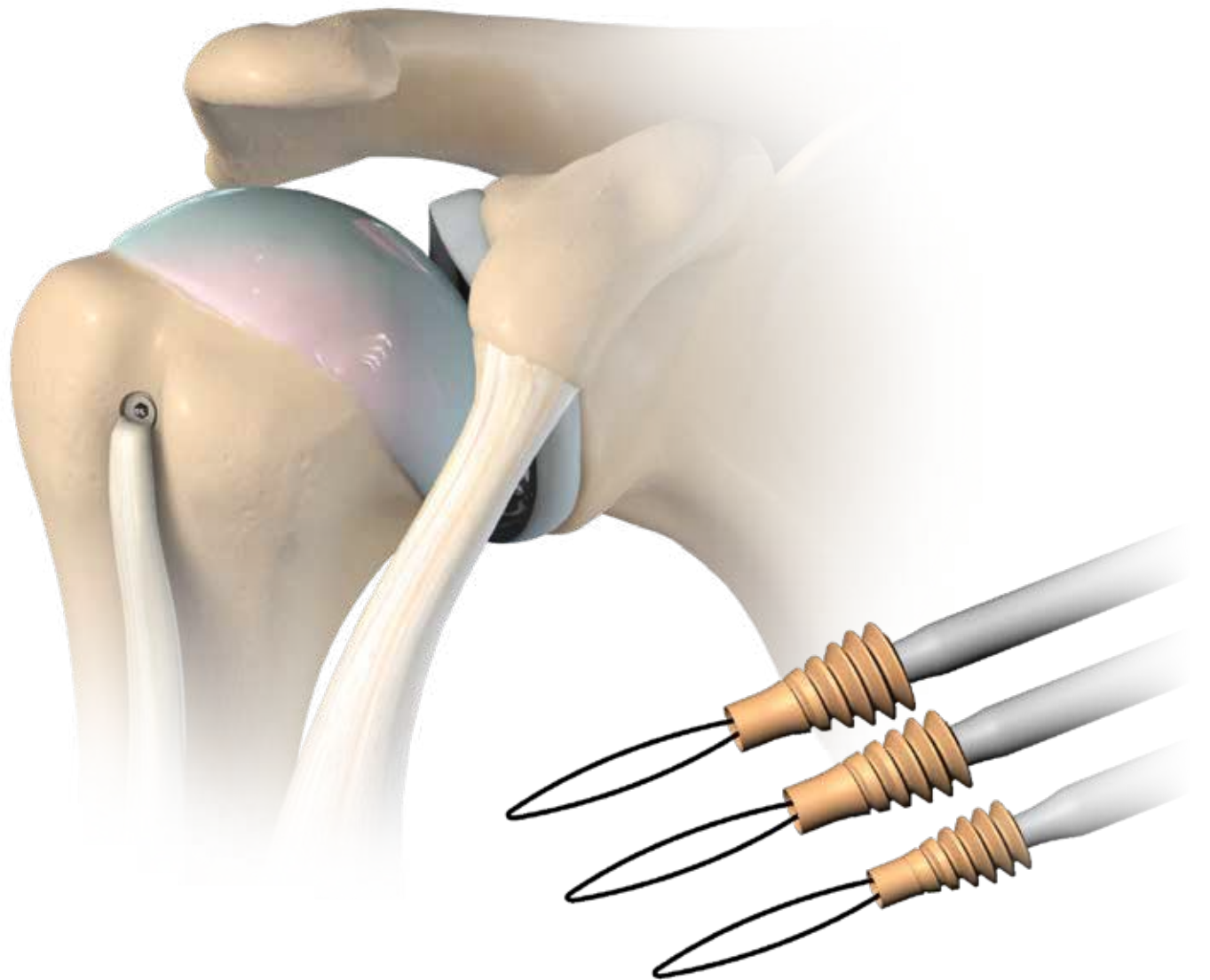
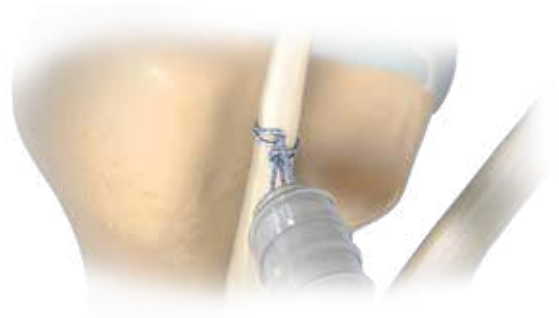
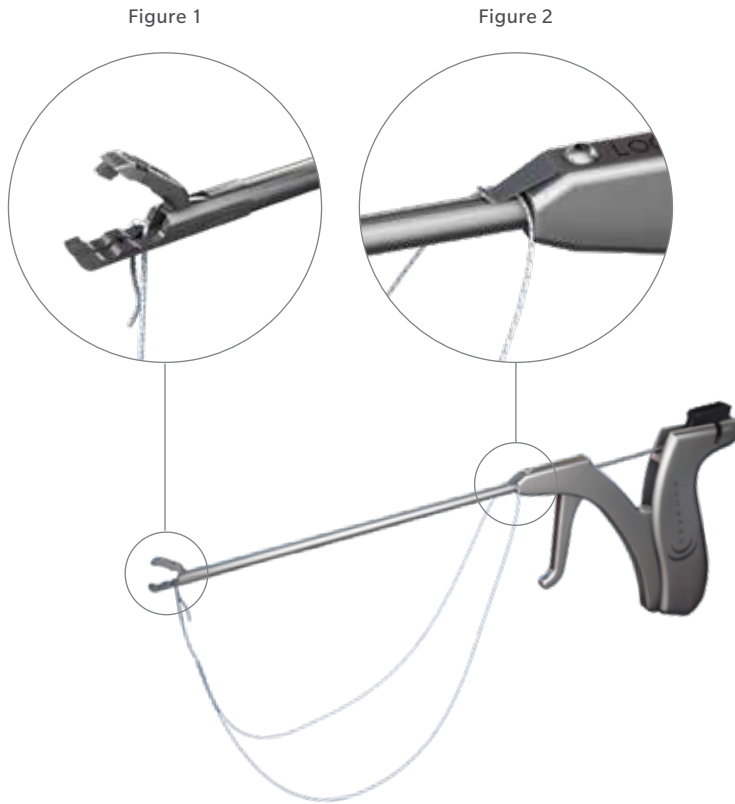


Quattro® Bolt Tenodesis Screw Proximal Bicep Repair

Surgical Protocol by Gregory Gilot, M.D.

Surgical Technique





Prepare the TRU-LOOP® Suture

Step 1

Load the tail of the TRU-LOOP suture loop into the Lock-Stitch® or Quattro GT Suture Passer (Figure 1).

Step 2

Once the suture is loaded into the passer, pull the loop section of the TRU-LOOP suture over the top of the passer shaft, so that the shaft is inside the loop with the top of the loop resting on the hand piece of the passer (Figure 2).

Tag the Tendon

Step 3

Place a tag stitch with the TRU-LOOP suture in the tendon using the Suture Passer several millimeters directly superior to the intended tenodesis site. Retrieve the suture limbs. Surgeon preference will determine tenodesis location (Figure 3).

Repeat previous step with another TRU-LOOP suture, tagging the tendon in the opposite orientation from the first stitch. Retrieve the suture limbs (Figure 4).

ⓘ **Note:** The TRU-LOOP suture will create an instantaneous cinching loop in the biceps tendon.



Figure 6



Figure 5

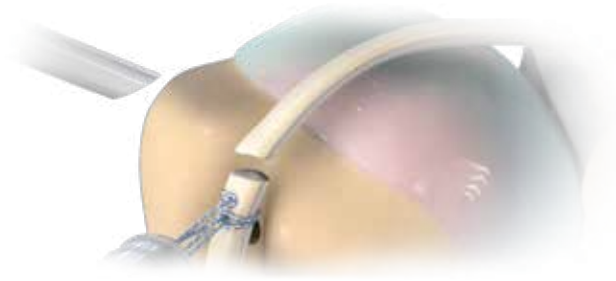


Figure 7

Prepare the Tenodesis Site

Step 4

Measure the diameter of the biceps tendon at the intended tenodesis site. This will determine the size of the pilot hole and implant to use.

Please refer to the recommended sizing table.

Tendon Size	Pilot Hole Size	Screw Size
5 mm	6 mm	7 mm
6 mm	7 mm	8 mm
7 mm	8 mm	9 mm

Note: Hard bone may require a larger hole size.

Step 5

Retract the biceps tendon with the TRU-LOOP sutures and freshen the bone at the intended tenodesis site (Figure 5).

Step 6

Drill the bone socket while continuing to retract the tendon away from the tenodesis site. Drill the socket a few millimeters deeper than the length of the screw size being used (ie: Drill to a depth of ~20 mm for the 8x16 mm Bolt screw). After creating the bone socket, clear surrounding soft tissue for easy screw insertion (Figure 6).

Step 7

Cut the tendon approximately 2-3 mm superior to the TRU-LOOP sutures (Figure 7).

Note: For required fixation, the threads of the Quattro Bolt Tenodesis Screw must engage bone in the bone socket on the cut tendon end.

Step 8

Tenotomize the tendon at its labral insertion site and remove remaining tissue.



Figure 8

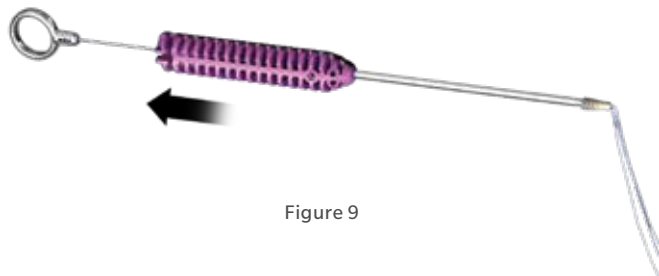


Figure 9

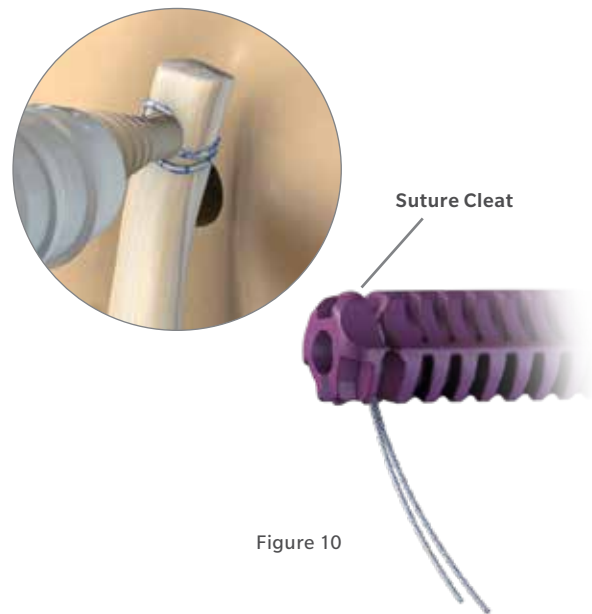


Figure 10

Anchor Insertion

Step 9

Load the TRU-LOOP suture tails through the snare of the Quattro Bolt Tenodesis Screw (Figure 8). Pull the snare ring from the proximal end of the driver to load the sutures into the screw. Sutures will now be exiting the proximal end of the driver (Figure 9).

Step 10

Feed the sutures through the Quattro Bolt Tenodesis Driver until the screw tip contacts the tendon. Secure the suture tails into the suture cleat of the driver to lock the tendon into place (Figure 10).

ⓘ **Note:** There should be no suture slack in between the tendon and the screw.

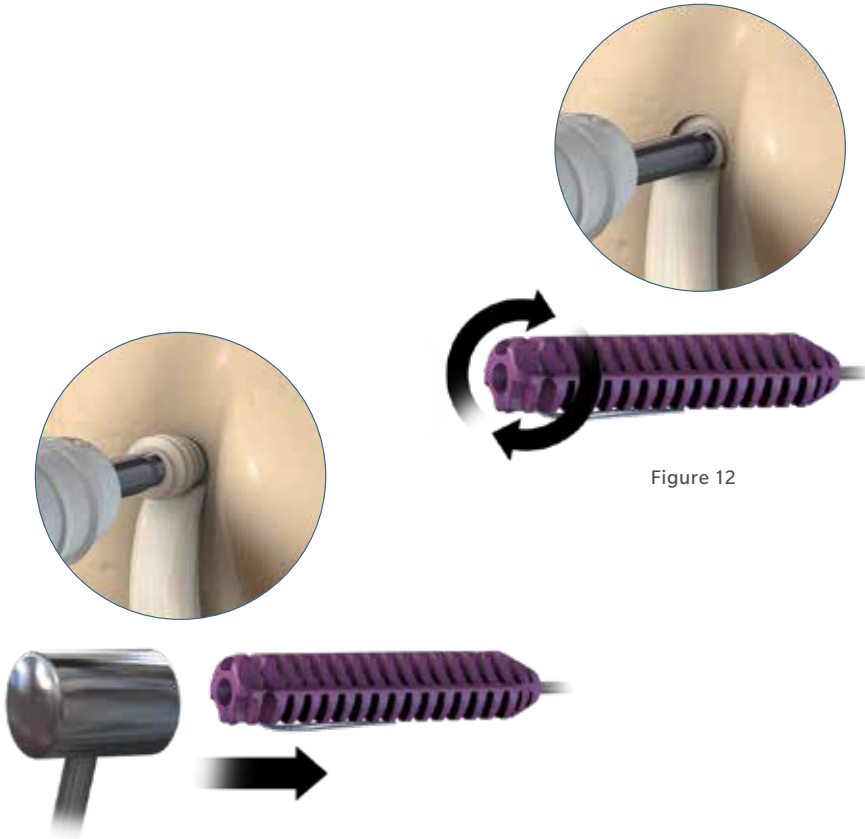


Figure 11

Figure 12



Figure 13

Step 11

Insert the Quattro Bolt Tenodesis Screw and tendon into the bone socket:

Step 11a

Mallet proximal end of driver until screw threads of the anchor contact the bone surface (Figure 11).

⊖ **Note:** For required fixation, the threads of the Quattro Bolt Tenodesis Screw must engage bone in the bone socket on the cut tendon end.

Step 11b

Using forward pressure, turn the screw driver clockwise to advance the screw into the socket until the screw head is flush with the bone surface (Figure 12).

Step 12

Release the suture tails from the suture cleat on the driver and pull back on the driver to disengage from the screw.

Step 13

Trim the excess suture. Repair is complete (Figure 13).

Ordering Information

Quattro Bolt Tenodesis Screw

Description	Size	Part Number
Quattro Bolt Tenodesis Screw	5 mm x 10 mm	CM-9505
	6 mm x 12 mm	CM-9506
	7 mm x 14 mm	CM-9507
	8 mm x 16 mm	CM-9508
	9 mm x 18 mm	CM-9509

The Lock-Stitch System

Description	Part Number
Lock-Stitch Suture Passer	CM-9010LS
Lock-Stitch Procedure Kit with 1-suture needle, 2-TRU-LOOP Size 2 Suture Loops (sterile)	CM-9500

Accessory Drill Kits

Description	Size	Part Number
Accessory Drill Kit	4 mm	CM-9540
	5 mm	CM-9550
	6 mm	CM-9560
	7 mm	CM-9570
	8 mm	CM-9580

INDICATIONS FOR USE

The Cayenne Medical, Inc. Quattro Bolt Tenodesis Screws are intended to be used for the reattachment of soft tissue to bone for the following indications:

Shoulder

- Biceps tenodesis

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 physician should carefully assess the device within immature bone.
- 7) The placement of this device should not impact or disrupt the growth plate.
- 8) Conditions which may limit the patient's ability or willingness to follow postoperative care instructions.

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