

BioWick®

Interpositional Bioresorbable Scaffold Wick
for Rotator Cuff Repair

Datasheet



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Addressing an Unmet Need in Rotator Cuff Repair

There are approximately 450,000 rotator cuff tears repaired annually in the United States.¹ 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 address the biology at the tendon-bone interface.²

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.³ 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. **The BioWick Implant 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 fiber alignment of the extracellular matrix (collagen) of the rotator cuff tendon. By placing the BioWick product at the tendon-bone interface, the BioWick implant is offering surgeons an entirely alternative approach for patients with rotator cuff tears.

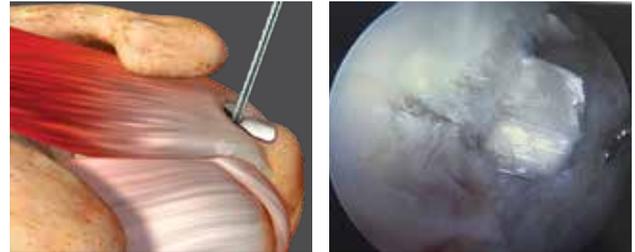
The BioWick SureLock[®] Implant delivers integrated anchor technology allowing surgeons to place the implant between tendon and bone using current standard arthroscopic techniques with minimum bone removal because of a small pilot hole.

Design Rationale

Positioning

Interpositional, Bioresorbable Scaffold Wick

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



Structure and Material

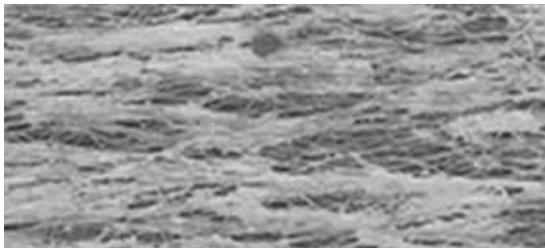
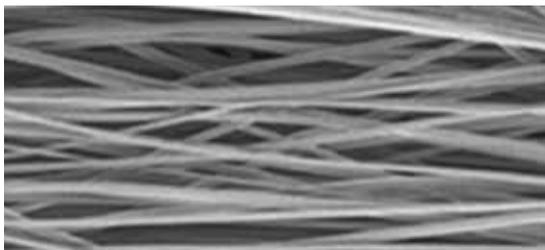
Aligned Fibers Designed to Mimic RTC Collagen

- Bioresorbable scaffold wick is composed of aligned, PLGA microfibers with the design intent to mimic the fiber alignment of the extracellular matrix (collagen) of the rotator cuff tendon⁴
- Research has shown scaffolds with a specific fiber diameter and alignment encourage fibroblasts to have similar orientation as the scaffold fibers^{5**}
- To contrast, randomly oriented fibers have shown more random fibroblast orientation.^{5*}

Porous Bioresorbable Scaffold Wick Design

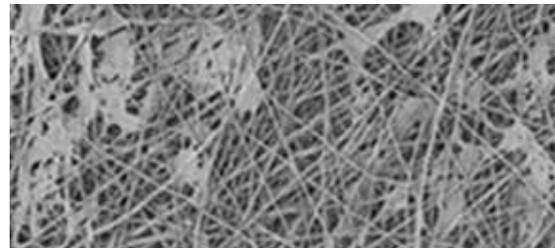
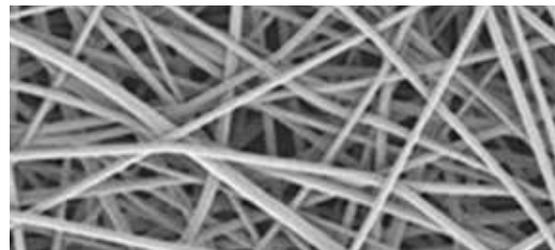
- BioWick bioresorbable scaffold wick is approximately 80% porous

Aligned Fibers



Aligned fibers show more organized tendon fibroblast orientation⁵

Randomly Oriented Fibers



Random fibers show more random fibroblast orientation⁵

VS.

* *In vitro* testing is not necessarily indicative of clinical performance.

Pre-clinical Data

BioWick SureLock Implant Good Lab Practices Sheep Study Conducted at Colorado State University**

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

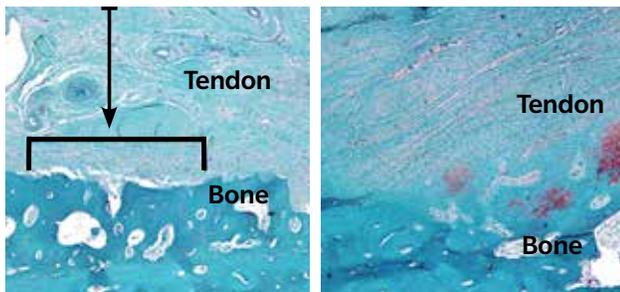
- Higher percentage of perpendicular fibers at the tendon-bone interface
- Higher percentage of tendon-bone integration with tissue
- Greater new bone formation at the tendon-bone interface
- Higher levels of Collagen III

Biocompatibility: 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.

Tissue Integration at the Tendon-Bone Interface

Bracketed area indicates lack of tendon – bone integration

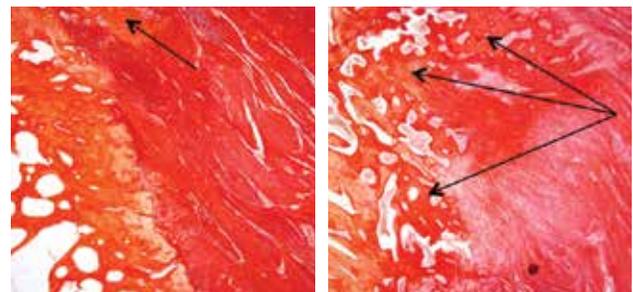


Control Group – 12 Weeks

BioWick Group – 12 Weeks

Area of New Bone Formation at Tendon-Bone Interface

New bone formation is indicated at each arrowhead



Control Group – 12 Weeks

BioWick Group – 12 Weeks

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

** Funding for the sheep study provided by Cayenne Medical, Inc. Animal study outcomes are not necessarily predictive of human results.

Surgical Technique

Simple, Reproducible Delivery

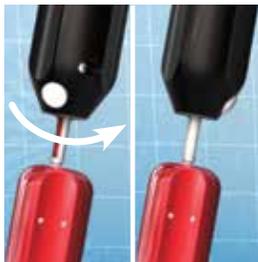
- Integrated anchor technology allows implant to be placed in between tendon and bone using the surgeon's current arthroscopic technique – requiring no extra steps in surgical procedure
- Comprehensive surgical technique guide available on zimmerbiomet.com

Reduced Bone Removal

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



1 Drill pilot hole



2 Insert implant into drill guide and orient scaffold wick in lateral direction



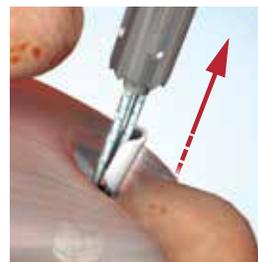
3 Insert implant into pilot hole



4 Rotate knob to deploy fixation



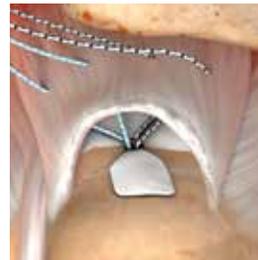
5 Implant fully deployed beneath cortex



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

Ordering Information

BioWick SureLock Implants (Sterile)

Description	Part Number
BioWick SureLock, 2.7 mm pre-loaded implant with (2), Size 2 UHMWPE Sutures	CM-6127

BioWick SureLock Disposable Instruments (Sterile)

Description	Part Number
Drill, BioWick SureLock, 2.7 mm	CM-6101
Hard Bone Drill, BioWick SureLock 2.7 mm	CM-6101H

SureLock Instruments (Non-Sterile)

Description	Part Number
Drill Guide, for BioWick SureLock	CM-6120
Obturator, for BioWick SureLock	CM-6121

INDICATIONS

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

CONTRAINDICATIONS

- 1) Surgical procedures other than those listed in the INDICATIONS section.
- 2) Presence of infection.
- 3) Patient conditions including insufficient quantity or quality of bone or soft tissue.
- 4) Insufficient blood supply or previous infections which may hinder the healing process.
- 5) Foreign body sensitivity. If material sensitivity is suspected, testing should be completed prior to device implantation.
- 6) The use of this device may not be suitable for patients with immature bone. The physician should carefully assess the device within cartilage epiphyseal growth plates or non-osseous tissue. The placement of this device should not impact or disrupt the growth plate.
- 7) Conditions which may limit the patient's ability or willingness to follow postoperative care instructions.

References

1. U.S. Soft Tissue Fixation Market – SmartTrack, 2017. Accessed December 18, 2017.
2. Wu, et al. "Intraoperative Determinants of Rotator Cuff Repair Integrity: An Analysis of 500 Consecutive Repairs". *The American Journal of Sports Medicine*, 2012
3. Eldracher, M., Orth, P., Cucchiari, M., Pape, D., & Madry, H. (2014). Small Subchondral Drill Holes Improve Marrow Stimulation of Articular Cartilage Defects. *The American Journal of Sports Medicine*, 42(11), 2741-2750. doi:10.1177/0363546514547029.
4. Clark, J.M., Harryman, D.T., "Tendons, Ligaments, and Capsule of the Rotator Cuff", *The Journal of Bone and Joint Surgery*, 1992
5. Erisken, et al "Scaffold Fiber Diameter Regulates Human Tendon Fibroblast Growth and Differentiation" *Tissue Engineering* 2013

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