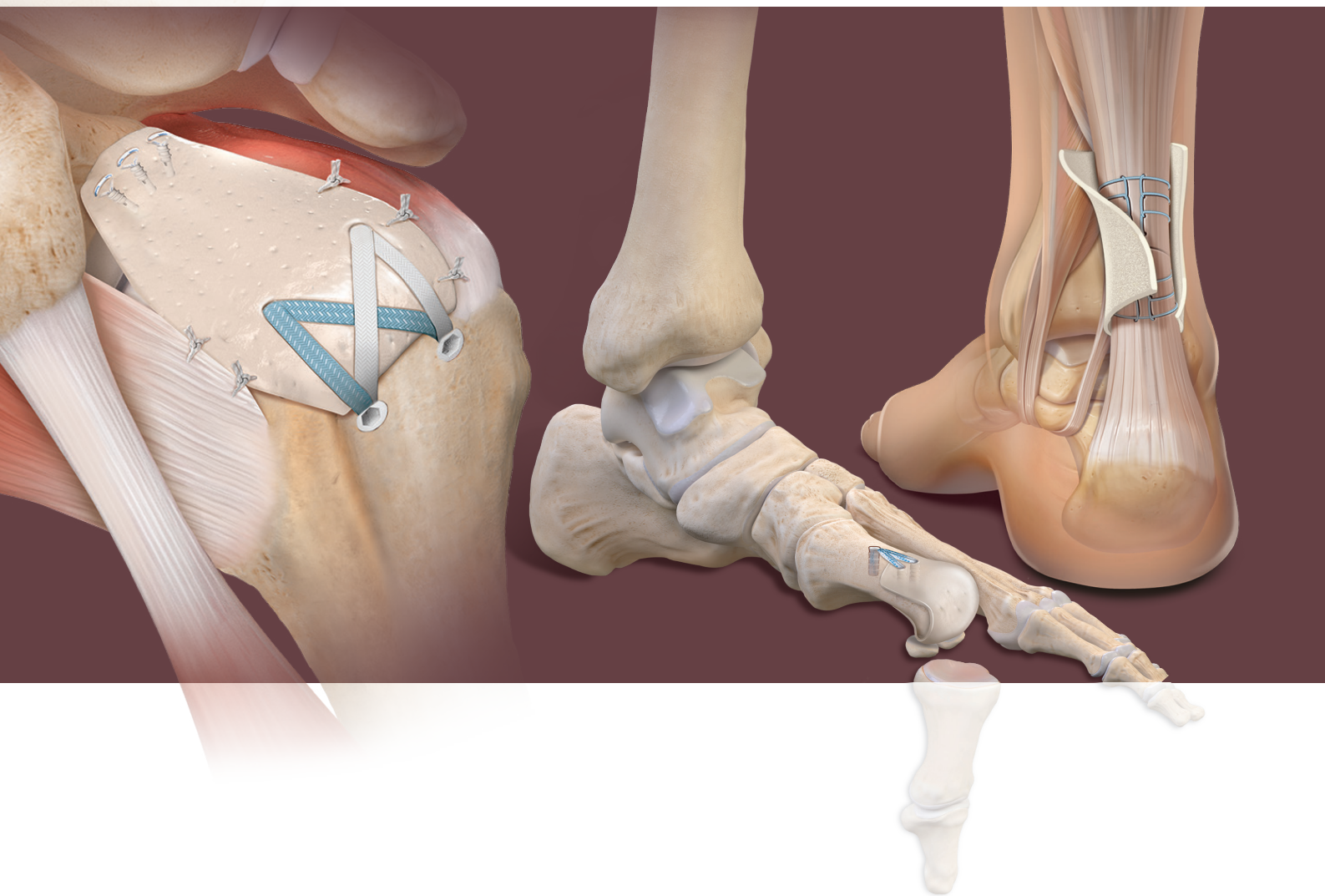


ArthroFLEX® Decellularized Bio-Implant for Soft-Tissue Repair



High-Performance Extracellular Matrix

ArthroFlex dermal allograft is a biohospitable, acellular dermal extracellular matrix intended for supplemental support and covering for soft-tissue repairs. LifeNet Health's patented and validated Matracell® decellularization process renders the ArthroFlex dermal allograft acellular without compromising its biomechanical or biochemical properties. Matracell technology removes donor DNA from the dermal matrix, ensuring a biocompatible scaffold that retains its growth factors, native collagen scaffold, and elastin.¹ Matracell technology is validated to retain less than 10 ng dsDNA/mg wet weight of tissue, far less than other commercially available acellular dermal matrices.¹

ArthroFlex dermal allograft is treated with Preservon®, a propriety and patented preservation technology that allows the graft to be fully hydrated at room temperature while avoiding the water-mediated lysis of the natural collagen and elastin scaffold.¹

ArthroFlex allograft is terminally sterilized with a 3-year shelf life.

Why use ArthroFLEX® dermal allograft?

- Augmentation with ArthroFlex dermal allograft has demonstrated improved clinical outcomes²
- ArthroFlex dermal allograft improves the strength of the repair and protects the repair to allow healing^{2,3}
- Augmentation with ArthroFlex dermal allograft can reduce re-tear rates^{2,3}
- Biomechanical testing has shown that ArthroFlex dermal allograft provides high ultimate load and suture retention strength⁴
- ArthroFlex dermal allograft used in superior capsular reconstruction has demonstrated improved clinical outcomes and decreased pain 2 years postoperatively^{5,6}
- ArthroFlex dermal allograft has demonstrated the ability to remodel and integrate with host tissue after implantation⁷



≥97% DNA Removed	Biocompatible ¹
Intact Acellular Extracellular Matrix	Provides a strong, biohospitable collagen scaffold for host cellular and vascular ingrowth ¹
Convenience	Excellent handling. Ready to use. Room temperature storage (15° - 30° C) ¹
Safety	10 ⁻⁶ SAL (sterility assurance level) reduces risk of disease transmission ¹
Promotes Rapid Healing	Retains growth factors, elastin, matrikines, cytokines, and collagens ¹

Matracell® technology was designed to remove donor DNA and cellular remnants from the dermal matrix, without causing damage or crosslinking, ensuring a biocompatible scaffold to facilitate repair.

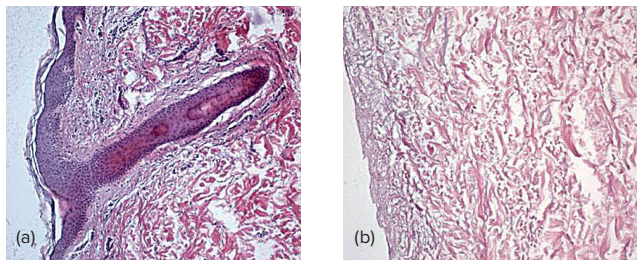


Figure 1. Human skin (a) pre and (b) post decellularization stained with hematoxylin and eosin demonstrates the removal of DNA and nuclear material as seen by lack of purple staining in (b).

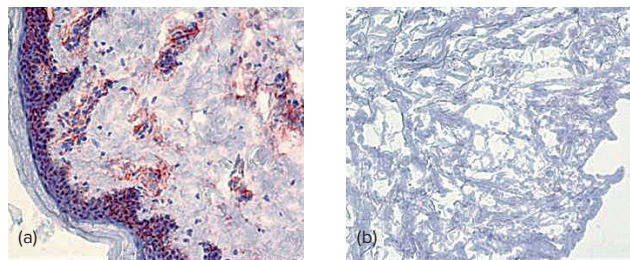


Figure 2. Human skin (a) pre and (b) post decellularization stained for major histocompatibility complex 1 staining shows reduction of potentially immunogenic components as seen by lack of red staining in (b).

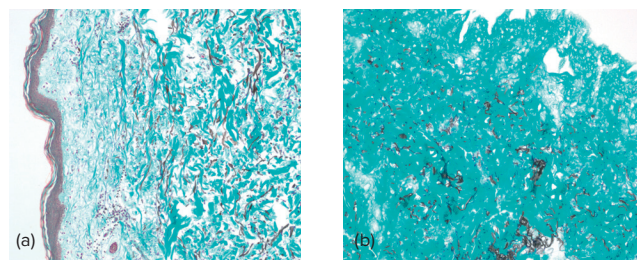


Figure 3. Elastin fibers are essential for skin elasticity. No significant difference was observed microscopically between (a) pre and (b) post decellularization on elastin fiber quantity (black stain) and distribution.

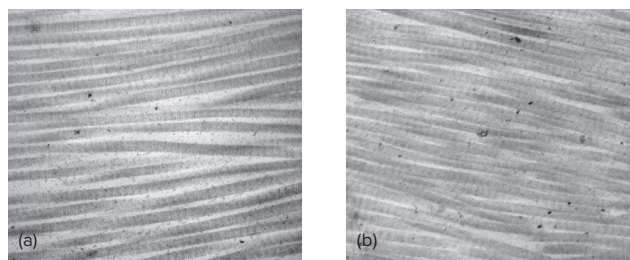


Figure 4. Transmission electron microscopy (TEM) images of 30K magnification of human skin (a) pre and (b) post decellularization and gamma irradiation demonstrates no change in collagen structure.



Explanted graft material was voluntarily submitted for histological analysis to study remodeling post-implantation.

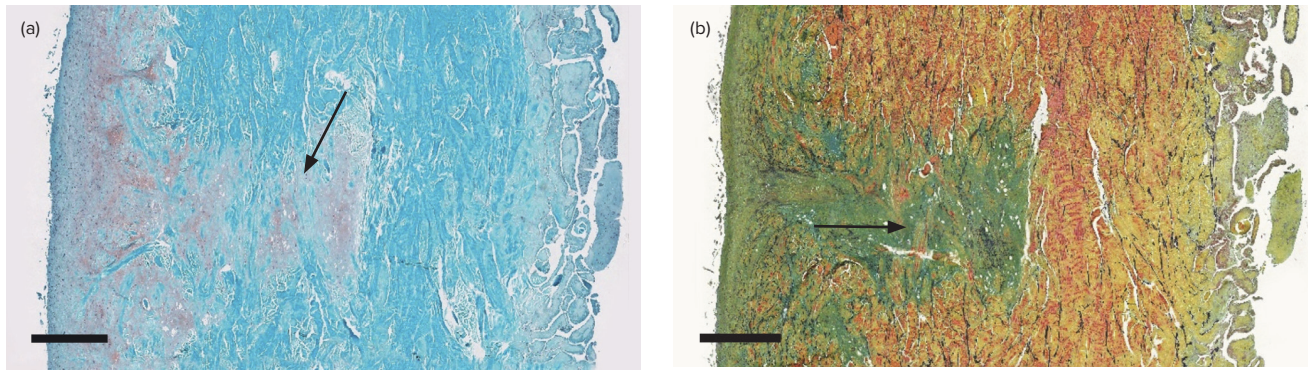


Figure 5. Development of fibrocartilage (black arrows) on articular surface demonstrated by (a) safranin O staining and (b) Russell-Movat pentachrome staining. Merged 10× images, scale bar = 500 μm.

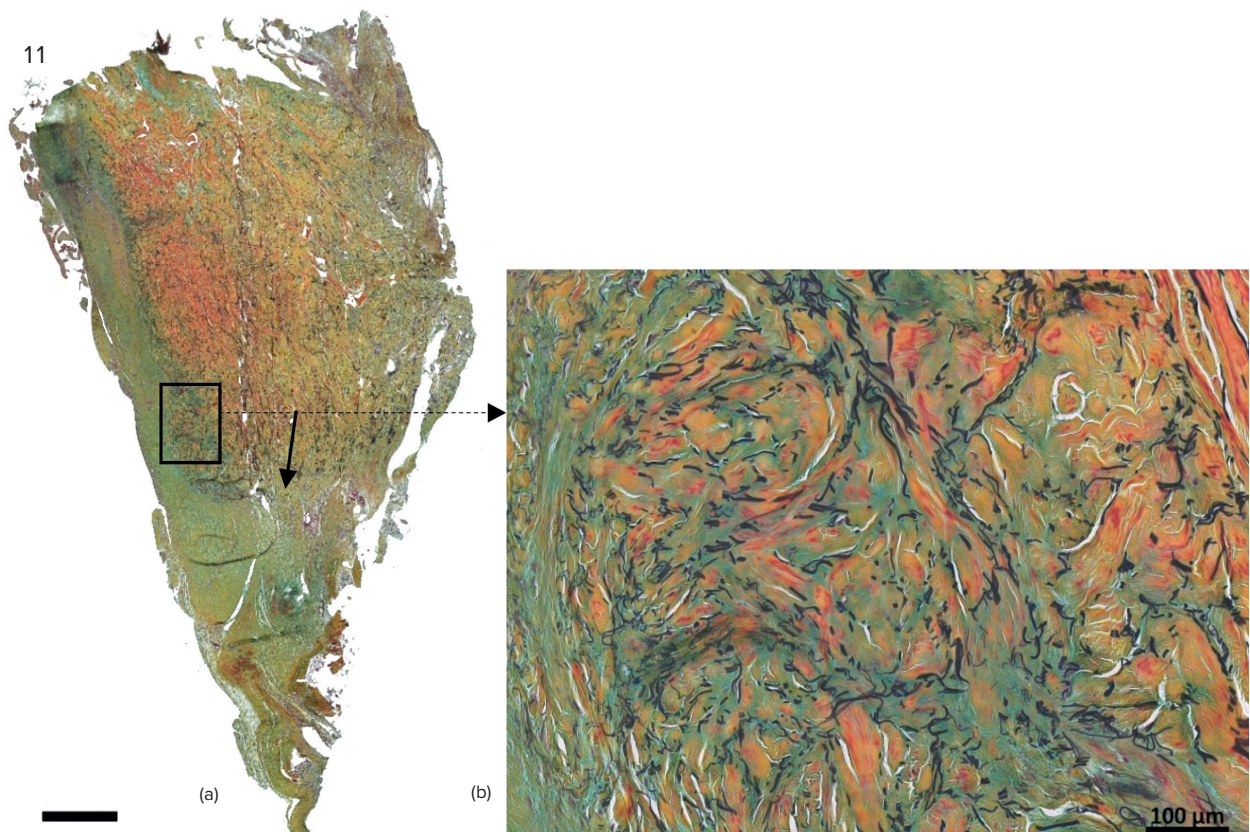
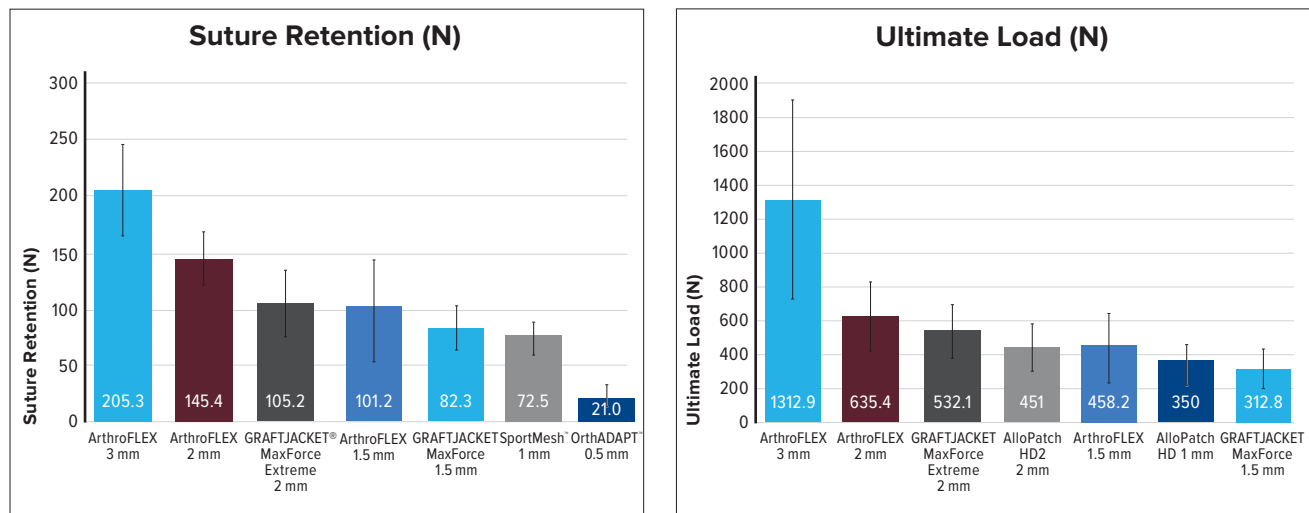


Figure 6a. Active remodeling of implanted graft tissue in piece 11 shown by Movat pentachrome staining. Image 10×, graft-host junction area indicated by black arrow.

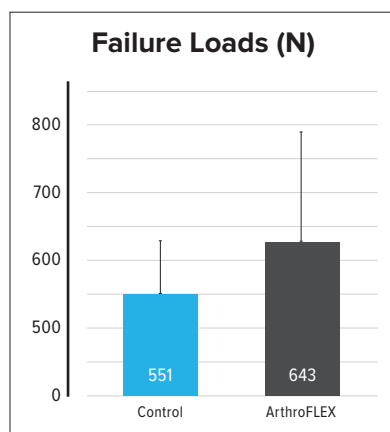
Figure 6b. In the inset image, the yellow/orange colors of collagen fibers are gradually changing into green shades of immature cartilage tissue. The elastin fibers are stained black.

Strength^{4,9}

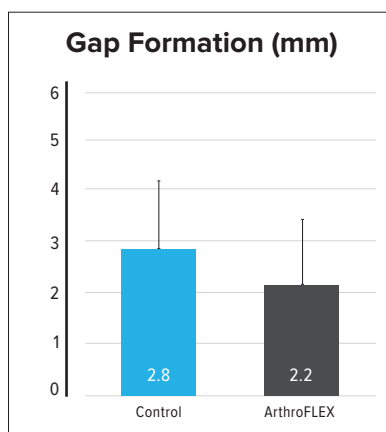
ArthroFlex dermal allograft provides unparalleled strength for supplemental support and covering for soft-tissue repairs.



Rotator Cuff Analysis³



Comparison of failure loads (N) of human dermal allograft extracellular matrix augmentation vs control.

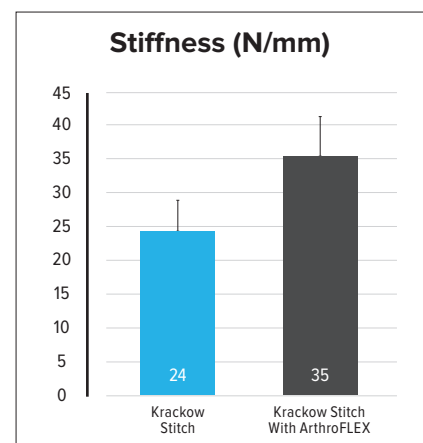
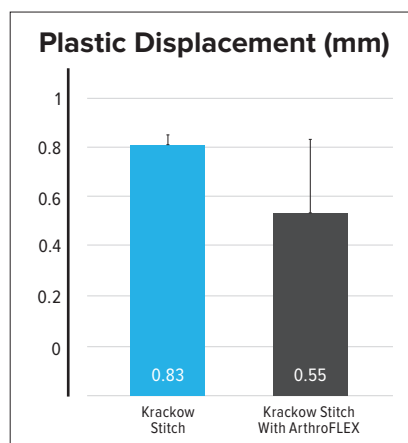
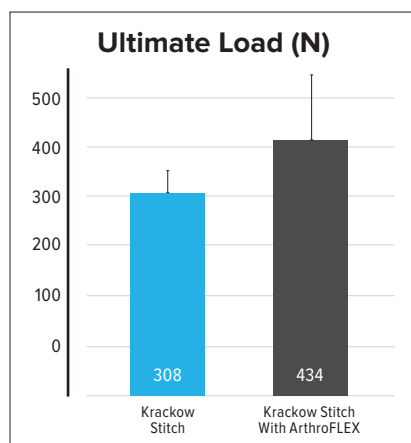


Comparison of gap formation (mm) of human dermal allograft extracellular matrix augmentation vs control.

The results suggest that the human dermal allograft is able to reinforce the repair site during the early healing period.

- Decreased gap formation = graft reinforces repaired tendon's ability to stay flush to insertion site
- Increased failure load = improved strength of repair

Achilles Tendon Analysis¹¹

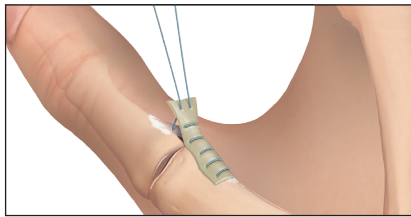


Cadaveric testing of midsubstance Achilles tendon repair with Krackow stitch alone compared to Krackow stitch augmented with ArthroFlex dermal allograft.

ArthroFLEX® Dermal Allograft Product Guide

Potential applications

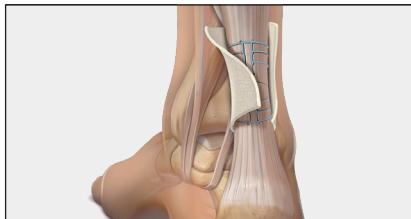
Hand/Wrist Tendon Sheath Augmentation



Product Description	Item Number
30 mm × 40 mm × .5 mm	AFLEX500
40 mm × 40 mm × 1.0 mm	AFLEX400



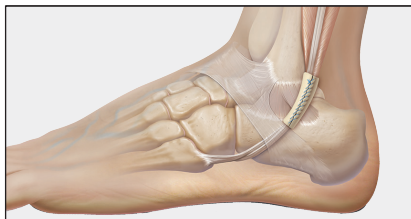
Achilles Tendon Augmentation



Product Description	Item Number
40 mm × 70 mm × 1.0 mm	AFLEX401
40 mm × 70 mm × 1.5 mm	AFLEX101
50 mm × 90 mm × 1.5 mm	AFLEX103
40 mm × 70 mm × 2.0 mm	AFLEX201



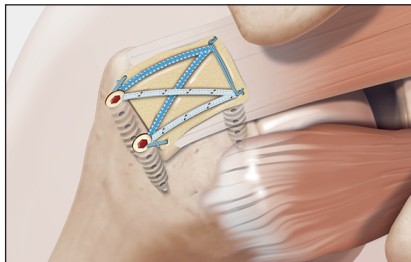
Peroneal/Tibial Tendon Augmentation



Product Description	Item Number
40 mm × 70 mm × 1.0 mm	AFLEX401
40 mm × 70 mm × 1.5 mm	AFLEX101
15 mm × 140 mm × 1.5 mm	AFLEX150



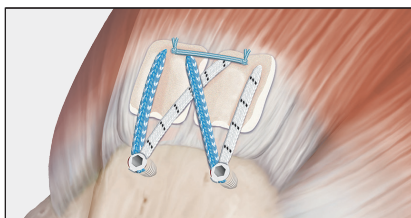
Rotator Cuff Augmentation



Product Description	Item Number
40 mm × 40 mm × 1.0 mm	AFLEX400
35 mm × 35 mm × 1.5 mm	AFLEX100
35 mm × 35 mm × 2.0 mm	AFLEX200
25 mm × 30 mm × 2.0 mm	AFLEX202
40 mm × 70 mm × 3.0 mm	AFLEX301

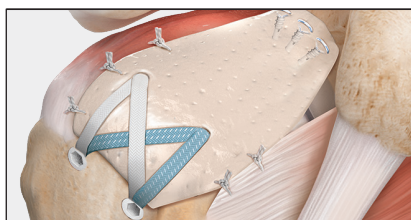


Suture Reinforcement



Product Description	Item Number
10 mm × 14 mm × 2.0 mm	AFLEX822

Capsular Reinforcement



Product Description	Item Number
40 mm × 50 mm × 3.0 mm	AFLEX300
40 mm × 70 mm × 3.0 mm	AFLEX301
50 mm × 60 mm × 3.0 mm	AFLEX302

Hallux Rigidus Arthroplasty¹⁰



Product Description	Item Number
40 mm × 70 mm × 2.0 mm	AFLEX201
40 mm × 50 mm × 3.0 mm	AFLEX300
40 mm × 70 mm × 3.0 mm	AFLEX301

Ordering Information

Product Description	Item Number
ArthroFLEX® Dermal Allograft 1.0 mm (Thickness = 0.76 mm - 1.24 mm)	
Decellularized Dermis With Matracell®, 40 mm × 40 mm	AFLEX400
Decellularized Dermis With Matracell, 40 mm × 70 mm	AFLEX401
Decellularized Dermis With Matracell, 20 mm × 25 mm	AFLEX402
Decellularized Dermis With Matracell, 25 mm × 30 mm	AFLEX403
ArthroFLEX 1.5 mm (Thickness = 1.26 mm - 1.74 mm)	
Decellularized Dermis With Matracell, 35 mm × 35 mm	AFLEX100
Decellularized Dermis With Matracell, 40 mm × 70 mm	AFLEX101
Decellularized Dermis With Matracell, 50 mm × 90 mm	AFLEX103
Decellularized Dermis With Matracell, 15 mm × 140 mm	AFLEX150
ArthroFLEX 4.0 mm and 5.0 mm	
Decellularized Dermis With Matracell, 25 mm × 35 mm × 4 mm	AFLEX600
Decellularized Dermis With Matracell, 25 mm × 35 mm × 5 mm	AFLEX650
Decellularized Dermis With Matracell, 40 mm × 70 mm × 4 mm	AFLEX601
Decellularized Dermis With Matracell, 40 mm × 70 mm × 5 mm	AFLEX651

Product Description	Item Number
ArthroFLEX 2.0 mm (Thickness = 1.76 mm - 2.24 mm)	
Decellularized Dermis With Matracell, 35 mm × 35 mm	AFLEX200
Decellularized Dermis With Matracell, 40 mm × 70 mm	AFLEX201
Decellularized Dermis With Matracell, 25 mm × 30 mm	AFLEX202
ArthroFLEX 3.0 mm (Thickness = 2.75 mm - 3.25 mm)	
Decellularized Dermis With Matracell, 40 mm × 50 mm	AFLEX300
Decellularized Dermis With Matracell, 40 mm × 70 mm	AFLEX301
Decellularized Dermis With Matracell, 50 mm × 60 mm	AFLEX302
BioWasher® Human Allograft Tissue 2.0 mm (Thickness = 1.76 mm - 2.24 mm)	
Decellularized Dermis With Matracell, 10 mm × 14 mm	AFLEX822

References

- Moore MA, Samsell B, Wallis G, et al. Decellularization of human dermis using non-denaturing anionic detergent and endonuclease: a review. *Cell Tissue Bank*. 2015;16(2):249-259. doi:10.1007/s10561-014-9467-4
- Gilot GJ, Alvarez-Pinzon AM, Barcksdale L, Westerdahl D, Krill M, Peck E. Outcome of large to massive rotator cuff tears repaired with and without extracellular matrix augmentation: a prospective, comparative study. *Arthroscopy*. 2015;31(8):1459-65. doi:10.1016/j.arthro.2015.02.032
- Ely EE, Figueroa NM, Gilot GJ. Biomechanical analysis of rotator cuff repairs with extracellular matrix graft augmentation. *Orthopedics*. 2014;37(9):608-614. doi:10.3928/01477447-20140825-05
- Arthrex, Inc. Data on file. Biomechanical properties of tendon augmentation material. material (LA0822-EN, TR-492) Naples, FL; 2011.
- Hirahara AM, Andersen WJ, Panero AJ. Superior capsular reconstruction: clinical outcomes after minimum 2-year follow-up. *Am J Orthop*. 2017;46(6):266-278.
- Burkhart SS, Prannum JJ, Hartzler RU. Superior capsular reconstruction for the operatively irreparable rotator cuff tear: clinical outcomes are maintained 2 years after surgery. *Arthroscopy*. 2020;36(2):373-380. doi:10.1016/j.arthro.2019.08.035
- Hartzler RU, Softic D, Qin X, Dorfman A, Adams CR, Burkhart SS. The histology of a healed superior capsular reconstruction dermal allograft: a case report. *Arthroscopy*. 2019;35(10):2950-2958. doi:10.1016/j.arthro.2019.06.024
- LifeNet Health. Data on file (65-027). Virginia Beach, VA.
- Barber FA, Aziz-Jacobo J. Biomechanical testing of commercially available soft-tissue augmentation materials. *Arthroscopy*. 2009;25(11):1233-1239. doi:10.1016/j.arthro.2009.05.01
- Aynardi MC, Atwater L, Dein EJ, Zahoor T, Schon LC, Miller SD. Outcomes after interpositional arthroplasty of the first metatarsal joint. *Foot Ankle Int*. 2017;38(5):514-518. doi:10.1177/1071100716687366
- Arthrex, Inc. Data on file (LA1-00009-EN_C). Naples, FL; 2017.
- Sterile decellularized dermis. Instructions for use (63-0050-01). Virginia Beach, VA; 2019.



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 or outcomes. LifeNet Health helps to save lives, restore health and give hope to thousands of patients each year. We are the world's most trusted provider of transplant solutions, from organ procurement to new innovations in bio-implant technologies and cellular therapies – a leader in the field of regenerative medicine, while always honoring the donors and health care professionals that allow the healing process.

View U.S. patent information at www.arthrex.com/corporate/virtual-patent-marking

arthrex.com

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