

The OPUS® AutoCuff® System Featuring Magnum® X for Rotator Cuff Repair

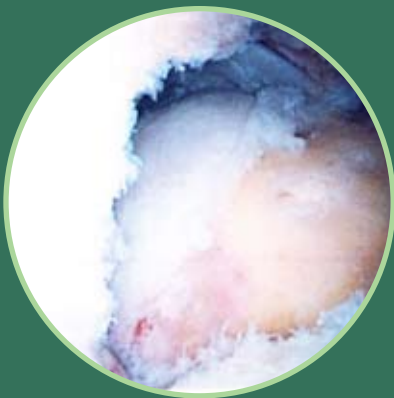
A revolutionary new system specifically
designed for rotator cuff repair surgery

System Includes:

- SmartStitch® Suturing Device
- The Magnum X Implant with Independent Tensioning
- The Magnum² Drill Bit or Magnum² Punch

Technique Guide

The AutoCuff System featuring the Magnum X knotless implant from ArthroCare® Sports Medicine's OPUS Collection is a revolutionary new system specifically designed for rotator cuff repair surgery. The AutoCuff System with Magnum X enables the surgeon to independently tension suture limbs and perform a secure knotless repair of the rotator cuff combined with improved snaring capabilities through a rapid and consistent arthroscopic or mini-open procedure. The system consists of two innovative devices, the SmartStitch Suturing Device and the Magnum X implant with independent tensioning.

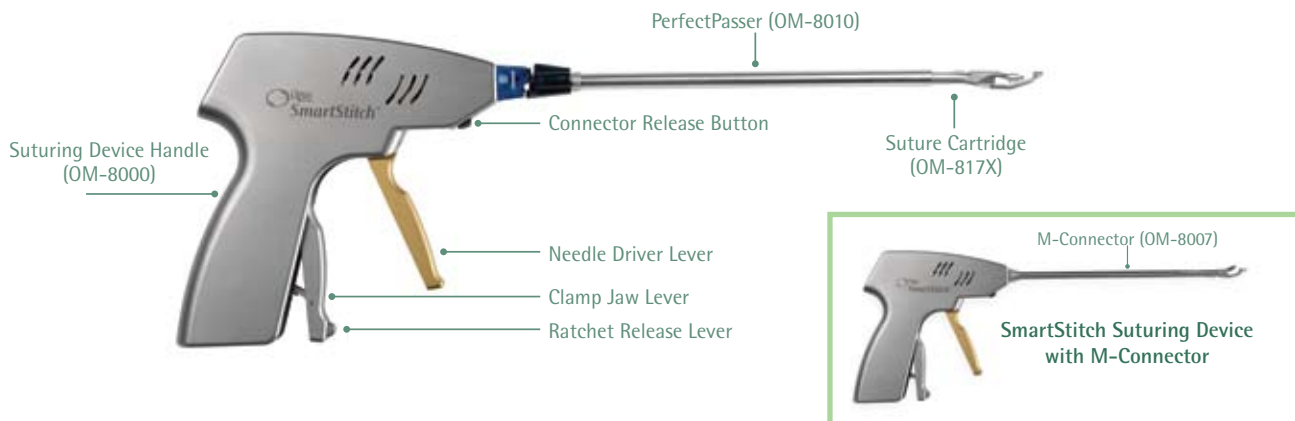


The System

The SmartStitch Suturing Device

The SmartStitch (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 handle and a single patient use M-Connector or PerfectPasser™ Connector. In addition, the suture is provided as a prepackaged suture cartridge. The suture material used is MagnumWire®, an ultra-high strength braided polyethylene suture available in multiple colors to facilitate suture management.

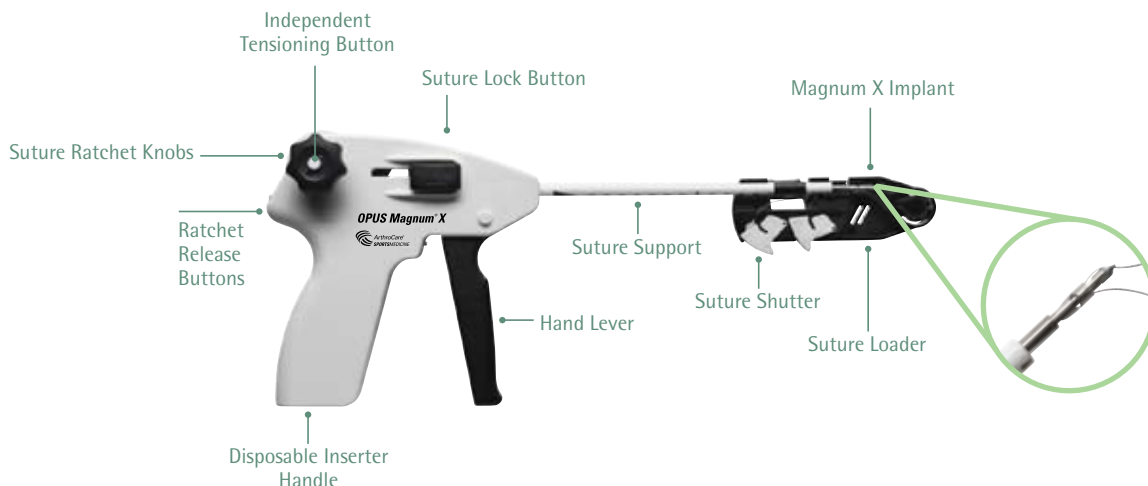
SmartStitch Suturing Device with PerfectPasser Connector



The Magnum X Implant With Independent Tensioning

The Magnum X implant, along with the Magnum X inserter handle (below), is a highly engineered device that achieves a strong bone lock, provides a ratchet mechanism, TensionLock™, to transport the rotator cuff tissue to the prepared footprint, can independently apply and maintain tension on each suture limb, and achieves a knotless intra-osseous suture fixation. Independent tensioning of the suture limbs, in a double row or single row repair, is important for maintaining the same overall pressure on the tendon to footprint contact area to maximize the ideal repair construct.

Magnum X Implant (OM-1503)



In addition, the system can be used with the Magnum² slotted drill guide with blunt obturator, drill, punch, and PathFinder®.

Independently Optimize Your Repair Construct to Meet the Demands of Most Tear Patterns

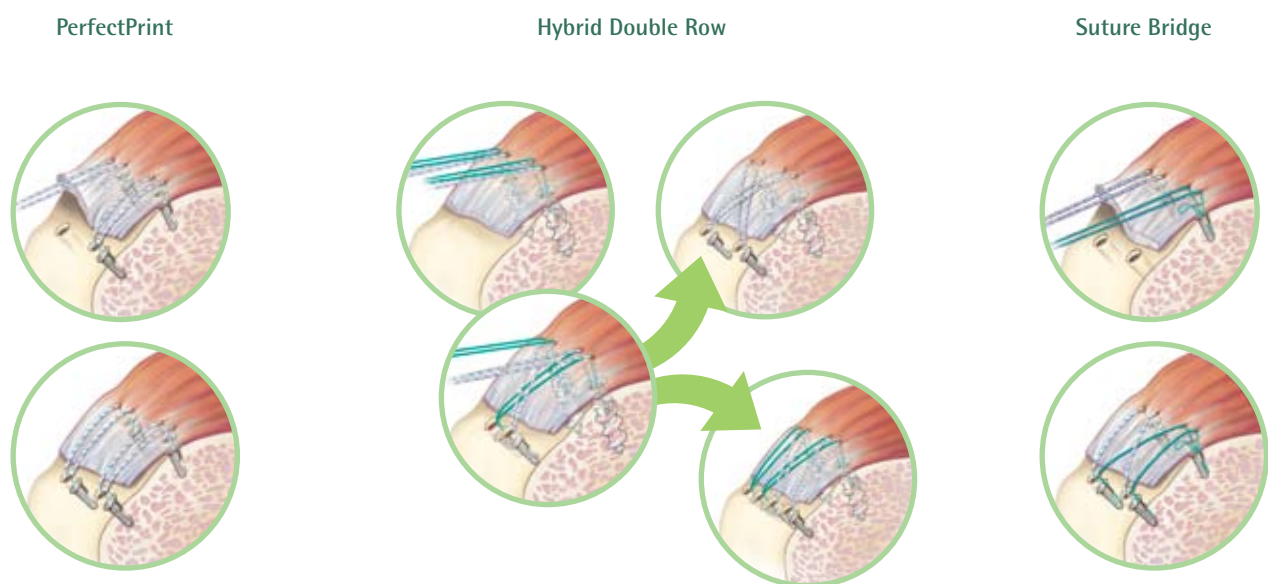
Magnum X applies independent, incremental tensioning on suture limbs to evenly distribute pressure on the tendon to footprint contact area. Improved strength during the rehabilitation period promotes the ideal repair by re-establishing the footprint of the rotator cuff.

X Marks the Spot

The OPUS Collection of products from ArthroCare Sports Medicine not only addresses the concerns of "spot welding" for single-row repairs, with its unique stitch and TensionLock mechanism, but also provides double-row repair constructs to restore the anatomical footprint of more challenging repairs and to address the key elements of an ideal repair. The lateral row of a double-row or single-row repair may have suture limbs that are fixed, but of different lengths. When the limbs are tensioned together unbalanced tension may be applied. Magnum X allows the suture limb to be adjusted and tensioned individually to provide a pressure distributed repair across the complete footprint.

The AutoCuff Magnum X System Provides:

- Ability to tension suture limbs independently
- Evenly distributed contact pressure on the footprint
- Improved snaring
- Strong cortical fixation
- High tensile strength suture
- Knotless suture lock eliminates complex knot tying and residual knot stacks



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 jaws 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.

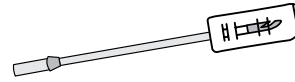
Loading the SmartStitch Suture Cartridge

Step 1 Remove the MagnumWire SmartStitch suture cartridge from its sterile packaging and carefully insert it into the barrel of the Connector. Take care not to kink the plastic tubing.

Step 2 Snap the plastic molded end of the suture cartridge onto the end of the Connector.

The SmartStitch suturing device is now ready to use.

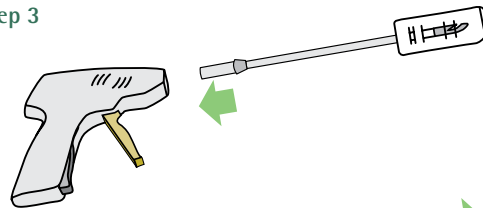
Step 1



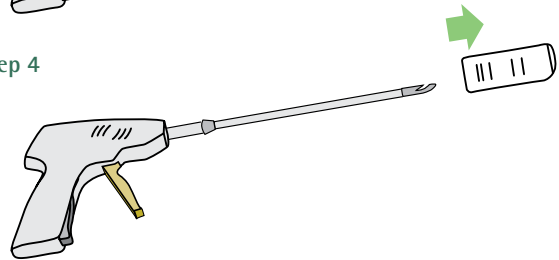
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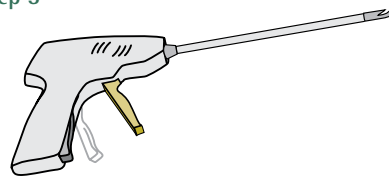
Step 3



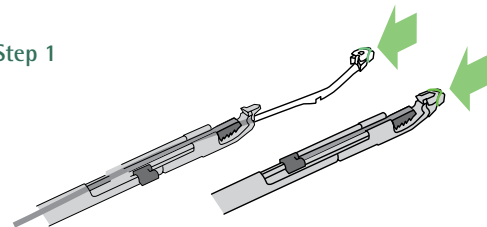
Step 4



Step 5



Step 1



Step 2

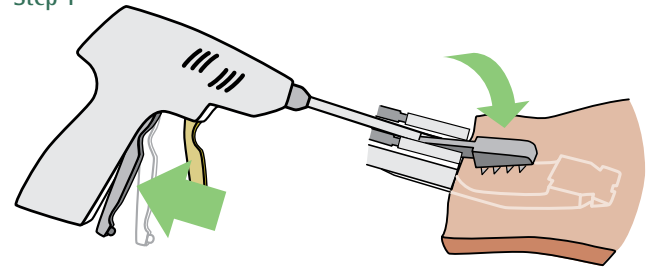


Surgical Technique

Placing the Incline Mattress Stitch

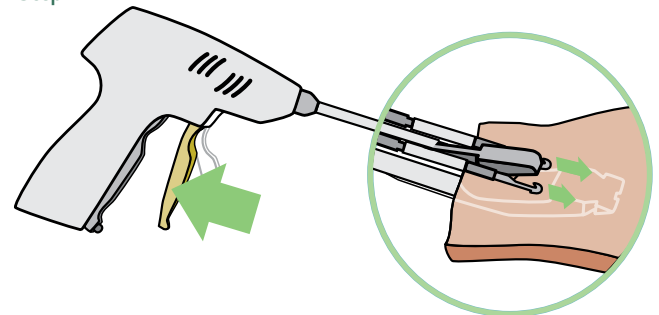
Step 1 Insert the SmartStitch through the lateral portal, usually without a cannula (if a cannula is desired, the diameter must be min. 8.25mm). Grasp the prepared edge of the tendon using the silver clamp jaw lever.

Step 1



Step 2 Activate the needles by completely squeezing the gold needle driver lever once, followed by a slow release. Release the silver jaw using the ratchet release button, and withdraw the SmartStitch from the operative site.

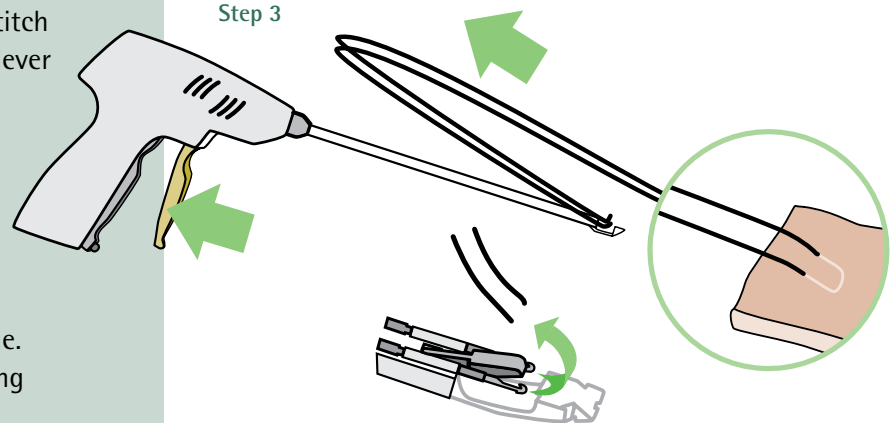
Step 2



This completes placement of the first Incline Mattress stitch.

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

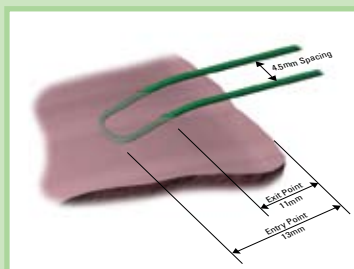
Step 3



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

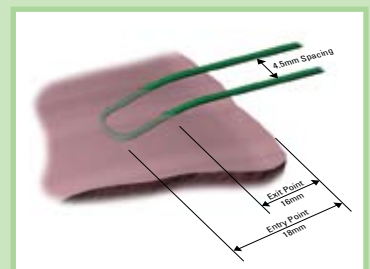
M-Connector Stitch

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.



¹ T. Schlegel, MD; R. Hawkins, MD; C. Lewis; A. Turner. An In Vivo Comparison of the Modified Mason Allen versus a Horizontal Mattress Stitch on Tendon Healing to Bone; A Biomechanical and Histological Study in Sheep. *Journal of Shoulder and Elbow Surgery* 2007; 16: 115-121.

Creating Drill/Punch Holes for the Magnum X 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 in preparation for implant placement. It is important not to decorticate bone in the vicinity of the implant sites as the Magnum X relies on an intact cortical layer for bone fixation.

- Step 1** Optionally insert the Magnum 2 drill guide, with blunt obturator, through the working portal.
- Step 2** If using the blunt obturator, remove the device and, using a suture retriever through the drill guide, shuttle one pair of sutures into the working portal.
- 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, to allow the perpendicular drill/punch angle. The perpendicular alignment should be confirmed with a spinal needle prior to creating the portal.*

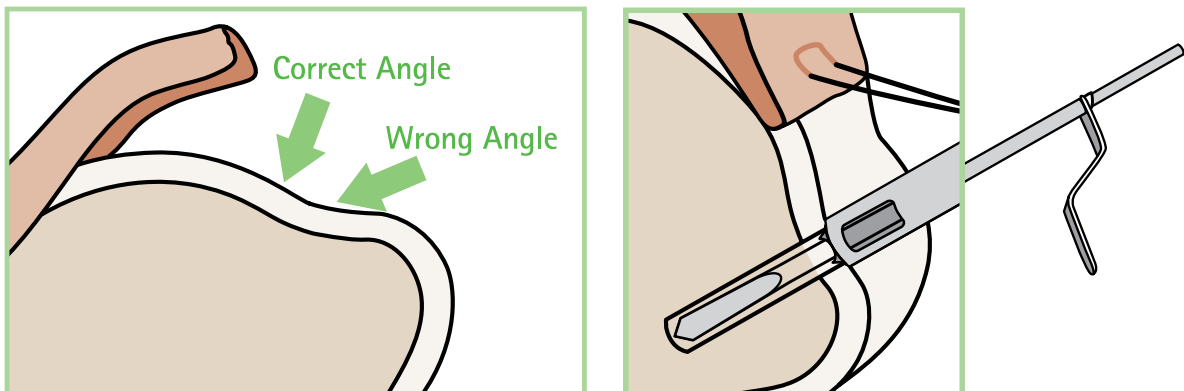
- Step 3** Make the drill or punch holes perpendicular to the bone surface (as opposed to a 45 degree angle), as this ensures optimal fixation by the Magnum X (Fig. 1). *It is important to penetrate the bone up to the collar on the drill (or punch) in order to achieve the correct depth for deployment of the Magnum X implant.*

Note: *If using the drill guide make sure to hold the sutures away in the slot of the guide while creating the hole.*

- Step 4** Once the hole is made, remove the drill (or punch) and optionally insert the PathFinder into the hole to maintain alignment while the Magnum X is prepared for insertion.

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

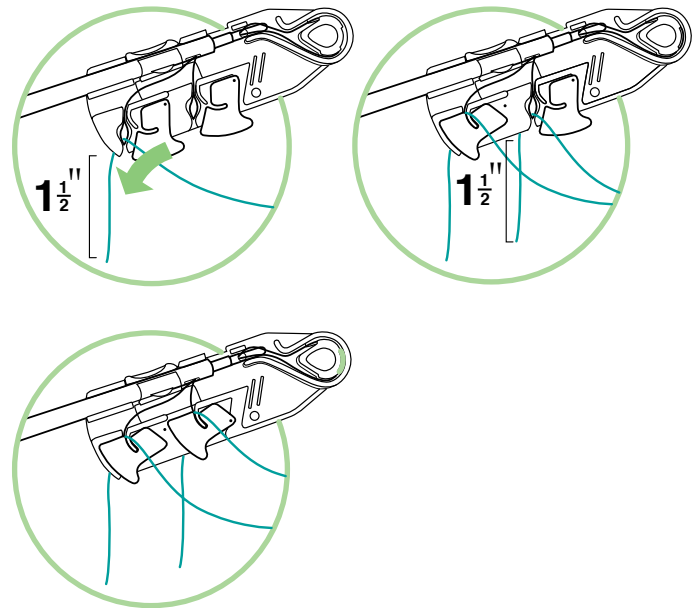
Figure 1



Deploying the Magnum X Implant

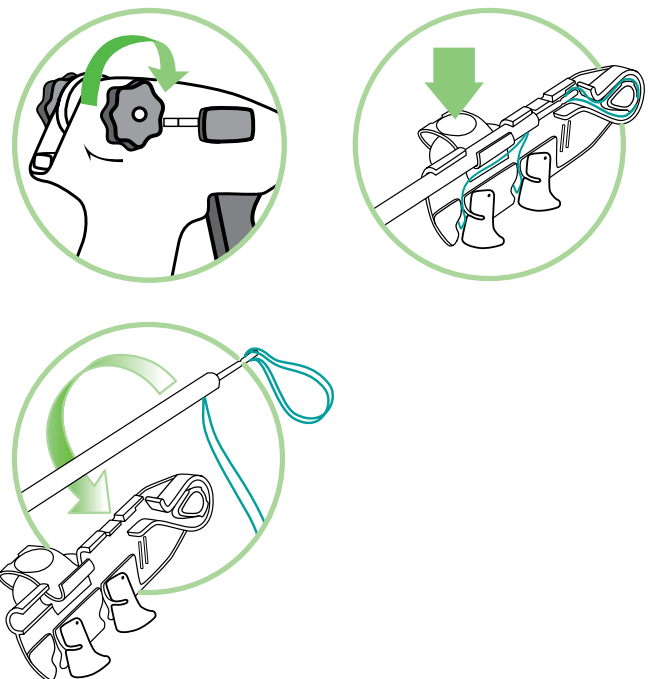
Step 1 Pass one limb of suture through each snare in the same direction. Adjust each suture so that approximately two inches or less of suture extends from the snares and then close the white shutters over the suture limbs.

Step 1



Step 2 With the independent tensioning button in the neutral middle position, take up suture slack by rotating the suture ratchet knobs in the direction of the arrows on the inserter handle until the suture ends enter the implant.

Step 2



Remove the suture loader by squeezing the tab and then pulling down and away from the Magnum X handle until the suture is completely free from the loader.

Note: *You will see 2 suture loops coming out of the implant. Continue to ratchet suture using ratchet knobs to take up slack.*

Step 3 If the PathFinder was inserted, remove and insert the Magnum X into the bone hole with the arrows on the suture support shaft aligned towards the rotator cuff.

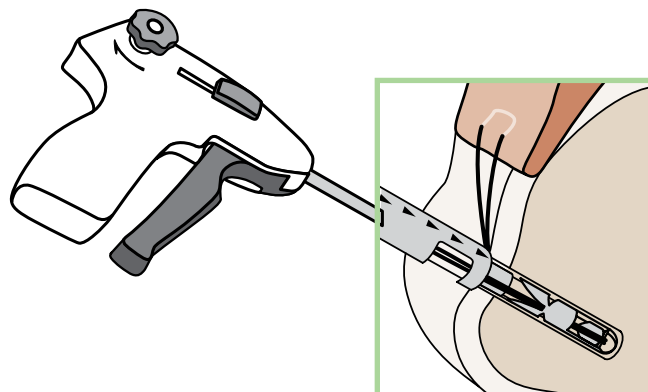
Note: *It is important to maintain perpendicular alignment during insertion of the Magnum X. Insert the Magnum X until the suture support shaft is fully seated against the bone.*

Step 4 With the independent tensioning button in the neutral middle position, 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.

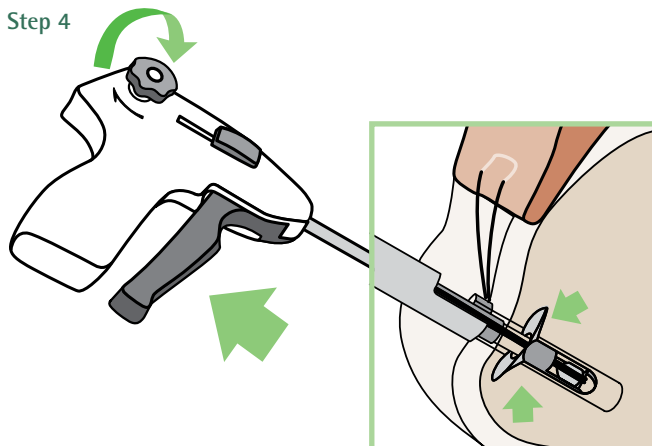
Activate the bone lock by a single squeeze of the black hand lever. Verify bone purchase with a firm tug.

Step 5 With the independent tensioning button left in the neutral middle position, tension both sutures by rotating the suture ratchet knobs with both hands in the direction of the arrows on the inserter handle. Sutures can also be tensioned individually by pressing the independent tensioning button to the left for the left suture or right for the right suture, then turning the corresponding reel to tighten the desired suture limb. The right suture ratchet button corresponds to the snare furthest from the handle.

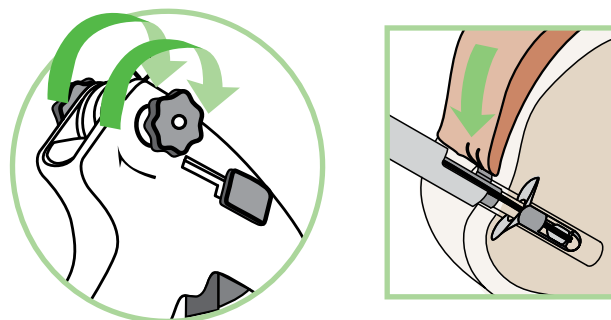
Step 3



Step 4



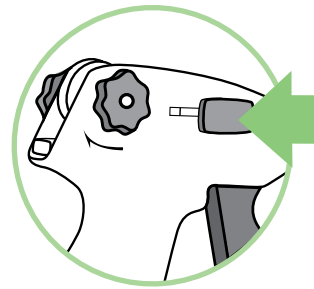
Step 5



Surgical Technique

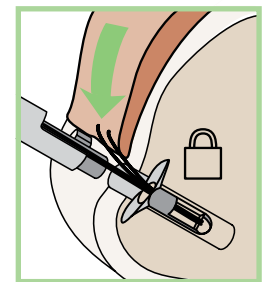
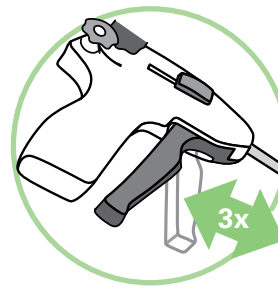
Step 6 When adequate tension between tendon and bone is achieved, press the suture lock button on the side of the inserter handle.

Step 6



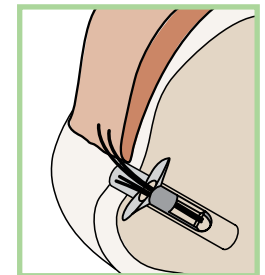
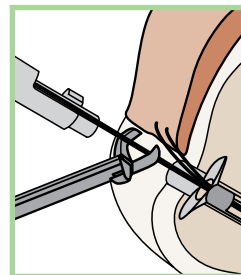
Step 7 Squeeze the black hand lever and release three times (the third squeeze is gentle) to activate the suture lock and allow withdrawal of the inserter handle.

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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