

The Opus™ LabraFix™ System for Labral Repair

A revolutionary new system specifically
designed for labral repair surgery

System Includes:

- SpeedStitch™ Suturing Device
- The Mini Magnum® Implant

Technique Guide

The LabraFix System from ArthroCare Sports Medicine's OPUS Collection is a groundbreaking new system specifically designed for labral repair surgery. The LabraFix System enables the surgeon to perform a secure knotless repair of the labrum through rapid suture and anchor placement combined with an unparalleled TensionLock™ mechanism in an arthroscopic or mini-open approach. The system consists of two innovative devices:

The SpeedStitch Suturing Device

The SpeedStitch suturing device has an integrated grasper and suturing design that allows the surgeon to stabilize the labral tissue and arthroscopically place a stitch in the tissue in a matter of seconds. The unique design of the SpeedStitch allows for easy access to all parts of the labral circumference, along with a deep bite into the labral and capsular tissue, enabling a strong tissue hold coupled with capsular tightening.

SmartStitch Suturing Device



The Mini Magnum® Implant

The Mini Magnum Implant is uniquely designed for use in the glenoid. The Mini Magnum combines a small profile with very strong bone hold. In addition, it provides an efficient mechanism to transport the labral tissue to the glenoid and achieves a strong knotless suture fixation in a minimal amount of time.

Mini Magnum Implant



SpeedStitch® Suturing Device Preparation

1. Loading the SpeedStitch Suturing Device Needles (OM-8850)

The needle used by the SpeedStitch is provided in a sterile package and housed inside a needle loader.

- a) Load the needle by squeezing the silver lever of the SpeedStitch (*fig. 1*) and inserting the cylindrical end of the loader over the telescoping jaw of the SpeedStitch. (*fig. 2a*)
- b) Push in the loader until its plastic tabs lock into the slots on the sides of the barrel of the SpeedStitch. (*fig. 2b*)
- c) Next, squeeze the gold needle driver lever of the SpeedStitch while holding the needle loader between thumb and forefinger (*fig. 3*). This maneuver will load the needle as well as eject the loader cartridge.
- d) Check that the SpeedStitch is ready to use by actuating both the silver jaw lever and the gold needle driver lever.

Fig. 1



Fig. 2a



Fig. 2b



Fig. 3



2. Loading the SpeedStitch Suture Cartridge

- a) Next load the suture cartridge by inserting its plastic end into the barrel of the SpeedStitch. (*fig. 4a*)
- b) Continue feeding the plastic tube into the barrel until the metal end of the suture cartridge locks in place (*fig. 4b*). Tug on the metal end to ensure firm coupling.

Fig. 4a



Fig. 4b



The SpeedStitch suturing device is now ready to use.

Surgical Technique

Placing the Labral Stitch

Step 1. Insert the closed suturing device into the glenohumeral joint through an anterior portal, using an 8.2mm cannula or greater. Closing the telescoping jaw using the silver handle ensures that the jaw does not inadvertently catch tissue during insertion. Insert the jaw of the suturing device into the space between the glenoid bone and the labral tissue. Then open the jaw and manipulate the SpeedStitch to engage the labral tissue into the jaw. This usually requires a simple 90-degree rotation.

Step 2a. Next, squeeze the silver lever of the SpeedStitch to advance the telescopic jaw.

Step 2b. Once the tissue is stabilized, squeeze the gold needle driver lever fully, followed by a gentle release. The stitch is now placed.

Step 3. Release the tissue by pressing the ratchet release button on the silver lever of the SpeedStitch, then close the jaw again and withdraw the instrument from the shoulder.

Step. 1

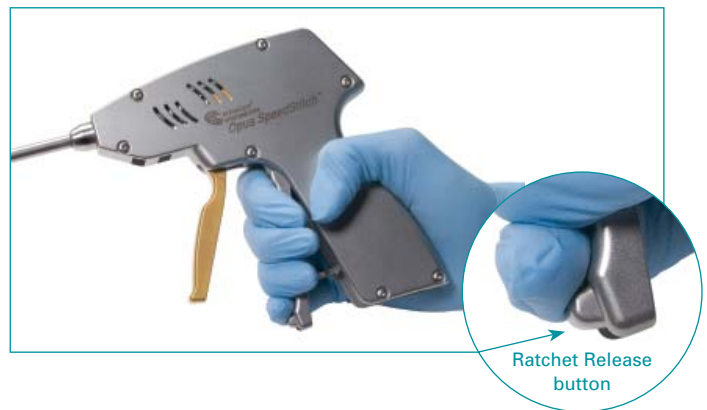


Step 2a

Step 2b



Step. 3



Technique Tip: portal placement

It is very important to have a good "angle of attack" for accessing the labrum, drilling holes into the glenoid, and placing the Mini Magnum. It is advisable to use a guidewire with the Atlantech™ Caps-Lock™ cannula or a spinal needle to identify appropriate portal location.

Technique Tip: labrum preparation

An ArthroCare CoVator® Coblation® Wand is specifically designed to elevate the labral tissue from the glenoid.

Preparing the Drill Holes for the Mini Magnum Implant:

The drill hole sites are planned by applying traction on the suture limbs. It is very important to drill the hole 2mm from the glenoid rim onto the articular surface of the glenoid. This helps create an anatomic "bumper" with the labrum. For superior implant sites, it is acceptable to drill on the glenoid rim.

Step 1 Through the same cannula, insert the LabraFix drill guide with the sharp-ended obturator. Place the tip of the drill guide at the desired site of the drill hole. Tap the proximal end of the obturator lightly to create a "starter hole".

Note:

- Drilling perpendicular is NOT required with the Mini Magnum. However, drilling at too shallow of an angle will result in the drill "walking" or a superficially placed implant.

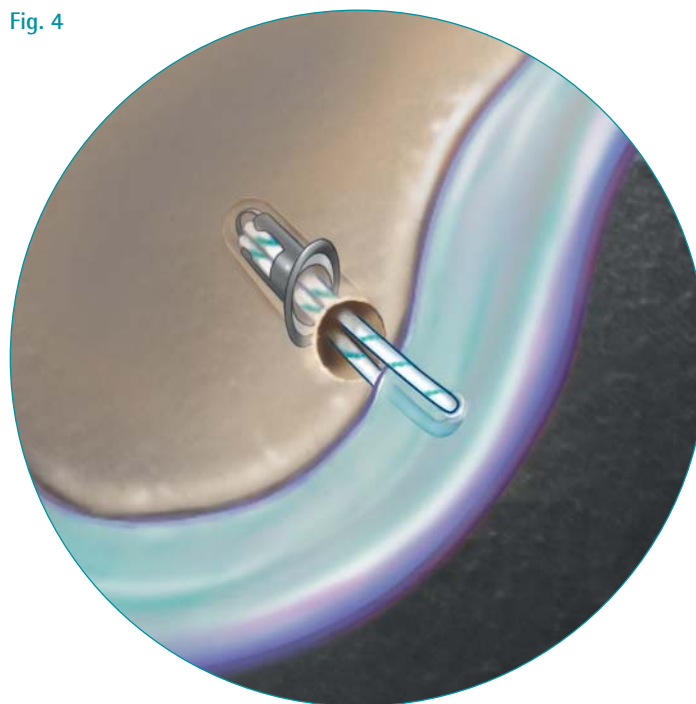
Step 2 Next, withdraw the obturator and insert the fluted Mini Magnum drill. Drill until the depth-stop at the proximal end of the drill is against the proximal end of the drill guide. This depth corresponds to a laser etched depth marker on the drill, visible in the arthroscopic view.

Note:

- While creating the hole, the drill should be angled into the scapular neck, to avoid drilling across the lip of the glenoid.
- While drilling the hole, it is important to hold the sutures taut to avoid tangling of the sutures on the drill

Step 3 Once the hole is made, remove the drill and insert the Mini Magnum Pathfinder™ into the hole to maintain alignment while the Mini Magnum is prepared for insertion.

Fig. 4



Surgical Technique

Deploying the Mini Magnum Implant

Step 1 Pass both ends of the suture through the distal snare wire loop of the Mini Magnum. Remove the distal snare (silver ring) and adjust the suture so that approximately 2 inches of suture extend from the distal end of the implant. Avoid pulling the suture away from the handle while adjusting the length or the sharp wings of the implant may shear the suture.

Step 2 Take up the suture slack by rotating the suture ratchet knobs in the direction of the arrows on the inserter handle.

Step 3a Remove the PathFinder and insert the Mini Magnum through the drill guide into the pre-drilled hole with the vertical laser mark facing opposite the suture stitch (towards the scope). Continue until the tip of the Mini Magnum is just inside the hole.

Step 3b Again rotate the suture knobs to take up further suture slack, until the entire length of suture is visible, from the labral tissue to the implant.

Step 4a Complete the insertion of the Mini Magnum until the horizontal laser etched depth marker on the metal shaft is flush with the glenoid.

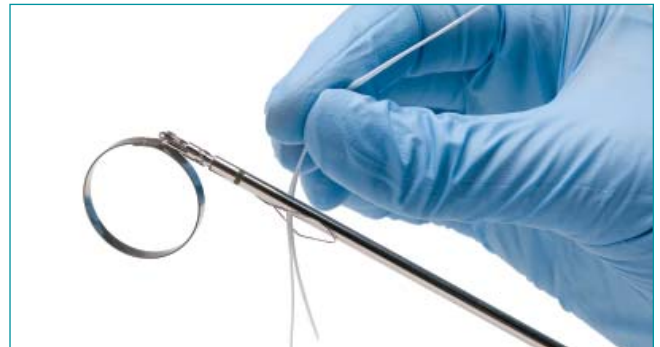
Step 4b Activate the bone lock with a single squeeze of the black hand lever. Verify bone purchase with a firm tug.

Alternative technique:

If the drill guide is not used, with the implant resting just outside the drilled hole, remove all of the suture slack in the joint before the implant is inserted. While pressing the ratchet release button, insert the anchor into the drilled hole. Pushing the ratchet release button allows the suture to pay out during insertion into the drilled hole.



Step 1



Step 2



Step 3



Step 4



Step 5 Tension the sutures by rotating the suture knobs with both hands in the direction of the arrows on the inserter handle.

Step 5



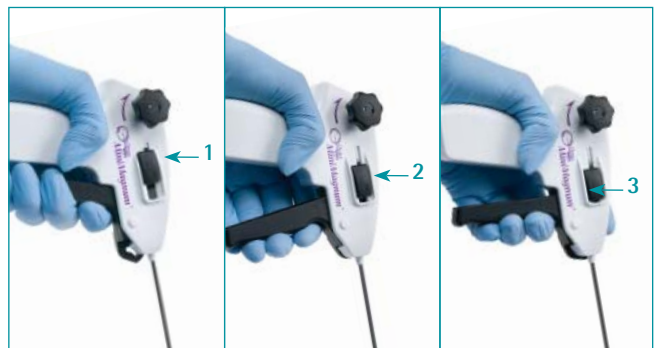
Step 6 When adequate tension is achieved, press the "Suture Lock" button on the side of the inserter handle.

Step 6



Step 7 Next, squeeze the black hand lever three times to activate the suture lock and allow withdrawal of the inserter handle.

Step 7



Step 8 Trim the sutures using the Opus MagnumWire suture cutters.

Step 8



The above sequence is repeated to place the desired number of implants to complete the labral repair.



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