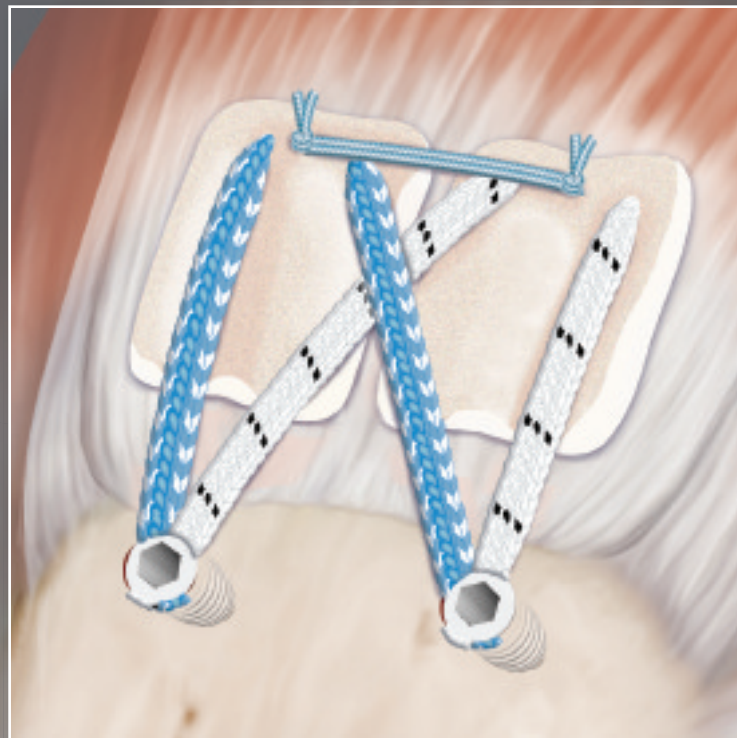




ArthroFlex® BioWasher™ for use with SpeedBridge™
Knotless Rotator Cuff Repairs

Surgical Technique



ArthroFlex BioWasher

Knotless SwiveLock Anchors with FiberTape Provide the Strongest and Lowest Profile Constructs

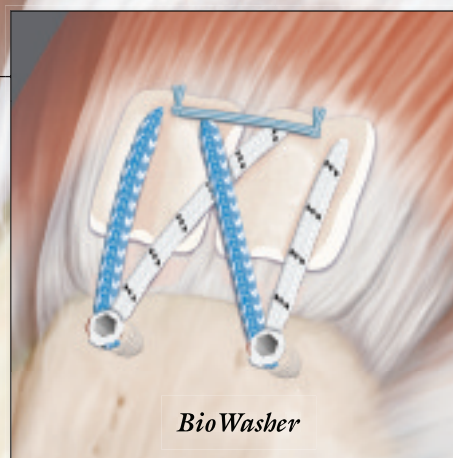
SpeedBridge | **Knotless Double Row Footprint Reconstruction**

- Medium to large tears
- Transosseous equivalent
- Maximizes contact between tendon and bone
- Knotless medial row minimizes potential for crepitus
- Protects healing zone from the synovial environment
- Requires only two suture passing steps

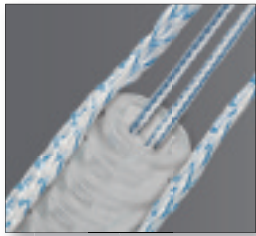
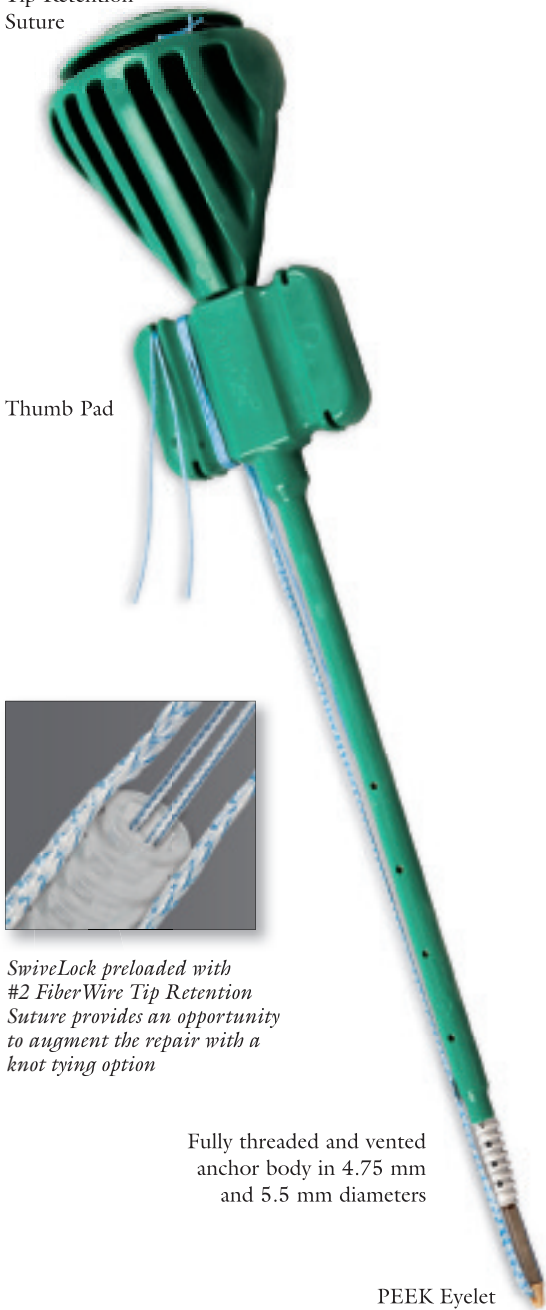


ArthroFlex BioWasher | **SpeedBridge Augmented Repair**

- Ideal for use in Revisions or in cases of poor tissue quality
- Reinforces suture-tendon interface preventing suture pull-through
- Easy to implant arthroscopically
- Decellularized for cellular repopulation and to promote healing



#2 FiberWire
Tip Retention
Suture



SwiveLock preloaded with #2 FiberWire Tip Retention Suture provides an opportunity to augment the repair with a knot tying option

Fully threaded and vented anchor body in 4.75 mm and 5.5 mm diameters

PEEK Eyelet

SwiveLock C

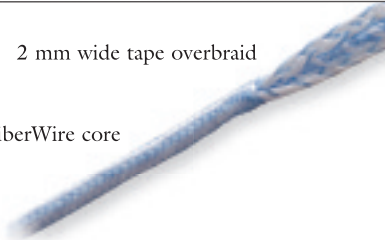
- The only fully threaded, bioabsorbable, knotless anchor on the market
- Cannulated and vented design minimizes material and may allow bony ingrowth
- Our maximum fixation strength
- Combines with many variations of FiberTape® and FiberWire® for extreme flexibility
- BioComposite, PEEK, PLLA and titanium material options

SwiveLock SP

- Self-punching design eliminates the need for a bone socket preparation step
- Facilitates repair visualization prior to insertion

FiberTape

- 2 mm wide FiberTape or TigerTape™ options provide broad compression and tissue cut-through resistance
- #2 FiberWire tails can be passed with a Scorpion™ Suture Passer

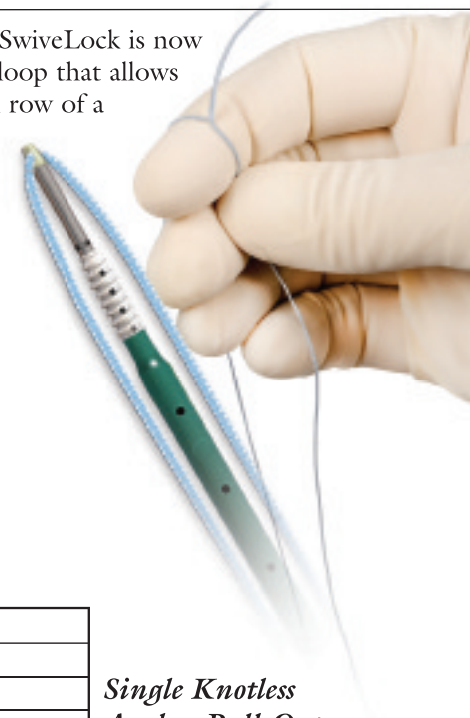


2 mm wide tape overbraid

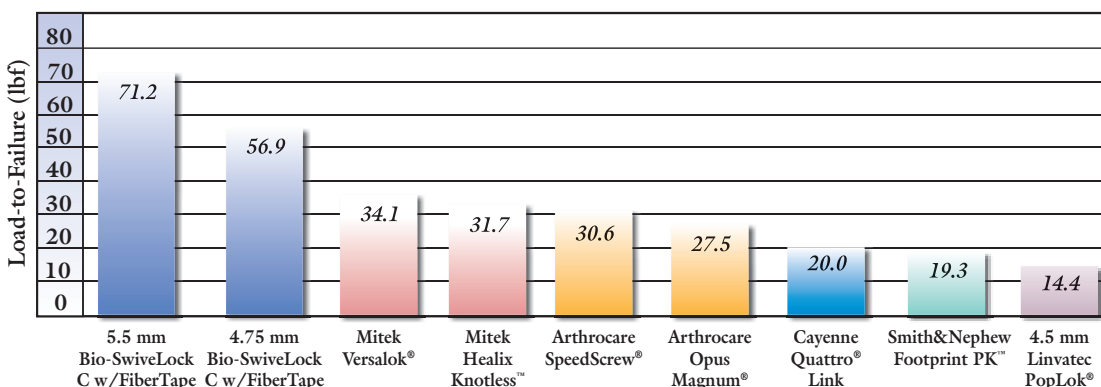
#2 FiberWire core

BioComposite Vented SwiveLock with FiberTape Loop

The 4.75 mm BioComposite Vented SwiveLock is now available with a preloaded FiberTape loop that allows easy FiberTape passage for the medial row of a SpeedBridge. The two limbs of the FiberTape are joined into a single tail that can be easily passed with a Scorpion Suture Passer, eliminating the need for more complex suture shuttling techniques.



The science behind the technology...



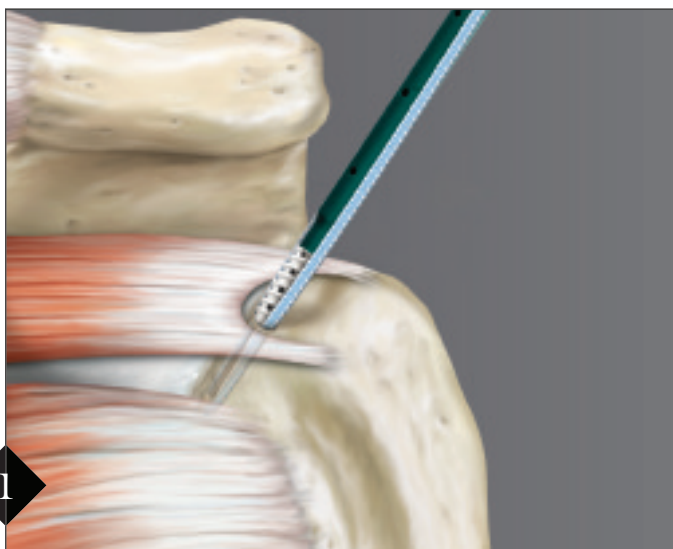
Single Knotless Anchor Pull-Out Strength

Data on file - straight axial pull-out in laminated foam block (10 pcf cancellous core with a 2 mm thick 20 pcf cortical shell)

ArthroFlex BioWasher for use with SpeedBridge Knotless Rotator Cuff Repairs

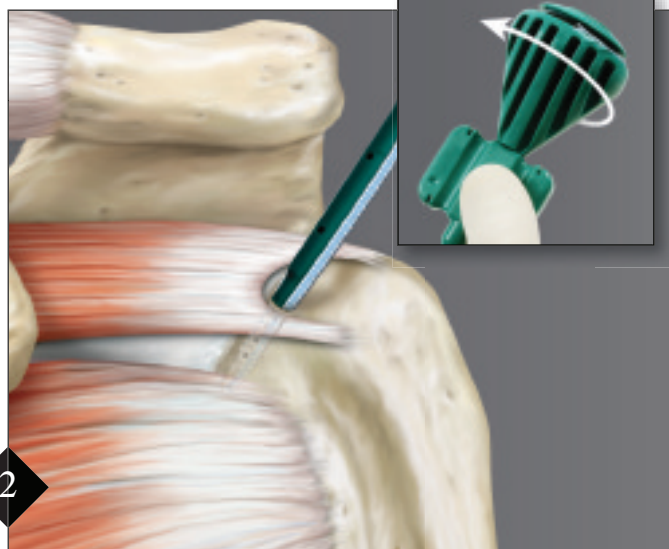
Developed in conjunction with Raffy Mirzayan, MD; Los Angeles, CA

The fully threaded SwiveLock C can be combined with FiberTape to create a quick and secure SpeedBridge construct with no knots. The result is a low profile, transosseous equivalent “suturebridge” that enhances the footprint compression to maximize contact between tendon and bone. The addition of the ArthroFlex BioWasher adds a biologic component to augment the tendon/suture interface.



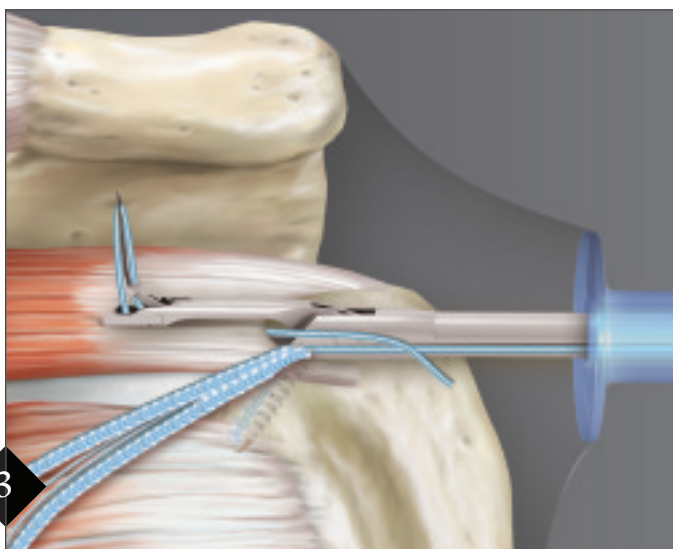
1

Preload a FiberTape into the eyelet of a BioComposite SwiveLock C for use as a medial row anchor. Prepare a bone socket using a punch. Insert the BioComposite SwiveLock C into the prepared medial bone socket until the anchor body makes contact with bone. Ensure that the FiberTape tails are parallel to the cuff, and not perpendicular to it.



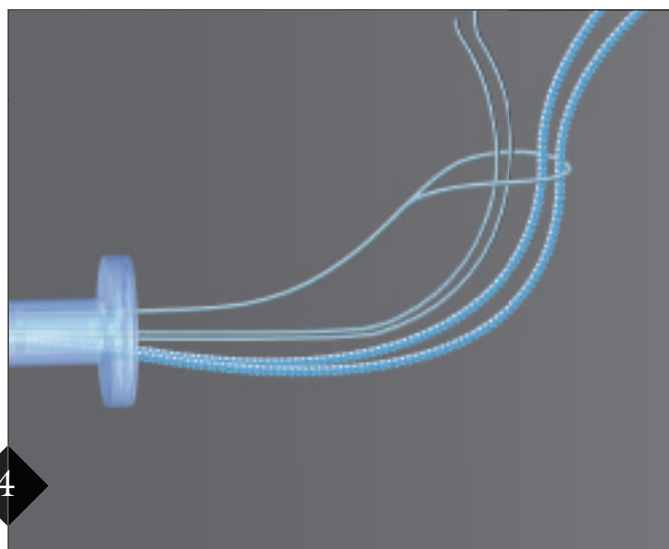
2

Hold the thumb pad steady and rotate the driver handle in a clockwise direction until the anchor body is flush with the bone. Unwind the #2 FiberWire tip retention suture that holds the PEEK tip in place during anchor insertion. This suture may be incorporated into the repair or discarded. Remove the driver.



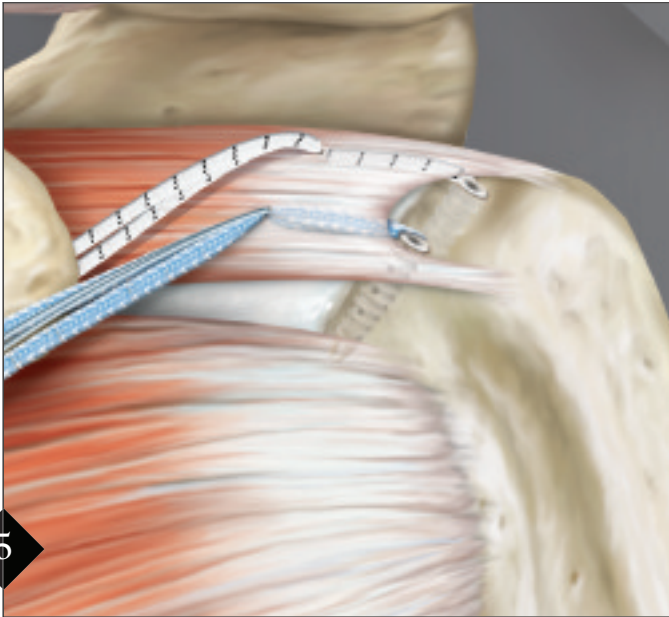
3

Pass the tail of a FiberLink™, for use as a suture shuttle, through the rotator cuff with a FastPass Scorpion. Move the FiberLink tail to the anterior portal.



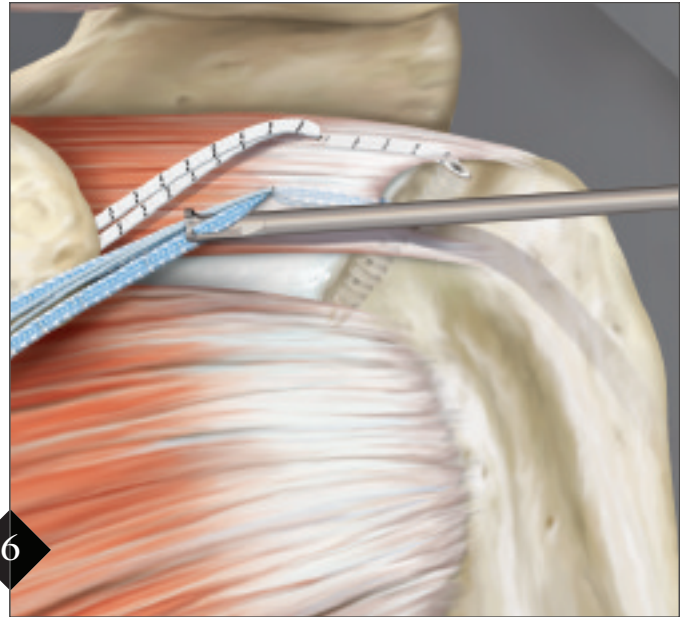
4

Retrieve the FiberTape tails and the #2 FiberWire tails through the lateral portal using a FiberTape Retriever. Load the FiberTape and FiberWire through the FiberLink loop. Pull on the FiberLink tail, through the anterior portal, to shuttle the FiberTapes and FiberWires through a single hole in the rotator cuff.



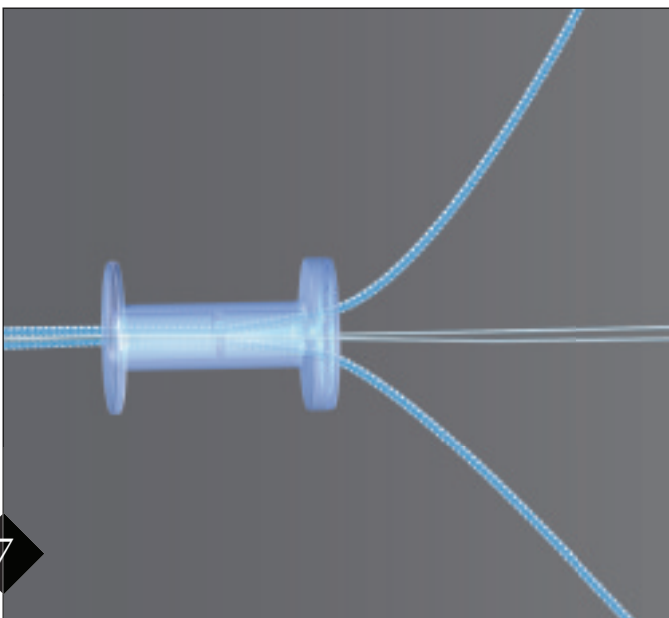
5

Repeat steps 1-4 for the anteromedial anchor, using a white/black TigerTape for easy suture management.



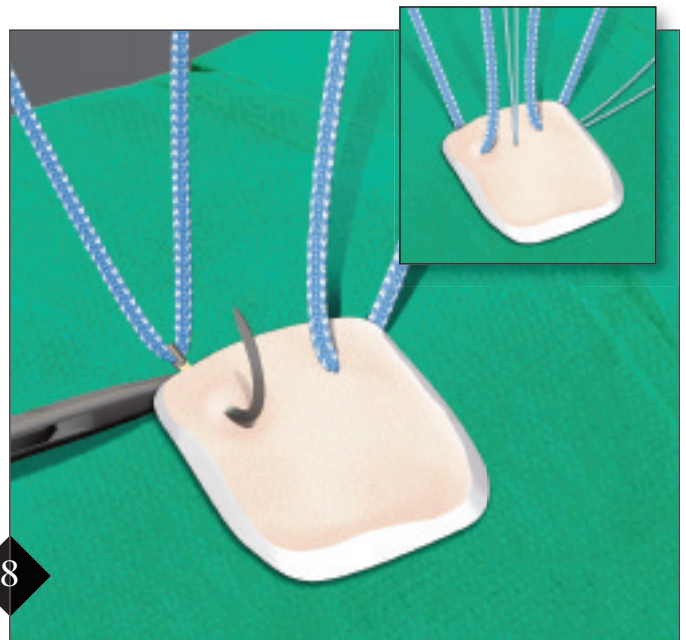
6

Use a CrabClaw™ Suture Retriever to grasp each FiberTape individually at the anchor and bring out of the PassPort Button Cannula, one at a time to prevent tangling of the FiberTape. If you plan on using the #2 FiberWire in the repair for a Medial Pulley, those should be brought out separately from the FiberTapes as a pair.



7

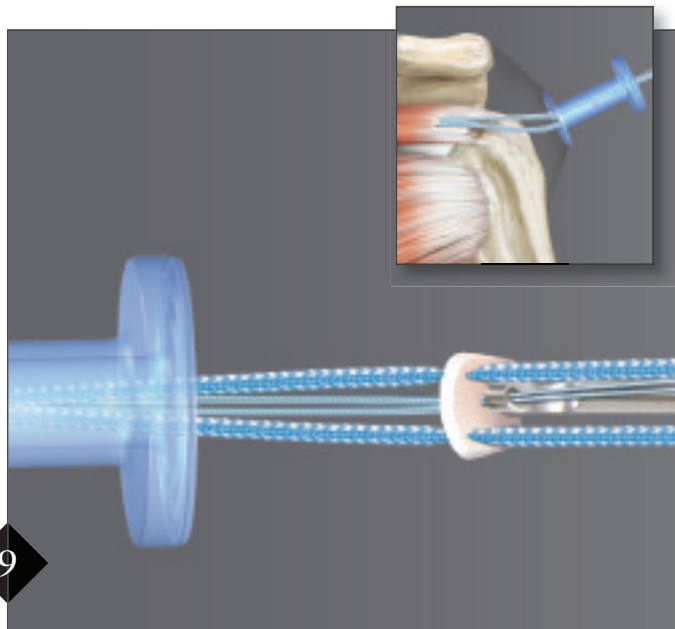
Suture management is key to passing the sutures in an appropriate manner. Notice the FiberTape and FiberWire position outside the cannula. This ensures the sutures are not crossed when passing suture through the BioWasher.



8

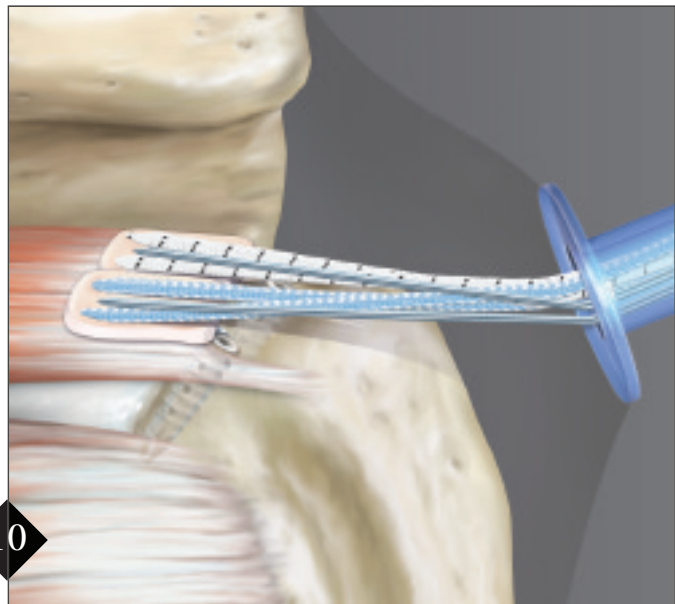
Place a folded towel on the patient's arm and place the BioWasher on the towel. Use the Arthrex Reverse Cutting Needle with Nitinol Loop or a cutting (trochar) free needle to pass the FiberTapes individually through the BioWasher. The two FiberTapes should be passed approximately 5.5 mm from each other. If the FiberWires are to be used, pass both limbs together through the BioWasher between the FiberTapes.

ArthroFlex BioWasher for use with SpeedBridge Knotless Rotator Cuff Repairs



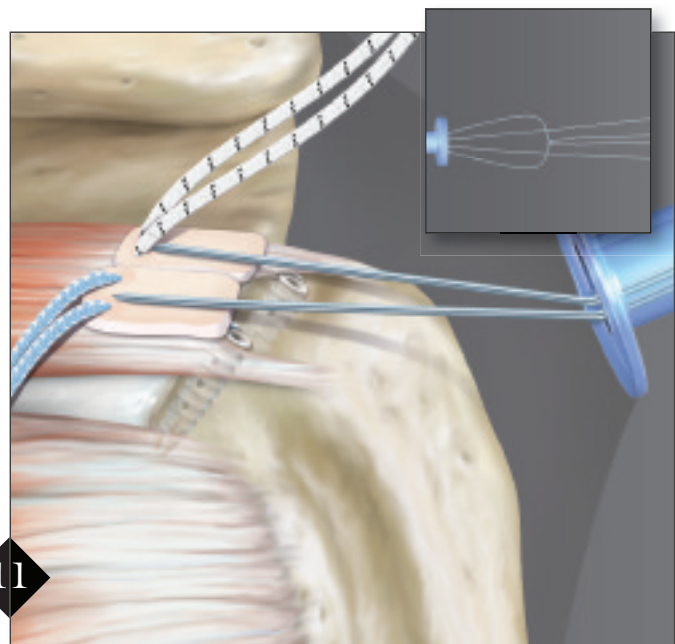
9

Pass both limbs of the FiberWire through an arthroscopic knot pusher and grasp the FiberWire and FiberTape and hold them under tension in line with the cannula. Using a “push-pull” technique, advance the BioWasher down the sutures, through the hub of the cannula, and then all the way down on top of the rotator cuff tendon. An arthroscopic probe may be used through the anterior portal to help lay the BioWasher down.



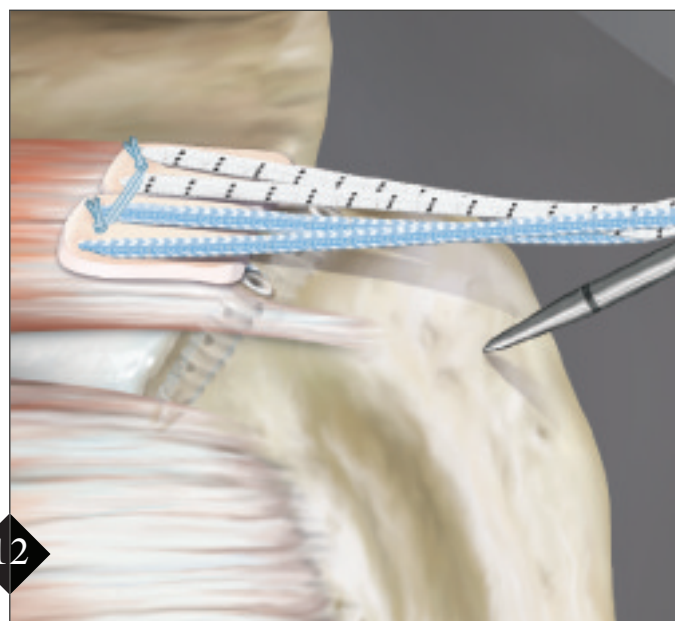
10

Repeat Steps 6-9 for the anterior BioWasher.



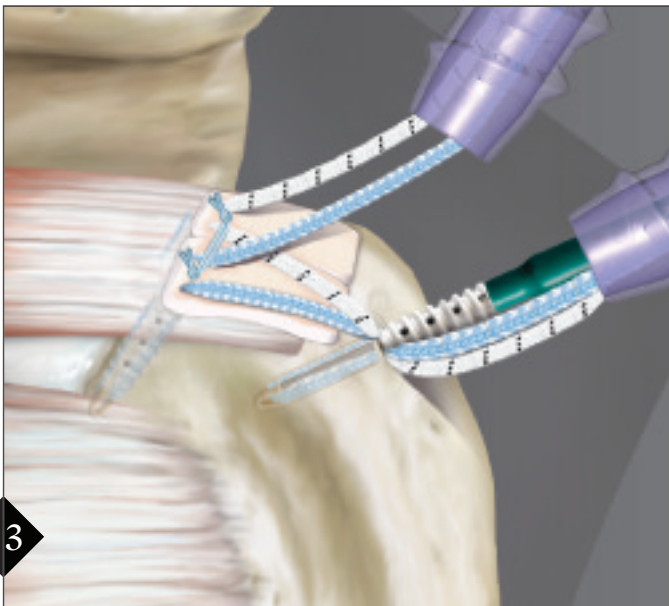
11

For suture management, shuttle the anterior anchor FiberTapes out through an anterior portal. Shuttle the posterior anchor FiberTapes through a posterior portal. Use the FiberWire sutures to tie a Medial Pulley. A rigid cannula can replace the PassPort Button Cannula.

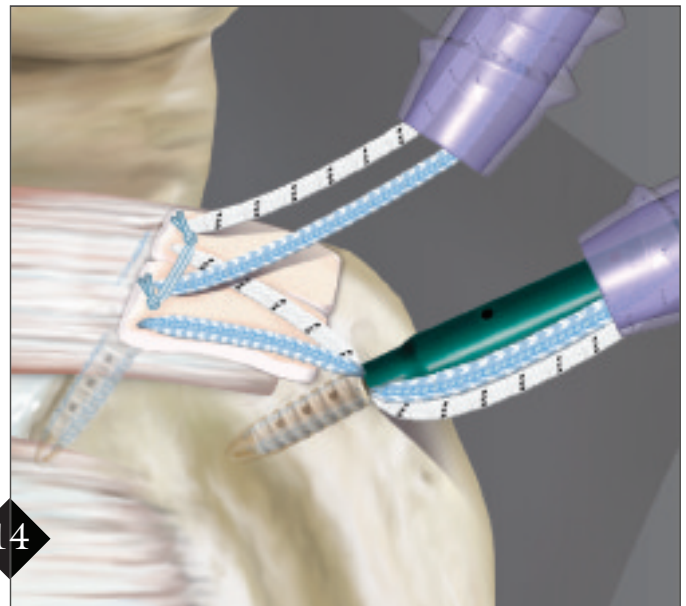


12

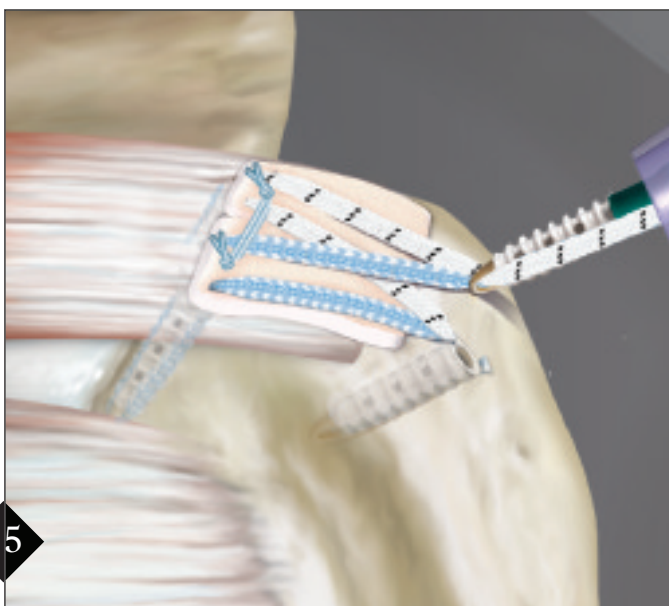
Retrieve on FiberTape tail from each medial anchor and preload them through the SwiveLock C eyelet. Prepare a bone socket using a punch. Anchor position is normally 5-10 mm lateral to the edge of the tuberosity.



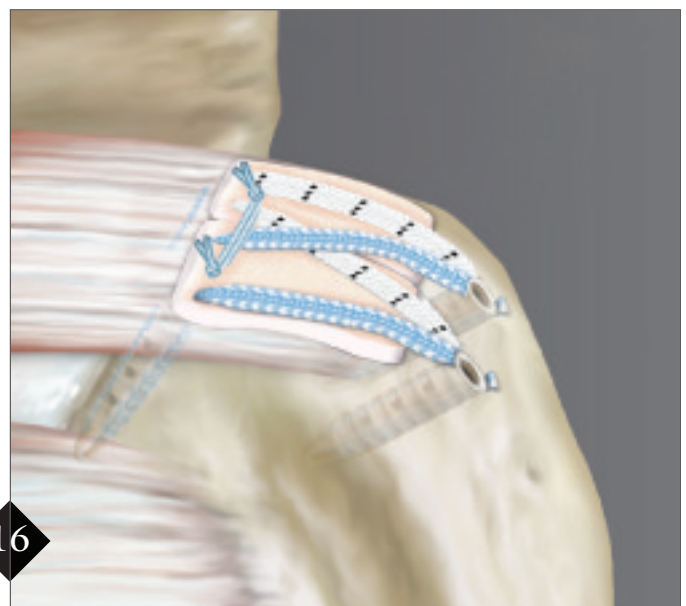
Bring the eyelet of the implant to the edge of the bone socket and remove slack from each FiberTape limb individually. Apply tension to the FiberTapes so that the tissue is reduced and compressed against the bone.



Completely advance the driver into the bone socket beyond the first laser line, until the anchor body contacts bone. Evaluate tissue tension. If it is determined that the tension is not adequate, the driver can be backed out and tension readjusted. Hold the thumb pad steady and rotate the driver in a clockwise direction until the anchor is flush with the bone.



Cut the FiberTape tails with a FiberTape Cutter. Repeat steps 12-15 for the second lateral anchor.



Final repair with BioWashers in place.

Ordering Information

Implants/Disposables:

BioComposite SwiveLock C, 4.75 mm x 19.1 mm, closed eyelet	AR-2324BCC
BioComposite SwiveLock C, 5.5 mm x 19.1 mm, closed eyelet	AR-2323BCC
BioComposite SwiveLock SP, 4.75 mm x 24.5 mm, self-punching	AR-2324BCM
BioComposite SwiveLock SP, 5.5 mm x 24.5 mm, self-punching	AR-2323BCM
BioComposite SwiveLock C w/blue FiberTape Loop	AR-2324BCCT
BioComposite SwiveLock C w/white/black FiberTape Loop (PEEK, PLLA and titanium anchor options also available)	AR-2324BCCTT
FiberTape, 2 mm, 7 inch (blue) each end tapered to #2 FiberWire, 30 inches	AR-7237-7
TigerTape, 2 mm, 7 inch (white/black) each end tapered to #2 TigerWire, 30 inches	AR-7237-7T
FiberTape, Collagen Coated, 2 mm, 7 inch (blue)	AR-7237-7B
FiberLink, #2 FiberWire (blue) w/closed loop	AR-7235
MultiFire Scorpion Needle	AR-13995N
PassPort Button Cannula, 8 mm I.D. x 20 mm	AR-6592-08-20
PassPort Button Cannula, 8 mm I.D. x 30 mm	AR-6592-08-30
PassPort Button Cannula, 8 mm I.D. x 40 mm	AR-6592-08-40
PassPort Button Cannula, 8 mm I.D. x 50 mm	AR-6592-08-50
PassPort Hemostat (used for PassPort insertion)	AR-6592
PassPort Measuring Device (used for determining proper PassPort length)	AR-6592M
Cannula, Twist-In, 7 mm I.D. x 7 cm	AR-6570
Reverse Cutting Needle with Nitinol Loop	AR-7280

SpeedBridge Implant System:

The SpeedBridge Implant System is a single convenience package that contains all implants and FiberTapes needed for a standard four-anchor SpeedBridge construct.

SpeedBridge Implant System w/BioComposite SwiveLock C	AR-2600SBS-4
SpeedBridge Implant System w/BioComposite SwiveLock SP	AR-2600SBS-5

Instruments:

Punch, for 5.5 mm Corkscrew FT and 4.75 mm and 5.5 mm SwiveLock	AR-1927PB
Disposable Punch, for 5.5 mm Corkscrew FT and 4.75 mm and 5.5 mm SwiveLock	AR-1927PBS
MultiFire FastPass Scorpion Suture Passer	AR-13997MF
Knot Pusher, Closed end	AR-1305
CrabClaw Knot Pusher/Suture Retriever	AR-12960
FiberTape Cutter	AR-13250
FiberTape Retriever w/SR Handle	AR-13974SR
FiberTape Penetrator™, w/SR Handle, Straight Shaft, Self-Ratcheting	AR-2167ST-3
FiberTape Penetrator™, 15° w/SR Handle, Up Curved	AR-2167-3

ArthroFlex BioWasher Decellularized Dermis

ArthroFlex BioWasher (thickness = 1.76 mm – 2.25 mm)

Decellularized Dermis 14 mm x 10 mm (qty. 2)	AFLEX822
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ArthroFlex BioWashers can be ordered through LifeNet Health Customer Service at 888-847-7831



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In doing so, the medical professional should rely on their own training and experience and should conduct a thorough review of pertinent medical literature and the product's Directions For Use.

View U.S. patent information at www.arthrex.com/corporate/virtual-patent-marking