PARCUS

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PATIENT INFORMATION LEAFLET

Synd-EZ (SS & Ti)

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Patient Information Leaflet

1.Device Information

a. Device Name: Synd-EZ
b. Model: Stainless Steel, Titanium

2.Indications

a. The Parcus Synd-EZ is intended to be used as an adjunct in fracture repair involving metaphyseal and periarticular small bone fragments where screws are not indicated, and as adjuncts in external and intramedullary fixation systems involving plates and rods, with fracture braces and casting.
b. The Parcus Synd-EZ is intended to provide fixation during the healing process following syndesmotic trauma, such as fixation of the syndesmosis (syndesmosis disruptions) in connection with Weber B and Weber C ankle fractures.

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 Synd-EZ is designed to provide stability to the syndesmosis following syndesmotic trauma that may or may not also include an ankle fracture. The Synd-EZ is intended to allow for some lateral movement between the tibia and fibula without permitting widening of the mortise.
b. As with any implantable device, the implantation of the Synd-EZ 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. Special consideration should be made to the material compatibility of fracture plates and/or screws that may be used in conjunction with the Synd-EZ device. Parcus Medical recommends that implants in direct contact with each other should be comprised of identical metallurgical composition.

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b. This device has not been evaluated for safety and compatibility in the MR environment. This device has not been tested for heating or migration in the MR environment. Use of MR technology in the presence of devices of this nature 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.
c. 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.

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 malfunctioning include increased swelling, increased pain and widening of the mortise visualized by radiograph.
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 the amount of time necessary for stabilization of the syndesmosis. However, it is not necessary to explant the device and therefore the lifetime of the device can be the lifetime of the patient.
e. Failure to follow the post operative regimen prescribed by the physician may result in a premature failure of the device.
f. Upon healing of the syndesmosis, the load applied to the Synd-EZ construct will be negligible.
g. Physician shall be followed up with in the instance of increased pain, increased swelling, or any other concerns related to the device.

8.Materials

a. The Synd-EZ Ti is comprised of the following materials:
Permanent Implant

- Top hat: Titanium 6Al-4V ELI
- Button: Titanium 6Al-4V ELI
- Washer: Titanium 6Al-4V ELI
- Adjustment Suture: UHMWPE with blue PET tracer

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Transient Devices
- Counter-traction Suture: Dyed UHMWPE
- Passing Suture: UHMWPE
- Toggle Suture: UHMWPE with black Nylon tracer
- 1.5mm K-wire: Stainless Steel 316L/316LVM
- 2.4mm Passing Pin: Stainless Steel 17-4 H900
- 3.5mm Cannulated Drill Bit: Stainless Steel 420B

Non Invasive
- Tension Handle: Delrin® Acetal

b. The Synd-EZ SS is comprised of the following materials:
Permanent Implant
- Top hat: Stainless Steel 316LS/316LVM
- Button: Titanium 6Al-4V ELI
- Adjustment Suture: UHMWPE with blue PET tracer

Transient Devices
- Counter-traction Suture: Dyed UHMWPE
- Passing Suture: UHMWPE
- Toggle Suture: UHMWPE with black Nylon tracer
- 1.5mm K-wire: Stainless Steel 316L/316LVM
- 2.4mm Passing Pin: Stainless Steel 17-4 H900
- 3.5mm Cannulated Drill Bit: Stainless Steel 420B

Non Invasive
- Tension Handle: Delrin® Acetal

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/