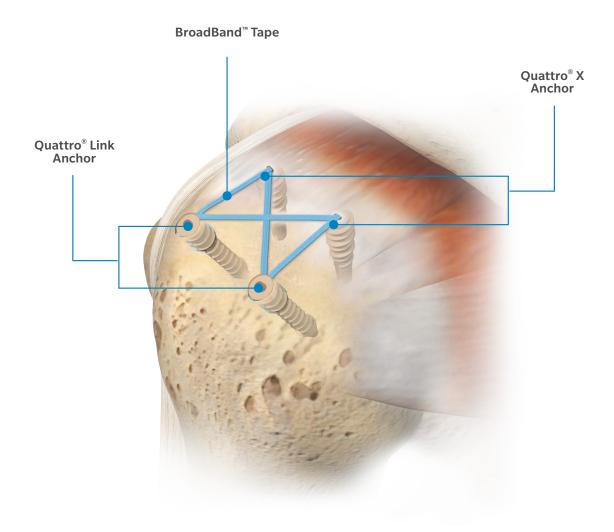


Rotator Cuff Repair -Knotless Bridge Repair With Quattro[®] X and Quattro[®] Link

Surgical Technique



INDICATIONS & CONTRAINDICATIONS

Quattro® X and X3 Suture Anchors

INTENDED USE

The Quattro® X and X3 Suture Anchors are intended for use for the reattachment of soft tissue to bone for Rotator Cuff Repairs.

INDICATIONS FOR USE

The Cayenne Medical, Inc. Quattro® X and X3 Suture Anchors are intended to be used for the reattachment of soft tissue to bone in Rotator Cuff Repair.

CONTRAINDICATIONS

- Surgical procedures other than those listed in the INDICATIONS section.
- Presence of infection.
- Patient conditions including insufficient or immature bone.
- Insufficient blood supply or previous infections which may hinder the healing process.
- Foreign body sensitivity. If material sensitivity is suspected, testing should be completed prior to device implantation.
- The physician should carefully assess the device within immature bone.
- The placement of this device should not impact or disrupt the growth plate.
- Conditions which may limit the patient's ability or willingness to follow postoperative care instructions.

Quattro[®] Link Knotless Anchors

INTENDED USE

The Cayenne Medical Quattro[®] Link Knotless Anchors are intended for use for the reattachment of soft tissue to bone for various procedures throughout the body.

INDICATIONS FOR USE

The Cayenne Medical, Inc. Quattro[®] Link Knotless Anchors are intended or use for the reattachment of soft tissue to bone for the following indications:

Hip

- Hip Capsule Repair
- Acetublar Labrum reattachment

Shoulder

- Capsular stabilization
 - Bankart repair
 - Anterior shoulder instability
 - SLAP lesion repairs
 - Capsular shift or capsulolabral reconstructions
- Acromioclavicular separation repairs
- Deltoid repairs
- Rotator cuff repairs
- Biceps tenodesis

Elbow, Wrist, and Hand

- Biceps tendon reattachment
- Ulnar or radial collateral ligament reconstruction

· Lateral epicondylitis repair

Knee

- Extra-capsular repairs
 - Medial collateral ligament
 - Lateral collateral ligament
 - Posterior oblique ligament
- · Patellar realignment and tendon repairs
- Vastus medials obliquous advancement
- Illiotibial band tenodesis

Foot and Ankle

- Hallux valgus repairs
- · Medial or lateral instability repairs/reconstructions
- · Achilles tendon repairs/reconstructions
- Midfoot reconstructions
- Metatarsal ligament/tendon repairs/reconstructions
- Bunionectomy

CONTRAINDICATIONS

- Surgical procedures other than those listed in the INDICATIONS section.
- Presence of infection.
- · Patient conditions including insufficient or immature bone.
- Insufficient blood supply or previous infections which may hinder the healing process.
- Foreign body sensitivity. If material sensitivity is suspected, testing should be completed prior to device implantation.
- The physician should carefully assess the device within immature bone.
- The placement of this device should not impact or disrupt the growth plate.
- Conditions which may limit the patient's ability or willingness to follow postoperative care instructions

BroadBand[®] and MaxBraid[™]

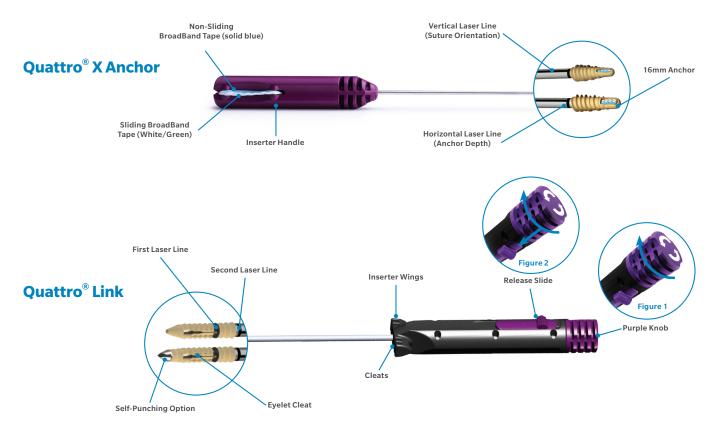
INDICATIONS

- BroadBand[™] / MaxBraid[™] sutures are indicated for use in general soft tissue approximation and/or ligation and the use of allograft tissues for orthopedic surgeries, but are not for use in cardiovascular procedures.
- BroadBand[™] / MaxBraid[™] sutures are intended for one-time use only, and are not to be re-sterilized.

CONTRAINDICATIONS:

• None known.

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Medial Row

- 1. Prepare medial row bone socket just lateral to articular margin with Quattro[®] X Awl (first laser line).
- Insert Quattro X Anchor loaded with BroadBand[®] Tape (Non-Sliding) into bone socket and screw clockwise until horizontal laser line is flush with bone. Uncleat sutures and pull axially to remove inserter.
- 3. Repeat steps 1 and 2 for second Quattro X Anchor loaded with BroadBand Tape (Non-Sliding).
- Load BroadBand Tape tails into Quattro GTS Side Loading Passer and pass through the rotator cuff tendon. Repeat for additional BroadBand Tape limbs.

Option: BroadBand Mini Loop can be used to pass both tapes through rotator cuff in a single pass, if needed..

Lateral Row

1. Retrieve one BroadBand Tape from each medial row anchor and load into Quattro Link Anchor.

Option: If dog-ear is pre-empted, pass tail of BroadBand Mini Loop through dog-ear and pass tail through loop to create a 'cinch' stitch configuration. Load tail into Quattro Link Anchor. The sliding suture from the Quattro X can be used if it were removed from the medial row anchor.

- Prepare lateral row bone socket 5 mm 10 mm lateral to edge of rotator cuff footprint with Quattro Link Awl (laser line).
- Insert Quattro Link Anchor into bone socket to first laser line. Apply counter pressure on inserter wings and tension each BroadBand Tape limb to reapproximate tendon. Rotate purple knob clockwise until it stops (Figure 1). Mallet anchor until 2nd laser line is flush with bone.

Option: Cleat BroadBand Tapes on inserter wing cleats to maintain tension.

- Release inserter from anchor. Push and hold down release slide and rotate purple tension knob clockwise (Figure 2) while gently pulling axially on inserter.
- 5. Cut BroadBand Tape tails.
- 6. Repeat steps for second lateral row Quattro Link Anchor.

Ordering Information

Part Number	Description
CM-9255BG	Quattro X Anchor, 5.5 mm Loaded with BroadBand Tape (Non-Sliding)
CM-9265BG	Quattro X Anchor, 6.5 mm Loaded with BroadBand Tape (Non-Sliding)
CM-9200	Quattro X Awl, 5.5 mm/6.5 mm
CM-9145	Quattro Link Knotless Anchor, 4.5 mm
CM-9145SP	Quattro Link Knotless Anchor, 4.5 mm Self Punching
CM-9155	Quattro Link Knotless Anchor, 5.5 mm
CM-9100	Quattro Link Awl, 4.5 mm/5.5 mm
CM-0304*	BroadBand Mini Loop: Black 3" Tape Loop (1.5 mm), 27" Tape Tail (1.5 mm)
CM-9011	Quattro Suture Passer Needle
CM-9010GTS	Quattro GTS Side-Load Suture Passer

This material is intended for health care professionals. Distribution to any other recipient is prohibited.

Please refer to the Instructions for Use and the package label for the products to be used with this Surgical Technique.

For indications, contraindications, warnings, precautions, potential adverse effects, and patient counselling information, see the package insert or contact your local representative; visit legal manufacturer website for additional product information.

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Products within this system are under the design control of various legal manufacturers. Refer to the product labeling of each device for the legal manufacturer.

This technique was developed in conjunction with health care professionals. This document is intended for surgeons and is not intended for laypersons.

Cayenne Medical is the legal manufacturer of Quattro X and Quattro Link Anchors.

*Riverpoint is the legal manufacturer of Broadband Mini Loop.

Each surgeon should exercise his or her own independent judgment in the diagnosis and treatment of an individual patient, and this information does not purport to replace the comprehensive training surgeons have received. As with all surgical procedures, the technique used in each case will depend on the surgeon's medical judgment as the best treatment for each patient. Results will vary based on health, weight, activity, and other variables. Not all patients are candidates for this product and/or procedure. Caution: Federal (USA) law restricts this device to sale by or on the order of a surgeon. Rx only.

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