

Instructions for Use

GENERAL INFORMATION

- Single-use product, do not reuse, even if it is in perfect condition;
- Sterile supplied product by EO;
- Prohibited reprocessing.

INTENDED USE

The STA - Achilles tendon suture system is a device to assist the surgeon in the treatment of acute rupture of the Achilles tendon. It is a minimally invasive procedure that allows a direct visual control of repair, as well as percutaneous introduction of the suture. The surrounding soft tissues and tendon are treated with care to avoid any local trauma.

INDICATIONS FOR USE

The product is indicated for cases of:

- Rupture of the Achilles tendon (less than 10 days);
- Rupture located between 2 and 8cm above the calcaneus;
- Open break (less than 6 hours) without skin detachment;
- Closed ruptures;

Other uses are the responsibility of the surgeon in charge.

CONTRAINDICATIONS

The product should not be used in patients who have a history of:

- Previous surgery at the same local;
- Chronic or neglected rupture;
- Patients using steroids;
- Open breaks (more than 6 hours);
- Completely open breaks with skin detachment;
- Pediatric age;

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- Rupture located between 0 and 2cm below the tuberosity of the calcaneus and greater than 8cm above the calcaneus tuberosity;
- Patients unable to walk on crutches;
- Patients who don't cooperate.

Each patient should be examined by a surgeon to determine the percentage of success and failure in view of the patient's health status, the surgeon's practice, his experience, and knowledge.

Each patient undergoing a surgical intervention may be exposed to pre and post operative complications. Tolerance to surgical intervention, medication and implantation of a foreign body may promote different reactions in each patient.

The probable risks, unfavorable reactions and complications associated with surgery and the type of surgical technique should be addressed with and understood by the patient before surgical intervention. It is the surgeon's responsibility to promote all surgical information to the patient.

Complications may include, but are not limited to:

- Pain, discomfort, and abnormal sensations;
- Risk of additional injury from a post operative trauma.

WARNINGS AND PRECAUTIONS

The STA Kit - Achilles Tendon Suture System should be used according to specific surgical techniques adopted by a professional duly trained and qualified in orthopedic foot surgery procedures.

Extreme care should be taken to ensure that the surgical instrument remains in good working condition. Any surgical techniques applicable to the use of this system should be carefully followed. During the procedure, it is extremely important to correct use of the surgical instrument. This instrument can be reused but must not be bent or damaged in any way. The misuse of the surgical instrument may cause corrosion, untightening, bending and/or fracture of any or all sections of the surgical instrument, and may inhibit its proper functioning.

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Do not use this instrument for any action for which it is not designed as leverage, lift weights, etc. Surgical instruments should be treated as any precision instrument and should be carefully packed in surgical whiting, cleaned after each use, and stored in a dry, weather-free environment. Only sterile instruments should be used in surgery. Improper use of surgical instruments as well as the use of damaged surgical instruments may cause injury or damage to the patient or staff in the operating room, for example, misuse may cause breakage and penetration of pieces or components into the patient or someone nearby. If damaged, do not reuse it, replace it.

Care in the distribution, storage, transportation, cleaning, storage, conservation, and traceability must follow the Good Practices of Storage and Distribution of Medical Products. Surgical instruments should be stored in a dry, airy, clean, weather-free, and room temperature-free place.

SIDE EFFECTS OR UNDESIRABLE SIDE EFFECTS

Secondary effects or collaterals may include, but are not limited to:

- Infections;
- Haematoma;
- Allergies;
- Skin necrosis;
- Venous thrombosis;
- Iterative tendon rupture;

Adverse effects may require re-operation.

REPORTING OF ADVERSE EVENTS

If the product presents adverse events not reported in the instructions for use or there are technical complaints about the product, the physician should immediately contact the manufacturer through the GMReis Customer Service (SAC), in addition to notifying the competent sanitary authority. The traceability of the product is ensured by the 05 traceability tags, provided within the packaging, along with the instructions for use.

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CUSTOMER COMPLAINT

If the medical product presents a risk specific unpredictable, being outside of its specifications or being generated any dissatisfaction, notify directly the GMReis Customer Service (SAC). The product should be sent cleaned and packed in plastic bag, properly identified and with the description of non-compliance to the following address: G. M. dos Reis Indústria e Comércio Ltda - Pierre Simon de Laplace Avenue, no. 600 Lote 3 - Quadra F – Quarteirão 9677 - TECHNOPARK – CEP: 13069-320 – Campinas – SP – BRAZIL or directly notify at Telephone Number:(0xx19)3765-9900/ E-mail: sac@gmreis.com.br.

SYMBOLISM OF LABELLING

The graphic symbols used in labelling are in accordance with the ISO 15223 Standard, as follows:

Symbols	Descriptions	Symbols	Descriptions
	Date of Manufacture		Caution. "See instructions for use"
	Use-by date		Keep way from light
	Keep dry		Manufacturer
	Do not re-sterilize		Batch code
	Sterile by EO		Do not use if the package is damaged
	Do not re-use		

Company Name / Manufacturer Name:

GM dos Reis Indústria e Comércio Ltda.

Avenida Pierre Simon de Laplace, no. 600 Lote 3 - Quadra F - Quarteirão 9677

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