GRAFTJACKET®
Regenerative Tissue Matrix
Arthroscopic Rotator Cuff Augmentation

SURGICAL TECHNIQUE

Presented by
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Wright recognizes that proper surgical procedures and techniques are the responsibility of the medical professional. The following guidelines are furnished for information purposes only. Each surgeon must evaluate the appropriateness of the procedures based on his or her personal medical training, experience, and patient condition. Prior to use of the system, the surgeon should refer to the product Instructions For Use package insert for additional warnings, precautions, indications, contraindications and adverse effects. Instructions For Use package inserts are also available by contacting the manufacturer. Contact information can be found on the back of this surgical technique and the Instructions For Use package inserts are available on wmt.com under the link for Prescribing Information.

Please contact your local Wright representative for product availability.
Rotator cuff tears present both a physical and biological challenge to the surgeon attempting to repair them. When the tears become large or involve two or more tendons the challenge is even greater. The cuff tissue is often retracted and degenerated. The muscle can be atrophied and infiltrated with fat. Despite attempts to completely mobilize the tendons, tears are often repaired under tension in efforts to close the defect. Many surgeons do not even attempt to repair large and massive tears because of the concerns for failure.

These larger tears with muscle degeneration can, however, be treated successfully, as shown in one recent study. Ideally, a repaired cuff will heal completely and research has shown that patients with complete healing have better functional scores than those that do not.

A surgeon who is considering an arthroscopic approach needs to be familiar with several arthroscopic techniques including suture passage, knot tying, and utilizing margin convergence sutures. The 4-corner augment is a method for passing GRAFTJACKET® Matrix into a space arthroscopically and securing it to the surrounding soft tissues. When used to augment rotator cuff repairs, the graft will “bypass” the repair due to its attachment medial to the tear and on the proximal humerus.
Intended Use

Indications

GRAFTJACKET® Matrix is used to provide supplemental support, protection, and reinforcement of tendon and ligamentous tissue; to be used as a periosteal patch or covering; or for protection and support of bone and tendons in foot & ankle and hand surgery.

Each package of GRAFTJACKET® Matrix is intended for use in one patient, on a single occasion.

Contraindications

GRAFTJACKET® Matrix is contraindicated for use in any patient who is sensitive to any of the antibiotics listed on the package or polysorbate 20.

Warnings

Processing of the tissue, laboratory testing, and careful donor screening minimize the risks of the donor tissue transmitting disease to the recipient patient. As with any processed donor tissue, the GRAFTJACKET® Matrix cannot be guaranteed to be free of all pathogens. No long-term studies have been conducted to evaluate the carcinogenic or mutagenic potential or reproductive impact of the clinical application of the GRAFTJACKET® Regenerative Tissue Matrix.

DO NOT sterilize GRAFTJACKET® Matrix.

DO NOT use GRAFTJACKET® Matrix if either the outer foil bag or the inner (Tyvek®) pouch is perforated or torn. A damaged foil bag or inner (Tyvek®) pouch may result in degradation or contamination of the product.

The inner (Tyvek®) pouch that contains the GRAFTJACKET® Matrix is NOT STERILE; DO NOT PLACE THE INNER (Tyvek®) POUCH IN THE STERILE FIELD.

Transfer GRAFTJACKET® Matrix from packaging aseptically. DO NOT place either the foil bag or the inner (Tyvek®) pouch in the sterile field. (See INSTRUCTIONS FOR REHYDRATION.)

Prior to use of the system, the surgeon should refer to the product Instructions For Use package insert for warnings, precautions, indications, contraindications and adverse effects. Instructions For Use package inserts are also available by contacting the manufacturer. Contact information can be found on the back of this surgical technique and the Instructions For Use package inserts are available on wmt.com under the link for Prescribing Information.
Positioning and Set-up

A standard arrangement for arthroscopic rotator cuff repair is used. Either beach-chair or the lateral decubitus position is appropriate. Standard suture passing instruments are used. For the graft, the physician will need free strands of high tensile strength suture, free needles, a small grasper, and a penetrator-grabber style of suture retriever.

Step 1

A glenohumeral arthroscopy is performed. Any intra-articular work i.e. biceps tenotomy, subscapularis, or labral pathology is treated. Any subscapularis tears should be repaired prior to moving to the subacromial space. The rotator cuff tear is evaluated | FIGURE 1 and the cuff can be preliminarily debrided. The scope is then moved subacromially and the bursa is debrided. The superior side of the cuff is evaluated and the tendon edges debrided. Using the shaver or an elevator, the cuff is mobilized from the scapula. Care should be taken not to damage the neurovascular pedicles of the cuff musculature. The coracohumeral ligament can be divided to allow better mobilization of the supraspinatus tendon. The tuberosity is prepared and the cuff repaired as much as possible. Typically, a combination of margin convergence sutures and suture anchors either in a single or double row are used to repair the cuff. | FIGURE 2

If a dual row repair is used, one anterior and one posterior mattress suture from the medial row can be passed through the cuff, medial to the tear, and be left untied. These sutures will create the medial two corners of the 4-corner augment. If a single row repair is used, sutures will be added later. If the musculotendinous junction and remaining tendon of the rotator cuff muscle can be reattached to near normal (10-15 mm) position then it is possible that an augmentation graft can be incorporated into the musculotendinous bone complex. Rehydrate the graft in saline according to the Instructions For Use prior to implantation. A GRAFTJACKET® MaxForce Extreme Matrix is recommended for augmentation of cuff repairs.
Step 2

The arthroscope is placed in the posterior portal for viewing. Two suture anchors are added to the proximal lateral humerus to create the lateral two corners of the 4-corner augment. Metal corkscrew anchors are preferred due to ease of insertion in this area. If a single row repair was performed, two free sutures are placed medial to the tear, at the musculotendinous junction of the cuff, one anterior and one posterior. FIGURE 3 A technique similar to passing a margin convergence suture can be used. The sutures now create the medial two corners of the 4-corner augment. The four corners are now in place and the length and width of the framework can be measured with a ruled probe or a suture knot configuration. FIGURE 4

Step 3

With the scope in the posterior portal, the suture pairs of the “corners” are brought out an 8mm cannula and held with clamps. To maintain proper suture management, the pairs should be placed to one side of the cannula in the same orientation outside the shoulder as they are in the subacromial space. The grasper should pass through the opposite side of the cannula to avoid suture entanglement.
Step 4

The graft is then cut. The graft should be cut approximately 20% (usually around 5 mm) shorter on each side than measured to allow for tension on the graft. The GRAFTJACKET® Matrix has limited elastic properties and will stretch to fit the 4-corner framework. The sutures from the corners are then passed through the graft in mattress fashion with a free needle. The sutures are then clamped in their respective pairs. A grasper is then used to grab the medial edge of the graft which is then passed down the lateral cannula into the subacromial space.  

| FIGURE 5 and FIGURE 6 | FIGURE 5 | FIGURE 6 | FIGURE 7 | FIGURE 6 | FIGURE 5
Once in the subacromial space, the corner sutures are tensioned to remove the slack. | FIGURE 7 The graft is now in the subacromial space and can be tied by retrieving suture pairs above the graft and tying arthroscopic knots. | FIGURE 8 and | FIGURE 9
Extra sutures can be placed along the sides if necessary using a margin convergence technique. | FIGURE 10 and | FIGURE 11

Explant Information
If the removal of the implant is required due to revision or failure of the device, the surgeon should contact the manufacturer using the contact information located on the back cover of this surgical technique to receive instructions for returning the explanted device to the manufacturer for investigation.

Postoperative Management
Postoperative care is the responsibility of the medical professional.
Ordering Information

**8600-4X07**
GRAFTJACKET® REGENERATIVE TISSUE MATRIX - MAXIMUM FORCE
4x7cm
Non-Meshed, Thick (Avg. Thickness = 1.4mm) 1EA.

**86MX-5X05**
GRAFTJACKET® REGENERATIVE TISSUE MATRIX - MAXIMUM FORCE
5x5cm
Non-Meshed, Thick (Average Thickness=1.5mm) 1EA.

INDICATIONS:
Augmentation, Rotator cuff, Achilles tendon, Quadriceps, Patellar tendon, Capsular reinforcement, and Extrasynovial ligament augmentation

**86UM-4X07**
GRAFTJACKET® REGENERATIVE TISSUE MATRIX MAXFORCE - EXTREME
4 x 7 cm
Non-Meshed, Thick (Average Thickness=2.0mm) 1EA.

INDICATIONS:
Augmentation, Rotator cuff, Achilles tendon, Quadriceps, Patellar tendon, Capsular reinforcement, and Extrasynovial ligament augmentation

**8600-5X05**
GRAFTJACKET® REGENERATIVE TISSUE MATRIX
5x5cm
Non-Meshed, Standard (Avg. Thickness = 1.0mm) 1EA.

INDICATIONS:
General tendon augmentation, Rotator cuff augmentation, Periosteal covering - small defects

**8600-5X10**
GRAFTJACKET® REGENERATIVE TISSUE MATRIX
5x10cm
Non-Meshed, Standard (Avg. Thickness = 1.0mm) 1EA.

INDICATIONS:
General tendon augmentation
Periosteal covering - large defects

Additional Products

**TENDON REPAIR**

**8600-2X04**
GRAFTJACKET® REGENERATIVE TISSUE MATRIX - HAND SURGERY
2x6cm
Non-Meshed, Thin (Avg. Thickness = 0.5mm) 1EA.

INDICATIONS:
Flexor/Extensor Tendon Reinforcement, Tendon sheath augmentation of the hand and foot

**8600-5X05**
GRAFTJACKET® REGENERATIVE TISSUE MATRIX
5x5cm
Non-Meshed, Standard (Avg. Thickness = 1.0mm) 1EA.

INDICATIONS:
General tendon augmentation, Rotator cuff augmentation, Periosteal covering - small defects
Appendix

Chapter 5

References

Additional Related Peer Reviewed Publications

BIOMECHANICAL

IN VITRO

IN VIVO

PLANTAR SOFT-TISSUE AUGMENTATION

RECONSTRUCTIVE SURGERY – FOOT & ANKLE

RECONSTRUCTIVE SURGERY – LARGE JOINTS

RECONSTRUCTIVE SURGERY – SHOULDER

The GRAFTJACKET® Regenerative Tissue Matrix is intended for the reinforcement of repair of damaged or inadequate integumental tissue and to reinforce primary tendon and ligament repairs. The GRAFTJACKET® Matrix is not indicated for use as an interpositional graft.
Many variables including patient pathology, anatomy, and surgical techniques may influence procedural outcomes. Before use, physicians should review all risk information, which can be found in the “Instructions for Use” attached to the packaging of each GRAFTJACKET® Graft.