



Patient Information Leaflet

AchilloCord^{PLUS}™ System Implant Set

Device Name

AchilloCord^{PLUS}™ System Implant Set

Product code: 102-1142

Device Type

Orthopaedic Implant – Achilles Tendon Repair

Device Description

Intended Purpose

The AchilloCord^{PLUS} is single-use and intended to be used in the repair of acute Achilles tendon ruptures.

Intended Performance

The AchilloCord^{PLUS} is intended to repair acute Achilles tendon ruptures whilst being minimally invasive. The AchilloCord^{PLUS} enables improved cosmetic and functional outcomes, fast return to everyday activities including work/sports, and is associated with low re-rupture rates.

Intended Patients

The AchilloCord^{PLUS} is indicated for patients with acute ruptures of the Achilles tendon and is particularly suited to patients where an extended period of postoperative immobilization is undesirable.

Expected Lifetime of the device and necessary follow-up

The AchilloCord^{PLUS} is a permanent implant intended to remain in the patient's body for the rest of their life. AchilloCord^{PLUS} is intended to function for one year during which time the patient's tendon is expected to heal completely. The patient should follow all the follow-up requirements of the treating surgeon i.e., restrict activities to prescribed levels or follow a rehabilitation program during the healing period.

Warnings & Precautions

AchilloCord^{PLUS} should not be used in patients with known hypersensitivity to polyethylene terephthalate (polyester). The patient should be warned not to exceed appropriate activity levels before complete healing has occurred.

The implant should not be used in patients unable or unwilling to restrict activities to prescribed levels or to follow a rehabilitation program during the healing period.

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 all the follow-up requirements prescribed by the treating surgeon i.e., restrict activities to prescribed levels or follow a rehabilitation program during the healing period.

Device Materials

The AchilloCord^{PLUS} is made from 100% Polyester (polyethylene terephthalate).

Undesirable Side Effects

The following undesirable side effects may occur as a result of any surgical procedure:

- Infection
- Wound management and healing complications

The following undesirable side effects may occur as a result of any acute Achilles tendon surgical repair:

- Sural nerve damage
- Achilles tendon re-rupture
- Deep vein thrombosis



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The following undesirable side effects may occur as a result of the use of synthetic implants, including the AchilloCord^{PLUS}:

- Implant rupture
- Minimal acute inflammatory tissue reaction
- Allergic reaction and transitory local irritation

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. The possible undesirable side effects are listed above.

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

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

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