ANIKA PARCUS

X-Twist PEEK Suture Anchor

Important Product Information

Instructions for Use

31843 Rev B ANIKA Eff. 04/22
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(941)755-7965
Mfd by:
Parcus Medical, LLC
6423 Parkland Dr.
Sarasota, FL 34243

1. Indications:

The X-Twist PEEK Suture Anchors are indicated for attachment of soft tissue to bone. These products are 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.
E. Patient's inability or unwillingness to follow 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.

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. Size selection of the implant should be made with care taking into consideration the quality and quantity of bone into which the implant is to be placed.
D. In cases where bone quality is suspect, the 6.25 mm X-Twist PEEK Anchors should be used to maximize fixation strength. The 6.25 mm X-Twist PEEK Anchors may also be used in cases in which attempted insertion of a 4.75 mm or 5.5 mm X-Twist PEEK Anchor does not offer satisfactory fixation strength.
E. 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.

F. Pre-operative planning and evaluation, surgical approaches and technique, and familiarity of the implant, including its instrumentation and limitations are necessary for achieving a good surgical result and minimizing the risks to patients associated with prolonged surgery time.
G. 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.
H. Insertion of the anchor off axis from the hole may result in implant failure.
I. Failure to insert the driver to the depth indicated by the laser mark may result in the anchor being left proud which could cause soft tissue irritation and pain.
J. Appropriate instrumentation should be used to implant this device.

5. MRI Safety Information:

A. The implantable portion of this device is MR Safe.

6. 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.

7. Sterilization:

A. This device is supplied in sterile packaging. The contents are sterilized by EO gas. This device must never be re-sterilized.
B. The reusable instrumentation used in conjunction with the X-Twist PEEK products shall be cleaned and/or sterilized only in accordance with the Instructions for Use included with those devices.

8. Storage:

A. 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. Material Specifications:

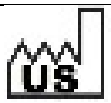
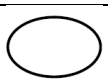
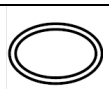
A. X-Twist PEEK Suture Anchor Body and Tip: The implantable anchor and tip portion of this device is polyetheretherketone (PEEK).
B. Suture/suture tape (as applicable): This device may be provided with implantable, non-absorbable, sterile, surgical suture products composed of ultra-high molecular weight 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, heat-tipped ends, or tipped ends using cyanoacrylate.
C. Inserter Shaft: Stainless Steel. This component is for single use and is not intended to be implanted. It is radio-opaque and can, therefore, be detected with conventional X-Ray or fluoroscopy.
D. Inserter Handle: Acrylonitrile butadiene styrene (ABS). This component is for single use and intended for non-invasive use.
E. Paddle: Acrylonitrile butadiene styrene (ABS). This component is for single use and intended for transient use.
F. Suture Threader: Nitinol and stainless-steel. This component is for single use and not intended for invasive use.

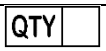
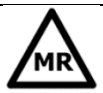
10. Specific Instructions for Use: When applicable, see the corresponding surgical technique for additional information.

A. X-Twist PEEK Suture Anchors:

i. This device is designed such that sutures will be placed through the distal eyelet in the PEEK tip and will be secured when the anchor is advanced into the prepared socket. The distal eyelet of the X-Twist PEEK Anchors will accommodate up to four (4) strands of 1.6 mm suture tape, #2 suture, or a combination thereof.

11. Symbol Glossary:

Symbol	Definition	Standard Used	Ref #
	Legal Manufacturer Country of Manufacture	ISO 15223-1	5.1.1 5.1.11
YYYY-MM 	Legal Manufacturer Date of Manufacture Country of Manufacture	ISO 15223-1	5.1.1 5.1.3 5.1.11
	Authorized representative in the European Community	ISO 15223-1	5.1.2
	Use-by-date	ISO 15223-1	5.1.4
	Batch code	ISO 15223-1	5.1.5
	Catalog number	ISO 15223-1	5.1.6
	Sterilized using ethylene oxide	ISO 15223-1	5.2.3
	Do not resterilize	ISO 15223-1	5.2.6
	Non-sterile	ISO 15223-1	5.2.7
	Do not use if package is damaged	ISO 15223-1	5.2.8
	Single sterile barrier system	ISO 15223-1	5.2.11
	Double sterile barrier system	ISO 15223-1	5.2.12
	Keep away from sunlight	ISO 15223-1	5.3.2

	Keep dry	ISO 15223-1	5.3.4
	Upper limit of temperature	ISO 15233-1	5.3.6
	Do not re-use	ISO 15223-1	5.4.2
	Consult instructions for use	ISO 15223-1	5.4.3
 www.anikaifu.com	Consult electronic instructions for use	ISO 15223-1	5.4.3
	Patient identification	ISO 15223-1	5.7.3
	Patient information website	ISO 15223-1	5.7.4
	Healthcare center or doctor	ISO 15223-1	5.7.5
	Date	ISO 15223-1	5.7.6
	Medical device	ISO 15223-1	5.7.7
	Unique device identifier	ISO 15223-1	5.7.10
	Quantity	NA	NA
	Caution: U.S. Federal law restricts this device to sale by or on the order of a physician	21 CFR 801	801.109
	MR Conditional	ASTM F2503	Table 2
	MR Safe	ASTM F2503	Table 2
	MR Unsafe	ASTM F2503	Table 2