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“The BioWick™ technology is an exciting innovation supported by robust scientific evidence that allows me to use my same surgical techniques for rotator cuff repair.”

Mark Frankle, MD  
Florida Orthopaedic Institute
Addressing an Unmet Need in Rotator Cuff Repair

There are approximately 450,000 rotator cuff tears repaired annually in the United States. Traditional solutions focus on improving the mechanical attachment of the tendon, but the biology of the repair is not always addressed. The lack of tendon-bone healing greatly influences the well-known 30% or more published failure rate of moderately sized or greater rotator cuff repairs; this is why current research has focused on solutions to improve the biology at the tendon-bone interface.\(^1\)

Many current concepts and new techniques have attempted to address the biological issue yet no single solution has been successful. For example, bone marrow venting (also known as “Crimson Duvet”), has portrayed some clinical benefit, but comes with a risk of weakening the footprint through decortication. Grafts (i.e. “patches”) have shown value for augmenting torn tissue and promoting tissue thickening on the bursal side, yet can be time consuming to implant and are typically placed on top of the rotator cuff, not interpositional – where healing occurs. To summarize, these concepts have yet to adequately address the biology of the repair.

Cayenne Medical sought to address the well-known failure rate by introducing a solution unlike any other product on the market. BioWick™ was designed with the intent to address the unmet need of rotator cuff repair failures while preserving bone and maintaining a surgeon’s standard practice.

Introduction

BioWick™ is an interpositional bioresorbable scaffold wick composed of aligned, polylactide-co-glycolic acid (i.e. PLGA) microfibers designed to mimic the extracellular matrix (collagen) of the rotator cuff tendon. By placing the BioWick™ product at the tendon-bone interface, BioWick™ is offering surgeons an entirely new category for patients with rotator cuff tears.

The BioWick™ SureLock® Implant delivers integrated anchor technology allowing surgeons to place the implant between tendon and bone using current standard arthroscopic techniques while reducing bone removal via a smaller pilot hole.

“The BioWick™ design attempts to address the large, well known high failure rate of rotator cuff repairs without changing the surgical technique or increasing O.R. time. The revolutionary design has changed the way I think about improving the problem at the tendon bone interface.”

Joseph Abboud, MD
The Rothman Institute in Philadelphia
Design Rationale of BioWick

Positioning:

Interpositional, Bioresorbable Scaffold Wick

- Arthroscopically deployed between tendon and bone
- Scaffold is placed at the tendon-bone interface

Structure & Material:

Aligned Fibers Designed to Mimic RTC Collagen

- Bioresorbable scaffold wick is composed of aligned, PLGA microfibers with the design intent to mimic the extracellular matrix (collagen) of the rotator cuff tendon.\(^2\)
- Research has shown scaffolds with a specific fiber diameter and alignment encourage fibroblasts to have similar orientation as the scaffold fibers.\(^3\)
  - To contrast, randomly oriented fibers have shown more random fibroblast orientation.\(^3\)

Porous Bioresorbable Scaffold Wick Design

- BioWick™ bioresorbable scaffold wick is approximately 80% porous

References

Preclinical Data

BioWick™ GLP Sheep Study Conducted at Colorado State University

The randomized, controlled 56 animal sheep study yielded statistically significant improvements in the treated group versus the control group.*

Improved Healing Parameters

- Higher percentage of perpendicular fibers at the tendon-bone interface
- Higher percentage of tendon-bone integration with tissue
- Greater new bone formation at the tendon-bone interface
- Higher levels of Collagen III

Safety: The study indicated no persistent test article-related toxicologically relevant histopathologic findings compared to control.

Control group: BioWick™ SureLock® Implant minus wick component with the same repair construct as the treated group.

Correlation of Histology and Biomechanical Results

Correlation analyses show a statistically significant, positive, linear correlation between increased levels of the following parameters and increased failure load at 12 weeks vs. control group:

- Percent perpendicular fibers at tendon-bone interface
- New bone formation at tendon-bone interface
- Percent tendon-bone integration with tissue
- Levels of Collagen III

*Animal study outcomes are not necessarily predictive of human results
Surgical Technique

Simple, Reproducible Delivery

- Integrated anchor technology allows implant to be placed in between tendon and bone using the surgeon’s current arthroscopic technique – requiring no extra steps in surgical procedure

1. Drill pilot hole
2. Insert implant into drill guide and orient scaffold wick in lateral direction
3. Insert implant into pilot hole
4. Rotate knob to deploy fixation
5. Implant fully deployed beneath cortex
6. Retract inserter to release bioresorbable scaffold wick
7. Bioresorbable scaffold wick is easily placed at the tendon-bone interface
8. Pass sutures and finalize repair with preferred technique

Reduced Bone Removal

- Requires smaller pilot hole compared to traditional fixation methods
- No need for decortication to create bleeding bony bed

Comprehensive surgical technique guide available on cayennemedical.com
**Indication**

The BioWick™ SureLock® Implant is intended to be used for the reattachment of soft tissue to bone in rotator cuff repairs.

**Ordering Information**

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Interpositional Bioresorbable Scaffold Wick for Rotator Cuff Repair

This description of technique is an educational tool and clinical aid to assist properly licensed medical professionals in the usage of specific Cayenne Medical products. The medical professional should rely on their own training and experience and should conduct a thorough review of pertinent medical literature as well as the product’s Instructions For Use.

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