



K041553: ARTHREX SUTURE GRAFT KIT

Lateral Ankle and Medial Deltoid suture constructs

The cleared 510(k) K041553 for the Arthrex Suture Graft Kit submitted to FDA is for FiberWire and FiberTape suture/allograft or suture/autograft constructs intended for use in soft tissue approximation and or ligation. The 510(k) submission indicates that the constructs may be used for the following procedures:

In the Foot and Ankle: Lateral stabilization or reconstruction with tendon graft with various techniques of replacement, Medial stabilization including repair of the Deltoid ligament complex, Achilles tendon repair including acute or chronic partial or complete disruptions of the Achilles and avulsion tears off the calcaneal insertion or reattachment to the calcaneas after bone removal, Hallux valgus reconstruction (bunion), or deformities of the first metatarsal and great toe that are surgically repaired by soft tissue realignment, bone removal, and metatarsal osteotomy i.e. Austin, Chevron, or Kalish osteotomies. Also Midfoot reconstructions including the midfoot bones (Navicular, Cuneiforms, Cuboid), flatfoot repair and arch reconstruction with tendon transfer and/or arthrodesis, and Metatarsal ligament repair where toes connect to foot for crossover toes, hammertoes, subluxations/dislocations.

Tendon transfer in the foot and ankle: Flexor hallucis transfer for Achilles insufficiency, Achilles transfer (Murphy, Flexor digitorum longus transfer for posterior tibial tendon dysfunction, Lateral ankle stabilization using adjacent peroneal tendons or a free graft used to reconstruct the ligaments, Tibialis anterior tendon transfer to weaken the deforming varus, Extensor digitorum longus transfer, or Hibbs procedure, where the EDL branches are cut at the toe level and transferred into the top of the midfoot to maintain dorsiflexion strength at the ankle but weaken the deforming force on the toes.

In the shoulder, hand, wrist, and elbow, including tendon transfers: Rotator Cuff Repairs including repairs of the supraspinatus, infraspinatus, subscapularis, Bankart Repair anterior stabilization, posterior stabilization, SLAP (superior

labrum anterior to posterior Lesion Repair), Biceps Tenodesis with the potential to repair the long head of the biceps tendon, Acromio-Clavicular Separation Repair (AC separation) or conoid, trapezoid and coracoacromial ligaments, Mumford procedure or distal clavicle excision (a portion of the repair), Deltoid Repair, and Capsular Shift in conjunction with a Bankart or Capsulolabral. In the elbow, Biceps Tendon Reattachment distal biceps tenodesis, Ulnar or Radial Collateral Ligament Reconstruction, and in the Hand/Wrist, Scapholunate Ligament Reconstruction, Ulnar Collateral Ligament Reconstruction, Radial Collateral Ligament Reconstruction, Carpometacarpal joint arthroplasty (basal thumb joint arthroplasty), Interphalangeal reconstruction, tendon transfer in the hand/ wrist such as the Royle Thompson Opponensplasty.



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