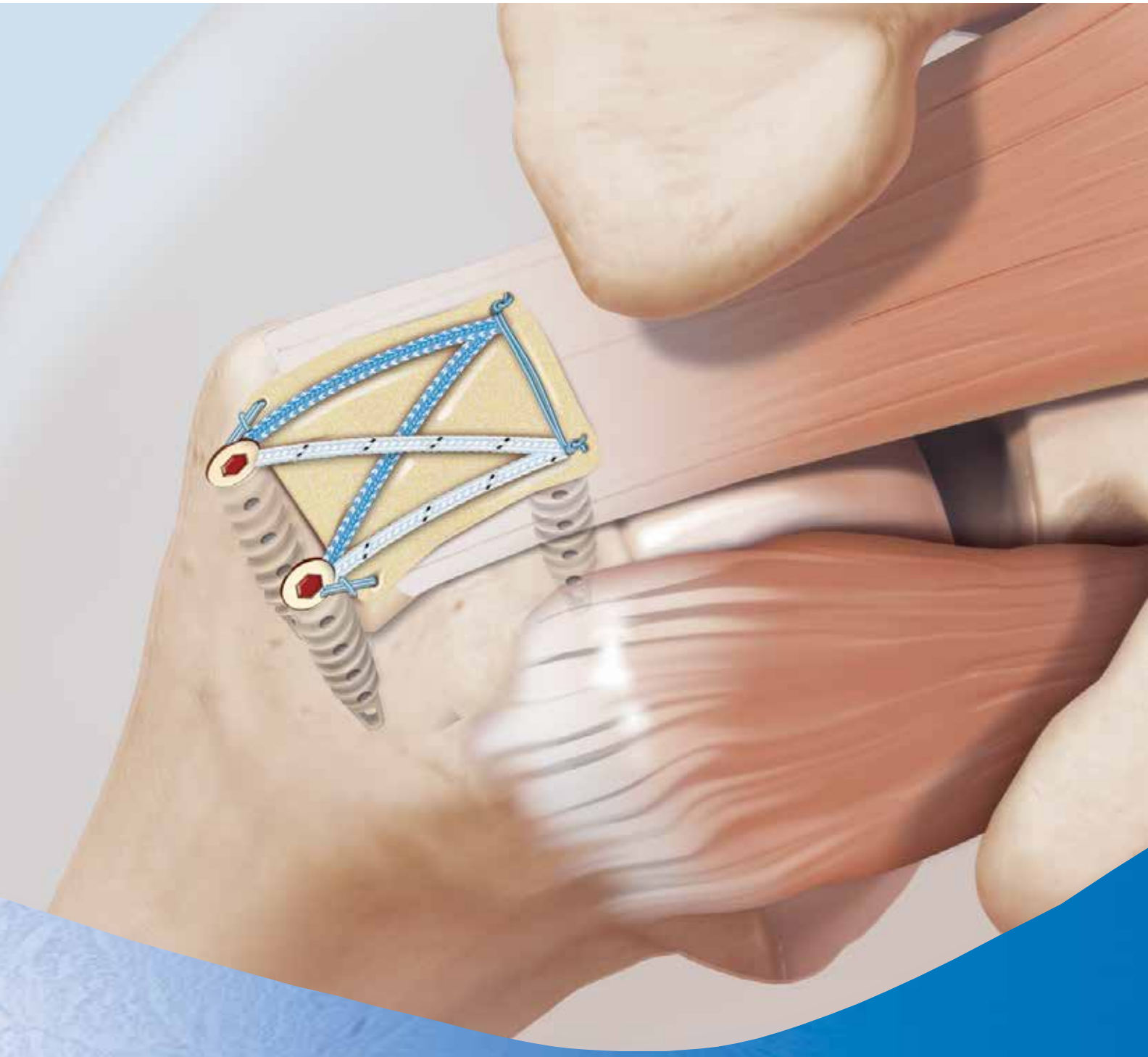
# ArthroFLEX®

Decellularized Bio-Implant for Soft Tissue Repair



LifeNet Health®
Saving Lives. Restoring Health. Giving Hope.

Arthrex®

# ArthroFLEX®

Decellularized Bio-Implant for Soft Tissue Repair

## HIGH PERFORMANCE EXTRACELLULAR MATRIX

ArthroFLEX® is an acellular dermal extracellular matrix (ADM) intended for supplemental support and covering for soft tissue repair. Matracell®, a patented and validated process by LifeNet Health, renders the ArthroFLEX allograft dermis acellular, without compromising biomechanical or biochemical properties. This process allows the matrix to retain its growth factors, native collagen scaffold, and elastin, which are required for healing.

ArthroFLEX is treated with Preservon®, a proprietary and patented preservation technology that allows the graft to be fully hydrated at room temperature.

| | |
|---|---|
| › 97% DNA Removed | Biocompatible |
| Intact Acellular Extracellular Matrix | Provides a strong, clean, collagen scaffold for host cellular and vascular ingrowth. |
| Convenience | Excellent handling. Ready to use. Room temperature storage (15˚ - 30˚ C) |
| Safety | $10^{-6}$ SAL (Sterility Assurance Level) Contains less than a single viable particle out of 1 million. |
| Promotes Rapid Healing | Retains growth factors, elastin, keratin, matrikines, cytokines, and collagens |

## WHY USE ARTHROFLEX?

- Augmentation with ArthroFLEX has demonstrated improved clinical outcomes[5]
- Augmentation with ArthroFLEX provides improved strength to protect repair to allow healing[1-5]
- Augmentation with ArthroFLEX can reduce re-tear rates.[1-5]
- ArthroFLEX has high ultimate load and suture retention strength.[2,3,6]

# PROCESSING ARCHITECTURE[7]

Matracell® removes donor DNA from the dermal matrix, without causing damage or crosslinking, ensuring a biocompatible scaffold to facilitate repair.

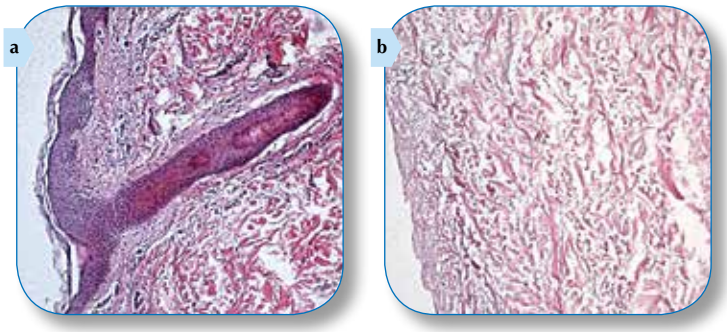



**Figure 1:** Human skin pre (a) and post (b) decellularization (Hematoxylin and Eosin staining). The Matracell process is designed to remove cellular materials from tissue. As shown in Figures 1(a) and 1(b), histological analysis demonstrates removal of cellular and potentially immunogenic components.

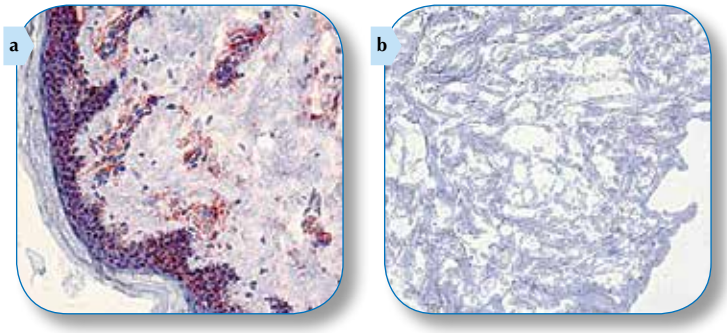



**Figure 2:** Human skin pre (a) and post (b) decellularization (Major Histocompatibility Complex 1 staining) *Note absence of MHC 1 staining material in ArthroFLEX.*

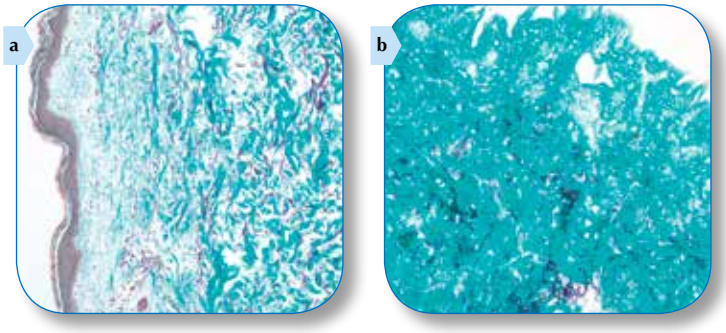



**Figure 3:** Elastin fibers are essential for skin elasticity. No significant difference was observed microscopically between pre (a) and post (b) decellularization on elastin fiber quantity and distribution.

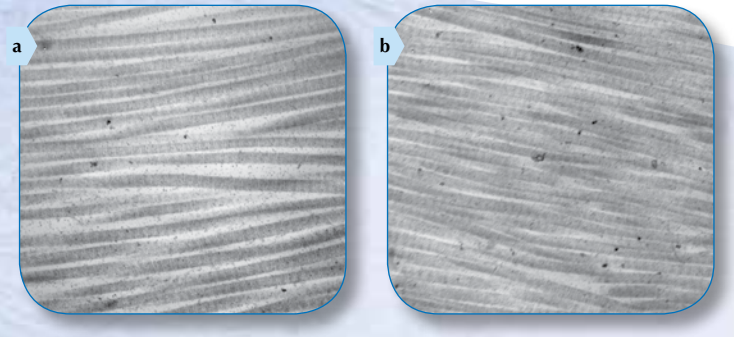
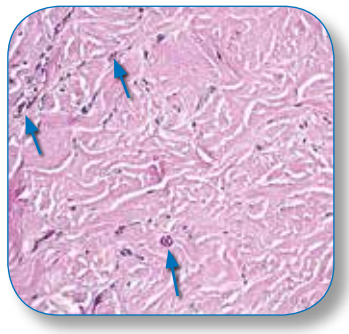



**Figure 4:** Human skin pre (a) and post (b) decellularization Electron Microscopy images of dermal collagen fibrils at 30K magnification shows no change in the collagen structure.

# PERFORMANCE[7]

An intact acellular matrix of collagen, elastin and growth factors provides a clean scaffold intended for supplemental support and covering for soft tissue repair.

**Figure 5:** ArthroFLEX® explanted after four weeks *in vivo* in a subcutaneous mouse model. Hematoxylin and Eosin staining was used to identify blood vessels (identified by arrows) in the explanted tissue.



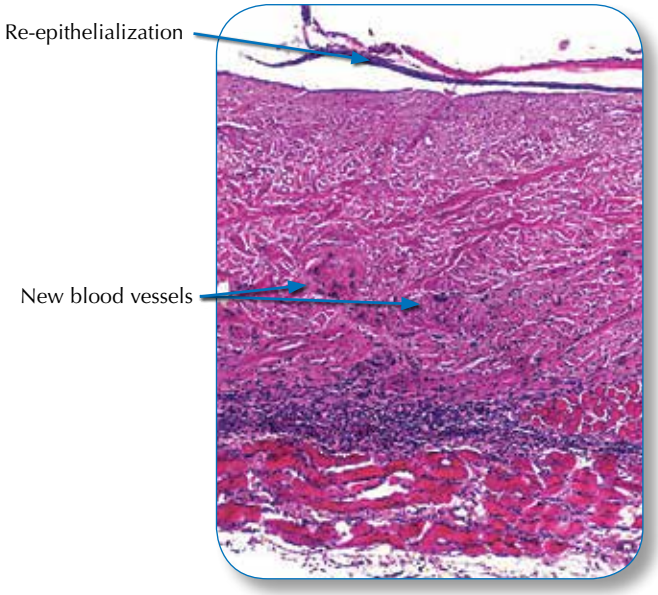
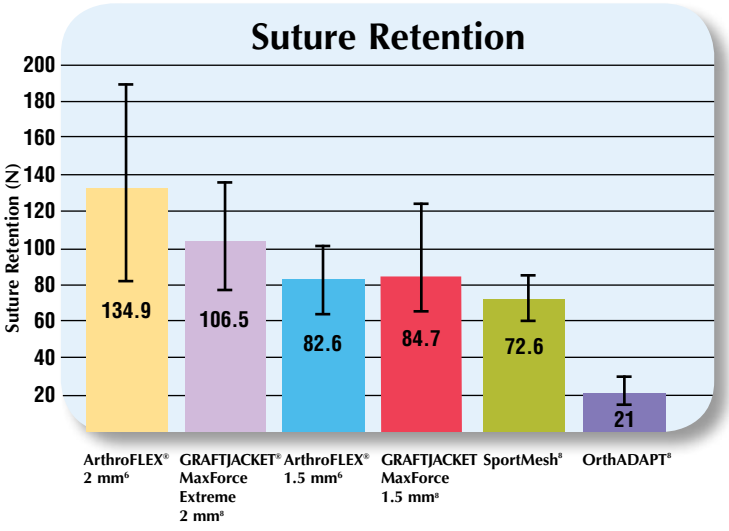
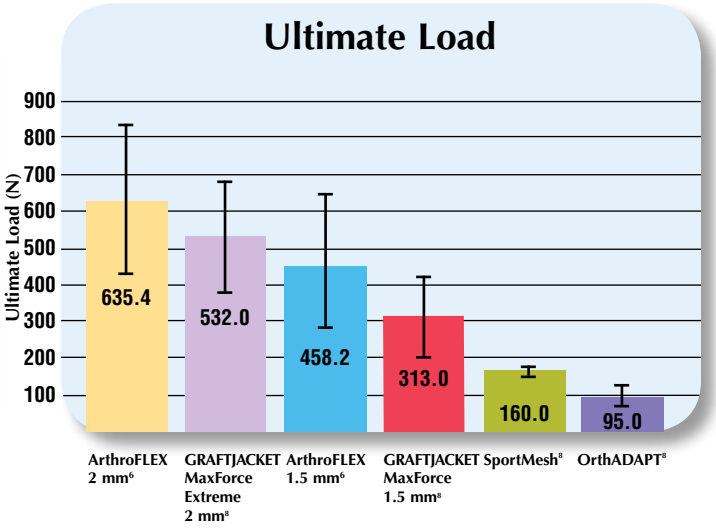



**Figure 6:** Histological analysis of Matracell Dermis explants using nude mouse skin excisional model. The implant was in place for 16 days prior to excision and analysis. The stain is Hematoxylin and Eosin for general cellular features. Note the presence of features indicating new blood vessels and epithelial layer.

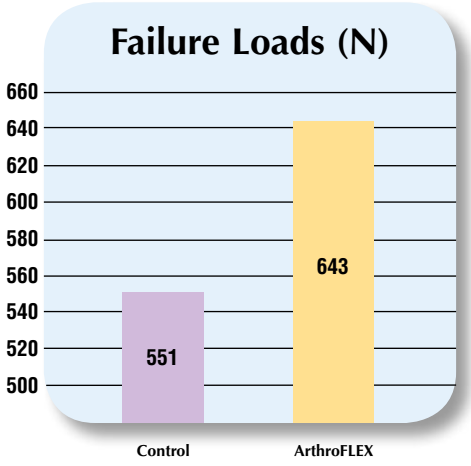
# STRENGTH[6, 8]

Elastin and collagen provide unparalleled strength for supplemental support and covering for soft tissue repair.

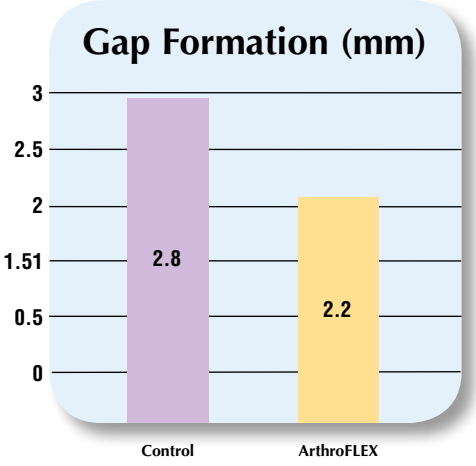



# ROTATOR CUFF ANALYSIS[3]




Comparison of failure loads (N) of human dermal allograft extra-cellular matrix augmentation vs control.

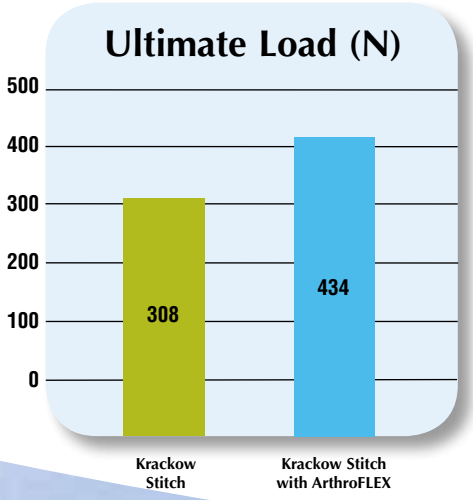


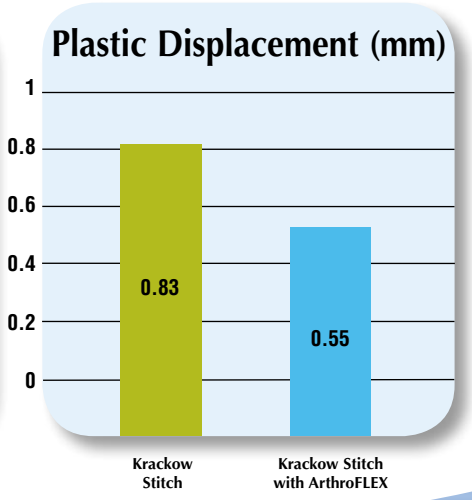

Comparison of gap formation (mm) of human dermal allograft extra-cellular matrix augmentation vs control.

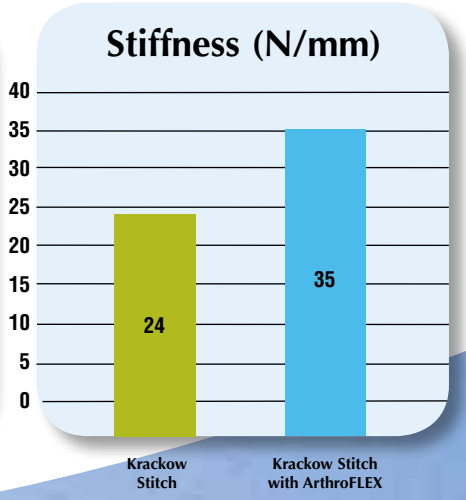
The results suggest that the human dermal allograft is able to provide load sharing to protect the repair site during the early healing period.

- Decreased gap formation = graft helps hold tendon down to bone
- Increased failure load = improved strength of repair

# ACHILLES TENDON ANALYSIS[6]




Cadaveric testing of midsubstance Achilles tendon repair with Krackow stitch alone compared to Krackow stitch augmented with ArthroFLEX.

# ARTHROFLEX® PRODUCT GUIDE

## Hand/Wrist Tendon Sheath Augmentation

AFLEX500 (30 mm x 40 mm x .5 mm)
AFLEX400 (40 mm x 40 mm x 1.0 mm)

## Achilles Tendon Augmentation

AFLEX401 (40 mm x 70 mm x 1.0 mm)
AFLEX101 (40 mm x 70 mm x 1.5 mm)
AFLEX103 (50 mm x 90 mm x 1.5 mm)
AFLEX201 (40 mm x 70 mm x 2.0 mm)

## Peroneal/Tibial Tendon Augmentation

AFLEX401 (40 mm x 70 mm x 1.0 mm)
AFLEX101 (40 mm x 70 mm x 1.5 mm)
AFLEX150 (15 mm x 140 mm x 1.5 mm)

## Rotator Cuff Augmentation

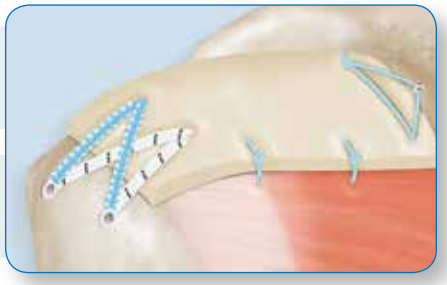
AFLEX400 (40 mm x 40 mm x 1.0 mm)
AFLEX100 (35 mm x 35 mm x 1.5 mm)
AFLEX200 (35 mm x 35 mm x 2.0 mm)
AFLEX301 (40 mm x 70 mm x 3.0 mm)

## Suture Reinforcement

AFLEX822 (10 mm x 14 mm x 2.0 mm)

## Capsular Reinforcement

AFLEX301 (40 mm x 70 mm x 3.0 mm)

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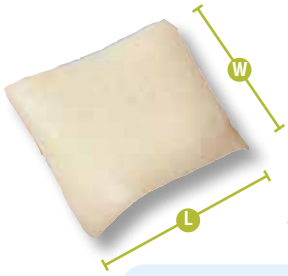
6. Data on file at Arthrex, Inc.
7. Data on file at LifeNet Health
8. Barber and Aziz-Jacobo, Selected data was derived from Figure 3 (Suture Pull-out) and Table 1 (Ultimate Tensile Strength) of this reference. The two studies were performed at different points in time; however, the exact same methods, fixtures, material testing machine, and facility were used for both studies. *Arthroscopy*, 2009; 25: 1233-1239.




# ArthroFLEX®

## ArthroFLEX Decellularized Dermis

| Product | Description | Size |
|---|---|---|
| | **ArthroFLEX 0.5 mm (Thickness = 0.3 mm - 1.0 mm)** | |
| AFLEX500 | Decellularized Dermis with MATRACELL | 30 x 40 mm |
| | **ArthroFLEX 1.0 mm (Thickness = 0.76 mm - 1.24 mm)** | |
| AFLEX400 | Decellularized Dermis with MATRACELL | 40 x 40 mm |
| AFLEX401 | Decellularized Dermis with MATRACELL | 40 x 70 mm |
| | **ArthroFLEX 1.5 mm (Thickness = 1.26 mm - 1.74 mm)** | |
| AFLEX100 | Decellularized Dermis with MATRACELL | 35 x 35 mm |
| AFLEX101 | Decellularized Dermis with MATRACELL | 40 x 70 mm |
| AFLEX103 | Decellularized Dermis with MATRACELL | 50 x 90 mm |
| AFLEX150 | Decellularized Dermis with MATRACELL | 15 x 140 mm |
| | **ArthroFLEX 2.0 mm (Thickness = 1.76 mm - 2.24 mm)** | |
| AFLEX200 | Decellularized Dermis with MATRACELL | 35 x 35 mm |
| AFLEX201 | Decellularized Dermis with MATRACELL | 40 x 70 mm |
| | **ArthroFLEX 3.0 mm (Thickness = 2.75 mm - 3.25 mm)** | |
| AFLEX301 | Decellularized Dermis with MATRACELL | 40 x 70 mm |
| | **BioWasher 2.0 mm (Thickness = 1.76 mm - 2.24 mm)** | |
| AFLEX822 | Decellularized Dermis with MATRACELL | 10 x 14 mm (2 pack) |

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*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.*

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.