

UltraSorb™

Rotator Cuff Repair Surgical Technique

BIOABSORBABLE
FIXATION DEVICE FOR
ROTATOR CUFF REPAIR

 Linvatec

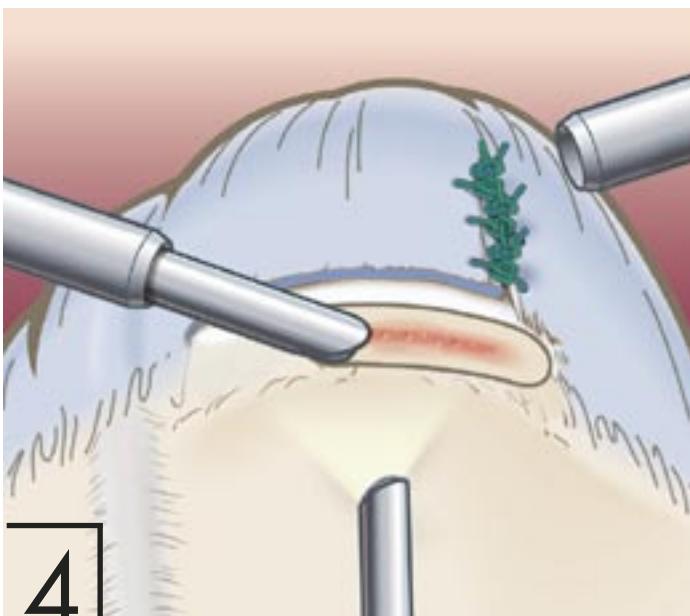
UltraSorb™

The UltraSorb Rotator Cuff Suture Anchor offers superior performance, reliability, and reproducibility for mini-open or arthroscopic repairs. The Poly-L-Lactide Acid (PLLA) UltraSorb Implant is pre-loaded on a sterile disposable inserter. The unique deployment mechanism allows for a simple and reproducible insertion of the anchor into bone. The Independent Suture Sliding (I.S.S.™) Eyelet design allows for the two pre-threaded sutures to independently move when passing through soft tissue or during knot tying. The sutures slide with relative ease, which allows for sliding knots to be tied without worry of locking the other strand and minimizes suture abrasion. In addition, The UltraSorb Implant is designed for improved pull-out strength in all types of bone quality.

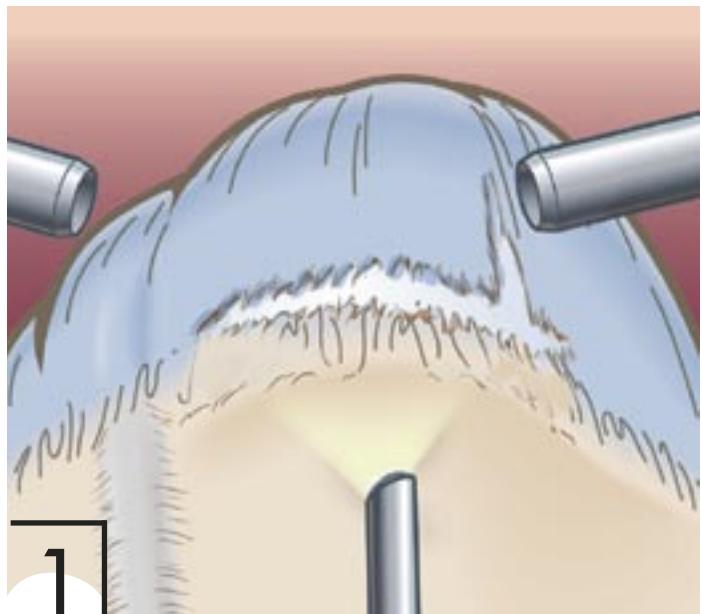
The UltraSorb Suture Anchor has additional bioabsorbable benefits, which include radiolucency and a lengthy history of clinical effectiveness and safety. The implant will retain its strength during the important healing period, but will slowly resorb into the body over a two to three year period.

The Linvatec UltraSorb Suture Anchor System is another example of Linvatec's commitment to the design, manufacture, sale and service of quality products and instruments for least invasive orthopaedic surgery.

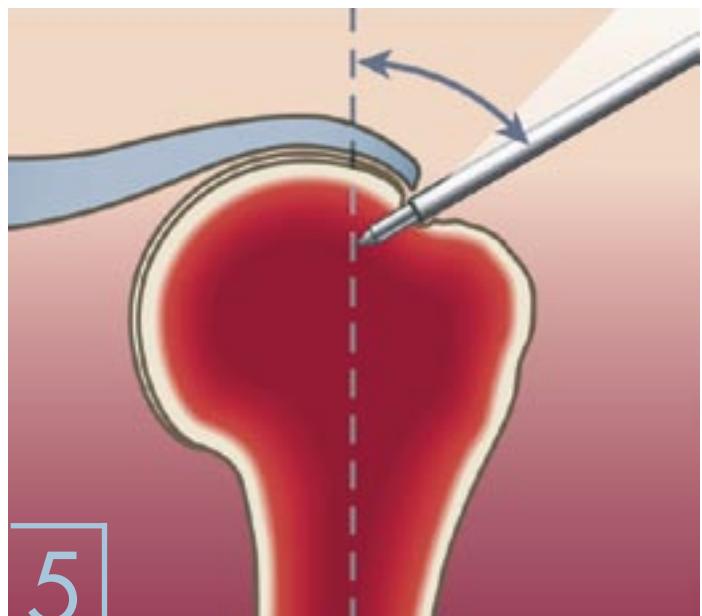
The surgeon must have an excellent understanding of the technique and must practice suture passing and knot tying before attempting the operation. The following outline highlights the important steps in a typical rotator cuff repair. Linvatec Corporation will be happy to provide more comprehensive videotape instructions. Information can be obtained by calling your local Linvatec representative or Customer Service at (800) 237-0169.



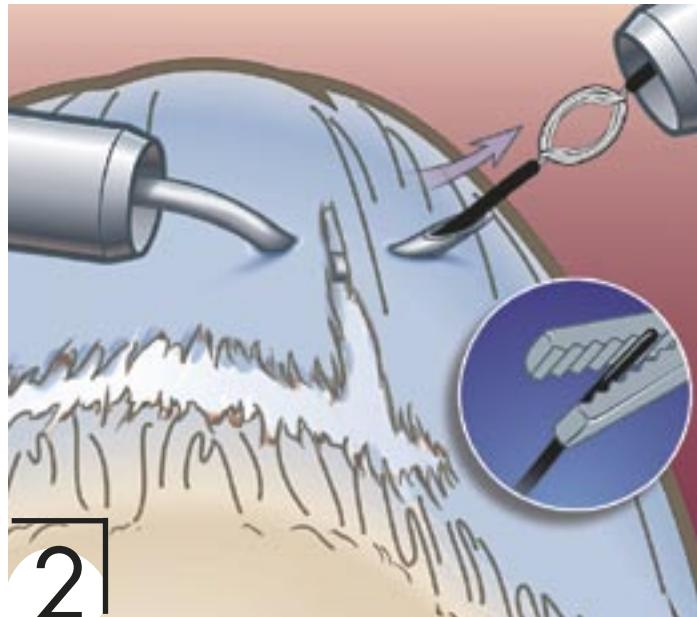
The bone is lightly decorticated at the anatomical neck of the humerus, adjacent to the articular cartilage, using a high speed bur and/or shaver. The rotator cuff is mobilized to minimize tension on the repair.



The rotator cuff tear is carefully evaluated with an arthroscope on both the articular and bursal sides, and the frayed edges of the cuff are debrided. The best view of the rotator cuff is usually "the 50 yard line" view with the arthroscope in a lateral subacromial portal which is located at the center point of the rotator cuff tear.

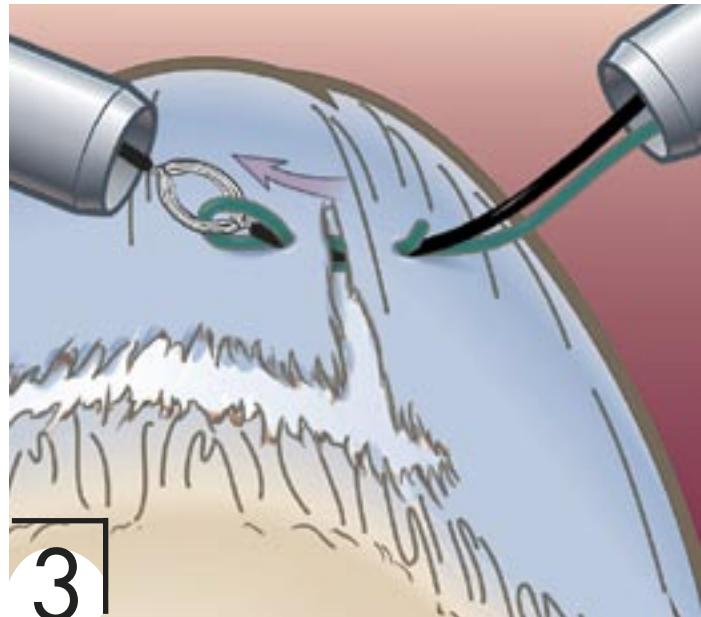


The UltraSorb Awl or Drill Bit is inserted through a small puncture wound adjacent to the lateral border of the acromion to create pilot holes for the anchors. The Awl is directed to enter the bone in a medial direction below the subchondral bone at approximately a 45° angle. An optional Drill Guide and Obturator can be used to enter the subacromial space to assist in the creation of the pilot hole and aid in the delivery of the implant. The pilot holes are angled away from the center of the trough in a fan-like pattern. (To ensure proper anchor placement, the Awl can be left in place until ready to place the inserter.)



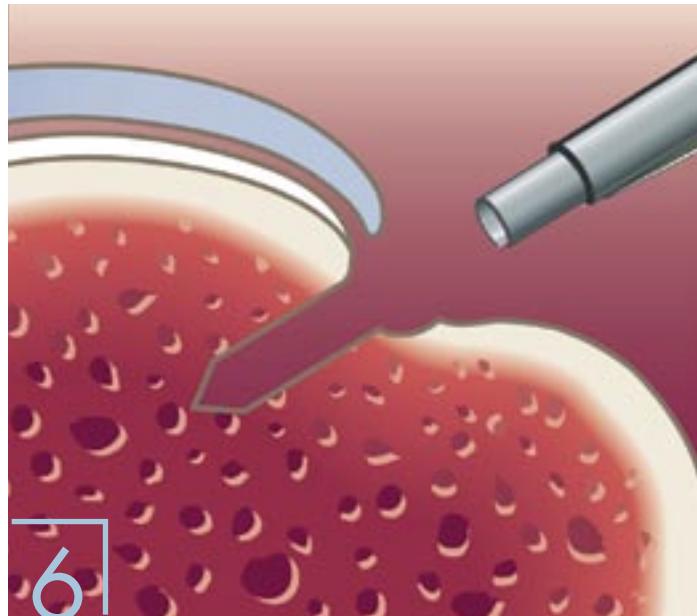
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A **Spectrum® Crescent Suture Hook** with a **Shuttle Relay™** or a **Blitz®** suture passer is used to perform a side-to-side repair of longitudinal tears in the rotator cuff tendon.



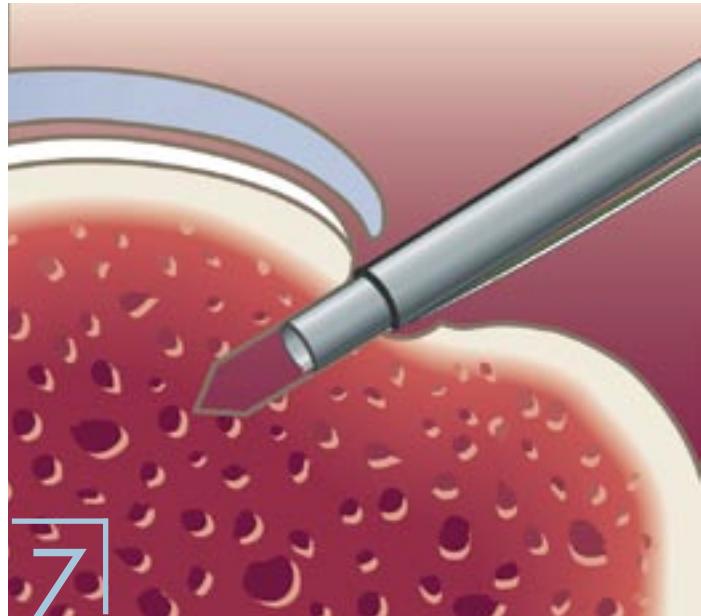
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After passing the curved suture hook across the tear, a strong, long lasting suture is carried across the tear and the suture limbs tied together.



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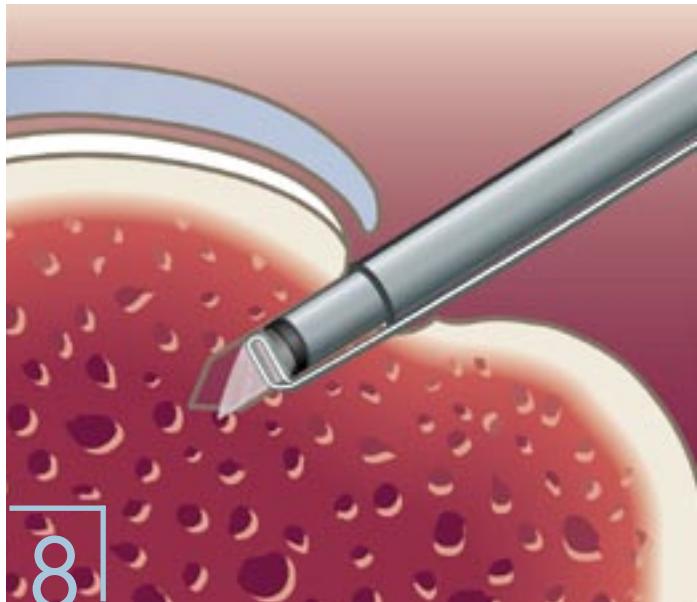
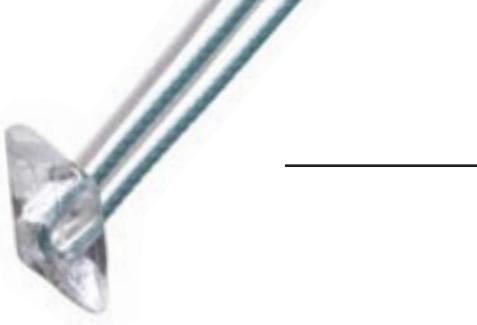
The UltraSorb inserter, with the pre-loaded anchor, is inserted directly through the percutaneous wound (no cannula is needed to insert this anchor).



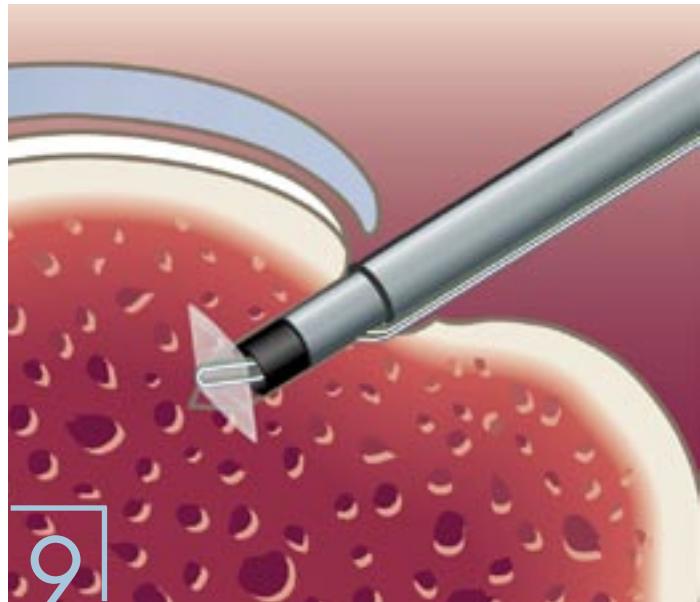
7

Push the inserter into the pilot hole until the wider shoulder touches the bone. A circular depth mark is located at the shoulder of the inserter. The vertical orientation mark, the solid line which indicates the direction the anchor eyelet is facing, is aligned toward the cuff edge. This ensures that the sutures pass in a direct line from the eyelet to the cuff without forming a twist.

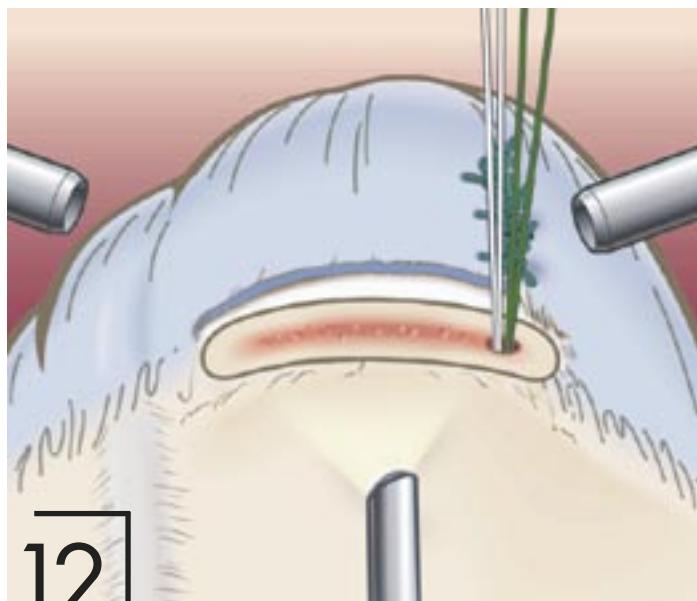
UltraSorb™



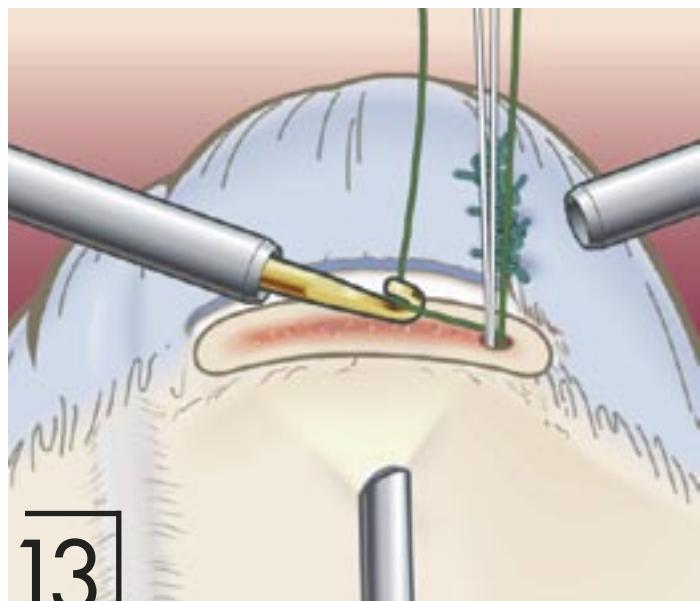
Maintain inserter contact with bone and maintain the same insertion angle by forward pressure, and squeeze the trigger fully until it cannot move any farther.



An audible click in the handle should be noticeable when fully squeezed.



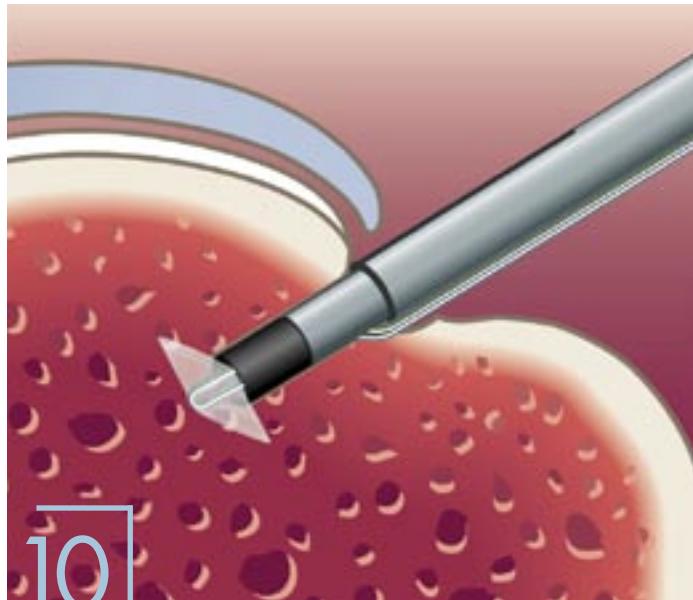
The arthroscope can be positioned in the anterior or posterior portal but most often the overall visualization is best from the lateral acromial portal.



A crochet hook or suture retrieval forceps is inserted through the anterior portal (Linvatec 6mm operating cannula) and retrieves the strand of the green suture that exits the anchor closest to the cuff. The retriever must pass behind (medial to) the suture limbs.

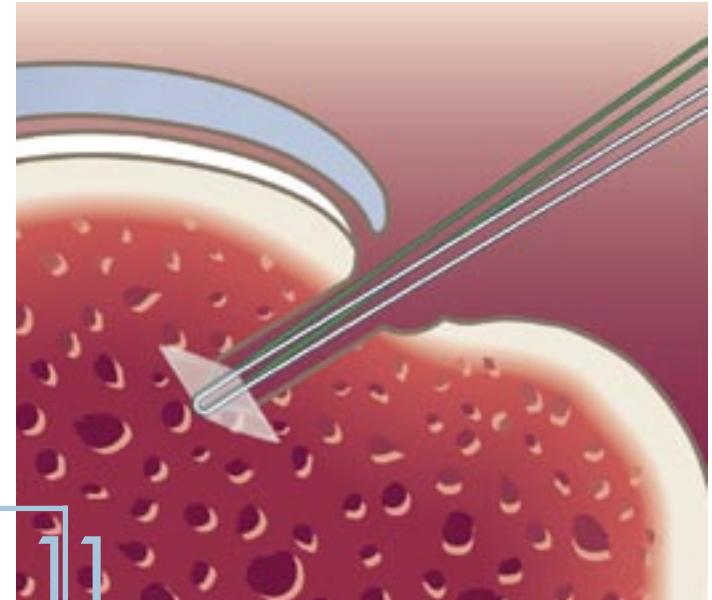
ARTHROSCOPIC ROTATOR CUFF REPAIR SURGICAL TECHNIQUE

Steps in repair technique



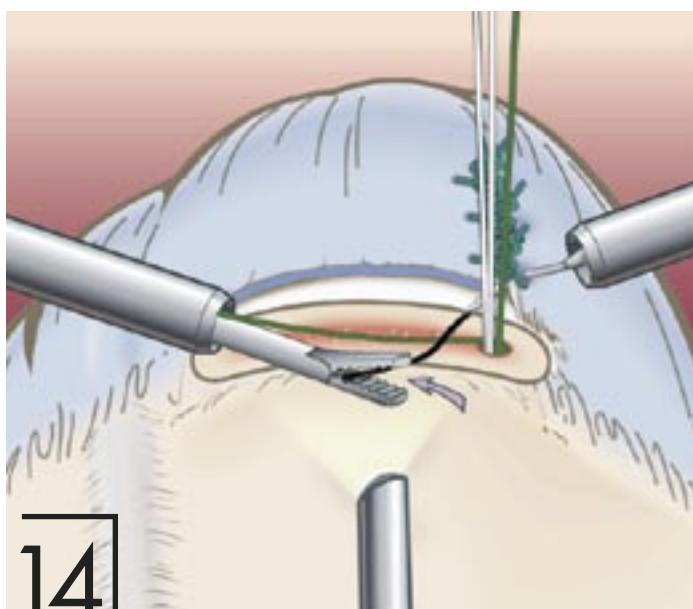
10

Withdraw the inserter from the pilot hole and subacromial space allowing the suture pack and needles to come out of the handle.



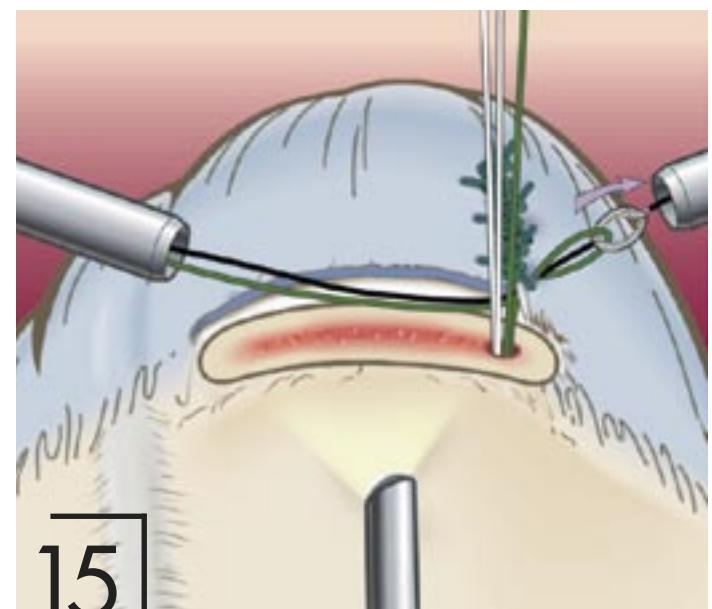
11

After insertion, test the anchor security by applying nominal tension to the suture limbs. (In soft bone, expect the anchor to withdraw slightly as the suture security is tested.)



14

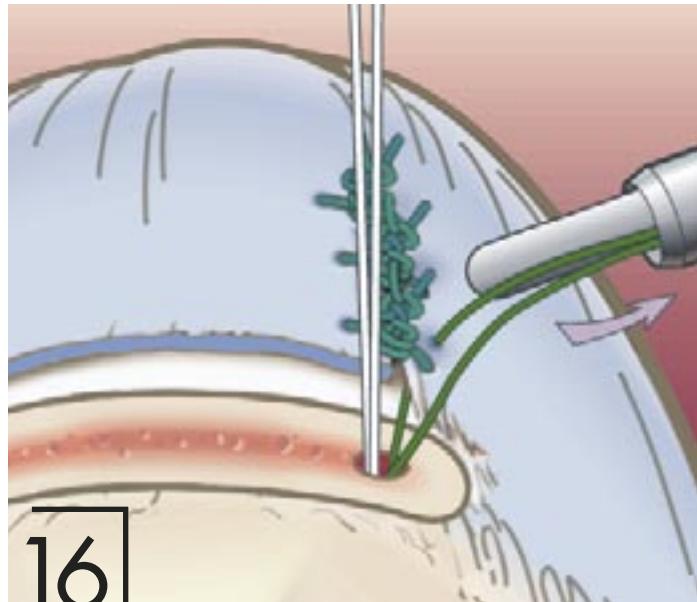
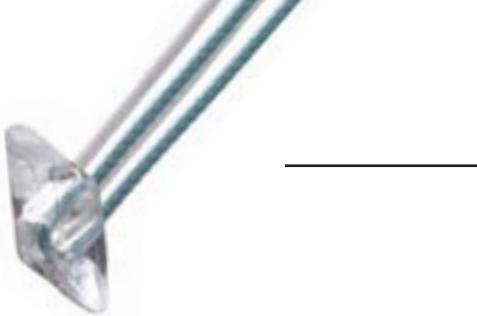
A **Spectrum Crescent Suture Hook** is inserted into the posterior cannula and through the bursal side of the posterior edge of the torn rotator cuff 5mm posterior to the anchor. The **Shuttle Relay** suture passer is sent through the hook and retrieved with a grasping forceps out the anterior cannula. Care must be taken to insure that the grasping forceps follows the same path as the green suture when retrieving the **Shuttle Relay** to avoid causing twists in the strands.



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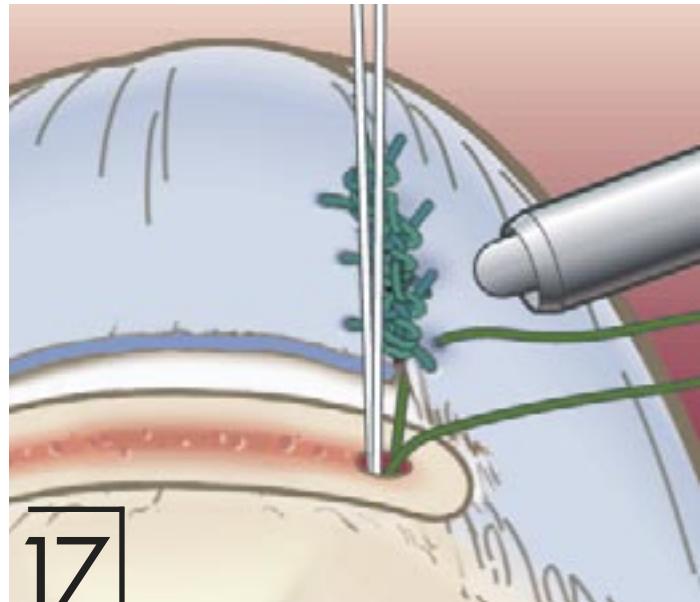
The green suture strand is loaded into the eyelet of the **Shuttle Relay** suture passer outside the anterior cannula. The suture is then carried through the cuff from the articular side to the bursal side by withdrawing the opposite end of the suture passer out the posterior cannula.

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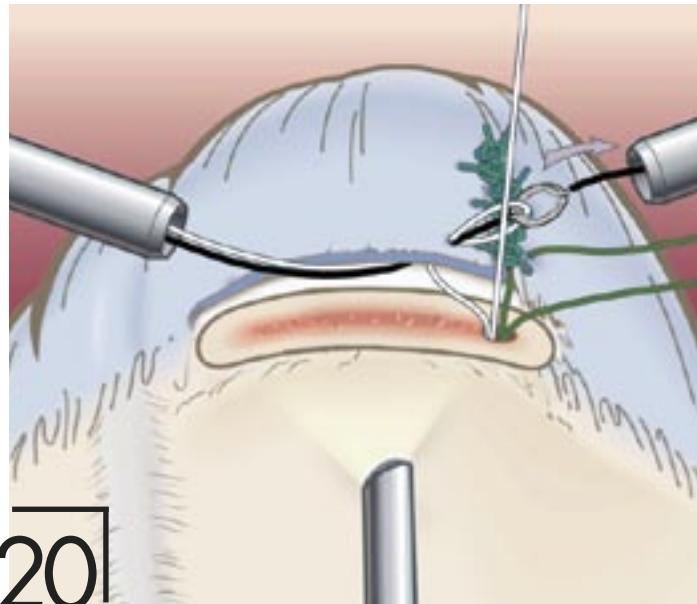
16

A crochet hook is used to retrieve the other limb of green suture into the posterior cannula. A switching stick is then inserted through the posterior cannula and the cannula is removed from the joint.



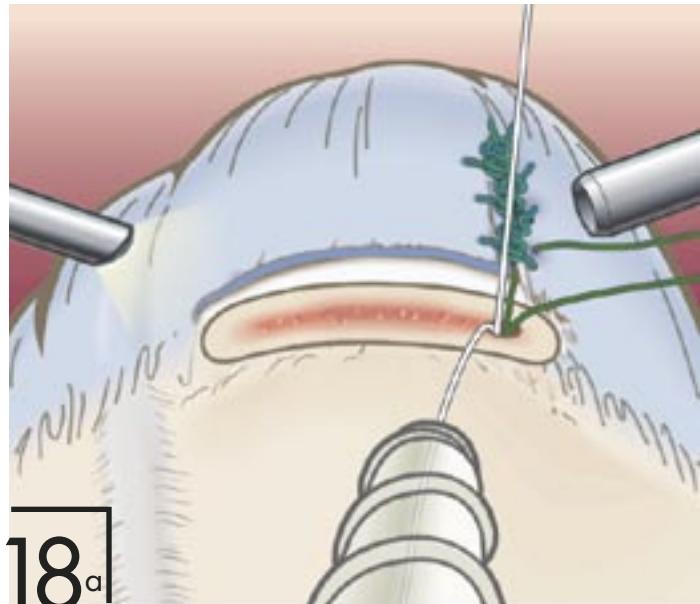
17

The cannula is reinserted over the switching stick leaving the sutures outside the cannula where they will be less likely to be tangled during stitching with the white sutures.



20

The white suture strand is loaded into the eyelet of the **Shuttle Relay** suture passer outside the anterior cannula. The suture is carried through the cuff from the articular side to the bursal side by withdrawing the opposite end of the suture passer out the posterior portal.

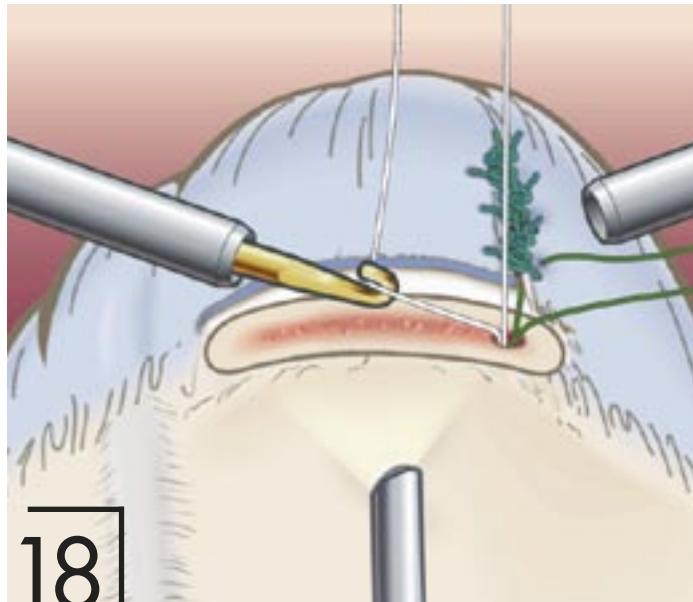


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ALTERNATIVE METHOD (MODIFIED CASPARI SUTURE PUNCH):
A crochet hook is used to retrieve the limb of white suture that is closest to the cuff. The suture is pulled out through the lateral cannula.

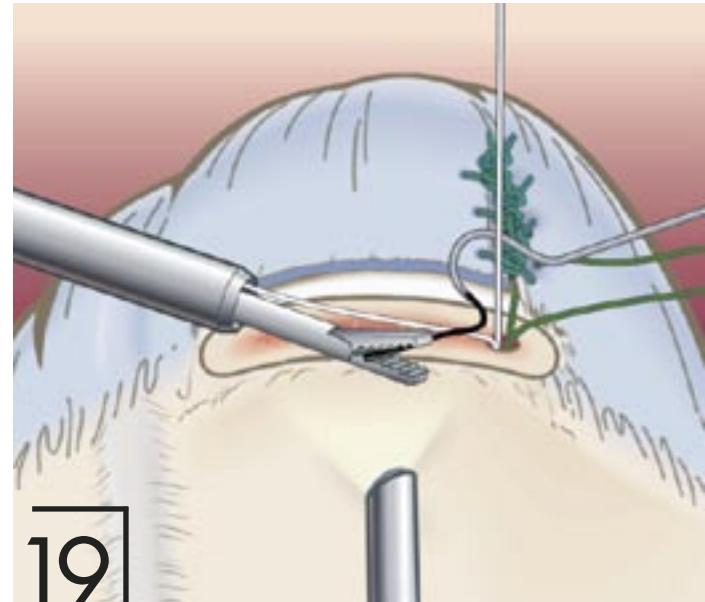
ARTHROSCOPIC ROTATOR CUFF REPAIR SURGICAL TECHNIQUE

Steps in repair technique



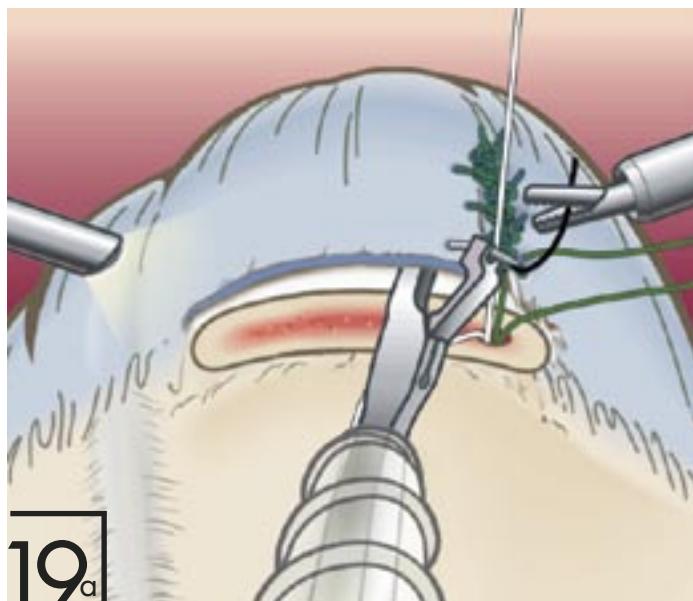
18

A crochet hook or suture retrieval forceps is used to retrieve the limb of white suture that exits the anchor eyelet closest to the rotator cuff. The suture is pulled through the anterior cannula.



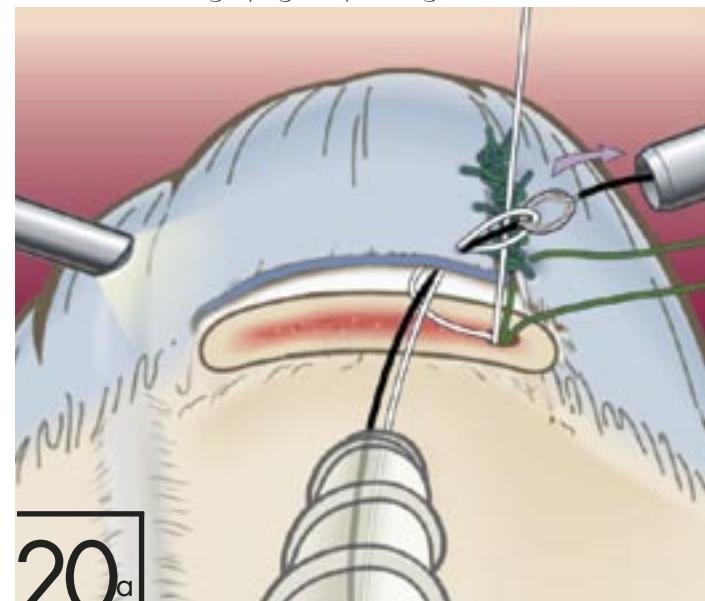
19

The **Spectrum Suture Hook** is passed through the torn rotator cuff from top to bottom approximately 5mm anterior to the anchor site. If a crescent suture hook is used again, it may be inserted through the posterior cannula. If a more angled suture hook is used, the posterior cannula can be removed and the hook passed directly through the portal without a cannula. The **Shuttle Relay** suture passer is passed through the hook and retrieved with a grasping forceps through the anterior cannula.



19a

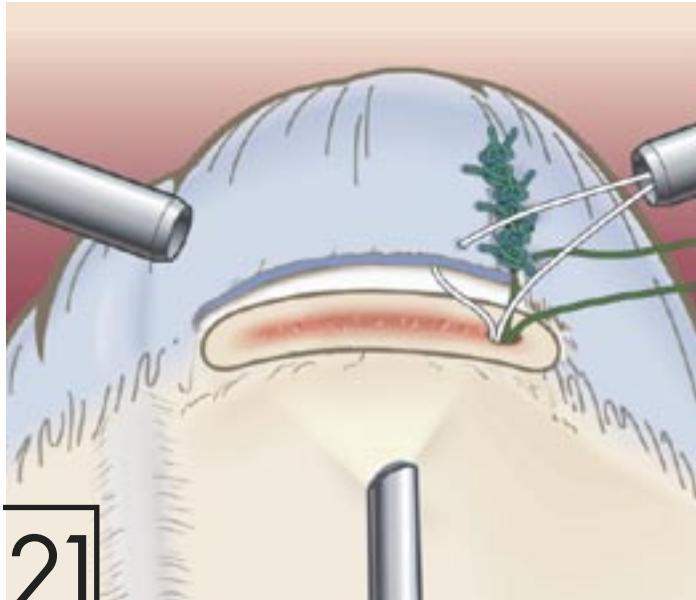
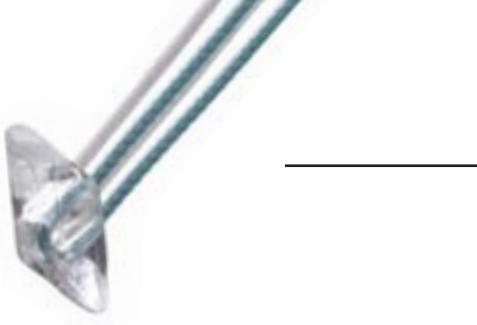
MODIFIED CASPARI SUTURE PUNCH CONTINUED: With the scope viewing from the anterior portal, a modified Caspari Suture Punch can be inserted through a **6.5mm ClearFlex Cannula** in the lateral portal to pass a **Shuttle Relay** suture passer from the bottom to top through the cuff. The suture passer is carried out the posterior cannula with a grasping forceps.



20a

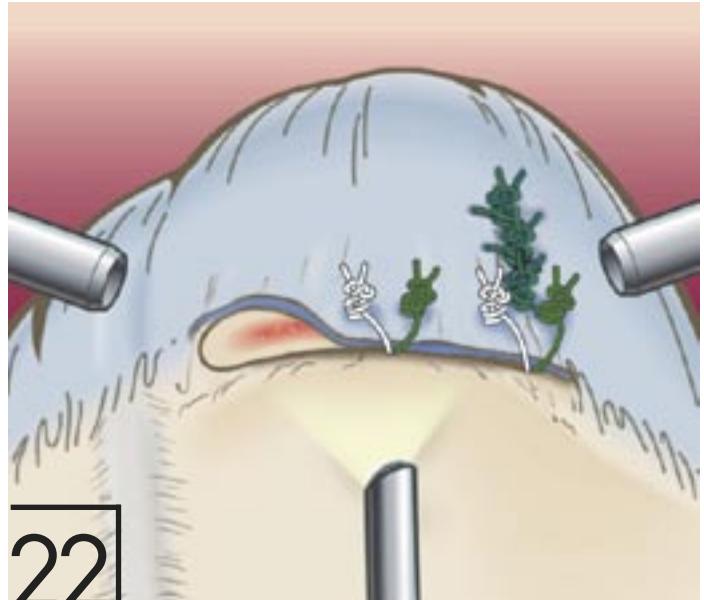
MODIFIED CASPARI SUTURE PUNCH CONTINUED: The eyelet of the **Shuttle Relay** suture passer is loaded with the suture outside the lateral cannula and carried through the cuff from bottom to top by pulling on the opposite end.

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The posterior cannula is reinserted and the remaining white suture limb is retrieved using a crochet hook or suture retrieval forceps.



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The ring handled knot pusher is threaded on to the green suture exiting the top of the cuff. It is passed into the joint to ensure there are no twists or obstructing soft tissue. The green and white suture limbs associated with the posterior anchor are first tied using a knot of choice. The second anchor is placed in a similar fashion, suture limbs passed, and tied down.

ARTHROSCOPIC KNOT TYING TECHNIQUE

REVO® KNOT

The arthroscopic Revo knot is an extremely important knot for all surgeons performing advanced shoulder reconstruction procedures. This knot can be used in any and all situations, whether or not the suture material slides freely through the tissue and anchor eyelet. If a complex stitch such as a figure-of-eight or double-pass mattress stitch is used, this knot is preferable to any sliding knot. In addition, when capsular plication is performed, it is important not to use a sliding knot because of the possible trauma to the labrum as the suture is pulled through.



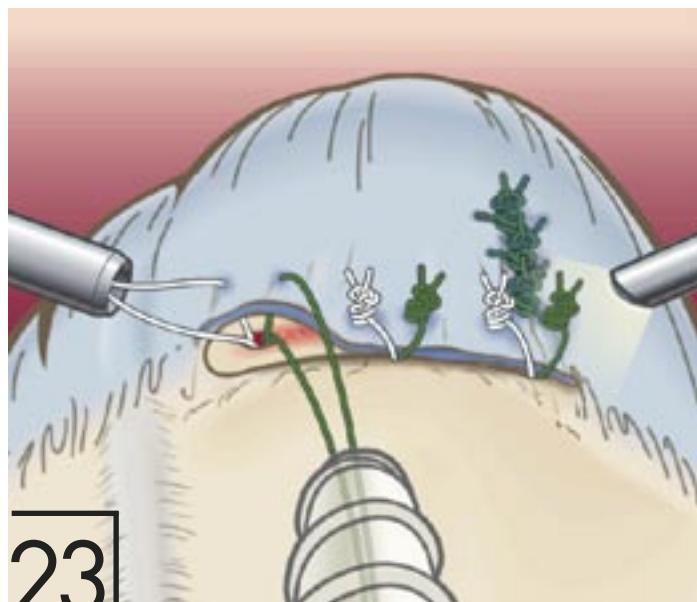
1. Both suture tails are the same length and the loop-handled knot pusher is threaded onto the suture which has been passed through the soft tissue. This original "post" is positioned on the left side, shown as the darker tail for illustration purposes. The knot pusher is passed down the original post suture to ensure that there are no twists or soft tissue obstructions.



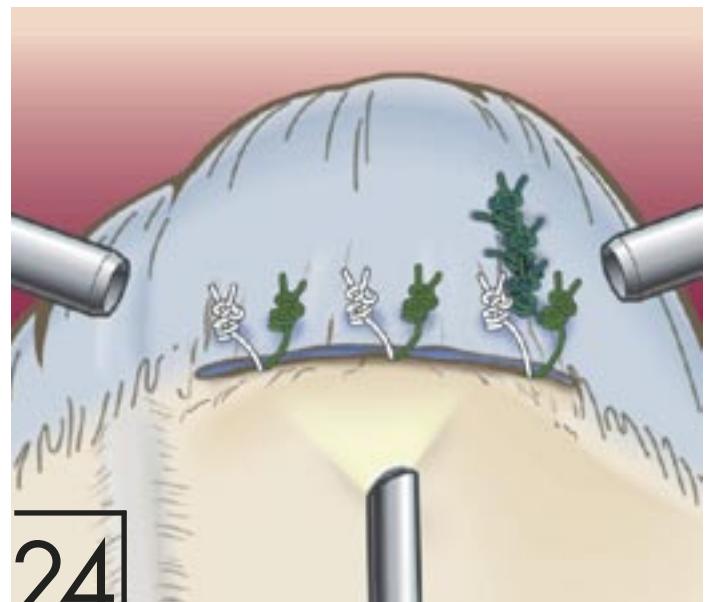
2. An **underhand** half-hitch is placed around the original post and advanced into position on the edge of the soft tissue.

ARTHROSCOPIC ROTATOR CUFF REPAIR SURGICAL TECHNIQUE

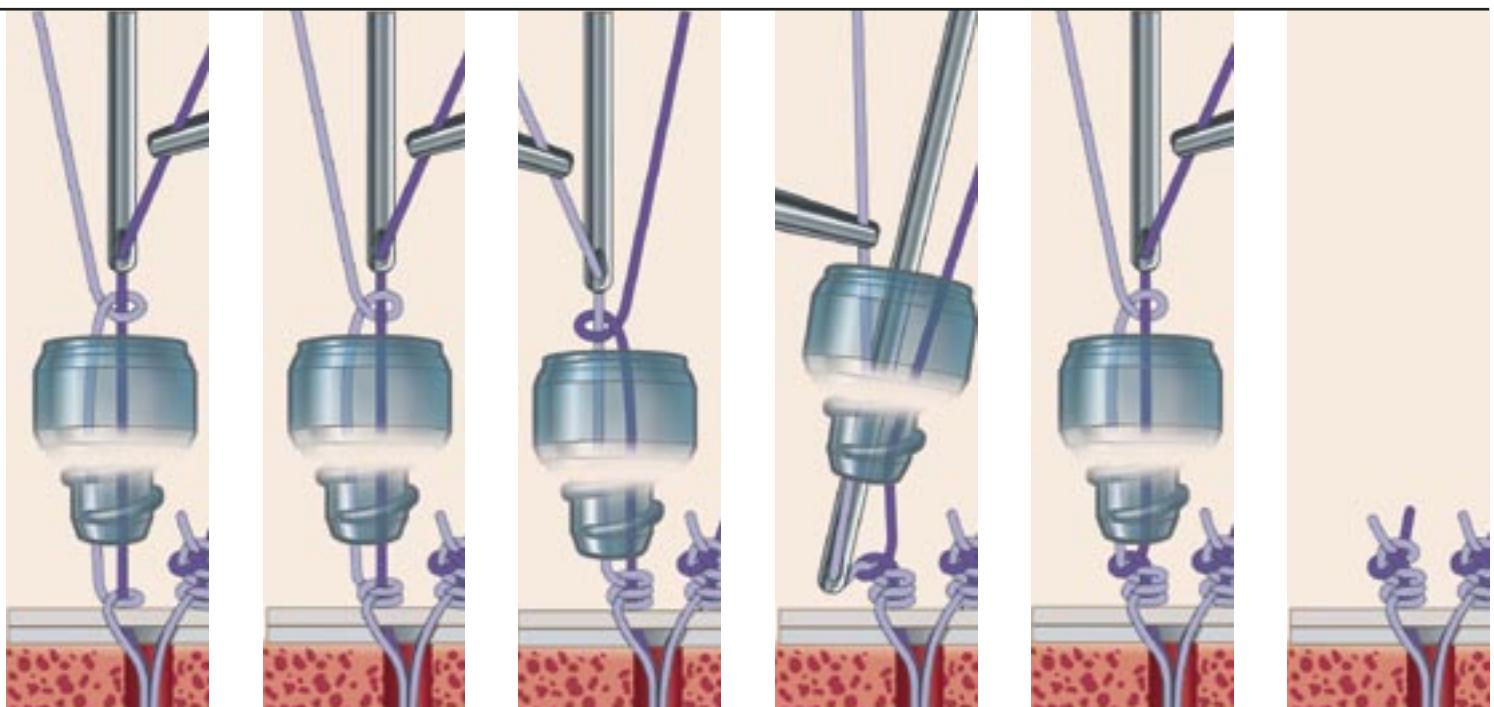
Steps in repair technique



The arthroscope may be moved to the posterior cannula for visualization. The third (anterior) anchor is placed in the same fashion and suture limbs passed through the cuff, usually suturing from the anterior portal.

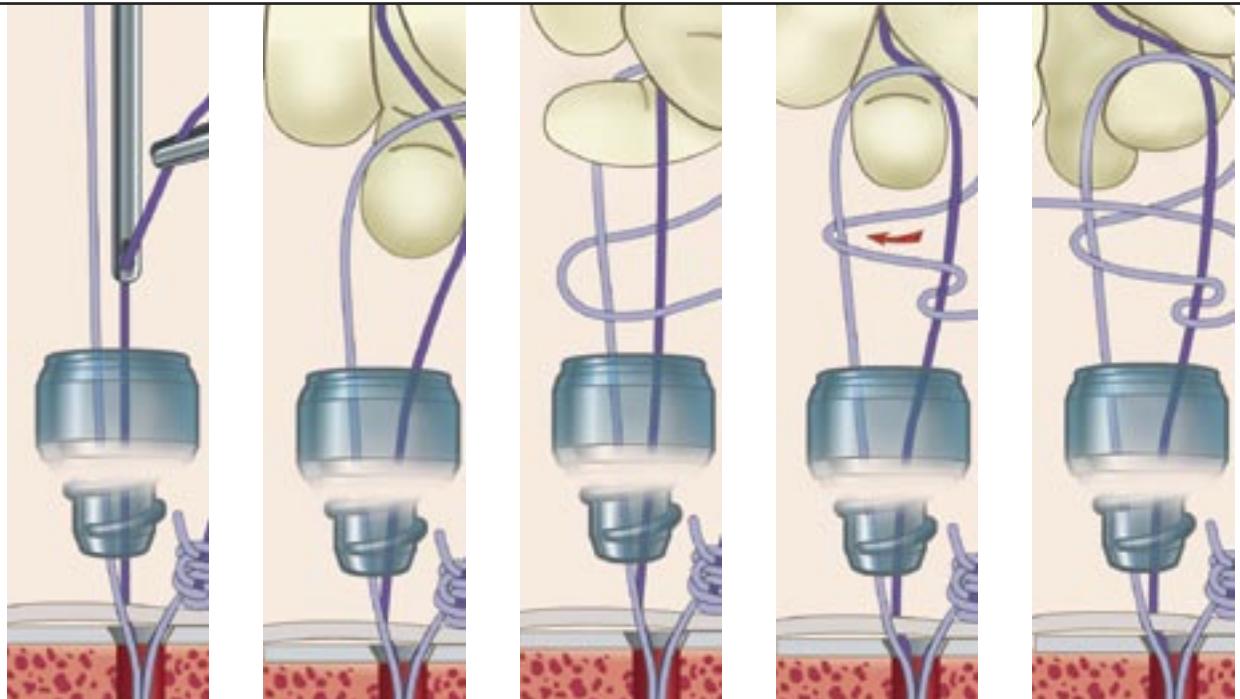


The illustration of the final repair shows three **UltraSorb** anchors in place. Each anchor has two fixation points through the rotator cuff oriented 45° from the anchor. Notice the final side-to-side repair. At the completion of the repair, the torn end of the rotator cuff is tightly opposed to the bone to promote strong rotator cuff tendon healing.



SMC KNOT

The SMC knot* is a unique sliding knot that utilizes a self-locking loop to achieve good initial knot security. The SMC knot is low profile and there is minimal or no slack once the knot is secured. The SMC Knot cannot be used if the sutures do not easily slide through the soft tissues. If there is any doubt about the freedom of suture passage, then the Revo knot should be used.



1. Thread the knot pusher on the post strand (held in the left hand) and place a clamp on the post. Pass the knot pusher into the joint to ensure that there are no twists or obstructing soft tissue. Arrange the suture so that the original post suture is short, with only 10cm of the suture outside of the cannula.

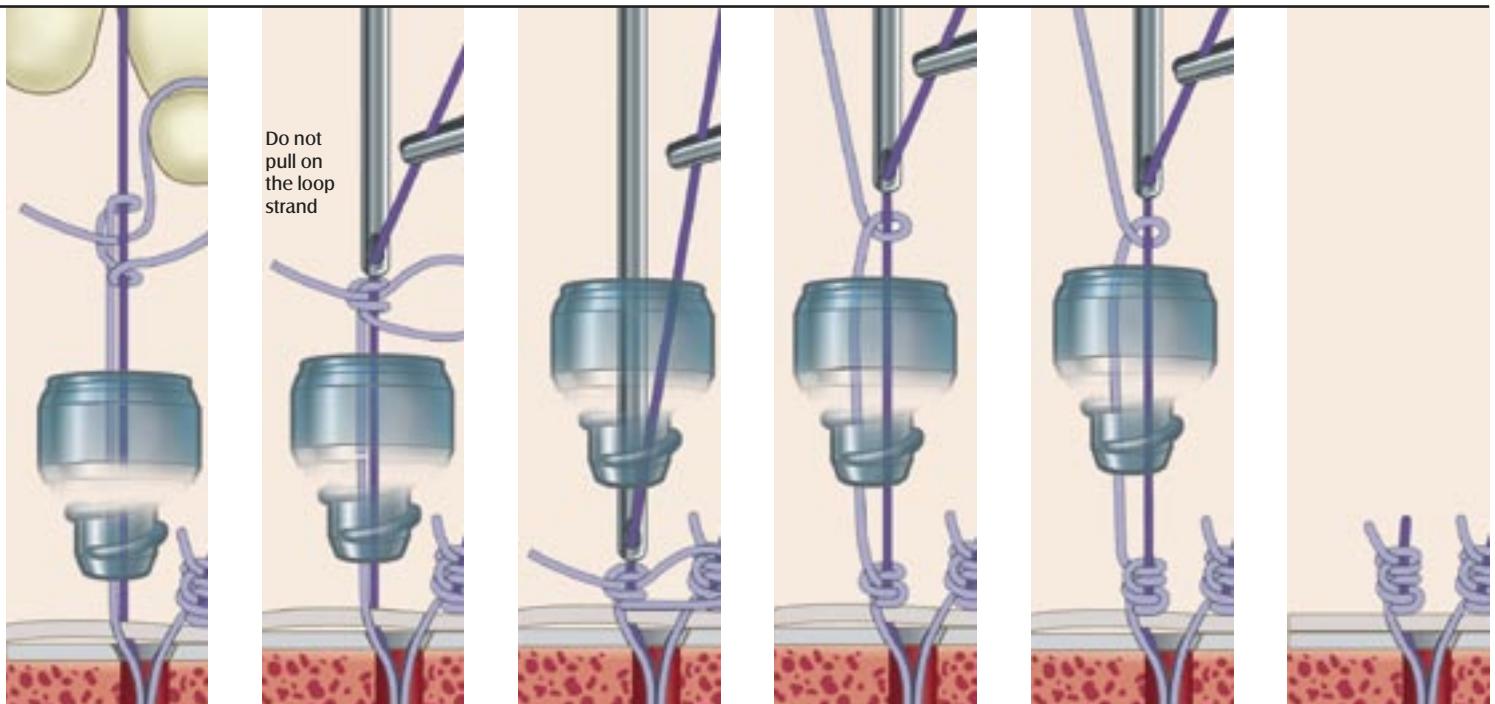
2. Pinch the two strands together between the thumb and index finger, crossing the loop strand over the post.

-3. Pass the loop suture under and then over both strands.

4. Pass the loop strand under the post strand between the two sutures and over the top of the post strand in a direction away from the pinching fingers. There will be a triangular interval formed between the two previous loops over the post strand (red arrow).

5. Feed the free end of the loop strand from bottom to top through this interval under the post strand. As the suture is pulled through, a "locking loop" is created (blue arrow).

*Developed by Seung-Ho Kim, M.D., Samsung Medical Center, Seoul, Korea



6. Release the thumb and index finger and place the left index finger into the "locking loop" from bottom to top to keep it open. Remove all slack (dress the knot) from the sutures with the index finger in place to avoid tightening the "locking loop" prematurely.

7. Pull on the post strand and use the knot pusher to guide the knot down to the tissue.
Do not pull on the loop strand until the knot is seated. Maintain tension on the post strand and back off the knot pusher to assess the knot.

8. Once satisfied that the knot is well seated, tighten the "locking loop" by pulling on the loop strand while maintaining pressure on the knot with the knot pusher.

9. The "locking loop" will slide over the knot pusher and secure the knot. For further security, an **underhand** half-hitch is worked down the post suture.

10. An **overhand** half-hitch is next placed on the post and worked down into position onto the knot stack.

11. Suture tails are cut with microscissors.

ORDERING INFORMATION

THE ULTRASORB™ SHOULDER FIXATION SYSTEM

UltraSorb Implant

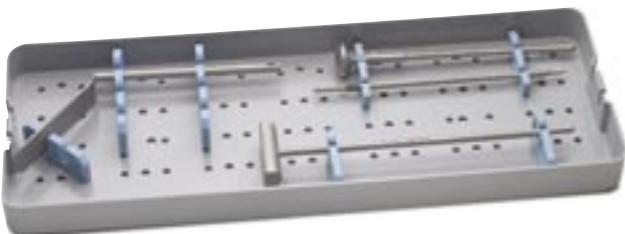
UltraSorb Bioabsorbable Rotator Cuff Kit 10400
(pre-loaded on a disposable inserter, pre-threaded with
two #2 braided sutures - green and white, tapered needles)

UltraSorb Instrument Set

UltraSorb Drill Bit, 4.0mm 10402
UltraSorb Awl, 4.3mm 10403
UltraSorb Drill Guide (6 point) 10418
UltraSorb Drill Guide Obturator 10433
UltraSorb Sterilization Tray 10423

Suture Passing Instruments

Slotted Jaw, Suture Punch, 4.0mm needle 18.1008
Spectrum Instrument Set:
 Suture Hook Handle 27.00011
 Suture Hook, Straight 97.10015
 Suture Hook, 45° Left Curve 97.14115
 Suture Hook, 45° Right Curve 97.14215
 Suture Hook, 90° Left Curve 97.19115
 Suture Hook, 90° Right Curve 97.19215
 Crescent Suture Hook, Small Curve, 3.0 x 15.0mm C8740
 Crescent Suture Hook, Medium Curve, 4.0 x 20.0mm C8741
 Crescent Suture Hook, Large Curve, 6.0 x 25.0mm C8742
Shuttle-Relay™ Suture Passer (10 per box) C6004
Blitz® Suture Retriever, Straight (6 per box) C6111
Blitz® Suture Retriever, 45° Left (6 per box) C6211
Blitz® Suture Retriever, 45° Right (6 per box) C6311
Hawkeye® Suture Needle (6 per box) C6001



UltraSorb Sterilization Tray with instruments



UltraSorb Implant and Disposable Inserter

Accessories

Loop Handle Knot Pusher C6112
Crochet Hook C6105
Teaser® Knot Tier C8004
Microscissors, 2.75mm Diameter, Straight 2.10011
Grasping Forceps, 3.4mm Diameter, Straight with Ratchet 11.1001
Suture Retrieval Forceps, 3.4mm Diameter 16.1018
Liberator Knife 25.50014

Entry Systems (Disposable)

6.5mm x 73.0mm Clear Flexible Cannula
with Disposable Conical Obturator C7312
6.0mm x 50.0mm Cannula with Disposable Conical Obturator
 Threaded Body C7322
 Smooth Body C7324
6.0mm x 75.0mm Cannula with Disposable Conical Obturator
 Threaded Body C7332
 Smooth Body C7334
6.0mm x 90.0mm Cannula with Disposable Conical Obturator
 Threaded Body C7342
 Smooth Body C7344
8.4mm x 50.0mm Cannula with Disposable Conical Obturator
 Threaded Body C7352
 Smooth Body C7354
8.4mm x 75.0mm Cannula with Disposable Conical Obturator
 Threaded Body C7362
 Smooth Body C7364
8.4mm x 90.0mm Cannula with Disposable Conical Obturator
 Threaded Body C7372
 Smooth Body C7374
70.0mm Universal Cannula Set with Fenestrations 9704
70.0mm Universal Cannula Set without Fenestrations 9718

Patent Pending



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