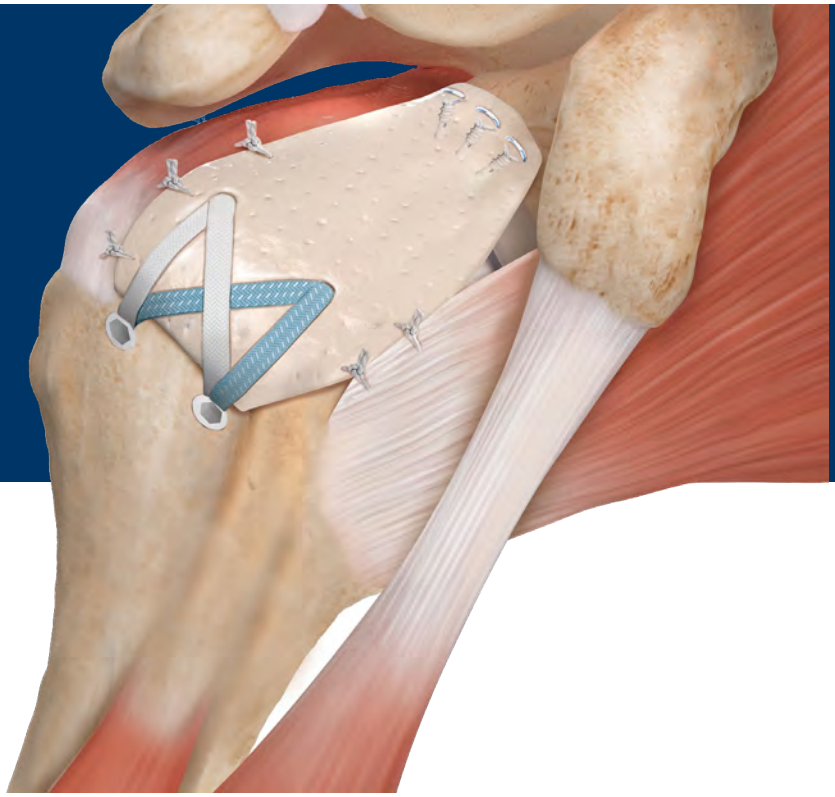
ArthroFLEX® SCR

The Gold Standard for Superior Capsular Reconstruction



TECHNICAL OVERVIEW

The proven acellular dermal matrix (ADM) fueled by innovation and backed by clinical outcomes.

Arthrex®

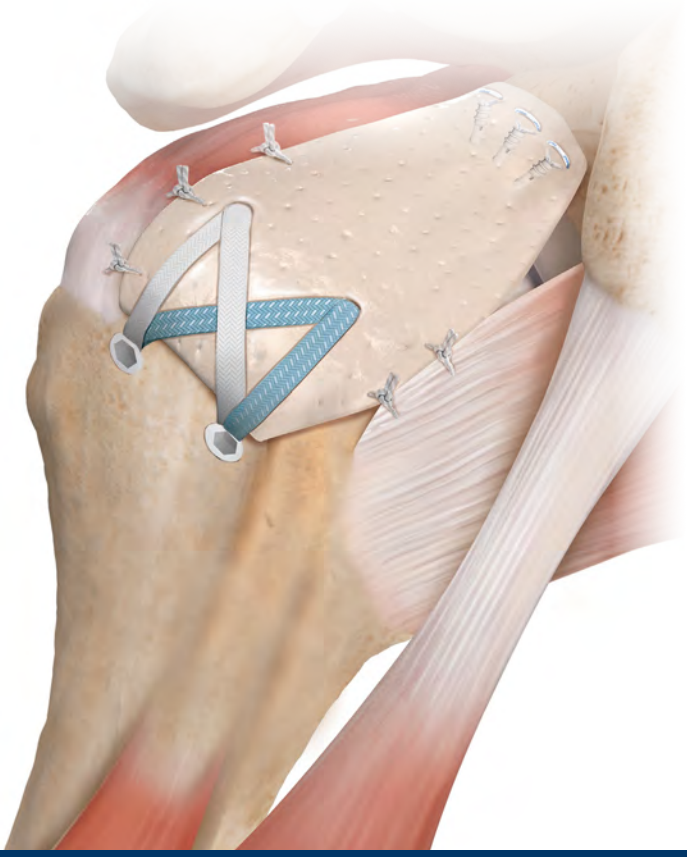
LifeNet Health®
Saving Lives. Restoring Health. Giving Hope.

ArthroFLEX® SCR

The Gold Standard for Superior Capsular Reconstruction

Superior Capsular Reconstruction (SCR)

Reconstruction of the superior capsule using ArthroFlex to provide a supplemental covering to the glenohumeral joint which keeps the humeral head centered on the glenoid, thereby restoring normal joint biomechanics and stability.



Why perform SCR?

- **Restores glenohumeral joint stability, allowing return of function and ROM[1-4]**
- **Reduces pain and improves patient-reported outcome scores[1-4]**
- **Increases acromiohumeral distance[3]**
- **Allograft tissue that has been shown to incorporate versus metal and plastic solutions[5]**
- **Minimally invasive – can be performed arthroscopically[1-4]**
- **Viable alternative to arthroplasty[1,3,4]**

"Our data showed SCR with dermal allograft effectively restored the superior restraints in the glenohumeral joint and yielded outstanding clinical outcomes even after 2 years, making it an excellent viable alternative to RTSA."[3]

(Hirahara et al, 2017)

Not all ADMs are the same.

ArthroFlex is the only truly **"decellularized"** acellular dermal matrix (ADM) for use in Superior Capsular Reconstruction.

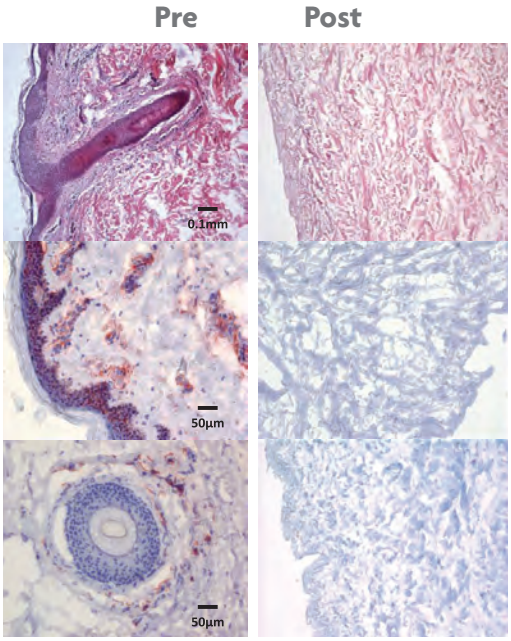
Although several dermal products claim to be "decellularized", not all decellularization processes meet the definition developed by Crapo, Gilbert and Badylak.[7] After evaluating remodeling responses and adverse cell and host responses, the authors determined that an ADM needs to meet certain criteria to satisfy the intent of decellularization.

Inadequate decellularization leaves DNA and residual cellular material in allografts that can elicit adverse host reactions and negate constructive tissue remodeling.

ArthroFlex has been shown to meet these decellularization criteria:

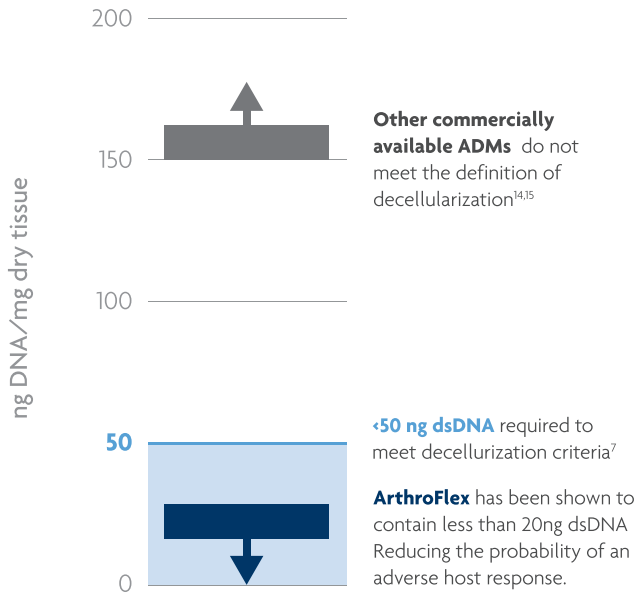
Lack of visible nuclear material in tissue

Histology demonstrates removal of DNA and potentially immunogenic components



‹50 ng dsDNA per mg ECM dry weight

ArthroFlex has been shown to contain less than 10 ng DNA/mg dry tissue



Decellularization and Preservation Technology Platforms Deliver Results while Preserving the Graft's Natural Ultrastructure.

MATRACELL™
The FUTURE Of Allograft Bio-Implant DECELLULARIZATION

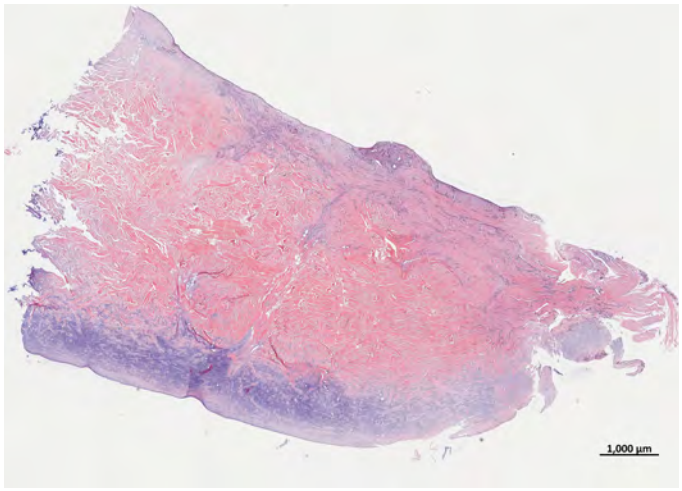
Process	Chemicals	Mode of Action and Potential impact
Matracell® Technology (ArthoFlex)	• N-Lauroyl sarcosinate (NLS)	• Non-denaturing detergent that effectively and efficiently solubilizes and removes cells and cellular remnants from the tissue while leaving the ECM biomechanically and physiologically intact.[5]
	• Endonuclease	• Effectively fragments DNA for removal.[7]
Tutoplast® (Matrix HD®)	• Acetone	• Removes lipids from tissue[8], but crosslinks and precipitates proteins, including collagen.[7]
	• Sodium hydroxide	• Reduces prion infectivity,[8] disrupts nucleic acids and may damage collagen, GAG, and growth factors.[7]
	• Hydrogen peroxide	• Oxidative treatment to remove soluble proteins and destroy viruses and bacterial spores.[8]
	• Hydrogen peroxide	• May damage collagen, GAG, and growth factors.[7]
Other Known Processing Reagents (GraftJacket® AlloPatch HD®)	• PolySorbate 20	• May disrupt and dissociate proteins in the ECM. [7]
	• Peracetic Acid	• Disinfection agent that can remove residual nucleic acid[7] but does not sufficiently remove cells.[12]
	• NaCl	• Lyses cells, but does not effectively remove cellular residues.[7]
	• Triton	• May effectively remove cell from tissue, but disrupts ECM.[7]
"Proprietary" (AlloMend® Coll-e-Derm™)	• Unknown	• Unknown impact on tissue

PRESERVON®
The FUTURE Of Allograft Bio-Implant PRESERVATION

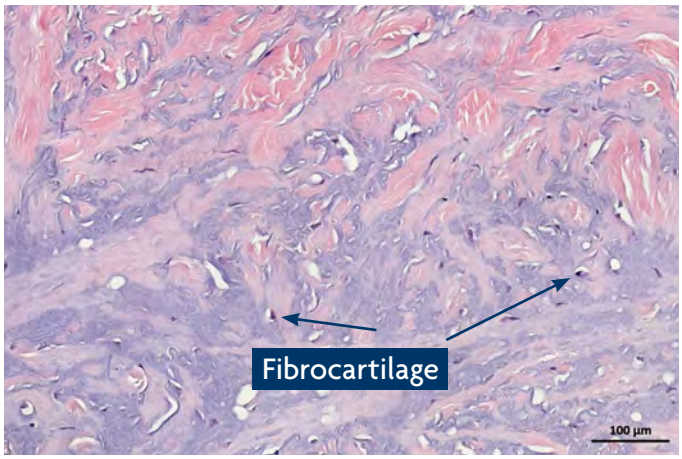
- Creates an environment that prevents free-water mediated degradation of the ECM[14]
- Maintains handling & suturability
- Allows for long term ambient storage.[13]
- No impact to graft.[13] Growth factors are retained.[13]

Other preservation methods such as ethanol, sterile water, freeze-drying and solvent dehydration may be less expensive; but they can also damage the ECM and negatively impact its biomechanical and biochemical properties.[7,9,10]

Biological Incorporation of ArthroFlex in Superior Capsular Reconstruction for Irreparable Rotator Cuff Repair.[5]



Cross-sectional view of quarter 1. Medial glenoid attachment is to the right, articular side is at the bottom of the image.



Identified fibrocartilage on explanted ArthroFlex.

Case Study*

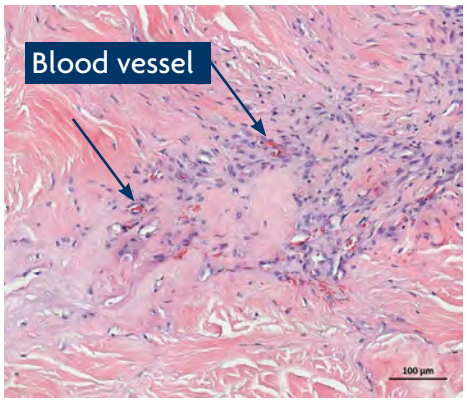
SCR with ArthroFlex SCR performed in 2015

- Sustained shoulder injury 10 weeks post-operative, and MRIs showed repair failure - suspected to be as a result of the fall.
- Graft explanted during a debridement surgery 13 months post-operative.

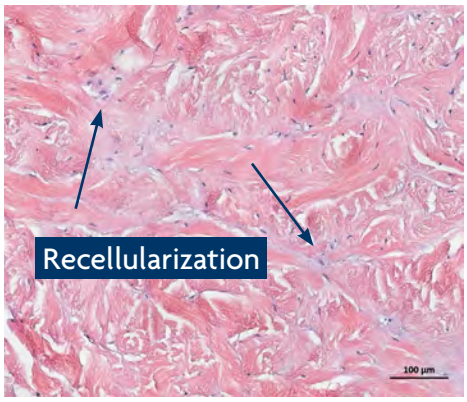
The graft was explanted during a debridement surgery 13 months post-op, sent to LifeNet Health courtesy of Dr. Lederman and prepared for histological analysis

Histological Analysis

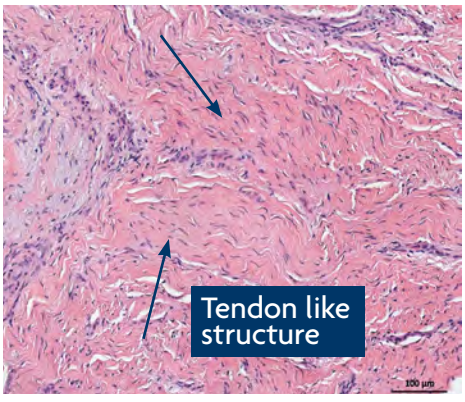
The explant sample was dissected to four quarters via the mid-line, formalin-fixed, paraffin-embedded, cross-sectioned, and stained with hematoxylin and eosin (H&E) for analysis. Histological analysis showed that ArthroFlex maintained the acellular dermal matrix structure. Infiltrated fibroblast-like cells and neovascularization were present. The center of the ArthroFlex tissue remained acellular and avascular, while no signs of necrosis or calcification were observed. Tendon-like tissue structure was found near the glenoid attachment point.



Abundant blood vessel formation on explanted ArthroFlex.



Recellularization observed on explanted ArthroFlex.



Tendon-like structures noted on explanted ArthroFlex.

* Results from case studies are not predictive of results in other cases. Results in other cases may vary.

Why Use ArthroFlex SCR?

- **ArthroFlex is the only truly decellularized ADM with published clinical results for SCR**
- **ArthroFlex SCR has been shown to be clinically effective[1-4,6]**
- **Shown to restore anatomy and biomechanical properties[1-4,6]**
- **Shown to revascularize, remodel and incorporate[5,13]**
- **Excellent ultimate load and suture retention strength[5,13]**
- **Ready to use and excellent handling**

To order: Contact your local LifeNet Health Representative or Arthrex Technical Consultant.

Order Code	Size
AFLEX301	4 x 7 cm, 2.5 - 3.5 mm thickness
AFLEX300	4 x 5 cm, 2.5 - 3.5 mm thickness

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