

The OPUS® AutoCuff® System for Rotator Cuff Repair

A revolutionary new system specifically
designed for rotator cuff repair surgery

System Includes:

- SmartStitch® Suturing Device
- The Magnum® PI Implant with Inserter Handle
- Magnum PI Undercut Punch
- Magnum PI Drill Bit or Magnum PI Punch

Technique Guide

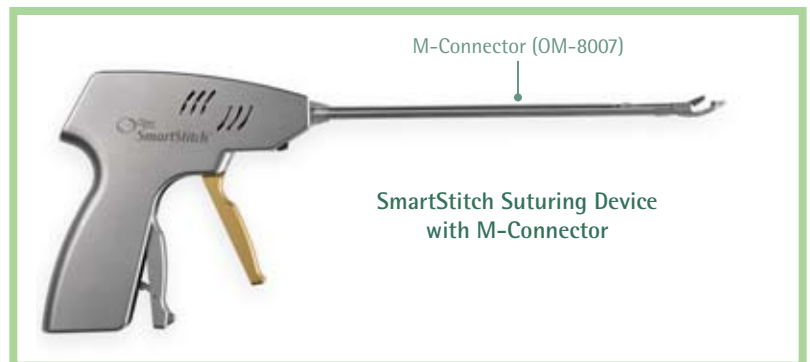
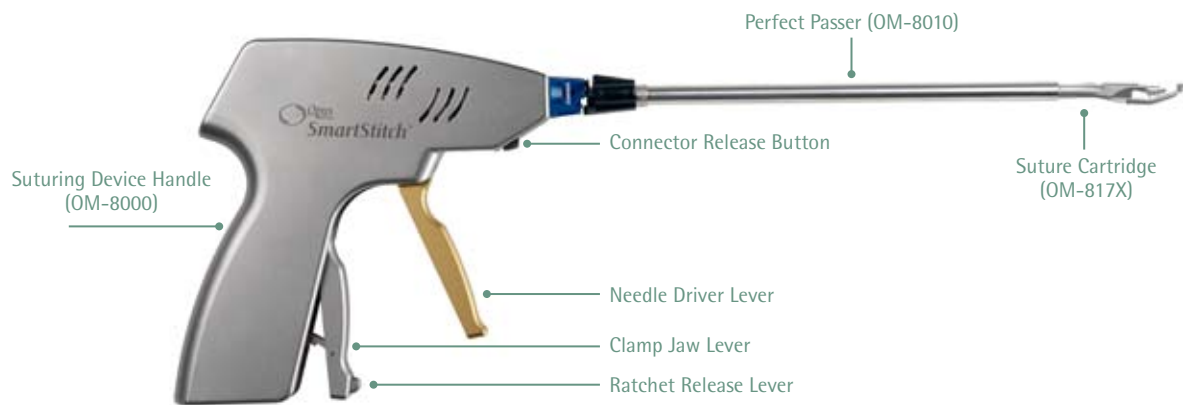
The System

The AutoCuff System with Magnum PI implant from ArthroCare Sports Medicine's OPUS Collection is a state-of-the-art system specifically designed for rotator cuff repair surgery. The AutoCuff System enables the surgeon to perform a secure knotless repair of the rotator cuff and restore the anatomic footprint with an unparalleled TensionLock™ mechanism through a rapid and consistent arthroscopic or mini-open procedure. The system consists of these innovative devices: The SmartStitch suturing device and the Magnum PI implant with inserter handle. Accessories include the Magnum PI undercut punch, drill bit and punch, as well as the AutoCuff drill guide and PathFinder® set.

The SmartStitch Suturing Device

The SmartStitch suturing device (below) is an integrated grasper and suturing device that allows the surgeon to grasp the cuff tissue and place an Incline Mattress® or side-to-side stitch in the tissue in a matter of seconds. The SmartStitch suturing device consists of a reusable suturing device handle and a single use M-Connector or PerfectPasser™ Connector. In addition, the suture is provided as a prepackaged suture cartridge. The suture material used with the Magnum PI is MagnumWire®, an ultra-high strength #2 braided polyethylene suture available in multiple colors to facilitate suture management.

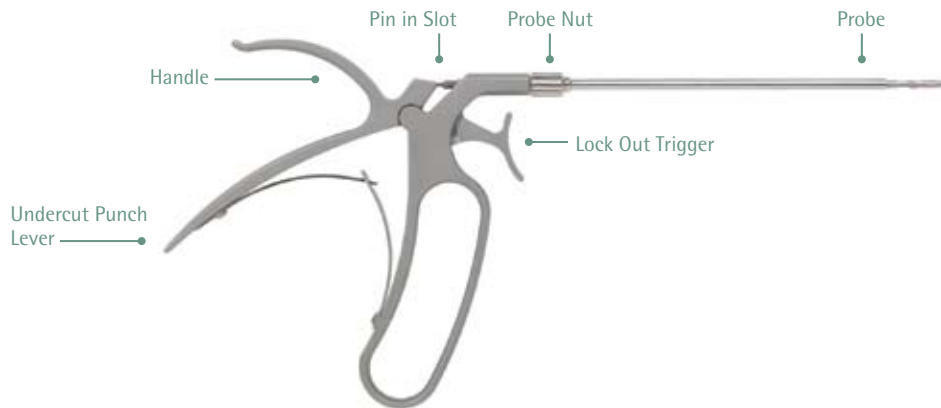
SmartStitch Suturing Device with PerfectPasser Connector



The Magnum PI Undercut Bone Punch

The Magnum PI Undercut Bone Punch was specifically engineered for use with the Magnum PI implant. After drilling or punching the implant holes the undercut punch cleanly places a trough in the bone for the Magnum PI implant to deploy. The lock out mechanism prevents the wings of the undercut punch from deploying during insertion or removal.

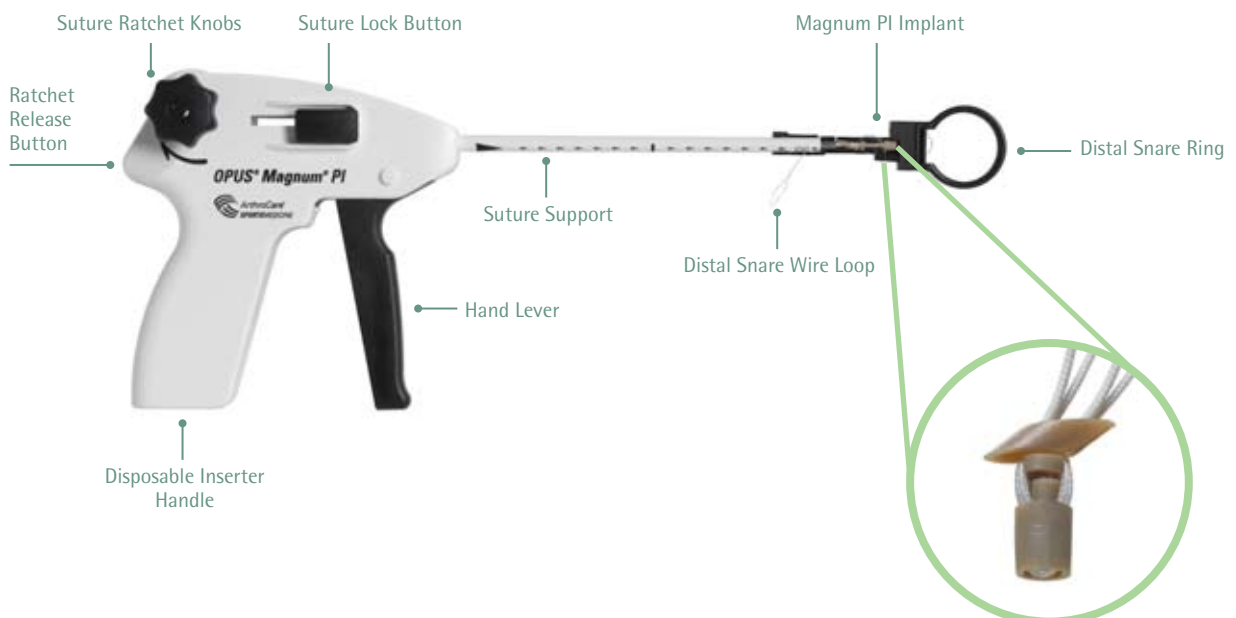
Magnum PI Undercut Punch (OM-9450)



The Magnum PI Implant

The Magnum PI implant (below) is a compact, radiolucent implant made with PEEK-OPTIMA® polymer that, when used with the Magnum PI undercut punch and Magnum PI inserter handle, achieves a strong bone lock, provides a ratchet mechanism, TensionLock, that transports the rotator cuff tissue to the prepared footprint and applies and maintains tension on the sutures for the ideal tendon to bone fixation.

Magnum PI Implant (OM-4500)



SmartStitch Preparation

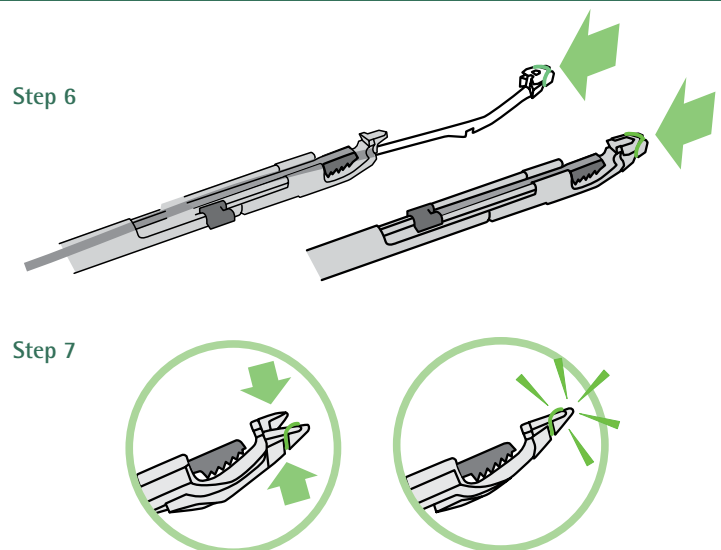
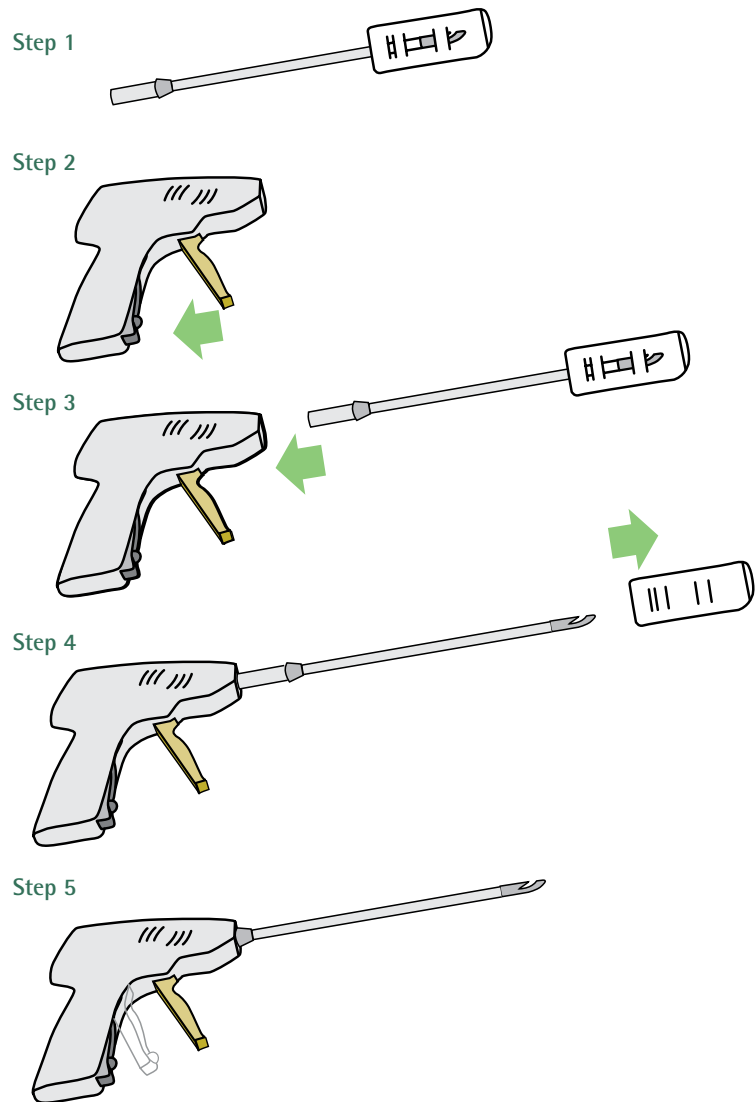
Coupling the Disposable Connector (OM-8007 or OM-8010) with the SmartStitch Handle

- Step 1** Remove Connector from its sterile packaging. Take care not to remove the tip protector until the Connector is coupled with the SmartStitch handle.
- Step 2** Squeeze and lock the silver clamp jaw lever of the SmartStitch handle in the closed position.
- Step 3** Insert the molded end of the Connector into the handle until it locks into position.
- Step 4** For the M-Connector, remove the tip protector by lifting the locking tab, rotating 1/4 turn and gently sliding off. For the PerfectPasser Connector, remove the tip protector by lifting the wings of the plastic tip protector and gently pulling it off.
- Both the clamp jaw lever and the needle driver lever are actuated to test controls. The silver clamp jaw lever operates the jaw of the SmartStitch, while the gold needle driver lever operates the suture needles.
- Step 5** Press the ratchet release lever to unlock the clamp jaw lever.

Loading the SmartStitch MagnumWire Suture Cartridge

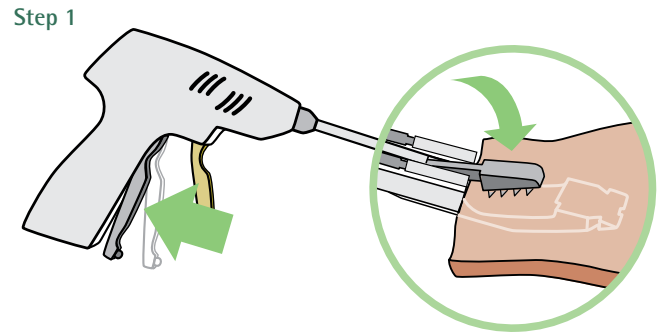
- Step 6** Remove the suture cartridge (OM-807X or OM-817X) from its sterile packaging and carefully insert it into the barrel of the Connector. Take care not to kink the plastic tubing.
- Step 7** Snap the plastic molded end of the suture cartridge on to the end of the Connector.
- The SmartStitch suturing device is now ready to use.

Note: Only MagnumWire USP #2 non-absorbable braided suture may be used with the Magnum PI implant. Using other suture may compromise suture lock.



Placing the Incline Mattress Stitch

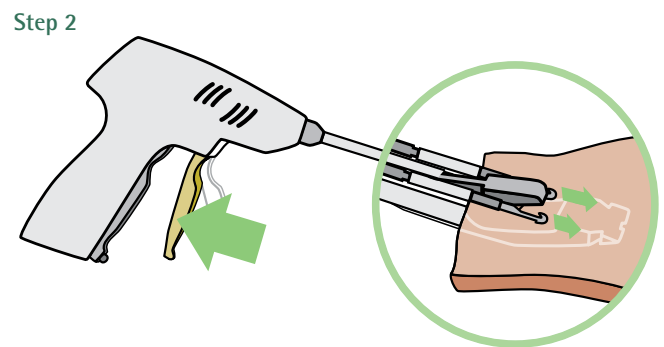
Step 1 Insert the SmartStitch through the lateral portal, usually without a cannula (if a cannula is desired, it must be min. 8.2mm). Grasp the prepared edge of the tendon using the silver clamp jaw lever.



Step 2 Activate the needles by completely squeezing the gold needle driver lever once, followed by a slow release.

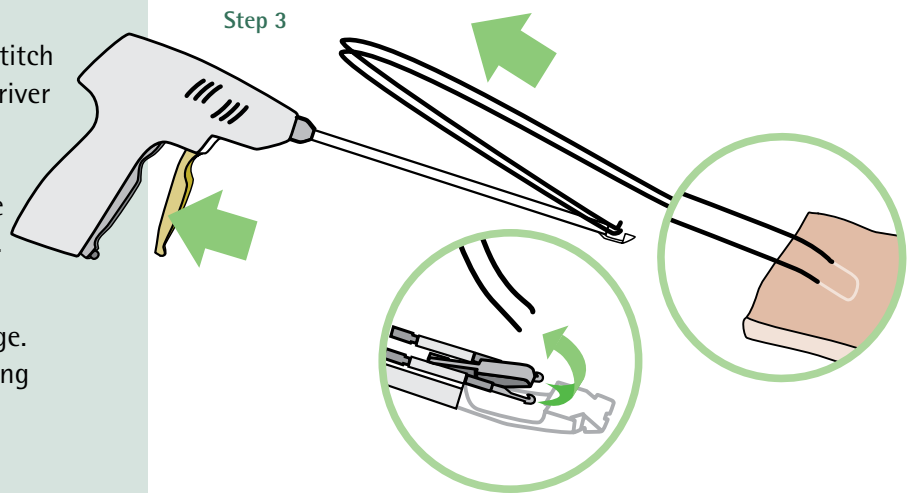
Release the jaw using the ratchet release lever, and withdraw the SmartStitch from the operative site.

This completes placement of the first Incline Mattress stitch.



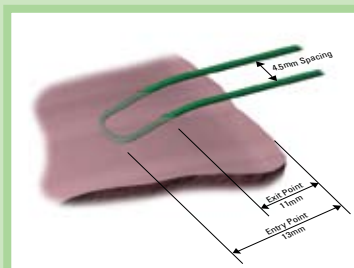
Step 3 Disengage the sutures from the SmartStitch needles by squeezing the gold needle driver lever halfway and pulling the sutures up and towards the handle for the M-Connector, or down and towards the handle for the PerfectPasser Connector.

If another stitch is needed, load the SmartStitch with a fresh suture cartridge. All sutures are placed first before creating implant holes.



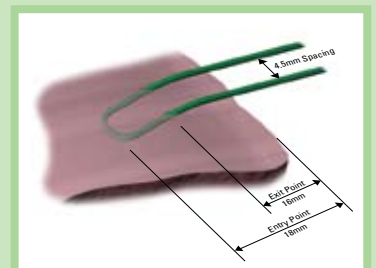
M-Connector Stitch

The SmartStitch places an Incline Mattress stitch in the cuff tissue. In addition to providing an extremely strong hold in the cuff tissue (comparable to a modified Mason-Allen¹), the Incline Mattress configuration also creates a downward force, compressing the tissue against the bone when the sutures are tensioned.



PerfectPasser Connector Stitch

The SmartStitch with PerfectPasser Connector allows for an even deeper bite to place an ideal stitch for double row repairs. If a wider stitch or margin convergence is needed, the independent needle deployment of the PerfectPasser Connector enables placement of both sides of the stitch, at variable widths, in one portal entry.



Creating Drill/Punch Holes for the Magnum PI Implant

The drill hole sites are planned by applying traction on the suture limbs. The cuff footprint is prepared by removing all soft tissue and creating a smooth bone surface. It is important not to decorticate bone in the vicinity of the implant sites as the Magnum PI relies on an intact cortical layer for bone fixation.

Step 1 Make the implant holes perpendicular to the bone surface (as opposed to a 45 degree angle); this ensures optimal fixation by the Magnum PI implant (figure 1).

Note: *If a perpendicular angle cannot be achieved through the standard lateral portal, it is recommended that an additional "superolateral" portal be made, closer to the acromion border. The perpendicular alignment should be confirmed with a spinal needle prior to creating the portal.*

Step 2 Insert the AutoCuff drill guide, with blunt obturator, through the portal used to create the holes.

Figure 1

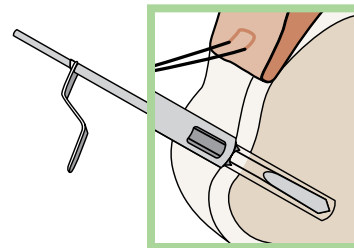


Step 3 Remove the blunt obturator and, using a suture retriever through the drill guide, shuttle one pair of sutures into the portal.

Note: *Hold the sutures away in the slot of the drill guide. Make the drill holes using the Magnum PI drill bit (green) or Magnum PI punch (green) through the drill guide. It is important to penetrate the bone up to the collar of the drill (or punch) in order to achieve the correct depth for deployment of the Magnum PI implant.*

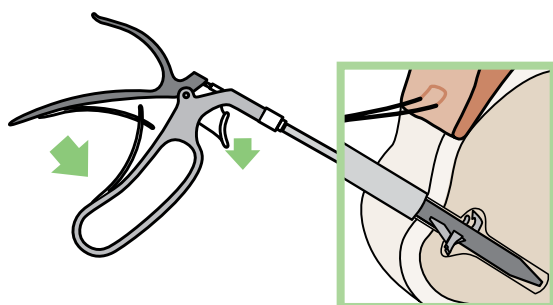
Step 4 Once the hole is made, remove the drill (or punch). Optionally, insert the AutoCuff PathFinder into the hole to maintain alignment while the Magnum PI Undercut Bone Punch is prepared for insertion.

Note: *If placing more than one implant, assure bone holes are at least 5mm apart.*



The OPUS Magnum PI Undercut Bone Punch

Step 1 Assemble the Magnum PI undercut punch probe into the undercut punch handle by aligning the pin on the probe with the slot on the handle while compressing the lockout trigger. Screw the probe nut all the way so that the pin is fully seated in the back of the slot while continuing to compress the lockout trigger.



Step 2 Insert the undercut punch into the bone hole until the shaft is fully seated against the bone, pointing the directional indicator towards suture insertion into the cuff. Pull the lockout trigger with a downward motion then squeeze and return the undercut punch lever fully to create an undercut in the bone hole. Once the undercut is created, confirm that the undercut punch is in the locked position and remove it from the bone hole. Optionally, insert the AutoCuff PathFinder into the hole to maintain alignment with the bone hold. Remove the PathFinder prior to inserting the Magnum PI implant.

Note: *The lockout trigger cannot be pulled if there is pressure on the undercut punch lever.*

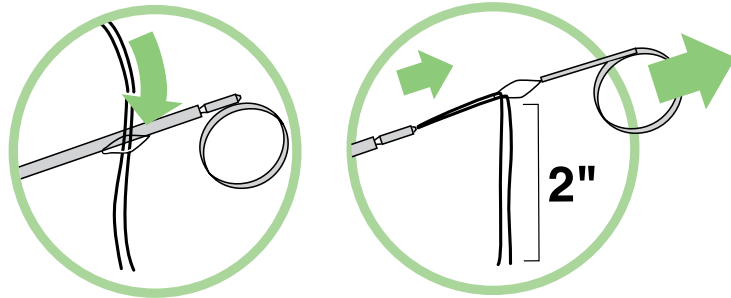
Surgical Technique

Deploying the Magnum PI Implant

Step 1 Pass both limbs of the stitch through the distal snare wire loop of the Magnum PI handle.

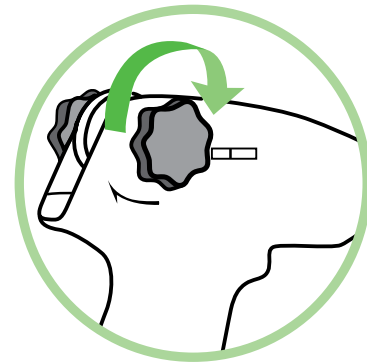
Remove the distal snare ring and evenly adjust both suture ends so that approximately two inches of suture extend from the distal end of the Magnum PI handle.

Step 1



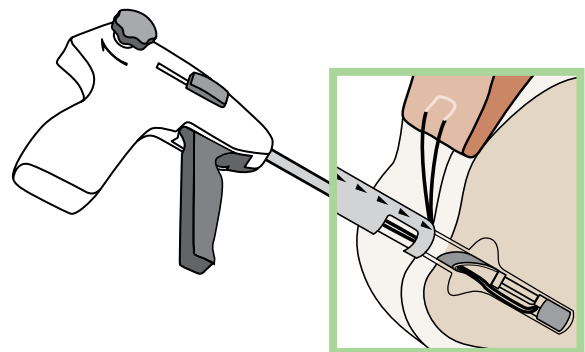
Step 2 Take up suture slack by rotating the suture ratchet knobs in the direction of the arrows on the inserter handle.

Step 2



Step 3 Remove the PathFinder and insert the Magnum PI into the pre-drilled (or punched) hole with the arrows on the suture support shaft aligned towards the rotator cuff.

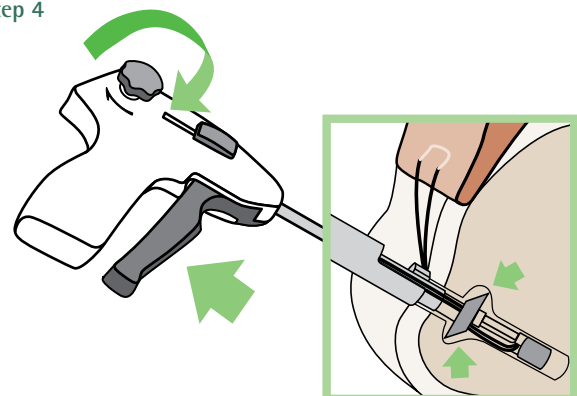
Step 3



Note: *It is important to maintain perpendicular alignment during insertion of the Magnum PI. Insert the Magnum PI until the suture support shaft is fully seated against the bone.*

Step 4 Rotate the suture ratchet knobs again to take up further suture slack until the entire length of suture is clearly visible, from the cuff tissue to the collar of the suture support shaft.

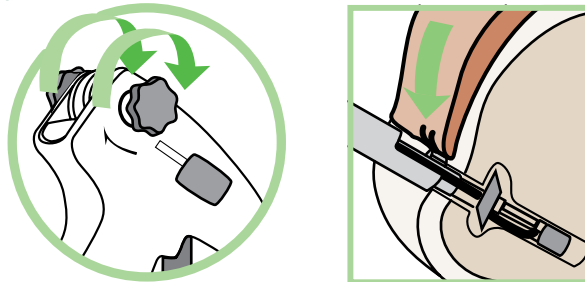
Step 4



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

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

Step 5



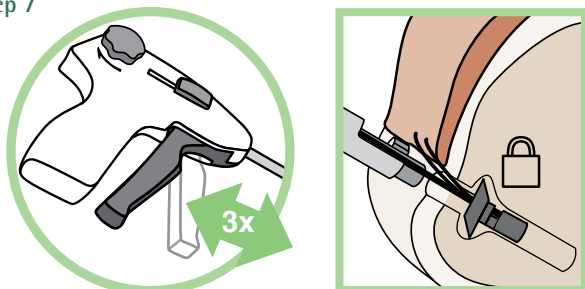
Step 6 When adequate tension between tendon and bone is achieved, press the suture lock button on the side of the inserter handle.

Step 6



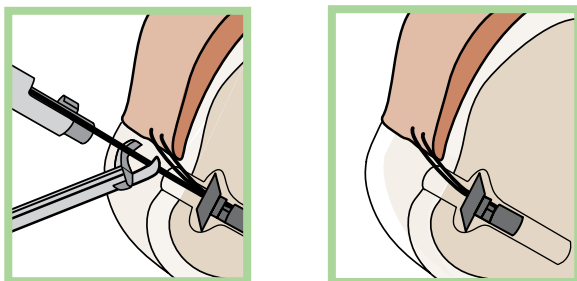
Step 7 Squeeze the black hand lever and release three times to activate the suture lock and allow withdrawal of the inserter handle.

Step 7



Step 8 Trim the sutures at the bone hole to complete the AutoCuff repair.

Step 8



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

To order or for more information, please contact your ArthroCare Sports Medicine representative or customer service at 800-797-6520.



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