Room environment of a healthcare facility.

Users must first undergo training by LinkBio before using the CORE Shoulder system. The use of these surgical instruments presupposes standard training for orthopaedic and surgical specialists and suitable experience with orthopaedic and surgical procedures.

5. WARNINGS

The system is designed and manufactured to meet the highest quality standards. We do not accept liability for products that have been modified, subjected to unintended use, or used improperly. Single-use products must not be reused.

- Ensure components are clean and sterile for use. Refer to IFUs below.
- The Workstation GUI may be controlled nearly completely from the wireless COREmote by the surgeon in the sterile field. However, it is recommended to have a non-scrubbed surgical team member available to operate the tablet in the circulating area.
- When the Sensor Unit reaches its maximum procedure count, it must be returned to LinkBio for evaluation. Contact a LinkBio Representative to exchange the Sensor Unit for a new one.
- The Power Unit contains a single primary battery, which must be removed and disposed of per local regulations after surgery.
  - When handling the opened Power Unit and exposed battery, do not touch the patient.
  - If battery breaks/leaks electrolyte, wear personal protective equipment (gloves/goggles/mask) and clean the spill with cloth and water. Do not use alcohol. Seal battery in a sturdy container and dispose per local regulations. If electrolyte spilled onto Power Unit, clean it with cloth and water.
  - Do not allow the lithium battery to be placed into biohazard waste. Biohazard waste could be incinerated, which could cause intense fire and/or explosion of the lithium battery.
- If the Power Unit is dropped on the floor, it must be discarded.
- If the Sensor Unit is dropped on the floor, do not continue the use of the system with this Sensor Unit. The Sensor Unit must be returned to LinkBio for evaluation.
- Take care to avoid damage to nervous and vascular structures when using standard probes to register landmarks or when drilling k-wires.
- Do not impact or hammer CORE Shoulder system components.
- Do not implant any CORE Shoulder system components.
- When in use during the surgery, the Workstation should be continuously connected to the power outlet via the Power Adapter for optimal performance.
- Ensure all parts are completely dry before placing them into the carrying case. Do not place wet parts into the carrying case.
- Do not lean on the Stand and Workstation.
- No modification of this equipment is allowed.
- Repair/service is only allowed by LinkBio-authorized personnel. LinkBio may make technical information available, if needed.

6. INSTRUCTIONS FOR USE (IFU), HANDLING, AND REPROCESSING

DOCUMENT ID	DOCUMENT TITLE	INSTRUCTIONS REGARDING	WEBSITE URL FOR IFU	WEBSITE QR CODE
87-9130-IFU-01	Reprocessing IFU	Storage, maintenance, and reprocessing (cleaning and sterilization) of the reusable components in the system.	https://coreifu.com/shld	
87-9130-IFU-02	Power Unit Insert	Storage and use of the single-use Power Unit.		

7. SYSTEM OVERVIEW

The CORE Shoulder system is composed of:

- A Workstation (tablet computer) which runs the CORE Shoulder software and wirelessly connects to the handheld COREmote.
- COREmote: a handheld instrument that is assembled in the OR by connecting two parts: the reusable Sensor Unit and single-use Power Unit. When assembled, the COREmote turns on and operates continuously until disassembled.
- Standard Probes: metal attachments that attach to the COREmote and are chosen depending on the size and operative side of the patient.
- Drill Guide Probe: an optional attachment that may be switched to near the end of the surgical workflow; for Trajectory Targeting

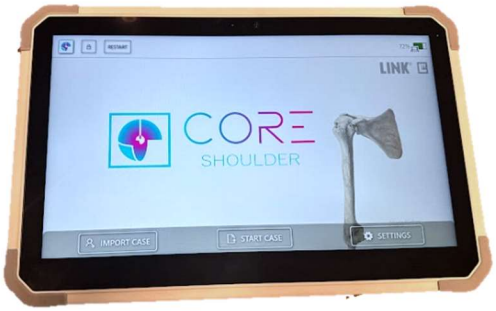
<table>
<tr>
<td>Expected Service Life
○ Sensor Unit is reusable for 20 reprocessing cycles.
○ Power Unit is single-use only.</td>
<td>Reset PIN: The Workstation requires a PIN login code and will lock after repeated failed attempts. To resolve a PIN issue, contact a LinkBio Representative.</td>
</tr>
<tr>
<td>Operating Conditions:
○ Temperature: 0°C (32°F) to 35°C (95°F).
○ Humidity: 10% RH to 90% RH (non-condensing)
○ Pressure: 80 kPa to 106 kPa</td>
<td>Markings and Symbols:
○ On-screen symbols are explained in Section “User Interface Symbols”
○ Other symbols are explained in Section “Regulatory Symbols”</td>
</tr>
<tr>
<td rowspan="2">Transport and Storage Conditions:
○ Treat components as fragile.
○ Should store parts in cool, dry, clean area. Keep out of direct sunlight.
○ Only transport reusable components within the Carrying Case.
○ Environmental Conditions for Transport & Storage:
▪ Temperature: -18°C (-0.4°C) to 60°C (140°F)
▪ Humidity: 10% RH to 90% RH (non-condensing)
▪ Pressure: 60 kPa to 106 kPa</td>
<td>Identifying Information:
○ Components are labeled with identifying information.
○ Workstation displays which software version is loaded.</td>
</tr>
<tr>
<td>Cybersecurity Updates: Ensure that cybersecurity updates are received from a LinkBio-authorized provider.

Ingress Protection: The COREmote and its components (Sensor Unit and Power Unit) have an IP rating of IPX0.</td>
</tr>
<tr>
<td>FCC ID Numbers of wireless communication components are:
○ X8WBT40F
○ 2AUX7-MD150</td>
<td>Protection against electric shock: Standard Probes and Drill Guide Probe are “Type BF” Applied Parts per Standard IEC 60601-1.
  </td>
</tr>
<tr>
<td colspan="2">This device complies with Part 15 of the FCC rules. Operation is subject to the following two conditions:
(1) this device may not cause harmful interference and
(2) this device must accept any interference received, including interference that may cause undesired operation.
This equipment has been tested and found to comply with the EMC limits of the Standard IEC 60601-1-2. These limits are designed to provide reasonable protection against harmful interference in a typical medical use environment. The equipment generates, uses, and can radiate radio frequency energy and, if not set up and used in accordance with these instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference with other devices, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:
• Relocate the receiving device.
• Increase the distance separation between the equipment.
• Consult a LinkBio Representative for assistance.</td>
</tr>
</table>

CARRYING CASE WITH REUSABLE PARTS

CORE Carrying Case
REF 87-9140

REUSABLE PARTS – NON-STERILE AREA



CORE Workstation
REF 87-9136

AC Adapter for Workstation
REF 87-9137

Workstation Stand Base
REF 87-9138-T08

Workstation Stand Pole
REF 87-9138-T07

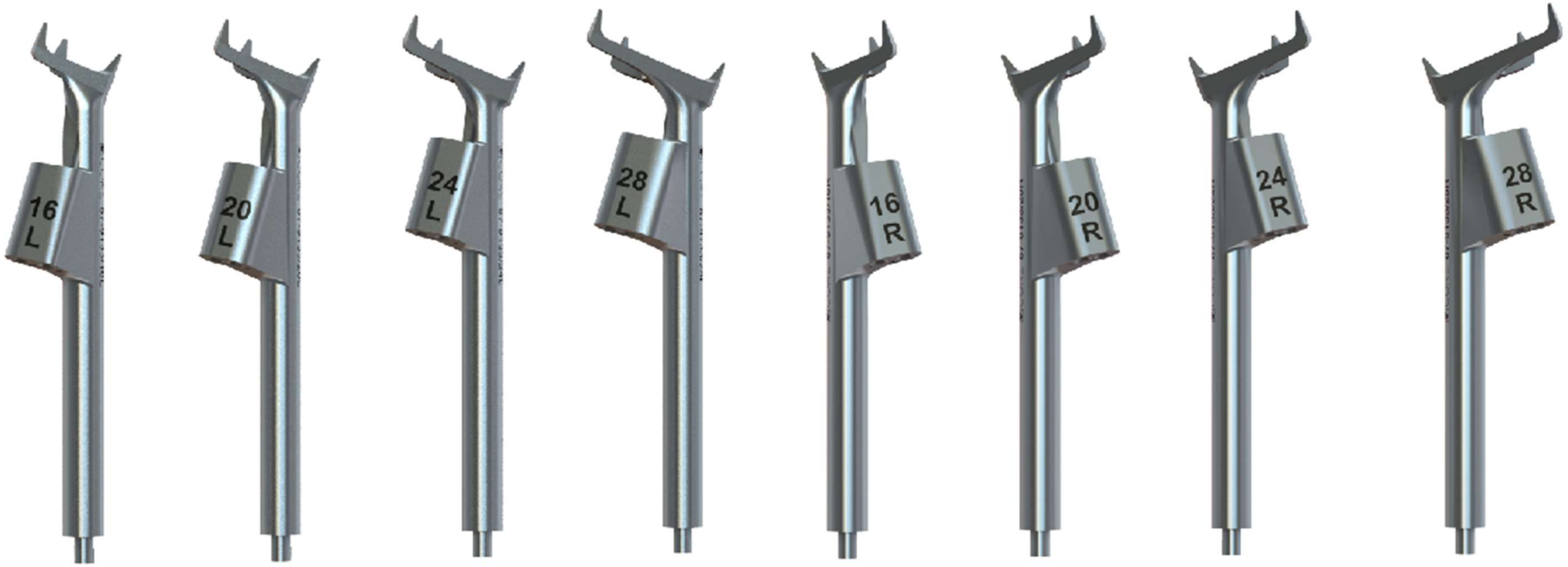
REUSABLE PARTS – STERILE AREA

COREmote Sensor Unit
REF 87-9131

Drill Guide Probe
REF 87-9134

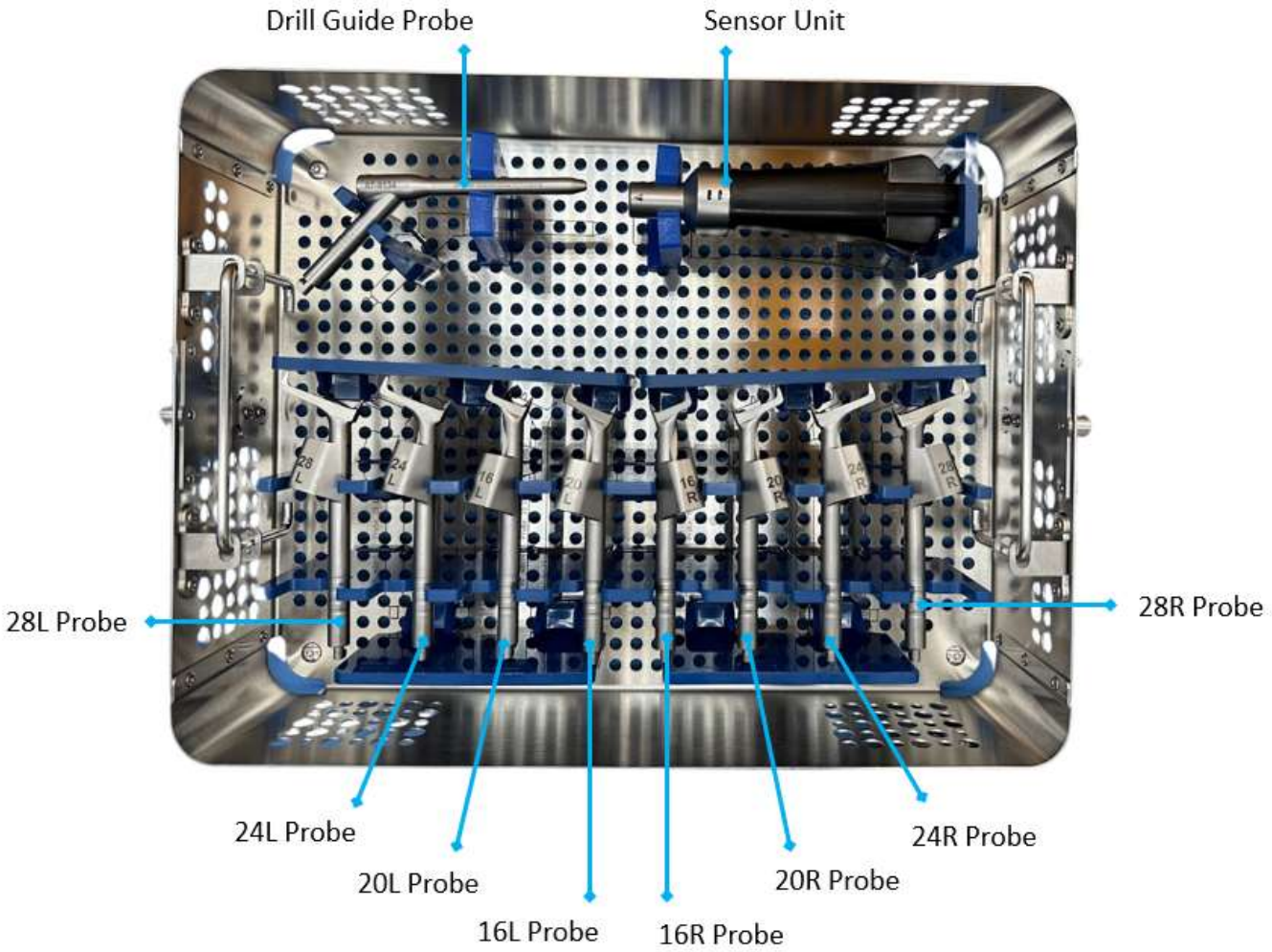
Standard Probes, Left

Standard Probes, Right



16mm Left Probe	20mm Left Probe	24mm Left Probe	28mm Left Probe	16mm Right Probe	20mm Right Probe	24mm Right Probe	28mm Right Probe
REF 87-9133/16L	REF 87-9133/20L	REF 87-9133/24L	REF 87-9133/28L	REF 87-9133/16R	REF 87-9133/20R	REF 87-9133/24R	REF 87-9133/28R

REUSABLE PARTS – STERILE AREA



Instrument Tray - Top-Down View – (Loaded)

REUSABLE PARTS – STERILE AREA

Instrument Tray – Side View - (Empty)
REF 87-9139

SINGLE USE PARTS, PRE-STERILE

COREmote Power Unit
REF 87-9132

Power Unit while inside of Sterile Packaging (Double Barrier Pouch Inside of a Carton)
REF 87-9149

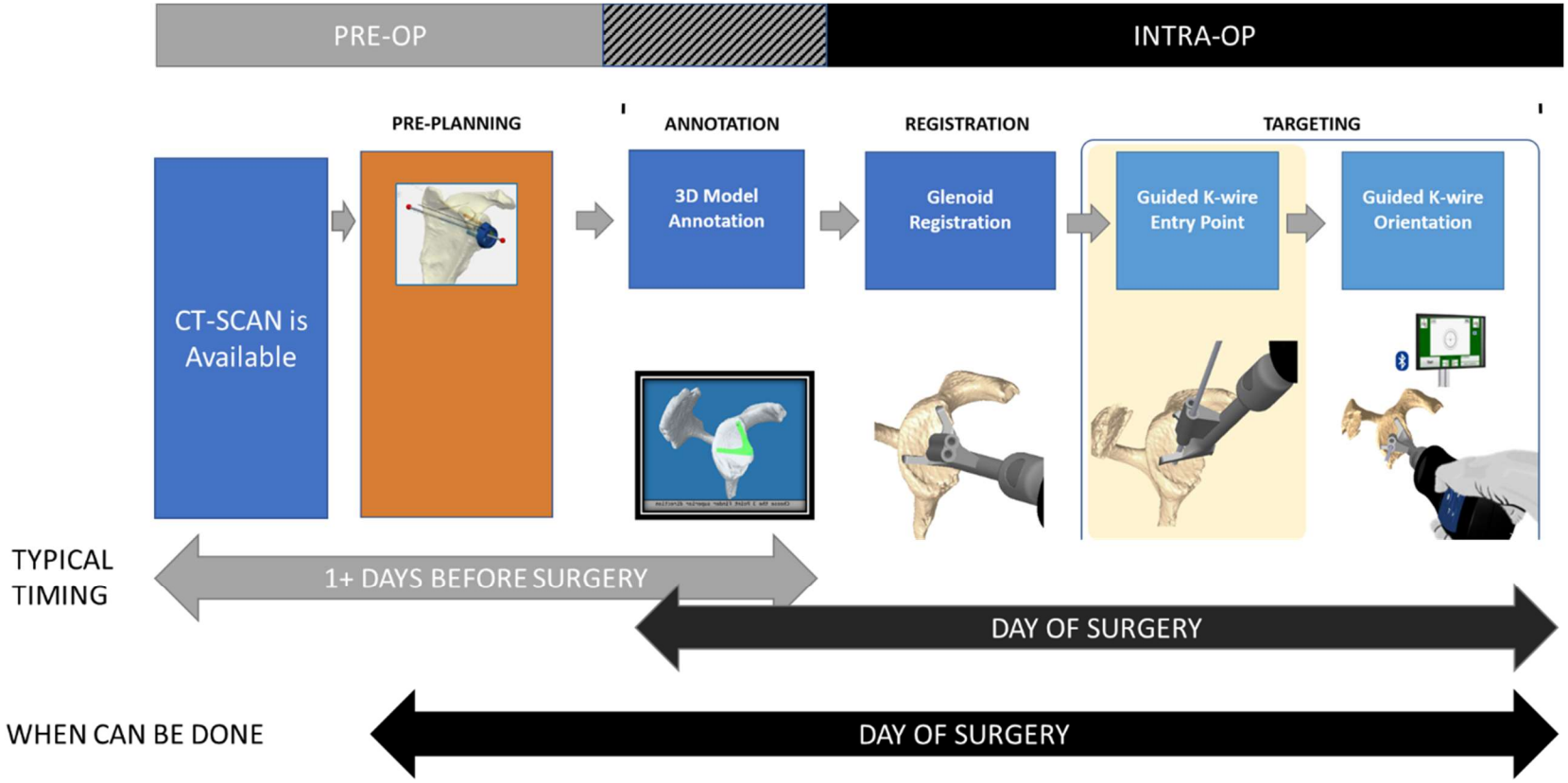
8. PRE-OP PROCEDURE

8.1. SURGICAL PRE-OP PLANNING

CORE Shoulder aids in targeting a k-wire based on a pre-op planned trajectory calculated by a pre-op planning software. The pre-op planning software is used to segment the CT of the patient's scapula and to virtually position the glenoid component. The pre-op planning software is not part of the CORE Shoulder system, but it is used to plan the implant position. The pre-op plan must be current for the patient's condition / health needs, as the data is utilized by CORE Shoulder software.

The plan can then be loaded on the CORE Shoulder software.

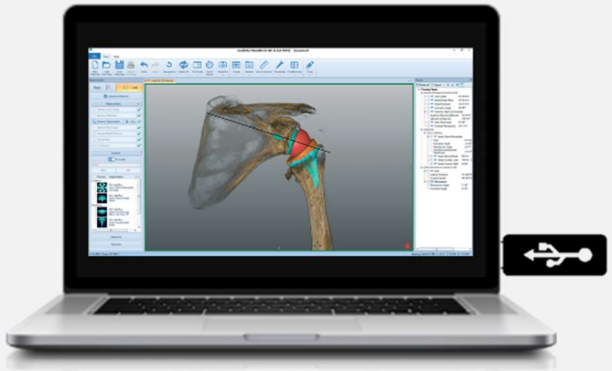
Complete the annotation on a case any time before the operation to save time. The annotation may also be changed intra-op as many times as is needed.



8.2. PRE-OP PLAN TRANSFER

Insert the USB drive in a USB port of the laptop where the Pre-op Planning software is installed.

Export the Pre-Op Plan for CORE Shoulder to the USB drive.



NOTE

Review Pre-op Planning Manual to identify the proper export procedure.

Plug the USB drive in a port of the CORE Workstation.

TIP

Press the power button on the top rim of the Workstation to turn it on.

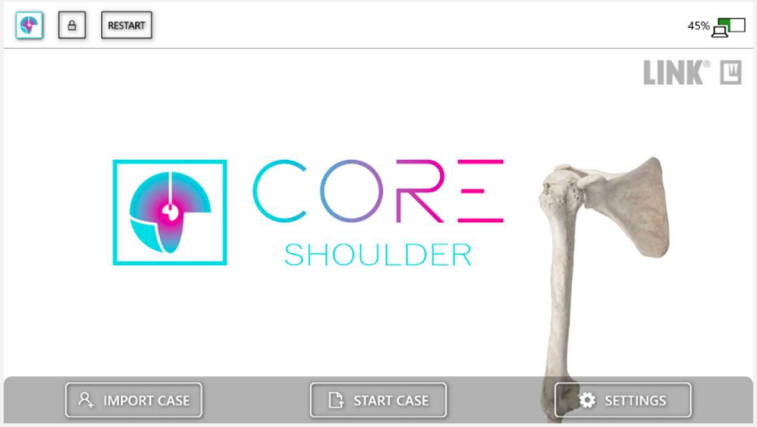
8.3. IMPORT PRE-OP PLAN & ANNOTATE THE CASE PLAN

Complete the annotation on a case any time before the operation to save time. The annotation may also be changed intra-op as many times as is needed.

Case Import

Tap 

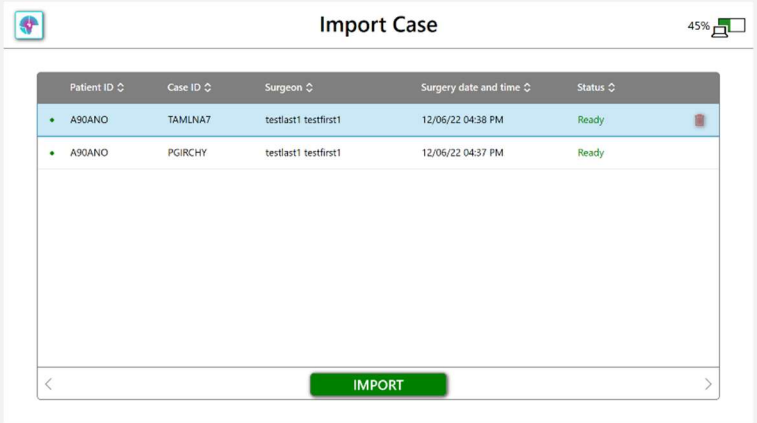
to access the Pre-Op Case Plans on the USB drive.



Select the Pre-Op Case Plan to be imported by tapping on its row.

Tap 

to import the Pre-Op Case Plan on the workstation.

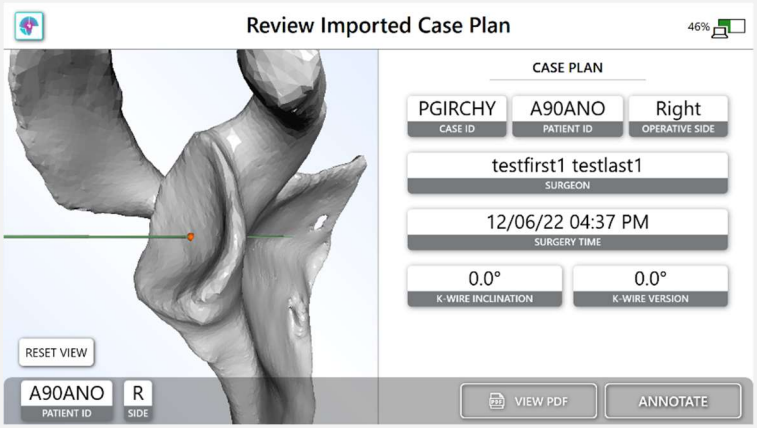


TIP
Tap the header arrows to sort the list by attribute

A preview of the case will be displayed.

Review and verify the surgical information.

Tap ANNOTATE to start the annotation.



TIP

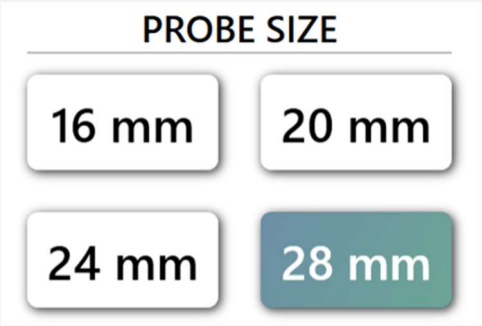
Tap VIEW PDF to display details about the pre-op plan.

NOTE

Case details are imported from the pre-op planning software. To modify the pre-op plan, return to the pre-op planning software and re-export it.

Annotation:
Select Probe Size

CORE Shoulder will recommend a probe size. Tap on a different size to annotate with a different probe.



TIP

Select a probe size that will fit comfortably on the glenoid. 2-4 mm less than the Anterior-Posterior diameter typically works.

Annotation:
Select Targeting Instrument

Select which targeting instrument will be used. The default is “Probe”, meaning the same instrument is used for both Registration and Targeting.

Tap OK to annotate with this probe.

NOTE
The targeting instrument can be changed intra-op. Follow instructions in the Drill Guide Probe Targeting section.

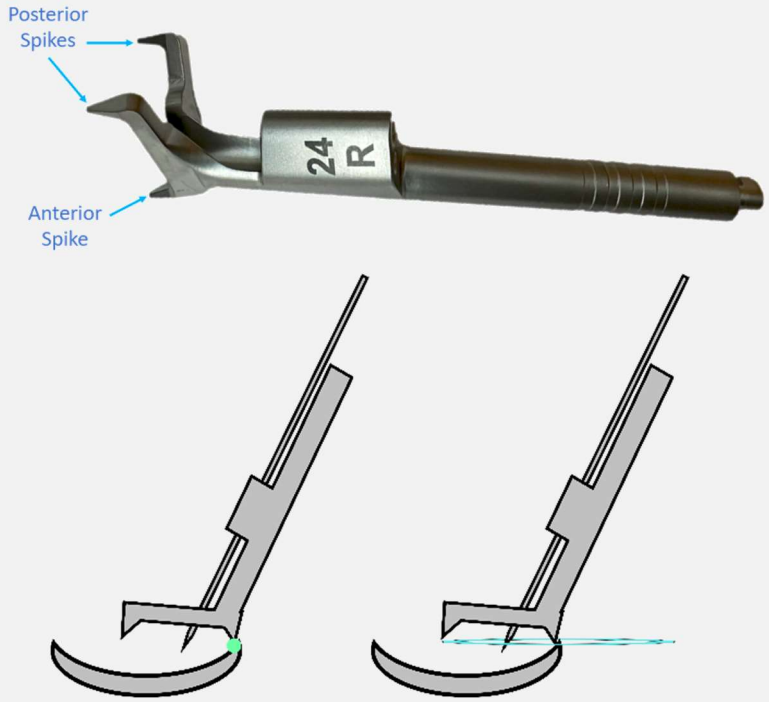
The Probe Anterior Point:

The next section refers to the Anterior Point. It is the point on the glenoid where the Probe’s anterior spike is placed during Registration.

The Probe will pivot on the Anterior Point, to reach different parts of the glenoid for Registration and Entry Point Targeting.

The device uses the Anterior Point as reference point, to calculate its position and movement on the glenoid.

The blue circular outline will indicate the reach of the Probe’s Posterior Spikes. This will serve as a reference for the step after “Annotation: Select Anterior Point”.

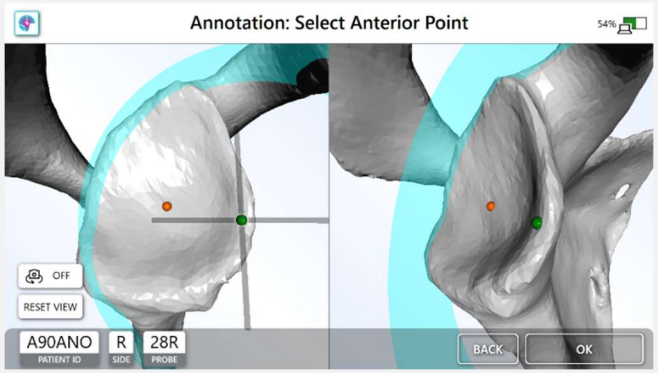


Annotation:
Select Anterior Point

Drag the cross-haired dot to place the anterior point.

- The dot will turn green when the anterior point is the appropriate distance from the Entry point for this probe size.
- The dot will be red if it is too close or too far from the Entry Point.

Tap OK to confirm the selection.



NOTE
The CORE SW displays the landing position of the probe's anterior spike using a colored dot and crosshair.

NOTE
A blue circular shadow shows the landing perimeter of the probe's posterior spikes.

TIP
Toggle the camera controls on/off with OFF.

Use the controls to rotate, pan, and zoom for a better look at the posterior aspect of the glenoid.

Click on RESET VIEW to restore the camera to its original view.

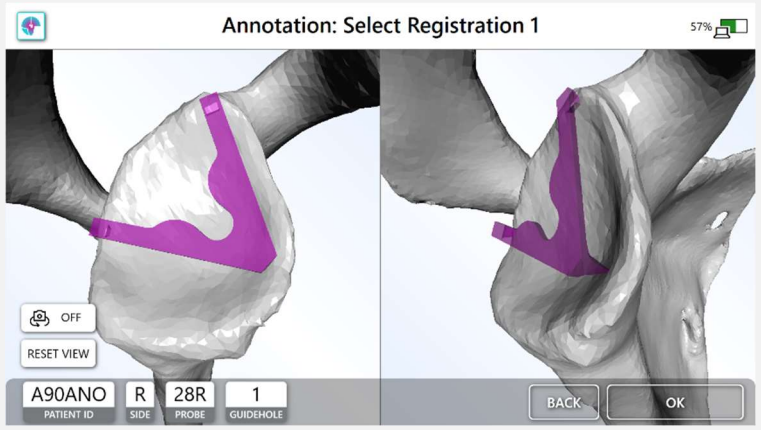
TIP
When choosing an anterior point for the Probe registration, it helps to choose a point that is:
- Closer to the entry point (EP)
- Directly anterior to the EP

This will limit the "tilt back" and "twist" motions required to hit the EP during the Entry Point Targeting step.

Annotation:
Select Registration 1

Use the touch screen to rotate the probe about its anterior point.

Tap OK to select Registration 1.



Try the following to get an Anterior Point which is closer to the EP:

1. Move the Ant. Point directly anterior to EP.
2. The Ant. Point will be colored red.
3. Then move the Ant. Point anteriorly until the point turns green.
4. This will give an Ant. Point which is fairly close to the EP.

TIP

Select a registration that is easy to reproduce on the glenoid anatomy. Look for natural landmarks.

NOTE

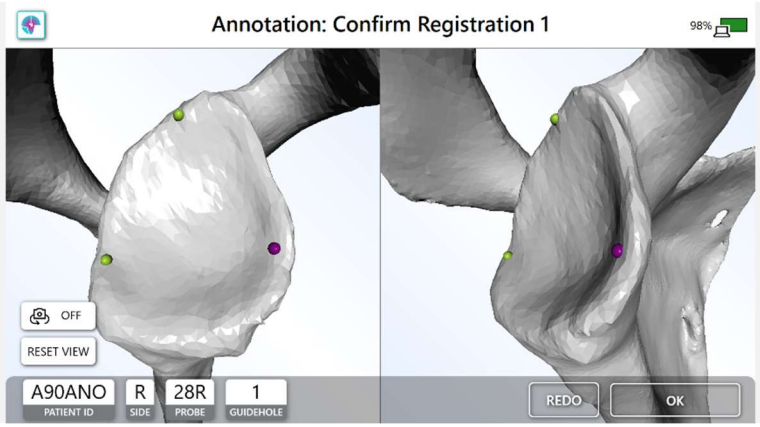
The 3D model of the Probe may float above or below the surface of the glenoid model rotating. It rotates on a single plane.

After pressing OK, the Probe spikes will be placed on the surface of the glenoid. It will show the result and ask to confirm that the placed points match the intended placement.

Annotation:
Confirm Registration 1

Registration 1 will be shown with 2 green dots.

Tap OK to confirm.

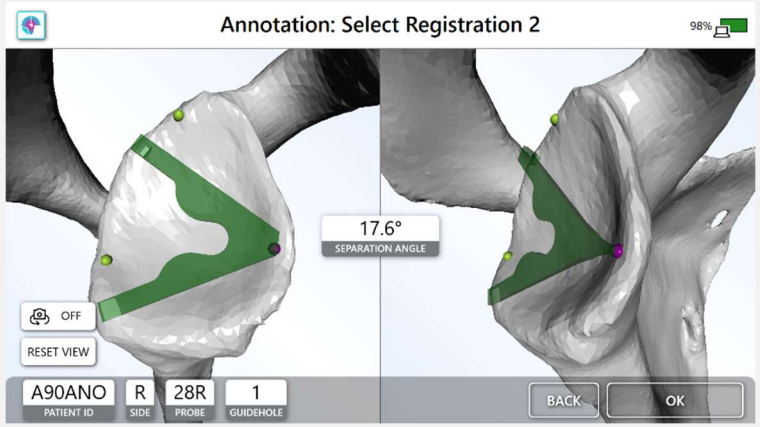


Annotation:
Select Registration 2

Select a second set of Registration points.

Use the touch screen to rotate the probe about its anterior point. The probe will turn green when the selection is deemed appropriate for an accurate registration, red otherwise.

Tap OK to select the second set of Registration points .



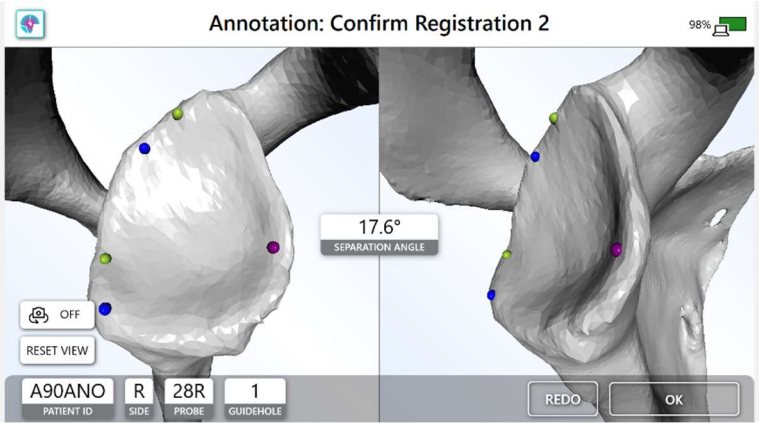
NOTE

A separation of at least 10 degrees is required between registration 1 and 2.

Separation greater than 35 degrees is not recommended.

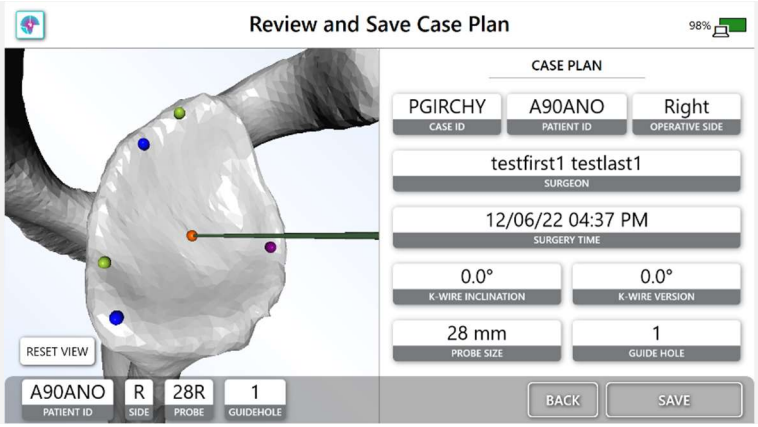
Annotation:
Confirm Registration 2

Registration 2 will be shown with 2 blue dots. Tap OK to confirm.



Review and Save Case Plan

Tap on SAVE to save the annotation.



NOTE

The App displays a summary of the pre-op plan case and annotation points.

Case plan saved

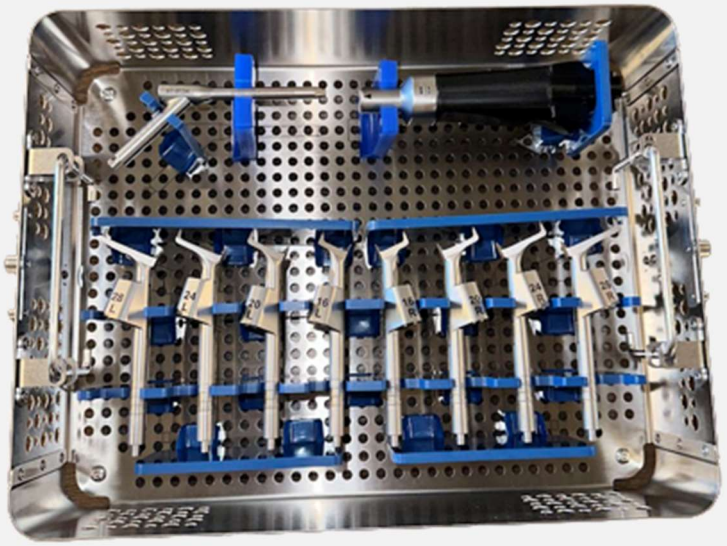
Tap on Start surgery for this case to start surgery for the case just annotated.

IMPORTANT

The case is not transferred to the workstation until the case plan annotation is saved.

8.4. PREPARE SURGICAL INSTRUMENTS

REUSABLE PARTS, AUTOCLAVABLE

PART		STERILIZATION
CORE Instrument Tray with reusable instruments. *Tray Part No. by itself* 87-9139		Clean and sterilize the reusable instruments within the CORE Instrument Tray. Follow the CORE Shoulder Reprocessing Instructions: **87-9130-IFU-01**

SINGLE USE PARTS, PRE-STERILE

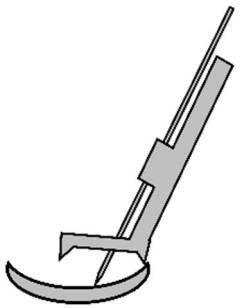
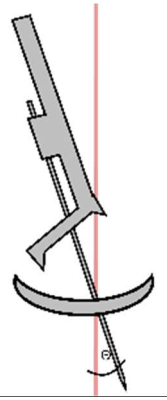
PART		STERILIZATION
CORE Power Unit *Part No. 87-9132* Within sterile package *Part No. 87-9149*		The Power Unit comes pre-sterilized in a double barrier sterile pouch, inside a carton. Refer to the CORE Shoulder Power Unit Insert: **87-9130-IFU-02**

9. INTRA-OP

9.1. THEORY - HOW IT WORKS

9.1.1. Registration

K-wire placement is determined by the pre-operative plan and has two components: Entry Point (position) and Trajectory (orientation). The device navigates to each separately, in that order.

K-wire Entry Point (Position)	K-Wire Trajectory (Orientation)
	

To navigate to the Entry Point, the device must register onto the physical glenoid position.

Pre-op, the user selects anatomic landmarks on a 3D model of the patient glenoid. Then intra-op, the user performs registration against the same landmarks on the physical glenoid.

IMPORTANT: Throughout registration, the device assumes the user is pivoting on a single constant point called the Anterior Point. The device Probe's anterior spike pivots on this point in order to reach the different anatomic landmarks.

It is critical to identify this Anterior Point accurately on the physical glenoid; this directly impacts the accuracy of the K-wire placement, especially the K-wire Entry Point.

When pivoting from the first set of points to the second set of points, the device records the change in position to complete registration. The device may now navigate to the trajectory (orientation).

<u>Registration becomes invalid and must be redone if the</u>:

- Device Probe's anterior spike loses contact with the glenoid.
- Device Probe's anterior spike slides/slips across the glenoid.
- Glenoid changes position/angle (not stabilized with retractors).

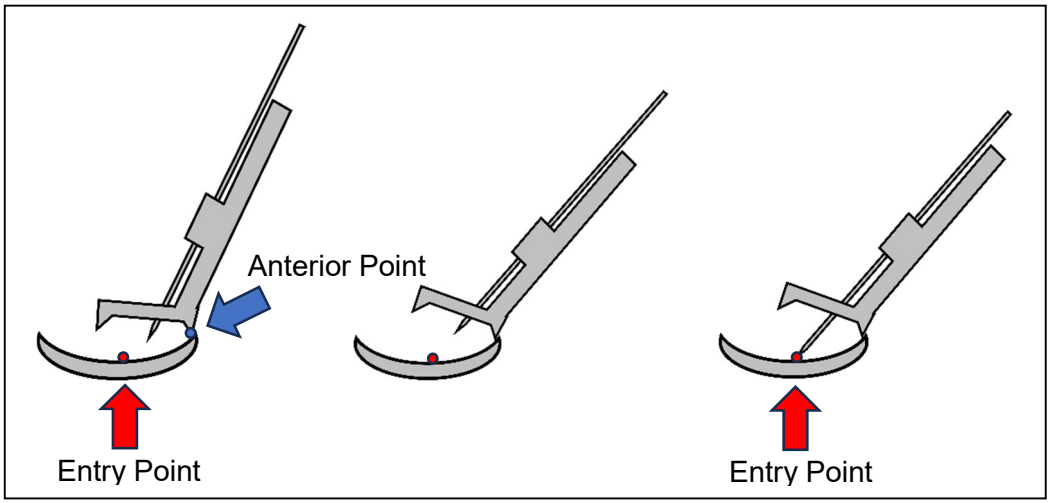
9.1.2. K-wire Entry Point (Position):

The Entry Point was determined by the pre-operative plan. The K-wire slides through the Probe to reach the Entry Point.

After Registration, the user will perform “Entry Point Targeting”, by following on-screen instructions to pivot/manipulate the device handheld instrument (“COREmote”) and the connected Probe so that the K-wire slides through the Probe and reaches the desired Entry Point.

The on-screen instructions state how far back to tilt the COREmote and how large of an angle to twist it, so that the K-wire can slide through to reach the desired Entry Point.

IMPORTANT: The device still pivots on the same Anterior Point (Ant. Point) as Registration. The selected Ant. Point from earlier will directly affect how much the COREmote needs to pivot to reach the Entry Point. Putting the Probe down on the annotated anterior point is crucial to targeting the entry point.

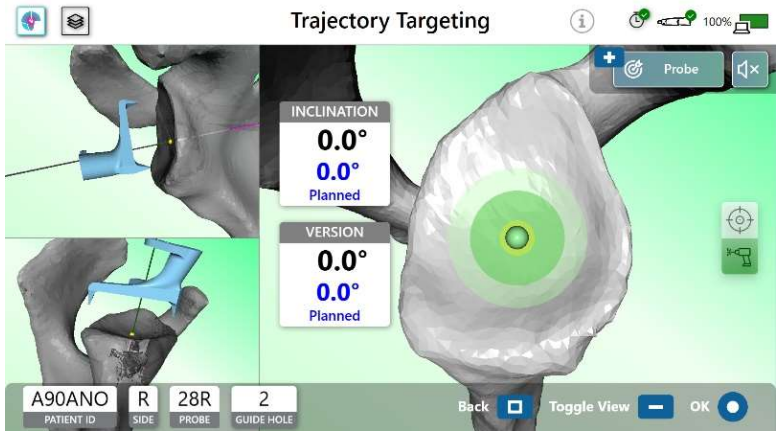


When the K-wire tip makes contact with the Entry Point, the Entry Point may be physically marked (typically to switch attachments). The device may then lose contact temporarily without issue, provided that the glenoid remains physically stable. Otherwise, continue as-is to Trajectory Targeting, without losing contact with the glenoid.

Registration becomes invalid and must be redone if the:

- Device probe’s anterior spike loses contact with the glenoid.
- Device probe’s anterior spike slides/slips across the glenoid.
- Glenoid changes position/angle (not stabilized with retractors).

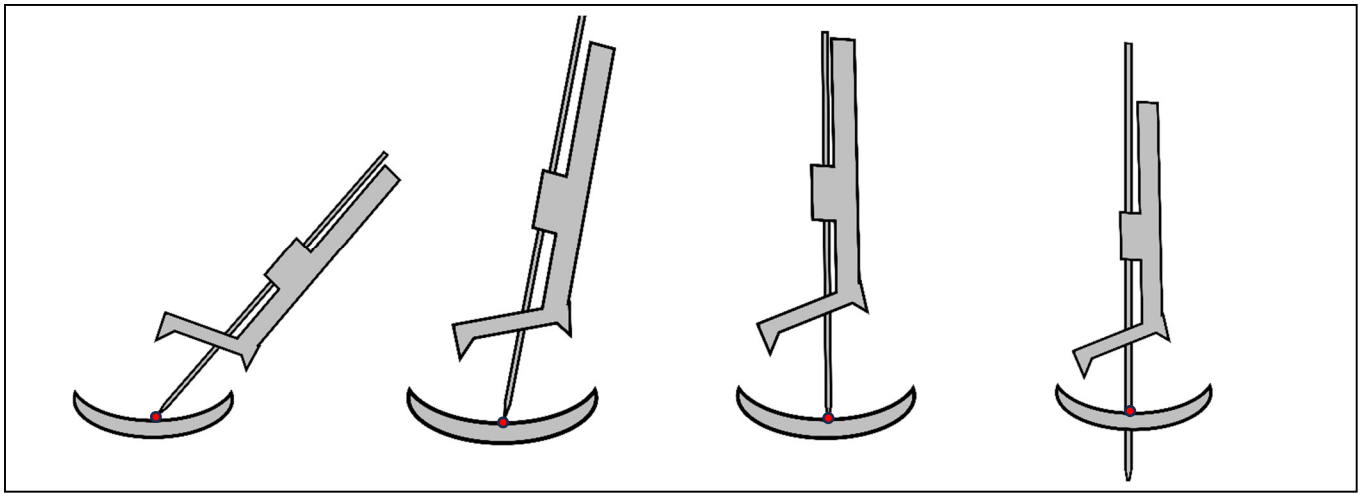
9.1.3. K-wire Trajectory (Orientation):



The Trajectory was determined by the pre-operative plan. Upon reaching the Entry Point, the user will then shift from pivoting off the device to pivoting off the K-wire instead. The K-wire is still inserted through the device Probe, so the device still knows where the K-wire is and can provide navigational instructions.

For “Trajectory Targeting”, follow on-screen instructions to pivot the K-wire (while holding the device) so that the K-wire obtains the desired inclination angle and version angle, to be drilled into the glenoid.

IMPORTANT: The device calculates the trajectory using the original registration. If the Entry Point was marked and K-wire tip temporarily loses contact with the glenoid, the device still knows the glenoid’s position and angle. Simply place the K-wire tip back on the marked Entry Point and continue, provided that the glenoid remains physically stable.

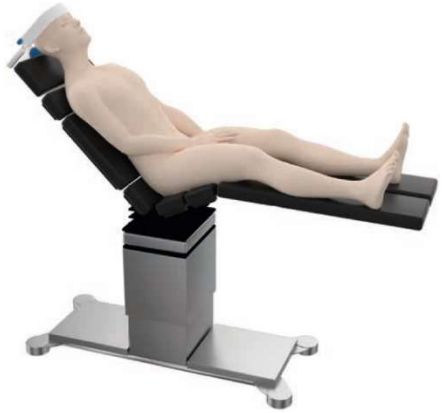


If registration becomes invalid at any point, then steps from registration onward must be re-done. Otherwise, K-wire placement will be inaccurate.

<u>Registration becomes invalid and must be redone if the</u>:

- K-wire loses contact with the glenoid and Entry Point was not already marked.
- K-wire slips/slides across the glenoid and Entry Point was not already marked.
- Glenoid changes position/angle (not stabilized with retractors).

9.2. PATIENT POSITIONING & OPERATING ROOM LAYOUT

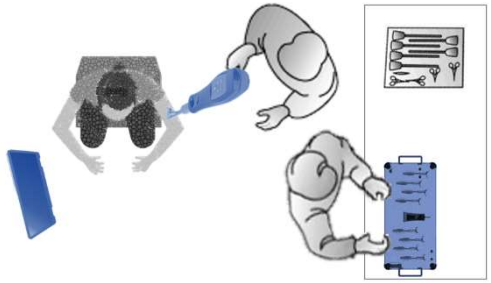


The CORE Shoulder medical device system relies on the physical stability of the scapula for accuracy.

Follow the recommendations about patient positioning, in addition to standard TSA practices, to achieve a satisfactory outcome when using the device.

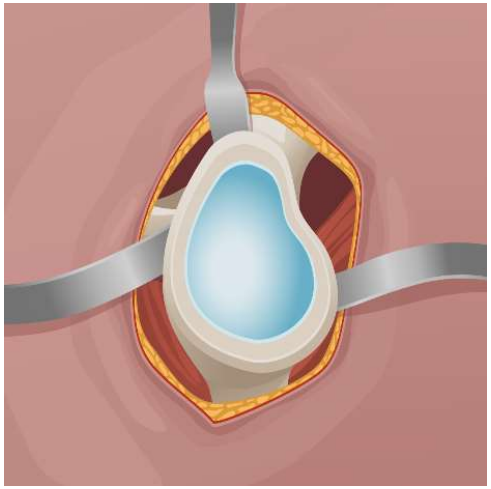
A. Position the patient in a beach chair or semi-beach chair.

B. Strap the patient to prevent movement and rotation of the torso and scapula. Place a rigid support between the most medial aspect of the operative scapula and the chair, to reduce the movements of the scapula intraoperatively.



C. Position the CORE Workstation on the opposite side of the operating shoulder. For optimal viewing, place the CORE Workstation within 6 feet of the surgeon.

D. **IMPORTANT:** Ensure that the retractors do not move and that the glenoid remains stabilized throughout the use of the CORE Shoulder system, starting at registration. If the retractors are moved and the glenoid is repositioned, then registration becomes invalid and must be re-done.



9.3. HANDLING THE COREMOTE

The COREmote is symmetrically designed to be used agnostically with either hand. It is advised to do the following:

- For **right**-side procedures, it is recommended to hold the COREmote with the **right** hand. Right hand holds the COREmote on the anterior side of the patient, while the left hand holds a medical drill on the posterior side.

- For **left**-side procedures, it is recommended to hold the COREmote with the **left** hand. Left hand holds the COREmote on the anterior side of the patient, while the right hand holds a medical drill on the posterior side.

There are recesses built in along the Sensor Unit at the front and the middle of the body, to allow full precision control of the COREmote by using a pencil-type grip. This allows the index finger to freely press the buttons on top. Thus, the user may operate the device Workstation with one hand, as if using a remote control.

In addition, the user may ask Non-scrubbed Personnel for assistance to operate the Workstation via the touchscreen buttons. This is useful when handling the COREmote and medical drill in each hand simultaneously.

9.4. WORKSTATION SETUP

Assemble Workstation Cart

Expand the CORE Workstation Stand Base.

Loosen the locking screws, extend the CORE Workstation Stand Pole, then tighten the locks.

Assemble the CORE Workstation Stand Pole into the Base and tighten the knob.

Assemble Workstation

Open the clamp on the back of the Workstation.

Slide the clamp around the pole and firmly fasten the Workstation tablet at an appropriate height.

Plug the power adapter into Workstation.

NOTE

Spin the nut on the clamp to loosen or tighten the opening of the clamp.

IMPORTANT

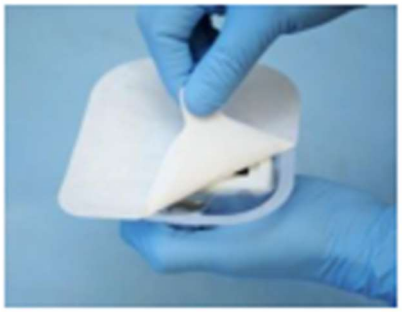
When charging the Workstation in the OR, ensure the AC Adapter cord is placed appropriately in order to avoid being a tripping hazard

Power on the Workstation by clicking on the power button.

9.5. STERILE BACK-TABLE SETUP

Assemble the Power Unit

Remove the Power Unit from pre-sterile pouch and place it on the sterile back-table.



Power on the COREmote

Assemble the COREmote by sliding the Power Unit onto the Sensor Unit from behind. It slides into the grooves. There should be an audible click when done.

The LEDs will turn on, which means it activated properly.

Once assembled, place the COREmote on the sterile back-table.

IMPORTANT

For increased accuracy, the COREmote must be powered for at least 30 minutes before using the CORE system.

Power the COREmote as early as possible during the surgical setup for the case.

Load the Case

Tap START CASE on the homepage.

Select the case to start by tapping on its row.

Tap START to open the case.

Load the Case

Select the probe based on the Operative Side & Probe Size

- For example, “Right+28mm” requires the **28R** Probe.

TIP

The probe size is marked on both the inside of the tray and on the guide block of the probe.

Engage Probe with COREmote

Engage the probe with the nose of the COREmote, using the arrows to align the parts and push them together until they click.

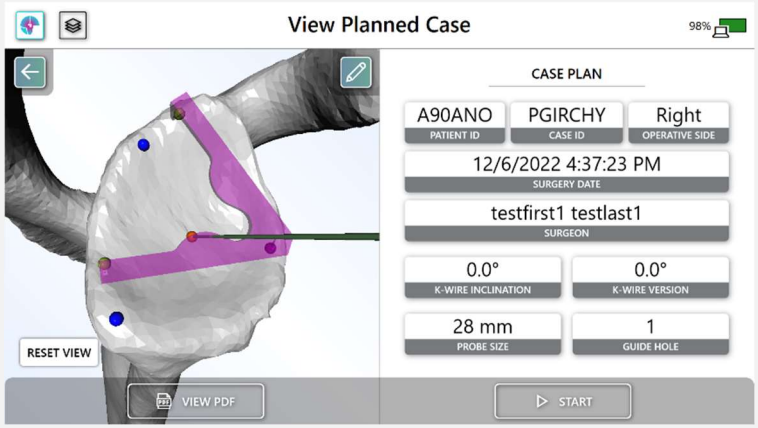
Place the COREmote down on the back table.

NOTE
Press the button on the underside of the COREmote to release the probe for disassembly.

9.6. SURGERY (STANDARD PROBE)

Load Case

Keep the Planned Case preview on the screen to direct the surgeon while he/she works on the exposure.



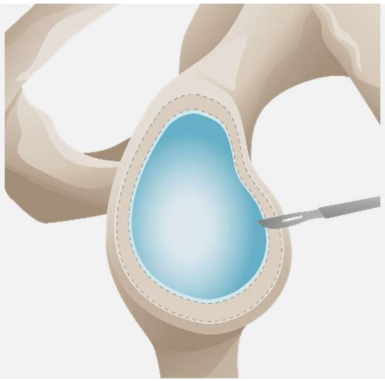
Exposure

Standard exposure should be gained to the glenoid humeral joint.

Using a curette or scalpel, remove the labrum and create

TIP
It is not recommended to use electrocautery to remove the labrum or cartilage, as this may create cavities in the surface of the glenoid.

sufficient exposure of the glenoid so that registration landmarks are identifiable.



Start Procedure

Tap on 

to start the procedure.

NOTE
This step is performed by non-scrubbed personnel. Every step after this one can be performed by scrubbed personnel by using the controls on the COREmote.

Connect to a COREmote

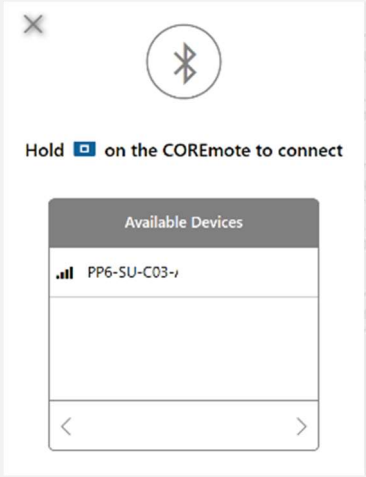
Hold  on the COREmote to start the connection process.

OR

Tap the COREmote ID then tap 

to start the connection process.

Hold  on the COREmote when prompted.



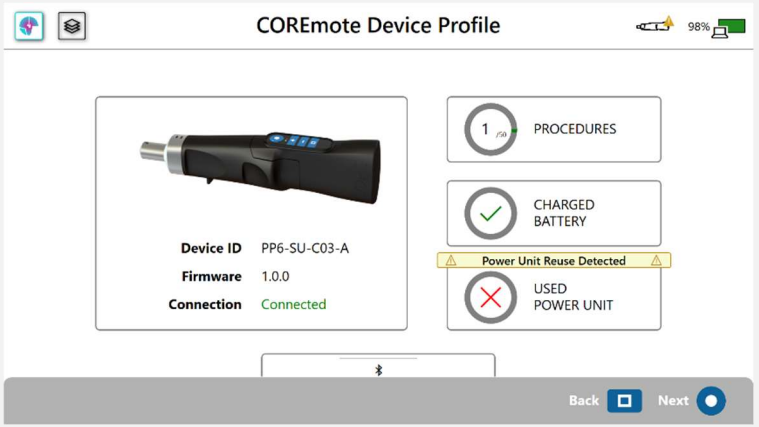
NOTE
The COREmote ID is marked on the nose of the COREmote.

Wait until the green light
on the COREmote starts flickering
then hold

COREmote Device Profile

The COREmote is now connected.

Click to continue to the Calibration page.



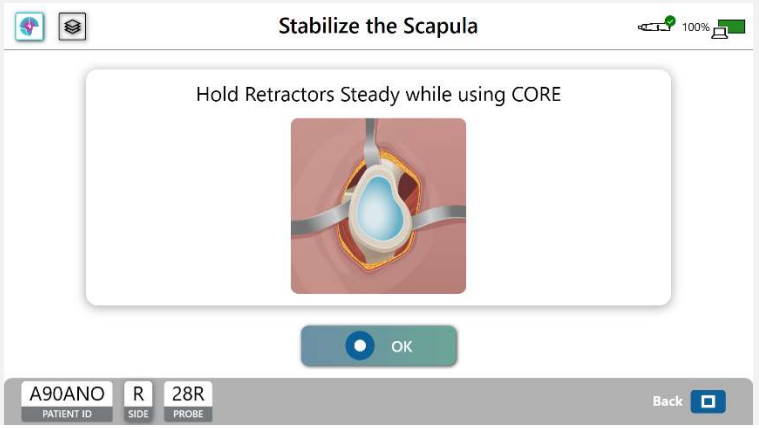
TIP

The PROCEDURES counter represents the number of procedures performed with the current Sensor Unit.

The USED POWER UNIT status detects whether a Power Unit has been used already.

Stabilize the Scapula

Click to acknowledge the instruction to stabilize the scapula.



IMPORTANT

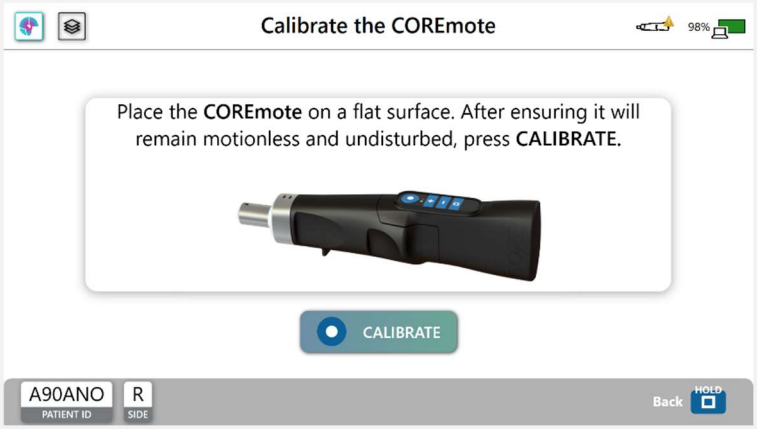
Do not reposition the retractors in the following steps.

Ensure the retractors and patient are stabilized from registration and until completing K-wire placement.

Calibrate the COREmote

Place the COREmote on a flat surface with the buttons facing up. Ensure it remains motionless and undisturbed.

Click ● to start the calibration. Wait until the on-screen instructions indicate that calibration has completed.



TIP

Controls that appear on the bottom of the UI can either be clicked on the COREmote or tapped on the Workstation.

Attach the appropriate probe to the COREmote. Ensure it snaps completely into place.

Click ● to advance through the surgical steps.

Ensure that the surface of the exposed glenoid corresponds with the one displayed on the screen.

<u>If it does not match</u>:

- It is possible that not enough cartilage or labrum was removed.
- Determine if the CT-scan reconstruction is appropriate. If it appears inaccurate, it is advised to discontinue use of CORE

Shoulder and proceed with the surgery without it.

Registration – Step 1

Introduce the COREmote probe to the glenoid fossa, aligning the 3 spikes of the probe to the first set of annotation points previously selected.

Click ⊙ on the COREmote to confirm.

NOTE

Ensure all 3 spikes are in contact with bone during registration.

TIP

Electrocautery can be used to mark the Anterior point as a visual landmark.

IMPORTANT

After registration, the patient and the glenoid should not be moved. If the patient, retractors, or scapular move, then re-register.

Do not reposition the retractors.

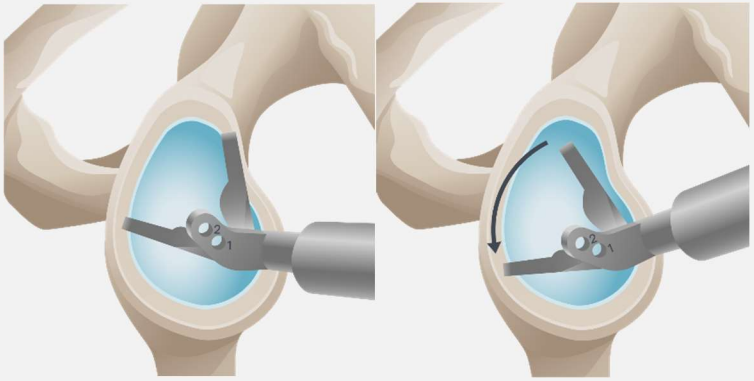
Any change in the glenoid or patient's position/orientation after Registration 1 will affect the system's accuracy.

It is possible to simulate the pin targeting motion on the glenoid, to determine whether retractors will cause physical impediment. If necessary, reposition retractors before Registration 1.

Registration – Step 2

Pivot the probe on the anterior spike, rotating the posterior spikes to match the second set of annotation points. Ensure all 3 spikes are in contact with the glenoid when capturing the position

Click on the COREmote to confirm.



IMPORTANT

It is critical to keep the Probe's anterior spike in contact with the glenoid when pivoting. The anterior point must not slide, move position, or lose contact with the glenoid.

If the spike slides, moves position, or loses contact with glenoid, then re-register.

Registration – Verify

Verify that the registration is accurate by rotating the posterior spikes to contact notable landmarks on the glenoid surface and the rim of the glenoid. The 3D models on-screen (movements & position) should match the physical COREmote & Probe.

Confirm registration accuracy by clicking on the COREmote.

Press after verifying registration is accurate

IMPORTANT

Keep the Anterior spike of the probe anchored in contact with the glenoid throughout the Registration and Entry Point Targeting process.

If the Anterior spike loses contact with the glenoid surface, re-perform registration by using to go back.

Entry Point Targeting

Slide the K-Wire into the correct guide hole as indicated by the CORE software (Guide Hole 1 or 2).

The K-wire should go all the way through the guide hole.

Do not use the drill while the K-wire tip is inside the guide hole.

NOTE

Remember the guide hole number and position indicated on-screen. The system cannot sense if the wrong hole is used.

USE GUIDE HOLE

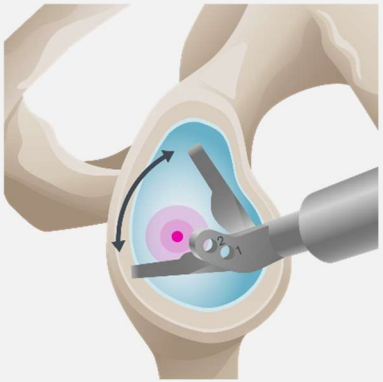
1

for entry point and trajectory targeting

Entry Point Targeting

Tilt and pivot the COREmote around the anterior spike until the twist and tilt spheres are centered in the bullseye of the vertical and horizontal targeting bars.

The interface will turn green when the desired entry point is located.



NOTE

Do not drill the K-wire in during this step.

IMPORTANT

If the Anterior spike becomes unanchored or the glenoid is moved, re-perform registration by using to go back.

Do not reposition retractors.

Ensure the retractors and patient are stabilized from registration and until completing K-wire placement.

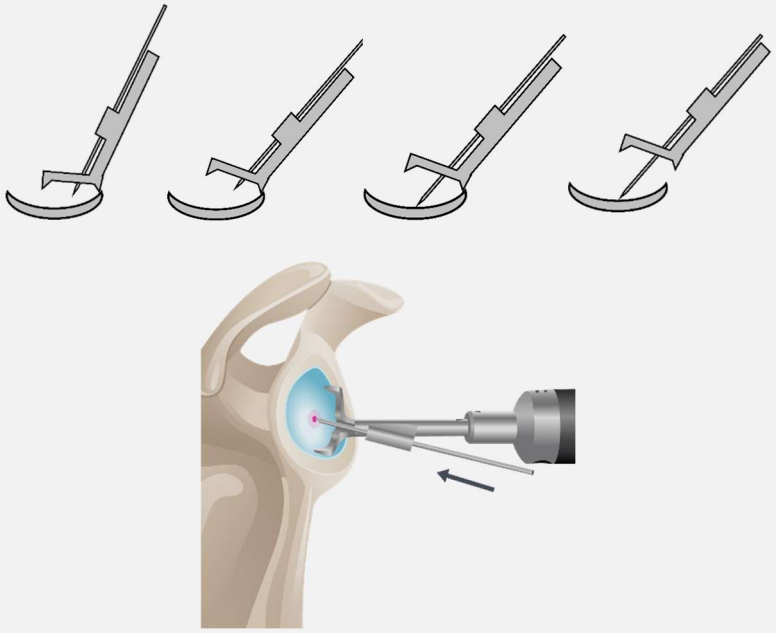
Entry Point Targeting

Slide the K-wire all the way through the guide hole. Press tip of K-wire into glenoid with moderate pressure. Shift all the force onto the glenoid from the Probe to the K-wire tip instead.

Now it is pivoting entirely off of the K-wire tip.

Slide the Probe up the K-wire and away from the glenoid, approximately 1 inch, allowing for free pivoting on the K-wire tip while keeping the COREmote close to the K-wire tip.

Stay like this for rest of surgical technique. (Unless switching to the Drill Guide Probe).



NOTE

If the Drill Guide Probe will be used for Targeting, mark the Entry point at this step, and jump to the Drill Guide Probe targeting section.

IMPORTANT

Keep the tip of K-wire in contact with the glenoid.

If the glenoid is moved, re-perform registration by using ◻ to go back.

Do not reposition retractors.

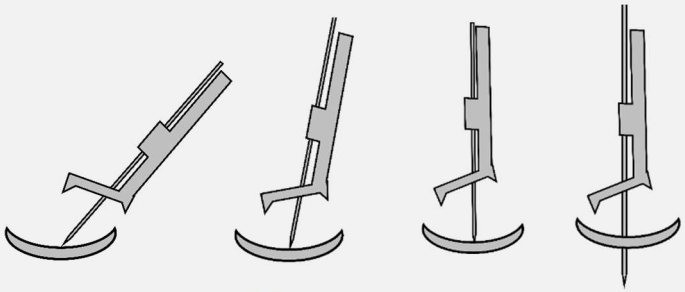
Ensure the retractors and patient are stabilized from registration and until completing K-wire placement.

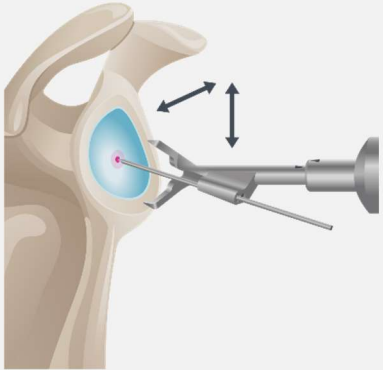
Click ◯ on the COREmote to advance to the Trajectory Targeting.

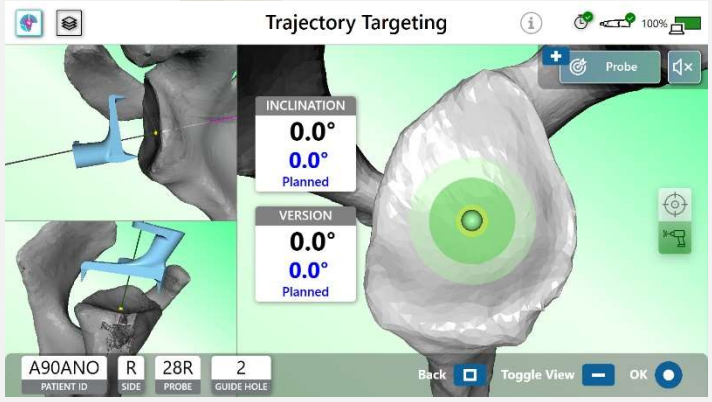
Trajectory Targeting [Standard Probe]

Referencing the interface, adjust the trajectory of the K-wire so that the yellow sphere matches the bullseye of the targeting interface.

The interface will turn green when the desired trajectory is achieved.







NOTE
Do not start drilling until after reaching the target on Trajectory Targeting.

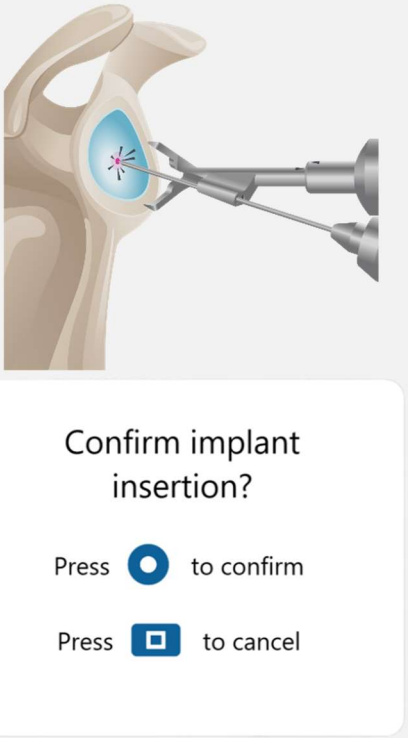
IMPORTANT
Maintain a secure grip on the device to prevent it from hanging on the K-wire which can lead to bending and subsequently reduce accuracy

Drill

Once the target is achieved, drill the K-wire bi-cortically into the glenoid vault. Stay on-target.

Click ⊙ to save the final K-wire trajectory.

Click ⊙ again to confirm.



TIP

Keep the probe close to the glenoid surface while drilling the K-wire in.

IMPORTANT

Keep the K-wire straight while targeting. Bending/flexing the K-wire excessively will decrease accuracy.

Do not apply excessive force onto the K-wire while grasping it with the drill.

Remove the COREmote and visually inspect K-wire for accuracy.

Proceed with standard glenoid preparation.

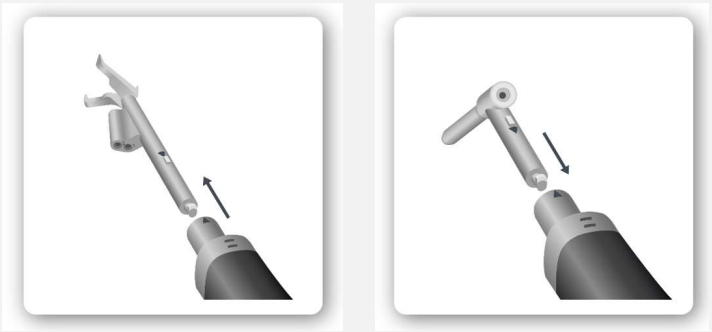
9.7. TARGETING (DRILL GUIDE PROBE)

Entry Point Targeting [Drill Guide Probe]

After the Entry Point has been found, mark the entry point on the glenoid.

Remove the COREmote from the glenoid, but keep it close to the patient glenoid. Move slowly.

Press the button on the Sensor Unit to release and uninstall the Standard Probe, then attach the Drill Guide Probe.



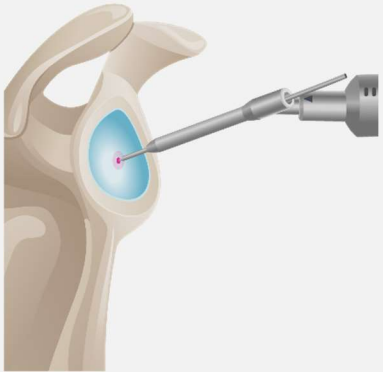
IMPORTANT

When switching attachments, do not hand off the COREmote.

Have another person hand the user the Drill Guide Probe, and then hand them the Standard Probe in return.

Quick/jerking motions with the COREmote can result in a warning and can affect accuracy.

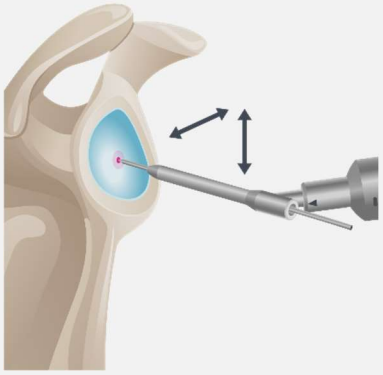
Slide the K-Wire into the Drill Guide Probe and align the K-wire tip with the entry point.

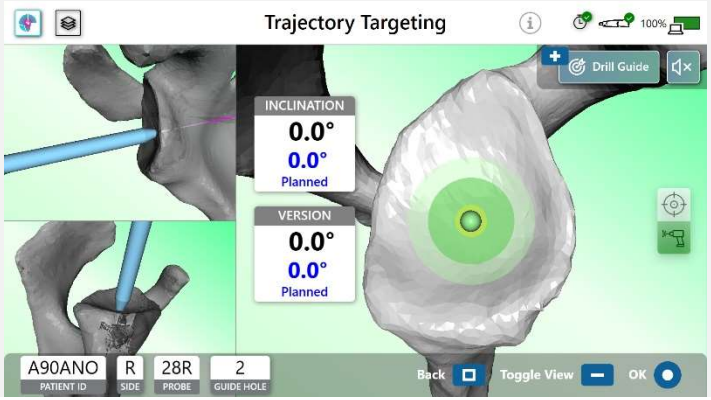


Trajectory Targeting
[Drill Guide Probe]

Referencing the interface, adjust the trajectory of the K-wire so that the yellow sphere matches the bullseye of the targeting interface.

The interface will turn green when the desired trajectory is achieved.



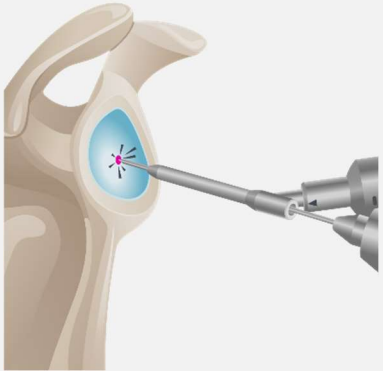


Drill

Once the target is achieved, drill the K-wire bi-cortically into the glenoid vault. Stay on-target.

Click ⊙ to save the final K-wire trajectory.

Click ⊙ again to confirm.



The Surgery Detail summary will appear. Remove the COREmote and visually inspect K-wire for accuracy. Proceed with standard glenoid preparation.	

9.8. INTRA-OP ANNOTATION

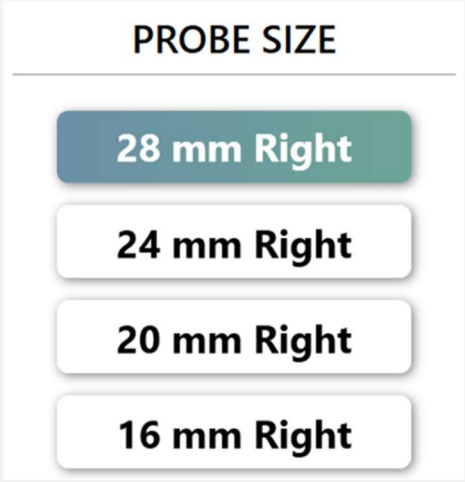
Change Registration Points

Click ➕ to edit the annotation, click ⭕ to confirm the selection.

NOTE
The annotation page can be accessed at any time during registration.

Annotation:
Select Probe Size

Use ➕ and ➖ to move up and down the list of probe size. Click ⭕ to confirm the selection.

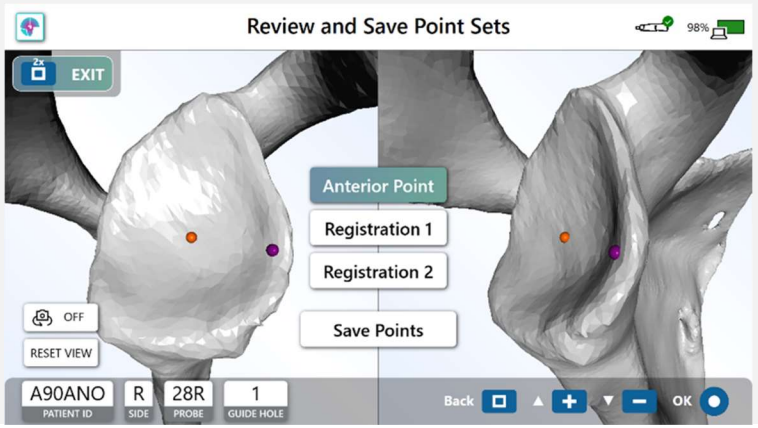


TIP
Select a probe size that will fit on the glenoid comfortably. 2-4 mm under the Anterior-Posterior diameter typically works.

Annotation:
Review Point Sets

Click + or − to move up and down the list of points. Select the desired point/s to change.

Click ● button to confirm the selection.



NOTE

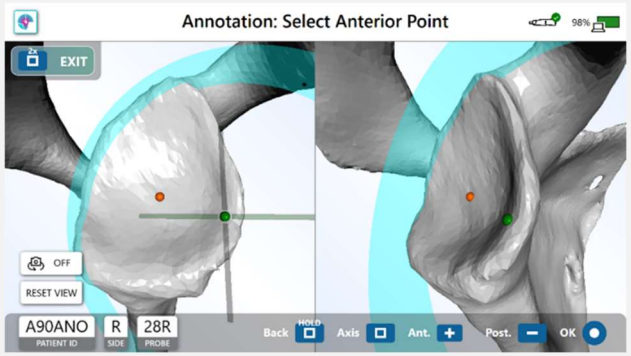
Updating Registration 1 will leave the Anterior Point unaltered.

Updating Registration 2 will leave the Anterior Point and Registration 1 unaltered.

Annotation:
Select Anterior Point

Click ▢ to change axis, the selected axis will turn green.
Click + or − to move the Anterior Point along the axis. The dot will turn green when the selection is conducive to a successful targeting, red otherwise.

Click ● button to confirm the selection.



NOTE

The CORE SW displays the landing position of the probe's anterior spike using a colored dot and crosshair.

NOTE

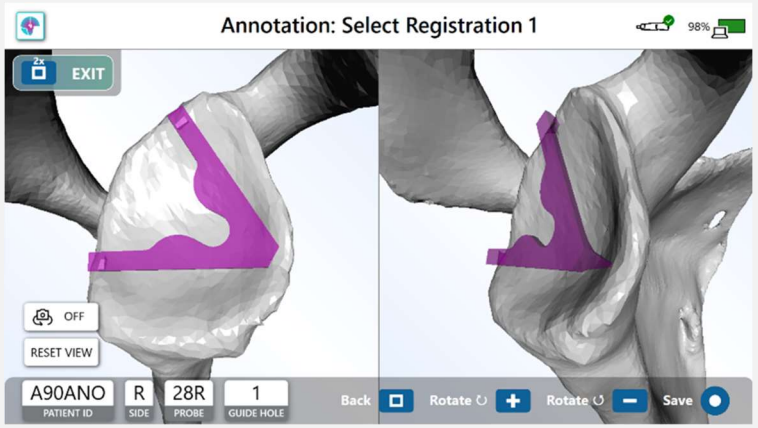
A blue circular shadow will show the landing perimeter of the probe's posterior spikes.

TIP

Use the camera controls OFF to change the views on the panel and better look at the posterior aspect of the glenoid. Click on RESET VIEW to restore the camera to its original view.

Annotation:
Select Registration 1

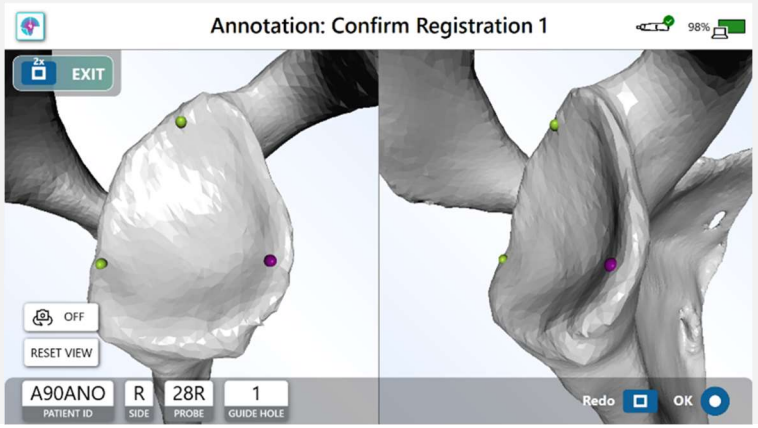
Click + or − to rotate the probe about its anterior point.
Click ● to confirm the selection.



TIP
Select a registration that is easy to reproduce on the actual patient. Look for natural landmarks.

Annotation:
Confirm Registration 1

Click to confirm the registration points on the glenoid's surface.

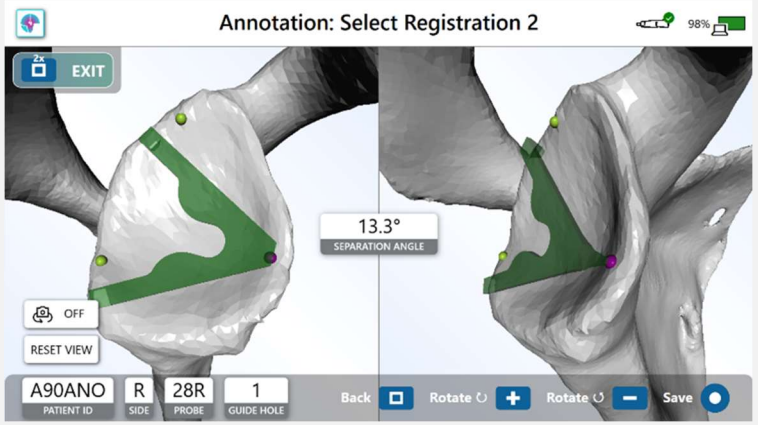


Annotation:
Select Registration 2

Click or to rotate the probe about its anterior point.

The probe will turn green when the selection is deemed appropriate for an accurate registration, red otherwise.

Click to confirm the selection.



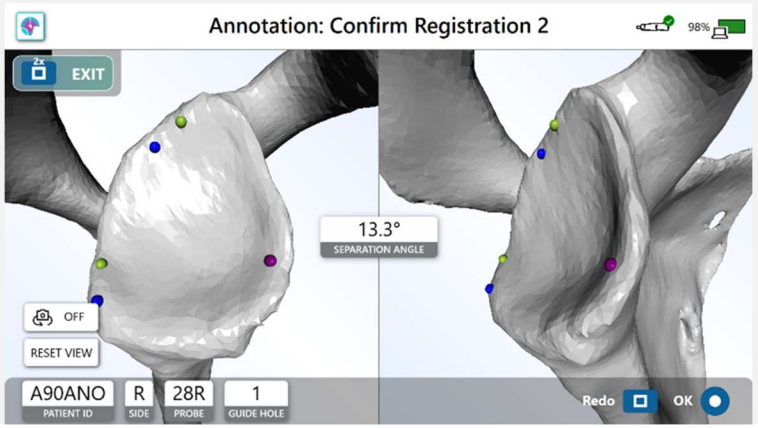
NOTE

A separation of at least 10 degrees is required between registration 1 and 2.

Separation greater than 35 degrees is not recommended.

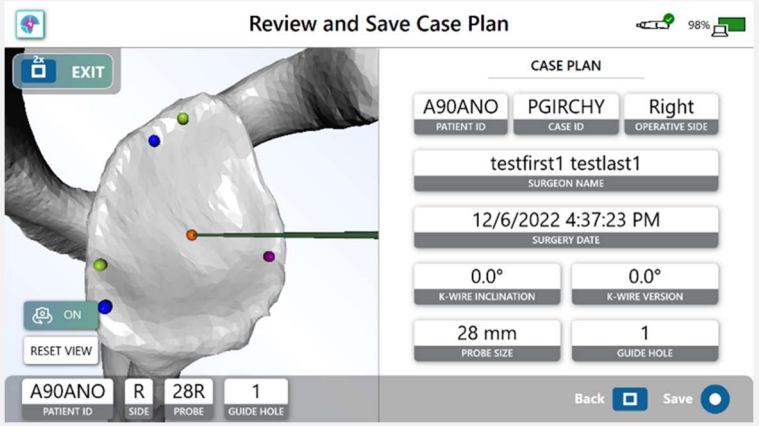
Annotation:
Confirm Registration 2

Click ● to confirm the registration points on the glenoid's surface.



Review and Save Case Plan

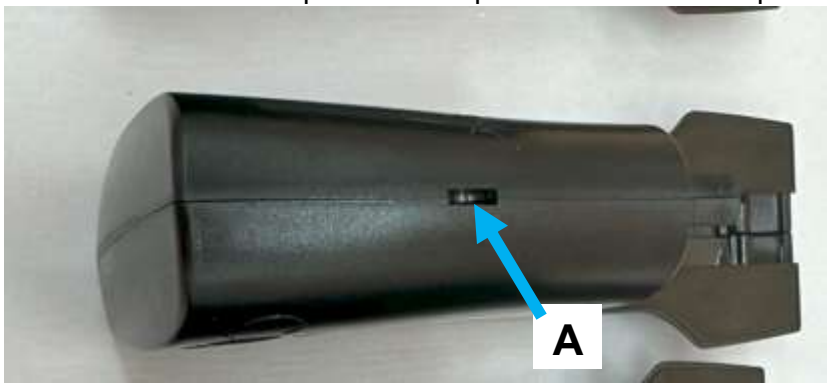
Click ● to save the annotation and resume the surgery.

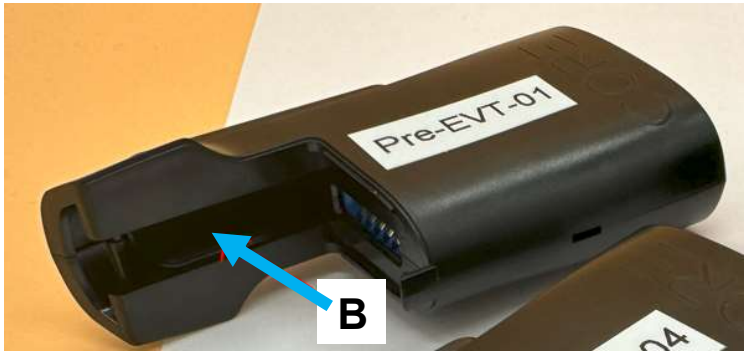


NOTE
The App displays a summary of the pre-op plan case and annotation points.

10. POST-OP PROCEDURE

- Disconnect the Sensor Unit from the Power Unit to power off the COREmote.
- Insert a tool into either position A or position B and lever open the two halves of the power unit to access and remove the battery.



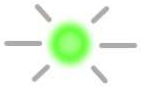
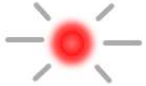


10.1. DISPOSAL OF BIOHAZARD WASTE

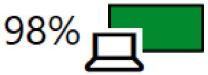
- The COREmote contains a Lithium Battery which must not be disposed of in a regular waste bin.
  - Dispose of the Power Unit following local disposal procedures and regulations for Lithium batteries and biohazard waste.
  - Do **not** discard the Sensor Unit because it is reusable. When the Sensor Unit reaches its maximum procedure count, it must be returned to LinkBio for evaluation. Contact a LinkBio Representative to exchange the Sensor Unit for a new one.

11. COREMOTE AND APP TROUBLESHOOTING

11.1. COREMOTE LED STATUS DEFINITIONS

	LED indication	This means…	What to do
During the connection process	Green – slow blink 	The COREmote is advertising its connection and waiting to connect to a Workstation.	Open the Workstation. Navigate to Settings > COREmote, then hold the Square button on the COREmote to pair it.
	Green – rapid blink 	The COREmote is waiting for the user to confirm connection.	Follow the on-screen instructions to complete the connection.
During the Surgical Workflow	Green – medium blink 	*[During Calibration]* COREmote is calibrating.	Leave the COREmote unperturbed on a table; follow the on-screen instructions.
	Green – rapid blink 	*[During Registration verification]* Indicates that the probe's posterior spikes should be in contact with the glenoid. [*During Targeting*] The COREmote is **on target**.	Follow the on-screen instructions.
During any part of the procedure	Green – solid 	The COREmote is powered on and connected with a Workstation.	No action needed. Ready to begin a case.
	Red – medium blink 	COREmote malfunction.	**If the COREmote was <u>just</u> powered on…** Unplug the COREmote Power Unit from the Sensor Unit, then slowly plug the Power Unit back in. If the red light persists, navigate to the Device Connection page (Settings > COREmote), follow the instructions for connecting to the Workstation. The Device Connection page will show any issues with the Sensor Unit and Power Unit. **If the COREmote has already been powered on for its warm-up period…** Do not unplug the Power Unit. Navigate to the Device Connection page (Settings > COREmote) and follow the instructions for connecting to the Workstation. The Device Connection page will explain any issues with the Sensor Unit or Power Unit.
	Red – rapid blink 	Excessive Motion has been detected.	The COREmote experienced excessive motion. Take caution to not move the COREmote rapidly. Follow the on-screen instructions to resolve the issue.

11.2. USER INTERFACE SYMBOLS

App Symbol	This means…
	**Return to the home screen.** If in the middle of a surgery, it will exit out of this surgery without saving and disconnect the COREmote.
	**Navigate to a previous step.**
	**View instructions for this page.**
	**Workstation Battery Indicator.** Keep the Workstation plugged into the wall outlet at all times during the surgery.
	COREmote status is good. No action is needed.
	COREmote status has a minor warning. No immediate action is necessary to continue the case.
	COREmote status is critical (low battery or internal error) and must be fixed before continuing the case. Follow the on-screen notifications to fix the error.
	**Camera control.** Toggle this on to zoom, pan, and rotate the view of the glenoid. The toggle must be *Off* to move points during annotation.
	**Edit the Annotation.** Edit the annotation during or before a procedure. This will save over the previous annotation for this case.
	**Accuracy Window.** When the timer turns yellow, the COREmote's accuracy has begun to decrease. CORE Shoulder will notify that a calibration is recommended in order to restore the systems accuracy. When the timer turns red, it is strongly recommended to calibrate soon.
	**Sound on/off.** Toggle the targeting sounds on or off.

11.3. TROUBLESHOOTING GUIDE

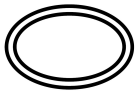
Category	Condition	Possible Causes	What to do
COREmote Troubleshooting	I plugged the Power Unit in with the Sensor Unit but the lights did not turn on.	Power Unit is not completely plugged in.	Push the Power Unit as far as possible with the Sensor Unit. The seam should look flush between the two units.
		The Power Unit battery is dead.	Open a new power unit and connect it to the Sensor Unit. If it still does not work, it may be a problem with the Sensor Unit. Contact a LinkBio Representative to exchange the Sensor Unit.
		The Sensor Unit has reached its lifespan	If a sterilized backup Sensor Unit is not available, continue the case without the use of the CORE navigational aid. Contact a LinkBio Representative to exchange the Sensor Unit.
	The light is flashing green on the COREmote, but I was unable to pair or connect it with the Workstation.	The COREmote has been disconnected.	Make sure the green light on the COREmote is flashing green. Navigate to Settings > COREmote (Device Connection Page) and tap the Bluetooth tray at the bottom of the page. Follow the on-screen instructions to pair and connect the device with the Workstation.
	The light is solid green on the COREmote, but I am unable to pair it with the Workstation.	The COREmote may be connected to another Workstation. The COREmote may be connected to the Workstation but is not responding properly.	Check if the COREmote is connected to a different Workstation. If it is not, reboot the Workstation. If that does not resolve the issue, reboot the COREmote by unplugging the Power Unit and plugging it in again.
	I want to connect the COREmote to a different Workstation.	--	Navigate to Settings > COREmote (Device Connection Page), tap the Bluetooth tray at the bottom of the page, then tap “Disconnect.”

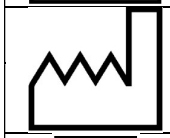
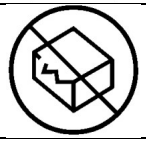
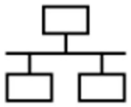
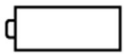
Category	Condition	Possible Causes	What to do
COREmote Device Profile Page	"Connection Failed. Please Try Again"		Tap the Bluetooth tray at the bottom of the page. Follow the on-screen instructions to pair and connect the device with the Workstation.
	 "Internal Error – COREmote Requires Reset"	An internal error has occurred.	Tap the "Reset COREmote" button to reset the connection. Follow the on-screen instructions to reconnect.
	 "Undercharged Battery" or "Low Battery"	The COREmote battery level is low.	Unplug the Power Unit. Open a new Power Unit and plug it to the Sensor Unit.
	 "Power Unit Reuse Detected"	The Power Unit has been used for a case already.	Dispose of the single-use Power Unit and use a new one for each case.
	"Procedure Limit has been reached"	The Sensor Unit has reached its maximum procedure limit.	For the best system accuracy, it is not recommended to continue using this Sensor Unit. Contact a LinkBio Representative for instructions on exchanging this Sensor Unit for a new one.
Workstation Troubleshooting	The Workstation doesn't turn on.	Workstation battery is low.	Plug the Workstation into a wall outlet via the AC Adapter. *TIP:* Keep the Workstation plugged into the wall outlet throughout the entire case.
		Workstation is either off or in sleep mode.	Hold the power button for 2 seconds and release. The Workstation should either boot up or wake up from Sleep mode.
Importing a Case	I don't see my case listed.	The case is not available on the USB drive.	Make sure the file is exported from the pre-op planning software and save the export file directly to the USB drive.

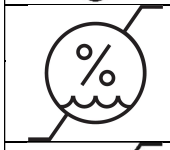
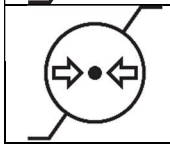
Category	Condition	Possible Causes	What to do
Importing a Case	I clicked import, but the case won't import.	The case has already been annotated.	There are 2 options: A) **Delete Case and reannotate from scratch.** Make sure the USB drive is still plugged in. Go to Start Case, tap the case that has already been annotated, then press the trash icon to delete it. The case will now be available from the "Import Case" page again. B) **Edit the existing annotation**. Go to Start Case, tap the case, then press "Start." Tap the pencil icon to edit this annotation.
		The case is in the wrong format or corrupt.	Re-export the case from the pre-op planning software. Contact a LinkBio Representative for assistance.
	I want to change the implant position.	--	The implant position (K-wire entry point, K-wire inclination, and K-wire version) cannot be adjusted in the CORE device. To **edit the plan,** it is necessary to instead return to the pre-op planning software and reexport the new plan,
Annotation	"Chosen anterior point is too far from entry point"	--	For each probe size, there is a maximum distance the anterior point can be from the pre-planned entry point. Choose a larger probe size or move the anterior point until it turns green.
	"Probe orientations are too far" or "Probe orientations are too close"	--	Select Registration 2 such that the separation angle is between 10 and 35 degrees.

Category	Condition	Possible Causes	What to do
System Accuracy Error	The angles/measurements displayed in the software are clearly wrong.	The COREmote has drifted or has reduced accuracy.	Tap  to recalibrate and re-register.
	"Excessive COREmote Motion Detected" 	The COREmote was shaken or moved quickly.	If this happened during Registration, Entry Point Targeting, or Trajectory Targeting, it is recommended to calibrate the system and redo Registration. Click  to proceed to Calibrate. If this happened after the K-wire has already been installed, calibration is not necessary.
Security and Access	Locked out of the app.	I forgot my pin.	Contact a LinkBio Representative.
		Exceeded maximum pin attempts.	Contact a LinkBio Representative.
	My time zone is wrong.	Time zone was set incorrectly or the workstation has moved locations.	Go to Settings > Time Zone. Choose the new time zone and tap "Set Time Zone".

12. REGULATORY SYMBOLS

Symbol	Reference	Standard Title	Symbol Title	Explanatory Text
	ISO 15223-1, Clause 5.1.1	Medical Devices – Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements.	Manufacturer	Indicates the medical device manufacturer.
	ISO 7000-3082	Graphical symbols for use on equipment.		
	ISO 15223-1, Clause 5.4.4	Medical Devices – Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements.	Caution	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.
	ISO 7000-0434	Graphical symbols for use on equipment		
	ISO 15223-1, Clause 5.4.3	Medical Devices – Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements.	Consult instructions for Use	Indicates the need for the user to consult the instructions for use.
	ISO 7000-1641	Graphical symbols for use on equipment.		
	ISO 15223-1, Clause 5.4.2	Medical Devices – Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements.	Do not re-use	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.
	ISO 7000-1051	Graphical symbols for use on equipment.		
	ISO 15223-1, Clause 5.2.6	Medical Devices – Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements.	Do not resterilize	Indicates a medical device that is not to be resterilized
	ISO 7000-2608	Graphical symbols for use on equipment.		
	ISO 15223-1, Clause 5.2.3	Medical Devices – Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements.	Sterilized using Ethylene Oxide	Indicates a medical device that has been sterilized using ethylene oxide
	ISO 7000-2501	Graphical symbols for use on equipment.		
	ISO 15223-1, Clause 5.2.12	Medical Devices – Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements.	Double Sterile Barrier System	Indicates two sterile barrier systems.
	ISO 7000-3704	Graphical symbols for use on equipment.		To indicate that there are two sterile barrier systems.
	ISO 15223-1, Clause 5.2.7	Medical Devices – Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements.	Non-sterile	Indicates a medical device that has not been subjected to a sterilization process.
	ISO 7000-2609	Graphical symbols for use on equipment.		
	-	-	Quantity of devices.	Number of units in the package.
	ISO 7000-2794	Graphical symbols for use on equipment.	Packaging unit	To indicate the number of pieces in the package.
	ISO 15223-1, Clause 5.1.6	Medical Devices – Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements.	Article number	Indicates the manufacturer's catalogue number so that the medical device can be identified.
	ISO 7000- 2493	Graphical symbols for use on equipment.		

Symbol	Reference	Standard Title	Symbol Title	Explanatory Text
	ISO 15223-1, Clause 5.1.7	Medical Devices – Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements.	Serial number	Indicates the manufacturer's serial number so that a specific medical device can be identified.
	ISO 7000-2498	Graphical symbols for use on equipment.		
	ISO 15223-1, Clause 5.1.5	Medical Devices – Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements.	Batch number	Indicates the manufacturer's batch code so that the batch or lot can be identified.
	ISO 7000-2492	Graphical symbols for use on equipment		
	ISO 15223-1, Clause 5.1.3	Medical Devices – Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements.	Date of manufacture	Indicates the date when the medical device was manufactured.
	ISO 7000-2497	Graphical symbols for use on equipment		
	ISO 15223-1, Clause 5.1.4	Medical Devices – Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements.	Use by	Indicates the date after which the medical device is not to be used.
	ISO 7000-2607	Graphical symbols for use on equipment		
	ISO 15223-1, Clause 5.2.8	Medical Devices – Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements.	Do not use if package is damaged and consult IFU	Indicates a medical device that should not be used if the package has been damaged or opened.
	ISO 7000-2606	Graphical symbols for use on equipment		
Rx only	21 CFR 801.15 (c) (1)(i)F	Labeling-Medical devices; prominence of required label statements	Prescription only	For the U.S.: Caution: Federal law restricts this device to sale by or on the order of a physician.
	21 CFR 801.109	Labeling-Prescription devices		
	ISO 15223-1, Clause 5.7.10	Medical Devices – Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements.	Unique device identifier	Indicates a carrier that contains unique device identifier information
	ISO 7000-5988	Graphic symbols for use on electrical equipment	Computer network	To identify the computer network itself or to indicate the connecting terminals of the computer network.
	ISO 7000-5001B	Graphic symbols for use on electrical equipment	Battery, general	On battery powered equipment.
	DIRECTIVE 2012/19/ EU (WEEE)	-	Collect separately	Separate collection for waste of electrical and electronic equipment. Do not dispose of battery in municipal waste. The symbol indicates separate collection for battery is required.
	IEC 60601-1, Table D.2, Symbol 20	Medical electrical equipment — Part 1: General requirements. for basic safety and essential performance	Type BF Applied Part	To identify a type BF applied part complying with IEC 60601-1

Symbol	Reference	Standard Title	Symbol Title	Explanatory Text
	ISO 15223-1, Clause 5.3.1	Medical Devices – Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements.	Fragile, handle with care	Indicates a medical device that can be broken or damaged if not handled carefully.
	ISO 7000-0621	Graphic symbols for use on electrical equipment		To indicate that the contents of the transport package are fragile and the package shall be handled with care.
	ISO 15223-1, Clause 5.3.2	Medical Devices – Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements.	Keep away from sunlight	Indicates a medical device that needs protection from light sources.
	ISO 7000-0624	Graphic symbols for use on electrical equipment		To indicate that transport package shall not be exposed to sunlight.
	ISO 15223-1, Clause 5.3.4	Medical Devices – Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements.	Keep dry	Indicates a medical device that needs to be protected from moisture.
	ISO 7000-0626	Graphic symbols for use on electrical equipment		To indicate that the transport package shall be kept away from rain and in dry conditions.
	ISO 15223-1, Clause 5.3.7	Medical Devices – Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements.	Temperature Limit	Indicates the temperature limits to which the medical device can be safely exposed.
	ISO 7000-0632	Graphic symbols for use on electrical equipment		To indicate the maximum and minimum temperature limits at which the item shall be stored, transported or used.
	ISO 15223-1, Clause 5.3.8	Medical Devices – Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements.	Humidity Limitation	Indicates the range of humidity to which the medical device can be safely exposed.
	ISO 7000-2620	Graphic symbols for use on electrical equipment		To indicate the acceptable upper and lower limits of relative humidity for transport and storage.
	ISO 15223-1, Clause 5.3.9	Medical Devices – Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements.	Atmospheric pressure limitation	Indicates the range of atmospheric pressure to which the medical device can be safely exposed.
	ISO 7000-2621	Graphic symbols for use on electrical equipment		To indicate the acceptable upper and lower limits of atmospheric pressure for transport and storage.