PATIENT INFORMATION LEAFLET

LIGAMENT & TENDON FIXATION IMPLANT

Device Information

- Device Model:

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

Ligament & Tendon Fixation Implants is Used For

The fixation devices are used for fixation of tendons and ligaments during orthopaedic reconstruction procedures such as anterior cruciate ligament (ACL) and posterior cruciate ligament (PCL) reconstruction.

Fixation screw, low profile cancellous screws, washer & staples are also intended to be used for internal bone fixation for bone fractures, fusions, osteotomies and non-unions in the ankle, foot, hand, wrist, clavicle, scapula, olecranon, humerus, radius, ulna, tibia, calcaneus, femur and fibula.

Product Description

Fixation screws are inserted into bone for fixation of tendons and ligaments during orthopaedic reconstruction procedures. The fixation screw has a low profile head to reduce soft-tissue irritation. The flat head design eliminates need of washer when tying sutures around a post. The respective size drill is used to broach the cortical bone and depth device is used to obtain accurate sizing information.

The **cancellous screws** are devices having a low profile head to reduce soft tissue irritation. Low profile cancellous screw and spiked washer set provide continuous strength for soft tissue fixation to bone.

The **washers** are intended as adjunct devices. Washers are used in conjugation with fixation screws/low profile cancellous screws for fixation of soft tissue or tendons directly to bone. A washer is intended to improve bone fixation to bone or soft tissue following orthopaedic procedures.

Staples are indicated for fixation of bone fractures, bone reconstruction, ligament, soft-tissue and tendon. The distal end of the staple can be used as drilling gauge as well as grip to put in the staple. Ligament staples with a low profile bridge, reduce the frequency of secondary removal due to patient discomfort caused by soft tissue irritation. The spiked fixation staple has sharp leg points for easier penetration into cortical bone without predrilling.

The **tibial base plates** are used for primary or auxillary fixation in ACL/PCL reconstruction. Used for fixating grafts with sutures.

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.

When Ligament & Tendon Fixation Implants Should Not be Used

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The following are contraindications for Ligament & Tendon Fixation Implants:

- 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.
- Patients with cognitive impairment or neurologic conditions who are unwilling or incapable of following postoperative care instructions.
- Acute or chronic local or systemic infection.
- Conditions which tend to limit the patient's ability or willingness to restrict activities or follow directions during the healing period.
- 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.
- Comminuted bone sur face, which would compromise secure implant fixation.
- Severe muscular, nervous, and/or vascular disorders that could endanger the limb.
- Any concomitant illness and/or dependence that could risk implanting function.
- Excessive body activities that could cause overloading of the implant.

Post Operative Care

After implanting the Ligament & Tendon Fixation Implants following 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 in adverse 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.

Magnetic Resonance Imaging/ Electromagnetic field/ Magnetic field

This device 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.

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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

Implanting Ligament & Tendon Fixation Implants carries some risks associated with any surgery:

- Infections, both deep and superficial.
- Foreign body reactions.

Seek medical advice if you experience any of these symptoms.
Any serious incident that occurs in relation to the device should be reported to both Chetan Meditech Pvt. Ltd. and the Therapeutic Goods Administration using the following contact information:

Therapeutic Goods Administration (TGA)	Chetan Meditech Pvt. Ltd.
iris@tga.gov.au	contact@biotekortho.com
http://reporting.tga.gov.au/mdir/mdir03.aspx	https://www.biotekortho.com/

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