

**GRAFTJACKET® Regenerative Tissue Matrix
Appeal Letter to Support Medical Necessity**

(date)

(Name)
(Address)
(City), (State) (Zip)

Re: (Patient Name)
(Insured's ID#)
(Date of Service)
(Product)

To Whom It May Concern:

I am writing to appeal the recent denial in reference to the above-referenced patient and service. I am including additional information for your review.

PATIENT'S MEDICAL HISTORY AND TREATMENT RATIONALE

[Insert patient's case history, patient's condition; clinical course prior to treatments, and the treatment rationale explaining why this procedure was chosen for this particular patient.]

PRODUCT AND PROCEDURE DESCRIPTION

GRAFTJACKET® Matrix is an acellular soft tissue graft marketed in the United States by Wright Medical Technology. It is indicated for soft tissue augmentation and reinforcement, including, but not limited, to the reinforcement of primary repair sites for chronic and acute Achilles tendon ruptures and the reinforcement of rotator cuff tears. GRAFTJACKET® Matrix is a soft tissue graft, composed solely of human dermal tissue, including its native protein and collagen structure and essential biochemical composition. However, cells and cell remnants are removed, minimizing the immune response from the recipient patient. This process results in a product that allows for cellular repopulation and revascularization while supporting the migration of new tissue across the primary repair. Because of the acellular nature and intact vascular channels, the graft is remodeled and incorporated over time (converted to the patient's own tissue), thereby reinforcing the soft tissue. The patient's native tissue, particularly in chronic cases, can be the weak link in the primary repair; thus, augmentation may be warranted. The reinforcement of chronic tears is a generally accepted method of treatment for tendon repair, but was previously done using autographs such as the flexor hallucis longus tendon. The use of the GRAFTJACKET® Matrix provides reinforcement without the additional surgical time and donor site morbidity inherent with autographs.

For the treatment of tendon rupture repair reinforcement, careful resection of any devitalized tissue is carried out to allow inspection and reapproximation of the tendon. The tendon is then repaired with the physician's preferred technique for primary tendon repair followed by application of the graft to reinforce native soft-tissue. The basement membrane surface (dull side) is superficial to the tendon and the graft's reticular surface. The scaffold is sutured to the tendon while carefully maintaining the same physiological tension as the healthy tendon on the opposing limb.

Several studies have been published recently demonstrating the clinical benefit of reinforcing primary repairs with the GRAFTJACKET® Matrix. Barber, et al. showed high suture retention strength for the GRAFTJACKET® Matrix which was significantly greater than other products on the market (2006 *Arthroscopy*). He further demonstrated the clinical relevance of these biomechanical properties in a cadaveric Achilles tendon primary repair model with the construct reinforced with the GRAFTJACKET® Matrix approximately twice the strength of primary repair alone (2008, *Foot & Ankle International*).

Several recent clinical series have supported the benefit of these biomechanical and biologic properties in the clinical setting for reinforcement of foot & ankle soft-tissue repair. Brigido, et al (2008, *Tech Foot Ank*

Surg) reported on 21 patients with chronic Achilles tendinosis with a return to activity at an average of 12.1 weeks following Achilles reconstruction using GRAFTJACKET® Matrix reinforcement. Lee supports this (2007, *J Foot Ank Surg*), showing an average RTA time of 15.2 weeks for nine patients having chronic Achilles tendon ruptures repaired with GRAFTJACKET® Matrix augmentation. These average RTA times are much lower than the average of 34 weeks reported by Saxena and Cheung (2003, *J Am Podiatry Med Assoc*) for five patients undergoing Achilles reconstruction without GRAFTJACKET® Matrix augmentation. Lee also demonstrates comparable results for patients with acute Achilles tendon rupture repairs (2008, *J Foot Ank Surg*). Eleven patients undergoing acute Achilles repair with GRAFTJACKET® Matrix augmentation averaged an 11.8 week RTA time, vs. an average of 13.1 weeks for patients with primary repair alone as reported by Aoki et al (1998, *Am J Sports Med*).

In addition, clinical series have been reported on the use of GRAFTJACKET® Matrix in shoulder surgery. In 2007 Burkhead, et. al. reported favorable results using GRAFTJACKET® Matrix to reinforce massive rotator cuff tears in a series of 17 consecutive patients with a mean follow-up of 1.2 years (2007, *Semin Arthro*). This cohort consisted of patients with 2, 3 and 4 tendon tears greater than 5cm with 11 patients presenting with primary tears and 6 with recurrent tears. Burkhead, et. al. reported a statistically significant improvement in UCLA scores in this patient population. In addition, of 12 patients available for post-operative imaging, 9 patients had intact rotator cuff repairs with 3 recurrent tears observed. These recurrent tears were smaller than the pre-operative MRIs.

I believe the GRAFTJACKET® Matrix product provides advantages for this patient. Based on the patient's medical history and other pertinent medical information contained in this letter, the procedure was medically necessary.

Thank you in advance for your kind consideration. Please feel free to contact me directly should you require any additional information.

Sincerely,

(Physician's Name)
(Address)
(City), (State) (Zip)
(Phone Number)