



CLOSING
THE GAP IN
ROTATOR CUFF
REPAIR

AutoCuff™ System *User Guide*

O P U S M E D I C A L

Opus AutoCuff™ System

- **SmartStitch®**

“Incline” mattress stitch

<5 second delivery

Integrated tissue grasper
and suturing device

Direct suturing of tissue

Stitch size: 11mm x 4.5mm

- **Magnum® Implant**

Completely knotless

Cinchable suture tension

Strong cortical bone lock¹

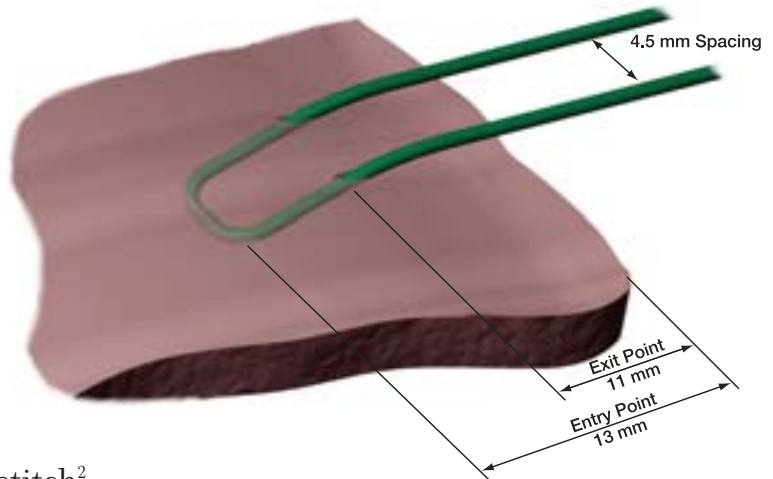
Reversible suture tension

No residual stack of knots



“Incline” Mattress Stitch

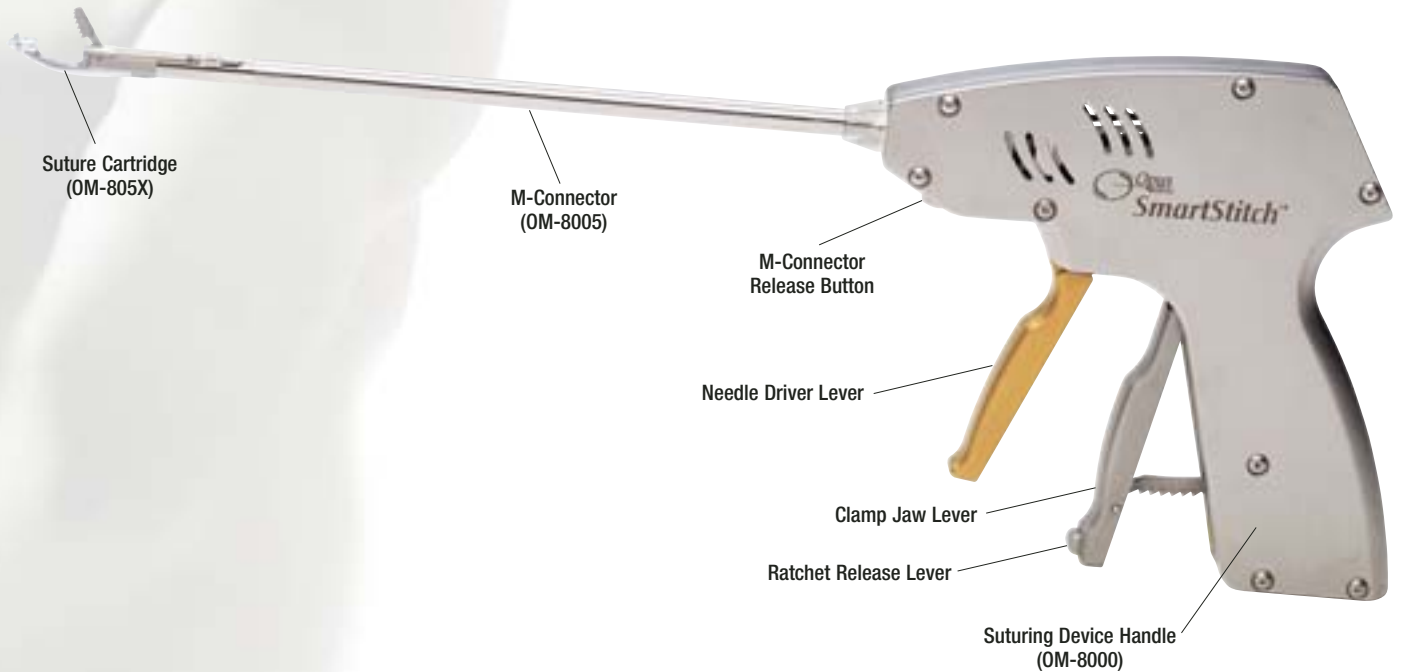
- Increased tissue surface area purchase
- Superior holding strength
- Equivalent to the modified Mason-Allen stitch²



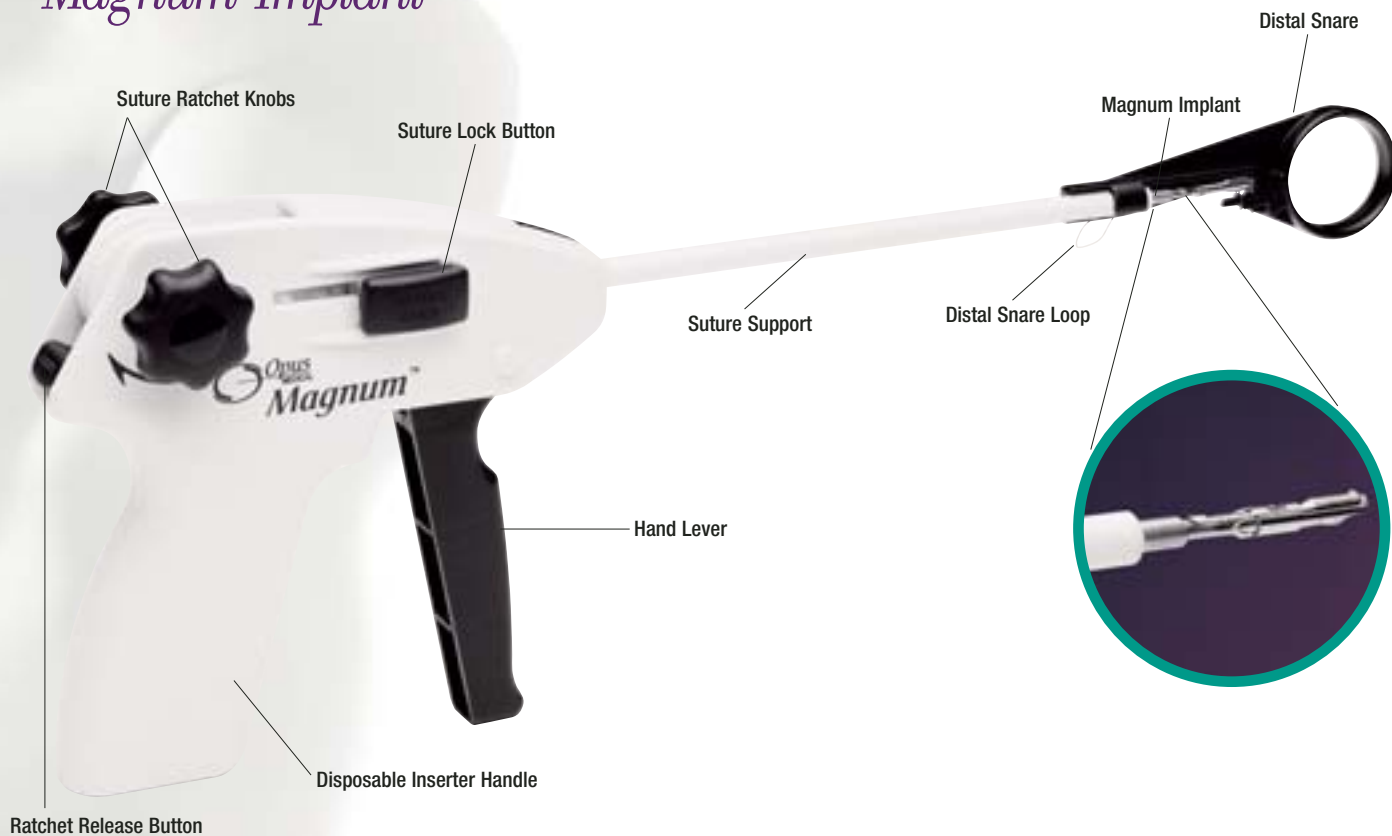
2. “An In-Vivo Comparison of the Modified Mason-Allen versus a Horizontal Mattress Stitch on Tendon Healing to Bone: A Biomechanical and Histologic Study in Sheep.” T. Schlegel, MD; R. Hawkins, MD; C. Lewis, A. Turner, BVSc, MS.

Presented at the Specialty Day Meeting of the American Shoulder and Elbow Surgeons, New Orleans, LA, February 2003.

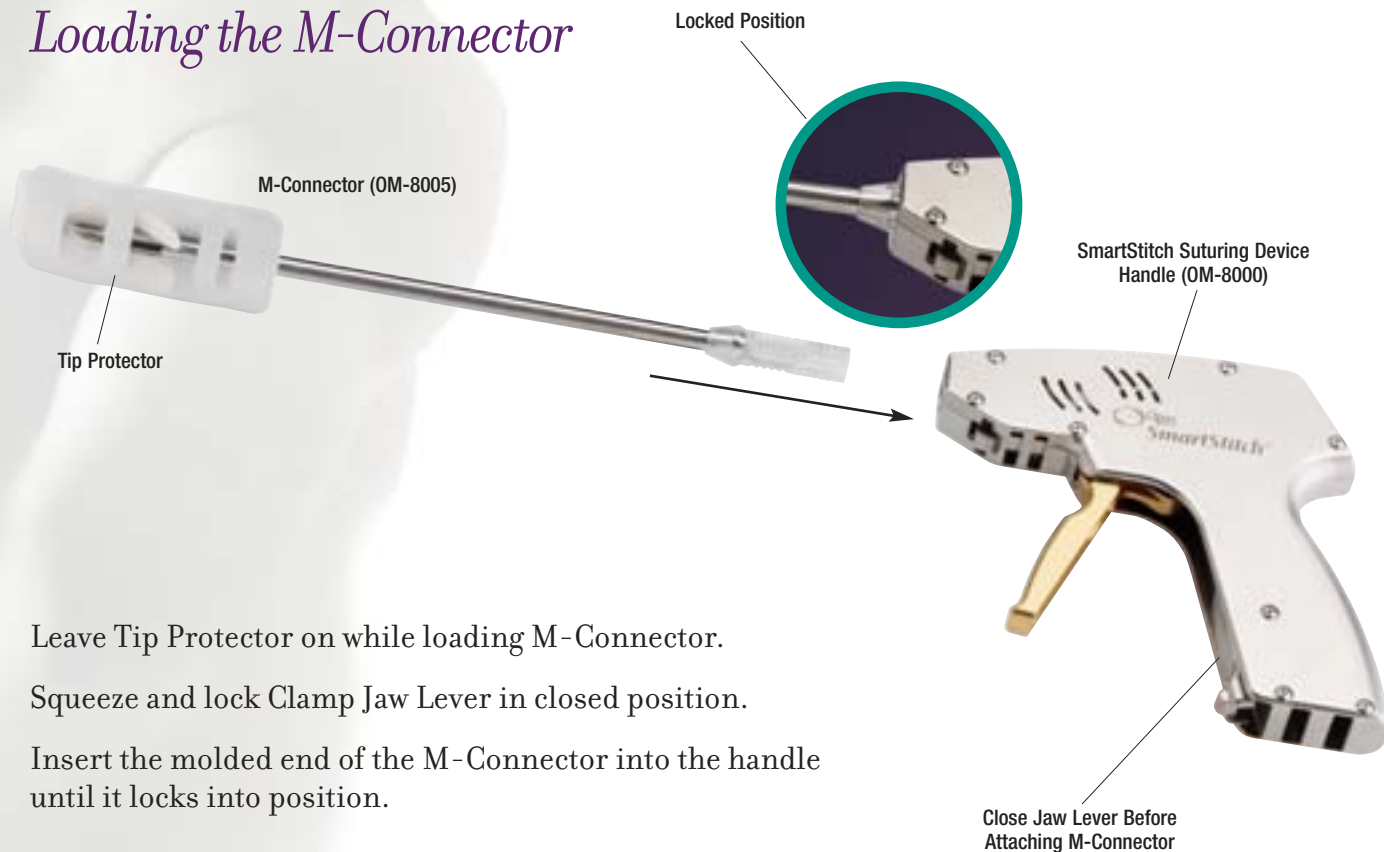
SmartStitch® Suturing Device



Magnum® Implant



Loading the M-Connector

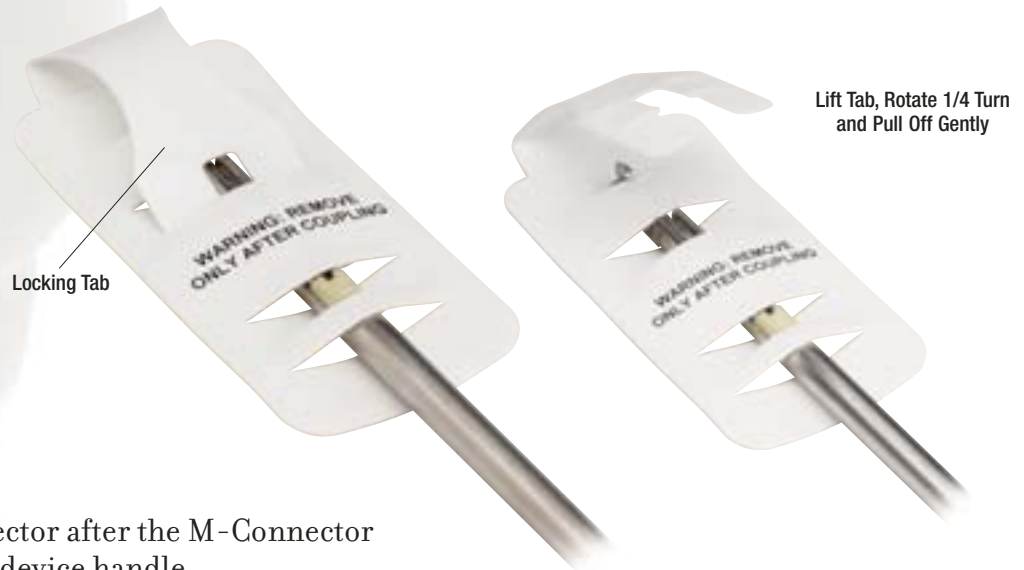


Leave Tip Protector on while loading M-Connector.

Squeeze and lock Clamp Jaw Lever in closed position.

Insert the molded end of the M-Connector into the handle until it locks into position.

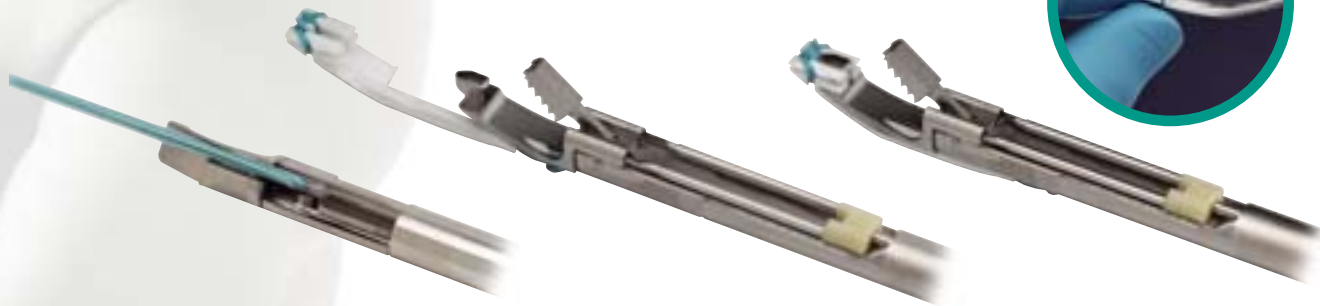
Removing the Tip Protector



Only remove the Tip Protector after the M-Connector is coupled to the suturing device handle.

After coupling M-Connector, remove the Tip Protector and actuate the Clamp Jaw Lever and Needle Driver Lever to test controls.

Loading the Suture Cartridge



Remove a SmartStitch® Suture Cartridge from its packaging.

Carefully insert the Suture Cartridge tube into the barrel of the M-Connector without kinking the plastic tubing.

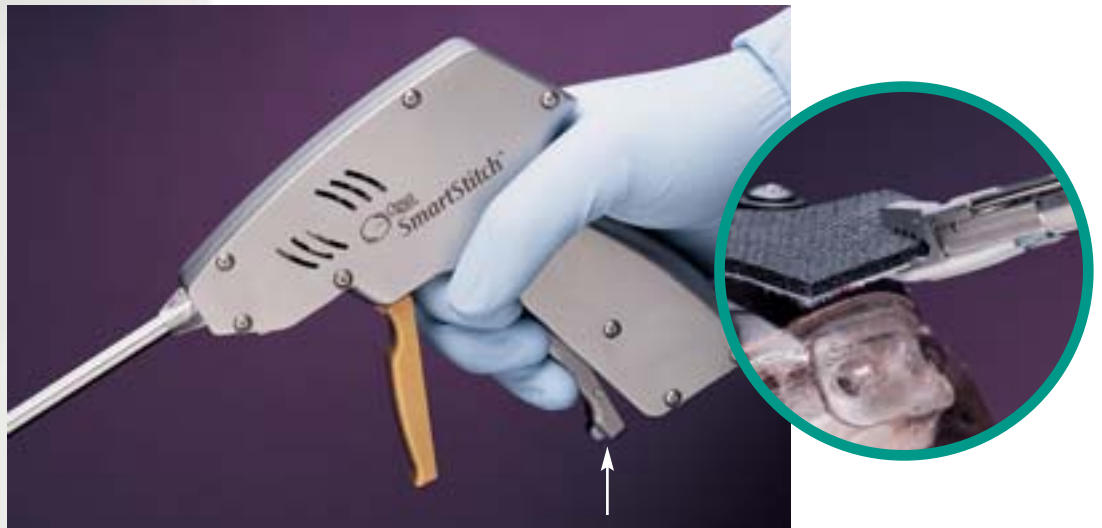
Snap the Cartridge onto the end of the M-Connector until a distinct click is heard.

Do not use the Suture Cartridge if tubing has been kinked.

When placing multiple sutures, use different colors (green, white, co-braid).

See Instructions for Use for the OM-8000 SmartStitch Suturing Device Handle, OM-8005 SmartStitch M-Connector, and OM-805x SmartStitch Suture Cartridges for complete discussion of the use of the SmartStitch Suturing system.

Using the SmartStitch® Suturing Device—1



Insert SmartStitch device directly through skin nick or min. 8.25mm cannula.

Grasp tendon with Clamp Jaw Lever.

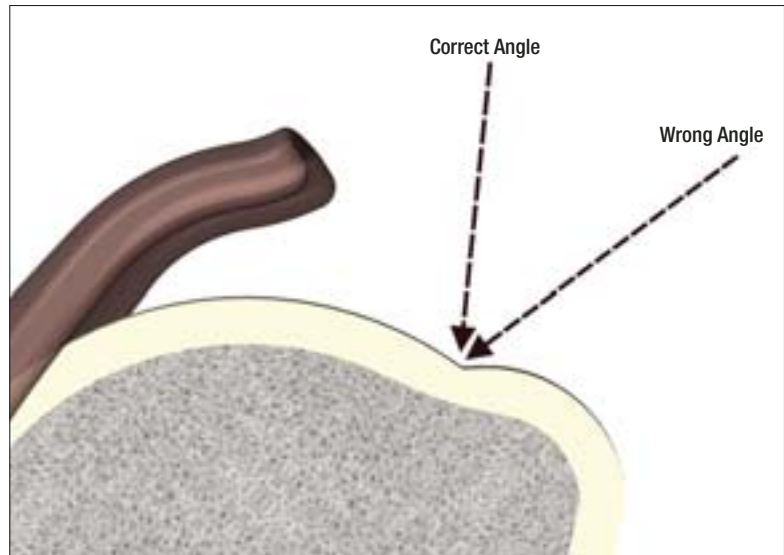
Using the SmartStitch® Suturing Device—2



Activate needles by squeezing the gold Needle Driver Lever once completely and releasing.

Use Ratchet Release Lever to open jaws and remove SmartStitch Handle from tendon.

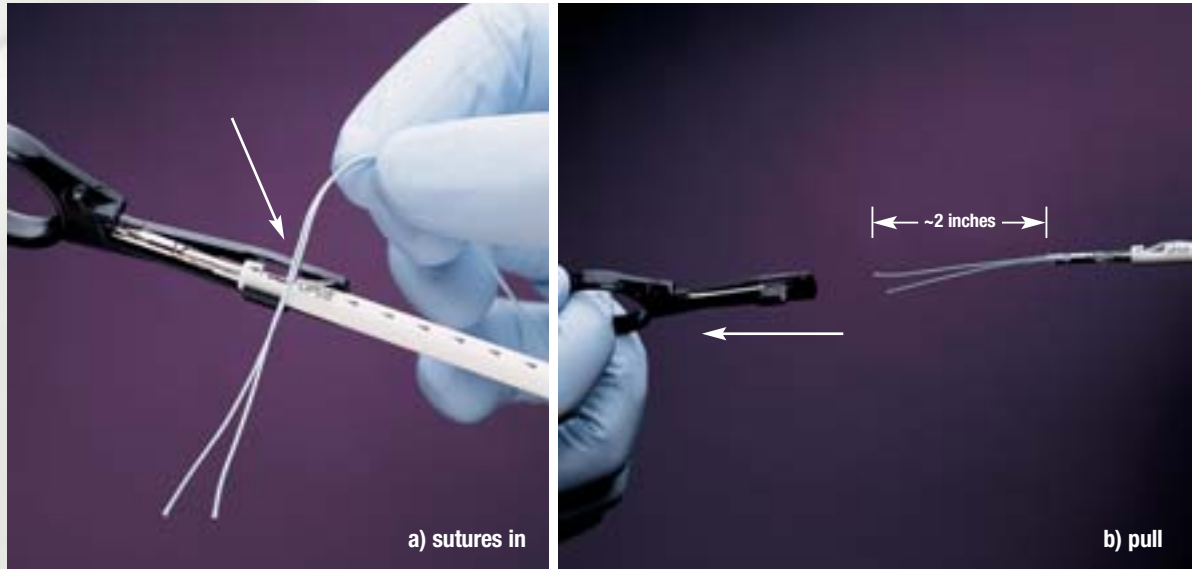
Drill/Punch Angle



Drill or punch Magnum® Implant site perpendicular to the bone surface.

Only use Opus Drill Bit or Punch.

Loading the Magnum®



Load both limbs of suture into the Distal Snare Wire Loop.

Remove Distal Snare by pulling snare ring forward.

Adjust suture length so that about 2 inches of suture are left extending from the distal end of the implant.

Removing Suture Slack



Remove suture slack by rotating the Suture Knob in the direction of the arrows on the Inserter Handle.

Insert Implant through Opus Drill Guide or minimum 6mm cannula.

Aligning the Magnum®



Align arrows on Suture Support shaft with the tendon.

Insert into pre-drilled or punched hole.

Ensure complete seating of the Suture Support shaft against the bone.

Bone Lock Deployment



After deployment, shaft automatically rotates 90 degrees to free sutures in window.

Activate bone lock by squeezing the black Hand Lever once.

Verify bone purchase by gently tugging the Implant Handle.

Cinching the Magnum®



Tension suture by rotating Suture Knobs with both hands in the direction of the arrows on the Inserter Handle.

To reverse tension, depress and hold Ratchet Release Button and loosen suture tension as desired with a crochet hook.

Activating the Suture Lock Button



Depress Suture Lock button on side of Inserter Handle.

Activate Suture Lock



Squeeze Hand Lever three times to activate Suture Lock and allow removal of the Magnum® Inserter Handle.

Complete the Repair



Trim sutures to complete the AutoCuff™ repair.



CLOSING THE GAP IN SOFT TISSUE REPAIR

1-800-809-OPUS (6787)
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