ComposiTCP[™] Suture Anchor with BroadBand[™] Tape

for Medial Row Fixation in Rotator Cuff Repair

Surgical Technique





ComposiTCP Suture Anchor with BroadBand Tape

ComposiTCP Suture Anchors are made of a biocomposite material composed of 30% β -Tricalcium Phosphate (β -TCP) and 70% Polylactic Acid (PDLLA).

ComposiTCP Suture Anchors with BroadBand Tape are designed with two tape construct options. "Sliding" and "Non-Sliding" BroadBand Tape variations are available to address multiple technique preferences.

The ComposiTCP Non-Sliding Anchors are double loaded with one (1) non-sliding blue and one (1) sliding green/white BroadBand Tape. The non-sliding anchors are designed to achieve an all-knotless double row rotator cuff repair, while still giving a surgeon the ability to augment the repair with the sliding green/ white tape strand, if desired.

The ComposiTCP Sliding Anchors are double loaded with two (2) sliding BroadBand Tape strands (blue and green/white).

Potential "Non-Sliding" Anchor Techniques:

- Double Row Knotless Repairs
- Medial Pulley Technique
- Medial Rip Stop Technique

Potential "Sliding" Anchor Techniques:

- Single Row Repairs
- Double Row Knotted Repairs

Instructions for Use

ComposiTCP Suture Anchor instruments should be used to ensure the proper insertion of the ComposiTCP Suture Anchor.



Site Preparation

Step 1

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

Create Pilot Hole

Step 2

Place the ComposiTCP punch/tap through a lateral accessory portal at an appropriate angle to the tuberosity by internally or externally rotating the arm.

Position the punch/tap at the articular margin. Mallet until the 1st thread on the punch/tap is flush with or just below the bone surface (Figure 1).

Continue to advance the punch tap with forward hand pressure and turning in a clockwise direction. Advance the punch/tap until the laser-etch line is flush with the bone.



Figure 3

Insert ComposiTCP Anchor

Step 3

Insert the tip of the ComposiTCP Anchor in an anterior to posterior direction through the portal and at the same angle as the threaded holes created by the punch/ tap. Screw the ComposiTCP Anchor clockwise until the horizontal laser-etch line on the inserter shaft is flush with the bone surface (Figure 2).

Note: For proper suture orientation, confirm that the vertical laser-etch line on the inserter shaft is facing or adjacent to the edge of the tissue.

Release Sutures

Step 4

Release the suture tape strands from the driver by releasing from the cleats and unwind from the inserter handle (Figure 3).





Remove Inserter

Step 5

Pull back slowly on the inserter handle to disengage the inserter shaft from the anchor (Figure 4).

Insert Second Medial Row Anchor (Optional)

Step 6

If desired, repeat steps 1-5 to insert a second medial row ComposiTCP Suture Anchor (Figure 5).



Pass Suture

Step 7

Pass the individual BroadBand Suture Tape limbs through the tissue using the Quattro[®] GT Suture Passer (Figure 6).

Note: For mini-open procedures, a free needle can be added to the end of the sutures to facilitate suture passing.







Finalize Repair

Step 8

Complete the repair with the preferred technique.

For Arthroscopic Knot Tying in Double-Row Repairs (Utilizing ComposiTCP Sliding Anchors):

Use secure knots and tie the medial row to repair the tendon from posterior to anterior, but do not cut the BroadBand Tape strands. These strands will span over and the lateral aspect of the tendon and be held in place with Quattro or Ventix[™] Link Knotless Anchors (Figure 7).

Note: Always tie the blue tape strands first when using the ComposiTCP Sliding Anchors to allow both BroadBand Tape strands to slide easily.

For Knotless Double-Row Rotator Cuff Repairs (Utilizing ComposiTCP Non-Sliding Anchors):

Prior to passing the tape strands through the tissue, remove the sliding green/white BroadBand Tape suture strands from both ComposiTCP Non-Sliding Anchors. Pass the blue non-sliding strands through the tissue. Retrieve one blue BroadBand Tape strand from each medial anchor and load into a Quattro or Ventix Link Knotless Anchor. Repeat for the second lateral row knotless anchor (Figure 8).





For Augmented Double-Row Rotator Cuff Repairs (Utilizing ComposiTCP Non-Sliding Anchors):

Figure 9

Pass the non-sliding blue and the sliding green/white BroadBand Tape strands through the tissue. Tie the sliding green/white strands from each anchor to augment the repair (i.e. creating medial pulley or rip stop stitch; Figures 9 & 10).

Retrieve one non-sliding blue BroadBand Tape strand from each medial anchor and load into a Quattro or Ventix Link Knotless Anchor. Repeat for the second lateral row knotless anchor. Note for All Double-Row Repairs: Load up to six (6) BroadBand Tape strands into a Quattro or Ventix Link Knotless Anchor to finalize the repair. Refer to the Quattro Link and Ventix Link Anchor Surgical Techniques for complete implantation surgical instructions.

Ordering Information

ComposiTCP Suture Anchors with BroadBand Tape

Part Number	Description
110026108	4.5mm ComposiTCP Suture Anchor Double Loaded with BroadBand Tape (Sliding)
110026109	5.5mm ComposiTCP Suture Anchor Double Loaded with BroadBand Tape (Sliding)
110026110	6.5mm ComposiTCP Suture Anchor Double Loaded with BroadBand Tape (Sliding)
110026113	4.5mm ComposiTCP Suture Anchor Double Loaded with BroadBand Tape (Non-Sliding)
110026114	5.5mm ComposiTCP Suture Anchor Double Loaded with BroadBand Tape (Non-Sliding)
110026115	6.5mm ComposiTCP Suture Anchor Double Loaded with BroadBand Tape (Non-Sliding)

ComposiTCP Suture Anchors with MaxBraid[™] Suture

Part Number	Description
110026105	4.5mm ComposiTCP Suture Anchor Double Loaded with MaxBraid Suture
110026106	5.5mm ComposiTCP Suture Anchor Double Loaded with MaxBraid Suture
110026107	6.5mm ComposiTCP Suture Anchor Double Loaded with MaxBraid Suture

ComposiTCP Suture Anchor Reusable Instruments

Part Number	Description
110026111	Punch Tap, 4.5mm ComposiTCP Suture Anchor
110026112	Punch Tap, 5.5/6.5mm ComposiTCP Suture Anchor Double Loaded with MaxBraid Suture

Quattro Link Knotless Anchors

Part Number	Description
CM-9145	4.5mm Quattro Link Knotless Anchor
CM-9145SP	4.5mm Quattro Link SP Knotless Anchor, Metal Tip
CM-9155	5.5 mm Quattro Link Knotless Anchor

Quattro Link Anchor Reusable Instruments

Part Number	Description
CM-9100	Awl, 4.5/5.5mm
CM-9130	Drill, 4.5/5.5mm
CM-9138	Hard Bone Drill, 4.5mm SP
CM-9148	Hard Bone Drill, 5.5mm

Ventix Link Knotless Anchors

Part Number	Description
110025990	4.75 mm Ventix Link Knotless Anchor
110025992	5.5 mm Ventix Link Knotless Anchor

Ventix Link Anchor Instruments

Part Number	Description
110025999	Tapered Awl/Punch, 4.75/5.5mm
110025998	Awl/Punch, 4.75/5.5mm
110026000	Tap, 4.75mm
110026001	Tap, 5.5mm
110026002	Disposable Drill, 4.75mm
110026003	Disposable Drill, 5.5mm

Instruments

Part Number	Description
CM-9010GT	Quattro GT Suture Passer
CM-9010	Quattro Suture Passer

Lock-Stitch[®] Procedure Kit

Part Number	Description
CM-9500	Lock-Stitch Procedure Kit (1-suture needle, 2 TRU-LOOP $^{ extsf{R}}$ Size 2 Suture Loops)

ComposiTCP Suture Anchors with BroadBand Tape Samples

Part Number	Description
110026105S	4.5mm ComposiTCP Suture Anchor Double Loaded with MaxBraid Suture Sample
1100261065	5.5mm ComposiTCP Suture Anchor Double Loaded with MaxBraid Suture Sample
110026108S	4.5mm ComposiTCP Suture Anchor Double Loaded with BroadBand Tape (Sliding) Sample
1100261095	5.5mm ComposiTCP Suture Anchor Double Loaded with BroadBand Tape (Sliding) Sample
1100261135	4.5mm ComposiTCP Suture Anchor Double Loaded with BroadBand Tape (Non-Sliding) Sample
110026114S	5.5mm ComposiTCP Suture Anchor Double Loaded with BroadBand Tape (Non-Sliding) Sample

Indications & Contraindications

INDICATIONS

The ComposiTCP threaded anchor system is intended for fixation of suture (soft tissue) to bone in the shoulder, foot/ankle, knee, hand/wrist, and elbow, but not limited to, the following procedures:

Shoulder: Rotator Cuff Repair, Bankart Repair; SLAP Lesion Repair; Biceps Tenodesis; Acromio-clavicular Separation Repair; Deltoid Repair; Capsule Shift or Capsulolabral Reconstruction;

Ankle/Foot: Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Hallux Valgus Reconstruction, Mid-foot Reconstruction, Metatarsal Ligament Repair/ Tendon Repair, Bunionectomy;

Knee: Anterior Cruciate Ligament Repair; Medial Collateral Ligament Repair; Lateral Collateral Ligament Repair; Patellar Tendon Repair; Posterior Oblique Ligament Repair; Iliotibial Band Tenodesis;

Wrist/Hand: Scapholunate Ligament Reconstruction; Ulnar or Radial Collateral Ligament Reconstruction; Radial Collateral Ligament Reconstruction.

Elbow: Biceps Tendon Reattachment; Ulnar or Radial Collateral Ligament Reconstruction; Tennis Elbow Repair and Lateral Epicondylitis Repair.

CONTRAINDICATIONS

- Insufficient quantity or quality of bone.
- Blood supply limitations and previous infections, which may retard healing.
- Foreign body sensitivity. Where material sensitivity is suspected, appropriate tests should be made and sensitivity ruled out prior to implantation.
- Any active infection or blood supply limitations.
- Conditions that tend to limit the patient's ability or willingness to restrict activities or follow directions during the healing period.
- The use of this device may not be suitable for patients with insufficient or immature bone. The physician should carefully assess bone quality before performing orthopedic surgery on patients who are skeletally immature. The use of this medical device and the placement of hardware or implants must not bridge, disturb or disrupt the growth plate.

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