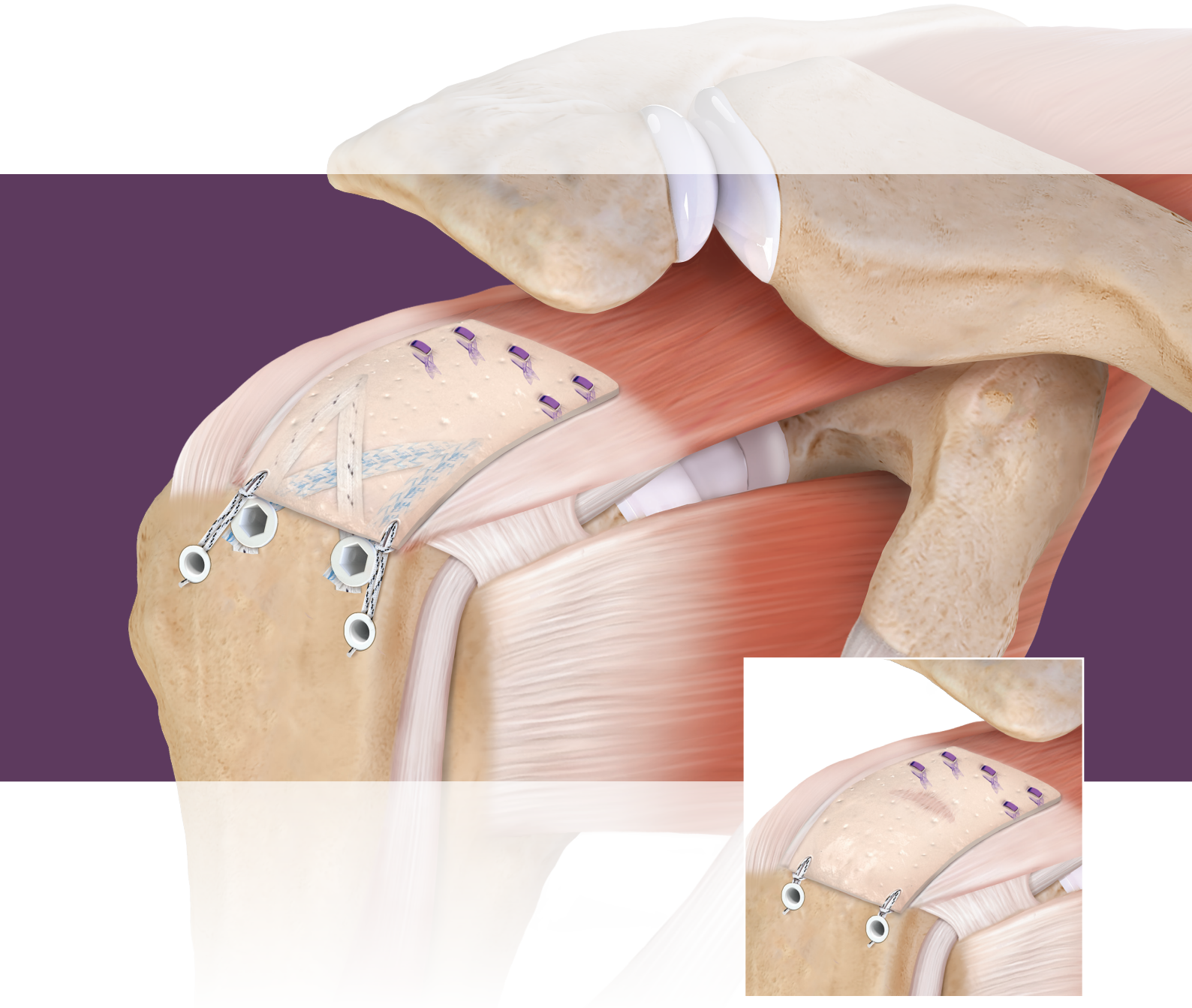
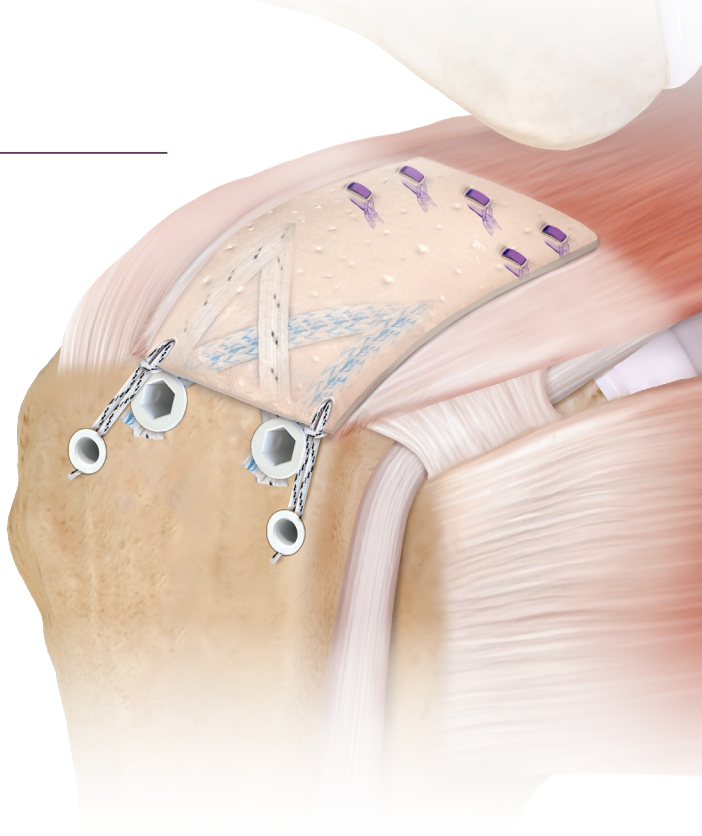
CuffMend™ Rotator Cuff Augmentation System

Surgical Technique



Arthrex®

CuffMend™ Rotator Cuff Augmentation System



Providing an efficient, simple approach to augmenting partial- and full-thickness rotator cuff tears, the CuffMend system incorporates human dermal allograft for mechanical strength and to support healing.[1,2] Insert the graft using the graft spreader and then securely fixate the graft using TissueTak™ tendon anchors for medial soft-tissue fixation and Knotless PushLock® anchors for lateral bony fixation. Scientific literature has demonstrated that rotator cuff augmentation with acellular dermal matrix can be effective.[2-4]

ArthroFLEX® Dermal Allograft

ArthroFlex dermal allograft is a biohospitable acellular dermal allograft intended for supplemental support and covering for soft-tissue repair.[2,5]

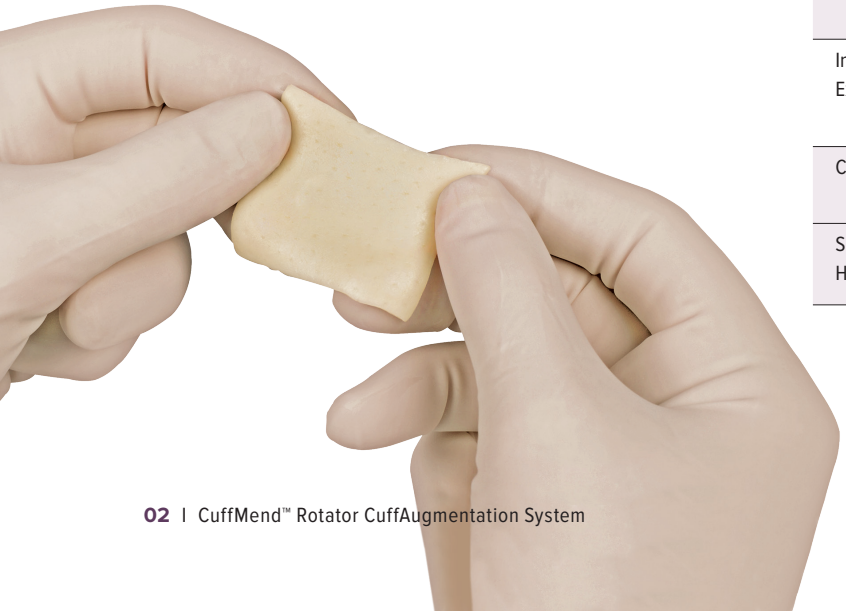
LifeNet Health's patented and validated Matracell® decellularization process renders the ArthroFlex dermal allograft acellular without compromising its biomechanical or biochemical properties. Matracell technology removes donor DNA from the dermal matrix, ensuring a biocompatible scaffold that retains its growth factors, native collagen scaffold, and elastin. Matracell technology is validated to retain <10 ng dsDNA/mg wet weight of tissue, far less than other commercially available acellular dermal matrices.[5]

ArthroFlex is treated with Preservon®, a proprietary and patented preservation technology that allows the graft to be fully hydrated at room temperature while avoiding the water-mediated lysis of the natural collagen and elastin scaffold.[5]

- Augmentation with ArthroFlex dermal allograft has demonstrated improved clinical outcomes[3,4]
- ArthroFlex dermal allograft improves the strength of the repair and protects the repair to allow healing[2]
- Augmentation with ArthroFlex dermal allograft can reduce retear rates[3]
- Biomechanical testing has shown that ArthroFlex dermal allograft provides high ultimate load and suture retention strength[6]
- ArthroFlex dermal allograft has demonstrated the ability to remodel and integrate with host tissue after implantation[1]

ArthroFLEX®

>97% DNA and Cellular Content Removed	Removing cells and immugenetic components allow host cells to readily infiltrate and proliferate[5]
Intact Acellular Extracellular Matrix	Provides a strong, biohospitable collagen scaffold for host cellular and vascular ingrowth[5]
Convenience	Excellent handling; ready to use; room temperature storage (15°C-30°C)[7]
Supports Rapid Healing	Retains growth factors, elastin, matrikines, cytokines, and collagens[8]



TissueTak™ Tendon Anchors

TissueTak absorbable tendon anchors feature an innovative fixation design for quickly and securely attaching the ArthroFlex dermal allograft to the rotator cuff tendon.

- Low-profile, closed-loop design provides superior fixation in muscle and tendon compared to standard tissue staples[9]
- Multifire inserter can rapidly deploy up to 10 consecutive implants
- Degradation profile allows for optimal fixation strength during critical healing period[10]
- PLGA anchor material fully absorbs in 12-18 months[10]

CuffMend™ Graft Spreader

The CuffMend graft spreader provides a straightforward approach to introducing the ArthroFlex dermal allograft and positioning it over the repair site for final fixation.

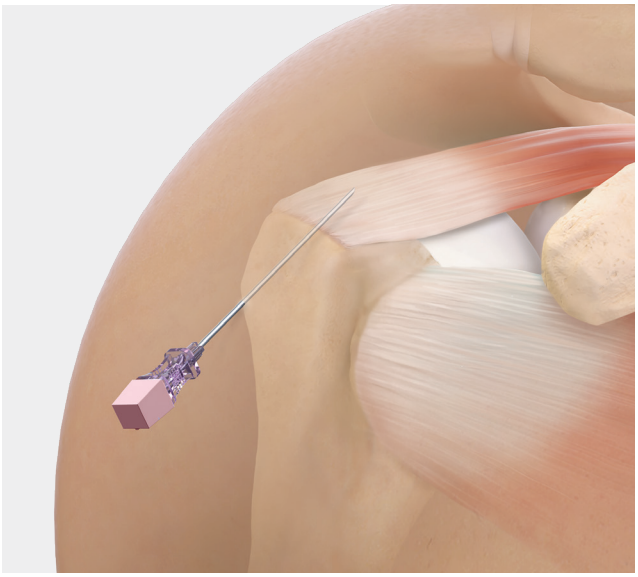
- Straightforward configuration for easily attaching the presutured ArthroFlex graft
- Low-profile design to simplify inserting the graft into the subacromial space
- Articulating arm effortlessly positions the graft over the repair site
- Versatile design for insertion through the anterior, lateral, or posterior portals

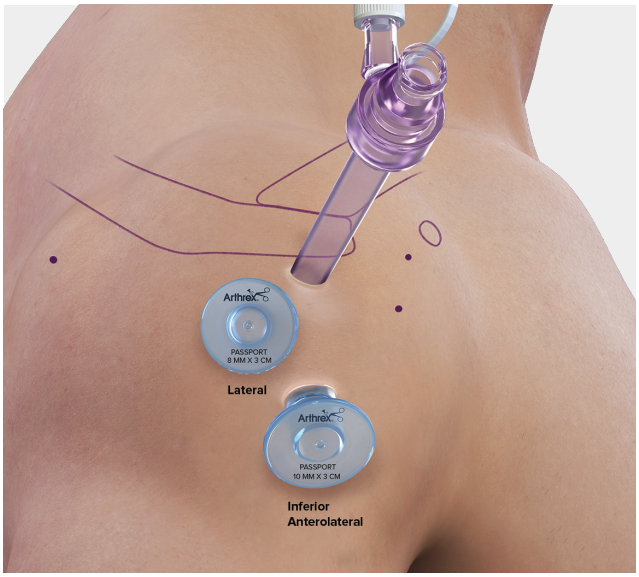
3.5 mm Knotless PushLock® Suture Anchor

The PushLock suture anchor, a trusted and familiar knotless solution, allows for tension adjustment to the repair construct, ensuring precise reduction and graft fixation.

- Simplified and familiar insertion technique
- Visualize and adjust suture tension prior to anchor insertion to prevent overtensioning of the graft construct
- Cannulated design minimizes anchor volume
- Available in biocomposite and PEEK materials

Portal Placement





Lateral Portal

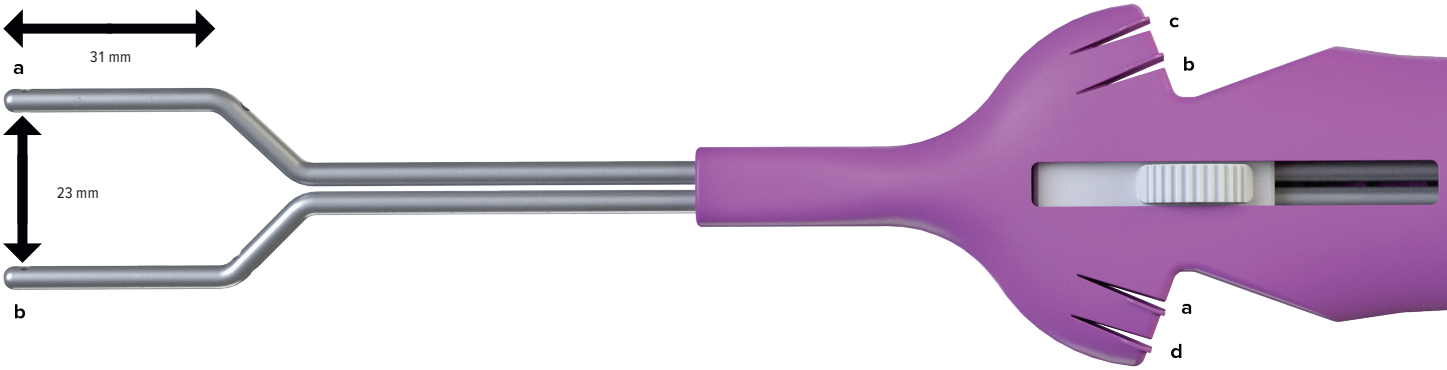
Use a spinal needle to create a lateral working portal for placement of a 10 mm PassPort Button™ cannula. It is very important to make the portal as parallel as possible to the surface of the rotator cuff, resulting in a lateral portal location that will be more inferior compared to a standard lateral working portal.

Superior Lateral Portal

A 5.75 mm cannula may be used in the superolateral portal to simplify insertion of the TissueTak™ inserter and to avoid introducing unwanted soft tissues when fixating the medial portion of the ArthroFlex dermal allograft.

Optional Inferior Anterolateral Portal

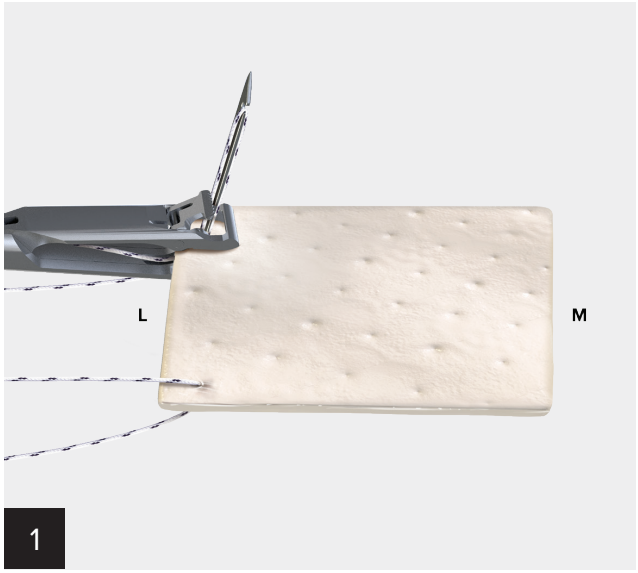
An auxiliary inferior anterolateral portal may also be created to introduce the graft spreader into the subacromial space.

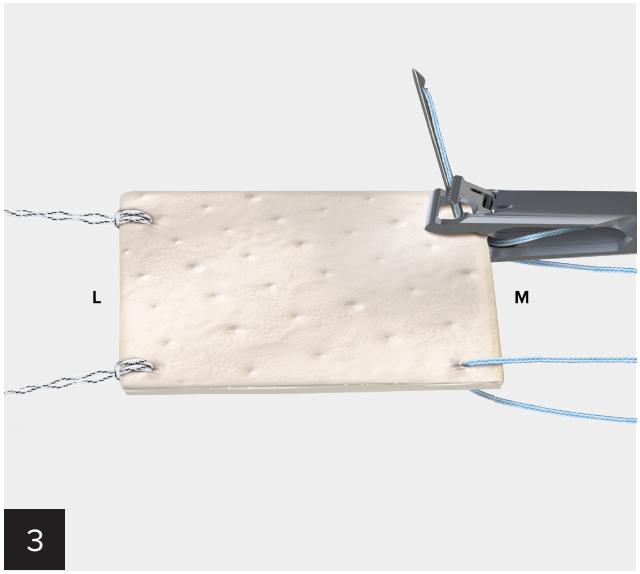


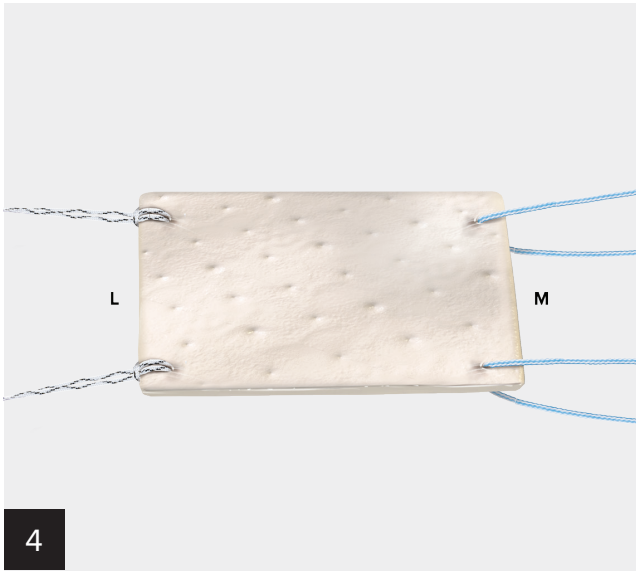
Graft Selection

Place the graft spreader into the subacromial space in the deployed position. The arm of the graft spreader from the tip to the first bend is 31 mm. Use this measurement as a reference for choosing the appropriately sized ArthroFlex precut graft.

Graft Preparation

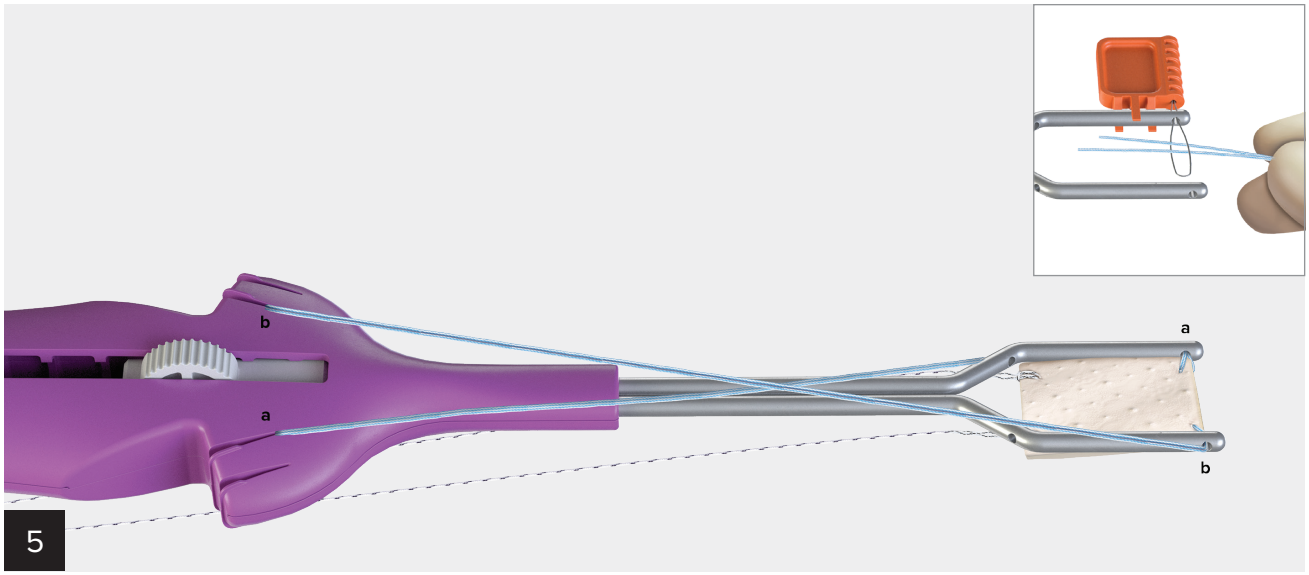




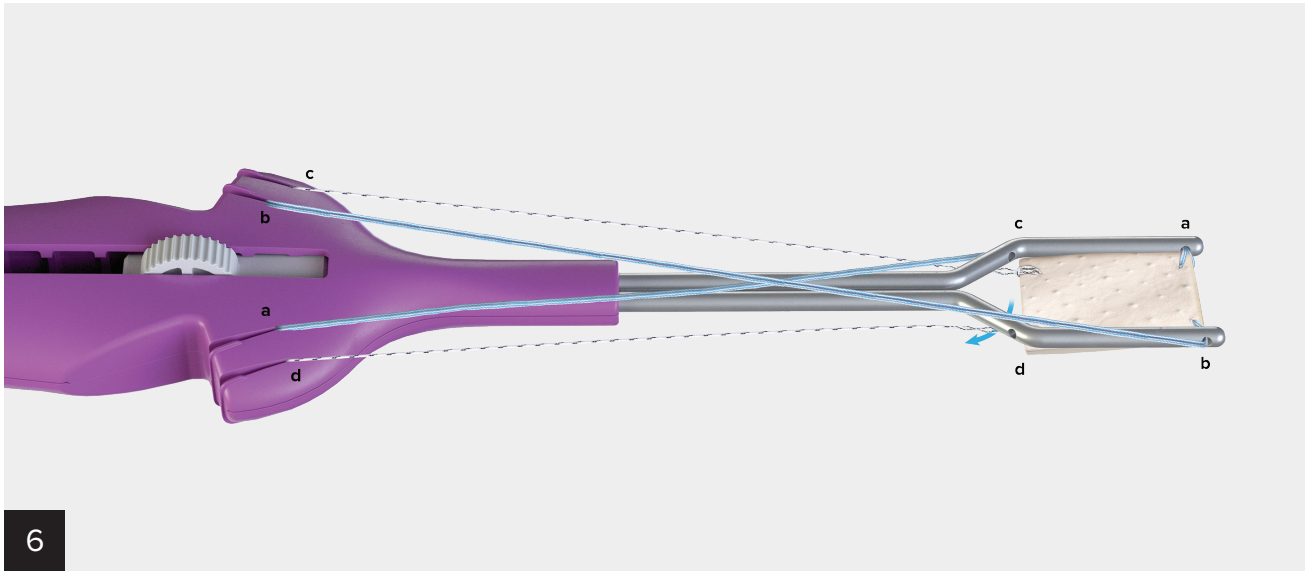


Using a Scorpion™ SL suture passer, place two 0.9 mm TigerLink™ SutureTapes into the lateral corners (L) of the ArthroFlex dermal allograft in a cinch stitch configuration. Prepare the medial corners (M) of the graft by passing a #0 FiberWire® suture in a simple pass configuration.

Graft Preparation

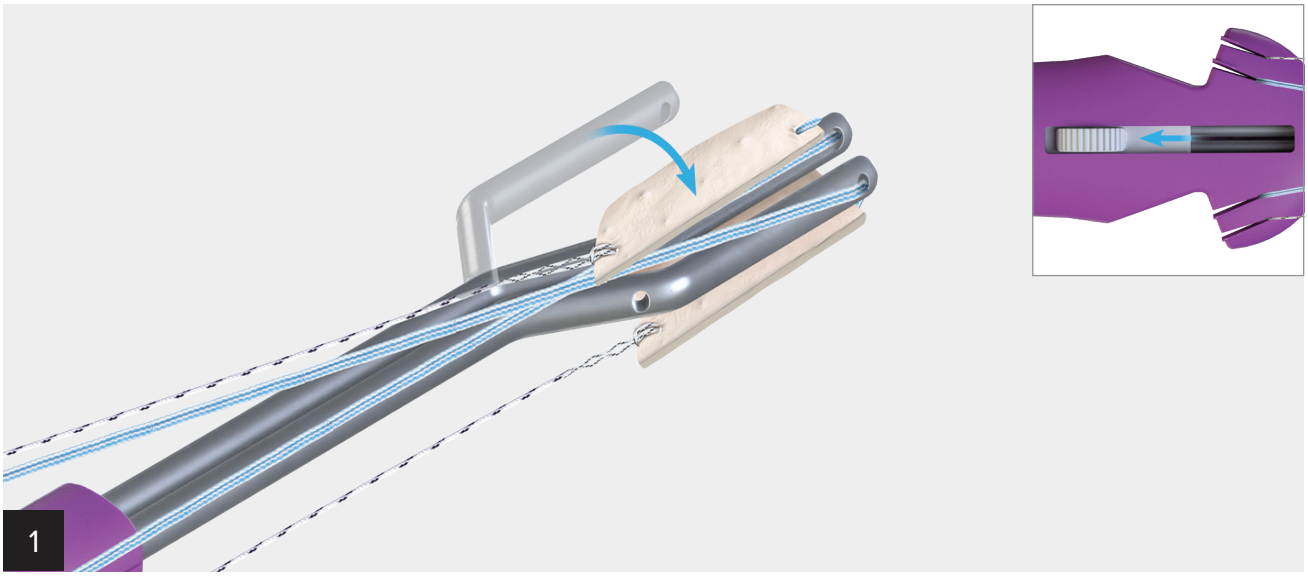


Using the orange suture passing flag, pass the #0 FiberWire® sutures from the medial aspect of the ArthroFlex graft into the suture channels at the distal end of the graft spreader (a, b). Take care to cleat the medial sutures on the inside cleats on the opposite side of the spreader arm it was passed through. This creates a crisscross pattern that eases passage through the 10 mm PassPort Button™ cannula and retains tension on the graft.

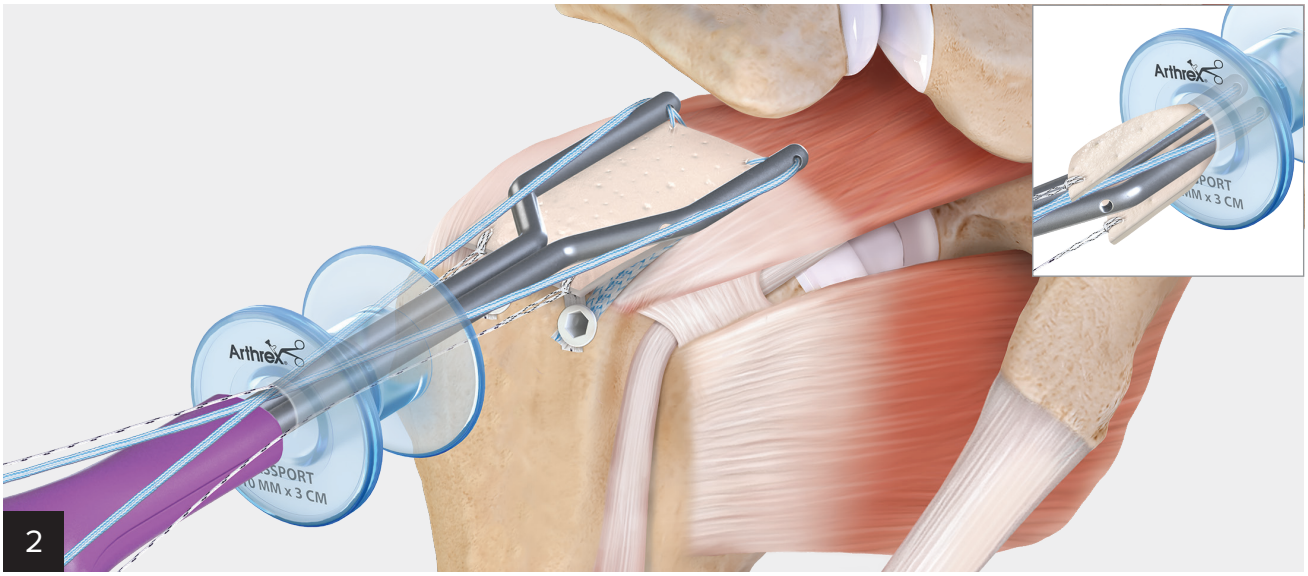


Pass the lateral TigerLink™ SutureTapes under the arms of the spreader and cleat them to the outside cleats (c, d) on the corresponding side of the handle. **Note: Do not pass the lateral link sutures through the lateral holes on the graft spreader arms as this will complicate removal after graft insertion.**

Graft Delivery

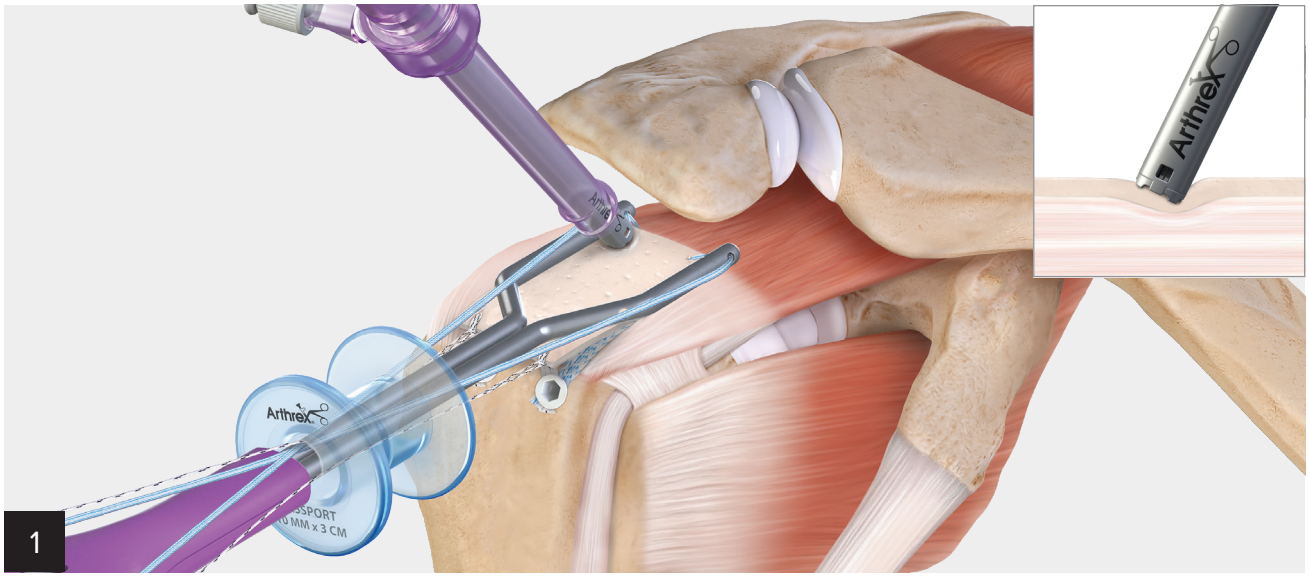


Once the ArthroFlex dermal allograft is loaded onto the graft spreader, retract the articulating arm by sliding the button toward the handle.

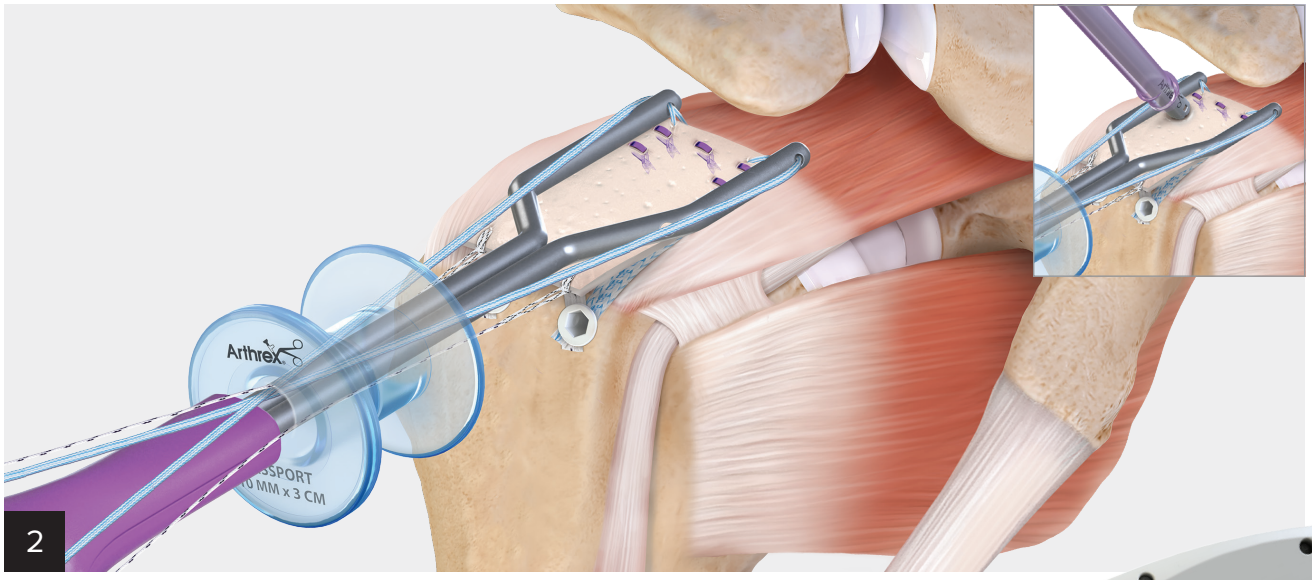


Introduce the retracted graft spreader through the lateral PassPort Button™ cannula. Once completely introduced into the subacromial space, open the articulating arm by sliding the button on the handle toward the tip of the device, spreading the ArthroFlex dermal allograft over the desired location on the rotator cuff. **Note: The graft spreader will only fit through a 10 mm diameter PassPort Button cannula or larger.**

Medial Graft Fixation

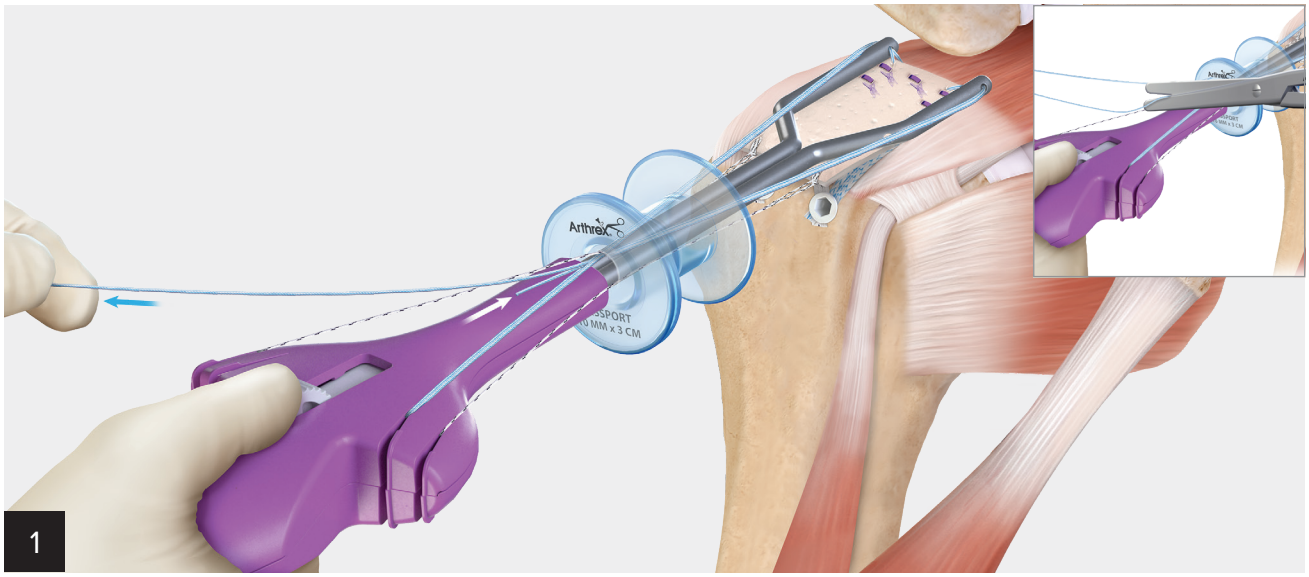


Introduce the TissueTak™ tendon anchor inserter through the superolateral cannula located just off the edge of the acromion. Prior to deploying each tendon anchor, take care to apply enough force on the TissueTak inserter shaft to slightly indent the tissue on top of the ArthroFlex dermal allograft (see inset).

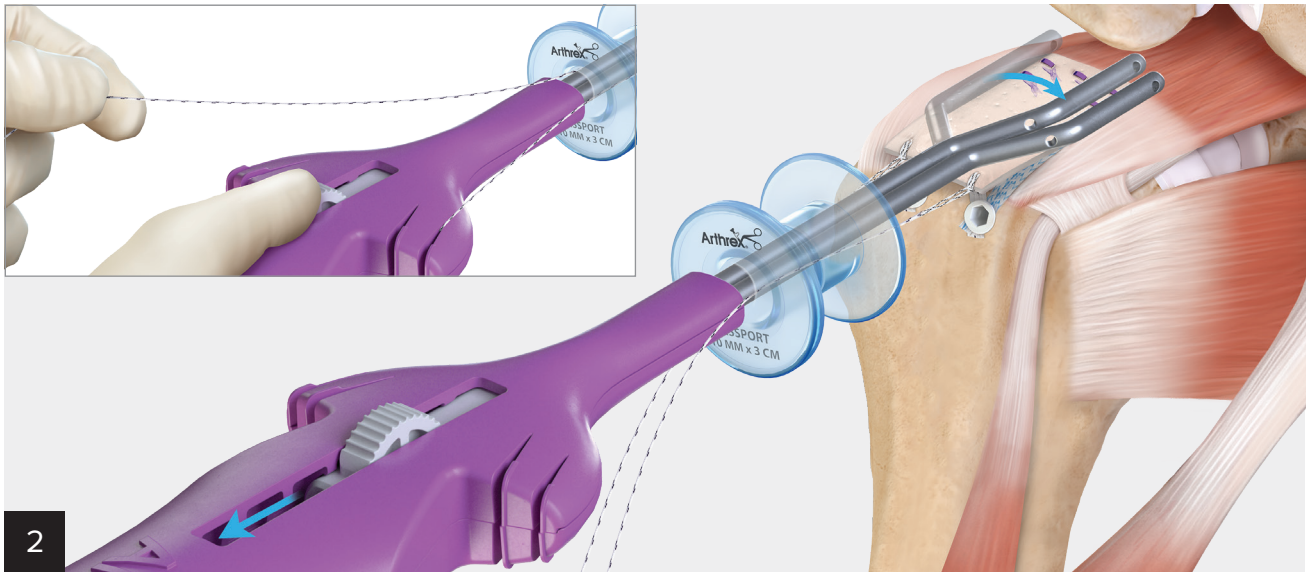


After confirming the desired graft position, consecutively deploy 3-5 TissueTak tendon anchors into the medial portion of the graft, fixating it to the surface of the rotator cuff tendon. **Note: TissueTak anchors must be inserted with the graft spreader in place. Do not insert additional TissueTak anchors after the graft spreader has been removed.**

Graft Spreader Removal

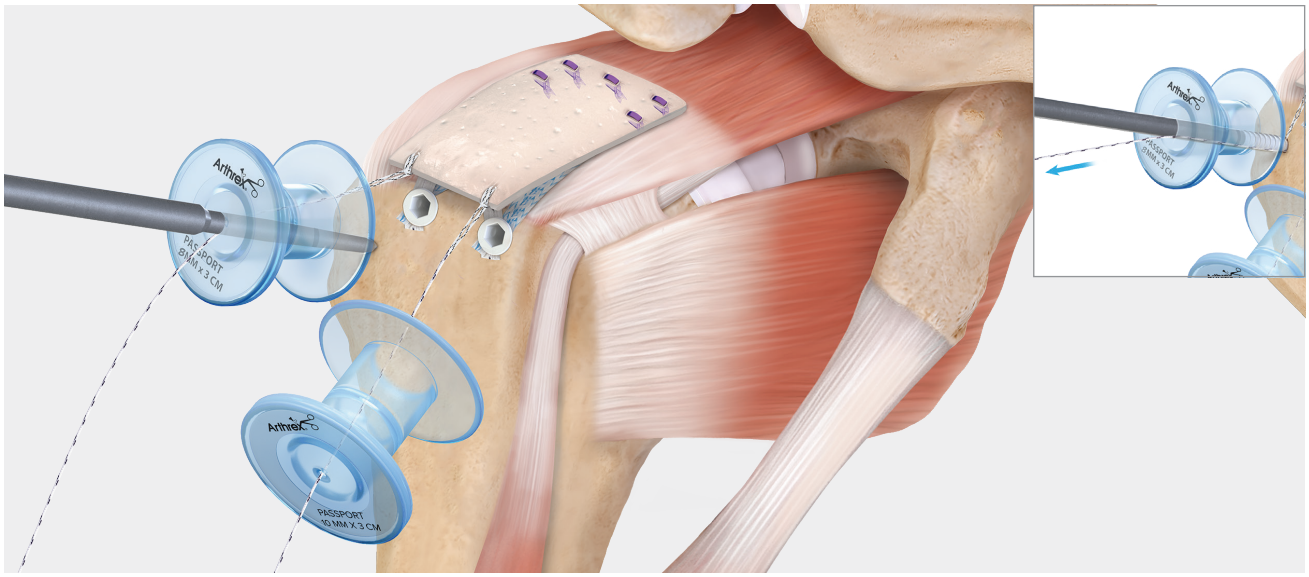


While holding the graft spreader in place, uncleat and remove the #0 FiberWire® sutures by cutting near the back of the PassPort Button™ cannula. Pull on the remaining suture limb to completely remove it from the ArthroFlex graft and graft spreader. Repeat to remove the remaining #0 FiberWire suture.



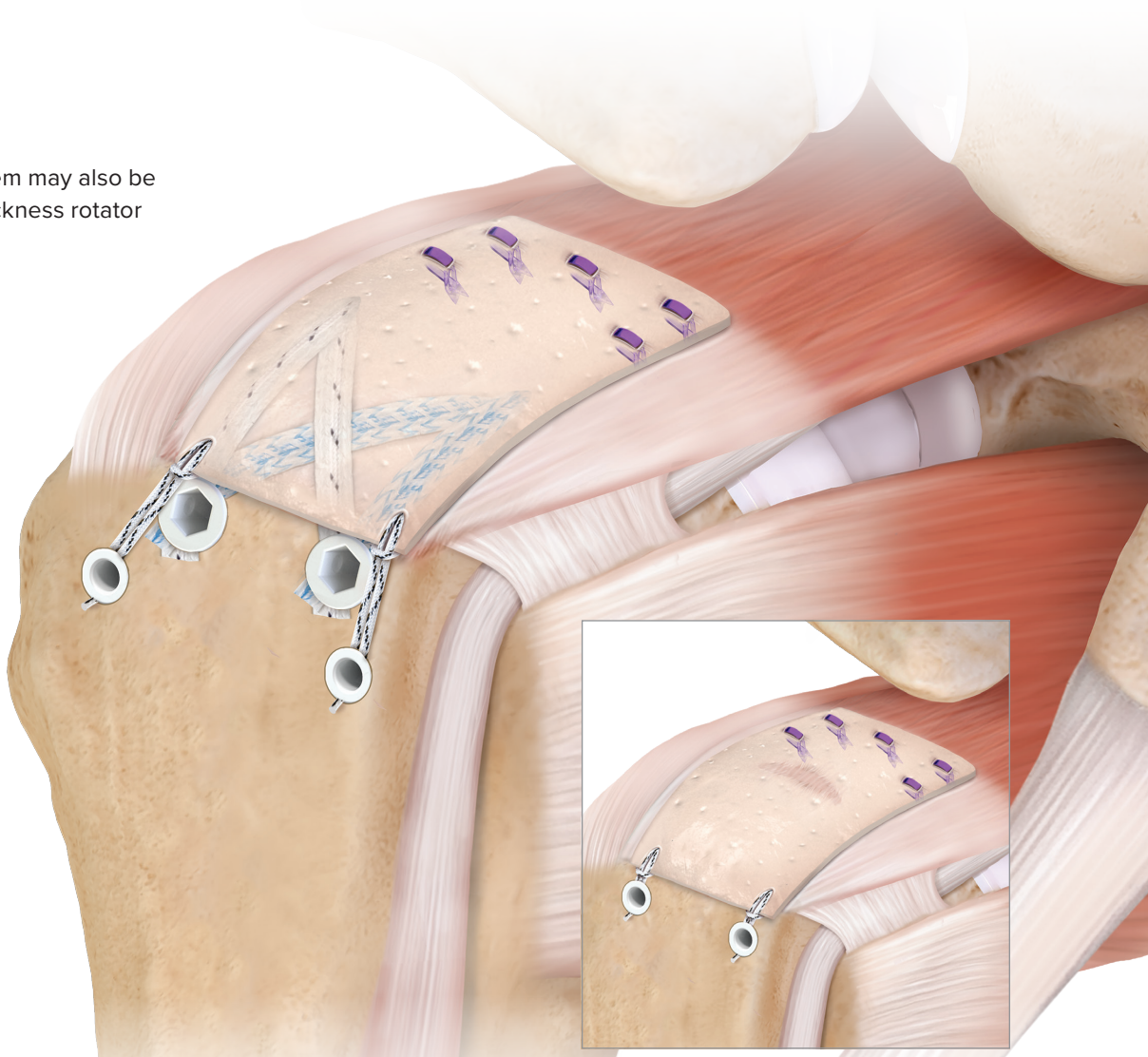
Uncleat the lateral 0.9 mm TigerLink™ SutureTapes from the graft spreader handle (see inset). Retract the arm by sliding the button toward the handle and carefully remove the graft spreader from the cannula.

Lateral Graft Fixation



Lateral to the graft, create a bone socket using the punch for the 3.5 mm PushLock® anchor. Take care to avoid existing lateral row anchors from the SpeedBridge™ repair construct. Load the 0.9 mm TigerLink™ SutureTape tail into the eyelet of the 3.5 mm PushLock anchor, introducing it through the lateral portal into the prepared socket and taking care to not overtension the suture. To complete fixation, repeat this step for the remaining lateral anchor.

The CuffMend™ system may also be used over partial-thickness rotator cuff tears (inset).



Ordering Information

Implants

Product Description	Item Number
TissueTak™ Tendon Anchor (1 TissueTak device contains 10 absorbable tendon anchors)	AR-**19021TT**
BioComposite PushLock Anchor, 3.5 mm × 19.5 mm	AR-**1926BC**
PEEK PushLock Anchor, 3.5 mm × 19.5 mm	AR-**1926PS**

Implant Instrumentation

Product Description	Item Number
Punch for 3.5 mm PushLock Anchor	AR-**1926P**

ArthroFLEX® Dermal Allograft

Product Description	Item Number
ArthroFlex Dermal Allograft, 20 mm × 25 mm × 1.0 mm, decellularized dermis w/ Matracell technology	**AFLEX402**
ArthroFlex Dermal Allograft, 25 mm × 30 mm × 1.0 mm, decellularized dermis w/ Matracell technology	**AFLEX403**

Graft Preparation

Product Description	Item Number
Graft Spreader	AR-**19007GS**
TigerLink™ SutureTape, 0.9 mm w/ loop (white/black)	AR-**7559T**
#0 FiberWire® Suture, 38 in (blue)	AR-**7254**
FastPass Scorpion™ SL Suture Passer	AR-**13999MF**
SCORPION-multifire Needle	AR-**13995N**
FiberWire Scissor	AR-**11796**
Suture Cutter, 4.2 mm, open end, left notch (used w/ all suture)	AR-**11794L**

Cannulas

Product Description	Item Number
PassPort Button™ Cannula, 10 mm I.D. × 2 cm	AR-**6592-10-20**
PassPort Button Cannula, 10 mm I.D. × 3 cm	AR-**6592-10-30**
PassPort Button Cannula, 10 mm I.D. × 4 cm	AR-**6592-10-40**
PassPort Button Cannula, 10 mm I.D. × 5 cm	AR-**6592-10-50**
5.75 mm ID × 7 cm, distal ring	AR-**6560**
5.75 mm ID × 7 cm, smooth	AR-**6562**
5.75 mm ID × 7 cm, partially threaded	AR-**6564**

Cannula Accessories

Product Description	Item Number
10 mm PassPort Button Inserter	AR-**6592-10PI**
Reusable Obturator for AR-6560, AR-6562, AR-6564	AR-**6563**

References

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