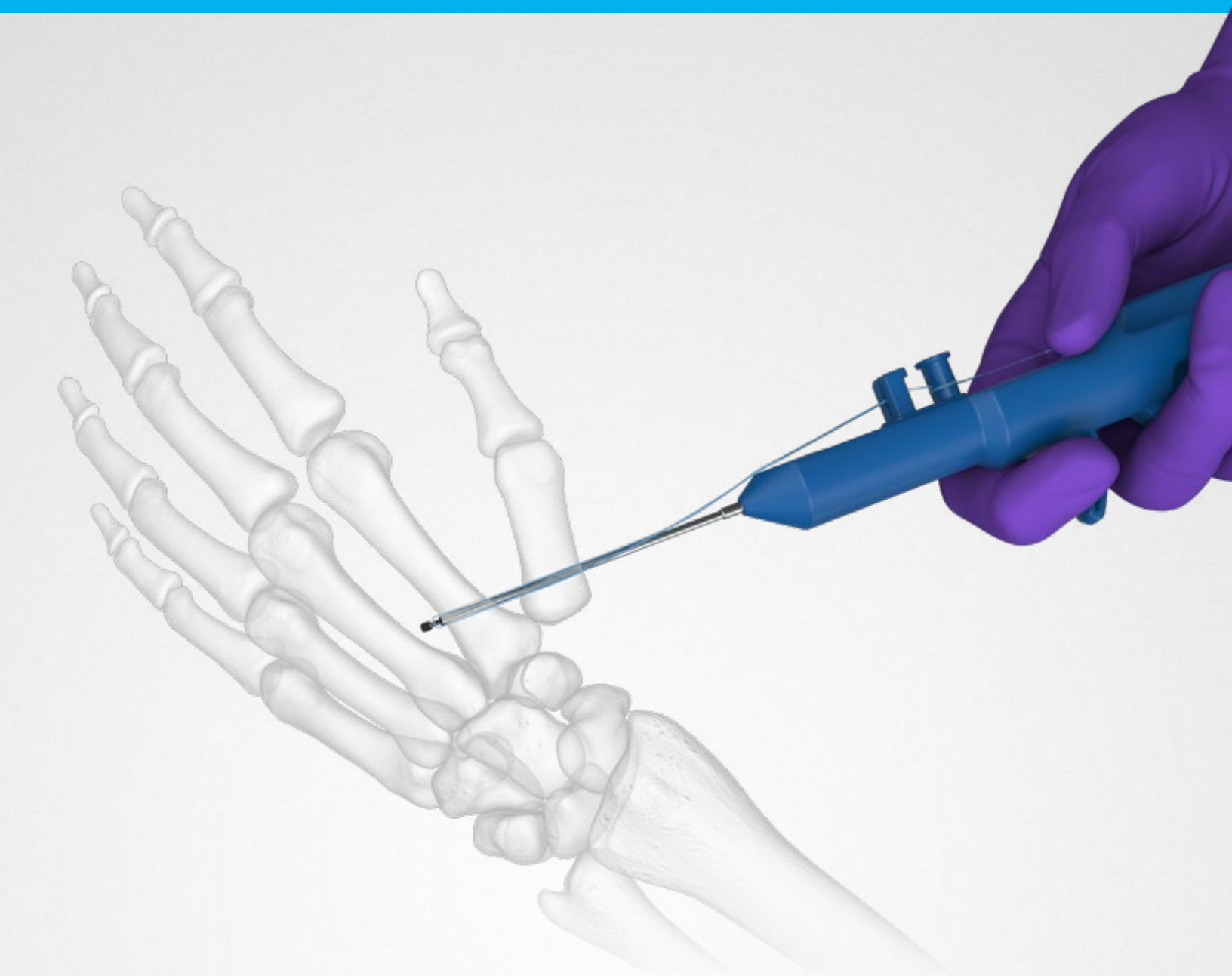
acumed®

Acu-Sinch® Knotless Mini System

Carpometacarpal Suspensionplasty

Surgical Technique



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Acumed® is a global leader of innovative orthopaedic and medical solutions.

We are dedicated to developing products, service methods, and approaches that improve patient care.

Acumed Acu-Sinch® Knotless Mini System

With an aging population, the incidence of symptomatic thumb carpometacarpal joint arthritis (CMC) is on the rise. The incidence is higher in women overall, with 25% of post-menopausal women and over 40% of women aged greater than 70 years presenting with symptomatic carpometacarpal joint arthritis. The thumb CMC joint is second only to the distal interphalangeal joint as the most common arthritic joint in the hand.

The thumb CMC joint is described as a saddle joint allowing multiple arcs and planes of motion. Surgical goals have focused on providing pain relief while maintaining motion and improving grip and pinch strength. Trapeziectomy with or without ligament reconstruction and tendon interposition (LRTI) have been advocated to as surgical treatment of choice for patients with debilitating CMC joint arthritis. Newer treatment methods to suspend the thumb metacarpal via a suture button suspensionplasty (SBS) have also shown favorable clinical results with superior biomechanical strength. It is the biomechanical superiority that may allow patients to achieve a successful outcome earlier and thus reduce their overall recovery time, returning to work and sport activities sooner.

The Acumed Acu-Sinch Knotless Mini was designed in conjunction with Drs. David Ruch, Jerry Huang, and Ryan Garcia as an alternative SBS to stabilize and suspend the thumb metacarpal following trapeziectomy. Innovative drill design incorporates a recession element that maintains the suspension and allows the Acu-Sinch Knotless Mini device to pass along the drill track. Once deployed, the unique design employs a simple method to tighten and sinch the suture material without bothersome suture knots.

	Definition
Warning	Indicates critical information about a potential serious outcome to the patient or the user.
Caution	Indicates instructions that must be followed in order to ensure the proper use of the device.
Note	Indicates information requiring special attention.

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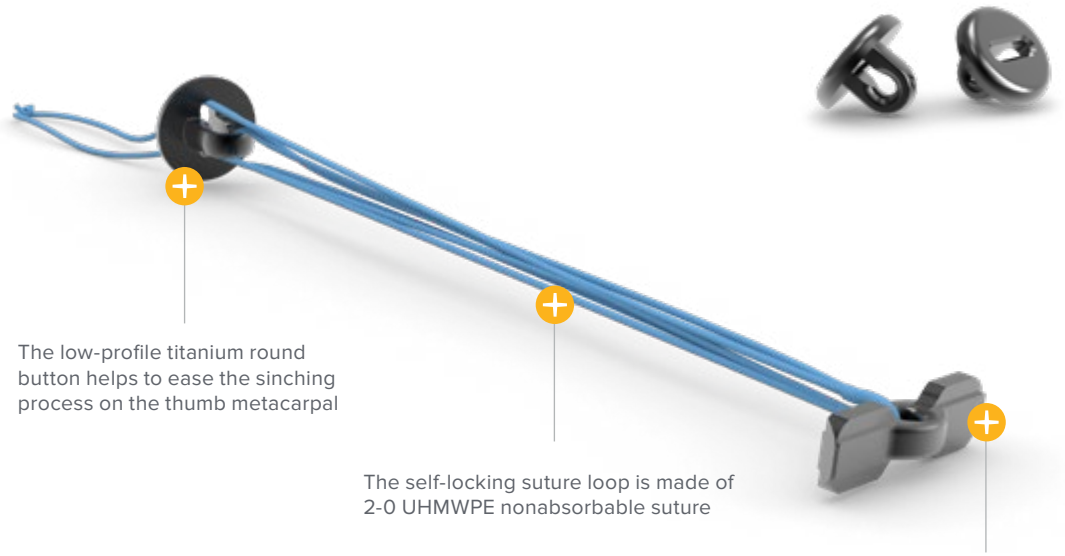
System Features

Acu-Sinch Knotless Mini System

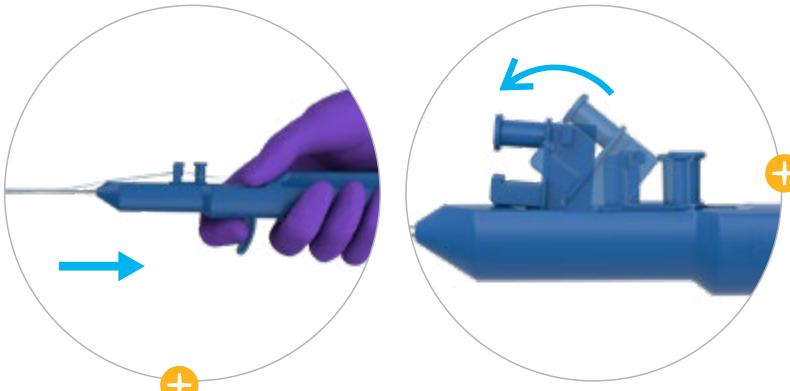
Round Buttons 4.1 mm



The low-profile titanium round button helps to ease the sinching process on the thumb metacarpal

The self-locking suture loop is made of 2-0 UHMWPE nonabsorbable suture

The titanium Flip-Button is designed to pass through the 2.3 mm bone tunnel and is engaged by simply pulling the trigger on the inserter handle



Suture carriage automatically deploys the flip-button and unfurls the suture as the user pulls the inserter handle

The trigger-operated, spring-loaded inserter handle enables the Flip-Button to deploy on the far cortex of the index metacarpal, obviating the need for manual flipping

The entire Acu-Sinch Knotless Mini System is sterile packed and disposable

System Features [continued]

A central ejector shaft facilitates button flipping

Fluoroscopy can be used to visualize the “indicating window” on the suture button prior to engaging the flip mechanism

The Acu-Sinch Knotless Mini System provides a slotted distal end design that allows for the maintenance of the drill tunnel alignment while passing the button and the suture

Indications for Use:

Acu-Sinch Knotless Mini System, when used for fixation of bone to bone or soft tissue to bone, is intended as a fixation post, a distribution bridge, or for distributing suture tension over areas of ligament or tendon repair. Specifically, the Acu-Sinch Knotless Mini System is indicated for Carpal Metacarpal (CMC) joint arthroplasty as an adjunct in the healing process of hematoma distraction arthroplasty by providing stabilization at the base of the first and second metacarpal when the trapezium has been excised due to osteoarthritis.

Acu-Sinch® Knotless Mini Surgical Technique
for Carpometacarpal Suspensionplasty

Figure 1

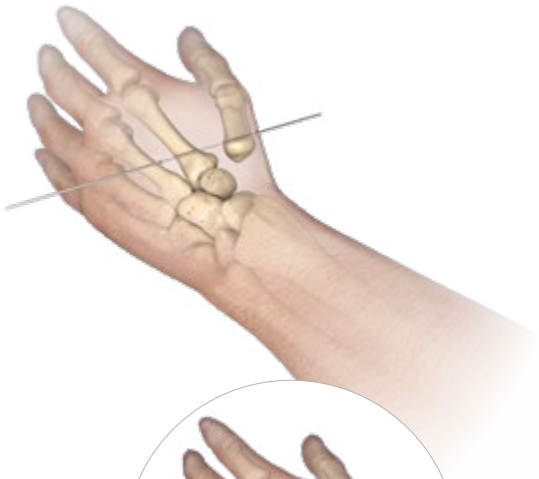


Figure 2

1 Trapeziectomy and Drill

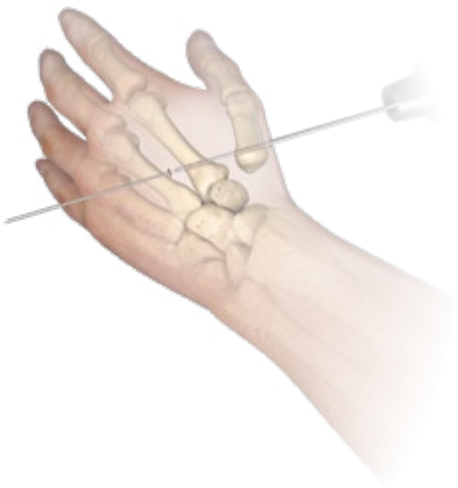
Make a dorsal or dorsolateral incision centered over the trapeziometacarpal joint. Use blunt dissection; identify and protect the dorsal radial sensory nerve to prevent nerve injury. Decompress the thumb extensor tendons and then identify the radial aspect of the thumb metacarpal base.

After performing a trapeziectomy, place a 1.1 mm K-wire through the dorsal radial third of the metacarpal, approximately 5 mm from the articular surface, stopping prior to entering the index metacarpal. Apply desired traction and abduction to the thumb, under fluoroscopy. When satisfactory orientation is achieved, advance the K-wire bicortically through the index metacarpal.

Make a second incision at the level of the K-wire exit site at the second metacarpal to enable passage of the cannulated drill and improve visualization.

Note: The trapeziectomy may be performed prior to or after drilling.

Figure 3



2 Drill Tunnel

Use the 2.3 mm drill to drill bicortically over the K-wire until the drill tip exits the ulnar cortex of the index metacarpal. Remove the wire driver and the K-wire, leaving the cannulated drill in place across the thumb and metacarpals.

Note: The use of fluoroscopy can aid in confirming the placement of both the guide wire and the cannulated drill.

Acu-Sinch® Knotless Mini Surgical Technique for Carpometacarpal Suspensionplasty [continued]

3 Device Insertion

Insert the Flip-Button on the tip of the Acu-Sinch Knotless Mini Installer handle into the slot in the back of the cannulated drill (Figures 5 and 6).

Push the inserter and drill assembly until the Flip-Button exits the ulnar cortex of the index metacarpal, taking care not to let the Flip-Button disconnect from the back of the drill.

The drill will slide smoothly across the bone tunnel due to the drill shaft having a smaller diameter than the drill tip.

Note: Apply slight back pressure on the drill towards the inserter while advancing through the bone tunnels to maintain the implant/drill connection.

Note: Make sure the device trigger is not pulled until the button position has been confirmed in the following step.

Figure 4

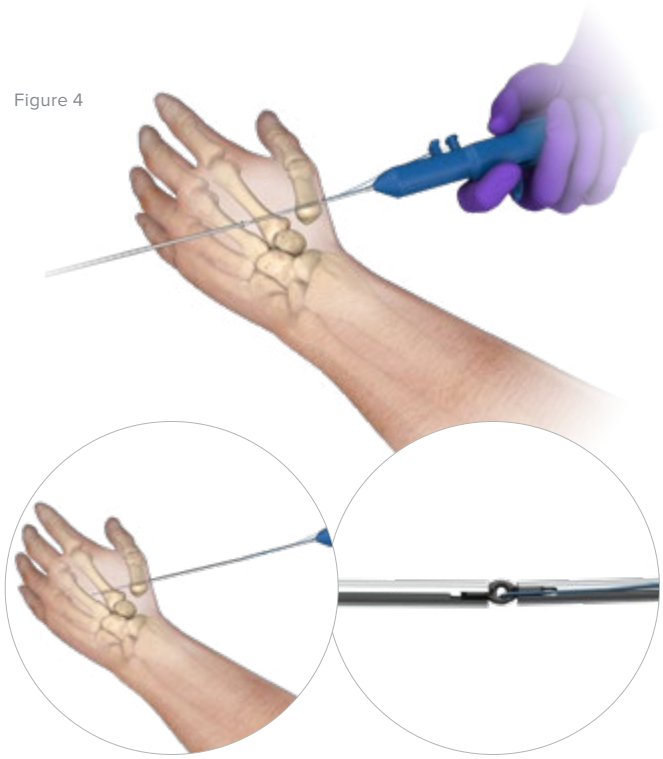


Figure 5

Figure 6

4 Confirm the Button Position

Under fluoroscopic visualization in anterior-posterior view, a gap can be seen between the button and inserter to indicate Flip-Button orientation and location. This feature should be outside the ulnar cortex of the index metacarpal.

Note: Further confirmation of Flip-Button positioning can be made by ensuring that the suture carriage on the ASK Mini handle is pointing up towards the ceiling.

Figure 7

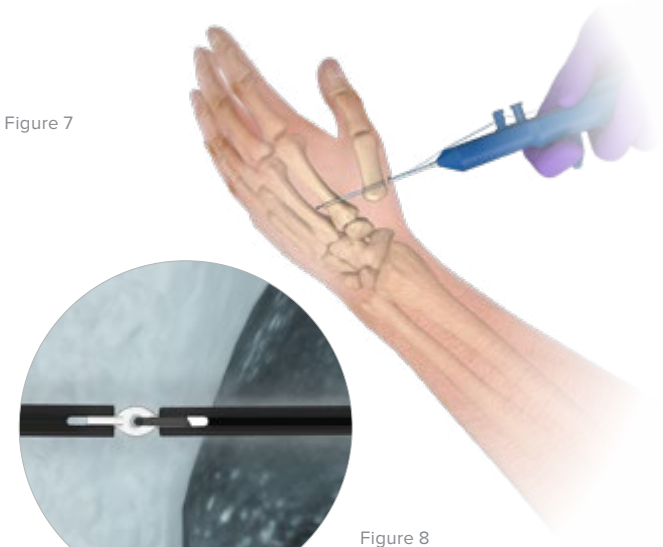
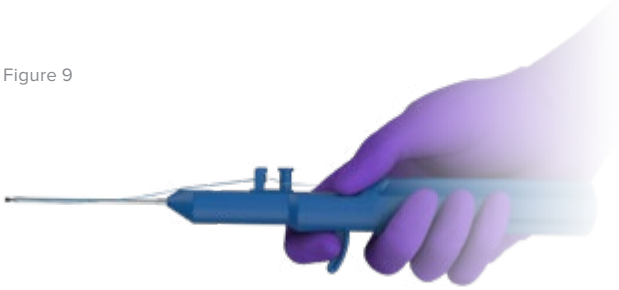


Figure 8

Acu-Sinch® Knotless Mini Surgical Technique
for Carpometacarpal Suspensionplasty [continued]

Figure 9



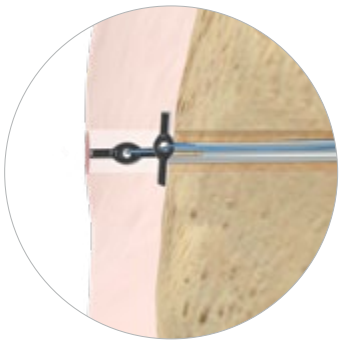


Figure 10

5 Deploy the Flip-Button

Pull the trigger on the handle of the Acu-Sinch Knotless Mini Inserter firmly to deploy the Flip-Button and then pull back on the insertion handle to seat the button against the cortex.

Note: The suture carriage will not deploy when the trigger is pulled.

Figure 11

Figure 12

6 Release from Inserter

Confirm that the button is flush against the cortex of the index metacarpal under fluoroscopy. Continue pulling the inserter handle laterally and away from the Flip-Button to release the Acu-Sinch Knotless Mini from the inserter.

Note: There is no need to unwrap the sutures from the inserter. The suture carriage automatically releases to unfurl the suture and Round Button.

Note: Use one hand to stabilize the thumb while pulling the handle during the release.

Note: You can apply pressure to the suture carriage with your thumb in order to facilitate the removal of the inserter handle from the surgical site.

Acu-Sinch® Knotless Mini System Surgical Technique
for Carpometacarpal Suspensionplasty [continued]

7 Reduction

Pull and place the suture loop on tension while manually reducing the round cortical button to the thumb metacarpal cortex. Ensure that any suture loops that form during the sinching process are pulled completely through the button prior to final tightening.

Note: Manually guide the round cortical button while maintaining suture tension and linear alignment.

Note: Pay close attention to the thumb positioning during reduction to make sure that it does not overtighten.

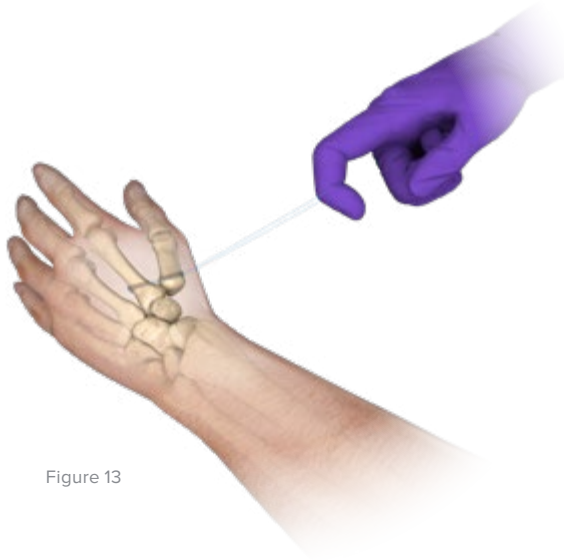


Figure 13

8 Final Tension

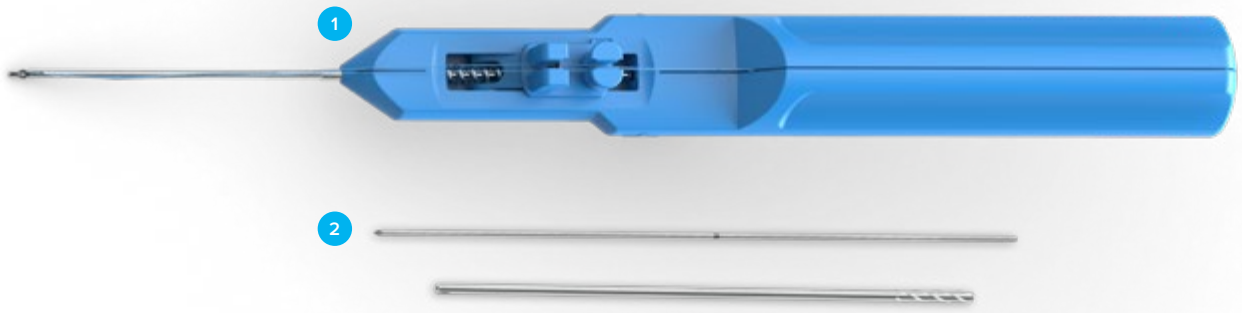
The position of the thumb is achieved with moderate traction and slight abduction. The base of the index metacarpal is a guide to the correct thumb suspension level. Sequential tightening can be accomplished by pulling the suture limbs apart. Range of motion of the thumb can be periodically checked during the tightening process. Avoid overtightening during the tightening process, which could lead to thumb and index metacarpal impingement. Once the tightening and tension on the suture suspension is complete, the suture limbs are cut at the level of the cortical button.

Note: Overtightening the Acu-Sinch Knotless Mini device should be avoided. Be sure to check tension frequently so as not to overtighten as the tension cannot be released once it is set.

Note: The Acu-Sinch Knotless Mini System consists of a self-locking suture (knotless); therefore tying a knot over the Round Button is not required. A hemostat can be placed between the first and second metacarpals, proximal to the suture, to help prevent overtensioning.

Figure 14

Ordering Information



Tray Components

Acu-Sinch Mini Knotless System

1	Acu-Sinch Knotless Mini System w/Inserter	46-0040-S
2	2.3 mm Cannulated Drill & 1.1mm K-wire	47-0019-S

Note: To learn more about the full line of Acumed innovative surgical solutions, please contact your authorized Acumed distributor, call 888.627.9957, or visit www.acumed.net.

Notes:

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