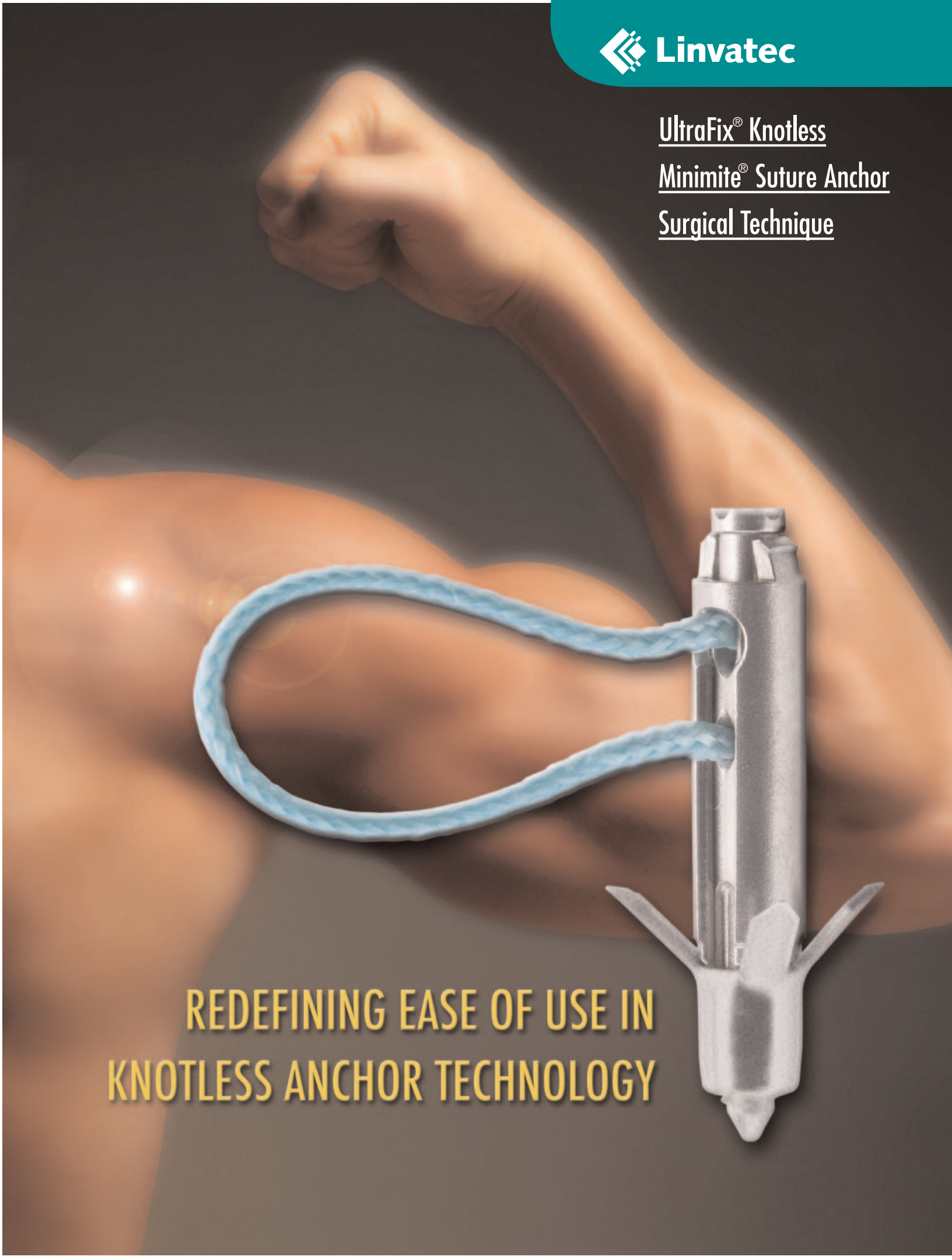


UltraFix® Knotless

Minimite® Suture Anchor

Surgical Technique



**REDEFINING EASE OF USE IN
KNOTLESS ANCHOR TECHNOLOGY**

ULTRAFIX[®] KNOTLESS MINIMITE[®] SUTURE ANCHOR

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INTRODUCTION

The Linvatec UltraFix Knotless MiniMite Suture Anchor System is designed for arthroscopic anterior shoulder instability procedures. The unique 2.3mm implant provides secure fixation while eliminating the difficult knot tying step. Prior to deploying the anchor in the bone the appropriate tension of the tissue can be achieved with a simple technique. This is critical in reconstructing the stabilizing structures in the glenohumeral joint. The Linvatec UltraFix Knotless MiniMite Suture Anchor redefines ease of use in knotless anchor technology.

It is recommended that the surgeon have an excellent understanding of the surgical technique and practice the steps of suture passing, anchor placement and tensioning of the tissue prior to clinical use. The following outline highlights the important steps in a typical arthroscopic Bankart repair. Linvatec Corporation will be happy to provide you with more comprehensive videotape instructions. You may also use an "Alex - The Shoulder Professor" shoulder model to practice these techniques prior to surgery. Information can be obtained by calling your local Linvatec representative or Customer Service at (800) 237-0169.

ULTRAFIX[®] KNOTLESS MINIMITE[®] SUTURE ANCHOR

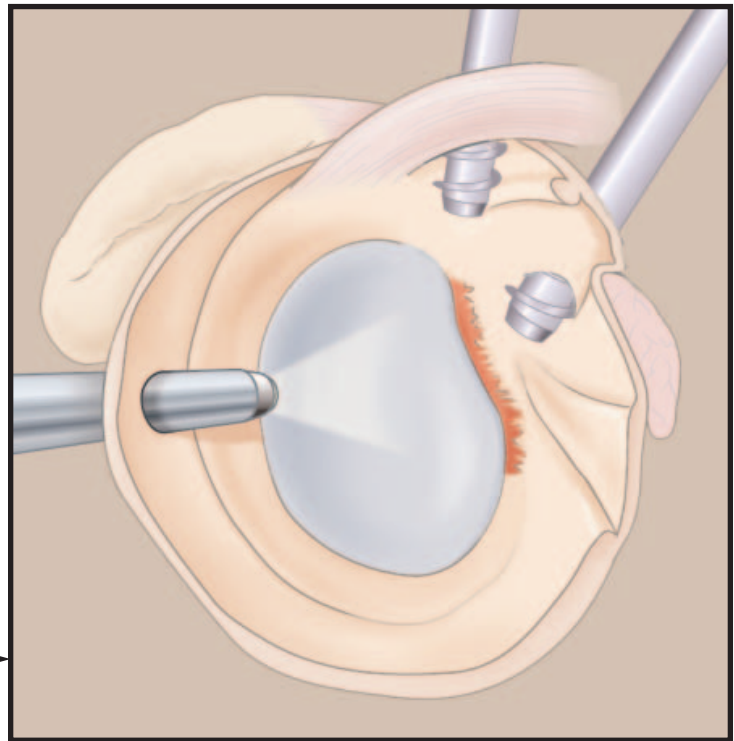
ULTRAFIX[®] KNOTLESS MINIMITE[®] SUTURE ANCHOR SURGICAL TECHNIQUE FOR BANKART REPAIR

The following technique is described by Hugh West, M.D., Salt Lake City, Utah

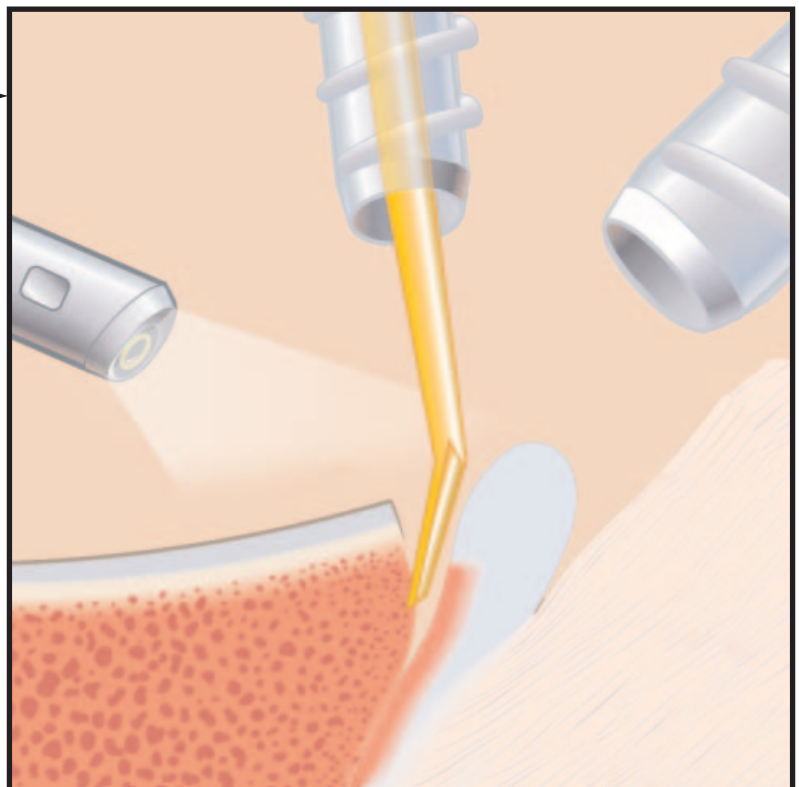
STEP 1 – ANATOMY EVALUATION & PREPARATION

With the arthroscope in the posterior portal, the Bankart lesion is evaluated and debrided with a Linvatec shaver (Fig. 1A), and the Liberator[™] Elevator is used to completely mobilize the capsule and labrum from the anterior neck of the glenoid. (Fig. 1B)

1A



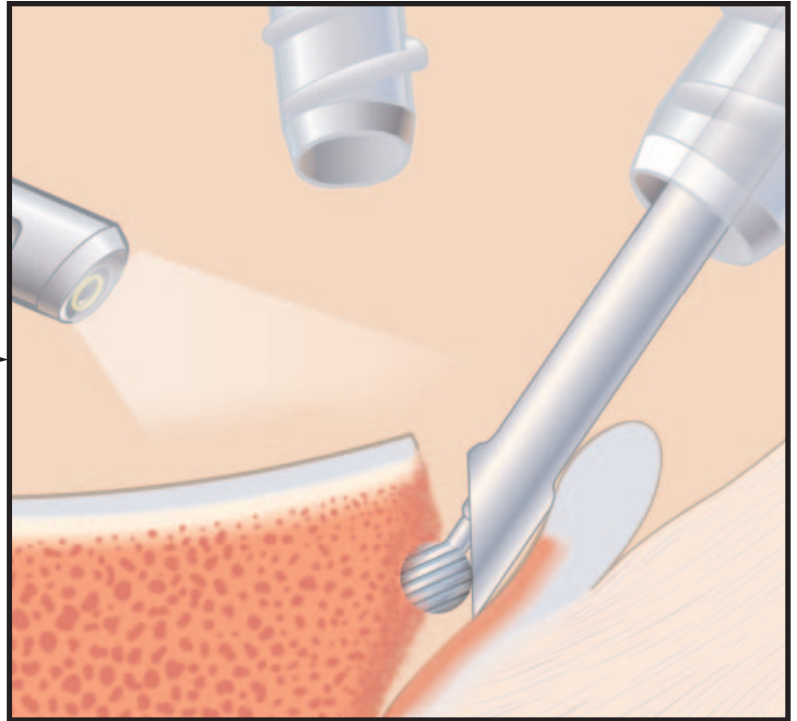
1B



**STEP 2 –
DECORTICATION**

A Linvatec bur lightly decorticates the glenoid rim and medial glenoid neck at the implantation site beginning at the edge of the articular surface.

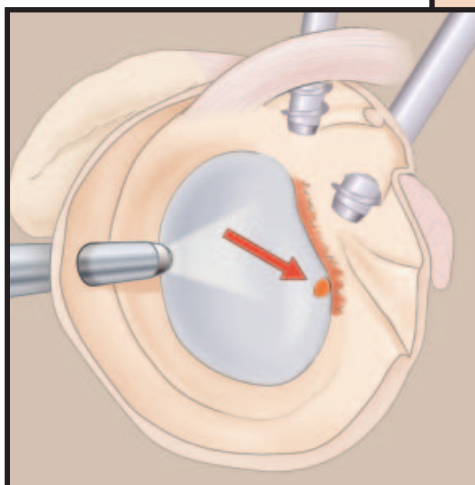
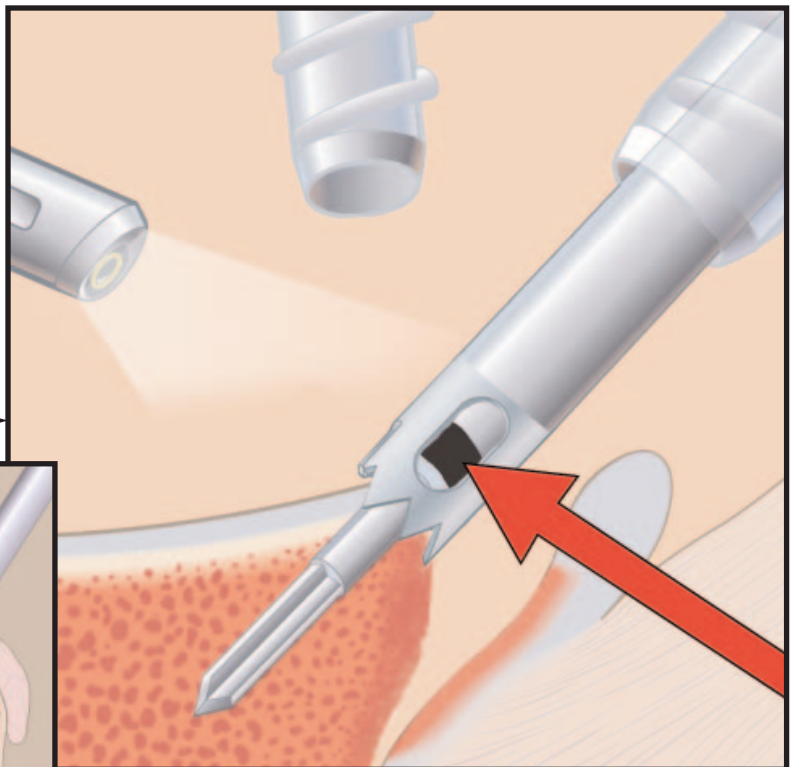
2



**STEP 3 –
DRILL THE PILOT HOLE**

An UltraFix Arthroscopic Drill Guide is inserted through the mid-glenoid cannula and positioned on the rim of the glenoid at the implantation site. A 3.5mm Knotless MiniMite Drill is inserted through the Drill Guide and drilled to the appropriate depth indicated when the distal depth stop bottoms on the bone surface. The drill depth stop is indicated by the black laser mark which can be visualized through the viewing window on the Drill Guide. The Drill Guide and Drill are removed from the cannula. **TIP:** A Linvatec Shutt® Forceps may then be used to mark the site of the hole by taking a small bite of articular cartilage adjacent to the tunnel entrance. This will aid in relocating the hole for placement of the anchor.

3



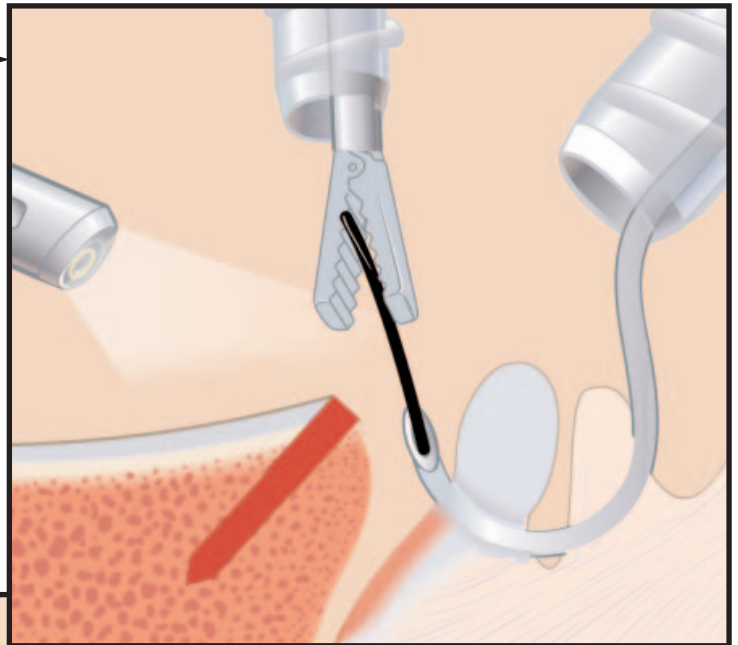
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4A

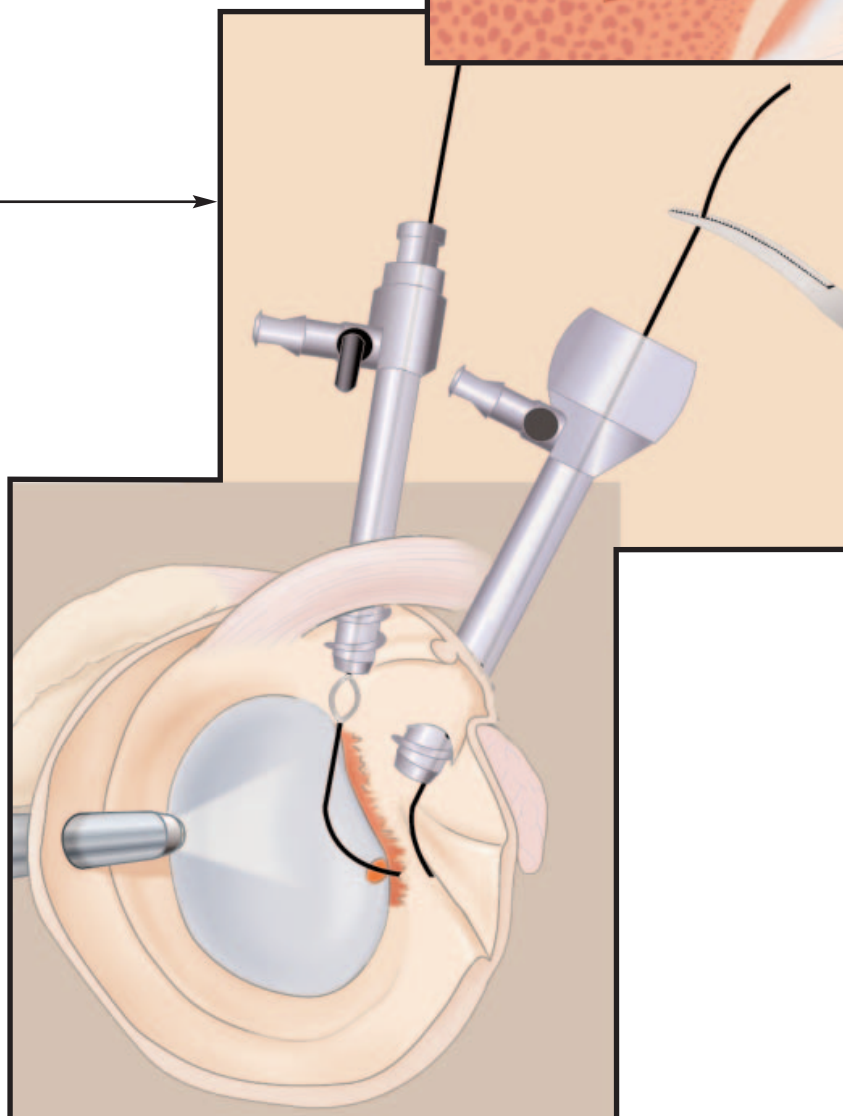
STEP 4 – PASS THE SHUTTLE RELAY™

4A. The appropriate Spectrum[®] Suture Hook is passed through the capsule and under the torn labrum towards the drilled hole. A Shuttle Relay™ Suture Passer is passed through the suture hook, and the passed limb is retrieved through the anterior superior cannula with a Linvatec Grasping Forceps.

4B. A hemostat is placed on the end of the Shuttle Relay that exits the mid-glenoid cannula.



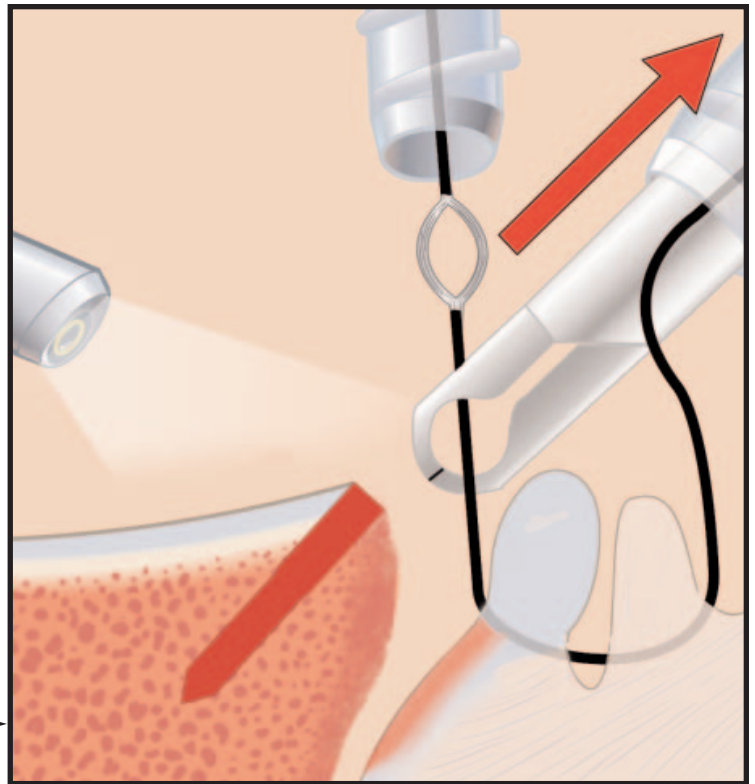
4B



STEP 5 –

RETRIEVE THE SHUTTLE RELAY™

The passed limb of the Shuttle Relay™ Suture Passer is then retrieved through the mid-glenoid cannula using a Suture Retrieval Forceps, so that both limbs are exiting the mid-glenoid cannula.

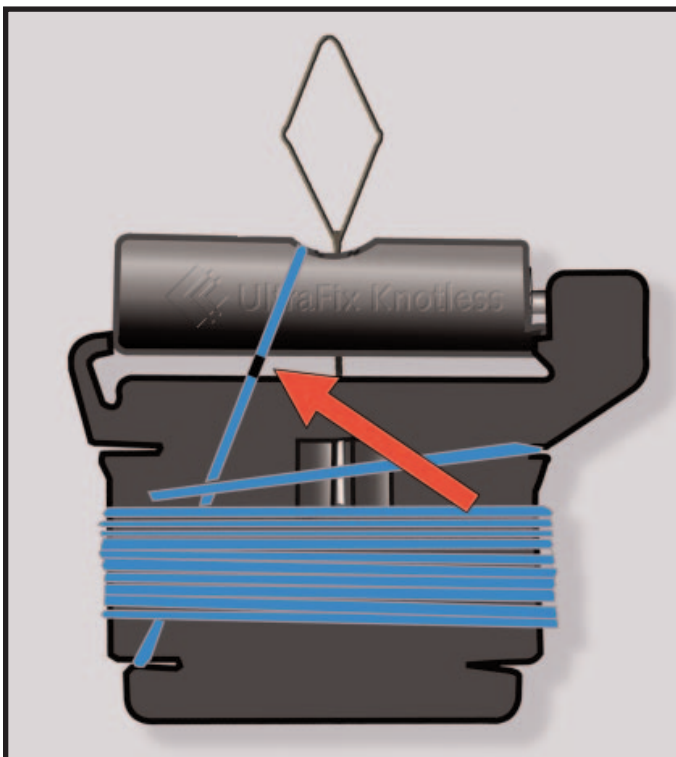


5

STEP 6 –

PREPARE THE ANCHOR SYSTEM

The Knotless Anchor-threader assembly is aseptically removed from the package. **TIP:** Using a sterile surgical marking pen, an optional mark may be placed on the suture at the gap between the threader sleeve and body (see red arrow). This mark provides a visual reference that will be explained further in step 10.



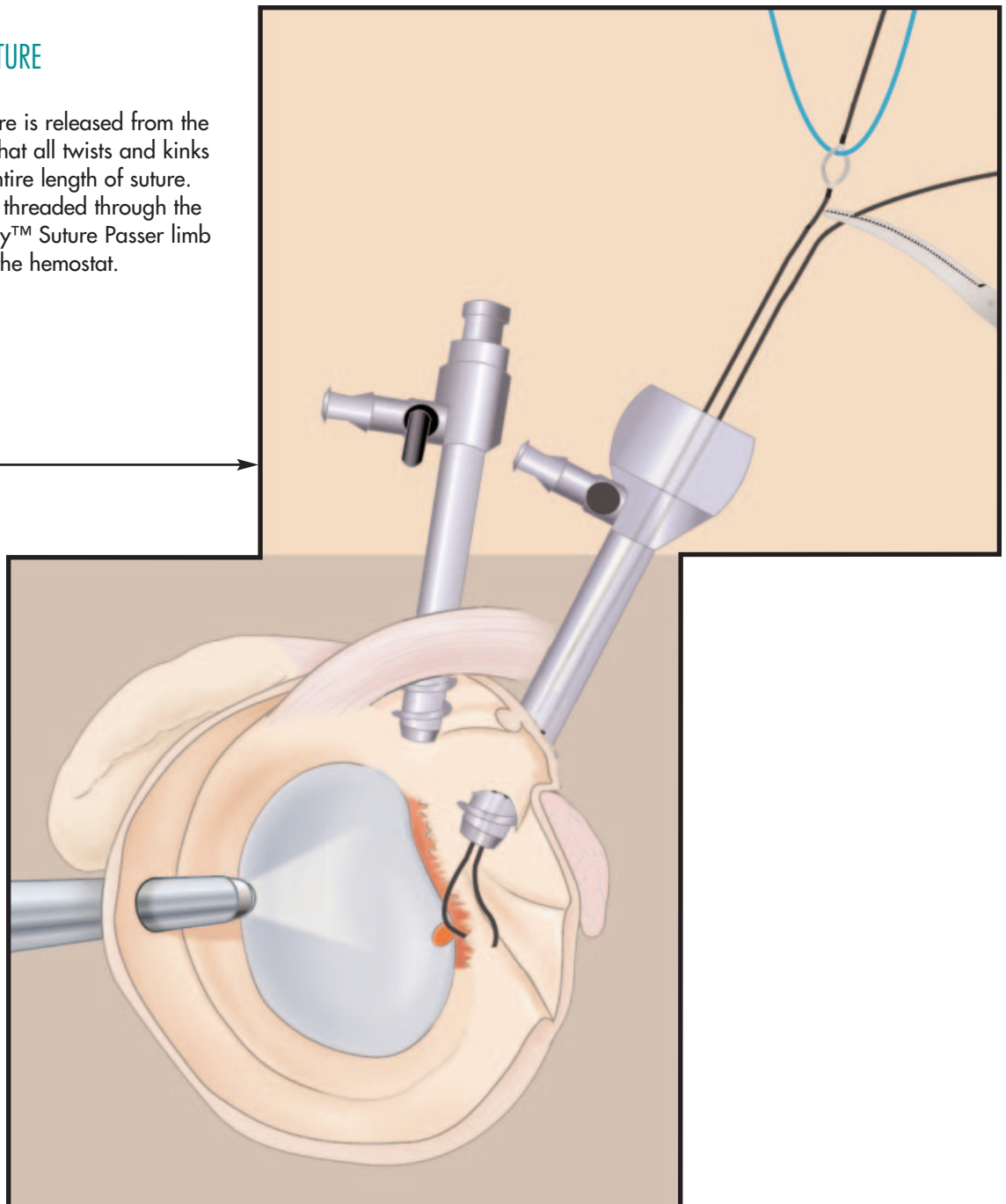
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ULTRAFIX[®] KNOTLESS MINIMITE[®] SUTURE ANCHOR SURGICAL TECHNIQUE FOR BANKART REPAIR

STEP 7 – PASS THE SUTURE

7A. The free end of suture is released from the threader body. Ensure that all twists and kinks are removed from the entire length of suture. The free end of suture is threaded through the eyelet of the Shuttle Relay[™] Suture Passer limb that is NOT marked by the hemostat.

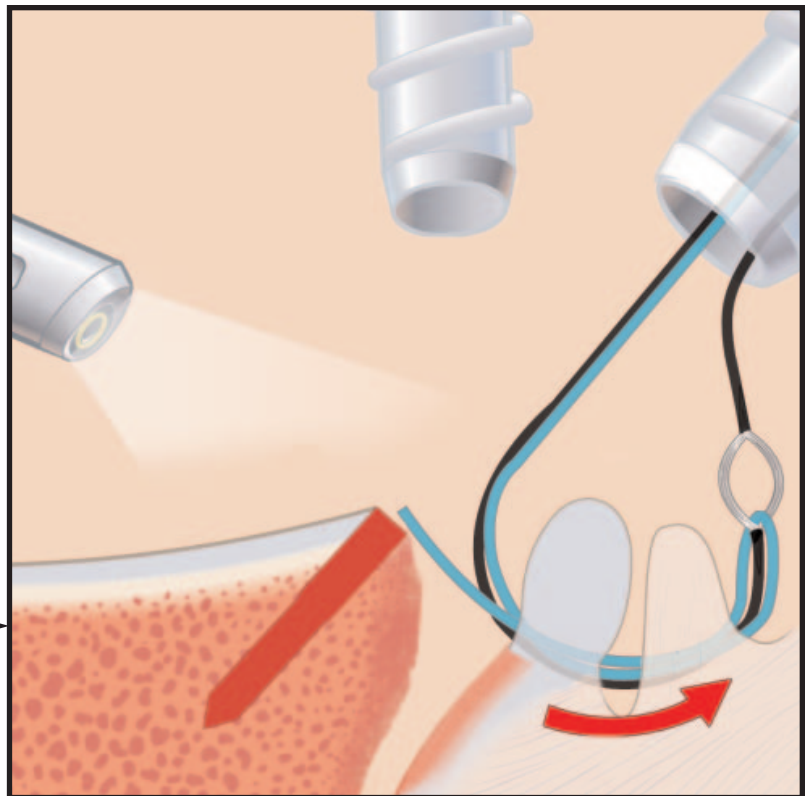
7A



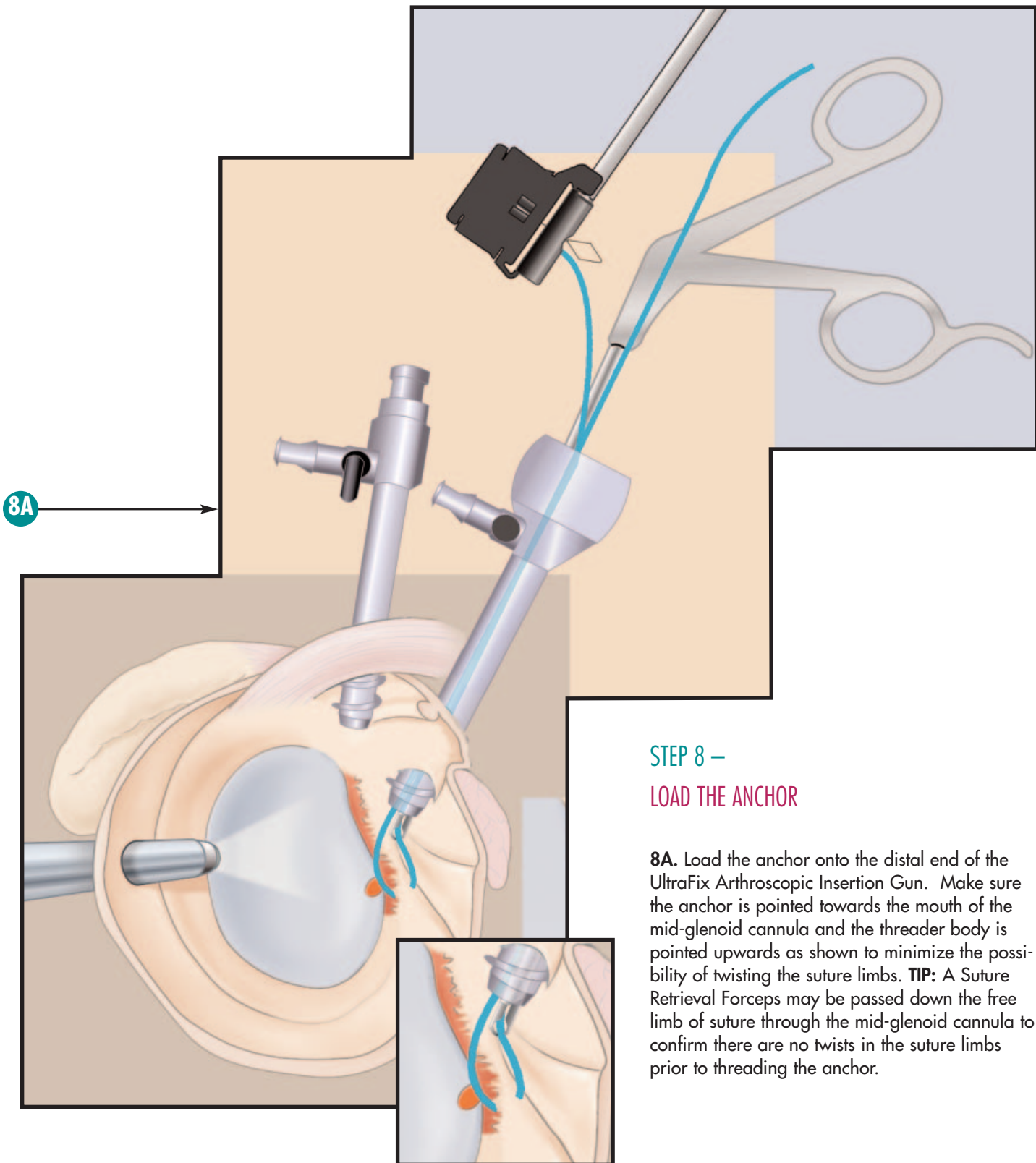
7B. The suture is then drawn through the labrum from the glenoid side towards the capsule (see red arrow) and out of the mid-glenoid cannula using the Shuttle Relay™ Suture Passer.

CAUTION: During suture passing, ensure that the anchor-threader assembly is maintained securely within the sterile field.

7B

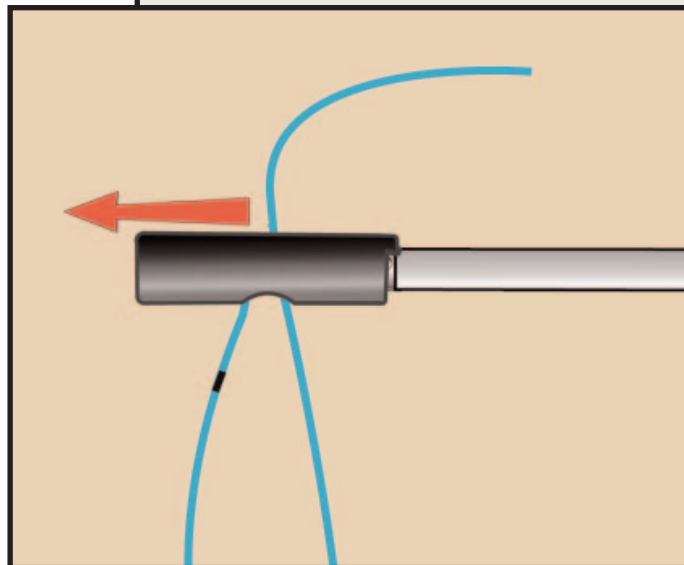
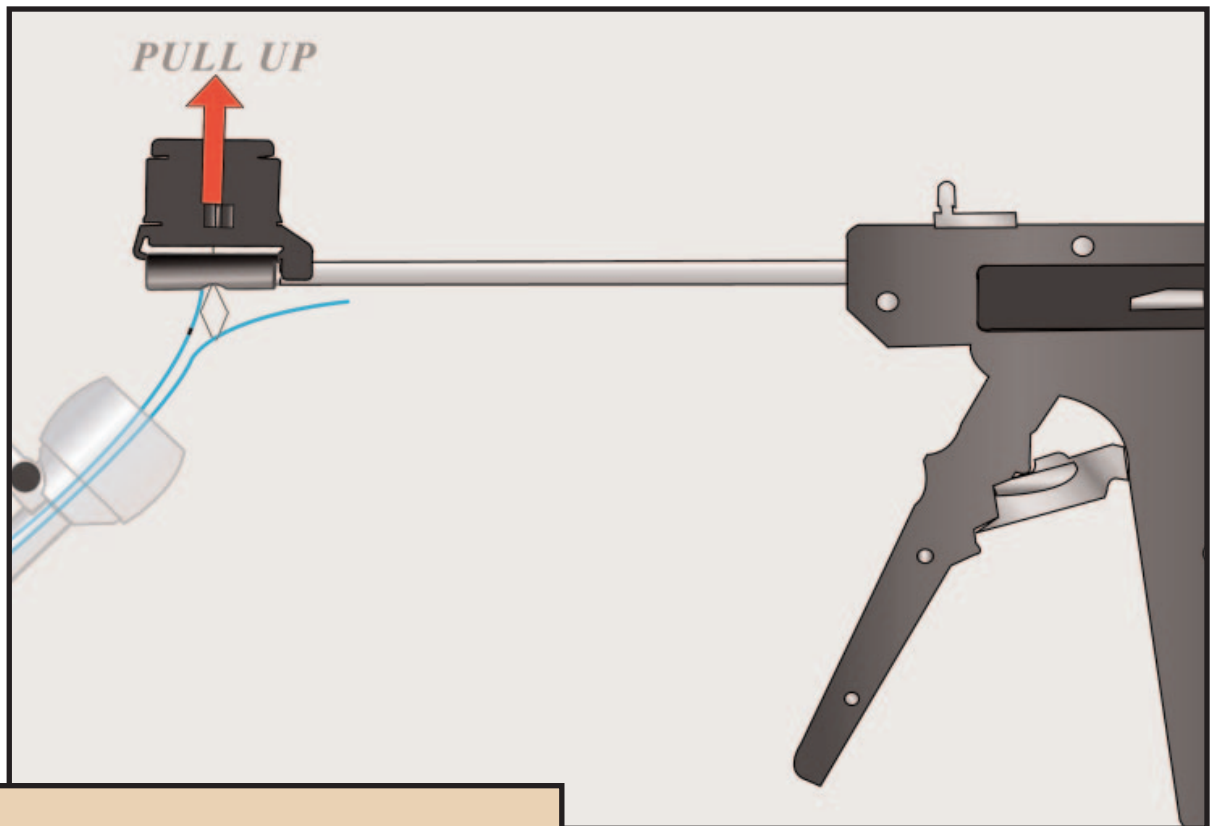


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STEP 8 – LOAD THE ANCHOR

8A. Load the anchor onto the distal end of the UltraFix Arthroscopic Insertion Gun. Make sure the anchor is pointed towards the mouth of the mid-glenoid cannula and the threader body is pointed upwards as shown to minimize the possibility of twisting the suture limbs. **TIP:** A Suture Retrieval Forceps may be passed down the free limb of suture through the mid-glenoid cannula to confirm there are no twists in the suture limbs prior to threading the anchor.



8B. Thread at least one inch of the free suture limb through the wire eyelet of the threader. Thread the anchor by pulling the threader body up and off of the sleeve, pulling the wire and free suture limb through the anchor body.

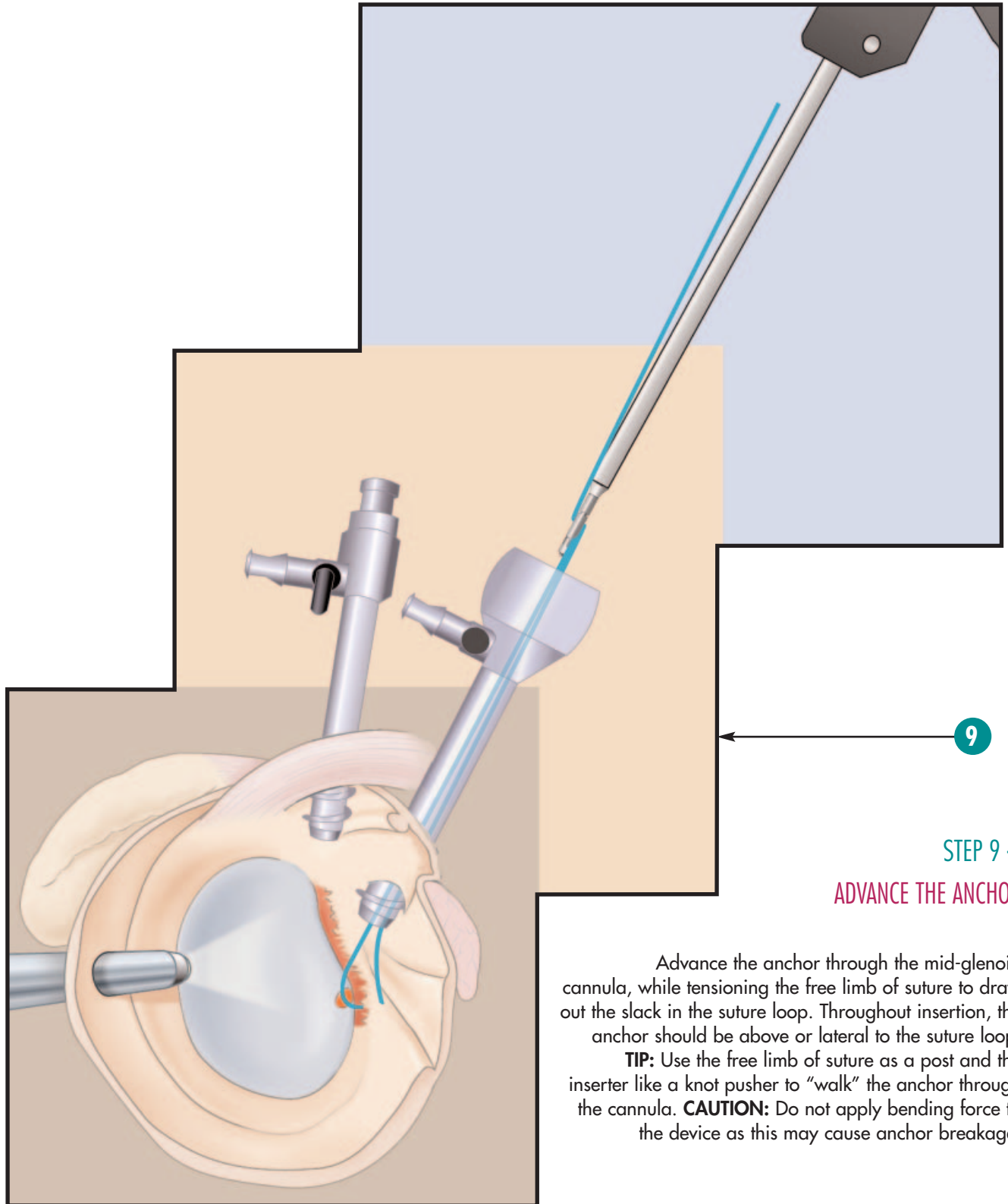
8B

8C. Remove the threader sleeve from the anchor.

8C

ULTRAFIX[®] KNOTLESS MINIMITE[®] SUTURE ANCHOR

SURGICAL TECHNIQUE FOR BANKART LESION REPAIR



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STEP 9 – ADVANCE THE ANCHOR

Advance the anchor through the mid-glenoid cannula, while tensioning the free limb of suture to draw out the slack in the suture loop. Throughout insertion, the anchor should be above or lateral to the suture loop.

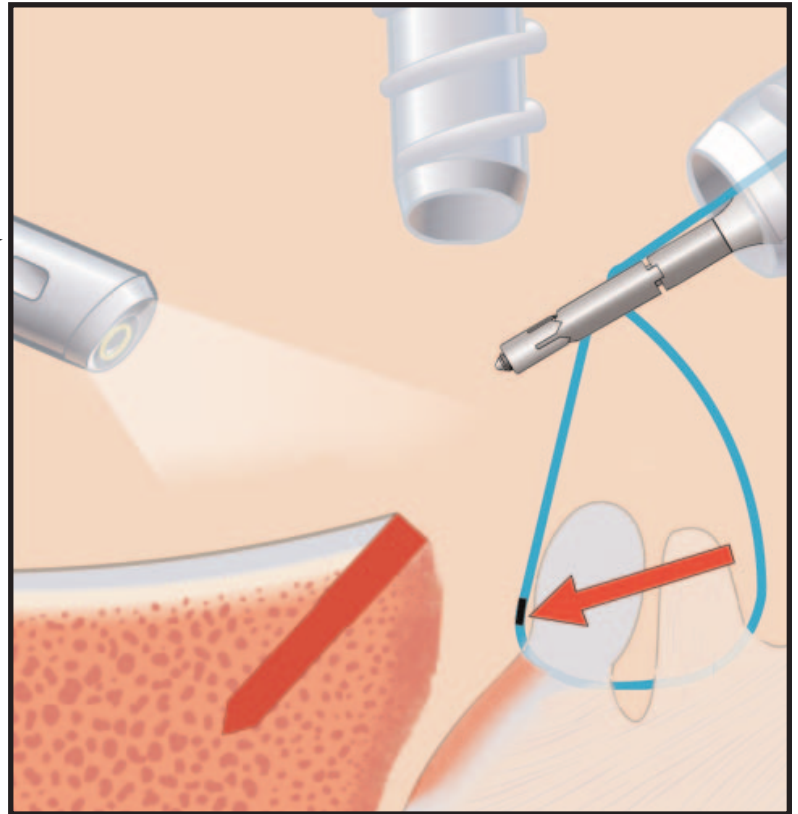
TIP: Use the free limb of suture as a post and the inserter like a knot pusher to “walk” the anchor through the cannula. **CAUTION:** Do not apply bending force to the device as this may cause anchor breakage.

10A

STEP 10 –

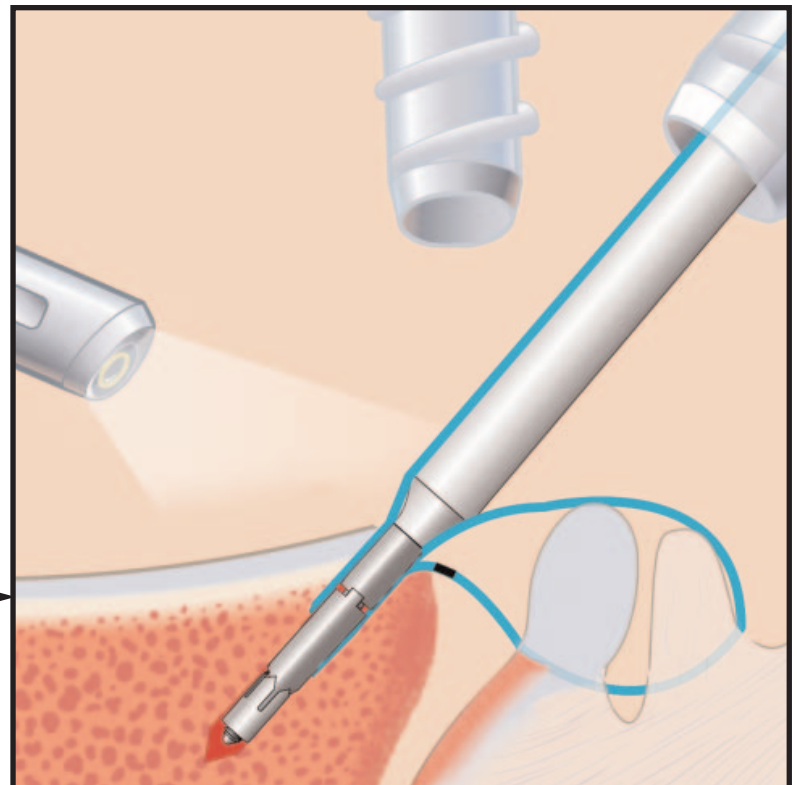
PLACE THE ANCHOR INTO THE HOLE

10A. Once the anchor reaches the distal end of the cannula, do **not** continue to draw slack out of the suture loop. If the optional suture mark is used, continue to draw out slack until the suture mark is within 1 to 3 mm of the labrum/capsule (see red arrow). This will allow enough slack to fully seat the anchor into the predrilled hole.



10B. Gently ease the anchor into the hole and make sure that the shoulder is fully seated onto bone. **CAUTION:** Do not apply off-axis loading to the device during insertion as this may cause anchor breakage. Care must be taken not to pass the anchor through the suture loop prior to insertion into the hole.

10B



ULTRAFIX[®] KNOTLESS MINIMITE[®] SUTURE ANCHOR SURGICAL TECHNIQUE FOR BANKART REPAIR

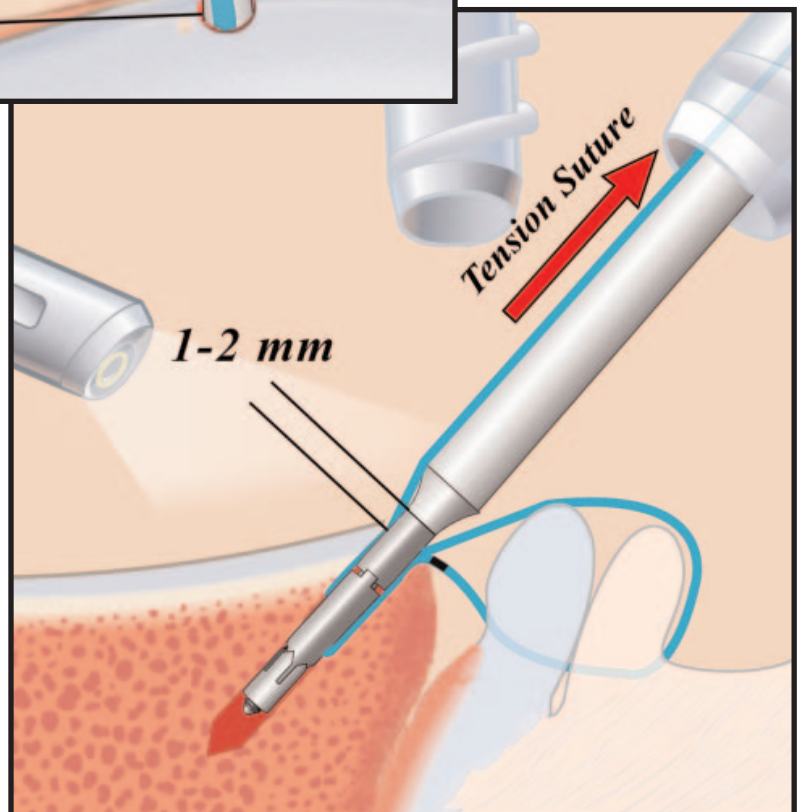
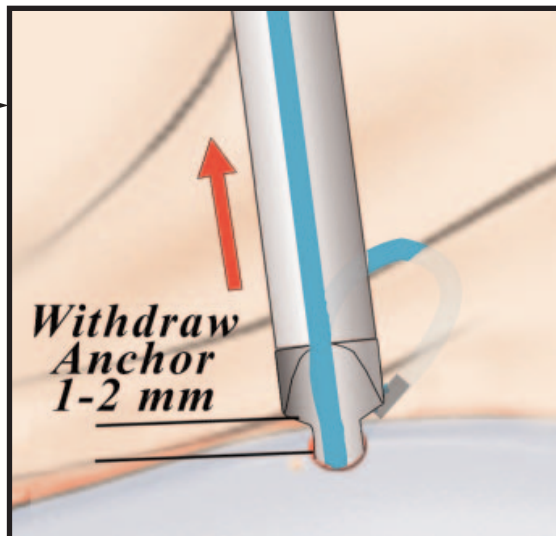
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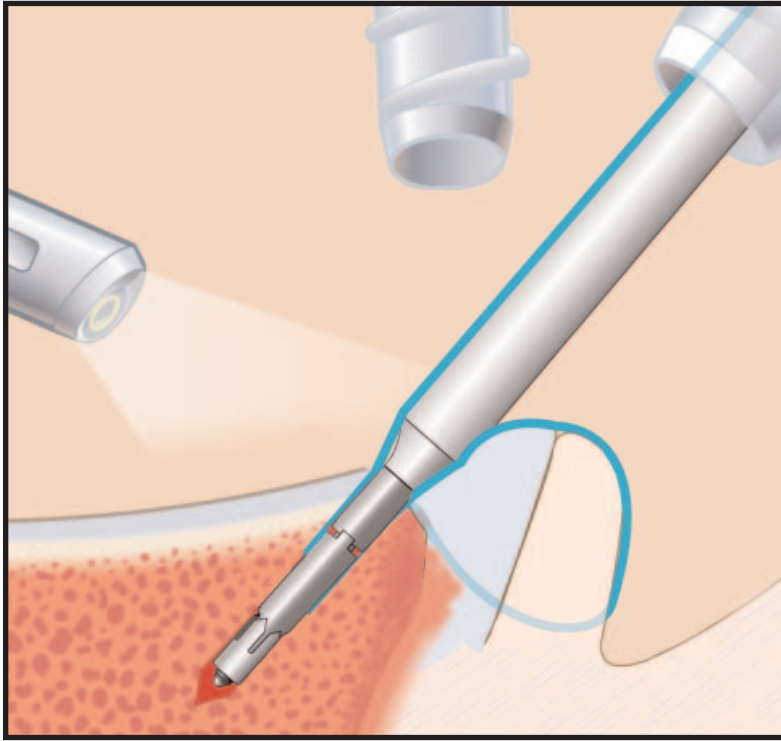
STEP 11 –

TENSION SUTURE TO REDUCE LABRUM

First, withdraw the anchor 1 to 2mm from the hole and then draw slack from the suture loop until the labrum is properly reduced.

TIP: Maintain axial force on the inserter during this step to prevent the anchor from withdrawing further from the hole.





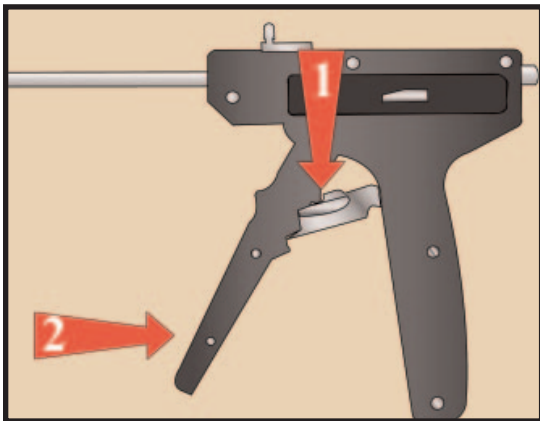
STEP 12 –

FULLY SEAT THE ANCHOR

While maintaining tension on the free limb of suture, apply axial force to the inserter to advance the anchor completely, drawing the labral edge into the hole. **THE SHOULDER MUST BE SEATED FIRMLY AGAINST THE GLENOID RIM TO ENSURE PROPER DEPTH OF DEPLOYMENT.**

TIP: If the labrum is too tight to fully seat the anchor, withdraw the anchor from the hole and create additional slack by pulling the anchor back into the cannula. Then repeat steps 10 and 11.

12

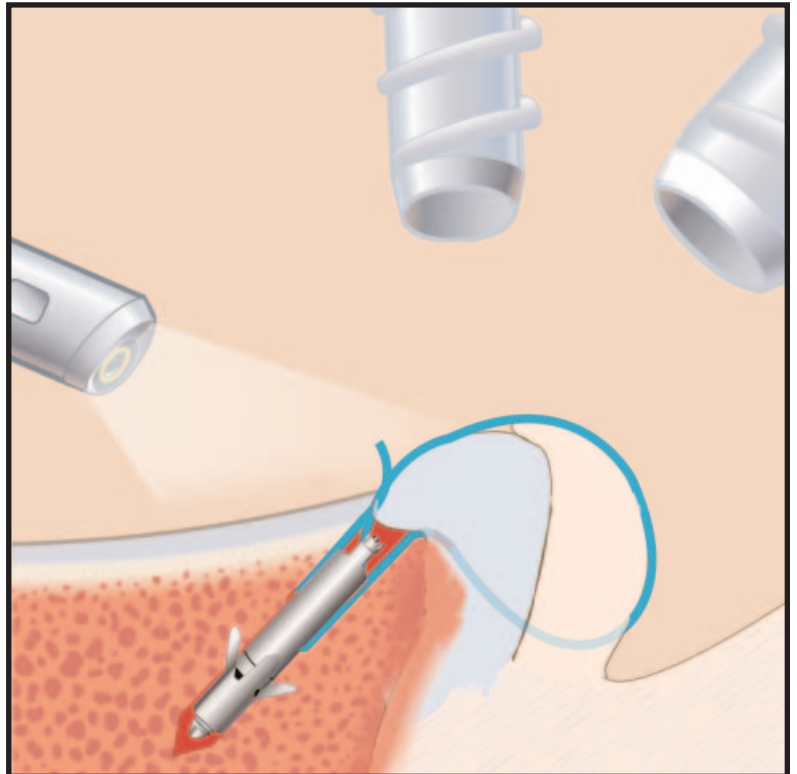


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STEP 13 –

DEPLOY THE ANCHOR

Once appropriate tension on the labrum is achieved, release the safety latch (1) on the inserter and squeeze the trigger (2) until a “pop” is heard to deploy the anchor. Maintain firm axial force on the inserter and tension on the free limb of suture during this step. Remove the inserter from the joint and discard the attached anchor cartridge.



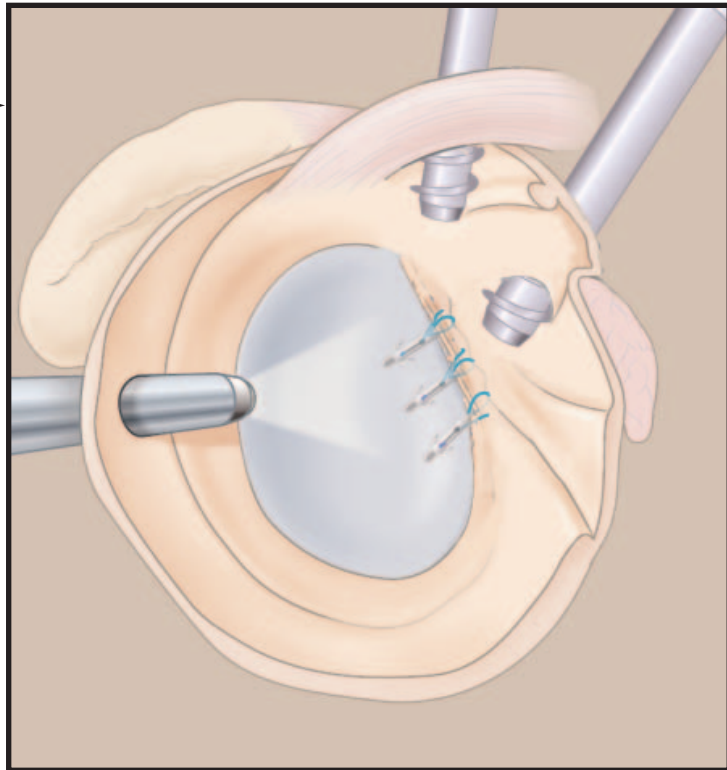
ULTRAFIX[®] KNOTLESS MINIMITE[®] SUTURE ANCHOR
SURGICAL TECHNIQUE FOR BANKART REPAIR

14

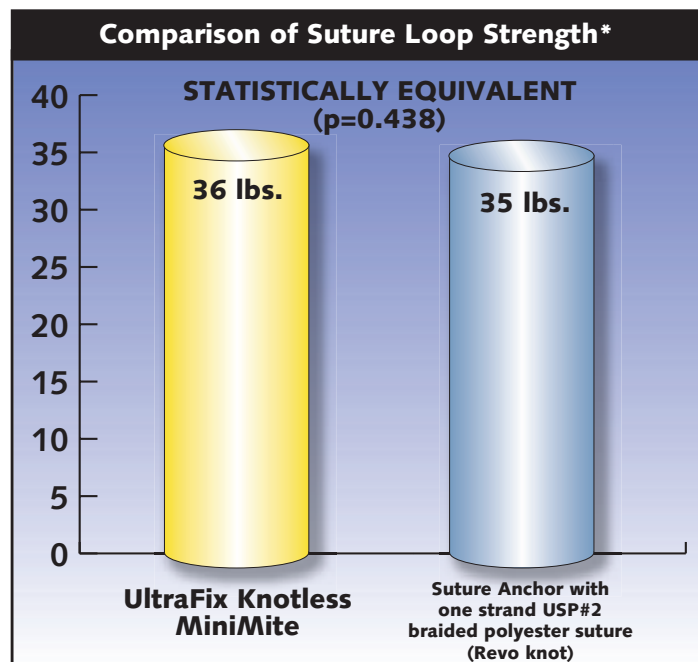
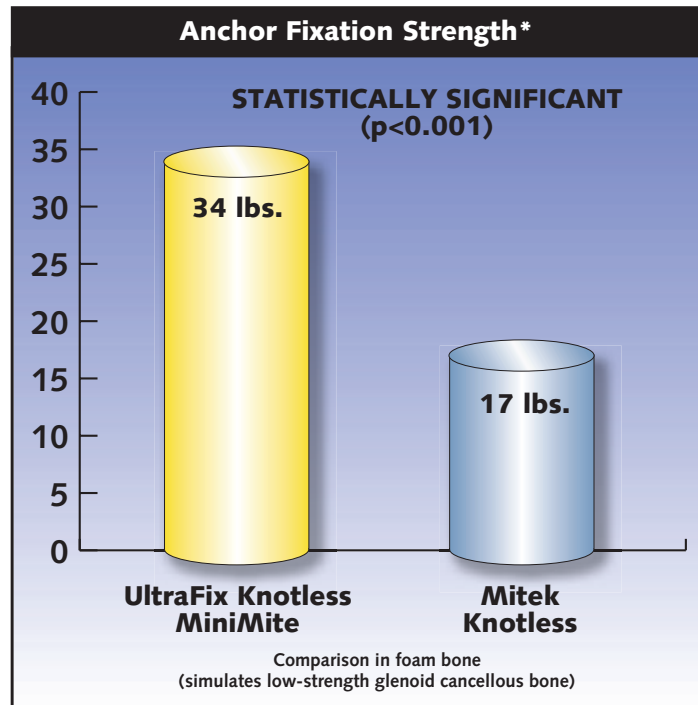
STEP 14 –

SECURE WITH ADDITIONAL ANCHORS

Additional anchors are placed as needed to reconstruct the anterior labral buttress and properly restore tension in the capsule and the gleno-humeral ligaments.



ULTRAFIX[®] KNOTLESS MINIMITE[®] SUTURE ANCHOR COMPARISON DATA



* Data on file at Linvatec

ULTRAFIX® KNOTLESS MINIMITE® SUTURE ANCHOR

UltraFix Knotless MiniMite Suture Anchor, 2.3mm dia., 1 each ..	10220
UltraFix Knotless MiniMite Suture Anchor, 2.3mm dia., 5 each ..	10221
3.5mm UltraFix Knotless MiniMite Drill Bit	10222
3.5mm UltraFix Knotless MiniMite Bone Punch	10223
Drill Guide, 6 point	10004
Insertion Gun	10085
Arthroscopic Drill Guide	10095
Arthroscopic Insertion Gun	10121
Anchor Tap Down Tool, 2.4mm Dia.	10279
Sterilization Tray	10053

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
Suture Tram, Straight, 3.3mm dia.	C6800
Suture Tram, 15° upswept, 3.3mm dia.	C6801

Accessories

Loop Handle Knot Pusher	C6112
Crochet Hook	C6105
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

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Acknowledgements:

Various components of this system have been designed in conjunction with Dr. Hugh West, M.D.

Patent pending.