Parcus Twist Biocomposite Suture Anchors

Important Product Information

Instructions for Use

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Twist Biocomposite Suture Anchors (English)

1. Indications:

The Parcus Twist Biocomposite Suture Anchors are indicated for attachment of soft tissue to bone. This product is intended for the following indications:

Shoulder	Rotator Cuff Repair, Acromioclavicular Separation Repair, Bankart Lesion Repair, Biceps Tenodesis, Capsular Shift or Capsulolabral Reconstruction, Deltoid Repair, SLAP Lesion Repair.
Knee	Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Posterior Oblique Ligament Repair, Extra Capsular Reconstruction, Iliotibial Band Tenodesis, Patellar Ligament and Tendon Avulsion Repair.
Foot/Ankle	Lateral Stabilization, Medial Stabilization, Midfoot Reconstruction, Achilles Tendon Repair, Hallux Valgus Reconstruction, Metatarsal Ligament Repair.
Elbow	Tennis Elbow Repair, Biceps Tendon Reattachment.
Hand/Wrist	Scapholunate Ligament Reconstruction, Ulnar or Radial Collateral Ligament Reconstruction, TFCC.

2. Contraindications:

A. Any active infection.
B. Blood supply limitations or other systemic conditions that may retard healing.
C. Foreign body sensitivity, if suspected, should be identified and precautions observed.
D. Insufficient quality or quantity of bone. Suture anchor performance is directly related to the quality of bone into which the anchor is placed.
E. Patient's inability or unwillingness to follow the surgeon's prescribed post-operative regimen.
F. Any situation that would compromise the ability of the user to follow the instructions for use or using the device for an indication other than those listed.

3. Adverse Effects:

A. Infection, both deep and superficial.
B. Allergies and other reactions to device materials.
C. Risks due to anesthesia.

4. Warnings:

A. Caution: Federal law restricts this device to sale by or on the order of a physician.
B. The fixation provided by this device should be protected until healing is complete. Failure to follow the postoperative regimen prescribed by the surgeon could result in the failure of the device and compromised results.
C. Anchor size selection should be made with care taking into consideration the quality of the bone into which the anchor is to be placed. Osteopenic bone poses fixation challenges which may be addressed by use of a Soft Bone Tap or larger diameter suture anchors.
D. Any decision to remove the device should take into consideration the potential risk of a second surgical procedure. Adequate postoperative management should be followed after implant removal.
E. Polyethylene polyblend sutures, as used in this device, elicit a minimal inflammatory reaction in tissues, followed by gradual encapsulation of the suture by fibrous connective tissue. Polyethylene polyblend suture is not absorbed, nor is any significant change in tensile strength retention known to occur in vivo.
F. The patient should be advised of the use and limitations of this device.
G. Pre-operative planning and evaluation, surgical approaches and technique, and familiarity of the implant, including its instrumentation and limitations are necessary components in achieving a good surgical result.
H. This device must never be reused. Reuse or re-sterilization may lead to changes in material characteristics such as deformation and material degradation which may compromise device performance. Reprocessing of single use devices can also cause cross-contamination leading to patient infection.
I. This device must never be re-sterilized.
J. Appropriate instrumentation should be used to implant this device.
K. This device must not be used if any of the temperature sensitive warning labels appear red in color.

5. Packaging and Labeling:

A. Do not use this product if the packaging or labeling has been damaged, shows signs of exposure to moisture or extreme temperature or has been altered in any way.
B. The Twist Biocomposite Suture Anchors are provided within two levels of sterile packaging. While the outer pouch provides a sterile and moisture barrier, the inner pouch only preserves the sterility of the device and does not prevent moisture from getting to the anchor body. Since the Twist Biocomposite Suture Anchors break down by means of hydrolysis, devices must be stored within both pouches. Devices found within only one layer of packaging should be discarded.
C. Please contact Parcus Medical Customer Service to report any package damage or alterations.

6. Material Specifications:

A. Anchor Body: The Twist Biocomposite Suture Anchors are manufactured using a composite of βTCP (beta tricalcium phosphate) and PLGA (poly lactic-co-glycolic acid). These devices are MR Safe.
B. Suture: The Twist Biocomposite Suture Anchors are provided with non-absorbable, sterile, surgical suture products composed of ultra high molecular weight polyethylene (UHMWPE). The suture or suture tape may be provided undyed

(white), dyed blue, dyed black or with trace filaments of black nylon, blue PET, or green PET. Suture products may be provided with stainless steel needles or tipped ends using cyanoacrylate.

C. Shaft: Stainless steel.
D. Handle: ABS.

7. Sterilization:

The Twist Biocomposite Suture Anchors and driver assemblies are supplied sterile. These products must never be re-sterilized.

8. Storage:

Products must be stored in the original unopened package in a dry place and must not be used beyond the expiration date indicated on the package. The Twist Biocomposite Suture Anchors must be stored below 25° C (77° F).

9. Instructions for Use

A. Identify bone of sufficient quantity and quality into which the anchor is to be placed.

Note: When bone quality is compromised, smaller diameter suture anchors may not provide adequate fixation. The use of the 4.5mm Twist Biocomposite Soft Bone Tap or a larger diameter suture anchor may provide an alternative solution.

B. Taking care to create an entry to the desired placement site as close to perpendicular as possible, insert the appropriate hole preparation instrument per associated instrumentation IFU. The instrumentation associated with each size anchor can be found in the table below.
   a. If desired, the quality of the patient's bone may be evaluated with the use of a Parcus Awl prior to tapping. The following guidelines should be used to ensure that use of the Awl does not compromise the fixation of the implant.

Anchor	Bone Condition	Awl/Drill	Awl/Drill Depth	Tap
4.5mm Twist Biocomposite Anchor	Soft	Parcus 3.2mm Awl; or	To Proximal Laser Line	4.5mm Twist Biocomposite Soft Bone Tap
		Parcus 3.2mm Drill Bit	To Distal Laser Line	
	Hard	Parcus 3.2mm Awl; or (Optional)	To Proximal Laser Line	4.5mm Twist Biocomposite Tap
		Parcus 3.2mm Drill Bit (Optional)	To Distal Laser Line	
5.5mm Twist Biocomposite Anchor	N/A	Parcus 4.1mm Awl (Optional)	To Laser Line	5.5mm Twist Biocomposite Tap
6.5mm Twist Biocomposite Anchor	N/A	Parcus 4.1mm Awl (Optional)	To Laser Line	6.5mm Twist Biocomposite Tap

C. Select the desired configuration (containing suture with or without needles) and aseptically open the package containing the suture anchor.
D. Place the Twist Biocomposite Suture Anchor into the prepared site and turn the driver handle clockwise until the circumferential laser etched line on the distal end of the driver shaft is flush with the surrounding bone.
E. If present, the longitudinal lines on the driver shaft are used to indicate the orientation of the suture passing around the post within the anchor. Placing the longitudinal lines in a plane perpendicular to the targeted tissue offers the best orientation to allow the suture anchor to function as intended.
F. If a suture anchor with needles is selected, release the suture loops from the back of the handle and disengage driver from anchor. The needles will now be loose and may be removed.
G. One, two, or three strands of polyethylene polyblend high strength suture either with or without needles are attached to the anchor. Note that each strand is a different color in order to aid in identification.
H. Pass the sutures through the targeted tissue in the user preferred manner.
I. Complete the tissue repair by securing the suture tails using the appropriate method. a Cut the suture tails above the region where they have been secured.