The BioWick™ SureLock™ Implant for rotator cuff repair is an interpositional, bioresorbable scaffold wick with benefits supported by statistically significant animal study results*. The design provides integrated anchor technology allowing the bioresorbable scaffold wick to be placed between the tendon and bone using current standard arthroscopic techniques for simple, reproducible delivery.

The bioresorbable scaffold wick component of the BioWick™ SureLock™ Implant is composed of aligned, PLGA microfibers with the design intent to mimic the fiber alignment of the extracellular matrix (collagen) in the rotator cuff tendon.
BioWick™ SureLock™ Implant for Rotator Cuff Repair

The use of approved Cayenne Medical, Inc. surgical instruments is required to prepare the insertion site for proper BioWick™ SureLock™ Implant placement.

Site Preparation

1. Prepare the patient pre-operatively according to standard procedures.

2. Prepare the repair site. Remove all soft tissue directly overlying the insertion site. **Do not decorticate bone surface.**

   *Note: BioWick™ SureLock™ implants rely on the cortical shell for retention, so care must be taken to preserve the cortical shell when preparing the insertion site.*

   **OR TIP:** Create a lateral accessory portal for BioWick™ SureLock™ Implant insertion.

3. Place the BioWick™ SureLock™ obturator in the BioWick™ SureLock™ drill guide. Insert drill guide and position at the medial edge of the anatomic footprint. **Ensure drill guide is positioned perpendicular to the bone surface.**

4. Remove the obturator and insert the BioWick™ SureLock™ drill into the proximal end of the drill guide.

   *Note: The BioWick™ SureLock™ Drill Guide must be used when creating the pilot hole.*

5. Create a pilot hole by drilling until the stop collar on the drill contacts the proximal end of the drill guide. A positive stop will indicate proper drill depth has been reached.

6. Remove the drill while maintaining alignment and position of the drill guide on the bone surface. This will allow for easy insertion of the BioWick™ SureLock™ Implant.
BioWick™ SureLock™ Implant Deployment

Note: Confirm the temperature indicator on the BioWick™ SureLock™ Implant is not black. Use proper sterile technique when removing the implant from its packaging.

7. Insert the tip of the implant into the proximal hole of the drill guide handle. Advance until the tip meets the bone surface.

Note: The BioWick™ SureLock™ Drill Guide MUST be used to insert and deploy the BioWick™ SureLock™ Implant for proper deployment and fixation.

8. The window in the distal end of the protective sheath indicates the bioresorbable scaffold wick orientation. Rotate inserter to orient the scaffold wick in the lateral direction (align with tendon fibers).

OR TIP: The bioresorbable scaffold wick orientation is also indicated by the white marker on the black inserter handle or the red line on the inserter shaft.

9. Lightly mallet the inserter to advance the implant into the pilot hole until the inserter handle comes into contact with the proximal end of the drill guide.

10. Turn the deployment knob on the proximal end of the inserter clockwise until it stops.

11. Pull back slowly on the inserter handle to release the inserter from the implant. Discard the inserter handle. Remove drill guide.

Note: If necessary, the sutures may be manually released from the inserter by cutting them through the two small slots in the bottom handle.

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.
Implant will be deployed beneath the cortex. Bioreabsorbable scaffold wick is placed at the bone-tendon interface.

**OR TIP:** After the inserter handle is removed, a probe can be used (if necessary) to gently manipulate the bioreabsorbable scaffold wick so that it lies in the desired location on the bone surface. Excessive or forceful manipulation should be avoided to decrease the chance of damaging the scaffold wick.

Utilizing the Quattro® GT Suture Passer, pass all four suture limbs and move sutures from lateral portal to anterior portal.

**SureLock™ All-Suture Anchor Deployment**

*Note: Surgeons may use their own preferred method for lateral fixation.*

14. Place the SureLock™ 2.2mm obturator in the SureLock™ 2.2mm drill guide. Insert drill guide to the lateral edge of the anatomic footprint. Ensure drill guide tip is positioned perpendicular to the bone surface.

*Note: The SureLock™ Drill Guide must be used when drilling the pilot hole.*

15. Insert the SureLock™ 2.2mm drill into the proximal end of the guide. Once the drill tip meets the bone surface, create a pilot hole by drilling until the two collars meet.

16. Remove the drill while maintaining alignment and position of the drill guide on the bone surface.

*OR TIP: This will allow for easy insertion of the SureLock™ All-Suture Anchor.*
17 Insert the SureLock™ 2.2mm anchor into the proximal end of the drill guide. Lightly mallet the anchor into the pilot hole until the inserter handle comes into contact with the proximal end of the drill guide.

18 Turn the deployment knob clockwise until it stops.

19 Pull back slowly on the inserter handle to release the inserter from the anchor. Remove the drill guide.

20 Pass three of the four suture limbs with the Quattro® GT suture passer. The forth limb will be used to create a simple stitch.

21 Tie the BioWick™ SureLock™ Implant sutures (medially) into two mattress stitches. Tie the SureLock™ 2.2mm Anchor sutures (laterally) into one mattress stitch and one simple stitch with the simple stitch passing between and just medial to the mattress stitch (also known as a modified Mason-Allen Stitch).

Note: The SureLock™ Drill Guide must be used for proper deployment and fixation of the SureLock™ All-Suture Anchor.

OR TIP: The lateral sutures will be tied in a modified Mason-Allen Stitch configuration.

Repair is complete.
BioWick™ GLP Sheep Study Conducted at Colorado State University

The randomized, controlled 56 animal 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
- Greater new bone formation at the tendon-bone interface
- Higher percentage of tendon-bone integration with tissue
- Higher levels of Collagen III

The histology results showed no adverse tissue response in the treated vs. control group.

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*Animal study outcomes are not necessarily predictive of human results

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| BioWick™ SureLock™ Ordering Information |
|-----------------------------|--------------------------------|
| **BioWick™ SureLock™ Implants (Sterile)** |
| CM-6127 BioWick™ SureLock™, 2.7mm pre-loaded implant w. (2) Size 2 UHMWPE Sutures |
| **BioWick™ SureLock™ Disposable Instruments (Sterile)** |
| CM-6101 Drill, BioWick™ SureLock™, 2.7mm |
| **BioWick™ SureLock™ Reusable Instruments (Non-Sterile)** |
| CM-6120 Drill Guide, for BioWick™ SureLock™ |
| CM-6121 Obturator, for BioWick™ SureLock™ |