

BioWick® X

Interpositional Scaffold-Anchor Implant
for Rotator Cuff Repair

Surgical Technique



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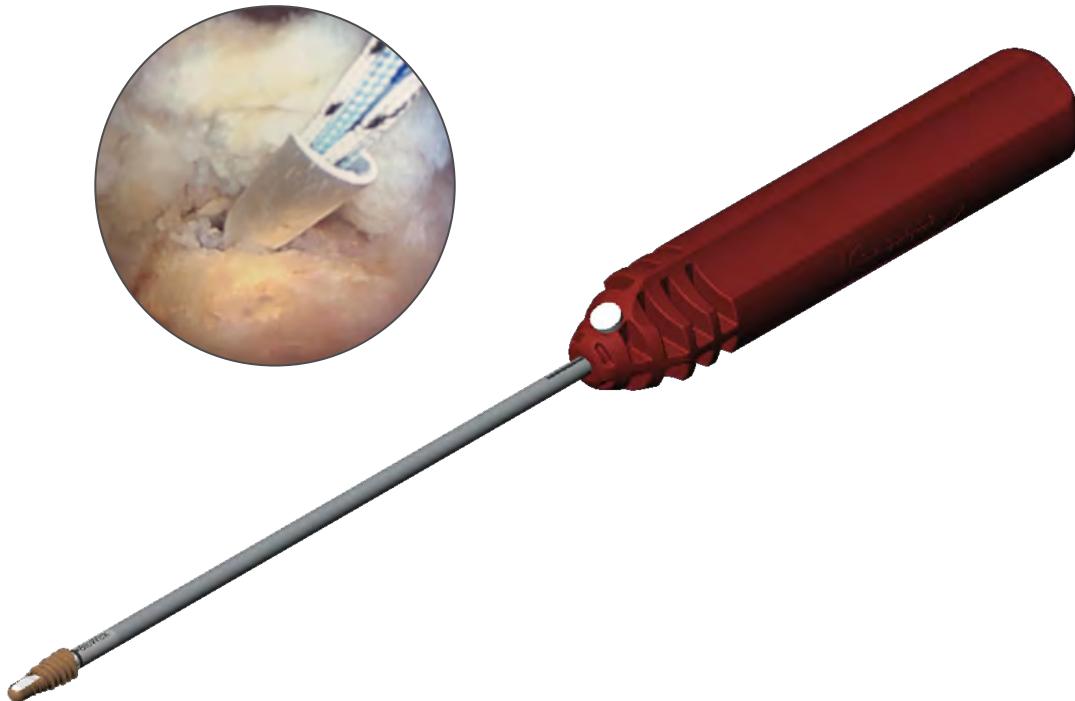


Figure 1

BioWick X Implant

The Cayenne Medical, Inc. BioWick X Implant is intended to be used for the reattachment of soft tissue to bone in rotator cuff repairs.

The BioWick X PEEK (polyetheretherketone) Implant is pre-loaded with an interpositional 85/15 PLGA (L-lactide/glycolide copolymer) scaffold wick and two (5.5 mm Implant) or three (6.5 mm Implant) size 2 UHMWPE (Ultra-High Molecular Weight Polyethylene) sutures.

Note: Prior to use, confirm that the temperature indicator dot on the implant packaging is **NOT** black.



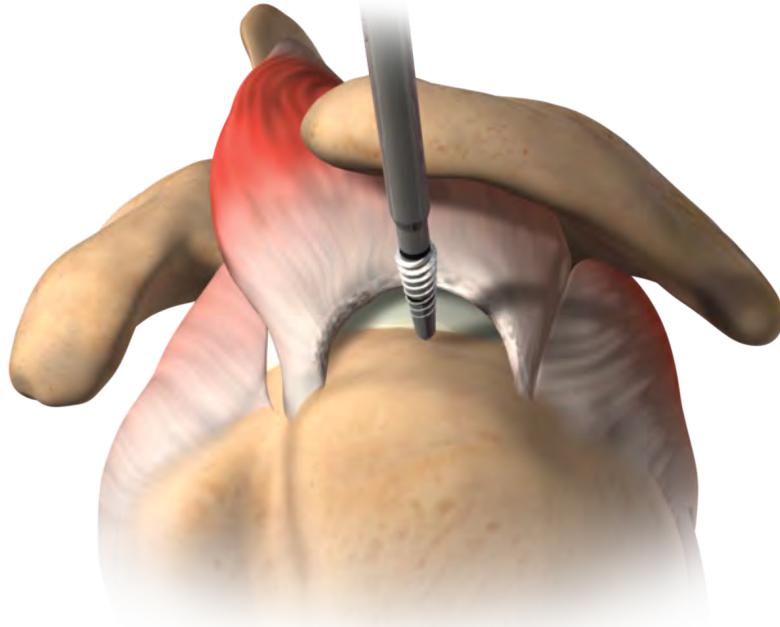


Figure 2

Site Preparation

Step 1

Use a shaver/burr/rasp to remove soft tissue directly overlying the insertion site.

Select Tap and Establish Alignment

Step 2

Use the appropriate BioWick X Tap (5.5mm or 6.5mm) to create a pilot hole for the implant. The Tap should be placed perpendicular to the bone at the medial edge of the anatomic footprint.

Note: The BioWick X Taps must be used for proper insertion of the implants. No other Tap or Awl should be used.

| BioWick® X Implant | Tap |
|--------------------|---|
| 5.5 mm (CM-6255) | Red Handle (CM-6201)  |
| 6.5 mm (CM-6265) | Red and Black Handle (CM-6202)  |

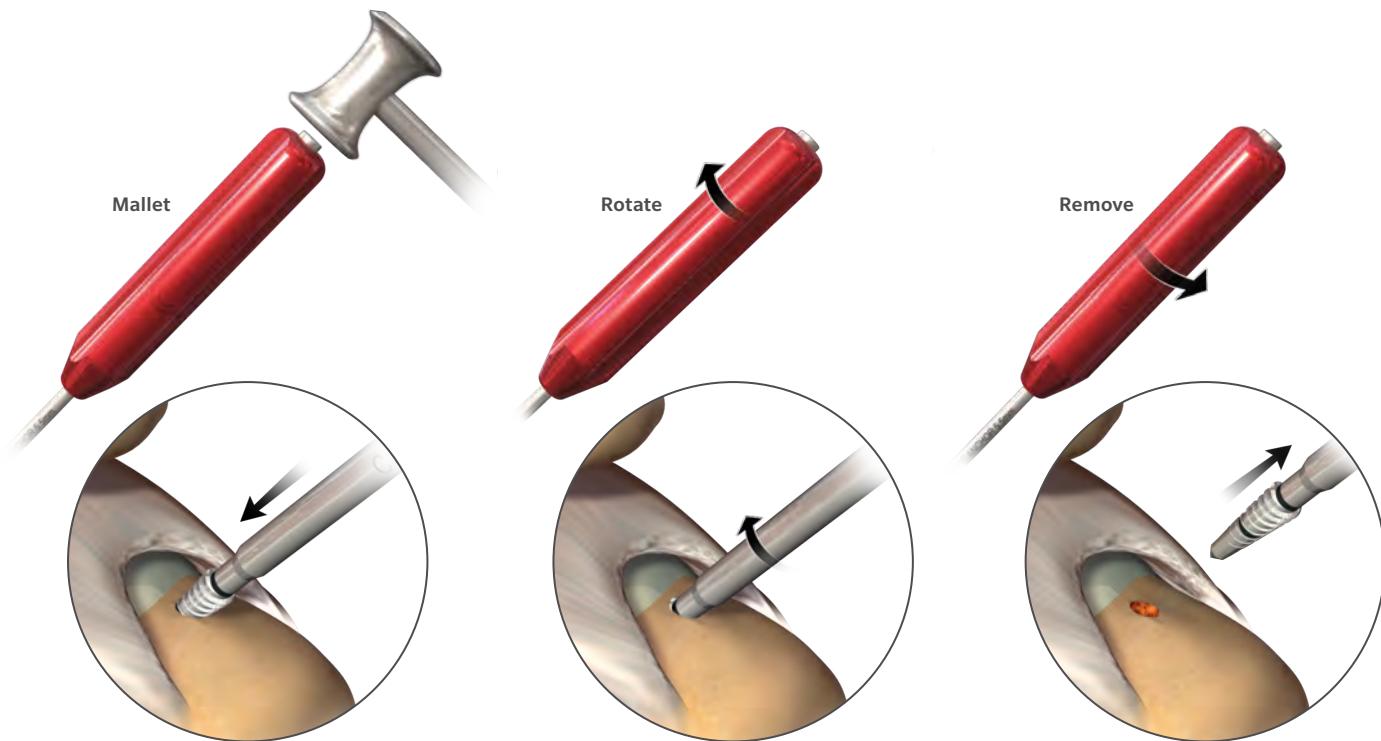


Figure 3

Figure 4

Figure 5

Create Pilot Hole

Step 3

Mallet the Tap until the **first (distal) horizontal marker band** is flush with the bone.

Step 4

While applying slight forward pressure, rotate the Tap clockwise until the **second (proximal) horizontal marker band** is flush with the bone surface.

Step 5

Rotate the handle counter-clockwise to remove the Tap.

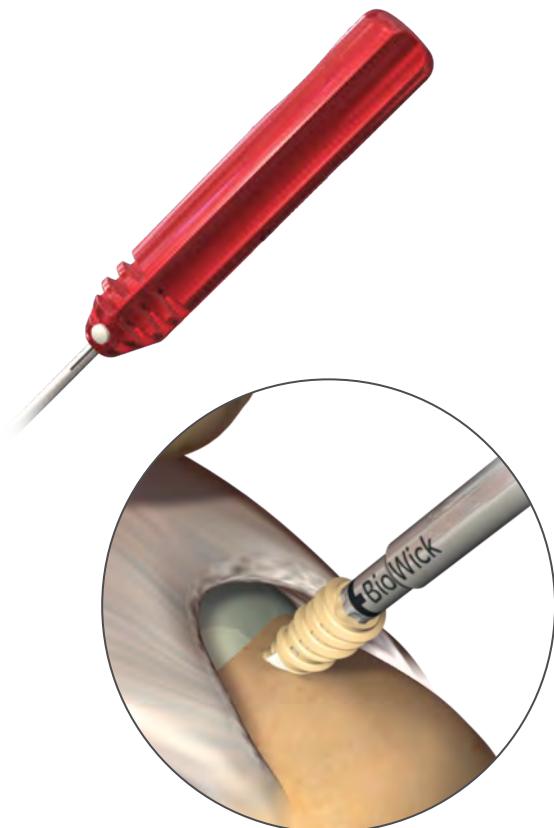


Figure 6

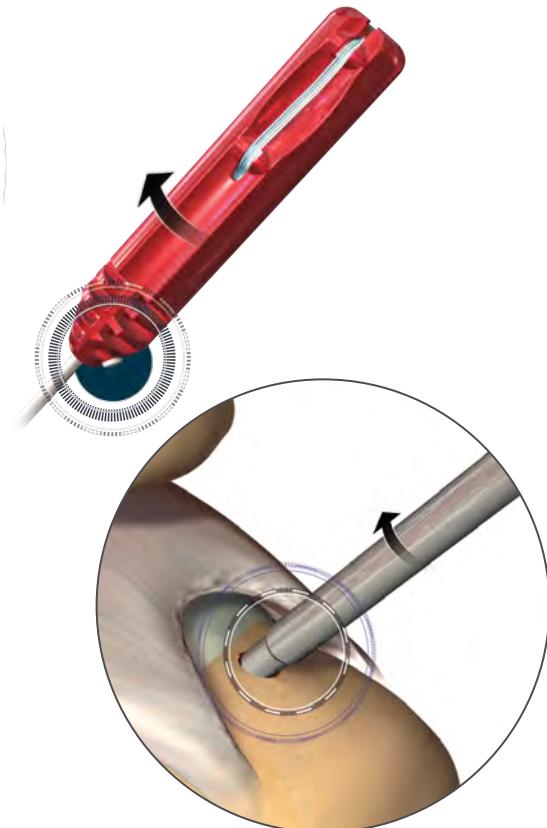


Figure 7

Insert BioWick X Implant

Step 6

Insert the tip of the BioWick X Implant into the prepared hole.

Step 7

Screw the implant into the bone until the horizontal marker band on the driver shaft is flush with the bone. Rotate the driver until the **white marker on the driver handle** is oriented in the **medial-lateral direction**.

Note: The BioWick text on the distal end of the driver shaft and the vertical marker band on the proximal end of the driver shaft also indicate wick orientation (medial-lateral direction).

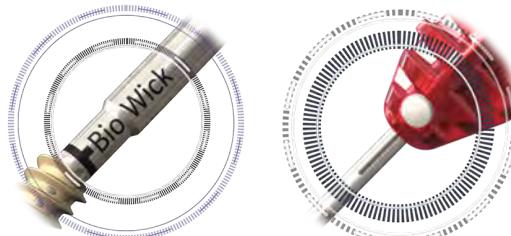




Figure 8

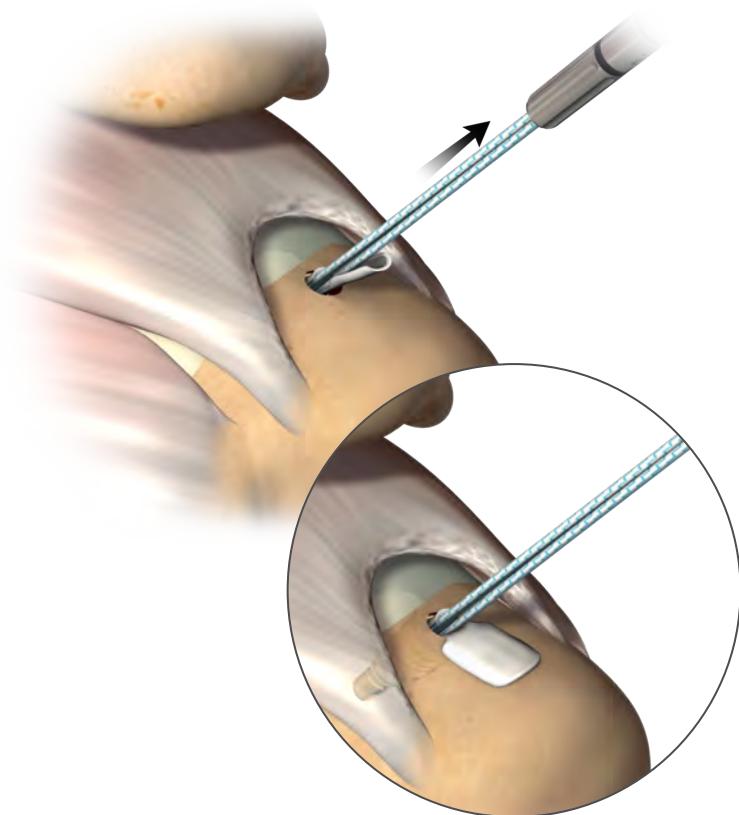


Figure 9

Release Sutures

Step 8

Pull the suture limbs completely out of the driver handle and release from cleat.

Deploy BioWick X Scaffold Wick

Step 9

Pull back slowly on the driver handle to disengage the inserter shaft from the implant and deploy the scaffold wick.

Note: The scaffold wick may not lay flat against the bone surface after deployment. The scaffold is secured in the implant and will lay flat once the rotator cuff is positioned over the top.

*If necessary, use a probe to VERY GENTLY manipulate the wick so it lies in the desired location. Excessive or forceful manipulation of the wick should be avoided to reduce the chance of damaging the wick.

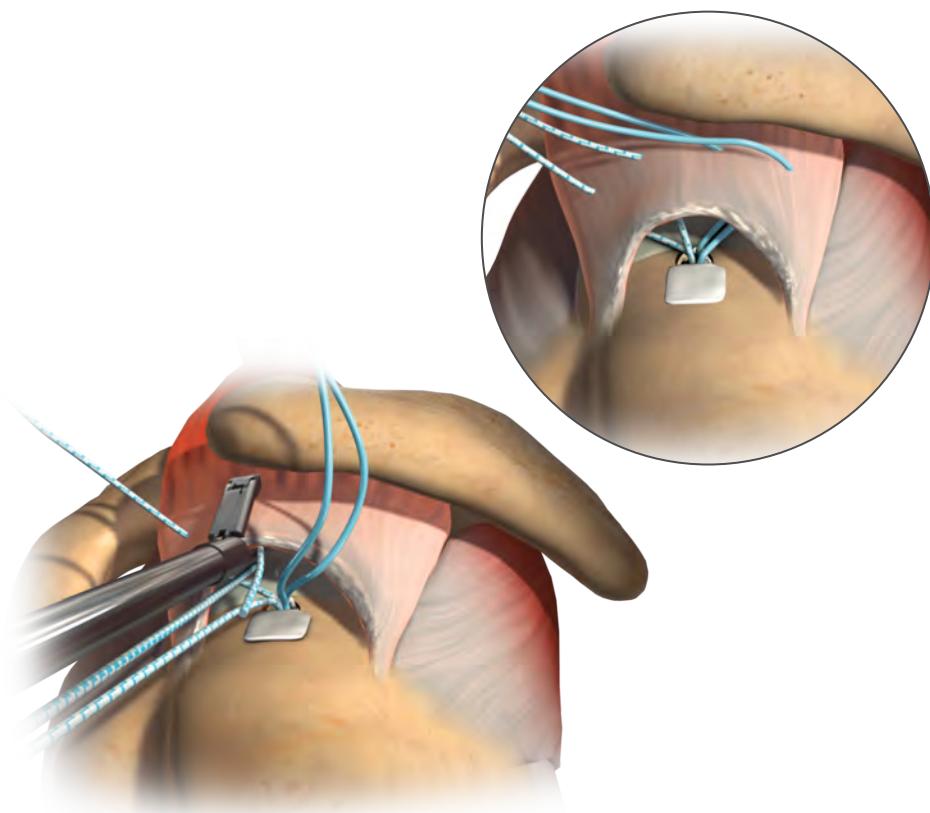


Figure 10

Finalize the Repair

Step 10

Pass the sutures through the tissue and complete the repair with the preferred technique.

Ordering Information

BioWick X Implants

| Part Number | Description |
|-------------|--|
| CM-6255 | BioWick X Implant, 5.5 mm PEEK implant preloaded with two (2) size 2 UHMWPE suture strands |
| CM-6265 | BioWick X Implant, 6.5 mm PEEK implant preloaded with three (3) size 2 UHMWPE suture strands |

BioWick X Reusable Instruments (Non-Sterile)

| Part Number | Description |
|-------------|-------------------------------|
| CM-6201 | Tap, 5.5 mm BioWick X Implant |
| CM-6202 | Tap, 6.5 mm BioWick X Implant |

Indications & Contraindications

INDICATIONS

The Cayenne Medical, Inc. BioWick X 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 and/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.

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Authorized Representative
Zimmer GmbH
Sulzerallee 8
8404 Winterthur
Switzerland



Legal Manufacturer
Cayenne Medical Inc.
16597 N. 92nd St
Suite 101
Scottsdale, AZ 85260
USA



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