PATIENT INFORMATION LEAFLET

Bioabsorbable Ligament Anchor with Fiber wire/Fiber Tape

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 Bioabsorbable Ligament Anchor with Fiber wire/Fiber Tape. 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 Bioabsorbable Ligament Anchor Device against the benefits that are expected. This leaflet does not contain all the available information about Bioabsorbable Ligament Anchor 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 Bioabsorbable Ligament Anchor Device?

Bioabsorbable Ligament Anchor with Fiber wire/Fiber Tape 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, through the eyelet of the anchor. It is made up of a non-absorbable material.

Bioabsorbable 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.

Bioabsorbable Ligament Anchor is Used For?

Bioabsorbable Ligament Anchor with Fiber wire/Fiber Tape is intended to reattach soft tissue to bone in orthopeadic surgical procedures in Shoulder. The system may be used in either arthroscopic or open surgical procedures. After the suture is anchored to the bone, it may be used to reattach soft tissue, such as ligaments, tendons, or joint capsules to the bone. The suture anchor system thereby stabilizes the damaged soft tissue, in conjunction with appropriate postoperative immobilization throughout the healing period.

When Bioabsorbable Ligament Anchor Should Not be Used?

The following are contraindications for Bioabsorbable Ligament Anchor with Fiber wire/Fiber Tape:

- 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, tumour 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.
- As with any biocomposite implant, there is a potential risk of an inflammation response during the material's osseointegration period and reactions to foreign bodies.
- Allergic, tissue irritation/inflammation and other reactions to device material.

What to do after Bioabsorbable Ligament Anchor 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 implanting the Bioabsorbable Ligament Anchor with Fiber wire/Fiber Tape 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 as 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.

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 Bioabsorbable Ligament Anchor with Fiber wire/Fiber Tape 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

Medical device made from Poly (L-Lactide-co-D, L-Lactide), tri-calcium phosphate (TCP), Ultra High Molecular Weight Poly Ethylene (UHMWPE) and Poly Ether Ether Ketone (PEEK) are 'MR safe' as they are non-conducting, non-metallic, non-magnetic items and poses no known hazard in MRI environment. Implants made from Titanium Ti-6Al-4V ELI 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.

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 Bioabsorbable Ligament Anchor with Fiber wire/Fiber Tape carries some risks associated with any surgery:

- Inadequate healing.
- Infections, both deep and superficial.
- Foreign body reaction.
- The complications usually encountered in all internal attachment surgery- Secondary tearing.
- As with any biocomposite implant, there is a potential risk of an inflammatory response during the material's osseointegration period and reactions to foreign bodies such as osteolysis and cyst formation.
- Allergic, tissue irritation/inflammation and other reactions to device material.
- Allergic-like reactions to PLA materials (PLLA, PLDLA) have been reported. These reactions have sometimes necessitated the removal of the implant. Patient sensitivity to device materials must be considered prior to implantation.

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 both Chetan Meditech Pvt. 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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