Patient Information Leaflet
Pitch-Patch Tissue Reinforcement

Device Name
Pitch-Patch Tissue Reinforcement
Product codes; 102-1090, 102-1091

Device Type
Orthopaedic Implant – Rotator Cuff Reinforcement

Device Description

Intended Purpose
The **Pitch-Patch** is a single-use device intended to be used for reinforcement of the rotator cuff following or during repair by suture or suture anchors, where weakness exists in the soft tissue.

Intended Performance
The **Pitch-Patch** is intended to provide reinforcement of the rotator cuff, preserving the rotator cuff repair and the associated benefits of the repair. The **Pitch-Patch** is not intended to replace normal body structure or provide the full mechanical strength to support the rotator cuff. Sutures, used to repair the tear, and sutures anchors, used to attach the tissue to the bone, provide mechanical strength for the repair.

The expected clinical benefits of **Pitch-Patch** when used according to the instructions for use and the surgical procedures and techniques involving sutures and/or suture anchors adhered to are:

- Preservation of rotator cuff repair and associated benefits
- Reduced risk or re-tears
- Improved functional outcomes
- Reduced pain
- No risk of allograft/xenograft rejection, donor disease transmission, variation in tissue quality or quick degradation as associated with allografts and xenografts

The **Pitch-Patch** has been designed with appropriate performance characteristics including high suture retention strength which provides stability to the rotator cuff and repair.

Intended Patients
The **Pitch-Patch** is indicated for patients requiring reinforcement of the rotator cuff where either the tear cannot be completely repaired using normal methods and/or the quality of the soft tissue is poor.

Expected Lifetime of the device and necessary follow-up
The **Pitch-Patch** is a permanent implant intended to remain in the patient's shoulder for the rest of their life. The device is intended to reinforce the rotator cuff where either the tear cannot be completely repaired using normal methods and/or the quality of the soft tissue is poor. The performance lifetime of the device is 2 years, after which complete healing should have occurred. The patient should follow the advice of their surgeon who will outline any follow-up requirements after the surgery.

Warnings & Precautions
The patient should be warned not to exceed the prescribed activity levels or to overload the repair before sufficient healing has occurred as this may lead to device rupture, or the sutures used to secure the **Pitch-Patch** elongating the device or the sutures breaking through the soft tissue. Do not exceed activity levels advised by the surgeon.

The **Pitch-Patch** should not be implanted if it is thought that the patient may have any adverse reactions to receiving an implant and appropriate tests should be made before any surgery takes place.

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

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

Device Materials
The **Pitch-Patch** is made from non-absorbable poly (ethylene terephthalate) fibres (polyester).

Undesirable Side Effects

- Inflammation
- Allergic reaction
- Irritation
- Infections
- Wound healing complications
- Frozen shoulder
- Creaking of shoulder joint
- Swelling of the shoulder
- Re-tear

If any of these conditions occur, the device may need to be removed at the surgeon's discretion.

The **Pitch-Patch** may rupture, or the sutures used to secure the **Pitch-Patch** may break through the device, or the sutures may break through the soft tissue if prescribed activity levels during rehabilitation are exceeded.

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

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 any 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 web-site for patients		Date of Implantation
UDI	Unique Device Identifier		Patient Name or Patient ID	MR	MR Safe

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