

PATIENT INFORMATION LEAFLET

FIBER WIRE/TAPE/LOOP

Device Information

- Device Model:

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

Fiber Wire/Tape/Loop is Used For

Fiber sutures are indicated for use in general soft tissue approximation and/or ligation, also used for allograft tissues for orthopedic surgeries. Fiber sutures are intended for one-time use only, and are not to be re-sterilized. These sutures may be incorporated, as components, into surgeries where constructs including those with allograft or autograft tissues are used for repair.

Product Description

Fiber Wire/Tape/Loop are non-absorbable, sterile, surgical sutures composed of ultra-high molecular weight polyethylene (UHMWPE). The suture braid is available undyed or dyed or with trace filaments for colour. These sutures meet all requirements established by the United States Pharmacopeia (USP) for non-absorbable surgical sutures except where indicated on the individual unit package.

Fiber Wire is constructed of a multi-strand, long chain ultra-high molecular weight polyethene (UHMWPE) core with a braided jacket of polyester and UHMWPE that gives Fiber Wire superior strength, soft feel and abrasion resistance that is unequalled in orthopedic surgery.

Fiber Tape are made up of same material as Fiber Wire and are similar in structure. However, the ends are tapered for easy suture passage. Increased contact area distributes the pressure, ideal where tissue pull-through may be a concern.

Fiber loop is a continuous loop of Fiber Wire with multiple needle options.

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 Fiber Wire/Tape/Loop Should Not be Used

The following are contraindications for Fiber Wire/Tape/Loop:

- Not for use in cardiac indications.

Post Operative Care

After implanting the Fiber Wire/Tape/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

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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.

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 Fiber Wire/Tape/Loop carries some risks associated with any surgery:

- Adverse effects associated with the use of this device include: wound dehiscence, calculi formation when prolonged contact with salt solutions occur, enhanced bacterial infectivity, minimal acute inflammatory reaction, and transitory local irritation at the wound site.
- Inadvertent needle sticks with contaminated surgical needles may result in the transmission of bloodborne pathogens.

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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