PATIENT INFORMATION LEAFLET

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

BIOTEK® we put life in metal

Device Information

- Device Model:

Place a copy of the Patient Label provided with the implant here.

What is in this leaflet?

This leaflet answers some common questions about Soft Tissue Anchoring Device. It does not contain all the available information. It does not take the place of talking to your surgeon.

All medical devices and implants have risks and benefits. Your surgeon has weighed the risks of using Soft Tissue Anchoring Device against the benefits that are expected. This leaflet does not contain all the available information about Soft Tissue Anchoring Device. Your surgeon has been provided additional information and can answer any questions you may have. Follow your surgeon's advice even if it differs from what is in this leaflet.

Please read this leaflet carefully and keep it in a safe place so you may refer to it in future if needed.

What is Soft Tissue Anchoring Device?

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.

Soft Tissue Anchoring Device is Used For?

Soft Tissue Anchoring Device is used 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.

Soft Tissue Anchoring Device can only be implanted surgically by a qualified surgeon. Your surgeon will choose the correct implant based on their professional judgment when determining the appropriate anchor, size based on the specific indication, preferred surgical technique, and patient history. As with any medical treatment, individual results may vary.

When Soft Tissue Anchoring Device Should Not be Used?

The following are contraindications for Soft Tissue Anchoring Devices:

- 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.

- 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.
- 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.
- Acute or chronic local or systemic infection.
- The use of this device may not be suitable for patients with insufficient or immature bone. The physician should carefully assess bone quality before performing orthopedic surgery on patients who are skeletally immature. The use of this medical device and the placement of hardware or implants must not bridge, disturb, or disrupt the growth plate.
- The device should not be used for surgeries other than those indicated.
- Severe muscular, nervous, and/or vascular disorders that could endanger the limb.
- Any concomitant illness and/or dependence that could risk implanting function.

What to do after Soft Tissue Anchoring Device has been implanted?

Protocol for Surgery and recovery can vary for each individual, and all issues related to surgical procedure or postoperative protocol should be discussed with your surgeon.

After the Soft Tissue Anchoring Device is implanted, following post-operative care should be taken:

- 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.
- In the case of any of the symptoms identified as adverse effect/side effect or any other concern regarding the device, patient shall follow-up with their physician.
- Failure to follow the post operative regiment prescribed by the physician may result in a premature failure of the device.
- Physician shall be followed up with in the instance of increased pain, increased swelling, or any other concerns related to the device.

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.

Device Life

The Soft Tissue Anchoring device is long lasting fixation devices which is designed to assist in the normal healing process. The device is not intended to withstand body weight or to replace normal body structure in the event of incomplete healing. If healing lasts for longer or does not occur, the device may break over time due to wear and tear.

Although healing time may vary based on patient condition, literature suggests that healing time for these devices last more than 12 weeks.

Safety Information for 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.

Adverse Effect/Side 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.

Contact Information*

Any serious incident that occurs in relation to the device should be reported to Chetan Meditech Pvt. Ltd., Stable Orthopaedic Pty Ltd and the Therapeutic Goods Administration using the following contact information:

Therapeutic Goods Administration (TGA)	Manufacturer	Manufacturer's Australian Sponsor
	Chetan Meditech Pvt. Ltd.	Stable Orthopaedic Pty. Ltd.
IRIS@health.gov.au	contact@biotekortho.com	feedback@stableortho.com
https://www.tga.gov.au/reporting-problems	https://www.biotekortho.com/	https://stableortho.com/

*This Information is applicable to Australia Only

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