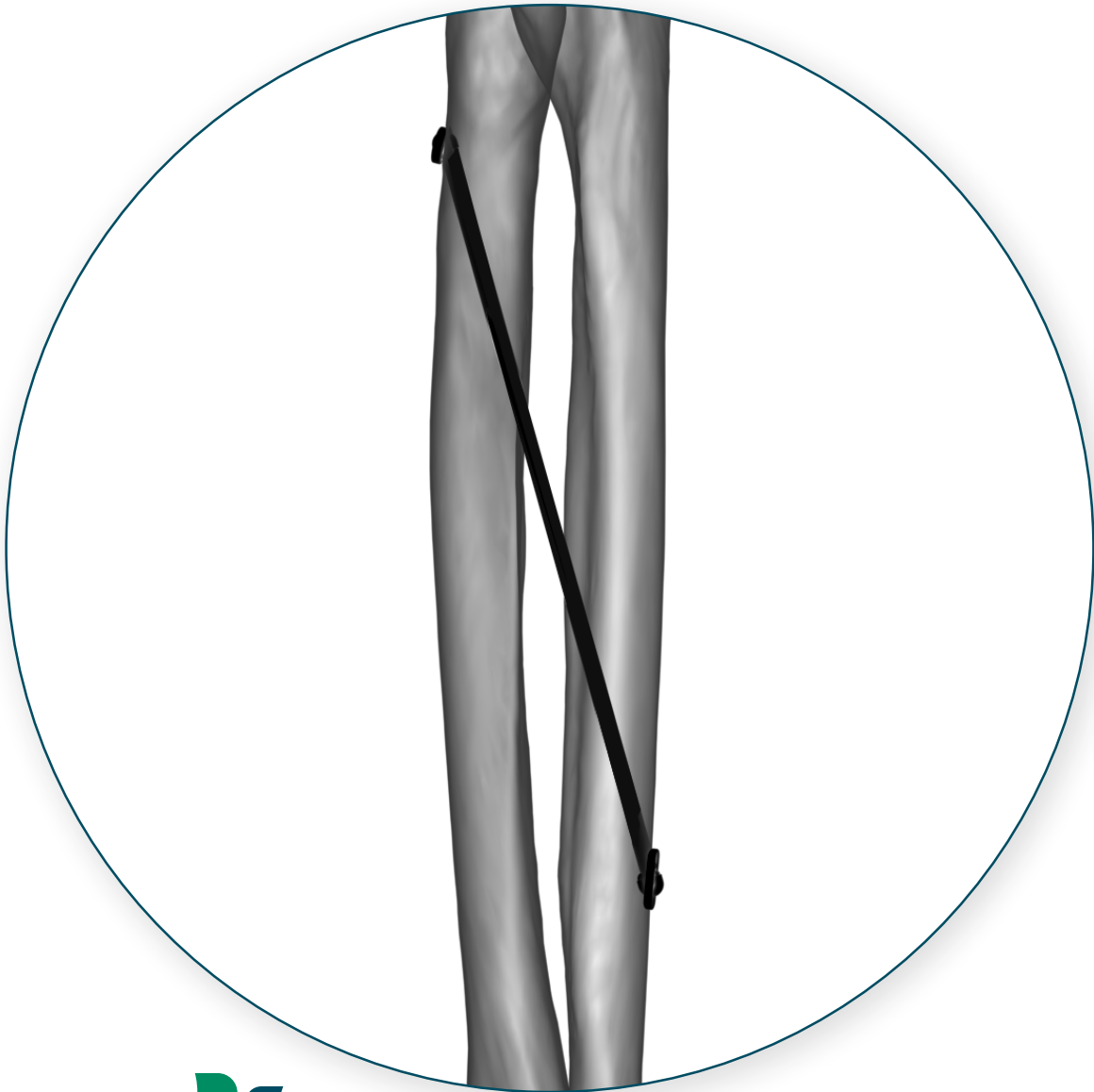


SURGICAL TECHNIQUE GUIDE

INTEROSSEOUS LIGAMENT RECONSTRUCTION



As described by:
Jorge L. Orbay, M.D.
Miami Hand & Upper Extremity Institute

INTEROSSEOUS LIGAMENT RECONSTRUCTION

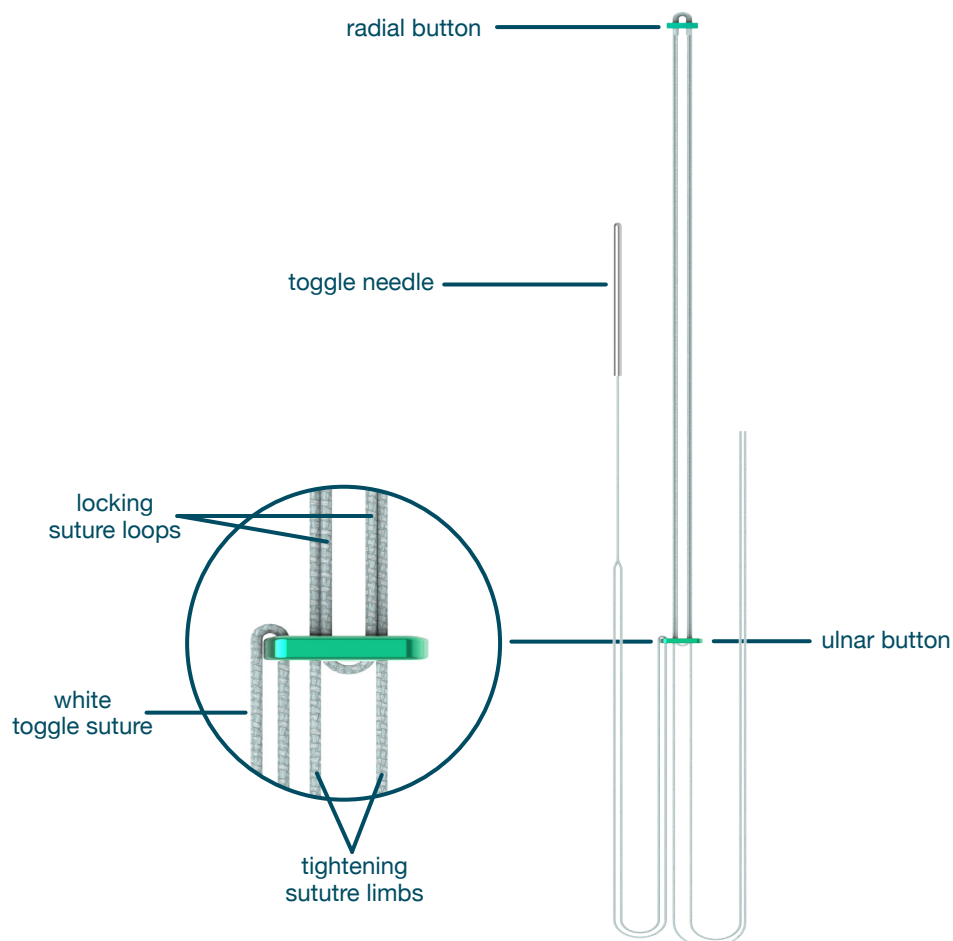
Description

The Skeletal Dynamics IOL Reconstruction system contains a suture-button construct that can be used for the repair or augmentation of the central band of the interosseous ligament associated with Essex Lopresti fractures. The system contains a custom angled drill guide assembly, suture and button assembly, suture tensioning device, suture passer, k-wire, cannulated drill, and a tissue protector.

The system implant is provided sterile. The instruments are provided non-sterile and sterilized at the user facility.

Indications for Use

The Suture Button Repair System is intended for fixation of bone and soft tissue in upper extremity orthopedic procedures requiring ligament or tendon reconstruction in the hand, wrist, forearm, elbow and shoulder.

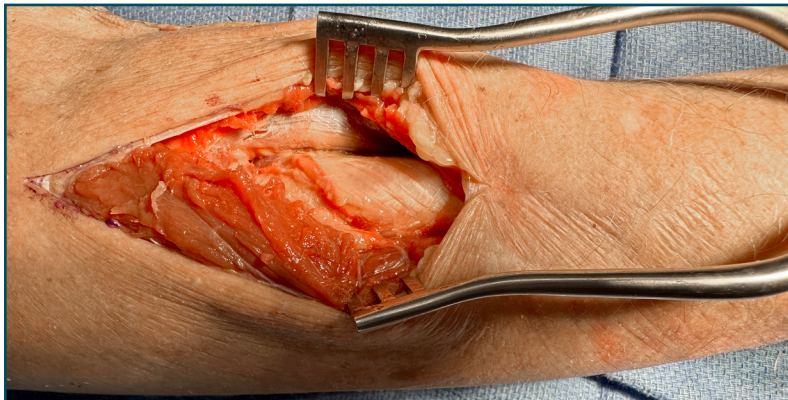


1

EXPOSURE – PROXIMAL RADIAL ATTACHMENT



At the proximal 1/3 of the radius, make a 4-6cm incision on the dorsal and lateral aspect of the forearm using a Thompson Approach. Identify the interval between the extensor digitorum communis and the extensor carpi radialis brevis (ECRB). Dissect and identify the pronator teres (PT) insertion at the radial shaft. The insertion of the central band on the radius is immediately proximal to this structure and on the opposite, sharp or medial edge of the radius.

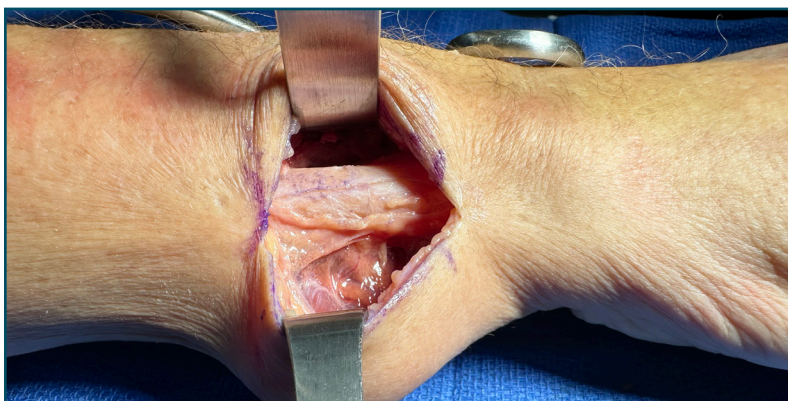


2

EXPOSURE – DISTAL ULNAR ATTACHMENT



Make an incision centered 6-8cm proximal to the styloid process over the subcutaneous border of the ulna.



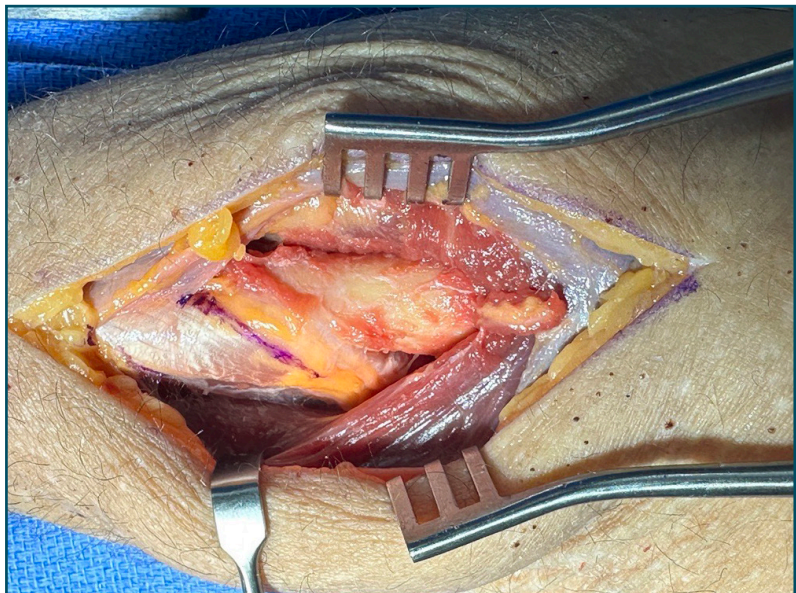
Identify the extensor carpi ulnaris (ECU) and flexor carpi ulnaris (FCU). Dissect between them and identify the distal origin of the central band on the opposite, lateral or sharp edge of the ulna.

Protect the posterior sensory branch of the ulnar nerve and the motor branches to EPL and EIP.

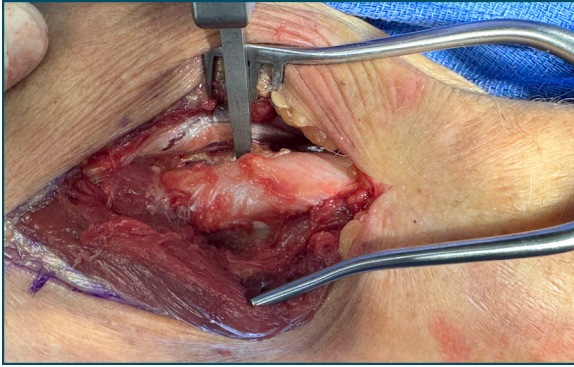
IDENTIFICATION OF ANATOMICAL LOCATION FOR DRILLING

4

Locate the central band's insertion on the proximal radius, which is just proximal to the pronator teres insertion. Once the location has been identified, use a marking pen to mark the desired tunnel location.



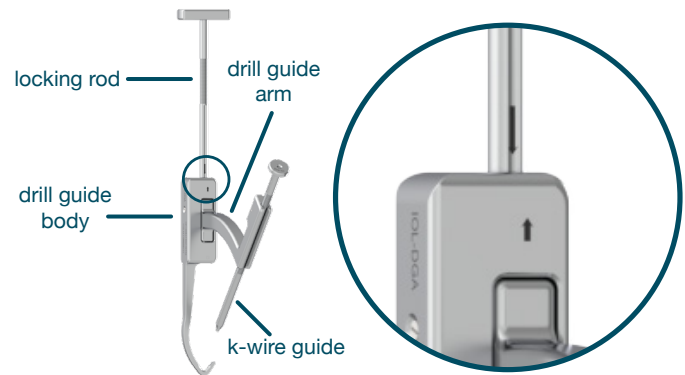
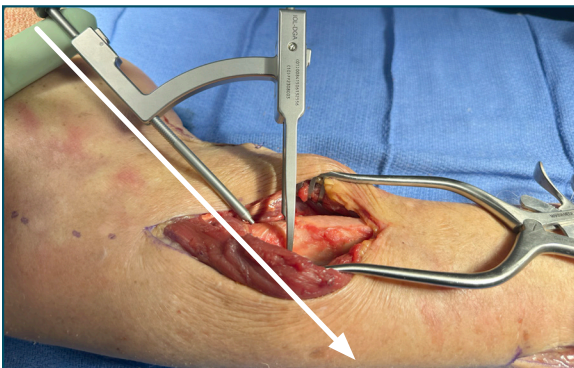
5 PROXIMAL RADIUS GUIDE POSITIONING



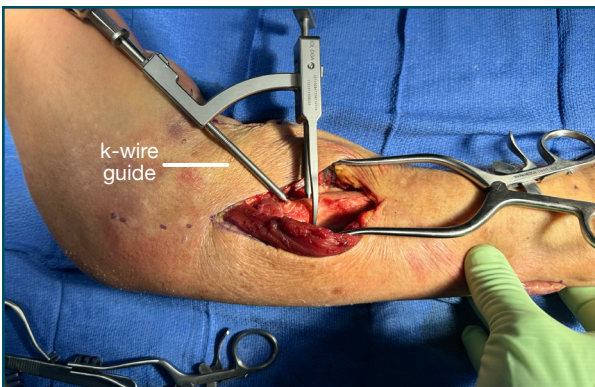
Fixate the hook of the IOL guide assembly proximal to the PT insertion, with the forearm in pronation. Use the locking rod to hold the guide in place. Insert the locking rod, aligning the laser etched arrows on the guide and rod. Ensure the guide arm is oriented in line with the IOL, from the proximal radius to the distal ulna.

Note:

If further compression is needed, rotate the head of the locking rod clockwise approximately 2-3 times.

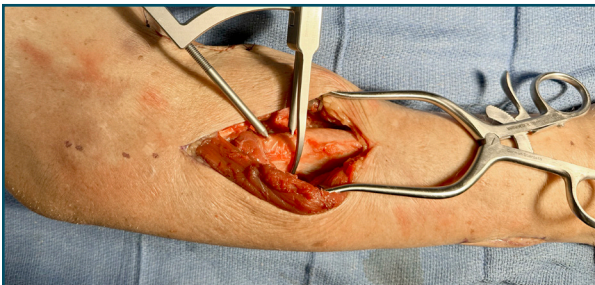


6 PROXIMAL RADIUS BONE PREPARATION



Ensure the k-wire guide is inserted into the IOL guide assembly. The k-wire guide should be secured against the surface of the radius.

Once the IOL guide assembly is fixed in place, insert the 1.4mm k-wire into the k-wire guide. The 1.4mm k-wire should be aiming in the direction of the distal ulna. Drill through both cortices of the radius. Disengage the locking rod by simultaneously pushing on the head and pressing the button. Remove the IOL guide assembly, leaving the 1.4mm k-wire in place and securing using a needle driver.



Confirm visually that the 1.4mm k-wire exits the radius at the medial sharp border.

Note:

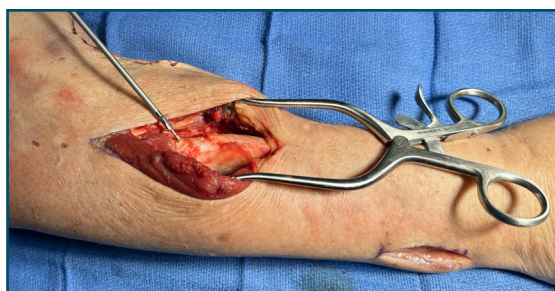
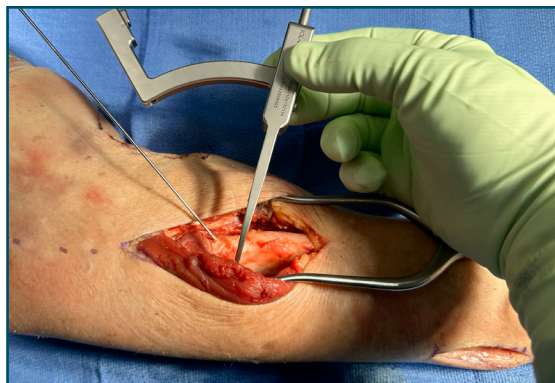
If additional compression was used, loosen the proximal portion of locking rod before disengaging.

PROXIMAL RADIUS TUNNEL PREPARATION

7

With the 1.4mm k-wire fixed in place, use the tissue protector and 3.5mm cannulated drill to create the radial tunnel. After drilling through both cortices of the bone, remove the 1.4mm k-wire.

If a tendon graft is to be used concomitantly, prepare a separate parallel tunnel for graft placement.



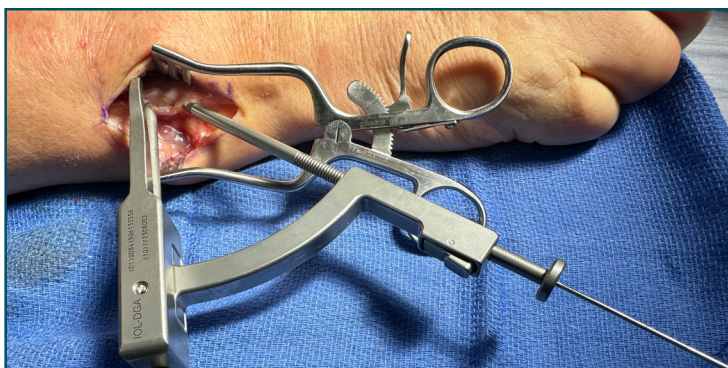
DISTAL ULNA GUIDE POSITIONING

8

Locate the distal insertion of the central band on the ulna for the IOL guide assembly placement. Place the guide hook at the distal insertion of the central band. Once the IOL guide assembly has been fixed in the desired position on the ulna, repeat steps 6-7 for drilling operations.

Note:

The IOL guide body and arm do not need to be re-assembled when switching from the radius to the ulna. The guide should only be re-assembled when used on the opposite arm side (left or right arm).



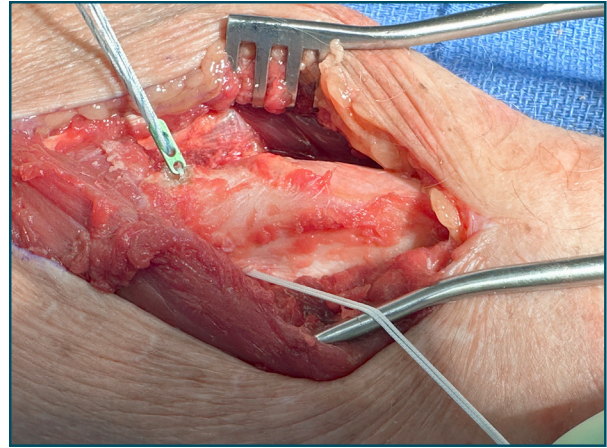
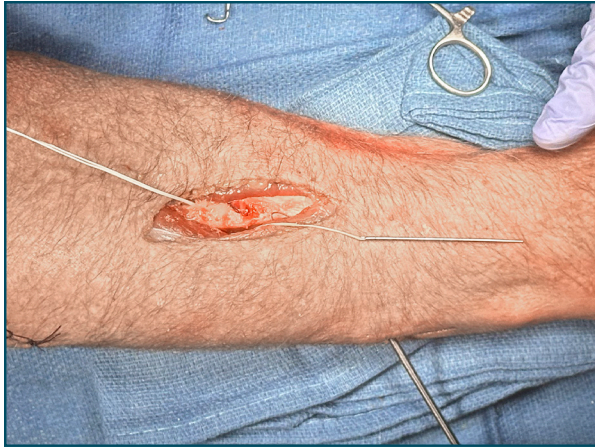
9

RADIAL TUNNEL BUTTON PASSAGE

Through blunt dissection, create a submuscular tunnel at the posterior aspect of the IOL to pass the suture from the radius to the ulna. After creating the radial tunnel, use the toggle needle and white suture to pass the ulnar button through the radial tunnel. Continue to hold the radial button until the ulnar button is placed in step 12. The suture assembly may be passed from radius to ulna or vice versa.

Note:

Maintain tension on both sides of the suture construct to prevent entanglement.



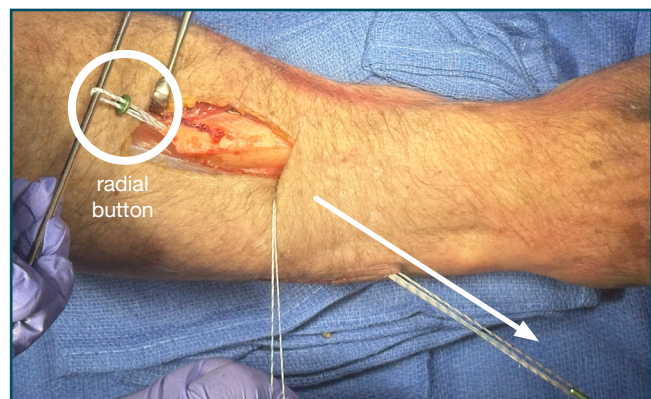
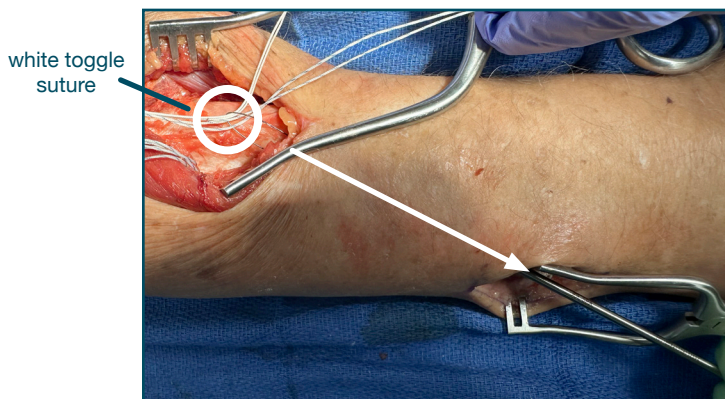
10

SUBMUSCULAR TUNNEL BUTTON PASSAGE

Insert the blunt end of the IOL suture passer into the radial incision and through the submuscular tunnel into the ulnar incision. Pass the white toggle suture through the nitinol loop on the IOL suture passer and pull back. Remove the IOL suture passer once the ulnar button is in position for passage through the ulnar tunnel.

Note:

Hold radial button during passage, maintain tension.



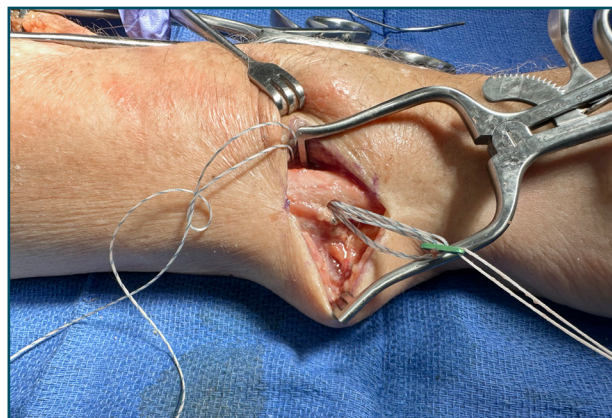
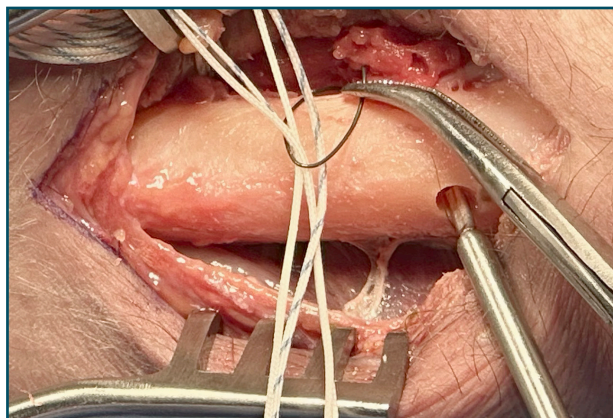
ULNAR TUNNEL BUTTON PASSAGE

11

Cut the toggle needle from the suture construct. Repeat step 10, using the suture passer to retrieve the white toggle suture through the ulnar bone tunnel.

Note:

Hold radial button during passage, maintain tension.



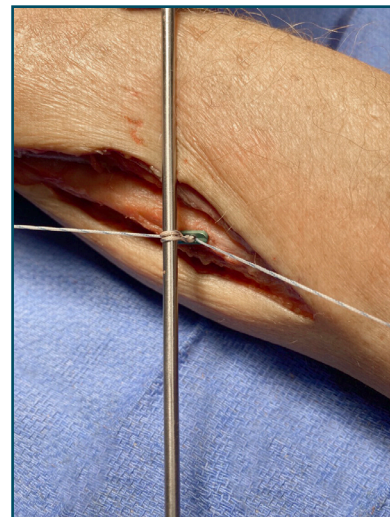
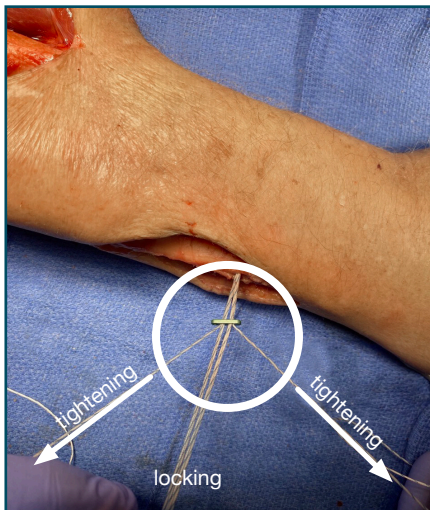
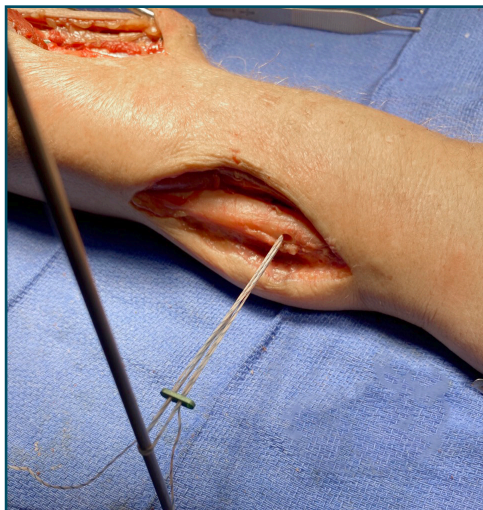
ULNAR BUTTON PLACEMENT

12

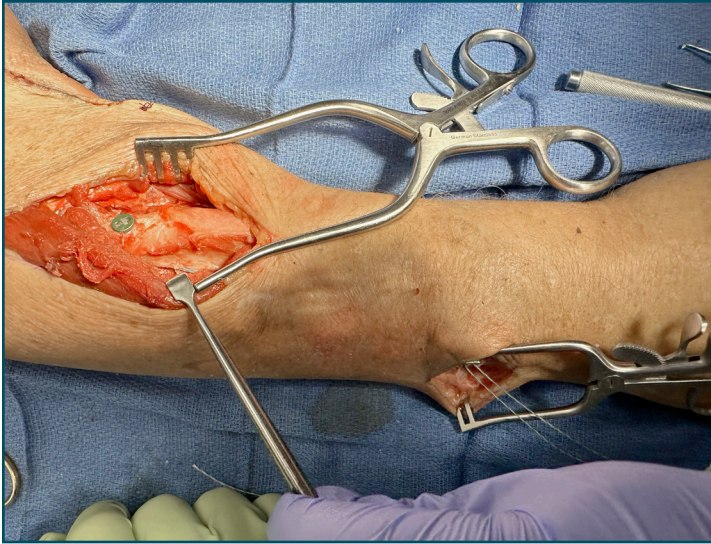
Retrieve the tightening suture limbs and separate the two locking suture loops away from the button holes, using the suture passer. While holding the two looped suture ends in place, push the ulnar button towards the bone until it sits flush on the bone surface. Alternating between each limb, simultaneously pull on each tightening limb until the locking suture loops are fully seated against the button.

Note:

Ensure the locking suture loops are not wrapped or tangled with the tightening suture limbs prior to tensioning. Verify the suture is fully taught, applying adequate tension.



13 PRELIMINARY SUTURE TIGHTENING



The locking suture loop can then be released, maintaining compression against the button surface. Care should be taken not to overtighten in acute cases as you may provide excessive negative ulnar variance. Use fluoroscopic imaging to confirm ulnar variance and button position.

Elevate and retract the surrounding soft tissues, ensuring the suture loops in the submuscular tunnel are fully taught.

Note:

Take care not to overtighten the suture at this stage. Before final tensioning is achieved, confirm proper button positioning.

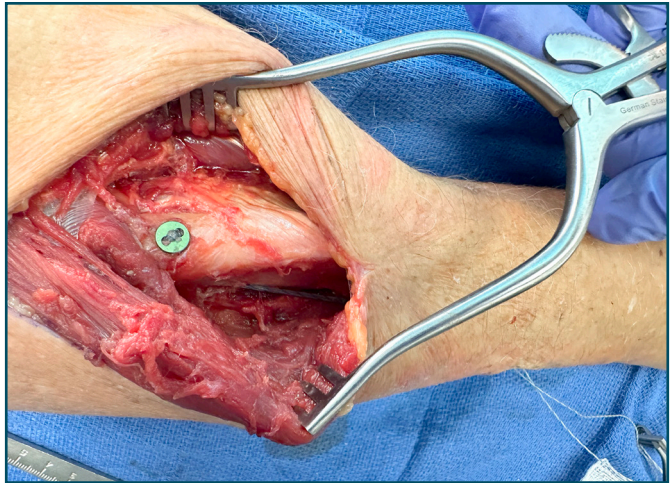
14 SUTURE TENSIONING

If neutral variance is not reached, tension the suture by pulling further on the two free tightening suture ends. If it is not possible to restore ulnar variance by hand tensioning, use the suture tensioner as described in steps 16 and 17.

FINAL CONFIRMATION

15

After the suture button assembly has been adequately tightened and confirmed fluoroscopically, rotate the forearm in pronation and supination to examine range of motion. After final confirmation, tie a series of knots based on surgeon preference.



SUTURE TENSIONER PREPARATION

16

If suture tensioning was achieved by hand, skip steps 17 and 18. If use of the suture tensioner is required, place the tensioner over the button using the recessed hole in the tensioner. Once the recessed hole is flush against the button, wrap both tightening suture ends through the spindle and lock the suture in place using the cleat on the tensioner.

Note:

The suture tensioner should only be used if proper tightening could not be achieved by hand.

17 SUTURE TENSIONING OPERATION

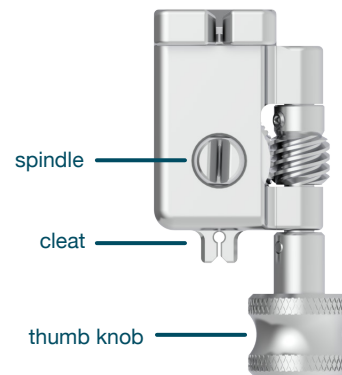


tightening
suture limbs

Use the thumb knob on the suture tensioner to further tension the suture. The thumb knob should be turned clockwise to tighten. Take care not to turn the thumb knob excessively to prevent over tensioning. A series of turns should be completed, while evaluating the tensioning in between turns. Fluoroscopy may be used as tensioning is being completed to prevent overtightening.

Warning:

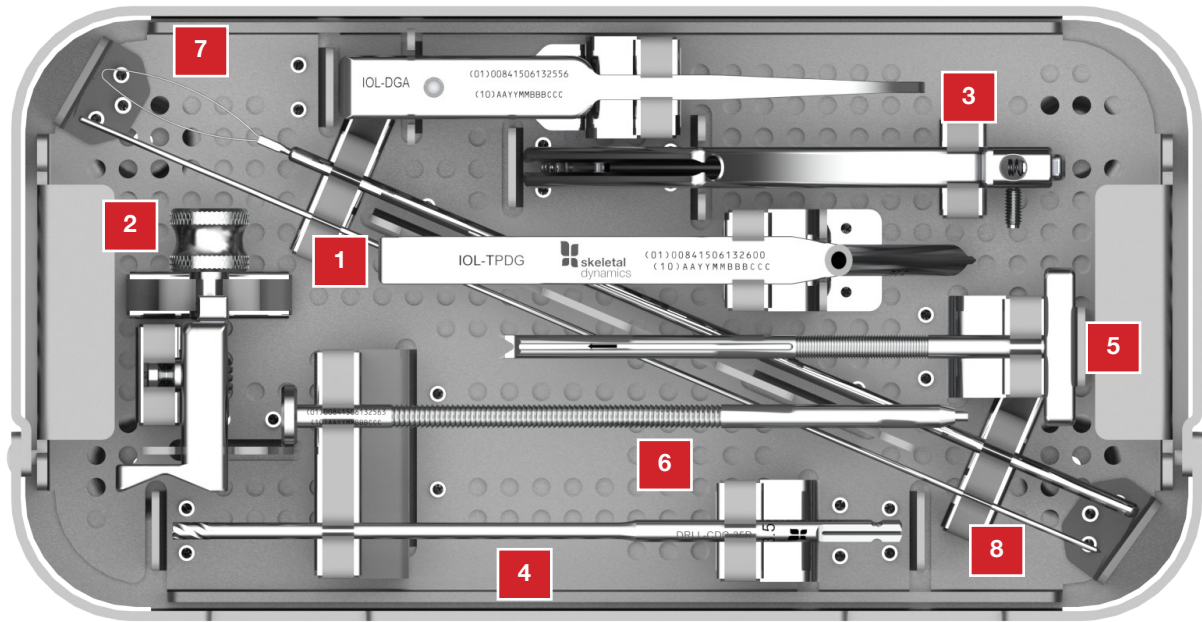
If the suture tensioner is turned excessively, suture rupture may occur.



18 CLOSURE

Close the wound per surgeon's preference.

INSTRUMENT TRAY



Loc #	Catalog #	Description
1	IOL-TPDG	Tissue Protector, 3.5mm, IOL
2	IOL-STA	Suture Tensioner Assembly
3	IOL-DGA	IOL Guide Assembly
4	DRLL-CDC-35	Drill, 3.5mm, Cannulated, IOL
5	IOL-LRA	Locking Rod
6	IOL-KGA	K-Wire Guide
7	IOL-SPA	IOL Suture Passer
8	KWIR-IOL-14222	K-Wire, 1.4mm x 222mm, Single Diamond Tip



Loc #	Catalog #	Description
1	IOL-SBA	#2 Suture Button Assembly, IOL



skeletal dynamics®
UNDERSTANDING THE UPPER EXTREMITY

