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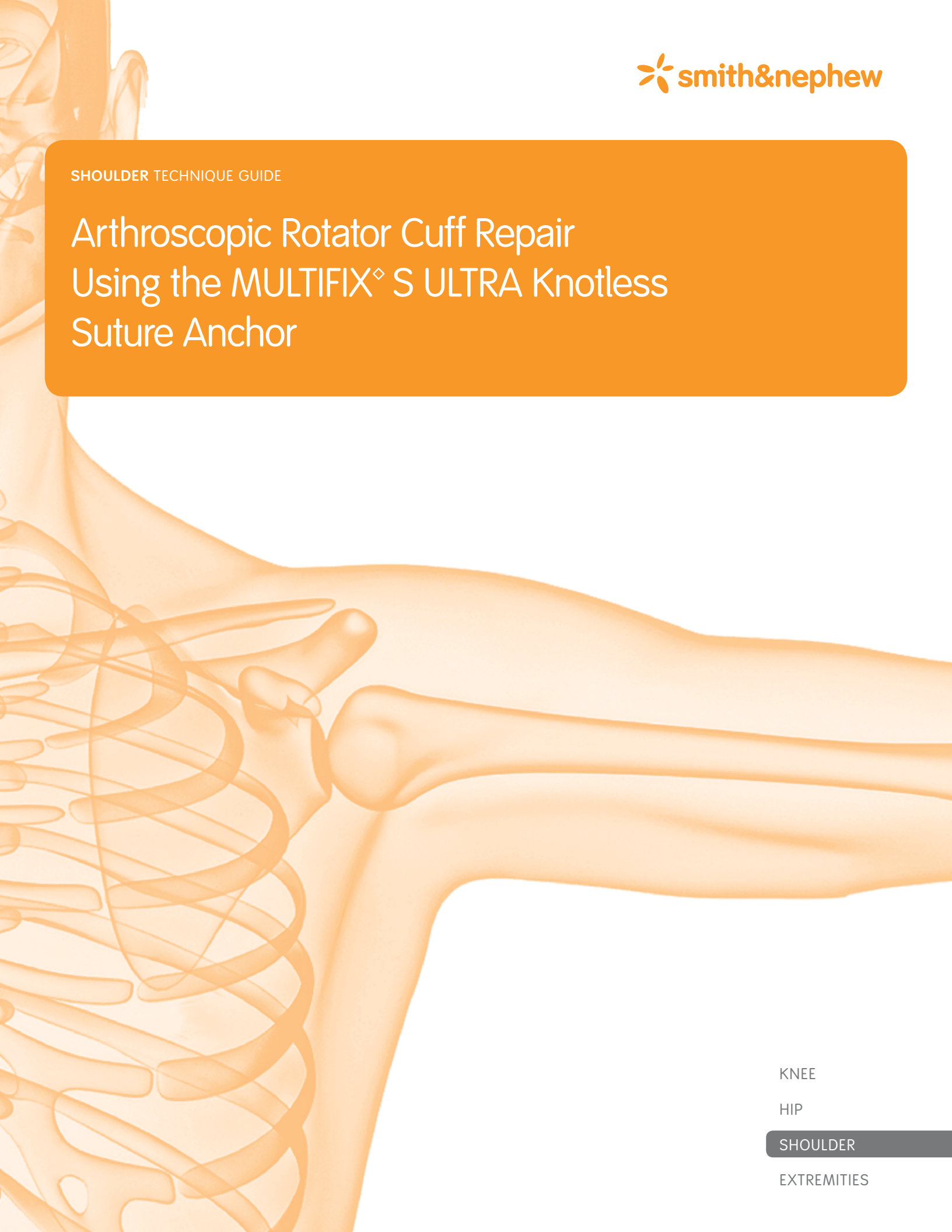
SHOULDER TECHNIQUE GUIDE

Arthroscopic Rotator Cuff Repair Using the MULTIFIX® S ULTRA Knotless Suture Anchor



KNEE

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EXTREMITIES

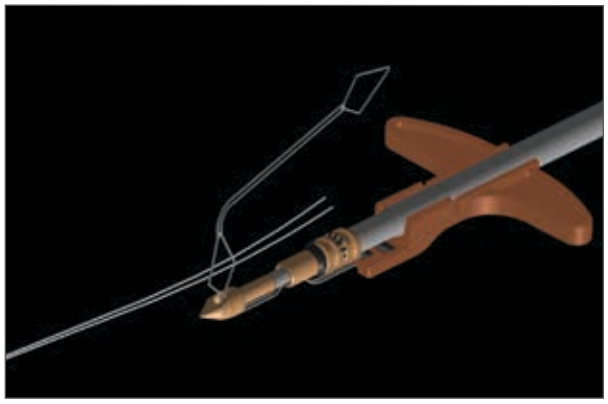
Arthroscopic Rotator Cuff Repair using the MULTIFIX® S ULTRA Knotless Suture Anchor

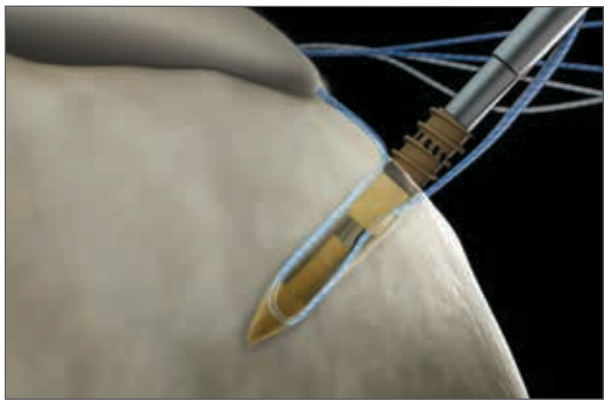
The following technique guide is intended for informational and educational purposes only. It is not intended to serve as medical advice. It is the responsibility of treating physicians to determine and utilize the appropriate products and techniques, according to their own clinical judgment, for each of their patients. For more information on MULTIFIX S ULTRA® Suture Anchors, as well as their indications for use, contraindications, and product safety information, please refer to the Product Label and Instructions for Use (IFU).

MULTIFIX S ULTRA Knotless Suture Anchor

The MULTIFIX S ULTRA Device offers 5.5mm and 6.5mm knotless, all-PEEK, pound-in anchors, providing multiple fixation options, a streamlined technique, and is ideal in multi-suture constructs that allow surgeons to meet the needs of a diverse patient population.

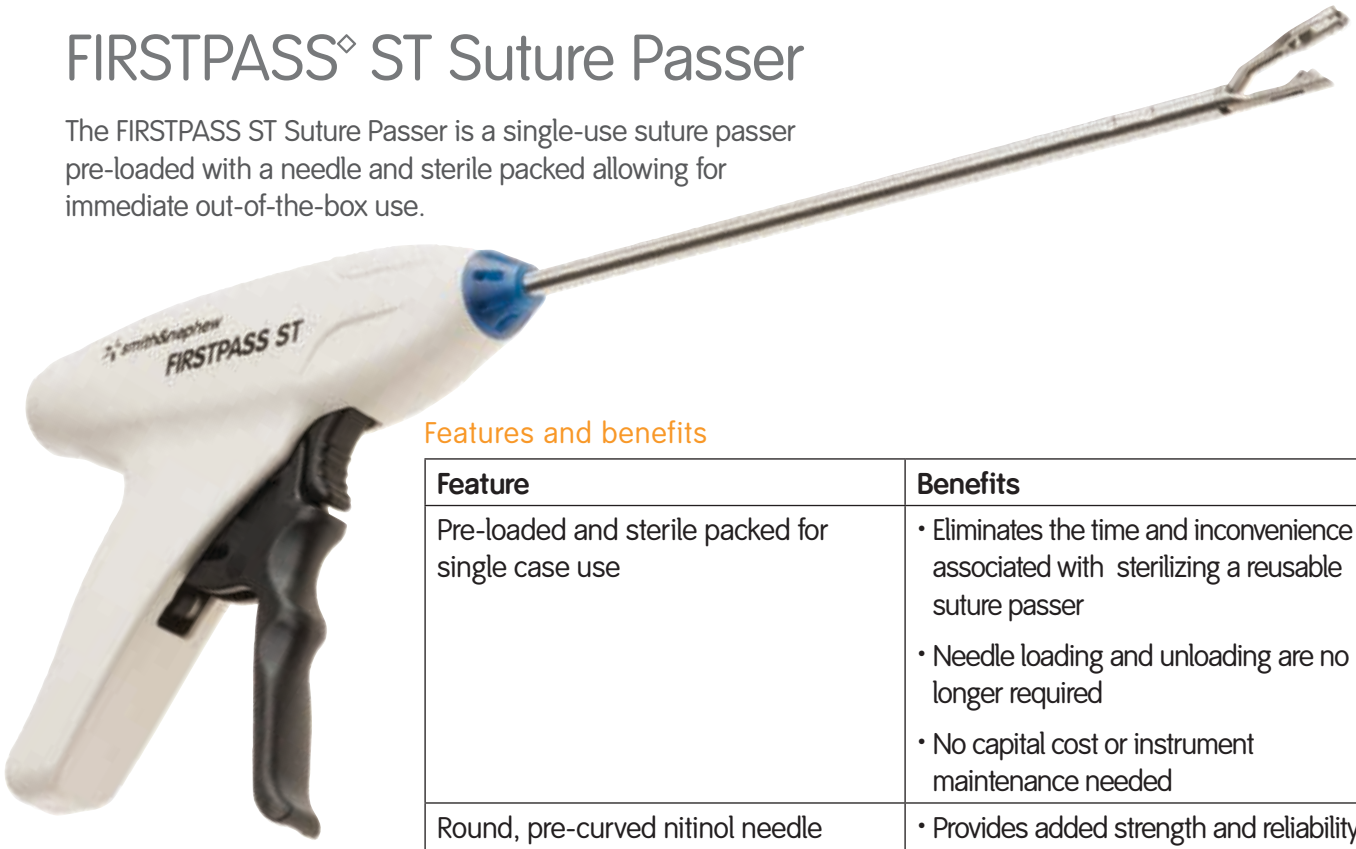
MULTIFIX S ULTRA Anchor





FIRSTPASS◇ ST Suture Passer

The FIRSTPASS ST Suture Passer is a single-use suture passer pre-loaded with a needle and sterile packed allowing for immediate out-of-the-box use.

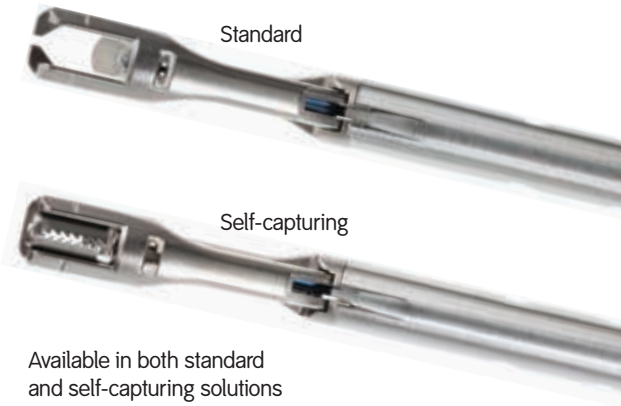


Features and benefits

Feature	Benefits
Pre-loaded and sterile packed for single case use	• Eliminates the time and inconvenience associated with sterilizing a reusable suture passer • Needle loading and unloading are no longer required • No capital cost or instrument maintenance needed
Round, pre-curved nitinol needle	• Provides added strength and reliability • Suture is carried in a recess on the needle which helps maintain suture integrity
Deep bite	Allows for tissue manipulation and suture passage through cuff tissue, up to 10mm in thickness and 18mm in bite depth
Ability to pass MAGNUMWIRE◇, ULTRABRAID◇ and ULTRATAPE◇ Sutures	The surgeon is not limited by suture type and can make product decisions based on the repair needs

Round pre-curved needle for reliability and strength

Two step trigger to grasp tissue and deploy needle



Available in both standard and self-capturing solutions

Surgical technique

Assess the patient's bone quality prior to use. If, in the physician's opinion, the bone is hard, create a bone hole with a punch such as the Tapered Punch. A bone hole is also required if the implant is to be placed at an angle other than perpendicular to the bone surface.

Preparation - Bone holes for the MULTIFIX® S ULTRA Anchor

The bone hole sites are planned by applying traction to the tendon to approximate implant location. The cuff footprint is prepared by removing all soft tissue and creating a smooth bone surface.

1. Insert the Insertion Guide with Obturator through the skin incision with the Insertion Guide handle oriented 180° from the sutures. Align the slit of the Insertion Guide in the direction of the stitch in the tissue. Remove the obturator from the Insertion Guide. Using a suture retriever, shuttle sutures into the working portal.
2. Using a punch, create a bone hole 25mm in depth.

   Caution: *Care must be taken to avoid creation of a shallow bone hole.*
3. Remove the punch from the bone.

   Note: *If placing more than one implant, ensure bone holes are at least 7mm apart.*

OM-9220 Tapered punch

OM-9615 Insertion Guide with Obturator

Procedure

1. Suture soft tissue utilizing the appropriate suture **(Figure 1)**.

   Note: *The MULTIFIX® S ULTRA Anchor can accommodate 2-4 suture strands, four strands of ULTRATAPE® Suture or 2 suture strands and 2 suture tapes.*

2. Insert the suture ends through the first snare loop. Ensure about 3 cm of each suture extends through the snare loop.

   Note: *The first snare loop can accommodate up to 2 strands of either suture or tape, two suture tapes, or one suture tape and one suture thread.* ***(Figure 2)****.*

3. To snare the sutures through the anchor, use a syringe type motion to pull the suture loader cross bar toward the handle **(Figure 3)**.

4. If additional strands of suture are to be used, thread those suture ends through the second snare loop. Ensure about 3 cm of each suture thread or tape extends through the second snare loop **(Figure 4)**.

   Note: *The volume of suture the second snare loop can accommodate is dependent on the volume of suture already threaded through the first snare loop. If the first snare loop had two or less suture threads, do not place more than two suture threads into the second loop. If the first snare loop already snared two suture tapes do not place more than two suture tapes or two suture threads through the second loop. The total volume of suture through both snare loops should not exceed a combined four strands of either suture or tape or 2 suture strands and 2 suture tapes.*

Figure 1

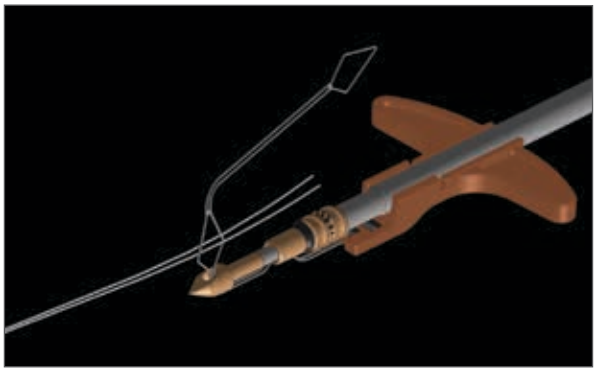


Figure 2

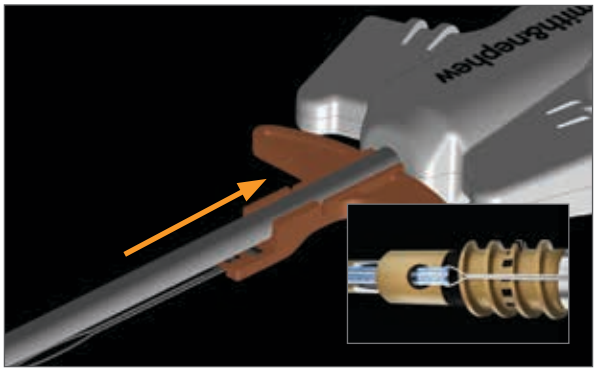


Figure 3

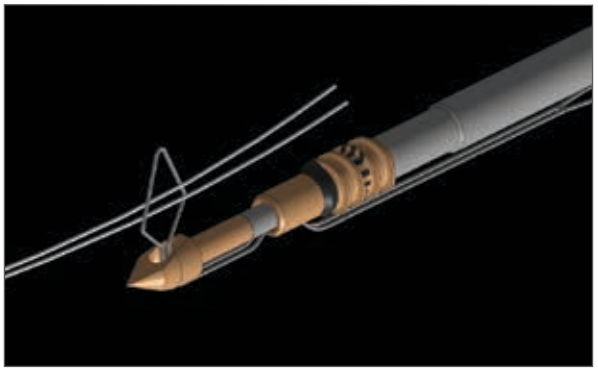


Figure 4

Please refer to the Instructions for Use (IFU) packaged with the product for a complete list of warnings, precautions and contraindications.

5. To snare the sutures through the anchor, pull the cross bar of the suture loader handle away from the shaft of the anchor inserter handle at approximately a 45° angle and pull the suture loader handle away from the anchor inserter. Discard the suture loader after the sutures have been passed through the anchor **(Figure 5)**.
6. Holding the free ends of the suture, advance the loaded anchor either percutaneously or through a cannula to the surface of the bone. Take up suture slack by pulling on the ends of the suture until suture can be clearly seen between the tissue and the anchor. Confirm that the suture is not wrapped around the device. If wrapped, pull the device out and repeat this step.
7. Place the pound-in tip of the anchor at the desired location lateral to where the soft tissue is to be secured. Assure the eyelet of the pound-in tip orients the sutures toward the tissue **(Figure 6)**. Do not split the sutures with the anchor. Establish axial alignment of the inserter shaft perpendicular to the bone. If a bone hole was created, establish axial alignment of the inserter handle with the bone hole.
8. Remove desired slack in the sutures by pulling on the ends of the suture **(Figure 7)**.
9. Use a mallet to tap the proximal end of the inserter handle to drive the pound-in tip into the bone. Tap the proximal end of the inserter until the laser mark on the leading thread of the screw body is sub-cortical **(Figure 8)**.

   Caution: *If the pound-in tip does not penetrate the bone on the first strike, create a bone hole according to step 3. Use a new anchor in the bone hole.*

   Caution: *Use care to properly align the anchor and inserter handle with the bone hole during pound-in. Avoid excessive probing. Do not bend or twist the inserter handle during and after insertion as damage to the anchor or incomplete insertion may result. Do not deploy a bent or damaged anchor.*

   Caution: *Incomplete insertion or poor bone quality may result in the anchor pulling out.*

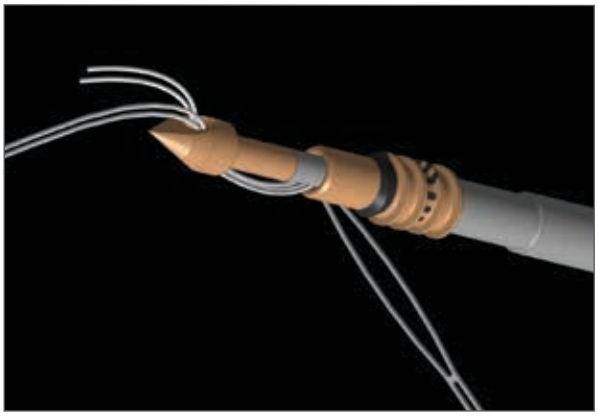


Figure 5

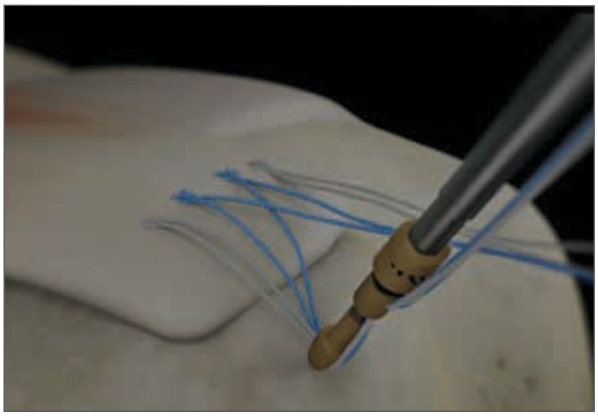


Figure 6

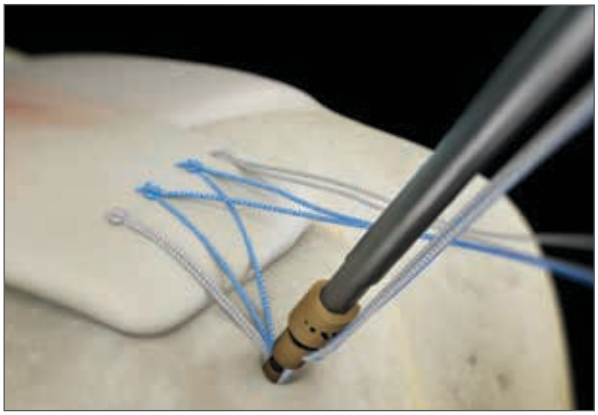


Figure 7

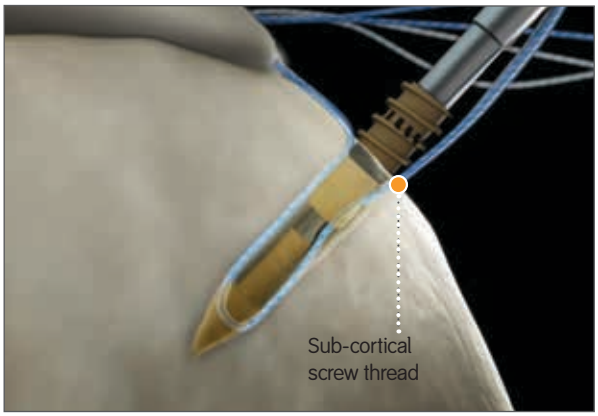


Figure 8

10 Tension will be applied to the tissue during advancement of the pound-in tip. If additional tension is required, individually pull the free suture tails in line with the axis of the inserter, while maintaining downward pressure on the inserter handle. Suture may be placed in the suture cleats for suture management if desired.

Caution: *Individually tensioning the sutures may cause the device to back out of the bone hole. If this occurs, advance the pound-in tip until the laser mark on the leading edge of the screw is subcortical before applying tension to the next suture.*

Caution: *Do not over tension the sutures as breakage or tissue pull through may occur. Additionally, over-tensioning the suture may result in incomplete insertion or anchor pull out.*

11 While continuing to maintain downward pressure on the inserter handle, deploy the screw by turning the deployment knob clockwise until the screw is flush or below the surface of the bone and the deployment knob has come to a hard stop **(Figure 9)**.

12 Disengage the inserter handle by turning the end cap counterclockwise a minimum of six turns.

13 If anchor extraction is indicated at this point, turn deployment knob counterclockwise to remove the anchor screw and pull on the ends of the suture to remove the anchor. If anchor has detached from inserter handle, or for post-operative repair, insert the Anchor Extraction Tool and turn counterclockwise to remove the anchor screw and then pull on the sutures to remove the anchor.

14 Disengage sutures from the cleats if needed prior to retracting the inserter handle. Trim remaining loose suture ends at the bone hole **(Figure 10)**.

15 If placing more than one anchor, assure that the anchors are located at least 7mm apart and repeat steps 1 through 14.

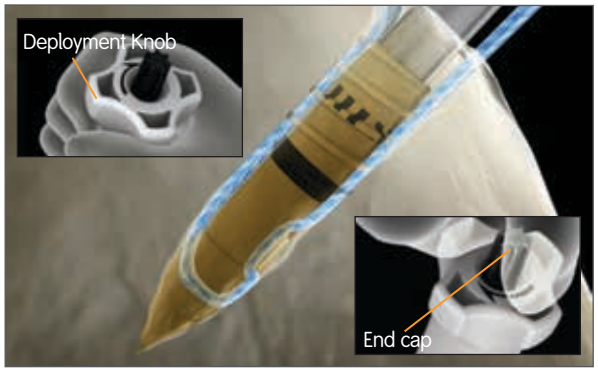


Figure 9

Figure 10

22-9005 Anchor Removal Tool

Ordering Information

To order the instruments used in this technique, call +1 800 343 5717 in the U.S. or contact an authorized Smith & Nephew representative.

Prior to performing this technique, consult the Instructions for Use documentation provided with individual components – including indications, contraindications, warnings, cautions and instructions.

MULTIFIX° S ULTRA Peek Knotless Fixation Anchors

Reference #	Description
72290001	MULTIFIX S ULTRA 5.5mm Knotless Suture Anchor
72290002	MULTIFIX S ULTRA 6.5mm Knotless Suture Anchor
OM-9220	Tapered Punch
OM-9615	Insertion Guide and obturator set: Insertion Guide with obturator
22-4038	FIRSTPASS ST Suture Passer, self capture
22-4039	FIRSTPASS ST Suture Passer, standard
22-9005	Anchor Removal Tool

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