PARCUS

Parcus Medical has joined Anika

ANIKA

PATIENT INFORMATION LEAFLET

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Patient Information Leaflet

1.Device Information

a. Device Name: Actiflip
b. Model: Cinch, Whip

2.Indications

The Parcus Actiflip is used for fixation of bone to bone or soft tissue to bone, and is intended as fixation post, a distribution bridge, or for distributing suture tension over areas of ligament or tendon repair in the knee, shoulder, and elbow and may include the following indications; anterior cruciate ligament, posterior cruciate ligament, pectoralis repair (minor/major), biceps tendon repair and reattachment (distal/proximal), acromioclavicular repair, and ulnar collateral ligament reconstruction.

3.Special Operating Instructions

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

4.Performance Device

a. The Parcus Actiflip is used for fixation of bone to bone or soft tissue to bone, and is intended as fixation post, a distribution bridge, or for distributing suture tension over areas of ligament or tendon repair in the knee, shoulder, and elbow.
b. As with any implantable device, the implantation of the AcTiFlip 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. 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.

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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 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 stabilisation, 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. The Actiflip is comprised of the following materials:
Permanent Implant

- Button: Titanium 6Al-4V ELI
- Suture: UHMWPE

Transient Devices

- 1.5mm K-wire: Stainless Steel 316L/316LVM
- 3.5mm Cannulated Drill Bit: Stainless Steel 420B

9. Adverse Events

a. Any serious incident that occurs in relation to the device should be reported to both Anika Theraputics 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/