

AlloConnex[®]

TENDONS, LIGAMENTS, FASCIA



DO MORE WITH LIFE



COMPREHENSIVE SOFT TISSUE PORTFOLIO

The AlloConnex® portfolio includes tendons, ligaments and fascia allografts designed to support a wide range of procedures that helps surgeons return their patients to active lifestyles.

Types of allografts include Achilles, anterior tibialis, gracilis, peroneus longus, posterior tibialis, semitendinosus, quadriceps, patellar ligaments and fascia.

TISSUE PROCESSING AND SAFETY

GUIDELINES

Donor eligibility and processing guidelines are critical to ensure the safety of allografts. AlloSource tissue safety standards are outlined below.

- Registered with the United States Food and Drug Administration (FDA)
- Accredited by the American Association for Advancing Tissue and Biologics (AATB)
- Compliant with Clinical Laboratory Improvement Amendments (CLIA) standards
- Certified to International Standards Organization (ISO) 13485 through British Standards Institution (BSI) for Quality Management System oversight

In addition, AlloSource's tissue recovery organizations comply with AATB and FDA requirements.

ALLOTRUE® CLEANSE AND STERILIZATION

Aseptic and sterile tendons are processed through the AlloTrue Cleansing Process. In addition, low dose electron beam (E-beam) irradiation is used to produce sterile tendons. Neither process impacts biomechanical properties of the tissue.

ALLOSOURCE'S TENDON PROCESS

Aseptic and sterile tendons go through AlloSource's proprietary AlloTrue Cleansing Process.

- Uses a combination of treatments consisting of antibiotics, alcohol and water rinses which penetrate deep within tissue to remove blood, lipids and microorganisms.¹
- Utilizes ultrasonic agitation and rotation to minimize tissue manipulation.

Sterile tendons, in addition to the AlloTrue Cleansing Process, also undergo E-beam terminal sterilization.

- Employs low-temperature (-20°C), low-dose (0.95–1.5 MRad) irradiation** for terminal sterilization.
- Maintains precise control and monitoring to ensure tightly controlled, low-dose ranges.
- Achieves a sterility assurance level (SAL) (10⁻⁶) commonly used with sterilizing medical devices

**E-beam irradiation, used for tendon sterilization, has been shown to produce safe, biomechanically uncompromised allografts.^{2,5}*

***Tendons treated with low dose irradiation (<2.0Mrad) show similar biomechanical properties to aseptic/non-sterile allografts.^{2,3,4,5}*

1. Data on file.

2. Elenes EY, Hunter SA. Soft-tissue allografts terminally sterilized with an electron beam are biomechanically equivalent to aseptic, nonsterilized tendons. *J Bone Joint Surg Am.* 2014;96(16):1321-1326.

3. Teiwani SG, et al. 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):2696-2705.

4. Vopat BG, et al. Terminal sterilization of anterior cruciate ligament (ACL) Allografts: a systematic review of outcomes. *Kans J Med.* 2020;13:23-28.

5. Lansdown D, et al. What factors influence the biomechanical properties of allograft tissue for ACL reconstruction? A systematic review. 2017;475(10):2412 - 2426.

PRECISION MEASURING

NON-BONE TENDON

Every non-bone tendon is measured for length, folded and single diameter (Figure 1).

- The folded diameter is measured with the tendon folded at the center and pulled through from larger to smaller diameters on the sizing block. The measurement is quantified by the largest hole size where the tendon lifts the sizing block.
- The single diameter is measured by pulling the tendon from end-to-end through the sizing block. The measurement is quantified by recording the largest hole size where the tendon lifts the sizing block off the field.
- The allograft length is also measured.

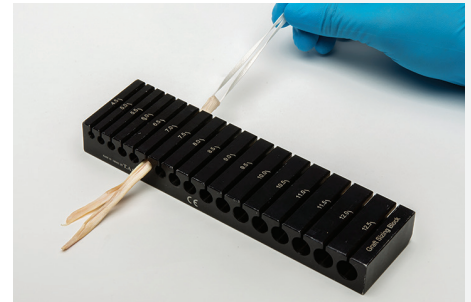


Figure 1

PATELLA LIGAMENT

Patella ligament (bone tendon bone – BTB) allografts (whole, hemi and pre-shaped) are measured for total allograft length, ligament length, ligament width and bone block dimensions (tibial and patella)(Figure 2).

- Two separate ligament length measurements are taken:
 - Ligament length 1 (LL1), the length of the ligament from the tibial insertion to the apex of the patella bone.
 - Ligament length 2 (LL2), the length of the ligament from the tibial insertion to the furthest attachment of the ligament to the patella bone.
- The total allograft length, ligament width and tibial and patella bone block dimensions are also measured.

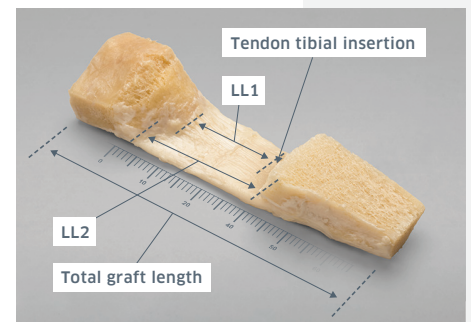


Figure 2

ACHILLES AND QUADRICEP TENDONS

Achilles and quadricep (bone tendons - BT) are measured for tendon length, tendon width and bone block dimensions of length, width and thickness.

- The tendon length is taken from the insertion of the bone block to the end of the tendon or from end to end of the tendon if a bone block is not present (Figures 3-4).
- Length, width and thickness measurements are taken on bone blocks for both Achilles and quadricep tendons if bone block is present (Figure 4).

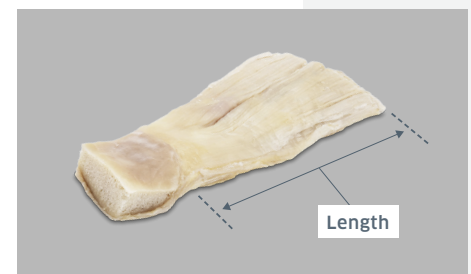


Figure 3

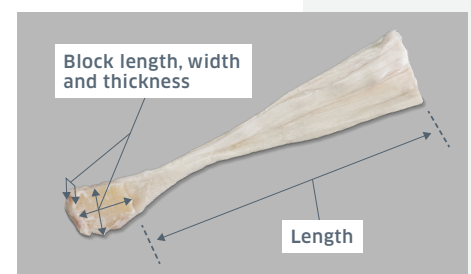


Figure 4

PRODUCT CONFIGURATIONS

- Commonly used in ACL, PCL and other soft tissue repair and reconstruction
- Full portfolio to accommodate various surgical procedures

NON-BONE TENDONS



Single Strand



Double Strand

PATELLA LIGAMENT (BTB)



Whole



Hemi



Pre-Shaped

- Multiple sizes to meet patient requirements
- Supports many fixation types for a variety of techniques

ACHILLES TENDON (BT)



With Bone Block



Pre-Shaped

QUADRICEP TENDON (BT)



With Bone Block



Without Bone Block



Pre-Trimmed

FASCIA LATA



AlloConnex® Tendons and Ligaments

ALLOGRAFT	DESCRIPTION	LENGTH	SINGLE D*	FOLDED D*	CONDITION	PRESERVATION	STORAGE	REF/PRODUCT #
Achilles	Pre-Shaped	≥ 19 cm			Aseptic	Frozen	Frozen	10022100
Achilles	w/ Bone Block	≥ 14 cm			Aseptic	Frozen	Frozen	10022000
Anterior Tibialis	Double Strand	≥ 23.5 cm		7.5 mm min.	Aseptic	Frozen	Frozen	41522000
Anterior Tibialis	Single Strand	≥ 18-22.9 cm	5.0 mm min.		Aseptic	Frozen	Frozen	44322000
Gracilis	Double Strand	≥ 23 cm		6.0 mm min.	Aseptic	Frozen	Frozen	26222000
Gracilis	Single Strand	≥ 20-22.9 cm	3.5 mm min.		Aseptic	Frozen	Frozen	44322002
Gracilis/Semitendinosus	Double Bundle	≥ 23 cm		4.0 mm min.	Aseptic	Frozen	Frozen	44222002
Patellar Ligament	Pre-Shaped	3-5 cm			Aseptic	Frozen	Frozen	18022000
Patellar Ligament	Hemi				Aseptic	Frozen	Frozen	17822000
Patellar Ligament	Whole				Aseptic	Frozen	Frozen	17922000
Patellar Ligament	Whole With Quad				Aseptic	Frozen	Frozen	24822000
Peroneus Longus	Double Strand	≥ 26 cm		7.5 mm min.	Aseptic	Frozen	Frozen	43922000
Posterior Tibialis	Double Strand	≥ 25 cm		8.0 mm min.	Aseptic	Frozen	Frozen	41622000
Posterior Tibialis w/ Node	Double Strand	≥ 23 cm		6.0 mm min.	Aseptic	Frozen	Frozen	41622001
Semitendinosus	Double Strand	≥ 23 cm		6.0 mm min.	Aseptic	Frozen	Frozen	18722000
Semitendinosus	Single Strand	≥ 18-22.9 cm	3.5 mm min.		Aseptic	Frozen	Frozen	44322003
Quadricep	w/ Patella				Aseptic	Frozen	Frozen	24922000
Quadricep	w/o Patella				Aseptic	Frozen	Frozen	24922001
Quadricep	Pre-Trimmed				Aseptic	Frozen	Frozen	25022000
Achilles	Pre-Shaped	≥ 19 cm			Sterile	Frozen	Frozen	10017100
Achilles	w/ Bone Block	≥ 14 cm			Sterile	Frozen	Frozen	10017000
Anterior Tibialis	Double Strand	≥ 23.5 cm		7.5 mm min.	Sterile	Frozen	Frozen	41517000
Anterior Tibialis	Single Strand	≥ 18-22.9 cm	5.0 mm min.		Sterile	Frozen	Frozen	44317000
Gracilis	Double Strand	≥ 23 cm		6.0 mm min.	Sterile	Frozen	Frozen	26217000
Gracilis	Single Strand	≥ 20-22.9 cm	3.5 mm min.		Sterile	Frozen	Frozen	44317002
Gracilis/Semitendinosus	Double Bundle	≥ 23 cm		4.0 mm min.	Sterile	Frozen	Frozen	44217002
Patellar Ligament	Pre-Shaped	3-5 cm			Sterile	Frozen	Frozen	18017000
Patellar Ligament	Hemi				Sterile	Frozen	Frozen	17817000
Patellar Ligament	Whole				Sterile	Frozen	Frozen	17917000
Patellar Ligament	Whole With Quad				Sterile	Frozen	Frozen	24817000
Peroneus Longus	Double Strand	≥ 26 cm		7.5 mm min.	Sterile	Frozen	Frozen	43917000
Peroneus Longus	Single Strand	≥ 18-22.9 cm			Sterile	Frozen	Frozen	44317004
Posterior Tibialis	Double Strand	≥ 25 cm		8.0 mm min.	Sterile	Frozen	Frozen	41617000
Posterior Tibialis	Single Strand	≥ 18-22.9 cm	4.5 mm min.		Sterile	Frozen	Frozen	44317001
Semitendinosus	Double Strand	≥ 23 cm		6.0 mm min.	Sterile	Frozen	Frozen	18717000
Semitendinosus	Single Strand	≥ 18-22.9 cm	3.5 mm min.		Sterile	Frozen	Frozen	44317003
Quadricep	w/ Patella				Sterile	Frozen	Frozen	24917000
Quadricep	w/o Patella				Sterile	Frozen	Frozen	24917001
Quadricep	Pre-Trimmed				Sterile	Frozen	Frozen	25018001

*D = Diameter

Fascia Lata

AREA	CONDITION	PRESERVATION	STORAGE	REF/PRODUCT #
9.0-34.9 cm ²	Sterile	Freeze-Dried	Ambient	14415034
35.0-45.9 cm ²	Sterile	Freeze-Dried	Ambient	14415045
46.0-83.9 cm ²	Sterile	Freeze-Dried	Ambient	14415095
84.0-150.9 cm ²	Sterile	Freeze-Dried	Ambient	14415150
151.0-260.9 cm ²	Sterile	Freeze-Dried	Ambient	14415260
≥ 261.0 cm ²	Sterile	Freeze-Dried	Ambient	14415261
9.0-34.9 cm ²	Sterile	Frozen	Frozen	14417034
46.0-83.9 cm ²	Sterile	Frozen	Frozen	14417095
84.0-150.9 cm ²	Sterile	Frozen	Frozen	14417150
151.0-260.9 cm ²	Sterile	Frozen	Frozen	14417260

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800. 557. 3587

AlloSource, a life sciences organization, helps restore patient functionality by transforming the gift of human tissue donation into enhanced medical products that enable a life of movement, health, and wellbeing. We partner with medical professionals and biomedical companies who share our drive for innovation and quality in the use of human tissue allografts for medical advancements. Headquartered in Centennial, Colorado, we have served a global marketplace since 1994. Learn more at allosource.org.

AlloConnex® Tendons, Ligaments and Fascia are regulated by the FDA under 21 CFR Part 1271 Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/PS). AlloSource® is registered with the FDA as a tissue establishment and accredited by the Association for Advancing Tissue and Biologics.

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