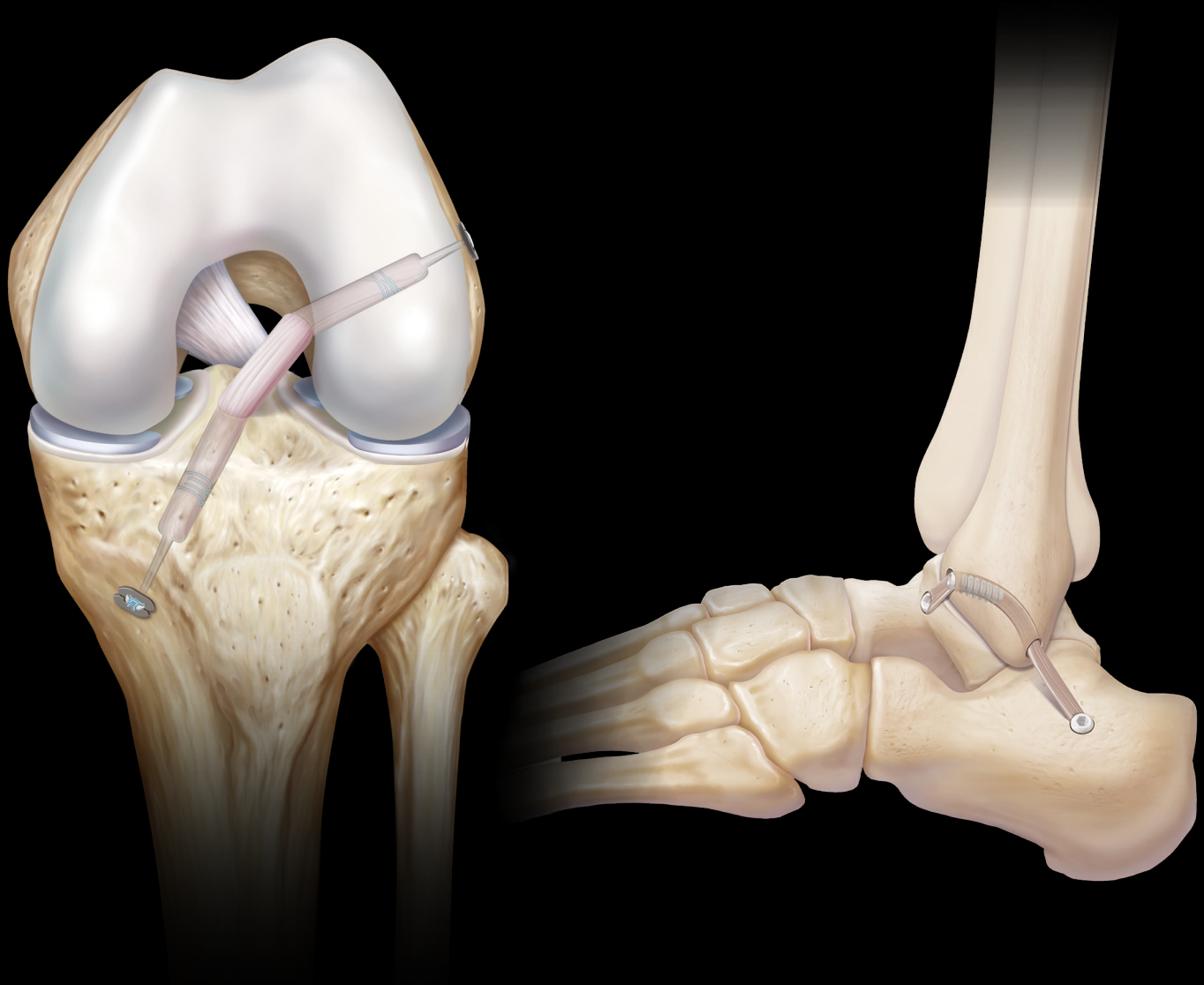
Allograft Tendons

A Comprehensive Portfolio



Arthrex®

Allograft Tendons

Overview

Since its inception, Arthrex has been committed to one mission: Helping Surgeons Treat Their Patients Better™. We are strategically focused on constant product innovation through scientific research, surgeon collaboration, and medical education to make less invasive surgical procedures simpler, safer, and more reproducible. Our strategic partnerships serve as the industry leaders in procurement, donor screening, and selection criteria.

Tissue processing by our partners balances safety with quality by ensuring the preservation of inherent biological properties of the tissue. Our partners provide state-of-the-art processing methods. LifeNet Health's Allowash XG® has been shown to render a sterility assurance level (SAL) of 10^{-6} and to inactivate viruses without compromising the biomechanical or biochemical properties of the tissue.[1,2] JRF Ortho's advanced cleansing technologies maintain tissue integrity with consistent processing, monitored temperature, and limited reagent exposure.

Regulatory / Compliance			
AATB	✔	CLIA	✔
FDA	✔	ISO	✔

The availability of allograft tendons provides surgeons with an invaluable tool for treating a variety of injuries. In the United States, it's estimated that there are 500,000 knee ligament procedures performed annually,[3] including an estimated 300,000 anterior cruciate ligament (ACL) surgeries.[4] The Arthrex portfolio of tendons provides surgeons with the widest selection of presutured and standard allograft tendons in the world.

Allograft tendons provide many benefits over autograft tendons in reconstructive procedures, such as less donor-site morbidity, fewer incisions, shorter operative time, larger grafts, lower incidence of postoperative arthrofibrosis, and less postoperative pain.[4,5]

Sterile Tendons

Since 2004, Arthrex has been a leading marketer of Allowash XG processed tendons. These tendons have been clinically proven in a variety of surgical applications with an unmatched safety record. The process renders the allografts sterile, without compromising biomechanical or biochemical properties.[6-10]

Allowash XG

- Patented and validated process that provides allografts with a SAL of 10^{-6}
- Incorporates 6 steps to ensure sterility
- Bioburden control
- Bioburden assessment
- Minimizing contamination
- Rigorous cleaning
- Disinfection and rinsing regimen
- Terminal sterilization
- Facilities and environmental controls designed to eliminate cross contamination
- Uses gentle detergents, antibiotics, and solutions known to be safe on tissue
- Eliminates blood, lipids, and marrow
- Flushing
- Centrifugation
- Hypotonic processes and ultrasonication
- Intensive decontamination, disinfection, and scrubbing regimen
  - Designed to eliminate bacteria and viruses

Cover histology image courtesy of Dr. Chantelle Bozynski, Thompson Laboratory for Regenerative Orthopaedics, University of Missouri.

Tendon Allografts

Product Description	JRF Ortho Item Number	LifeNet Health Item Number
Achilles Tendon w/ Bone Block	ACT-**001**	**FATB**
Achilles Tendon w/o Bone Block	AWO-**001**	**FAT**
Anterior Tibialis Tendon, short length, D ≥ 7.5 mm, L = 170 mm-200 mm	SAT-**001**	**FANT-SL**
Posterior Tibialis Tendon, short length, D ≥ 7.5 mm, L = 170 mm-200 mm		**FPOST-SL**
Peroneus Longus Tendon, short length, D = 8 mm-11 mm, L = 170 mm-200 mm		**FPLT-SL**
Tibialis Tendon, anterior	DAT-**001**	**FANT/TIB/T**
Tibialis Tendon, posterior	DPT-**001**	**FPOST.TIBIAL**
Gracilis, double strand	DSG-**001**	
Patellar Tendon, bisected/hemi	HPL-**001**	**FBPL**
Patellar Tendon, bisected, small block		**FBPLSB**
Patellar Tendon, whole	WPL-**001**	**FWPL**
Patellar Tendon, whole - small block		**FWPLSB**
Patellar Tendon, whole w/ quadriceps		**FWPLQ**
Patellar Tendon, whole w/ extensor mechanism		**FWPLQEXT**
Peroneus Longus, double strand	DSP-**001**	
Peroneus Tendon		**FPLT**
Preshaped Achilles, 9 mm	ATP-**091**	
Preshaped Achilles, 10 mm	ATP-**101**	**FATB10**
Preshaped Achilles, 11 mm	ATP-**111**	**FATB11**
Preshaped Patellar Tendon, 10 mm	PLP-**101**	**FPL10**
Preshaped Patellar Tendon, 11 mm	PLP-**111**	**FPL11**
Quadruple Strand Semitendinosus/ Gracilis	QSG-**001**	
Quadriceps Tendon w/ Bone	QDT-**001**	**FQUADB**
Preshaped Quadriceps Tendon, 10 mm	QDT-**101**	
Semitendinosus, single strand	SST-**001**	
Semitendinosus, double strand	DST-**001**	
Semitendinosus and Gracilis Tendons		**1FST+1FGRACILIS**
Semitendinosus Tendon, ≥ 230 mm, min D > 4 mm		**FST**
Semitendinosus Tendon, L = 160 mm-250 mm, D = 4 mm-6 mm		**FSTP**
Gracilis Tendon, short length	SSG-**001**	**FGRACILIS**
Fascia Lata, small, 30 mm × 60 mm		**FL S**
Fascia Lata, medium, 30 mm × 150 mm		**FL M**
Fascia Lata, large, 80 mm × 200 mm		**FL L**
GraftRope		**FROPE**

Aseptic Tendons

Arthrex offers a full complement of aseptically processed tendons that are never treated with irradiation. Our partner for aseptic tendons, JRF Ortho and its recovery and processing partners, uses extensive evaluation criteria to identify and qualify suitable donors in accordance with American Association of Tissue Banks (AATB) standards.

Advanced cleansing technologies:

- Designed to cleanse while preserving tissue integrity
- Proprietary cleansing reduces bioburden without using harsh reagents like hydrogen peroxide
- Bioburden reduction steps that remove blood and lipids

Maximizing safety while providing quality tendons:

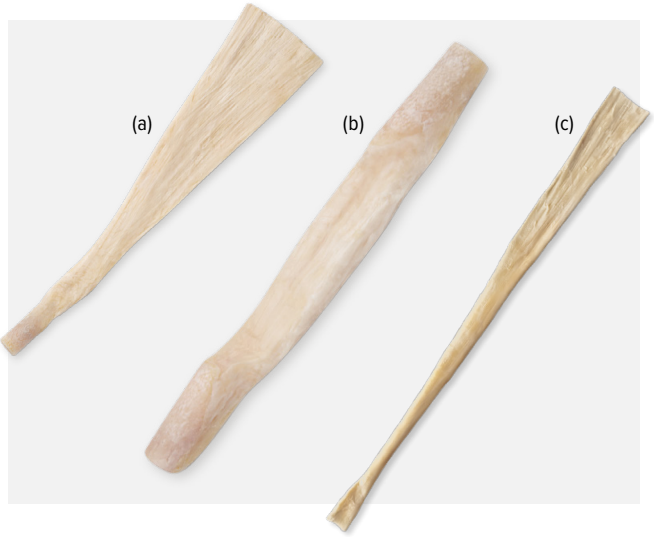
- Aseptically processed allografts are manufactured in a controlled environment with patented methods
- Use of highly sensitive nucleic acid testing (NAT)
- Comprehensive donor screening

Fluid extraction testing:

- This testing is more accurate because contamination is difficult to detect by swabbing the external surface of the graft
- Tissue is released after no growth culture results from a validated and highly sensitive fluid membrane filtration test
- Approximately 35% of all tendons qualify for transplant without the need for ultra-low-dose irradiation

Aseptic Tendons

Product Description	JRF Ortho Item Number
Achilles Tendon w/ Bone Block	ACT-**002**
Achilles Tendon w/o Bone Block	AWO-**002**
Achilles Tendon, preshaped, 9 mm **(a)**	ATP-**092**
Achilles Tendon, preshaped, 10 mm	ATP-**102**
Achilles Tendon, preshaped, 11 mm	ATP-**112**
Hemi-Patellar Ligament	HPL-**002**
Whole-Patellar Ligament	WPL-**002**
Whole-Patellar Ligament w/ Quadriceps	WPQ-**002**
Quadriceps Tendon w/ Bone	QDT-**001**
Quadriceps Tendon w/ Bone, preshaped, 10 mm	QDT-**102**
Patellar Ligament, preshaped, 10 mm **(b)**	PLP-**102**
Patellar Ligament, preshaped, 11 mm	PLP-**112**
Double Strand Semitendinosus Tendon	DST-**002**
Double Strand Peroneous Longus	DSP-**002**
Double Strand Anterior Tibialis	DAT-**002**
Double Strand Posterior Tibialis	DAP-**002**
Quadruple Strand Semitendinosus/Gracilis	QSG-**002**
Single Strand Semitendinosus Tendon	SST-**002**
Single Strand Anterior Tibialis **(c)**	SAT-**002**

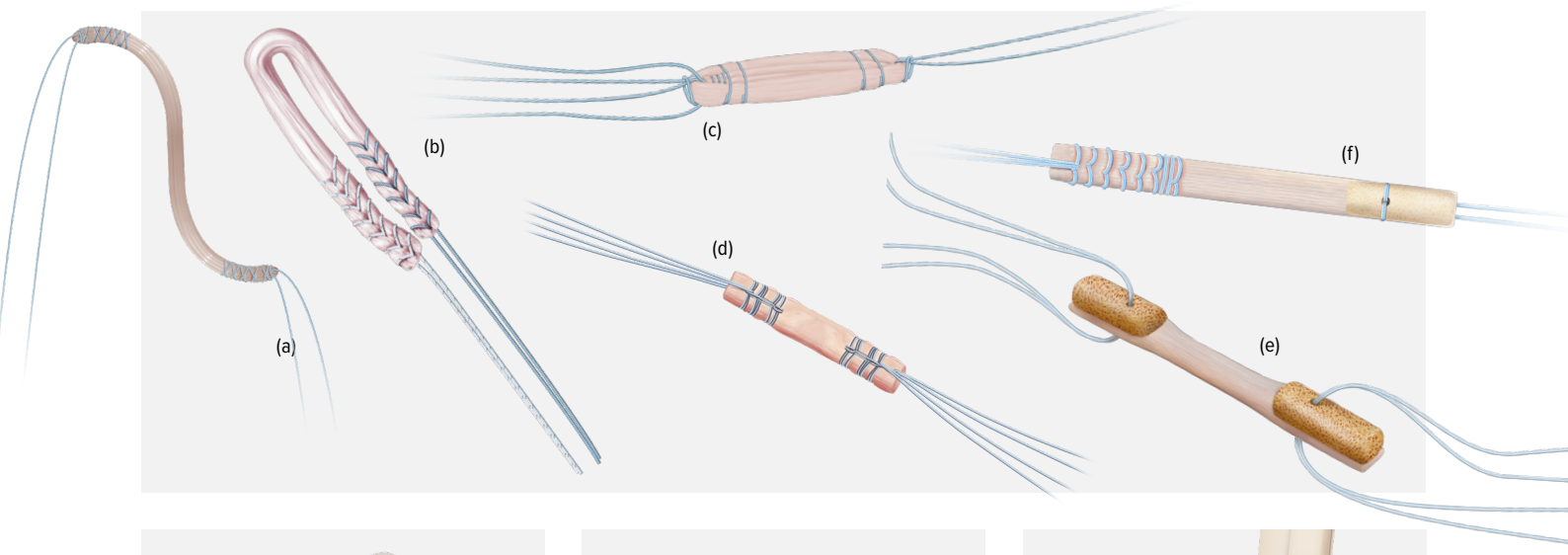


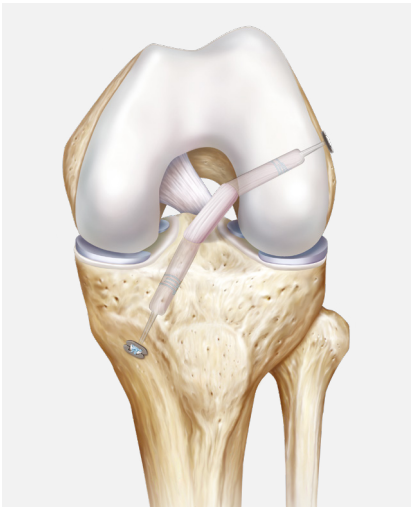
Presutured Tendons

Arthrex offers the largest portfolio of presutured tendon allografts for your ligament reconstruction procedures. Presutured tendons are preassembled by qualified tissue technicians for consistency. These tendons are sterilized under low-dose, low-temperature irradiation for patient safety. The convenience of a presutured tendon allows for an off-the-shelf solution with minimal preparation time.

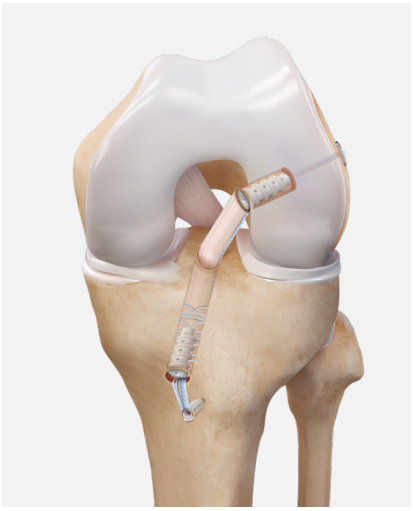
Presutured Tendons

Product Description	JRF Ortho Item Number	LifeNet Health Item Number
VersaGraft® Tendon **(a)**	VRG-**001**	
VersaGraft 3.5 Tendon	VRG-**351**	
SpeedGraft® Tendon **(b)**	SPD-**001**	
GraftLink® XL Tendon (PCL)	GRX-**001**	
Allograft GraftLink® Tendon **(c)**		**FGL**
Allograft GraftLink Triple Strand		**FGLTS**
QuadLink™ Construct Tendon **(d)**		**FQL**
FlexiGRAFT® Connect Tendon		**FCON**
FlexiGRAFT Connect EXT Tendon		**FCONEXT**
DualLink Presutured Construct		**FDL**
PilotGraft™ BTB Tendon **(e)**	PSP-**101**	
SpeedGraft Achilles Tendon **(f)**	PSA-**101**	

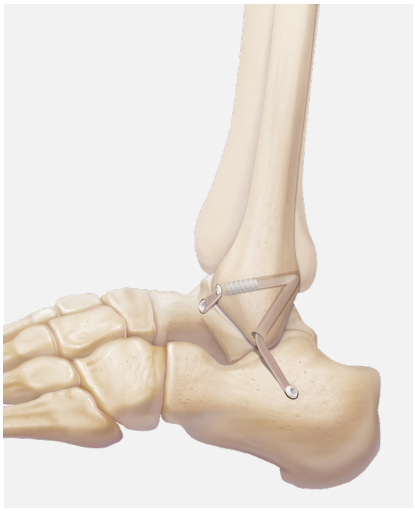




GraftLink Allograft Tendon
for All-Inside ACL Reconstruction

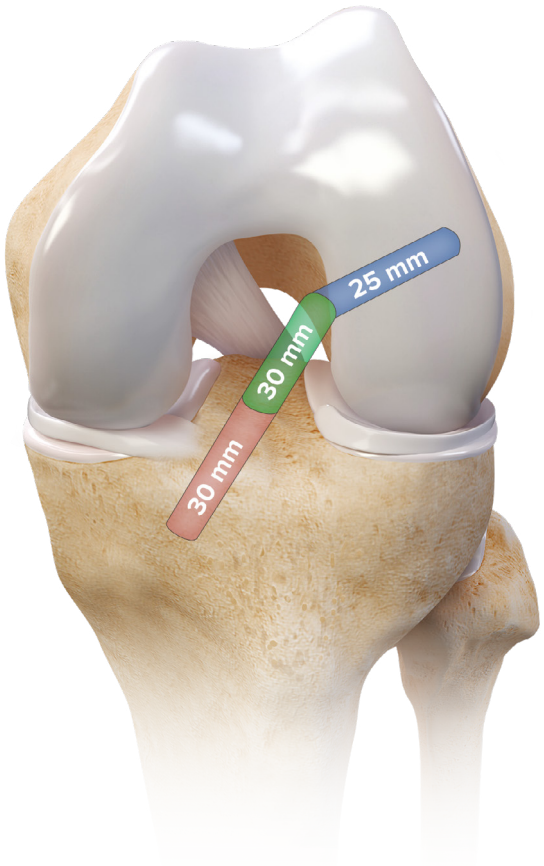


SpeedGraft Achilles Tendon
for ACL Reconstruction



VersaGraft Tendon
for Lateral Ankle Reconstruction

Graft Sizing and Socket Creation



Arthrex graft tubes are ideal for sizing and compressing allograft GraftLink® constructs. These full-length, clear tubes facilitate graft compression, sizing, and preparation.

Graft Sizing
Measure the graft length and diameter. Pass both the femoral and tibial ends of the graft into the sizing block to measure diameter for socket drilling.

Socket Creation
The length from the end of the femoral socket to the end of the tibial socket should be at least 10 mm longer than the graft to ensure the graft can be tensioned fully.

Example: 70 mm length

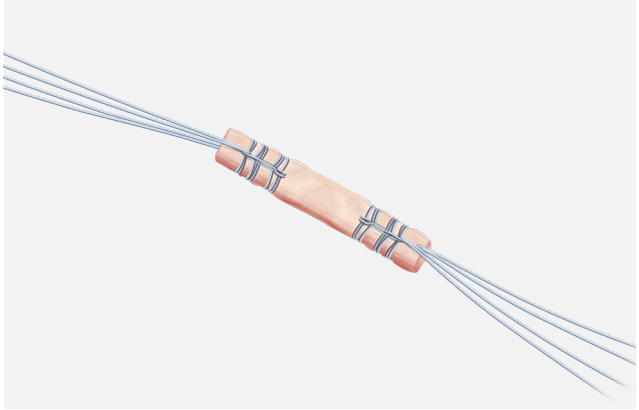
Allograft QuadLink™ Construct

The QuadLink construct is a presized and preassembled allograft quadriceps tendon presutured with #2 FiberLoop with FiberTag™ suture, designed to be used with ACL TightRope® implants. The all-inside ACL technique is ideal for quadriceps grafts, as only a graft length of 60 mm to 75 mm is needed. ACL TightRope II implants are used to fixate the graft in minimally invasive sockets created with a FlipCutter® III drill. A standard all-inside technique is used to implant the graft.

QuadLink presutured constructs are preassembled by qualified technicians that have trained and certified to ensure construct consistency. The tendons are provided as a sterile allograft construct via the Allowash XG process for patient and surgeon safety.

Allograft QuadLink Construct Features and Benefits:

- Minimal graft preparation time
- Presized diameter and lengths
- Allowash XG technology
- Preassembled with #2 FiberLoop with FiberTag suture
- Preloaded with passing sutures to facilitate loading with ACL TightRope II implants



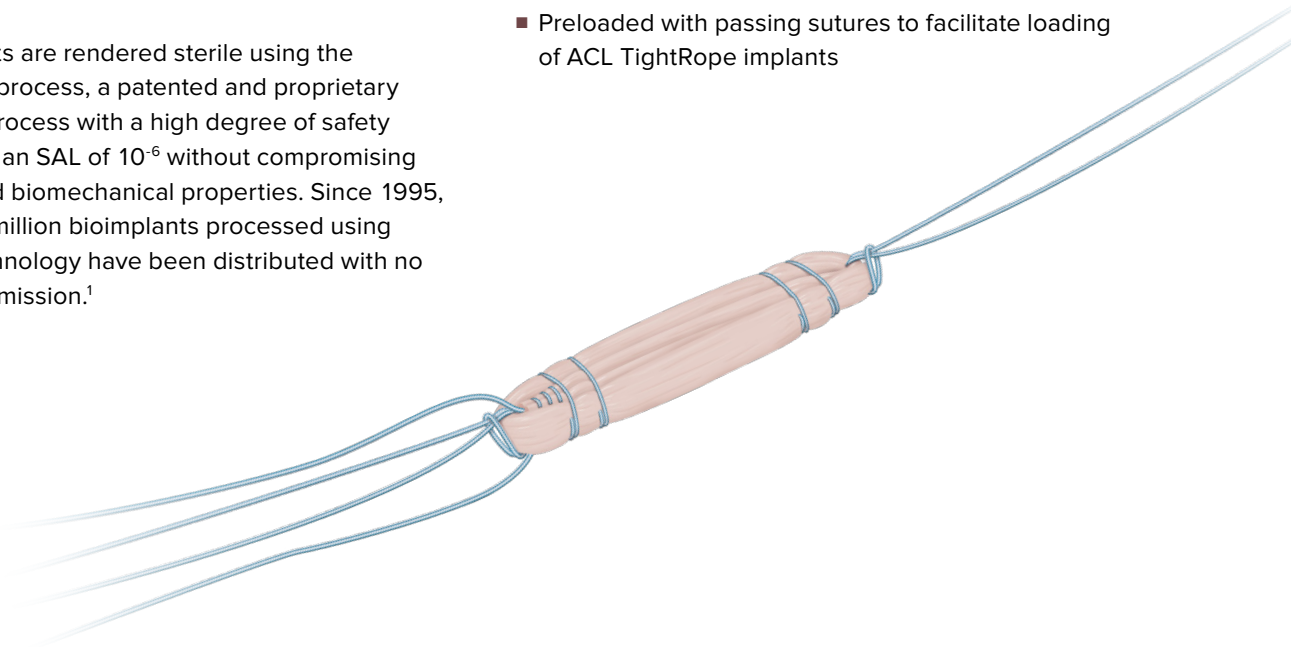
Allograft GraftLink® Construct

Consisting of preconstructed allograft tendon, GraftLink constructs are designed for use with the GraftLink ACL technique and TightRope® implants. Each construct is precisely assembled according to Arthrex specifications by trained tissue technicians to ensure it meets the requirements of the GraftLink technique and allows for an anatomic, minimally invasive, and reproducible ACL reconstruction.

The constructs are rendered sterile using the Allowash XG process, a patented and proprietary sterilization process with a high degree of safety that achieves an SAL of 10^{-6} without compromising biological and biomechanical properties. Since 1995, more than 6 million bioimplants processed using Allowash technology have been distributed with no disease transmission.[1]

Allograft GraftLink Construct Features and Benefits:

- Allowash XG technology
- Preassembled with #2 FiberWire® suture
- Minimal graft preparation time
- Presized to specifications of GraftLink all-inside ACL technique
- Preloaded with passing sutures to facilitate loading of ACL TightRope implants



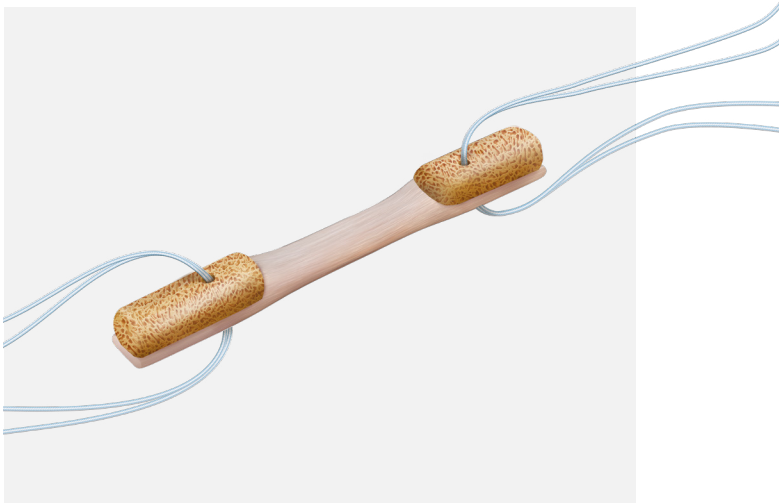
PilotGraft™ BTB Tendon

PilotGraft BTB tendons are preshaped, predrilled, bone-tendon-bone allografts that can be used in ACL and PCL reconstruction procedures.

Two preshaped 10 mm bone block, each with a 2 mm predrilled hole through the bone, facilitate insertion into bone tunnels. Looped #2 FiberLoop® suture is preinserted through the tunnels to help with suture shuttling. It can be removed if securing the tendon with an interference screw. Bone dowels are available in lengths from 20 mm to 30 mm. Available intra-articular lengths range from 25 mm to 45 mm and can be selected based on surgeon requirements.

PilotGraft BTB Tendon Features and Benefits:

- Multiple size options (65 mm to 95 mm total length)
- No donor-site morbidity
- 3-year shelf life
- Sterile (10^{-6} SAL)



SpeedGraft® Achilles Tendon

This presutured Achilles tendon, which includes a bone block predrilled with a 2 mm tunnel, provides for bone-to-bone fixation on the femoral side and efficient soft-tissue fixation on the tibial side. Looped #2 FiberLoop® suture is preinserted through the tunnel to help with suture shuttling. It can be removed if securing the tendon with an interference screw.

SpeedGraft Presutured Double Strand Tendon

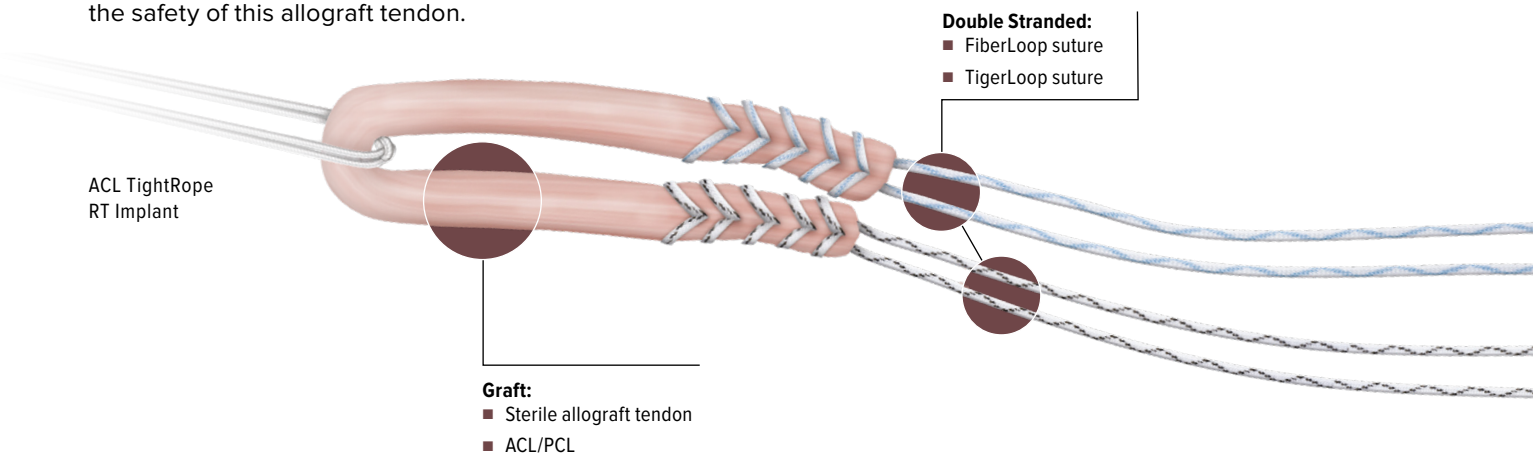
Designed for use with the ACL TightRope® implant for ACL and PCL reconstructions, the SpeedGraft allograft is a presutured, double strand, sterile tendon with individually sutured tails that can be identified by their color. This design allows for multiple fixation methods, providing flexibility for the surgeon.

Each tendon is assembled according to Arthrex specifications, by trained tissue technicians, ensuring that the presutured tendon meets the requirements of the procedure to allow for an anatomic, minimally invasive, and reproducible ACL or PCL reconstruction.

SpeedGraft presutured tendons are processed with a validated and patented cleaning treatment designed to facilitate the removal of cellular elements from tissue while maintaining the structural integrity of the allograft. This process has been proven to reduce the potential danger of disease transmission by removing over 99% of blood, lipids, and marrow from the allograft. The incorporation of a rigorous donor-screening process and terminal sterilization enhances the safety of this allograft tendon.

SpeedGraft Tendon Features and Benefits:

- Preassembled with #2 FiberLoop® and #2 TigerLoop® suture
- Minimal preparation time
- 10^{-6} SAL for patient safety
- Use with ACL TightRope RT implant
- Presized lengths and diameters for patient customization
- Tendon lengths: 175 mm to 295 mm
- Tendon diameters: 8 mm to 11 mm

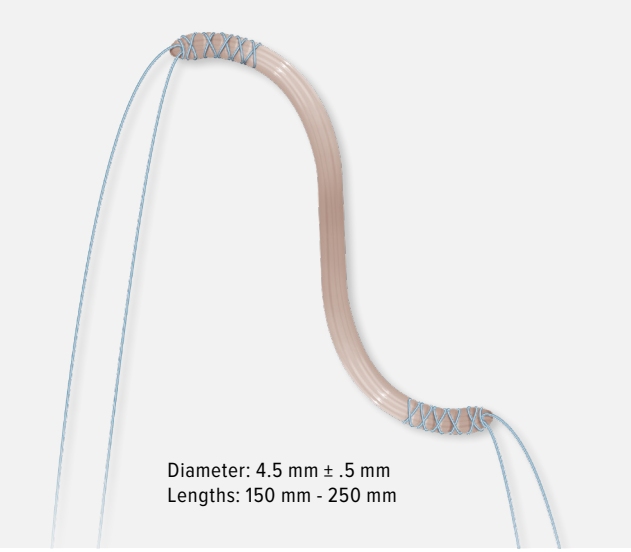


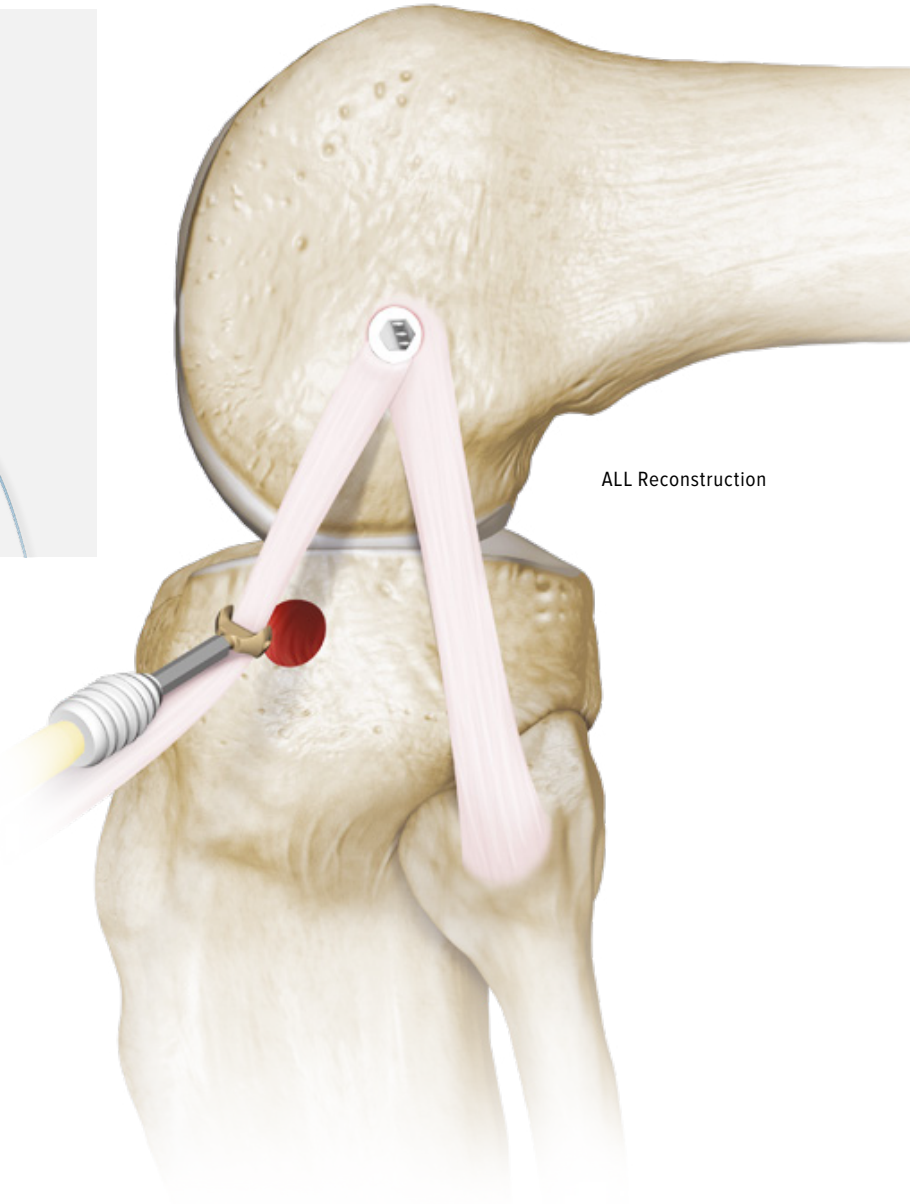
VersaGraft® Tendon

The VersaGraft presutured tendon is a preassembled, presized, sterile allograft tendon with simple tensioning and rigid fixation that can be used for anatomic reconstruction of the anterior talofibular (ATFL) and calcaneofibular (CFL) ligaments. All tendons are precisely assembled by highly trained tissue technicians, according to Arthrex specifications, to ensure each construct meets the requirements of the lateral ankle reconstruction technique.

Potential Applications

- Medial patellofemoral ligament (MPFL)
- Medial collateral ligament (MCL)
- Lateral collateral ligament (LCL)
- Patellar tendon repair
- Elbow ligament repair
- Lateral ankle stabilization
- Medial deltoid reconstruction
- Anterolateral ligament (ALL) reconstruction
- Acromioclavicular (AC) joint reconstruction





ALL Reconstruction

VersaGraft® 3.5 mm Tendon

The VersaGraft 3.5 mm presutured tendon provides time and cost savings to physicians. Presutured tendon constructs are sterile and preassembled with Arthrex sutures for speed and convenience. Each construct is assembled according to Arthrex specifications, by trained technicians, ensuring that the presutured tendon construct meets the requirements of the procedure to allow for anatomic, minimally invasive, and reproducible reconstruction.

Commonly used for MPFL reconstructions, the VersaGraft 3.5 tendon comes preassembled with #0 FiberLoop® suture and has a diameter of 3.5 mm to 4.5 mm and length of 190 mm to 240 mm.

FlexiGraft® Connect™ Tendon

The FlexiGraft Connect tendon is presutured with #2 FiberLoop® suture for 15 mm to 19 mm of length on one end and a locking tag stitch on the opposite end. The tendon has a diameter of 4.5 mm ± 0.5 mm and a length of 150 mm to 250 mm.

FlexiGraft Connect EXT Tendon

This small-diameter, presutured tendon is can be used for distal extremity procedures such as metatarsophalangeal joint reconstruction, distal extremity tendon transfer, elbow and thumb ulnar collateral ligament (UCL) procedures, hallux varus/valgus reconstruction, spring ligament reconstruction, and scapholunate ligament reconstruction. It's similar in design to the FlexiGraft Connect tendon but smaller in diameter and suture size.

References

1. Moore MA. Inactivation of enveloped and non-enveloped viruses on seeded human tissues by gamma irradiation. *Cell Tissue Bank*. 2012;13(3):401-407. doi:10.1007/s10561-011-9266-0
2. LifeNet Health. Data on file (TR-0020, TR-0023). Virginia Beach, VA.
3. SmartTRAK Market Research, Graft Market – US, 2018.
4. Garrett WE, Jr, Swiontkowski MF, Weinstein JN, et al. American Board of Orthopaedic Surgery practice of the orthopaedic surgeon: part II. Certification examination case mix. *J Bone Joint Surg Am*. 2006;88:660-667. doi:10.2106/JBJS.E.01208
5. Edgar CM, Zimmer S, Kakar S, Jones H, Schepsis AA. Prospective comparison of auto and allograft hamstring tendon constructs for ACL reconstruction. *Clin Orthop Relat Res*. 2008;466(9):2238-2246. doi:10.1007/s11999-008-0305-5
6. Samsell BJ, Moore MA. Use of controlled low dose gamma irradiation to sterilize allograft tendons for ACL reconstruction: biomechanical and clinical perspective. *Cell Tissue Bank*. 2012;13(2):217-23. doi:10.1007/s10561-011-9251-7
7. Balsly CR, Cotter AT, Williams LA, Gaskins BD, Moore MA, Wolfinbarger L Jr. Effect of low dose and moderate dose gamma irradiation on the mechanical properties of bone and soft tissue allografts. *Cell Tissue Bank*. 2008;9(4):289-98. doi:10.1007/s10561-008-9069-0
8. Tejwani SG, Chen J, Funahashi TT, Love R, Maletis GB. Revision risk after allograft anterior cruciate ligament reconstruction: association with graft processing techniques, patient characteristics, and graft type. *Am J Sports Med*. 2015;43(11):2696-705. doi:10.1177/0363546515589168
9. Greaves LL, Hecker AT, Brown CH Jr. The effect of donor age and low-dose gamma irradiation on the initial biomechanical properties of human tibialis tendon allografts. *Am J Sports Med*. 2008;36(7):1358-66. doi:10.1177/0363546508314394
10. Rihn JA, Irrgang JJ, Chhabra A, Fu FH, Harner CD. Does irradiation affect the clinical outcome of patellar tendon allograft ACL reconstruction?. *Knee Surg Sports Traumatol Arthrosc*. 2006;14(9):885-96. doi:10.1007/s00167-006-0036-7

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