

The purpose of this document is to help hospital administrators realize the clinical and financial value of an important new advancement in the surgical repair and reconstruction of musculoskeletal soft tissue injuries. The OrthADAPT® Bioimplant is an implantable, single-use device used by Sport Medicine, Orthopedic and Podiatric surgeons while addressing various soft tissue injuries that require repair, augmentation, reconstruction, or reinforcement.

REGULATORY APPROVAL

The U.S. Food and Drug Administration (FDA) granted market clearance to OrthADAPT® Bioimplant on August 5, 2005 as a Class II Mesh. Defined by the FDA, a mesh is a polymeric screen intended to be implanted to reinforce soft tissue where weakness exists (K043388).

INDICATION FOR USE

The OrthADAPT® Bioimplant is intended to be used for implantation to reinforce the repair or reconstruction of soft tissues, including the reinforcement of soft tissues repaired by sutures or suture anchors during surgical repair. This includes reinforcement of rotator cuff, patellar, achilles, biceps, quadriceps, or other tendons. OrthADAPT® Bioimplants are not intended to replace normal body structures or provide the full mechanical strength of the tendon repair. Sutures, used to repair the tear, and sutures or bone anchors, used to attach the tissue to the bone, provide biomechanical strength for the tendon repair.

PRODUCT DESCRIPTION

The OrthADAPT® Bioimplant is manufactured by Synovis Orthopedic & Woundcare, Inc. (Irvine, California), the leader in the design, development and production of advanced biologic scaffolds. The OrthADAPT® Bioimplant from Synovis Orthopedic & Woundcare, Inc. is a highly organized collagen scaffold that can be used for implantation to reinforce the repair or reconstruction of soft tissues. The OrthADAPT® Bioimplant allows for a stronger repair over time and the potential for minimal pain and swelling. Using proprietary technologies, the bioimplant is flexibly crosslinked and sterilized* which make it resistant to premature enzymatic degradation, biocompatible, and safe.

PROCEDURAL CODING CONSIDERATIONS

Surgeons, administrators and coders all agree that coding the professional and technical components of procedures rely upon details provided in the patient's medical record, especially the surgeon's operative notes. While Synovis Orthopedic & Woundcare believes this information to be correct, it is shared for educational and strategic planning purposes only. The actual selection of codes remains the sole responsibility of the provider. Since individual insurers have different requirements and coding is subject to change without notice, providers are encouraged to confirm their coding selections with their payers, as needed. Providers should recognize that there are numerous coding considerations related to implantation of a surgical mesh during soft tissue repairs.

*Passes USP Sterility Testing. Data on file: Synovis Orthopedic & Woundcare, Inc.

Physician Considerations may include, but are not limited to:

CPT ¹	Description
23410	Repair of ruptured musculotendinous cuff (eg, rotator cuff) open; acute
23412	Repair of ruptured musculotendinous cuff (eg, rotator cuff) open; chronic
23420	Reconstruction of complete shoulder (rotator) cuff avulsion, chronic (includes acromioplasty)
24342	Reinsertion of ruptured biceps or triceps tendon, distal, with or without tendon graft
27650	Repair, primary, open or percutaneous, ruptured Achilles tendon
27658	Repair, flexor tendon, leg; primary, without graft, each tendon
27664	Repair, extensor tendon, leg; primary, without graft, each tendon
27675	Repair, dislocating peroneal tendons; without fibular osteotomy
28200	Repair, tendon, flexor, foot; primary or secondary, without free graft, each tendon
28208	Repair, tendon, extensor, foot; primary or secondary, each tendon
29827	Arthroscopy, shoulder, surgical with rotator cuff repair

Source: American Medical Association's CPT 2009.

Facility Considerations - DRG considerations associated with tendon repairs may include, but are not limited to:

DRGs	Description
500	Soft Tissue Procedures with MCC
501	Soft Tissue Procedures with CC
502	Soft Tissue Procedures without CC/MCC
503	Foot Procedures with MCC
504	Foot Procedures with CC
505	Foot Procedures without CC/MCC
507	Major Shoulder or Elbow Joint Procedures with CC/MCC
508	Major Shoulder or Elbow Joint Procedures without CC/MCC
509	Arthroscopy
510	Shoulder, Elbow or Forearm Procedure, Except Major Joint Procedure with MCC
511	Shoulder, Elbow or Forearm Procedure, Except Major Joint Procedure with CC
512	Shoulder, Elbow or Forearm Procedure, Except Major Joint Procedure without CC/MCC

Source: DRG Expert 2009

APC considerations associated with soft tissue tendon repairs may include, but are not limited to:

APCs	Description
41-42	Level I - Level II Arthroscopy
49-52	Level I, Level II, Level III or Level IV Musculoskeletal procedures except hand and foot

Source: HOPPS CY 2009

HCPCS considerations may include, but are not limited to:

HCPCS ²	Description
C1781	Mesh (implantable)
J3590	Unclassified biologics

Source: Healthcare Common Procedure Coding System, HCPCS 2009.

For additional information about the OrthADAPT® Bioimplant, please speak with your Synovis Orthopedic & Woundcare sales professional or call Customer Service at 1-800-650-1816.

1. CPT is a registered trademark of the American Medical Association. Providers are encouraged to personally review a current copy of CPT 2009 when preparing an insurance claim.
2. Healthcare Common Procedure Coding System, HCPCS 2009. Medicare's National Level II Codes. Published by the American Medical Association

Refer to the Synovis Orthopedic & Woundcare, Inc. Instructions for Use for the proper use, precautions, warnings, approved indications and labeling of the OrthADAPT® Bioimplant. CAUTION: Federal law restricts this product to sale by or on the order of a physician. OrthADAPT® is a registered trademark of Synovis Orthopedic & Woundcare, Inc.

This document has been prepared for educational purposes only. Since coding, coverage, and reimbursement determinations are subject to frequent changes, providers should check with their payers before submitting claims. Synovis Orthopedic & Woundcare, Inc. assumes no responsibilities or liabilities for the information contained in this document. We respect that the actual selection of codes remains the sole responsibility of providers.