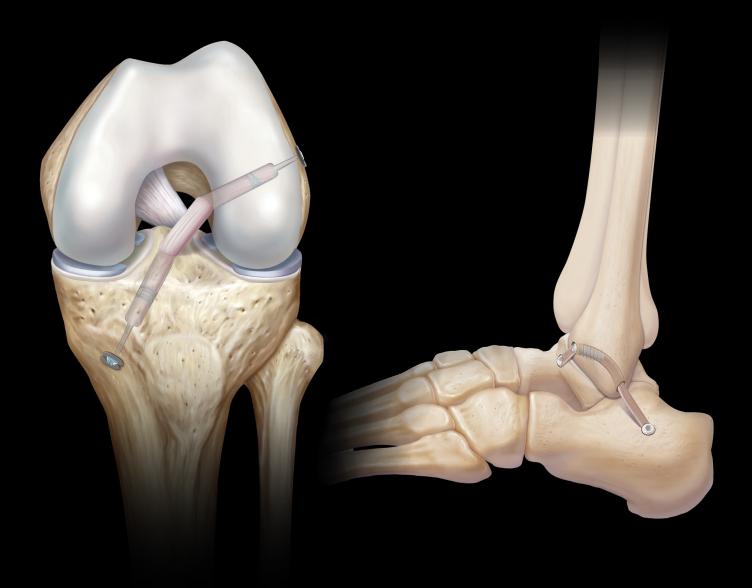
# Allograft Tendons A Comprehensive Portfolio





# 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<sup>-6</sup> and to inactivate viruses without compromising the biomechanical or biochemical properties of the tissue.<sup>1,2</sup> JRF Ortho's advanced cleansing technologies maintain tissue integrity with consistent processing, monitored temperature, and limited reagent exposure.

Regulatory / Compliance					
AATB	<ul> <li>Image: A set of the set of the</li></ul>	CLIA	~		
FDA	<b>v</b>	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,<sup>3</sup> including an estimated 300,000 anterior cruciate ligament (ACL) surgeries.<sup>4</sup> 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.<sup>4,5</sup>

# 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.<sup>6-10</sup>

#### Allowash XG

- Patented and validated process that provides allografts with a SAL of 10<sup>-6</sup>
- 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- <b>001</b>	FATB
Achilles Tendon w/o Bone Block	AWO- <b>001</b>	FAT
Anterior Tibialis Tendon, short length, $D \geq 7.5~\text{mm},~\text{L}$ = 170 mm-200 mm	SAT- <b>001</b>	FANT-SL
Posterior Tibialis Tendon, short length, D $\geq$ 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- <b>001</b>	FANT/TIB/T
Tibialis Tendon, posterior	DPT- <b>001</b>	FPOST.TIBIAL
Gracilis, double strand	DSG- <b>001</b>	
Patellar Tendon, bisected/hemi	HPL- <b>001</b>	FBPL
Patellar Tendon, bisected, small block		FBPLSB
Patellar Tendon, whole	WPL- <b>001</b>	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- <b>001</b>	
Peroneus Tendon		FPLT
Preshaped Achilles, 9 mm	ATP- <b>091</b>	
Preshaped Achilles, 10 mm	ATP- <b>101</b>	FATB10
Preshaped Achilles, 11 mm	ATP- <b>111</b>	FATB11
Preshaped Patellar Tendon, 10 mm	PLP- <b>101</b>	FPL10
Preshaped Patellar Tendon, 11 mm	PLP- <b>111</b>	FPL11
Quadruple Strand Semitendinosus/ Gracilis	QSG- <b>001</b>	
Quadriceps Tendon w/ Bone	QDT- <b>001</b>	FQUADB
Preshaped Quadriceps Tendon, 10 mm	QDT- <b>101</b>	
Semitendinosus, single strand	SST- <b>001</b>	
Semitendinosus, double strand	DST- <b>001</b>	
Semitendinosus and Gracilis Tendons		1FST+1FGRACILIS
Semitendinosus Tendon, $\ge$ 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- <b>001</b>	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		FLL
GraftRope		FROPE

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:

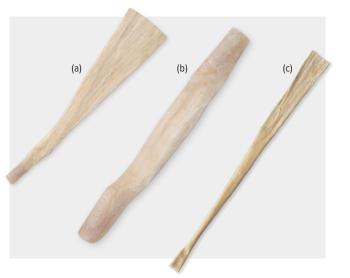
- Aseptically processed allografts are manufactured in a controlled environment with patented methods
- Use of highly sensitive nucleic acid testing (NAT)
- Comprehensive donor screening

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



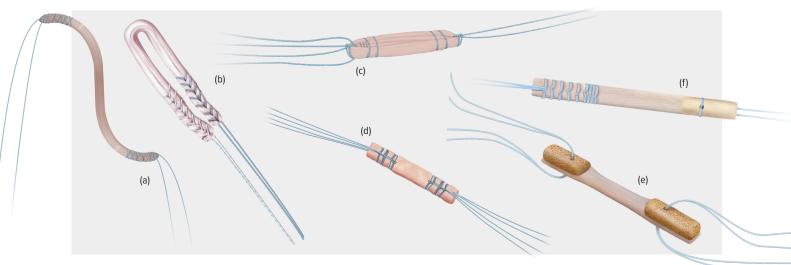


# **Presutured Tendons**

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- <b>001</b>	
VersaGraft 3.5 Tendon	VRG- <b>351</b>	
SpeedGraft® Tendon (b)	SPD- <b>001</b>	
GraftLink® XL Tendon (PCL)	GRX- <b>001</b>	
Allograft GraftLink® Tendon <b>(c)</b>		FGL
Allograft GraftLink Triple Strand		FGLTS
QuadLink <sup>™</sup> Construct Tendon <b>(d)</b>		FQL
FlexiGRAFT <sup>®</sup> Connect Tendon		FCON
FlexiGRAFT Connect EXT Tendon		FCONEXT
DualLink Presutured Construct		FDL
PilotGraft <sup>™</sup> BTB Tendon (e)	PSP- <b>101</b>	
SpeedGraft Achilles Tendon (f)	PSA- <b>101</b>	





GraftLink Allograft Tendon for All-Inside ACL Reconstruction

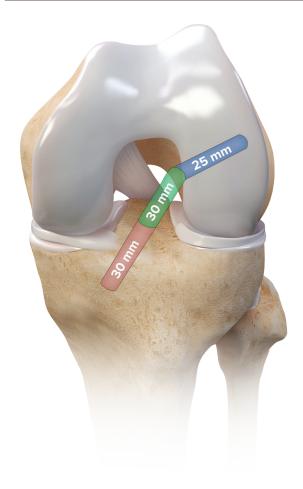


SpeedGraft Achilles Tendon for ACL Reconstruction



VersaGraft Tendon for Lateral Ankle Reconstruction

# Graft Sizing and Socket Creation



Arthrex graft tubes are ideal for sizing and compressing allograft GraftLink<sup>®</sup> 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.



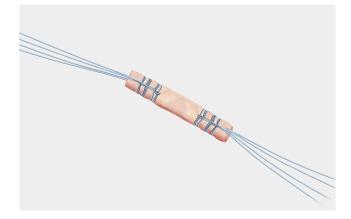
# Allograft QuadLink<sup>™</sup> Construct

The QuadLink construct is a presized and preassembled allograft quadriceps tendon presutured with #2 FiberLoop with FiberTag<sup>™</sup> suture, designed to be used with ACL TightRope<sup>®</sup> 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<sup>®</sup> 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



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<sup>-6</sup> without compromising biological and biomechanical properties. Since 1995, more than 6 million bioimplants processed using Allowash technology have been distributed with no disease transmission.<sup>1</sup>

#### Allograft GraftLink Construct Features and Benefits:

- Allowash XG technology
- Preassembled with #2 FiberWire<sup>®</sup> 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

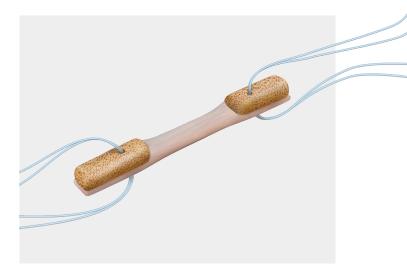
# PilotGraft<sup>™</sup> BTB Tendon

PilotGraft BTB tendons are preshaped, predrilled, bonetendon-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<sup>-6</sup> SAL)



# SpeedGraft<sup>®</sup> Achilles Tendon

This presutured Achilles tendon, which includes a bone block predrilled with a 2 mm tunnel, provides for boneto-bone fixation on the femoral side and efficient softtissue fixation on the tibial side. Looped #2 FiberLoop<sup>®</sup> 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

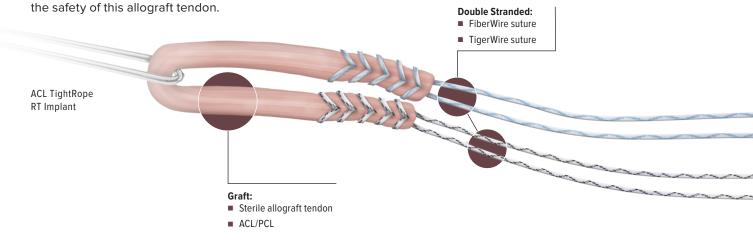
Designed for use with the ACL TightRope® implant for ACL and PCL reconstructions, the SpeedGraft allograft is a presutured, double strand, sterile tendon with individually sutured tails that can be identified by their color. This design allows for multiple fixation methods, providing flexibility for 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 FiberWire<sup>®</sup> and TigerWire<sup>®</sup> suture
- Minimal preparation time
- 10<sup>-6</sup> 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



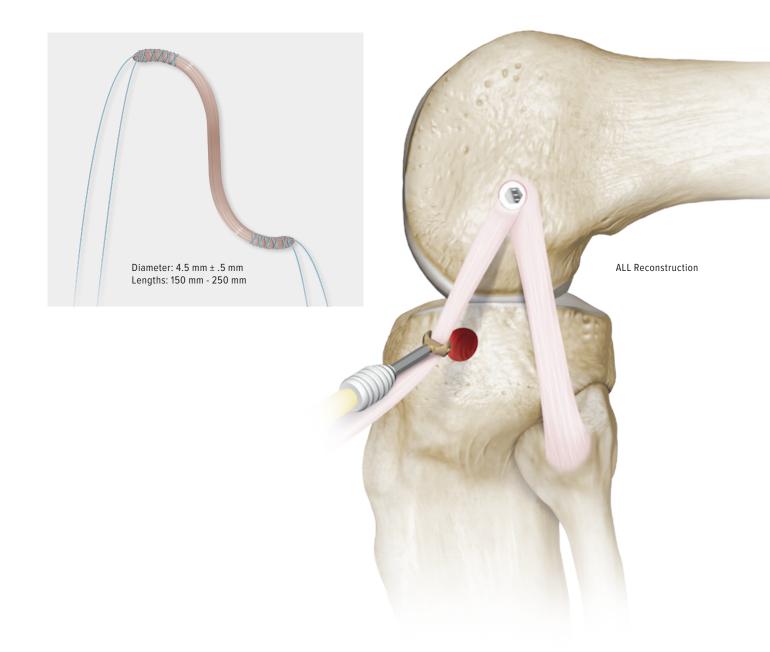
# VersaGraft® Tendon

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



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.



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  $\pm$  0.5 mm and a length of 150 mm to 250 mm. 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.



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Allowash XG technology is a registered trademark of LifeNet Health.



This description of technique is provided as an educational tool and clinical aid to assist properly licensed medical professionals in the usage of specific Arthrex products. As part of this professional usage, the medical professional must use their professional judgment in making any final determinations in product usage and technique. In doing so, the medical professional should rely on their own training and experience, and should conduct a thorough review of pertinent medical literature and the product's directions for use. Postoperative management is patient-specific and dependent on the treating professional's assessment. Individual results will vary and not all patients will experience the same postoperative activity level and/or outcomes.

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