Patient Information Leaflet
LK-2™ Polyester Fabric (**Poly-Tapes**)

Device Name
LK-2™ Polyester Fabric (Poly-Tapes)
Product codes; 102-2210, 102-2280, 102-2215, 102-2281, 102-2220, 102-2282, 102-2230, 102-2283, 102-2240, 102-2284, 102-2202, 102-2246.

Poly-Tapes
Product codes; 102-1010, 102-1080, 102-1081, 102-1082, 102-1083, 102-1084

Device Type
Orthopaedic Implant – Tissue Approximation

Device Description

Intended Purpose
The **Poly-Tapes** are single-use devices intended to be used for tissue approximation in orthopaedic procedures, including use in reconstructing damaged or torn ligaments or tendons according to the surgeon's own preferred technique and at his/her discretion.

Also supplied for soft tissue (tendon and ligament) fixation to bone during orthopaedic reconstruction procedures.

Intended Performance
The **Poly-Tapes** are intended to reconstruct or repair damaged ligaments or tendons without the need to graft tissue from elsewhere as in autograft, allograft or xenograft. They enable improved ability to function after surgery, reduction in pain and allow for a return to everyday activities including work/sports.

Intended Patients
The **Poly-Tapes** are intended for any patients requiring soft tissue approximation and reconstruction of ligaments and tendons.

Expected Lifetime of the device and necessary follow-up
The **Poly-Tapes** are permanent implants intended to remain in the patient's body for the rest of their life. The device is intended to function while natural healing of the tendon or ligament occurs, which can be up to five years. The patient should follow all the follow-up requirements of the treating surgeon.

Warnings & Precautions
Following the surgery, the wound should be protected from the environment to prevent infection and poor wound healing. The wound should be protected from stresses which may cause it to re-open.

The patient should be warned not to exceed the prescribed activity levels or to overload the repair before complete healing has occurred.

These devices are Magnetic Resonance safe (i.e. an item that poses no known hazards in all MR environments).

The device is not for use as a synthetic ligament where a non-synthetic graft source (allograft and autograft) is available.

This device is not for intra-articular use.

This device is not for use in transvaginal pelvic organ prolapse repair or treatment of stress urinary incontinence.

Information for Safe Use
The patient should follow the rehabilitation programme prescribed by the treating surgeon.

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Device Materials
The **Poly-Tapes** consist of a tubular or single thickness open weave tape made from 100% Polyester (Polyethylene Terephthalate). The sheathing, intended to be entirely removed and not implanted, is made from polyethylene.

Undesirable Side Effects
The following undesirable side effects may occur as a result of any tissue approximation or reconstruction of ligaments and tendons:

- Infection
- Wound management and healing complications
- Failure of reconstruction
- Nerve damage and trapped nerves
- Pain over the area where the implant is attached to the body

The following undesirable side effects may occur as a result of the use of synthetic implants, including the **Poly-Tapes**:

- Allergic and/or inflammatory tissue reactions
- Irritation or skin problems at the implantation site
- Bone damage/fracture including the device breaking through bone tunnels

When to contact a health professional
All operations involve some risk, the risk and complications of this procedure are small. Contact a health professional if you experience abnormal levels of the above listed undesirable side effects.

Residual Risks
As with any procedure of this type, there is a risk that surgery may not be effective in treatment or may cause worsening symptoms.

Any serious incident that occurs in relation to the device should be reported to the manufacturer and the Therapeutic Goods Administration www.tga.gov.au

Symbols

MD	Medical Device / Device Name		Name and Address of Manufacturer		Name & address of implanting healthcare institution/provider
LOT	Lot number		Information website for patients	31	Date of Implantation
UDI	Unique Device Identifier		Patient Name or Patient ID	MR	MR Safe

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