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.
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.”\(^5\)

(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. 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
- ArthroFlex has been shown to contain less than 10 ng DNA/mg dry tissue
- <50 ng dsDNA per mg ECM dry weight
- Other commercially available ADMs do not meet the definition of decellularization
- <50 ng dsDNA required to meet decellularization criteria
- ArthroFlex has been shown to contain less than 20ng dsDNA
  Reducing the probability of an adverse host response.
Decellularization and Preservation Technology Platforms Deliver Results while Preserving the Graft’s Natural Ultrastructure.

<table>
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<tr>
<th>Process</th>
<th>Chemicals</th>
<th>Mode of Action and Potential impact</th>
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| Matracell® Technology          | 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.  
• Effectively fragments DNA for removal. |
| (ArthoFlex)                    | Endonuclease                     |                                                                                                     |
| Tutoplast®                     | Acetone                          | • Removes lipids from tissue, but crosslinks and precipitates proteins, including collagen.           |
| (Matrix HD®)                   | Sodium hydroxide                 | • Reduces prion infectivity, disrupts nucleic acids and may damage collagen, GAG, and growth factors.|
|                                | Hydrogen peroxide                | • Oxidative treatment to remove soluble proteins and destroy viruses and bacterial spores.            |
|                                | Hydrogen peroxide                | • May damage collagen, GAG, and growth factors.                                                     |
| Other Known Processing Reagents| PolySorbate 20                   | • May disrupt and dissociate proteins in the ECM.                                                    |
| (GraftJacket®                  | Peracetic Acid                   | • Disinfection agent that can remove residual nucleic acid but does not sufficiently remove cells.  |
| (AlloPatch HD®)                | NaCl                             | • Lyses cells, but does not effectively remove cellular residues.                                     |
|                                | Triton                           | • May effectively remove cell from tissue, but disrupts ECM.                                          |
| “Proprietary”                  | Unknown                          | • Unknown impact on tissue                                                                          |
| (AlloMend®                     |                                  |                                                                                                     |
| (Coll-e-Derm™)                 |                                  |                                                                                                     |

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

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

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.

* 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.

<table>
<thead>
<tr>
<th>Order Code</th>
<th>Size</th>
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<tbody>
<tr>
<td>AFLEX301</td>
<td>4 x 7 cm, 2.5 - 3.5 mm thickness</td>
</tr>
<tr>
<td>AFLEX300</td>
<td>4 x 5 cm, 2.5 - 3.5 mm thickness</td>
</tr>
</tbody>
</table>

References

8. Schoepg, C. The Tutoplast® Process: A Review of Efficacy. 4627 R0 02-28-08