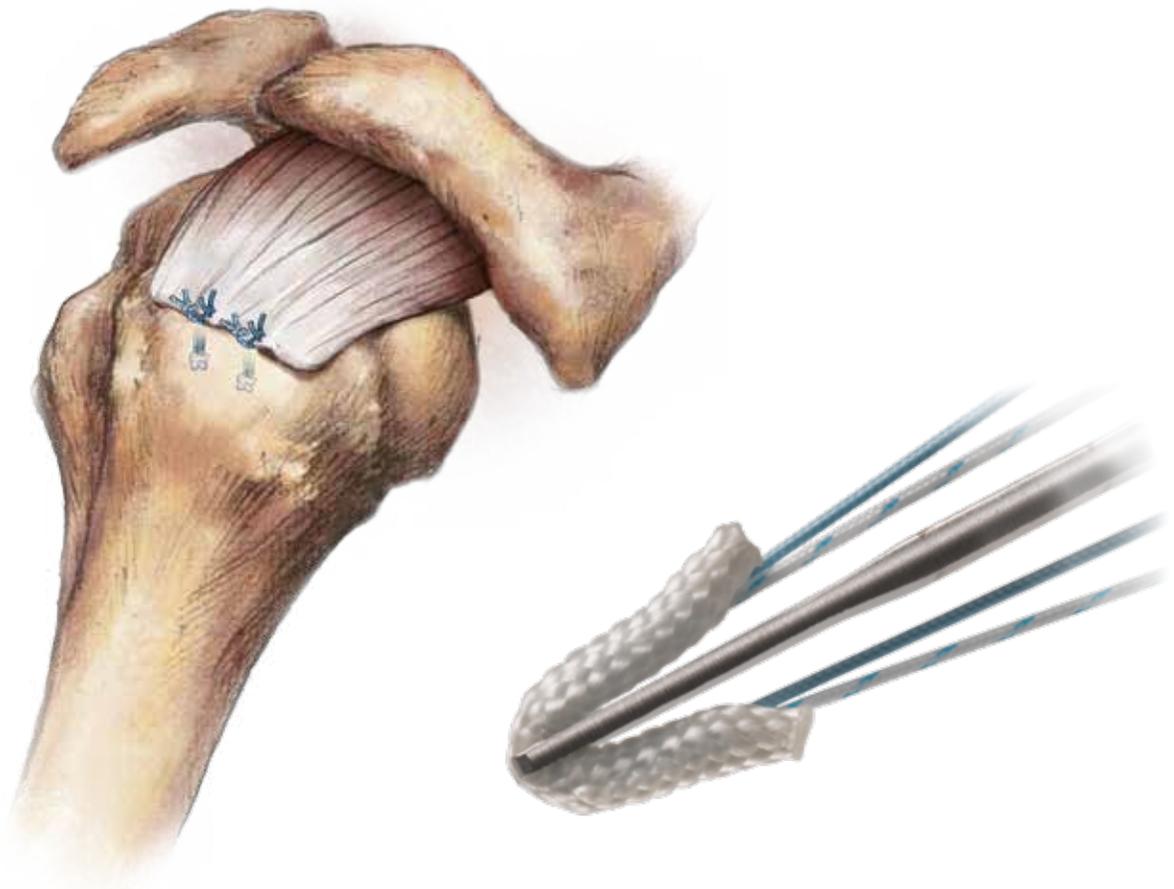


JuggerKnot

SOFT ANCHOR



Arthroscopic and Mini-Open Rotator Cuff Repair

using JuggerKnot Soft Anchor -2.9 mm
with ALLthread Knotless PEEK-Optima Anchor Surgical Technique

BIOMET

It's small. It's strong. And it's all suture.

The JuggerKnot Soft Anchor represents the next generation of suture anchor technology. The 2.9 mm deployable anchor design is a completely suture-based system, and is the first of its kind.

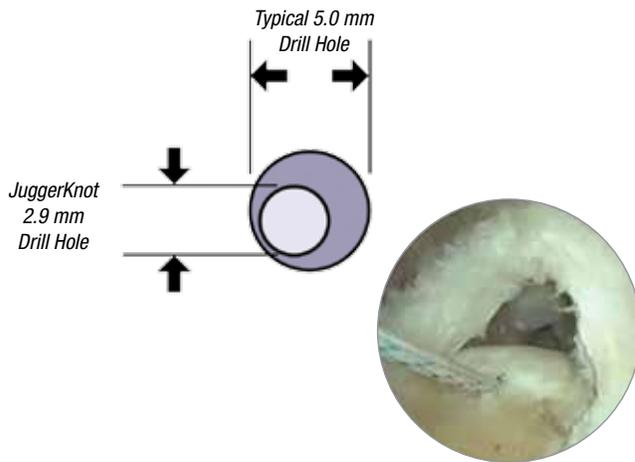
The JuggerKnot Soft Anchor—2.9 mm with Needles is a guideless deployment, specifically designed for those who perform mini-open repairs. This system design includes a rigid drill, short inserter and tapered or cutting needles to facilitate efficient tissue to bone attachment.



Soft Material

- Soft anchor deployment system—completely suture based implant
- Eliminates the possibility of rigid material loose bodies in the joint
- Polyester implant

This material represents the surgical technique utilized by Vivek Agrawal, M.D., Patrick Connor, M.D., Don D'Alessandro, M.D., David J. Chao, M.D., Scott Kuiper, M.D. Biomet does not practice medicine. The treating surgeon is responsible for determining the appropriate treatment, technique(s), and product(s) for each individual patient.

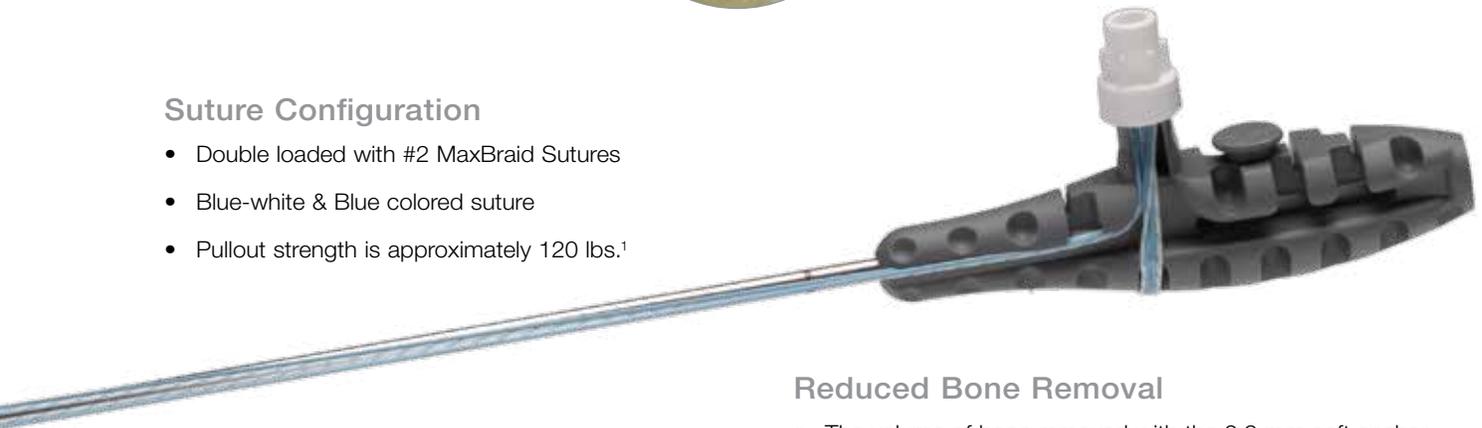


Minimal Size

- Smaller drill guide is less invasive to surrounding tissue
- Smaller anchor diameter allows multiple anchors to be placed
- Reduces likelihood of intersecting anchors when placing multiple anchors

Suture Configuration

- Double loaded with #2 MaxBraid Sutures
- Blue-white & Blue colored suture
- Pullout strength is approximately 120 lbs.¹



Reduced Bone Removal

- The volume of bone removed with the 2.9 mm soft anchor is less than that of a 5.0 mm traditional anchor.
- Drill depth 18 mm

JuggerKnot Soft Anchor–2.9 mm with Needles

- Guideless design allows for a mini-open repair
- Tapered and cutting needle options
- Working length of inserter is 5.75 inches



JuggerKnot Soft Anchor—2.9 mm

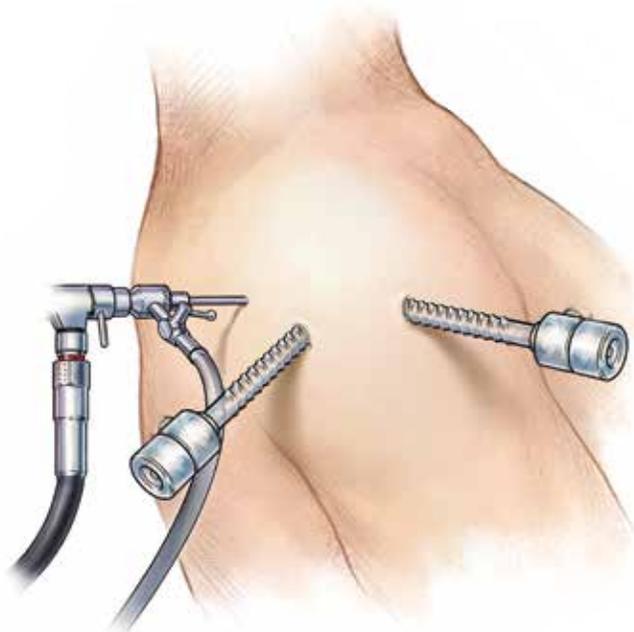


Figure 1



Figure 2

Mini-Open

Place patient in the preferred position and create standard incision. Dissect down using the standard technique. Once tear is visualized proceed with alternative anchor insertion located on page 12.

Arthroscopic Repair Portal Placement

Place the shoulder in either a Beach Chair or Lateral Decubitus position, depending on surgeon preference. Utilize a standard posterior portal along with a traditional anterior portal for diagnostic arthroscopy and instrument passage. Address intra-articular pathology and evaluate the undersurface of the rotator cuff. Debride frayed or damaged cuff tissue. Then pass the arthroscope into the subacromial space via the posterior portal (Figure 1). To accomplish the subacromial aspects of the procedure, create lateral and anterior portals. As an alternative to the anterior portal, a posterolateral portal can be created. Place the lateral portal about 3 cm directly lateral to the anterior acromial margin. Use this portal for the shaver,

burr and suture passing instruments. If desired, place the posterolateral portal midway between the lateral and posterior portals. Placing the arthroscope through this portal allows for improved visualization of the cuff and keeps the posterior portal available for suture management (Figure 1).

Visualization of the Subacromial Space

Visualize the subacromial space using the posterior or posterolateral portal while performing a bursectomy through the lateral portal. Use a combination of a shaver and electrocautery to visualize the subacromial space, acromion, coracoacromial ligament and rotator cuff (Figure 2). Perform any other indicated procedures in the subacromial space such as an acromioplasty, distal clavicle resection or Coracoacromial (CA) ligament release addressing AC Joint pathology prior to repairing the rotator cuff.

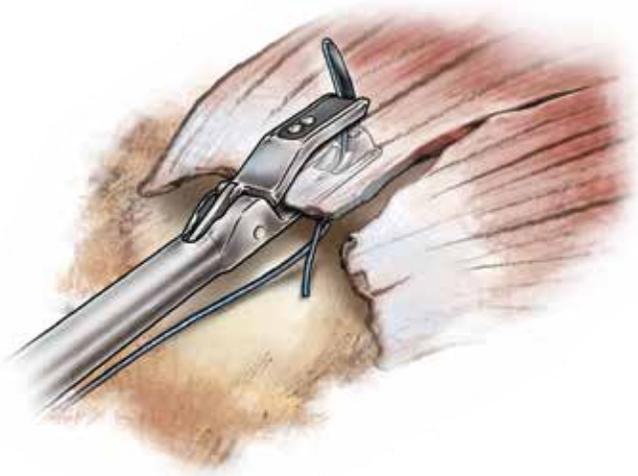


Figure 3

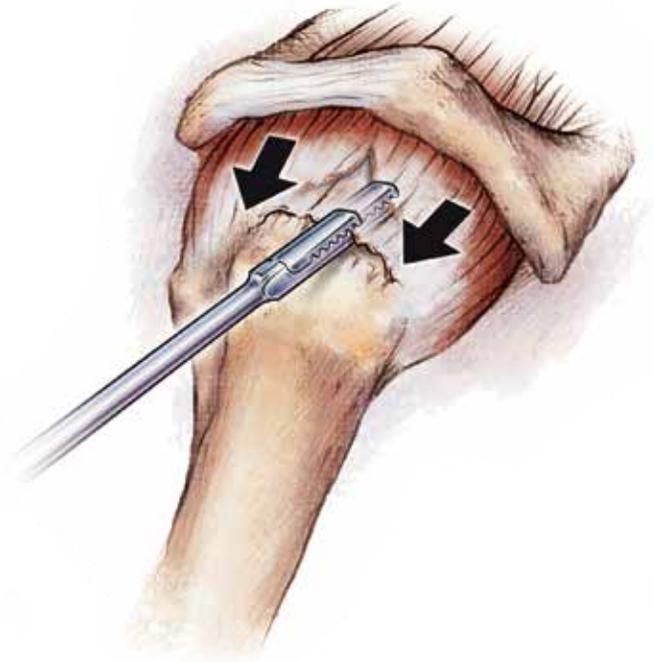


Figure 4

Visualize the rotator cuff tear via the posterior or posterolateral portal. Debride the avascular or frayed edges of the cuff to prepare the tissue for repair. Examine the tear from the various portals to determine tear type, configuration, and size, as well as amount of retraction.

Mobilization of the Rotator Cuff

If retracted, mobilize the rotator cuff by freeing it both superiorly and inferiorly in the planes medial to the glenoid, keeping the anatomic course of the suprascapular nerve in mind to prevent iatrogenic injury. Perform anterior and posterior slide procedures if the rotator cuff is severely retracted and scarred. Utilize margin-convergence techniques to repair splits in the tendon anteriorly and posteriorly. Perform margin-convergence repair using the appropriate passing device or BiPass device to pass MaxBraid suture across the tear (Figure 3). When repairing anterior and/or posterior

splits in the tendon, evaluate the remaining defect for repair to the greater tuberosity.

Utilize a tissue grasper to confirm the tendon can be reduced to bone without any undue tension (Figure 4). While viewing through either the posterolateral or anterior portal and working through the lateral portal, use a high-speed shaver to lightly decorticate the rotator cuff footprint area of the greater tuberosity.

Note: Cortical bone must be present at the sites where suture anchors will be placed.

JuggerKnot Soft Anchor—2.9 mm



Figure 5

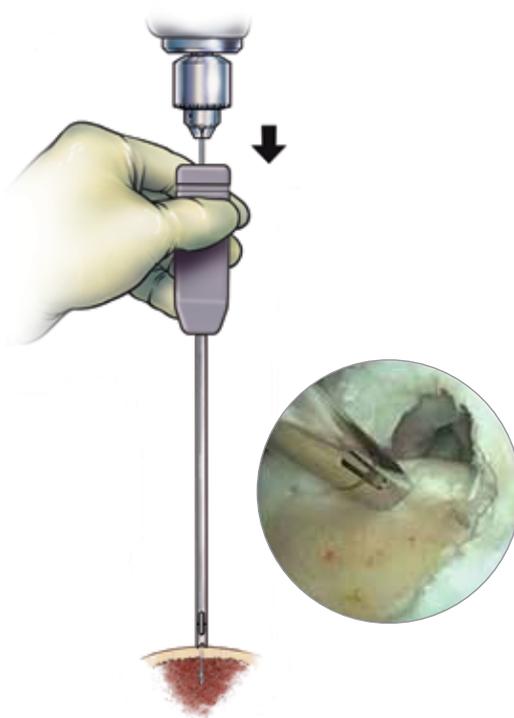


Figure 6

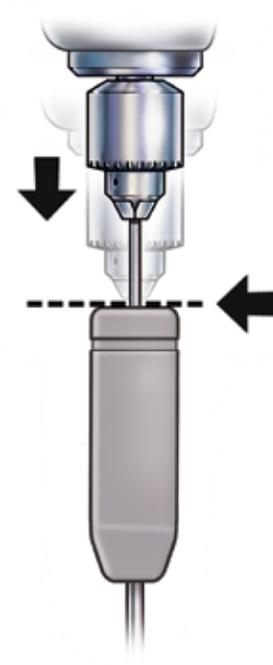


Figure 7

Placement of the JuggerKnot Guide

The small diameter of the JuggerKnot guide allows easy access to the greater tuberosity for anatomical re-attachment of the cuff. Use a spinal needle to localize and ensure proper location and angle for the guide (Figure 5). Position the JuggerKnot guide at the desired angle and location on bone via a cannula or percutaneous portal. For the percutaneous approach use a sharp trocar through a small incision just off the lateral edge of the acromion. Alternatively, use a blunt obturator through a 7 mm AquaLoc Cannula in the lateral portal.

Drill Pilot Hole

Affix the power drill chuck over the JuggerKnot drill bit at the proximal laser-etch line, to determine appropriate depth. The collar of the drill will bottom-out on top of the guide. Insert the JuggerKnot drill bit into the drill guide (Figures 6 & 7). Advance drill bit until contact is made between the power drill and the guide. The JuggerKnot in-guide punch can also be used based upon surgeon preference.

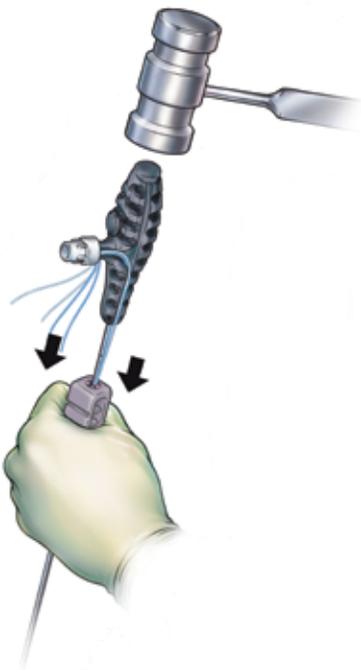


Figure 8

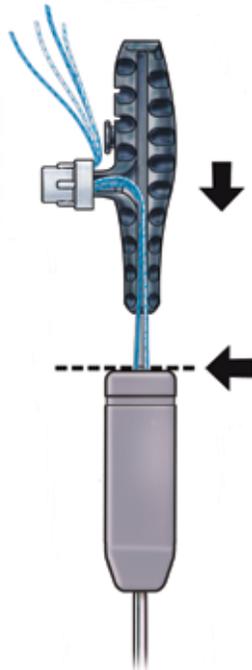


Figure 9

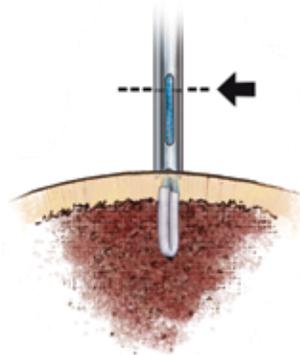


Figure 10

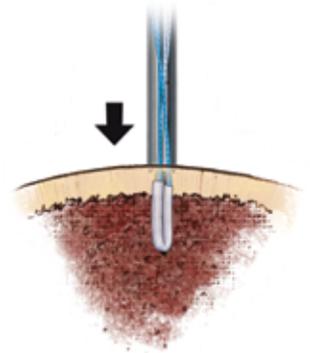


Figure 11

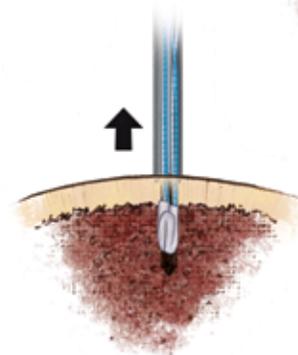


Figure 12

Insert Anchor

Remove the drill. Keeping the guide steady over the drilled hole, do not move it away from hole after drill is removed.

The guide must be positioned exactly over the pilot hole, with no angle deviation with respect to the bone, for proper anchor placement. While maintaining the guide position firmly against the bone, insert the JuggerKnot Soft Anchor through the guide and into the pilot hole. Lightly tap the inserter handle with a mallet until the laser-etch line is even with the top of the guide, to fully seat the anchor into bone. (Figures 8 & 9).

Note: Do not impact inserter handle to the top of the guide, as it may drive the guide through the cortex of the bone.

Double check that the laser etch marks on the inserter are visible in the guide window to ensure anchor is inserted to appropriate depth (Figure 10).

Deploy Anchor

Once anchor is fully seated into bone (Figure 11), pull back firmly until resistance from anchor engagement is felt. This signifies anchor sleeve deployment under the cortex (Figure 12). Once resistance is felt on the sutures, release them from the inserter and remove both the inserter and drill guide. Release sutures from the handle by removing suture retention cap or luer lock (Figure 13). First remove the inserter by pulling it directly out of the guide, and then remove the guide.

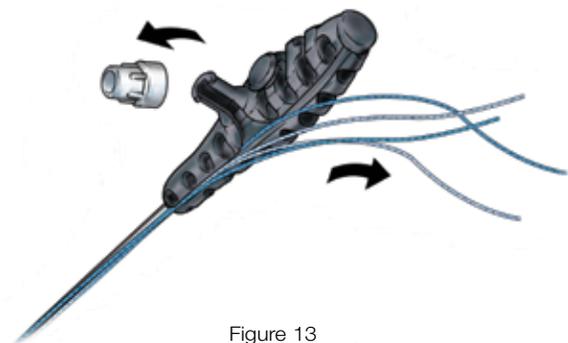


Figure 13

JuggerKnot Soft Anchor—2.9 mm

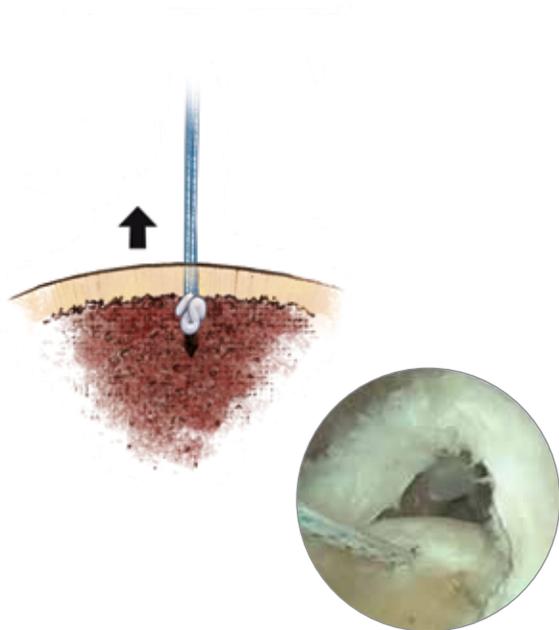


Figure 14

Set the Anchor

Using a slow and steady motion, lightly pull on all suture limbs by hand to set the anchor. This completes the setting process of the soft suture sleeve expanding up against the proximal cortex. Once the anchor is set, verify that the sutures slide freely for tying arthroscopic surgical knots (Figure 14).

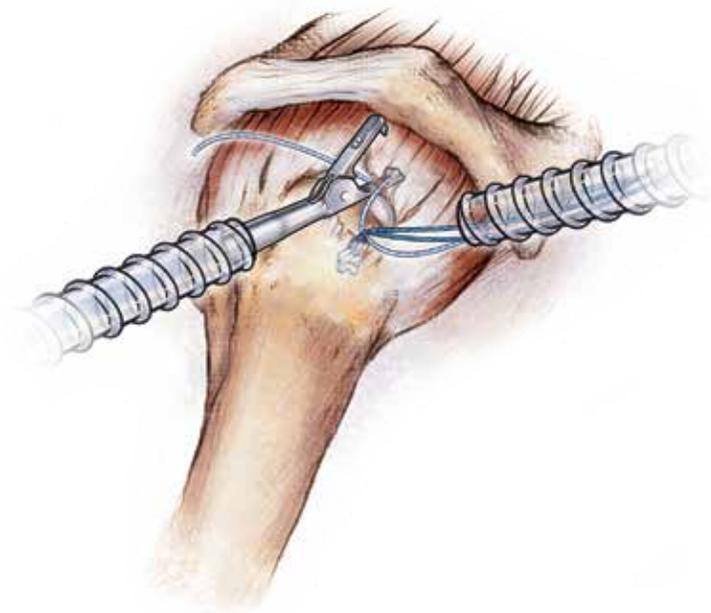


Figure 15

Pass the Suture Through the Rotator Cuff

Pass individual sutures from the anchor out the lateral portal. Use the BiPass Suture Passer for passing suture through the rotator cuff tendon (Figure 15). Load MaxBraid Suture into the slot on the lower jaw of the BiPass, approximately 2 cm from the end of the suture. Pass suture through the tendon, and back out the lateral portal with the BiPass Suture Passer. This suture can then be passed out either the posterior or anterior portal for suture management. This procedure is repeated until one limb of each suture has been passed through the rotator cuff tendon for simple suture repair of rotator cuff to bone.



Figure 16a

bleeding bone
from anchor hole

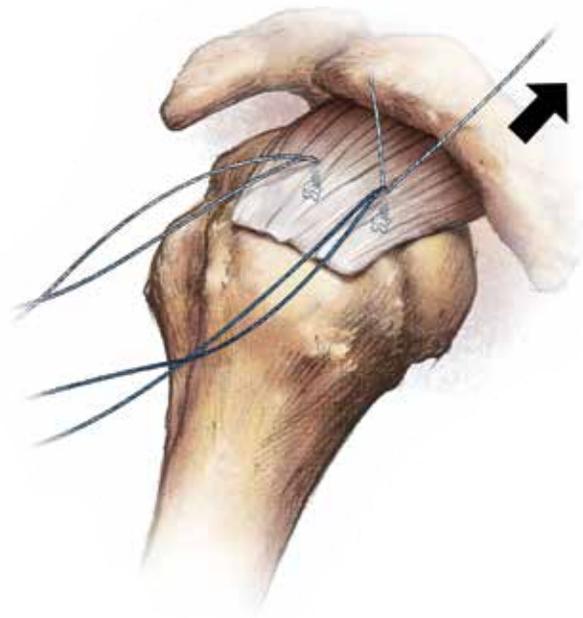


Figure 16b

Single Row Repair

After all sutures have been passed, repair of the tendon progresses from posterior to anterior. Use a secure knot with a minimum of three half-hitches while alternating posts to secure the tendon to the tuberosity. Use a probe to check fixation. Cut the suture limbs with a MaxCutter instrument and the Single Row technique is complete using the JuggerKnot 2.9 mm Soft Anchor (Figure 16a).

Double Row Repair

If utilizing a double row repair, place the initial anchors along the articular cartilage margin and pass sutures through the tendon 1 cm medial to the lateral edge of the tendon using a horizontal mattress configuration prior to traditional lateral footprint anchor placement (Figure 16b).

Note: A suture can be pulled out of the anchor depending on surgeon preference.

JuggerKnot Soft Anchor—2.9 mm

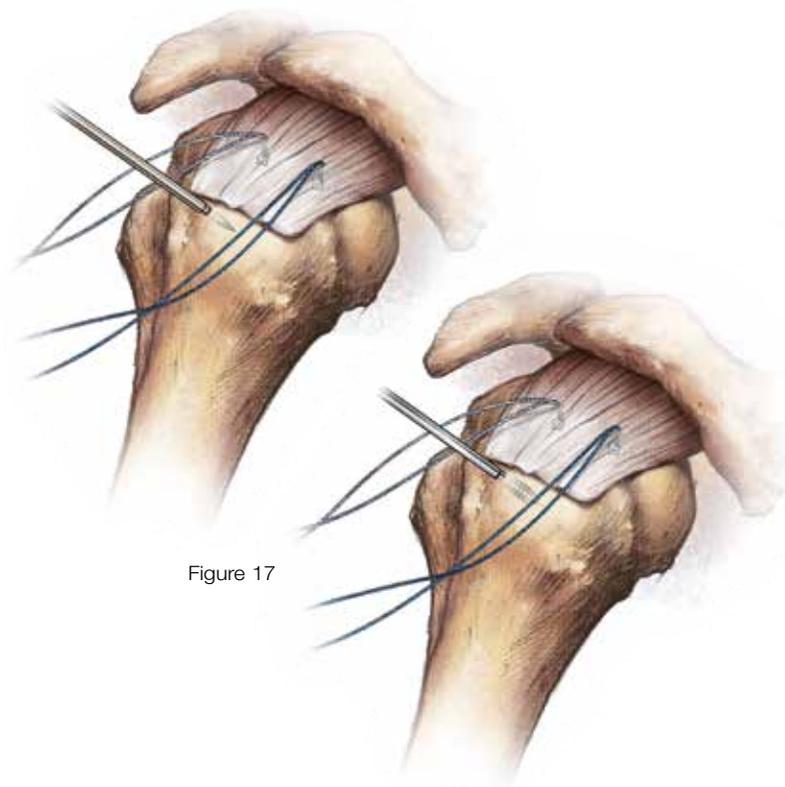


Figure 17

Figure 18

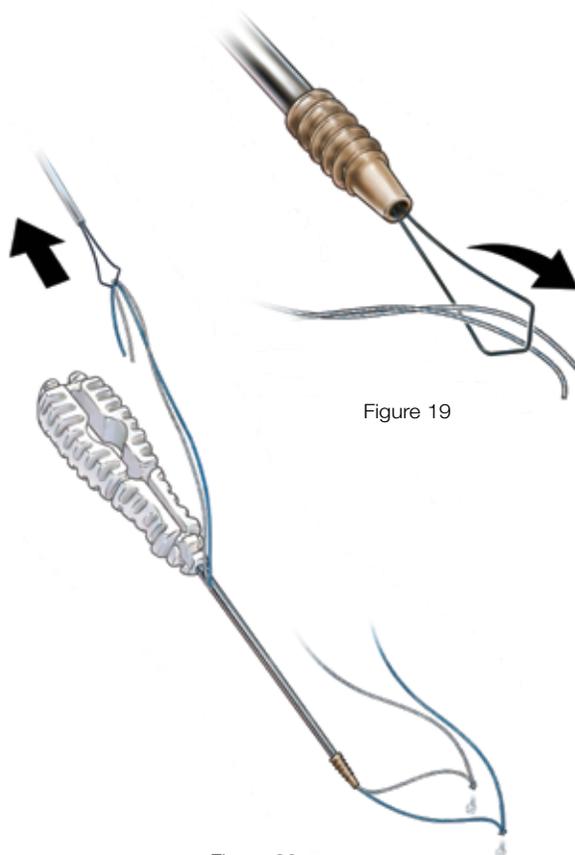


Figure 19

Figure 20

Make a Pilot Hole for the Knotless ALLthread Suture Anchor

Prepare the lateral row pilot hole for the posterior-most lateral anchor through the lateral portal. Debride additional tissue from the tuberosity using a shaver to ensure proper visualization for anchor insertion. Use the Knotless ALLthread Punch to make a pilot hole in soft or intermediate bone (Figure 17). Use a Knotless ALLthread Tap to make a pilot hole in hard bone (Figure 18). In cases of extremely soft bone, the location of the pilot hole may be moved more laterally down the neck for stronger bone.

Load Suture into Knotless Anchor

Pull one suture limb from the posterior/medial anchor and one suture from the anterior/medial anchor through the lateral portal. Pass approximately 4 cm of each suture end through the passing wire at the tip of the Knotless anchor (Figure 19). Pull the passing wire to deliver the suture ends through the inserter handle and out the slot. Discard the passing wire and hold the suture ends routed out of the slot in the inserter (Figure 20). Up to four suture limbs can be shuttled through the anchor. If shuttling four sutures, load two limbs (2 cm lengths) through the proximal nitinol loop and the remaining two suture limbs (2 cm lengths) through the distal nitinol loop.

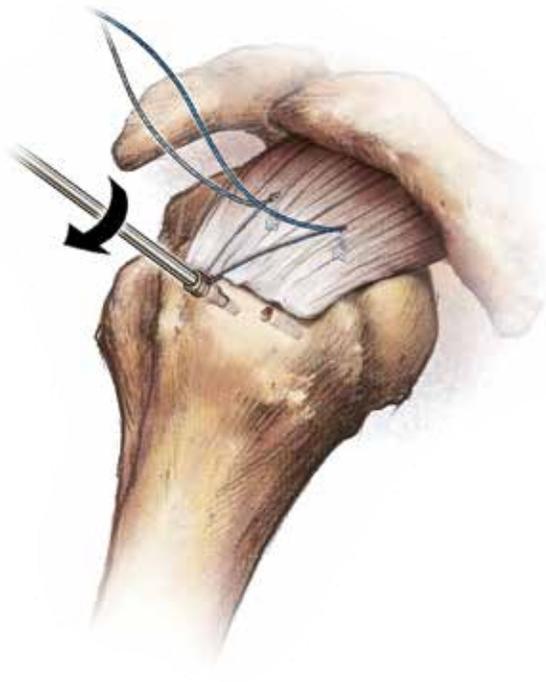


Figure 21



Figure 22

Insert the Knotless ALLthread Suture Anchor

Pass the inserter carrying the Knotless ALLthread Suture Anchor through the lateral portal and position the anchor relative to the posterior lateral pilot hole (Figure 21). To ensure smooth anchor insertion, maintain the same angle of insertion as the Knotless ALLthread punch. The Knotless ALLthread tap may need to be used if it is difficult to find the pilot hole to insert the anchor.

Completing the Double Row Technique

Before inserting the Knotless ALLthread Suture Anchor into the posterior lateral pilot hole, pull the suture ends away from the inserter to lightly facilitate control of the suture tension. While maintaining gentle tension on the suture, push the nose of the anchor into the bone to provide continued tensioning and securing of the suture during insertion of the anchor. A light mallet may be utilized in place of pushing the nose of the anchor into the bone. Mallet until the first threads begin to engage in the bone.

Once the threads of the anchor have engaged the bone, release the suture (Figure 21) and firmly screw the anchor to continue tensioning of the suture until the anchor is flush with the bone. Pull the inserter handle out of the anchor and cut the suture limbs right over the implanted anchor using a MaxCutter suture cutter. Take the remaining sutures from the medial row anchors and repeat the above steps for the spanning technique to secure the lateral/anterior anchor (Figure 22).

Note: After inserting the anchor, no further tensioning or securing of the suture is possible.

JuggerKnot Soft Anchor—2.9 mm

Mini-Open Repair Utilizing the JuggerKnot Soft Anchor—2.9 mm with Needles

Placement of Drill

After the initial incision has been made and the tear has been assessed, visualize the bone and place the drill bit at the desired site of anchor insertion. Advance the drill until the laser etch line is even with the surface of the cortex or 18 mm. An alternative technique is to use the 2.9 mm punch; advancing it until the laser etch line is even with the surface of the cortex.

Insert Anchor

While maintaining the angle orientation of the drill, place the tip of the JuggerKnot Soft Anchor—2.9 mm with needles in the freshly drilled hole. To advance the inserter, lightly mallet until the laser etch line is flush with the cortex.

Deploy Anchor

Pull back on the inserter to set the anchor. Carefully remove the needles from the Styrofoam inside the handle and unwrap the suture from around the handle. Remove the inserter by pulling straight back.

Set the Anchor

Gently pull back on all the sutures until the anchor sets against the cortex. Ensure the sutures slide inside the anchor and continue with soft tissue repair per surgeon preference located on page 8.

JuggerKnot Soft Anchor—2.9 mm

JuggerKnot Soft Anchor—2.9 mm

Part Number	Description
912029	Double Loaded #2 MaxBraid Blue Suture—Single
912529	Double Loaded #2 MaxBraid Blue Suture—10pk

JuggerKnot Soft Anchor—2.9 mm Instruments

Part Number	Description
912057	Disposable Instrument Kit—Drill Guide, Obturator, Drill Bit
912064	Reusable In-Guide Punch
912090G	Reusable Drill Guide
912091	Drill Bit
912092G	Reusable Obturator
912093G	Reusable Trocar

JuggerKnot Soft Anchor—2.9 mm with Needles

Part Number	Description
110005093	Double Loaded #2 MaxBraid Suture with Cutting Needles
110005096	Double Loaded #2 MaxBraid Suture with Tapered Needles
110005241	Double Loaded #2 MaxBraid Suture with Cutting Needles 10pk
110005242	Double Loaded #2 MaxBraid Suture with Tapered Needles 10pk

JuggerKnot Soft Anchor—2.9 mm with Needles Instruments

Part Number	Description
110005306	Drill Bit Short Shaft Sterile Pack
912059	Short Punch

ALLthread Knotless PEEK-Optima Anchors

Part Number	Description
904840P	4.5 mm
904843P	5.5 mm
904844P	6.8 mm

ALLthread Knotless PEEK-Optima Instruments

Part Number	Description
904845	4.5 mm Tap
905955K	4.5/5.5 mm Punch
905958	5.5 mm Tap (Fixed Handle)
905959	6.8 mm Tap (Fixed Handle)

JuggerKnot Soft Anchors

INDICATIONS

The JuggerKnot Soft Anchors are intended for soft tissue to bone fixation for the following indications:

Shoulder

Bankart lesion repair
SLAP lesion repair
Acromio-clavicular repair
Capsular shift / capsulolabral reconstruction
Deltoid repair
Rotator cuff tear repair
Biceps tenodesis

Foot and Ankle

Medial / lateral repair and reconstruction
Mid- and forefoot repair
Hallux valgus reconstruction
Metatarsal ligament/tendon repair or reconstruction
Achilles Tendon Repair

Elbow

Ulnar or radial collateral ligament reconstruction
Lateral epicondylitis repair
Biceps tendon reattachment

Knee

Extra-capsular repair: MCL, LCL, and posterior oblique ligament
Iliotibial band tenodesis
Patellar tendon repair
VMO advancement
Joint capsule closure

Hand and Wrist

Collateral ligament repair
Scapholunate ligament reconstruction
Tendon transfers in phalanx
Volar plate reconstruction

Hip

Acetabular labral repair

CONTRAINDICATIONS

1. Infection.
2. Patient conditions including blood supply limitations and insufficient quantity or quality of bone or soft tissue.
3. Patients with mental or neurologic conditions who are unwilling or incapable of following postoperative care instructions or patients who are otherwise unwilling or incapable of doing so.
4. Foreign body sensitivity. Where material sensitivity is suspected, testing is to be completed prior to implantation of the device.

ALLthread Knotless PEEK-Optima Anchors

INDICATIONS

The Knotless Anchor is indicated for use in soft tissue reattachment procedures in the shoulder, wrist/hand, ankle/foot, elbow, and knee. Specific indications as follows:

Shoulder

Bankart repair, SLAP repair, acromio-clavicular separation, rotator cuff repair, capsule repair or capsulolabral reconstruction, biceps tenodesis, and deltoid repair.

Wrist/Hand

Scapholunate ligament reconstruction and ulnar/radial collateral ligament reconstruction.

Ankle/Foot

Lateral stabilization, medial stabilization, Achilles tendon repair/reconstruction, hallux valgus reconstruction, and mid- and forefoot reconstruction.

Elbow

Ulnar or radial collateral ligament reconstruction, biceps tendon reconstruction, and lateral epicondylitis repair

Knee

Medial collateral ligament repair, lateral collateral ligament repair, posterior oblique ligament repair, joint capsule closure, iliotibial band tenodesis, patellar ligament/tendon repair, extra-capsular repair, patellar realignment and repair, and Vastus Medialis Obliquus (VMO) Muscle Advancement.

The Knotless Anchors are single-use devices.

CONTRAINDICATIONS

1. Infection.
2. Patient conditions including blood supply limitations, and insufficient quantity or quality of bone or soft tissue.
3. Patients with mental or neurologic conditions who are unwilling or incapable of following postoperative care instructions.
4. Foreign body sensitivity. Where material sensitivity is suspected, testing is to be completed prior to implantation of the device.

References

1. Data on file at Biomet Sports Medicine. Test Report: AT47D.
Bench testing not necessarily indicative of clinical performance.

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