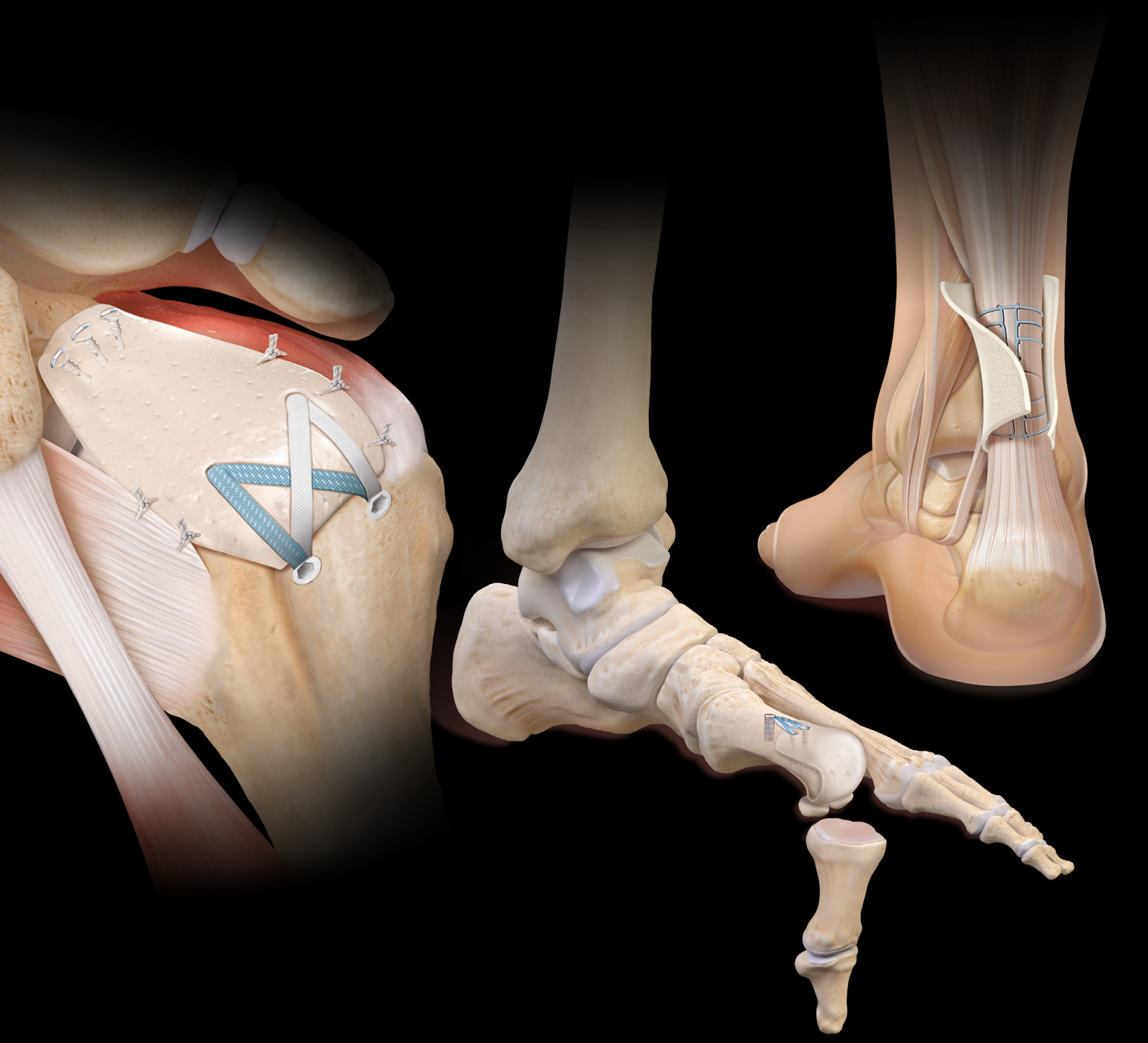
ArthroFLEX® Decellularized Bio-Implant for Soft-Tissue Repair



Arthrex®

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?

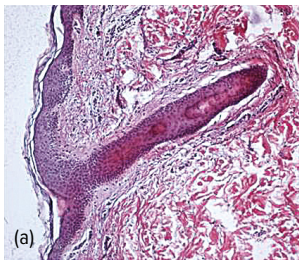
- Augmentation with ArthroFlex dermal allograft has demonstrated improved clinical outcomes[2]
- ArthroFlex dermal allograft improves the strength of the repair and protects the repair to allow healing[2,3]
- Augmentation with ArthroFlex dermal allograft can reduce re-tear rates[2,3]
- Biomechanical testing has shown that ArthroFlex dermal allograft provides high ultimate load and suture retention strength[4]
- 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 implantation[7]

ArthroFLEX®

≥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]

Processing Architecture[1,8]

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.



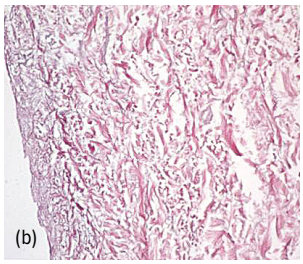
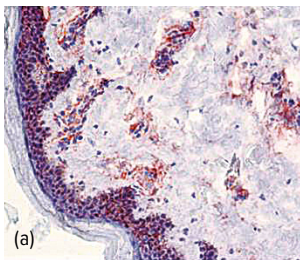


Figure 1. Human skin (a) pre and (b) post decellularization stained with hematoxylin and eosin demonstrates the removal of DNA and nuclear material as seen by lack of purple staining in (b).



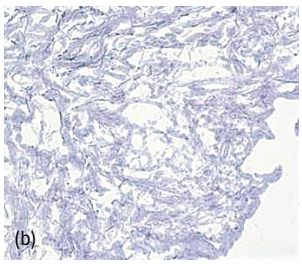
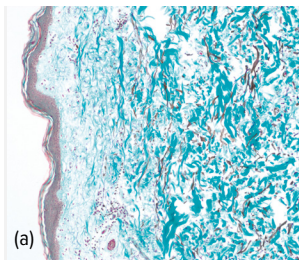


Figure 2. Human skin (a) pre and (b) post decellularization stained for major histocompatibility complex 1 staining shows reduction of potentially immunogenic components as seen by lack of red staining in (b).



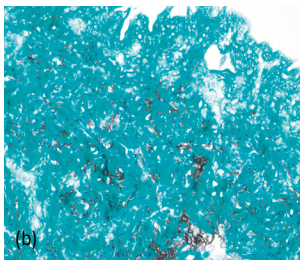
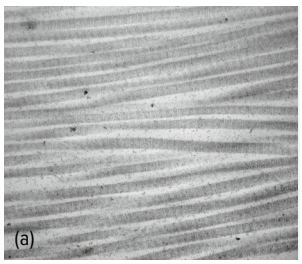


Figure 3. Elastin fibers are essential for skin elasticity. No significant difference was observed microscopically between (a) pre and (b) post decellularization on elastin fiber quantity (black stain) and distribution.



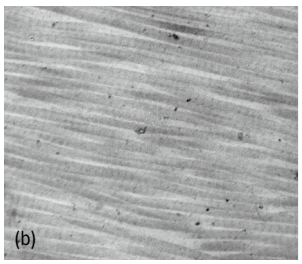


Figure 4. Transmission electron microscopy (TEM) images of 30K magnification of human skin (a) pre and (b) post decellularization and gamma irradiation demonstrates no change in collagen structure.

Performance[7]

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

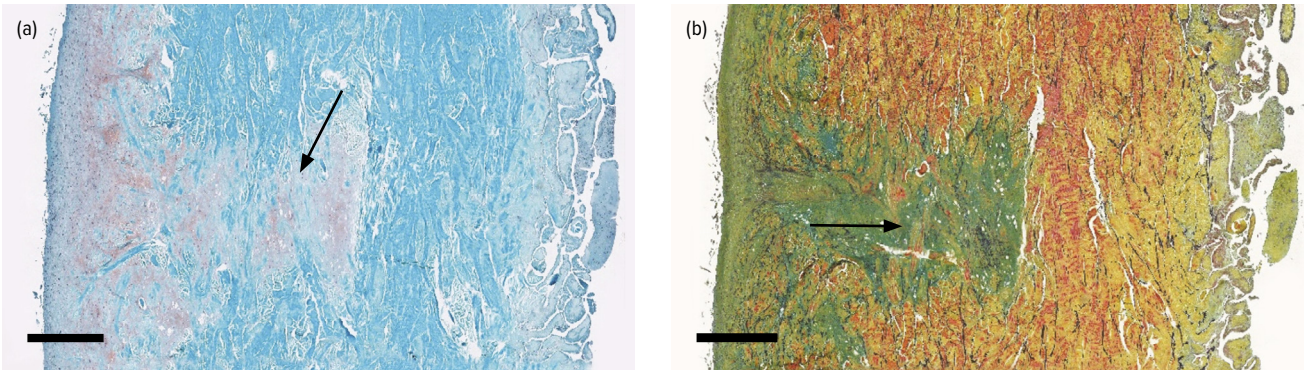


Figure 5. Development of fibrocartilage (black arrows) on articular surface demonstrated by (a) safranin O staining and (b) Russell-Movat pentachrome staining. Merged 10× images, scale bar = 500 µm.

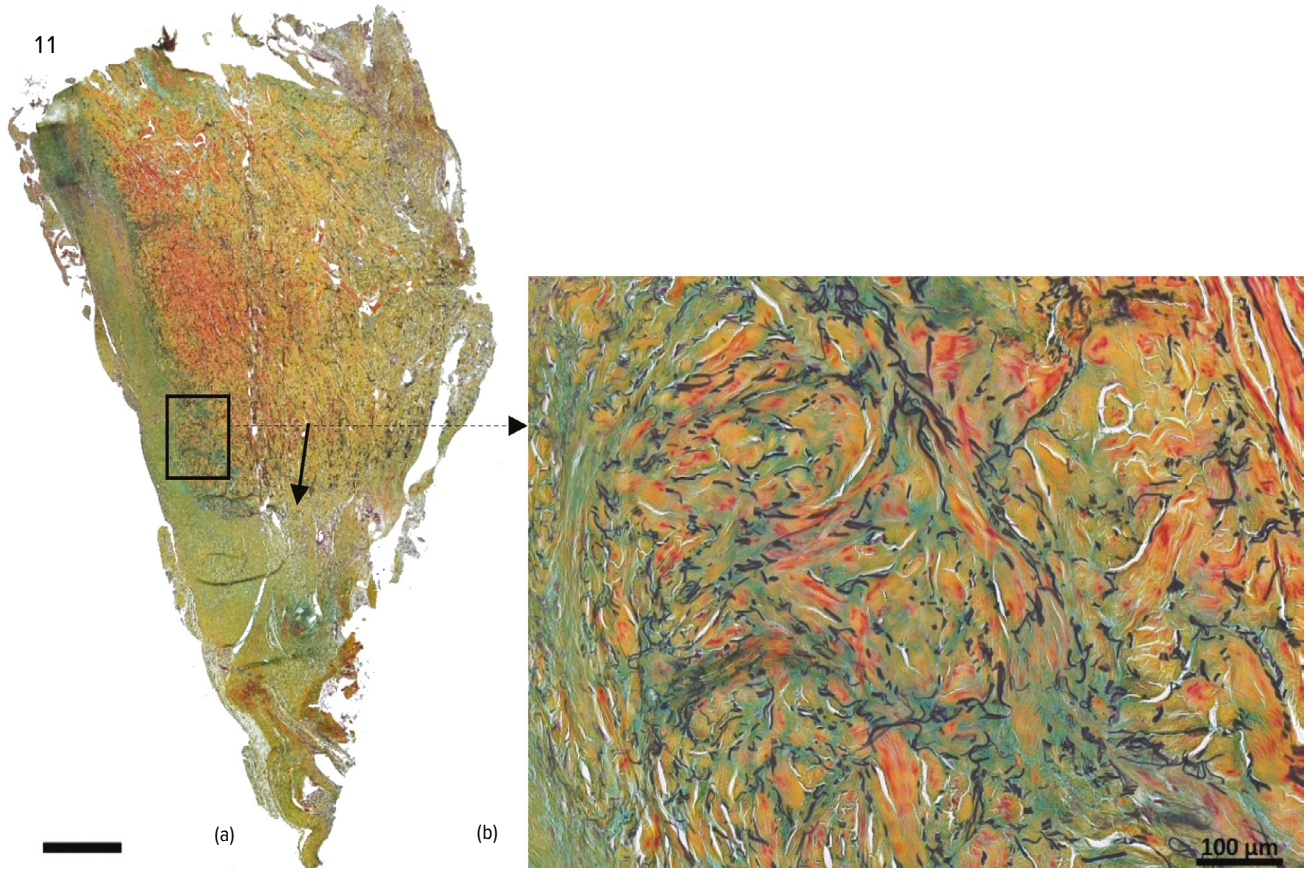
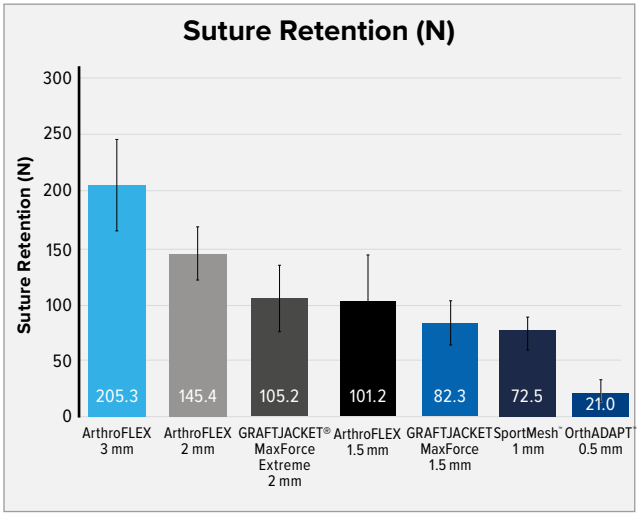


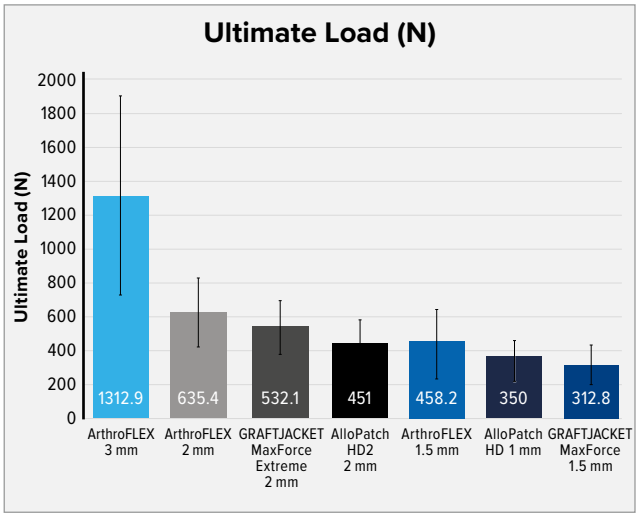
Figure 6a. Active remodeling of implanted graft tissue in piece 11 shown by Movat pentachrome staining. Image 10×, graft-host junction area indicated by black arrow.

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.

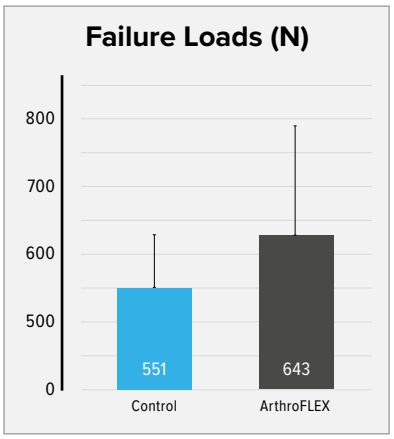
Strength[4,9]

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

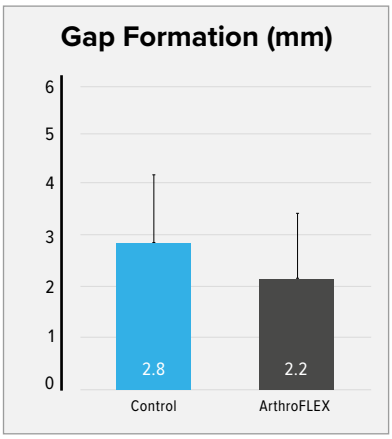




Rotator Cuff Analysis[3]



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

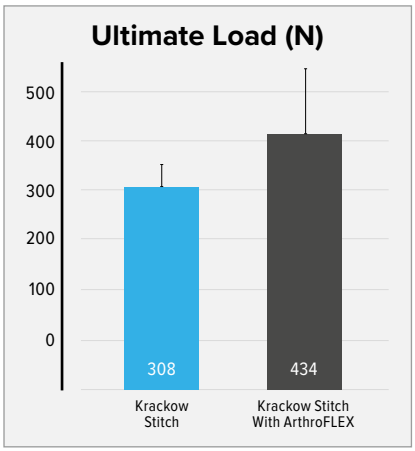


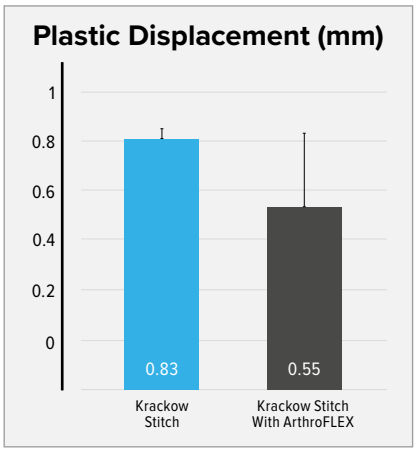
Comparison of gap formation (mm) of human dermal allograft extracellular matrix augmentation vs control.

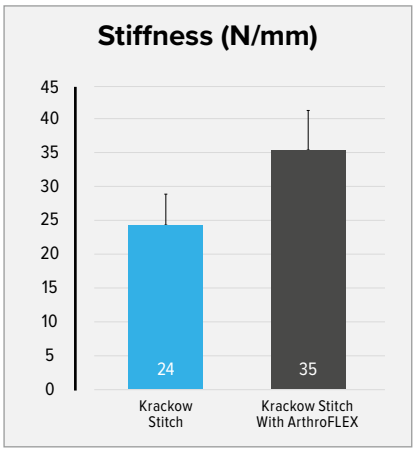
The results suggest that the human dermal allograft is able to reinforce the repair site during the early healing period.

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

Achilles Tendon Analysis[11]





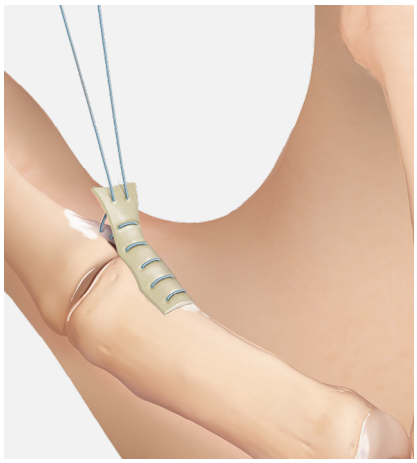


Cadaveric testing of midsubstance Achilles tendon repair with Krackow stitch alone compared to Krackow stitch augmented with ArthroFlex dermal allograft.

Potential applications

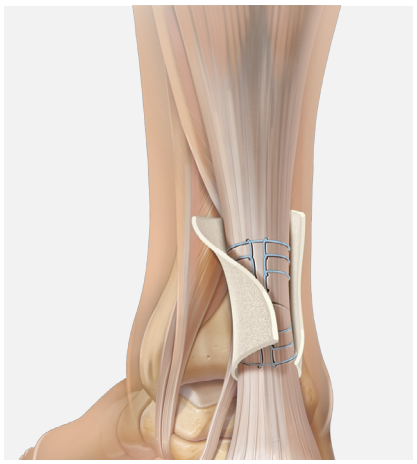
Hand/Wrist Tendon Sheath Augmentation

Product description	Item number
30 mm × 40 mm × 0.5 mm	AFLEX**500**
40 mm × 40 mm × 1 mm	AFLEX**400**



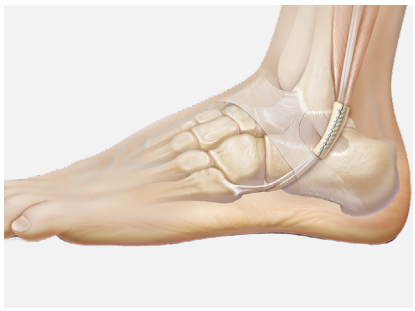
Achilles Tendon Augmentation

Product description	Item number
40 mm × 70 mm × 1 mm	AFLEX**401**
40 mm × 70 mm × 1.5 mm	AFLEX**101**
50 mm × 90 mm × 1.5 mm	AFLEX**103**
40 mm × 70 mm × 2 mm	AFLEX**201**



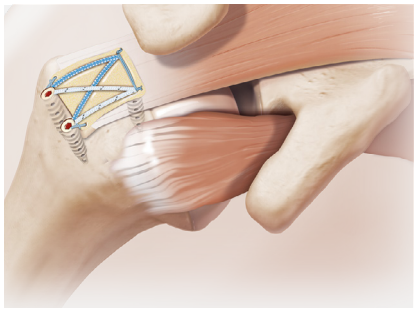
Peroneal/Tibial Tendon Augmentation

Product description	Item number
40 mm × 70 mm × 1 mm	AFLEX**401**
40 mm × 70 mm × 1.5 mm	AFLEX**101**
15 mm × 140 mm × 1.5 mm	AFLEX**150**



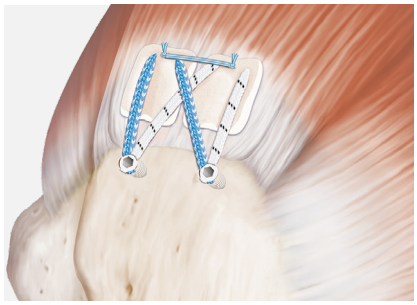
Rotator Cuff Augmentation

Product description	Item number
40 mm × 40 mm × 1 mm	AFLEX**401**
35 mm × 35 mm × 1.5 mm	AFLEX**101**
35 mm × 35 mm × 2 mm	AFLEX**200**
25 mm × 30 mm × 2 mm	AFLEX**201**
40 mm × 70 mm × 3 mm	AFLEX**301**



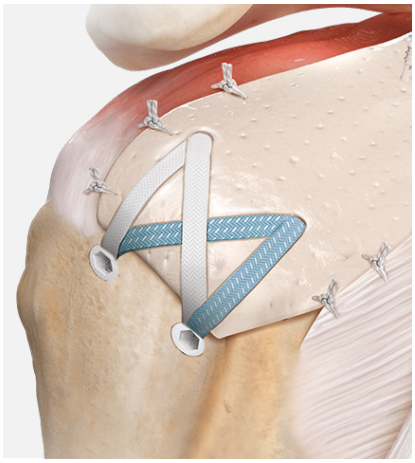
Suture Reinforcement

Product description	Item number
10 mm × 14 mm × 2 mm	AFLEX**822**



Capsular Reinforcement

Product description	Item number
40 mm × 50 mm × 3 mm	AFLEX**300**
40 mm × 70 mm × 3 mm	AFLEX**301**
50 mm × 60 mm × 3 mm	AFLEX**302**



Hallux Rigidus Arthroplasty[10]

Product description	Item number
40 mm × 70 mm × 2 mm	AFLEX**201**
40 mm × 50 mm × 3 mm	AFLEX**300**
40 mm × 70 mm × 3 mm	AFLEX**301**

Ordering Information

Product Description	Item Number
ArthroFLEX® dermal allograft, 1 mm	
Decellularized dermis w/ Matracell®, 40 mm × 40 mm	AFLEX**400**
Decellularized dermis w/ Matracell, 40 mm × 70 mm	AFLEX**401**
Decellularized dermis w/ Matracell, 20 mm × 25 mm	AFLEX**402**
Decellularized dermis w/ Matracell, 25 mm × 30 mm	AFLEX**403**
ArthroFLEX 1.5 mm	
Decellularized dermis w/ Matracell, 35 mm × 35 mm	AFLEX**100**
Decellularized dermis w/ Matracell, 40 mm × 70 mm	AFLEX**101**
Decellularized dermis w/ Matracell, 50 mm × 90 mm	AFLEX**103**
Decellularized dermis w/ Matracell, 15 mm × 140 mm	AFLEX**150**
ArthroFLEX 2 mm	
Decellularized dermis w/ Matracell, 35 mm × 35 mm	AFLEX**200**
Decellularized dermis w/ Matracell, 40 mm × 70 mm	AFLEX**201**
Decellularized dermis w/ Matracell, 25 mm × 30 mm	AFLEX**202**
BioWasher® human allograft tissue 2 mm	
Decellularized dermis w/ Matracell, 10 mm × 14 mm	AFLEX**822**

Product Description	Item Number
ArthroFLEX 3 mm	
Decellularized dermis w/ Matracell, 40 mm × 50 mm	AFLEX**300**
Decellularized dermis w/ Matracell, 40 mm × 70 mm	AFLEX**301**
Decellularized dermis w/ Matracell, 50 mm × 60 mm	AFLEX**302**
ArthroFLEX 4 mm	
Decellularized dermis w/ Matracell, 25 mm × 35 mm	AFLEX**600**
Decellularized dermis w/ Matracell, 40 mm × 70 mm	AFLEX**601**
Decellularized dermis w/ Matracell, 20 mm × 30 mm	AFLEX**603**
ArthroFLEX 5 mm	
Decellularized dermis w/ Matracell, 20 mm × 30 mm	AFLEX**652**
Decellularized dermis w/ Matracell, 25 mm × 35 mm	AFLEX**650**
Decellularized dermis w/ Matracell, 40 mm × 70 mm	AFLEX**651**

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Saving Lives. Restoring Health. Giving Hope.

Arthrex®

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.

Arthrex manufacturer, authorized representative, and importer information (Arthrex eIFUs)

US patent information

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