PATIENT INFORMATION LEAFLET

INTERFERENCE SCREW

Device Information

- Device Model:

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

Interference Screw is Used For

These devices are intended to be used for fixation of tissue, including ligament or tendon to bone, or a bone/tendon to bone. Also intended to provide soft tissue reattachment (i.e. fixation of ligament and tendon graft tissue).

Product Description

Fixation with an interference screw is achieved by engaging the tendon with the screw threads and compressing it against the cortical bone or bone tunnel wall. Interference fixation generates increased local pressure around the tendon-cancellous bone interface, which is thought to augment bone healing.

The screw is for single use only.

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 Interference Screw Should Not be Used

The following are contraindications for Interference Screw:

- 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.

PATIENT INFORMATION LEAFLET

INTERFERENCE SCREW

- 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 Interference Screw 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 Interference Screw carries some risks associated with any surgery:

- Complications which are seen with any method of internal fixation include failure to regain full extension or flexion, patella femoral complications, fixation complications, hardware irritation, impingement to the graft, and arthrofibrosis.
- Additional complications may include fixation failure, and migration of the screw.
- Infections, both deep and superficial.
- Foreign body reactions.
- Metal implants only: Shoulder dislocation/subluxation
- Under insertion of the device may leave the proximal end of the implant protruding beyond the cortical bone, which could potentially cause soft tissue irritation and/or pain post-operatively

PATIENT INFORMATION LEAFLET

INTERFERENCE SCREW

- Severe osteoporosis, severe malformations, local bone tumors, metabolic disorders, infections, severe falls, drug and/or alcohol abuse, overweight, and excessive vibration stress on implants can have a negative effect on the result. Possible well-known effects are: Loosening and drifting of the implant, Dislocation of the implant, Infection, Venous thrombosis and pulmonary embolism, Cardiovascular Disorders & Hematoma.

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/

PATIENT INFORMATION LEAFLET

INTERFERENCE SCREW

Chetan Meditech Pvt. Ltd.
MD-04, Sanand-II, GIDC, Ahmedabad
Gujarat INDIA- 382110
Phone (Worldwide): +91-9924032223
www.biotekortho.com

BT/PI/07, Rev:00