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PATIENT INFORMATION LEAFLET

ANCHORS

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Patient Information Leaflet

1.Device Information

a. Device Name: Anchor
b. Model: Knotless PEEK CF, Knotless PEEK, Twist Knotless, Slik, Slik Fix, V-LoX, V-LoX3 PEEK CF, Twist & Triple Twist, V-LoX, V-LoX3, Miti, PEEK CF Push-in, Draw Tight

2.Indications

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. Hip - Acetabular Labral Repair
b. Anchor selection will be determined by your health care professional.

3.Special Operating Instructions

Not applicable. Following implantation, no additional actions are necessary for the proper functioning of anchors.

4.Performance Device

a. Anchors are indicated for attachment of soft tissue to bone.
b. As with any implantable device, the implantation of anchors could result in infection or patient reaction to the materials of the implant. Post-operative wound care and activity level requirements shall be provided by your Healthcare Provider and shall be strictly followed.

5.Residual Risks

a. 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 the potential of compromised results.
b. Any decision to remove the device should take into consideration the potential risk of a second surgical procedure. An adequate postoperative management plan should be implemented after implant removal

6.Warnings

a. The PEEK & PEEK CF anchors have been evaluated for safety and compatibility in the MR environment. The Titanium devices have not been tested for heating or migration in the MR environment. Use of MR technology in the presence of devices of this nature

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may cause magnetically induced displacement forces and torques, radio frequency heating and image artifacts. Standard MRI screening guidelines for post-operative patients should be followed.

7.Post Operative Care

a. Postoperatively and until healing is complete, fixation provided by this device should be considered as temporary and may not withstand weight bearing or unsupported stress. The fixation provided by this device should be protected. The postoperative regimen prescribed by the physician should be strictly followed to avoid adverse stresses applied to the device and bone.
b. Symptoms indicating that the device may be malfunction include increased swelling and increased pain.
c. In the event of any of the symptoms identified above or any other concern regarding the device, patient shall follow-up with their health care provider.
d. The functional lifetime of this device is the amount of time necessary for stablisation, please contact your health care provider for more information regarding this.
e. Failure to follow the post operative regimen prescribed by the health care provider may result in a premature failure of the device.
g. For any other concern please contact your Health care provider.

8.Materials

a. Anchors are comprised of the following materials:
Permanent Implant

- Anchor: Titanium 6Al-4V ELI, PEEK CF, PEEK
- Suture: UHMWPE

9. Adverse Events

a. Any serious incident that occurs in relation to the device should be reported to both Parcus Medical and the Therapeutic Goods Administration using the following contact information.
Therapeutic Goods Administration (TGA)

- IRIS@health.gov.au
- https://www.tga.gov.au/reporting-adverse-events

Anika Theraputics

- parcusCS@anika.com
- https://parcusmedical.com/