# Patient Information

BIOTEK® we put life in metal

## SOFT TISSUE ANCHORING DEVICES

**Titanium Ligament Anchor with Fiber Wire/Fiber Tape, PEEK Ligament Anchor with Fiber Wire/Fiber Tape, Soft Ligament Anchor Knotted/ Knotless**

### Soft Tissue Anchoring Devices is Used For

Soft Tissue Anchoring Devices are intended to aid in arthroscopic and orthopaedic reconstructive procedures requiring soft tissue fixation to bone in the shoulder, wrist/hand, ankle/foot, elbow, hip and knee, due to injury or degenerative disease.

### Product Description

The Soft Tissue Anchoring Device are made up of:

1. The Anchor - which is inserted into the bone. This may be a screw mechanism or an interference fit.
2. The Eyelet - is a hole or a loop in the anchor to through which the suture passes. This links the anchor to the suture.
3. The Suture - is attached to the anchor by through the eyelet of the anchor. It is made up of a non-absorbable material.

Titanium or PEEK or soft ligament anchors consist of anchors with an integral or separate eyelet. They are preloaded on a handled inserter. Suture, with or without needles, and a suture threader may also be provided. Soft Ligament Anchors consist of a sleeve and a suture strand and needles. The soft anchor is preloaded on a disposable inserter designed to facilitate the deployment of the anchor. When the suture strand is pulled tight, the Sleeve locks against the bone, fixating the soft tissue.

### Precaution

Postoperative care is important. Instructions by the surgeon should be followed. The patient should be instructed on the limitations of the implant and should be cautioned regarding weight bearing and body stresses on the implant prior to secure bone healing. Soft tissue irritation and/or pain post–operatively due to any potential cause must be reported promptly to your doctor. You may also report it to Chetan Meditech Pvt. Ltd. at +91-9924032223 or directly to the Therapeutic Goods Administration at this link: https://www.tga.gov.au/reporting-problems

### When Soft Tissue Anchoring Device Should Not be Used

The following are contraindications for Soft Tissue Anchoring Devices:

- Foreign body sensitivity or Known hypersensitivity to the implant material. Where material sensitivity is suspected, appropriate tests should be made and sensitivity ruled out prior to implantation.
- Insufficient quantity or quality of bone or soft tissue. Pathological conditions of bone & soft tissue, such as cystic changes, tumor or severe osteopenia, which would compromise secure implant fixation.
- Patient conditions including Blood supply limitation and previous infections which may tend to retard healing. Acute or chronic local or systemic infection.
- Patients with cognitive impairment or neurologic conditions who are unwilling or incapable of following postoperative care instructions.
- Conditions which tend to limit the patient's ability or willingness to restrict activities or follow directions during the healing period.
- Excessive body activities that could cause overloading of the implant.

### Adverse Effect

Implanting Soft Tissue Anchoring Devices carries some risks associated with any surgery:

- Pain, discomfort, or abnormal sensation due to the presence of the device.
- Inadequate healing.
- Intraoperative or postoperative bone fracture and/or postoperative pain.
- Infections, both deep and superficial

- Foreign body reactions.

Seek medical advice if you experience any of these symptoms.

## Magnetic Resonance Imaging/ Electromagnetic field/ Magnetic field

Soft Tissue Anchoring Devices has not been evaluated for safety and compatibility in the magnetic resonance (MR) environment. This device has not been tested for heating, migration or image artifact in the MR environment. The safety of the device in the MR environment is unknown. Scanning a patient who has this device may result in patient injury. If the implant is manufactured from a metallic material, surgeons can expect that MR artifacts will be present during routine MR imaging.

Implants made from PEEK (Poly Ether Ether Ketone as per ASTM F2026) OR Polyethene (UHMWPE) are 'MR safe' as they are non-conducting, non-metallic, non-magnetic items and poses no known hazard in MRI environment.

## Record Keeping

It is important that you keep a record of your implant. You will be sent a small Record that you can keep with you which will have the details of your implant printed on it.

## Manufacturer

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