PATIENT INFORMATION LEAFLET

FIXATION BUTTON WITTH ADJUSTABLE LOOP

Device Information

- Device Model:

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

Fixation Button with Adjustable Loop is Used For

Fixation Button with Adjustable Loop are intended to be used for fixation of bone-to-bone or soft-tissue-to-bone, as fixation posts, distribution bridge, or for distributing suture tension over areas of ligament or tendon repair.

Product Description

- The fixation device is composed of two components: a suture loop and a fixation device. The suture portion of the fixation device is made of a UHMWPE braid (Ultra High Molecular Weight Poly Ethylene braid) (IUPAC: Polyethene). The fixation device is made of titanium alloy Titanium Ti-6Al-4V which meets ISO 5832-3/ASTM F 136 or PEEK.
- The use of the fixation device provides the orthopedic surgeon a means of accurate suture fixation in reconstructive surgery. The fixation device allows for endoscopic ligament reconstruction without the requirement for an ancillary lateral incision. Refer the label on the packaging for complete specifications and material information of the product.
- Soft-tissue to bone or bone-to-bone fixation constructs via fixation buttons can be classified as suspension fixation which requires fixation distant from the actual insertion site.

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 Fixation Button with Adjustable Loop Should Not be Used

The following are contraindications for Fixation Button with Adjustable Loop:

- 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.

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- 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.

Post Operative Care

After implanting the Fixation Button with Adjustable Loop 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.

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 Fixation Button with Adjustable Loop carries some risks associated with any surgery:

- Wound dehiscence, calculi formation in urinary or biliary tract such as bile or urine occurs, infected wounds, minimal acute inflammatory tissue reaction and transitory local irritation.
- Pain at the incision or surgical site
- Osteomyelitis surrounding the device
- Rediastasis resulting from a failure of the implant insertion technique
- Fiber Wire polyethylene wear-related painful aseptic osteolysis.

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- Infections, both deep and superficial.
- Foreign body reactions.
- Implant pullout
- Bone damage or fracture
- Injury to surrounding tissues
- Embolus or blood clotting issues (e.g., pulmonary embolus, deep vein thrombosis, etc.)
- Nerve injury or palsy
- Implant or treatment failure
- Secondary surgical interventions may include, but are not limited to:
- Removal of implant
- Placement of new or additional implant(s)

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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