

The LabraFix™ System Featuring LabraLock™ P for Labral Repair

A revolutionary new system specifically
designed for labrum repair surgery

System Includes:

- SpeedStitch® Suturing Device
- The LabraLock P Implant



Tip Close-Up

Technique Guide

The LabraFix System from ArthroCare Sports Medicine's OPUS™ Collection is a groundbreaking new system specifically designed for labrum 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 labrum 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 labrum circumference, along with a deep bite into the labrum and capsular tissue, enabling a strong tissue hold coupled with capsular tightening.

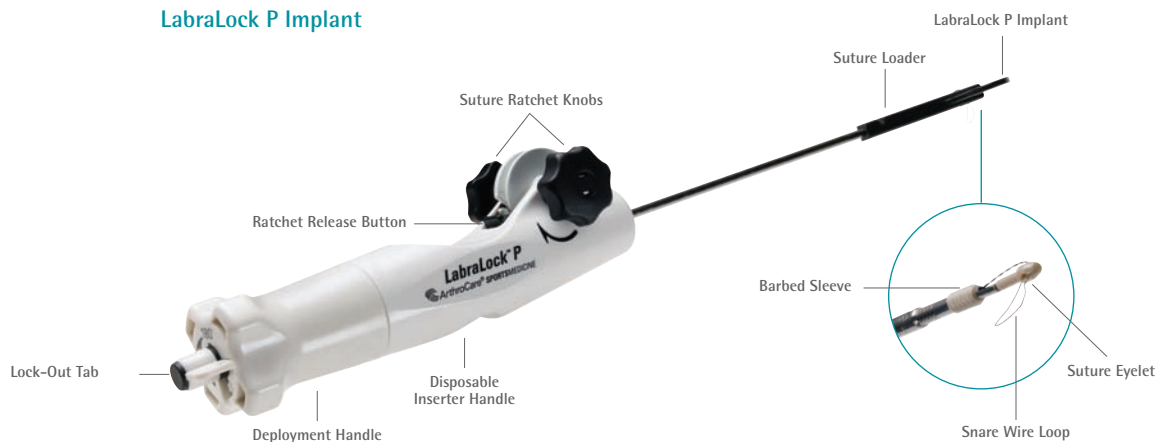
SpeedStitch Suturing Device



The LabraLock P Implant

The LabraLock P Implant is uniquely designed for use in the glenoid. The LabraLock P is a compact radiolucent PEEK anchor featuring interference bone fixation. The LabraLock P provides an efficient mechanism to transport the labrum tissue to the glenoid and secure the repair with a patented TriLock™ suture lock.

LabraLock P 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.

Step 1 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*)

Step 2 Push in the loader until its plastic tabs lock into the slots on the sides of the barrel of the SpeedStitch. (*fig. 2b*)

Step 3 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.

Step 4 Check that the SpeedStitch is ready to use by actuating both the silver jaw lever and the gold needle driver lever.

2. Loading the SpeedStitch Suture Cartridge

Step 5 Next load the suture cartridge by inserting its plastic end into the barrel of the SpeedStitch. (*fig. 4a*)

Step 6 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.

The SpeedStitch suturing device is now ready to use.

Fig. 1



Fig. 2a



Fig. 2b



Fig. 3



Fig. 4a



Fig. 4b



Surgical Technique

Placing the Labrum 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 labrum tissue. Then open the jaw and manipulate the SpeedStitch to engage the labrum 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 4. To remove the suture from the suture hook, first depress the silver lever partially. Next deploy the gold lever and pull down and towards the handle on the suture. Clear the suture hook of any particles before placing another stitch.

Step. 1

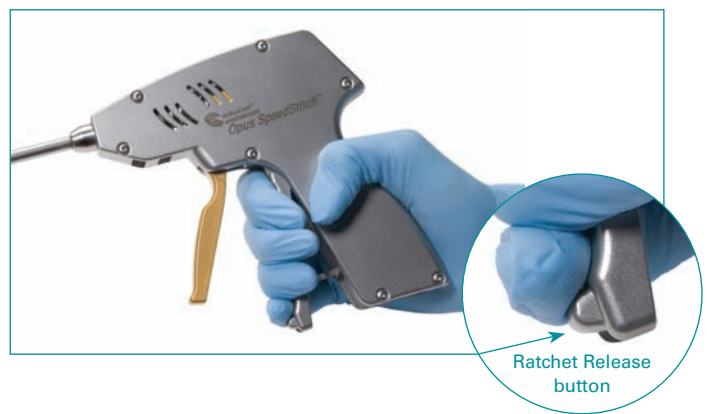


Step 2a

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 LabraLock P. It is advisable to use a guide-wire 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 LabraLock P 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 LabraLock P. However, drilling at too shallow of an angle will result in the drill "walking" or a superficially placed implant.

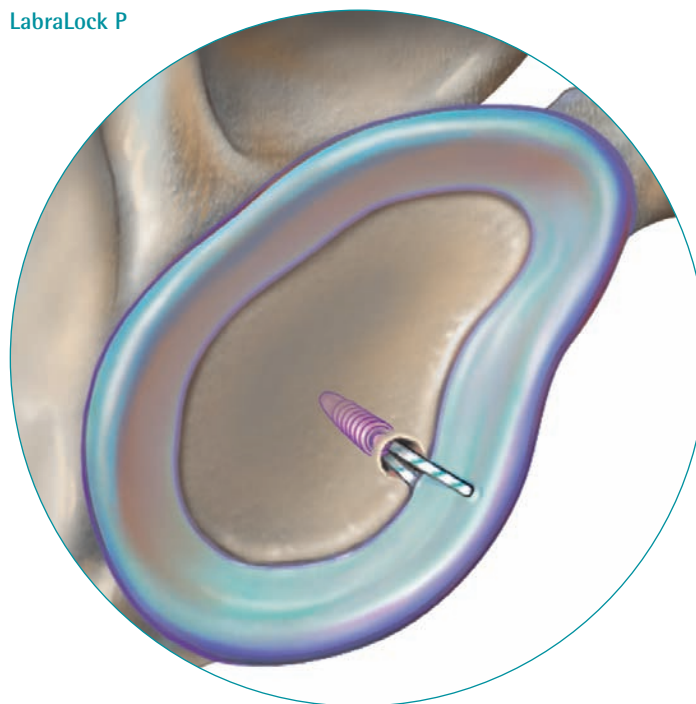
Step 2 Next, withdraw the obturator and insert the fluted 2.6mm LabraLock P drill (blue). Drill until the depth-stop at the proximal end of the drill is against the proximal end of the drill guide. This depth corresponds to a laser etched depth marker on the drill, visible in the arthroscopic view.

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. Alternatively, drill holes may be created before the suture is placed.

Step 3 Once the hole is made, remove the drill and insert the LabraLock P PathFinder™ (blue) into the hole to maintain alignment while the LabraLock P is prepared for insertion.

LabraLock P



Deploying the LabraLock P Implant

Step 1 Pass both ends of the MagnumWire suture through the snare wire loop, ensuring that both ends of the suture are of equal length. Adjust the suture so that approximately 2 inches of suture extend from the distal end of the implant.

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

Step 3a When preparing to insert the implant into the drill guide, remove the black suture loader by pulling the tab in the direction of the arrow. Ensure that the drill guide slit is aligned with the direction of the suture to the tissue.

Step 3b Remove the PathFinder and insert the LabraLock P through the drill guide into the pre-drilled hole with the suture coming from the eyelet straight up into the inserter handle facing opposite the suture stitch (towards the scope). Continue ratcheting slack until the anchor is walked approximately halfway down the drill guide.

Caution: Check that the entire length of the suture is visible, from the labrum to the implant. Ensure that there is adequate suture slack to insert the suture eyelet fully into the hole. Do not split the sutures with the implant.

Step 4 Complete the insertion of the LabraLock P suture eyelet until the distal end of the barbed sleeve is at the articular surface of the glenoid. The leading barb(s) of the sleeve may be buried and not visible. This may make suture tensioning tight at first.

Step 1

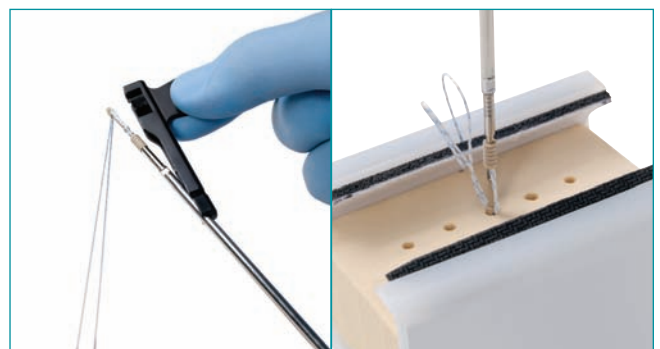


Step 2



Step 3a

Step 3b



Step 4



Step 5a Continue to approximate the tissue to the anchor by rotating the suture ratchet knobs with *both hands on the knobs* in the direction of the arrows on the inserter handle until the anchor begins to back out of the hole (~1mm).

Step 5b To determine the tension on the tissue, press down on the inserter handle until the distal end of the barbed sleeve is in contact with the articular surface and the stepped edge of the inserter handle is in contact with the proximal end of the barbed sleeve.

Step 5c To further tension the tissue, repeat Step 5a and evaluate the tension on the tissue as in Step 5b. Remember, each click of the ratchet is 0.5mm.

Step 6a When desired tension is achieved, relax the downward pressure on the handle. Maintain position of the handle with a light grip. Turn the lock-out tab at the proximal end of the inserter handle a quarter turn clockwise, until it is aligned with the slot in the deployment knob.

Step 6b Without putting downward pressure on the anchor, maintain a light grip of the inserter handle and tap the tab until it is flush with the back end of the deployment knob. At this point at least the first horizontal laser mark on the inserter handle should be under the articular surface. Each horizontal laser mark is 1mm apart. *Remember:* Avoid placing downward pressure on the handle during tapping.

Step 7 Detach the inserter handle by turning the deployment handle 180° clockwise; then remove the handle.

Step 8 Trim the sutures using the arthroscopic MagnumWire suture cutter.

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

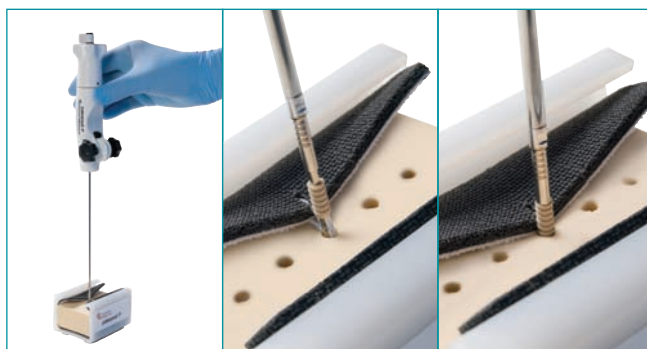
Technique Tip:

If a slight increase in tension is desired once the inserter handle is removed, reinsert the inserter handle into the appropriate hole until it is seated properly with the anchor. Then, lightly tap the inserter handle until the desired tension is achieved. Do not use any other device to drive the anchor down further as it may damage the anchor.

Step 5a



Step 5b



Step 6a

Step 6b



Step 7

Step 8





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P/N A1044 Rev B