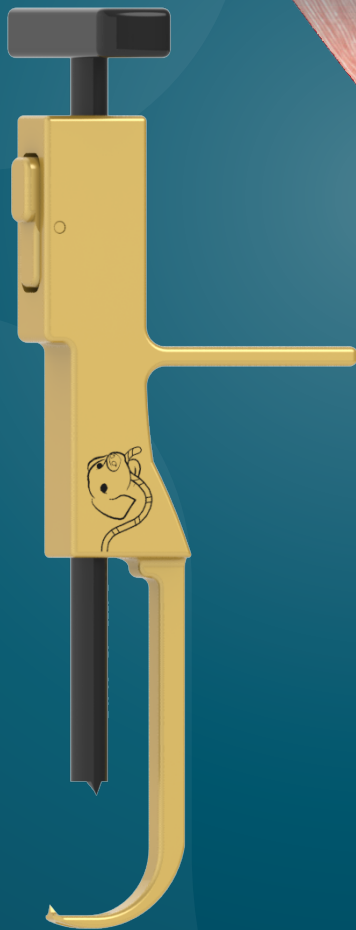


SURGICAL TECHNIQUE GUIDE

supin^X[™]

DISTAL BICEPS REPAIR



As described by:
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Miami Hand & Upper Extremity Institute





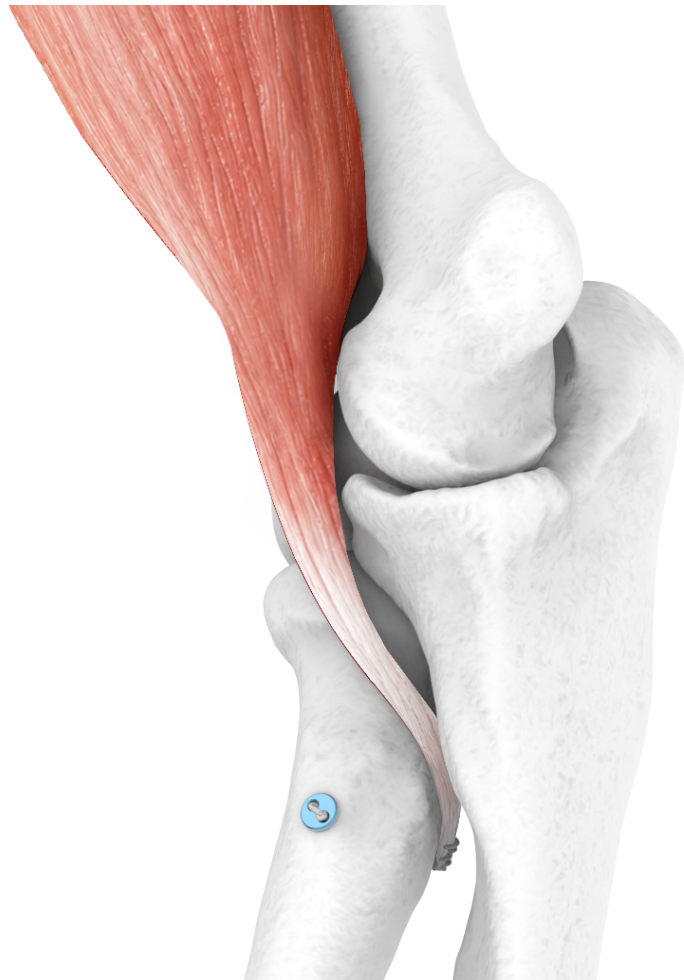
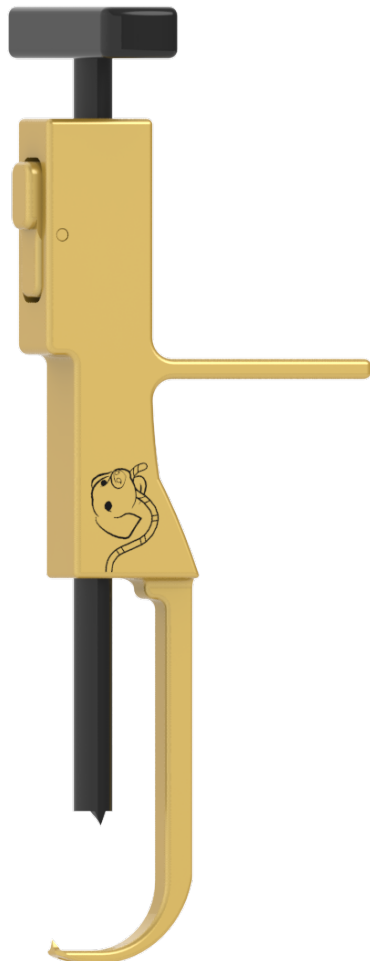
DISTAL BICEPS REPAIR

Description

The Supin-X Distal Biceps Repair System provides the user the ability to repair a distal biceps rupture to its anatomical insertion point. This can be completed with a single head repair technique, or a double head repair technique. The system consists of a Suture Passing Needle and a custom Drill Guide (Golden Retriever) used to re-attach the biceps tendon on the dorsal aspect of the bicipital tuberosity through a single incision. The implant is a titanium button with #2 UHMWPE suture to reattach the distal biceps tendon.

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.

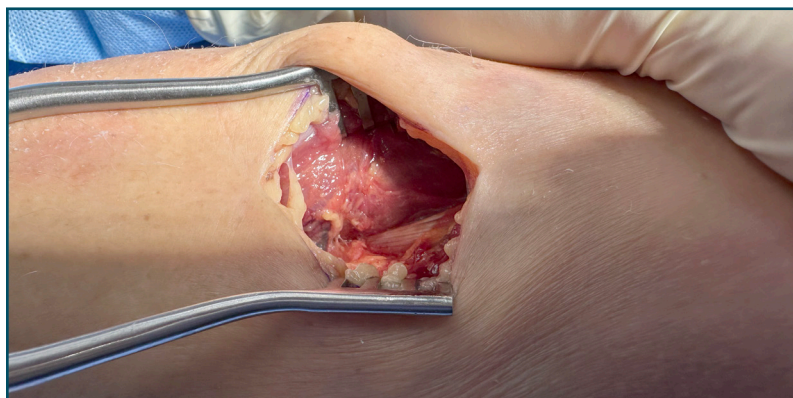


1

EXPOSURE DETAILS

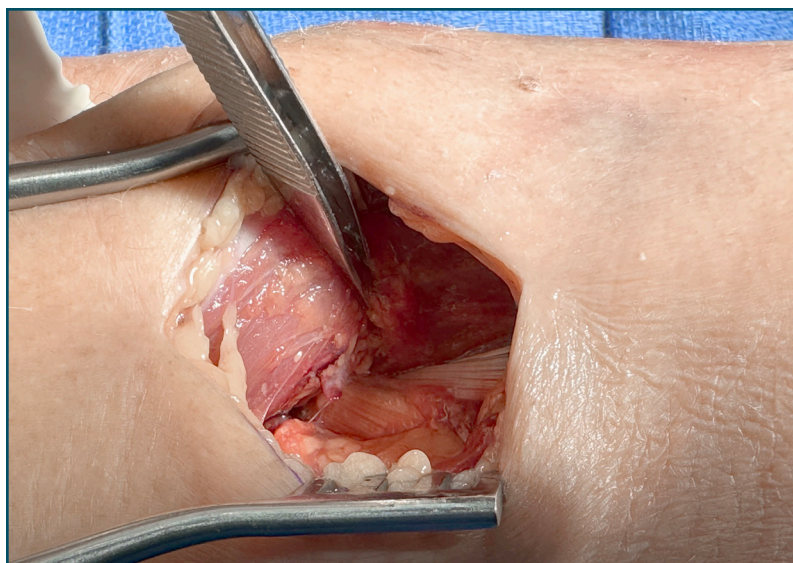


Position the patient with their arm on a hand table in full extension and supination. Make a 4-5cm longitudinal incision approximately 2cm distal to the elbow crease and expose the subcutaneous tissues.



2

SUPERFICIAL EXPOSURE



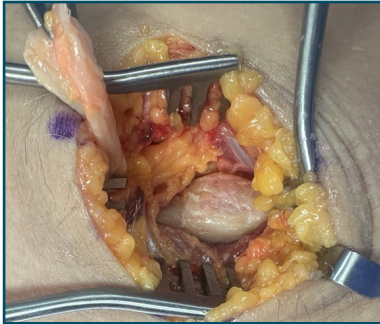
Use caution to identify and release the lateral antebrachial cutaneous nerve and retract laterally. Identify and retract the brachioradialis laterally.

Note:

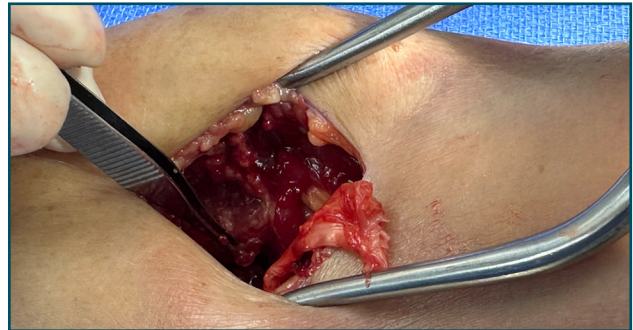
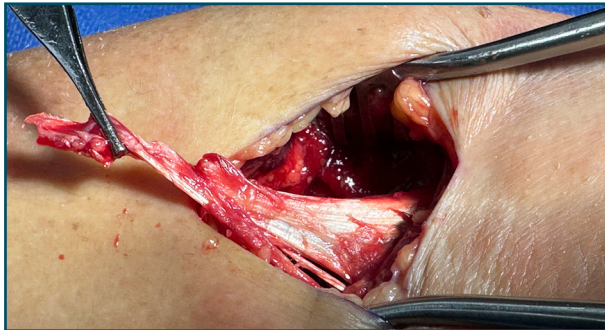
Identify and protect the nerves and vasculature.

DEEP EXPOSURE

3

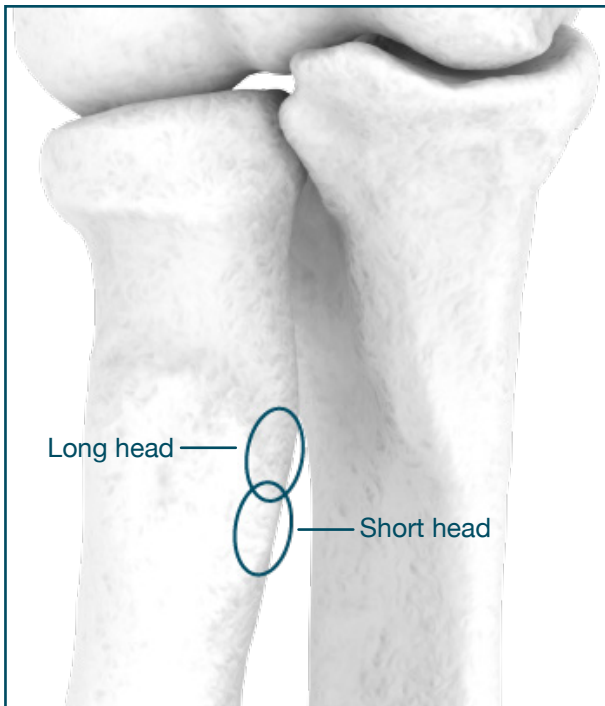


Identify the ruptured distal biceps tendon. Use a blunt retractor to allow for exposure above the elbow crease. Once located, grasp the tendon and pull it distally, freeing it from surrounding adhesions.



BICEPS TENDON PREPARATION (SHORT AND LONG HEAD REPAIR)

4



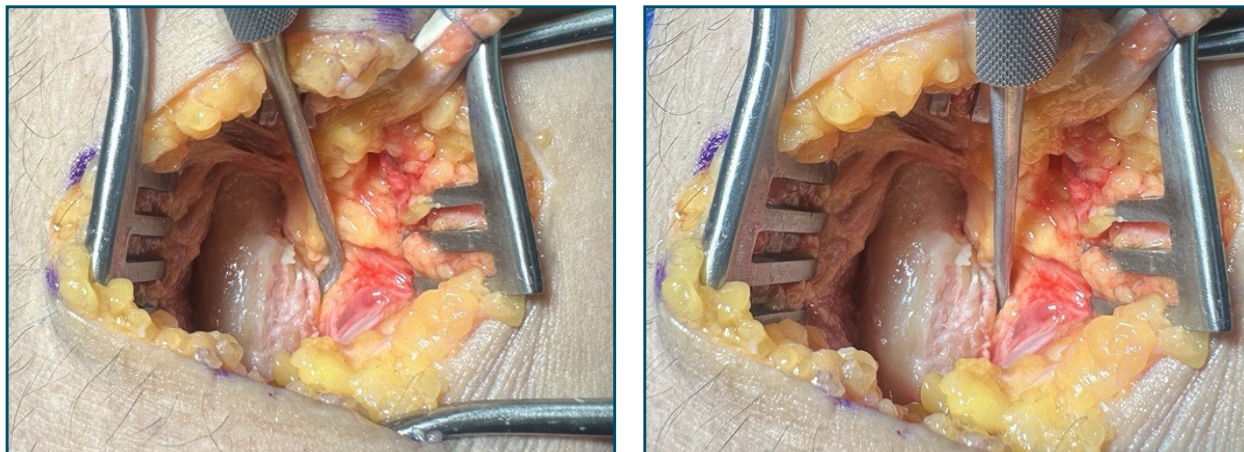
Note (Double head repair):

The Supin-X Distal Bicep Repair system allows the repair of each head (short and long) individually to accomplish an anatomical repair. However, if a single suture repair technique is preferred, skip to Step 5.

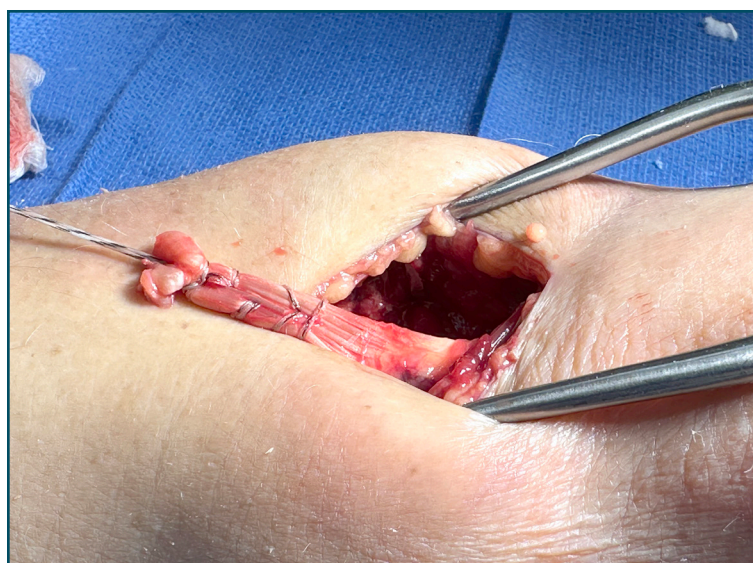
Identify the short and long head of the distal biceps tendon. The short head runs more medial in the arm and inserts distally on the bicipital tuberosity. The long head runs more lateral in the arm and inserts proximally on the bicipital tuberosity. Use the White-Blue #2 Suture and White-Black #2 Suture to whipstitch the individual tendon heads spanning approximately 2cm in length. (Color preference can be determined by the surgeon. Each suture color can be used interchangeably.)

5 BICIPITAL TUBEROSITY PREPARATION

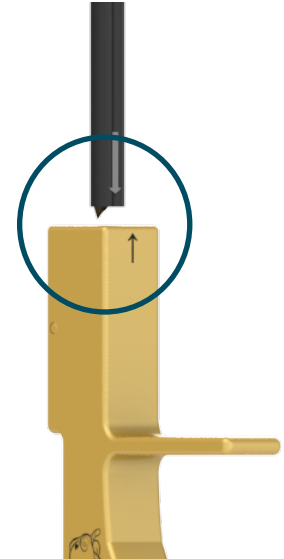
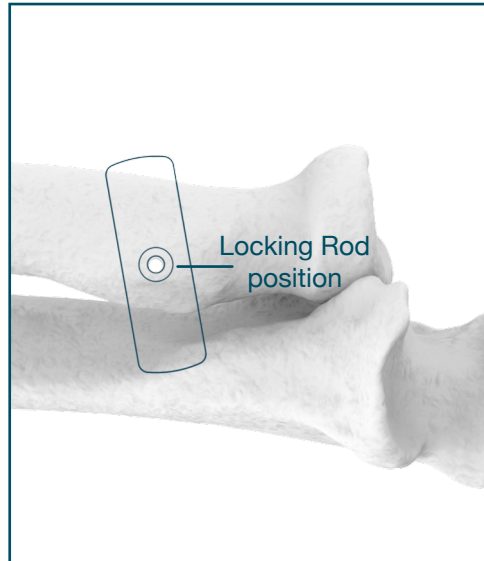
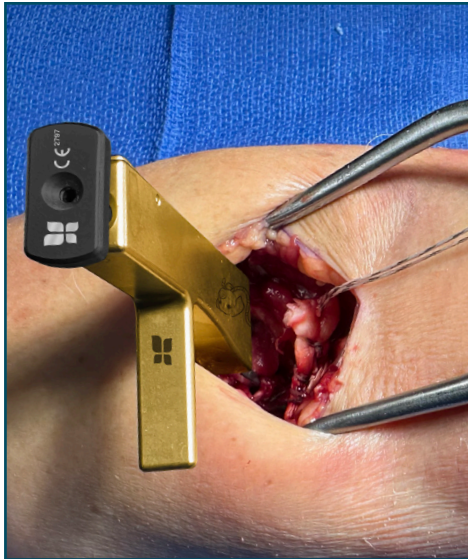
Use the Volar Capsule Elevator to elevate the distal tendon fibers, periosteum, and soft tissue opposite to the tuberosity.



6 BICEPS TENDON PREPARATION (SINGLE SUTURE REPAIR)



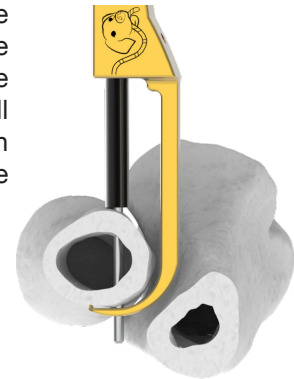
Use the #2 Suture Loop to prepare the tendon using a whipstitch technique spanning approximately 2cm in length.



Rotate the forearm to approximately 45 degrees of supination and slide the Drill Guide (Golden Retriever) between the radius and ulna at the level of the bicipital tuberosity. Pronate the forearm until the tuberosity contacts the guide. Insert the Locking Rod, aligning the laser etched arrows on the Drill Guide and Locking Rod. Use the Locking Rod to lock the guide in place at an approximately neutral position. If further compression is needed, rotate the head of the Locking Rod clockwise 2 times.

Caution:

Do not over-torque Locking Rod.



PILOT HOLE PREPARATION

8

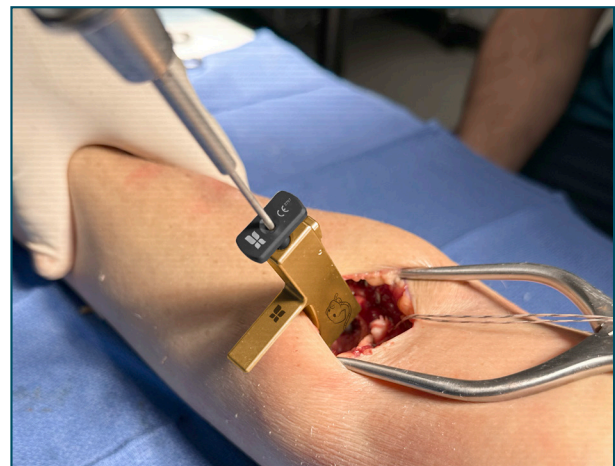
Insert the 2.0mm Drill Bit into the Locking Rod of the Drill Guide from the anterior side of the radius and create a bi-cortical bone tunnel. Make sure the drill clears the far cortex. Leave the Drill Guide and Locking Rod locked, in preparation for the Suture Passing Needle.

Note (Double head repair):

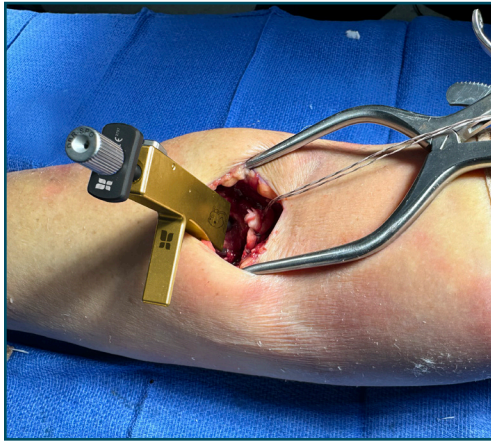
If the short and long head repair is being completed, repeat this step a second time. Ensure the bone tunnels created are approximately 12mm apart to prevent fracture or splitting of bone.

Warning:

When drilling through far cortex of tuberosity, beware of drill depth. Ensure the 2.0mm Drill Bit does not damage soft tissue.



9 INSERTING THE SUTURE PASSING NEEDLE



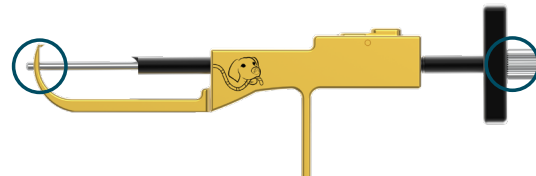
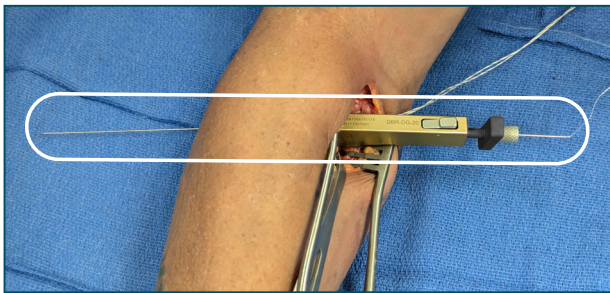
Insert the Suture Passer Guide into the Locking Rod of the Drill Guide until it has passed through both cortices and the slot on the Drill Guide tip (see rendering below). Ensure the thick portion of the Suture Passer Guide is flush with the Locking Rod (see rendering below). Position the elbow in approximately 45 degrees of flexion to allow for the identification and removal of the 2-0 Suture Passing Needle. Use a marking pen to mark the straight portion of the suture on the Suture Passing Needle. Insert the 2-0 Suture Passing Needle into the Suture Passer Guide and pass it through until the needle pierces the skin on the opposite side of the forearm.

Note:

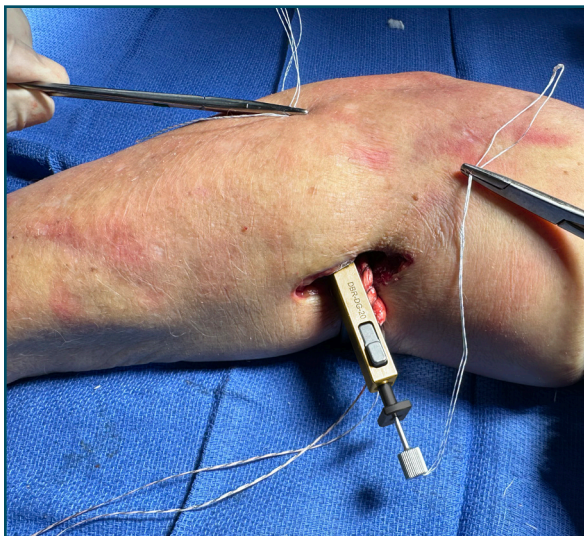
Ensure the Suture Passer Guide is flush with the Locking Rod.

Note:

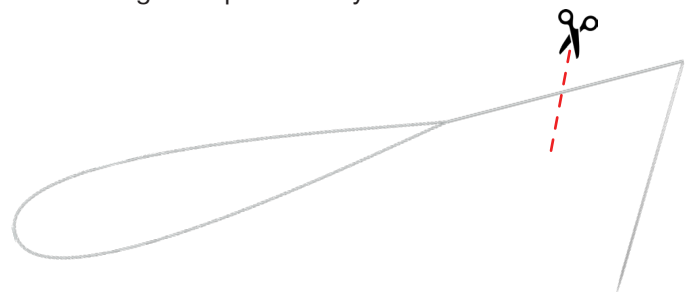
Ensure the Suture Passing Needle does not hit the ulna upon exit. To avoid this collision, use fluoroscopy to ensure the arm is pronated enough to allow the Suture Passing Needle to exit the skin.



10 PREPARING SUTURE RETRIEVAL



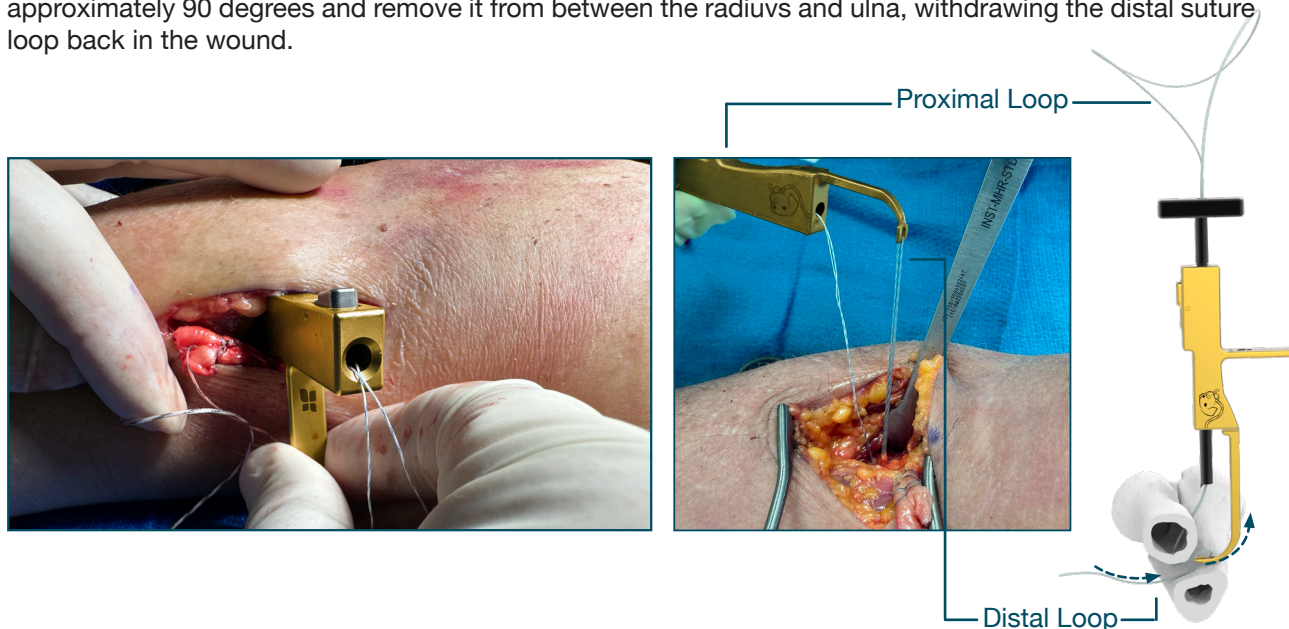
Pull on the Suture Passing Needle until approximately 10-12cm of the suture are through the dorsal surface. Proceed to cut the suture, halfway above the Passing Needle (see rendering below). Grasp the suture limbs on both the anterior and posterior side of the forearm with hemostats or a needle driver to prevent the suture from sliding back prematurely.



REMOVING THE SUTURE PASSER GUIDE AND DRILL GUIDE

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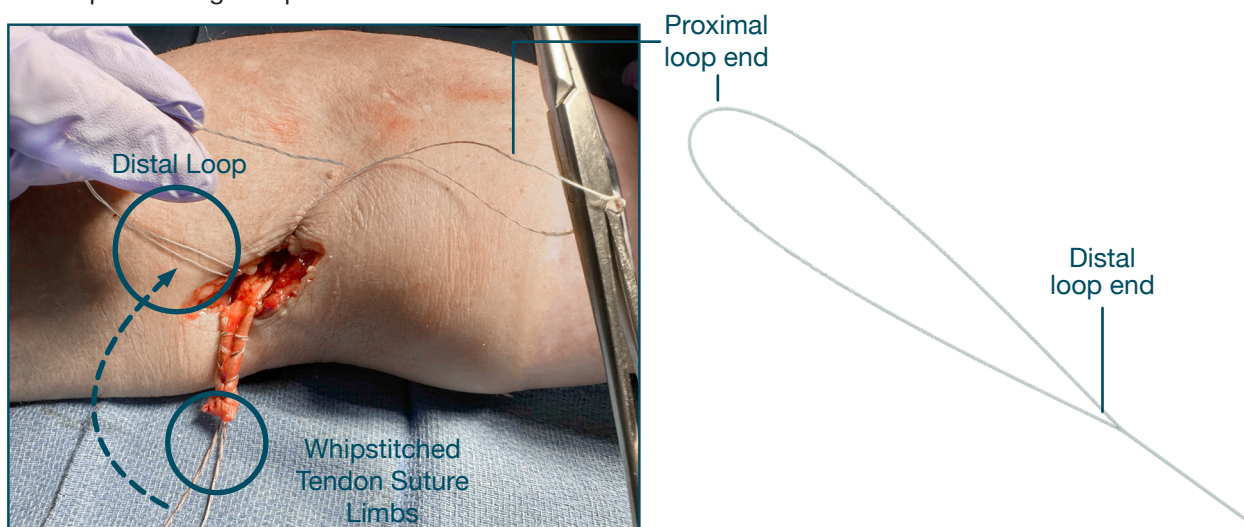
Carefully remove proximal hemostat and remove the Suture Passer Guide from the Drill Guide. Disengage the Locking Rod by simultaneously pushing down on the head of the Locking Rod and pressing the button on the Drill Guide body. If additional compression was used, loosen the proximal portion of Locking Rod before disengaging. Remove the Locking Rod. Carefully remove distal hemostat and rotate the Drill Guide approximately 90 degrees and remove it from between the radius and ulna, withdrawing the distal suture loop back in the wound.



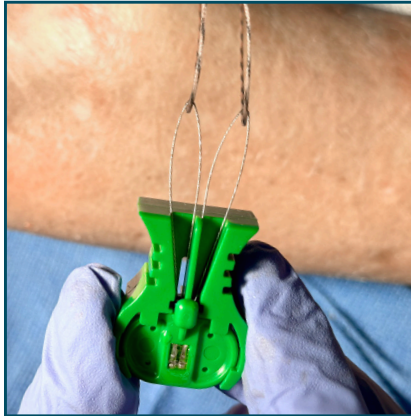
PASSING THE TENDON SUTURE

12

Pass the two Whipstitched Tendon Suture Limbs from the tendon stump through the distal loop (see rendering). This suture loop can be identified as the marked distal loop of the suture construct. Pull the proximal suture loop through the bone tunnel from the dorsal to the anterior aspect. Ensure the head of the tendon has been pulled down to the anatomical insertion site. Repeat this step if the double-head technique is being completed.



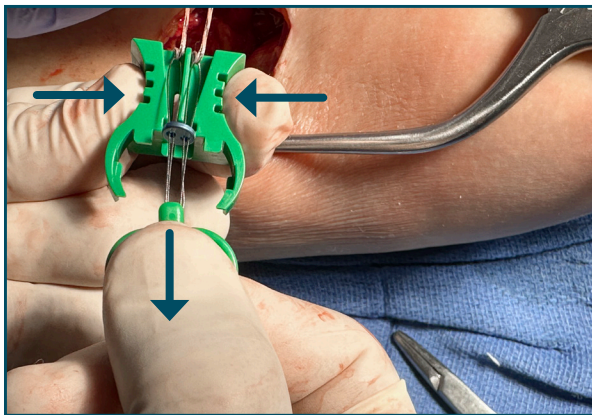
13 THREADING THE BUTTON



Once the sutures have been passed through the bone tunnel, use the green Button Threader to pass the Whipstitched Tendon Suture Limbs through the button holes. Load each nitinol loop separately and hold the green button threader with two fingers, while simultaneously grabbing and pulling the green tab back.

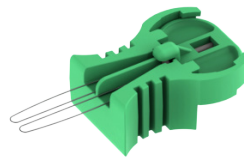
Note:

Do this step slowly and slide the button down on the suture as needed.



Note:

Save the green button threader if using the Knot Pusher is preferred. The tab can be used to load the suture to the Knot Pusher.



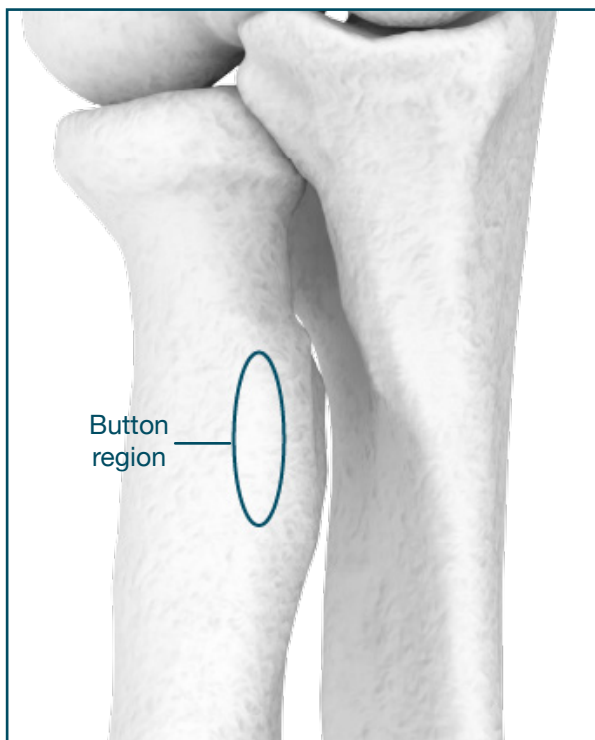
KNT-PSH, Knot Pusher

14 CYCLING THE FOREARM TO PREVENT SUTURE CREEP

Position the elbow in approximately 90 degrees of flexion while holding the suture limbs. Apply tension to the suture limbs while rotating the forearm in pronation and supination.

CONFIRMING BUTTON POSITION PRIOR TO FINAL TIGHTENING

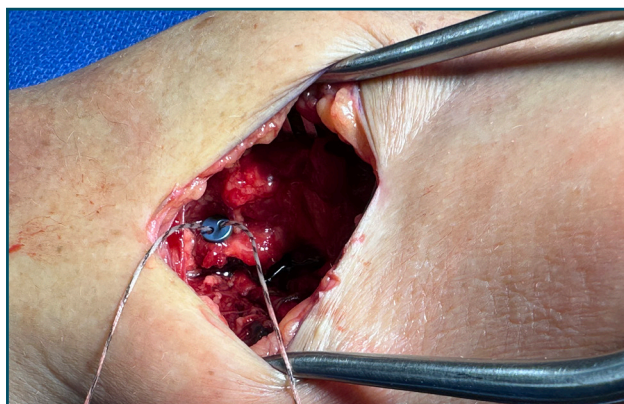
15



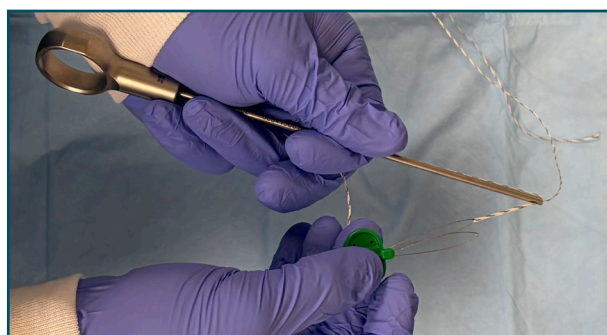
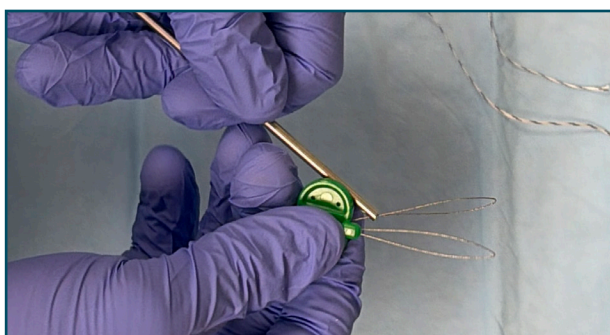
Provisionally lock the suture using a half hitch knot. Confirm that the button position is down on the bone surface. Apply tension to the suture limbs with the elbow in approximately 90 degrees of flexion. Use 6-7 half hitch knots to lock the suture. Confirm proper ROM.

Note:

A Knot Pusher is provided in the set to assist with tying secure knots as needed.



KNT-PSH, Knot Pusher



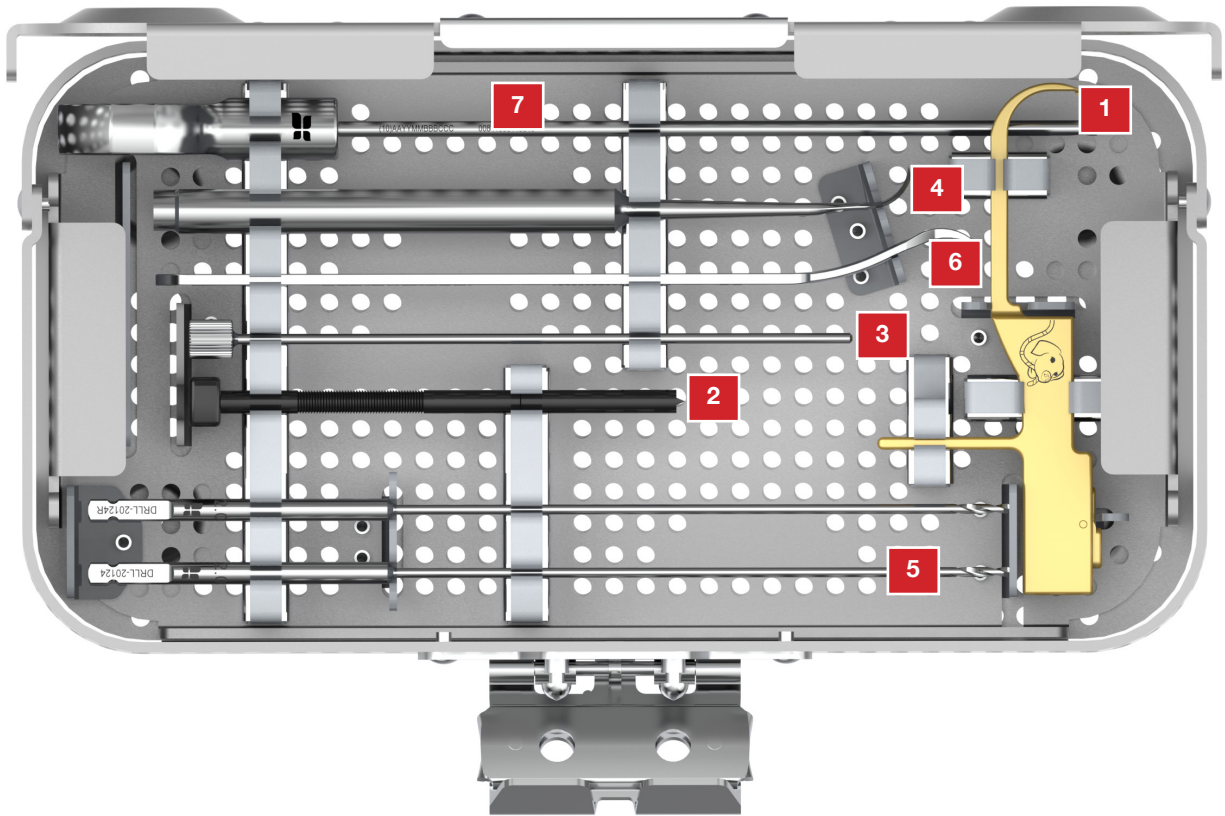
As needed, wet the suture tips to make it easier to pass the suture through the Knot Pusher hole. The disposable green threader tab can also be saved and used to load the suture into the Knot Pusher before tying the knot.

CLOSURE

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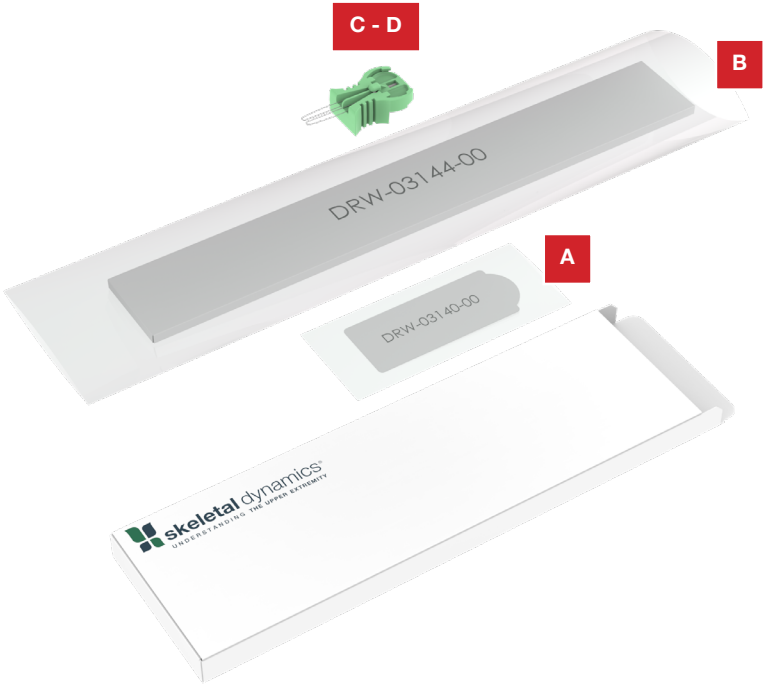
Close the wound per surgeon's preference.

INSTRUMENT TRAY



1	DBR-DG-20	Drill Guide
2	DBR-DG-LR	Drill Guide Locking Rod, Distal Biceps Repair
3	DBR-SPG	Suture Passer Guide
4	STX-VCE	STABLYX, Volar Capsule Elevator/Shoehorn
5	DRLL-20124	Distal Biceps Drill, 2.0mm x 124mm
6	INST-MHR-STD	Instrument, Mini-Hohmann Retractor, Standard
7	KNT-PSH	Knot Pusher

STERILE DISTAL BICEPS KIT



Loc # Catalog # Description			Loc # Catalog # Description		
1	DBR-BLU-01	Distal Biceps Repair, Sterile Kit, Blue	2	DBR-BLK-01	Distal Biceps Repair, Sterile Kit, Black
1a		#2 Suture Loop, ST Needle, White-Blue/Black	1a		#2 Suture Loop, ST Needle, White/Black
1b		2-0 Suture Passing Needle Assembly	1b		2-0 Suture Passing Needle Assembly
1c		Button Threader Assembly	1c		Button Threader Assembly
1d		Circular Button, #2 Suture	1d		Circular Button, #2 Suture

