

Parcus MiTi Suture Anchor
Product Information Sheet and Directions for Use:

1. Indications:

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

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

2. Contraindications:

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

3. Adverse Effects:

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

4. Warnings:

- The Parcus MiTi Suture Anchors have not been evaluated for safety and compatibility in the MR environment. The Parcus MiTi Suture Anchors have not been tested for heating or migration in the MR environment.
- This product should only be used by or on the order of a physician.
- 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.
- 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 larger diameter V-LoX PEEK CF or V-LoX Titanium Suture Anchors as the size of the anchor placement site dictates.
- 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.
- 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.
- The patient should be advised of the use and limitations of this device.
- Pre-operative planning and evaluation, surgical approaches and technique, and familiarity with the implant,

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- Pre-operative planning and evaluation, surgical approaches and technique, and familiarity with the implant,

including its instrumentation and limitations are necessary components in achieving a good surgical result.

- I. This device must never be reused.
- J. This device must never be re-sterilized.
- K. Appropriate instrumentation should be used to implant this device.
- L. Never use a bent Drill Bit.
- M. The Drill Bit is not intended for use as an implant.
- N. Loading the Drill Bit in an off axis manner may result in breakage or bending.

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. Please contact Parcus Medical Customer Service to report any package damage or alterations.

6. Material Specifications:

The MiTi Suture Anchor is supplied with or without needles attached to the high-strength, braided, polyethylene polyblend sutures. Contrasting suture colors are used in suture anchors supplied with multiple sutures. The anchor material is Ti-6Al-4V ELI (ASTM F136). The Drill Bit is manufactured from a Stainless Steel Alloy. The materials used in the manufacture of this device that are intended to be placed inside the body are radio-opaque and can, therefore, be detected with conventional X-Ray or fluoroscopy.

7. Sterilization:

The MiTi Suture Anchor, driver assembly and Drill Bit is 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.

9. Directions for Use

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

Note: In cases where bone quality is suspect and a MiTi Suture Anchor does not provide the desired fixation, the larger diameter V-LoX Titanium or PEEK CF Suture Anchor may provide an alternative solution.

- B. Place the Drill Bit into the chuck of a purpose designed drill or wire driver. Taking care to create an entry to the desired placement site as close to perpendicular as possible, use the appropriate MiTi Suture Anchor Drill Bit to prepare a hole in the bone. Insert the Drill Bit into the bone to the depth indicated by the laser line on the distal end of the Drill Bit.
- C. Place the MiTi Suture Anchor into the prepared site, as described above, 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. The orientation of the sutures passing through the implant may be visualized as they are exterior to the shaft. Placing the sutures in a plane perpendicular to the targeted tissue offers the best orientation to allow the suture to slide through the anchor.
- D. One or two strands of polyethylene polyblend high strength suture either with or without needles can be found attached to the anchor.
- E. As applicable, remove needles from keeper and pass the sutures through the targeted tissue in the user preferred manner.
- F. Complete the tissue repair by tying knots of the surgeon preferred configuration and cutting the suture tails above the knots.

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