PARCUS

Parcus Medical has joined Anika

ANIKA

# PATIENT INFORMATION LEAFLET

## BTCP/PLGA Suture Anchors

Parcus Medical has joined Anika

# Patient Information Leaflet

## 1.Device Information

a. Device Name: Anchor
b. Model: AP Push-In, Twist Biocomposite

## 2.Indications

The Parcus Knotless AP and 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.

## 3.Special Operating Instructions

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

## 4.Performance Device

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 compromised results.
b. Anchor size selection should be made with care taking into consideration the quality of the bone in which the anchor is to be placed. (Osteopenic bone poses fixation challenges which may be addressed by larger diameter suture anchors.)
c. As with any implantable device, the implantation of this device 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.Infection, both deep and superficial.
b.Allergies and other reactions to device materials.
c.Risks due to anesthesia

## 6.Warnings

a.Caution: Federal law restricts this device to sale by or on the order of a physician.

# Patient Information Leaflet

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 compromised results.
b.Anchor size selection should be made with care taking into consideration the quality of the bone in which the anchor is to be placed. (Osteopenic bone poses fixation challenges which may be addressed by larger diameter suture anchors.)
c.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.
d.The patient should be advised of the use and limitations of this device.
e.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.
f.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.
g.This device must never be re-sterilized.
h.Appropriate instrumentation should be used to implant this device.
i.The device must not be used if the temperature indicator sticker on the exterior of the box appears red in color.

**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, increased pain or limited mobility.
c.In the event of any of the symptoms identified above or any other concern regarding the device, patient shall follow-up with their physician.
d.The functional lifetime of this device is approximately 12 weeks. While the implant does not need to be explanted, this is sufficient time for your body to heal and this device will carry very little, if any, load.
e.Failure to follow the post-operative regiment prescribed by the physician may result in a premature failure of the device.
f.Physician shall be followed up with in the instance of increased pain, increased swelling, limited mobility or any other concerns related to the device.

# Patient Information Leaflet

## 8.Materials

a.The Twist Biocomposite Suture Anchor is comprised of the following materials:
Permanent Implant:

- Anchor Body: βTCP (beta tricalcium phosphate) and PLGA (poly lactic-co-glycolic acid)
- Suture or Suture Tape: Undyed (white), dyed blue, dyed black or with trace filaments of black nylon, blue PET, or green PET

Transient Devices:

- Inserter Shaft: Stainless Steel 304 or Stainless Steel 17-4 H900

Non-invasive Devices:

- Inserter Handle: ABS (Cycolac or Lexan)
- Protective Tube: Vinyl
- Inner pouch: PET/Tyvek
- Outer pouch: PET/Foil

b.The Knotless AP Suture Anchor is comprised of the following materials:
Permanent Implant:

- Anchor Body: βTCP (beta tricalcium phosphate) and PLGA (poly lactic-co-glycolic acid)

Transient Devices:

- Inserter Shaft: Stainless Steel 304 or Stainless Steel 17-4 H900

Non-invasive Devices:

- Suture threader handle: Stainless Steele 303
- Suture threader wire: Nitonol
- Inserter Handle: ABS (Cycolac or Lexan)
- Protective Tube: Vinyl
- Inner pouch: PET/Tyvek
- Outer pouch: PET/Foil

## 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/