3. INSTRUCTIONS FOR USE

3.1. General Product Identification Information

Product supplied in sterile form by ethylene oxide (ETO) according to ISO 11135 - "Preview Sterilization of health-care products -- Ethylene oxide -- Requirements for the development, validation and routine control of a sterilization process for medical devices".

Single use product.

Do not reuse.

Product shelf life: 3 years

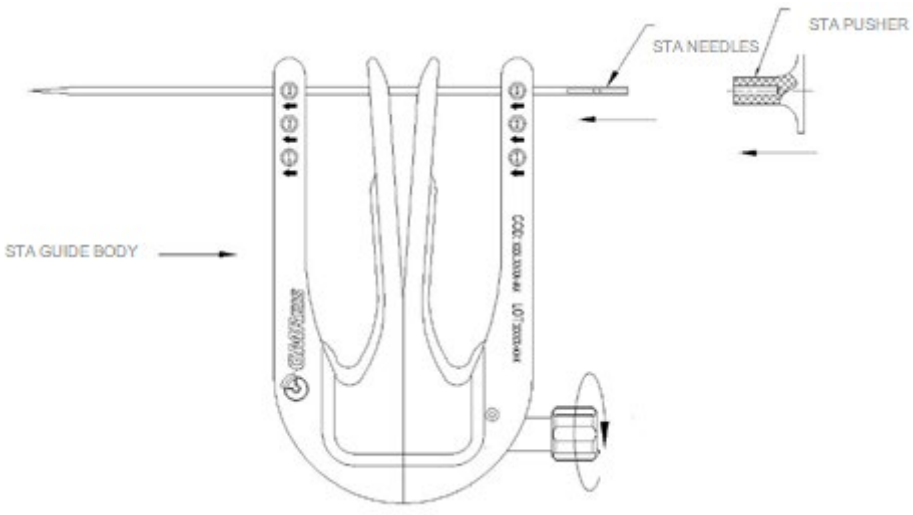
3.1.1. Information necessary for the user to identify the product and its contents

3.1.1.a. Technical Name: Instrument, ligature passing and knot tying

3.1.1.b. Trade Name: STA – Achilles tendon suture system

3.1.1.c. Graphic information that allows the visualization of the final product, description, part number and composition of the material.

Table 1. Components of the STA – Achilles tendon suture system procedure: Graphics information, composition and codes.

233-01 STA – ACHILLES TENDON SUTURE SYSTEM			
			
COMPONENTS	PRODUCT DESCRIPTION	QUANTITY	RAW MATERIAL
233-01-01	STA GUIDE BODY	1	STAINLESS STEEL ASTM F899; POLYACETAL COPOLYMER ASTM F1855; STAINLESS STEEL ASTM F138; TEFLON ABNT NBR ISO 16061
233-01-02	STA PUSHER	1	POLYACETAL COPOLYMER ASTM F1855

233-01-03	STA NEEDLES	3	STAINLESS STEEL ASTM F899

3.1.1.d. Identification

The components of the STA Kit – Achilles Tendon Suture System are laser marked with batch number, code, GMReis mark.

3.1.1.e. Description of the physical principle and fundamentals of technology, applied for its operation and its action

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.

The system includes:

- 1 STA guide body;
- 3 STA needles;
- 1 STA pusher.

The STA – Achilles tendon suture system procedure should be used according to specific surgical techniques adopted by a professional duly trained and qualified in an achilles tendon rupture procedure, that is, by a surgeon whose technique to be adopted by him is part of his professional training, thus being the decision of the professional where and how to use them.

3.1.1.f. Support materials that accompany the product for its assembly and protection

All additional information regarding how to use is described in the product usage instruction contained within the product packaging.

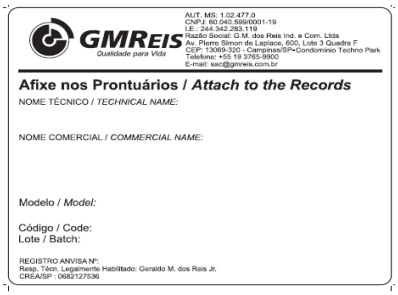
3.1.1.g. Presentation form

The product will be marketed in individual form, single use, sterilized by ethylene oxide.

It is an open system, having as a commercial presentation the packaging in blister packs in PETG, thermosealed in Tyvek, and packed in box, duly labeled on the back, where the components are supplied. Accompany the product: 5 traceability labels and a manual of how the user can obtain the *Instructions for Use* of the product, ***through the unprinted format, at no additional cost, including shipping.*** This information is compatible with product labeling.

PORTUGUÊS (PT)	ENGLISH (EN)	ESPAÑOL (ES)	
A Instrução de Uso para este produto está disponível no website www.gmreis.com.br/produtos/IFU, (formato não impresso) e sempre estará de acordo com a última versão vigente, aprovada pela Anvisa	The Instruction for USE (IFU) for this product is available on the website: www.gmreis.com.br/produtos/IFU (printed format) and will always be in accordance with the latest version, approved by Anvisa	La Instrucción de Uso para esto producto está disponible en el sitio web: www.gmreis.com.br/produtos/IFU (formato impreso) y siempre será con arreglo a la última versión en vigor, aprobado por la Anvisa	GMREIS Qualidade para Vida
No campo de busca, procure pelo nº do Registro da Anvisa do Produto ou nome comercial, descrito no rótulo, na embalagem do produto. Para visualização do documento é preciso ter o Adobe Reader. Obtenha gratuitamente no website acima.	In the search field, look for ANVISA registration number or commercial name, described on label in the product packaging. In order to view the document, you must have Adobe Reader, which can be downloaded for free from the website above.	En el campo de búsqueda, busque por el número Registro ANVISA del producto o nombre comercial, descrito en la etiqueta del envase de producto. Para visualizar el documento es necesario tener el Adobe Reader. Reciba gratis en el sitio web arriba.	PT - Guia para acesso das Instruções de Uso GMReis (IFU) EN - GMReis Instructions for Use (IFU) access guide
Caso necessite receber uma versão impressa da IU, sem custo adicional, inclusive de envio, solicite gratuitamente pelo e-mail: sac@gmreis.com.br ou telefone disponível na rotulagem	If you need a printed copy at no extra cost, including shipping, please contact the e-mail: sac@gmreis.com.br or phone number available on labelling	Caso necesite recibir una versión impresa de IFU, sin costo adicional, incluyendo el envío, solicite gratis por el correo electrónico: sac@gmreis.com.br o teléfono disponible en el etiquetad	ES - Guía para acceder a las instrucciones de uso (IFU) IFUGMREIS – Rev.01

Figure: Manual that accompanies the product.


GMREIS Qualidade para Vida

AUT. MS: 1.02.477.0
CNPJ: 60.040.599/0001-19
I.E.: 244.342.283.119
Razão Social: G.M. dos Reis Ind. e Com. Ltda
Av. Pierre Simon de Laplace, 600, Lote 3 Quadra F
CEP: 13069-320 - Campinas/SP+Condomínio Techno Park
Telefone: +55 19 3765-9900
E-mail: sac@gmreis.com.br

Afixe nos Prontuários / *Attach to the Records*

NOME TÉCNICO / *TECHNICAL NAME:*

NOME COMERCIAL / *COMMERCIAL NAME:*

Modelo / *Model:*

Código / Code:
Lote / Batch:

REGISTRO ANVISA Nº:
Resp. Técn. Legalmente Habilitado: Geraldo M. dos Reis Jr.
CREA/SP : 0682127536

Figure: Traceability label.

3.1.2. Special storage, handling and/or transportation care and associated risks

The product must be stored, handled and transported in such a way as to prevent any damage or alteration to its characteristics and packaging.

The medical product should be handled with all care, in order to avoid sudden shocks, falls and other risks and / or imperfections that affect the quality of the same and also the safety of the user.

The handling of the product should be done exclusively by medical-hospital professionals, properly trained, qualified and familiar with the technique and procedures involved.

The effects of vibration, shocks, faulty seating and improper stacking during transport should be avoided.

GM REIS RECOMMENDS SINGLE USE.

If the product is stored, handled and/or transported outside the specific conditions above may pose risks to the procedure and the patient.

3.1.3. Instruction for the use and indication of training

3.1.3.1. Instruction for use

Only orthopedic surgeons properly qualified, capacitate and trained in orthopedic foot surgery should use the product.

• Make vertical and medial incision to the tendon, length; 1,5 a 2 cm

• With scalpel blade (number 15, smaller size), gently dissect thin subcutaneous tissue;

• Retract the skin and skin tissue layer with 2 (two) small retractor hooks (Guillis type). Carefully identify the paratendon;

• Make a vertical incision of in the paratendon;1,5 a 2 cm

• Place a temporary suture on each edge of the paratendon. The space under the paratendon is identified and marked proximally and distally to visualize its tunnel shape. This maneuver will facilitate the introduction of the product;

• Identify both proximal and distal tendon stumps. On the medial side, the plantaris tendon can be visualized;

Note: In most cases tendon stumps become worn out. If the point is particularly difficult to locate, the skin incision can be extended proximally or distally;

• Insert the STA guide body into the closed position (minimum width) under the paratendon, proximally. The tendon stump is located between the two inner branches;

• As soon as the STA guide body is introduced, it is progressively opened, while the tendon stump is held firmly with a thin forceps or clamp passed under the STA guide body;

• Before inserting the threads for sutures, the appropriate position and angulation of the STA guide body are confirmed by external digital palpation. The tendon must be between the two central branches of the instrument

• Using the needle driver, the first STA needle is inserted according to the arrows and numbers printed on the STA guide;

• Three sutures are passed and kept out, and the end of each suture is fastened with a small tweezers to keep the sutures away from each other;

• The STA guide body is gently removed to avoid any suture or soft tissue damage. While being removed, the STA guide body is progressively closed;

Note: From an extra cutaneous position, the tendon becomes the only tissue fixation for the suture.

• A clamp is placed on the 3 sutures that exit laterally and another clamp is placed on the 3 surgical suture coming out medially;

• Each clamp must remain on its respective side. In this way sutures will not cross the median line;

Note: If any suture fails, it should be replaced by repeating the previous technique.

• The same sequence is performed on the distal stump. The STA guide body is inserted under the paratendon and pushed until it touches the calcaneus. Again 3 sutures are placed;

• Properly arrange the suture pairs. They shouldn't cross the median line. The surgical sutures coming out of the lateral side have to remain lateral and those on the medial side have to remain medial;

• The sutures are connected by matching pairs;

• Tendon reduction is controlled under direct visualization. If the tendon is so worn that it prevents any landmark for length control, the tendon tension should be compared to the opposite leg;

• Carefully close the skin and paratendon;

• The ankle is held at 30° degrees of plantar flexion, with a splint, during the first three weeks;

• It is then progressively brought to the neutral position during the next five weeks,

• Always be sure of patient conformity.

3.1.3.2. Indication of training

The product is indicated for cases of:

• Acute 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 responsible.

3.1.4. Precautions, restrictions, warnings, special care and clarification on product use, storage, handling and transportation

3.1.4.a. General

The instruments of 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.

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.

3.1.4.b. Product load restriction

The product is not designed to withstand load, only as a conductive biomaterials element.

3.1.4.c. Conformity limit

No component of the product should be mold.

3.1.4.d. Checking the surface state of the product that restricts use

Products that for some reason were not used during surgery and had the packaging open, or suffered damage and/or falls cannot be reused and/or reprocessed, and must be discarded in the hospital itself according to medical-hospital procedure and/or local legislation or according to the instructions of the Hospital Infection Control Commission - CCIH. If the product has any abnormality in its operation, a new unit must be opened and put into use.

The person responsible for the procedure shall send GMReis the non-conformity product, duly decontaminated, packed with batch, product code and declaration of non-conformity that has occurred.

3.1.4.e. Procedure in case of product fall

In the event of a fall of any of the components of the STA Kit – Achilles Tendon Suture System, the Kit should be unused and discarded in full according to the procedure of disuse and disposal.

3.1.4.f. Patient instructions

The patient should be instructed regarding the limitations of the product to be used, and should be warned about its limitations, according to the guidance of the responsible physician. The patient should follow the post operative and rehabilitation guidance recommended by the responsible physician.

The patient should be advised to report any pain, decreased range of motion, swelling, fever, and unusual incidences. The patient should be advised to take care of physical activities, protect the operated local from efforts. The surgeon should alert the patient to possible surgical risks and adverse reactions of the surgical procedure.

3.2. Indication, purpose or use for which the product is intended

3.2.a. Indication of correct use, purpose or 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 responsible.

3.2.b. 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;
- 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.

3.2.b.1. Undesirable side effects

Secundary 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.

3.3 Detailed information on the characteristics of all parts, accessories and materials intended for use with the product

No component of the STA – Achilles Tendon Suture System, can be used in conjunction with another non-implantable component other than the STA - Achilles Tendon Suture System, and no other non-implantable component can be used with the components of the STA - Achilles Tendon Suture System. If misuse occurs, risks may occur to the patient, the surgical procedure and with room staff, being the responsibility for such improper combination of the surgeon responsible for the surgical procedure.

3.6. Characteristics associated with the integrity of the packaging, how to manipulate the product and open the packaging in order to ensure sterility

If any of the packages are tampered with or damaged, all components of the STA – Achilles tendon suture system must be discarded, even if they are in perfect condition.
In blister packs (PETG – Polyethylene Terephthalate Glycol) thermoselated in Tyvek® Adhesive PTH 026, the integrity of the closure can influence the shelf life of the products packaged in them, since failures in the thermoselation are in the entry points of microorganisms, air and/or moisture or even for loss of gas mixtures and organic vapors.
Closure integrity problems can lead to products aseptically packaged, to be contaminated by the entry of microorganisms.
A closure is considered intact when it ensures the product, at least, the same protection that is conferred by the packaging material.

The integrity of the packaging must be preserved during the transport, handling, storage and distribution of the product.

In addition, the termselaing procedure establishes a parameter of operation andcontrol that ensures biological watertightness.

GMReis Quality System includes methods for assessing packaging integrity by visual inspection in 100% of samples. In this inspection, the presence of blisters, wrinkles, folds and/or obstructed material is verified in the region of the termselation, non-uniform marking of the mandible profile used, delamination of the seal material, in addition to other defects that evidence the use of inadequate temperature and pressure.

This product will be supplied sterile by ethylene oxide; therefore, it should be kept in its original packaging until the time of its use, according to hospital medical asepsis procedures.

Restrictions and instructions on packaging damage

The product must be unusable and disposed of in accordance with the procedure of disuse and disposal in the following circumstances:

- Safety seal of the tampered packaging;
- Physical damage to any of the packages;
- The illegible label or identification code;
- Expiration date reached.

Disuse and disposal

Before disposal, all components must be unused with the aid of moulders, refans, any other instruments or ways, until it is clearly identified that the product is unsuitable for its use, and there is no possibility of it being reused. After use, the product should be discarded according to the hospital area procedure.

Restrictions on resterilization and reuse

Single-use sterile supplied product (disposable) should not be resterilized and reused, as the performance of the product is not guaranteed for intended use if resterilized and reused.

3.8. / 3.9. Additional information about the procedure prior to use of the product

As the product is supplied sterile, there is no need for any preliminary procedure to use such as cleaning, sterilization and decontamination of the product.

3.14. Physician-specific guidance on reporting adverse events and technical complaints

If the product presents adverse events not reported in the instruction of use or has technical complaints about the product, the surgeon should immediately contact the manufacturer through the Customer Service (SAC) of GM Reis, in addition to notifying the competent health authority.

To ensure traceability of the product, the surgeon should proceed according to the "product traceability procedure". Product traceability is ensured through the 5 traceability labels provided inside the package, together with the product, as described in the item "Product Traceability Procedure".

3.17. Customer Complaint

If the medical product presents a specific unpredictable risk, is out of its specifications or is generating any dissatisfaction, notify GM Reis Customer Service (SAC) directly. The product should be forwarded clean and packed in a plastic bag, duly identified and with the description of non-conformity to the following address: **Av. Pierre Simon de Laplace, 600 - Lote 3 - Quadra F - Block 9677 - ZIP Code 13069-320 - Condominium Technopark - Campinas, SP, Brazil or** notify **directly at Tel.: (0XX19) 3283-9020 / Fax.: (0XX19) 3283-9111 / E-mail: sac@gmreis.com.br.**

3.18. Symbology of Labelling

The graphic symbols used in the labeling are in accordance with the NBR ISO 15223 Standard as follows:

SYMBOLS	DESCRIPTIONS	SYMBOLS	DESCRIPTIONS
	Date of manufacture		Single-Use Product *"Do not reuse"*
	Use-by date		Do not re-sterilize
	Do not use if the package is damaged.		Caution, consult accompanying documents *"Attention See Instructions for Use"*
	Manufacturer		Batch code
	Sterilized by ethylene oxide		Keep way from light
	Keep dry		Prescription only

ALERT TO THE CUSTOMER

These Instructions for Use are made available in unprinted format, through the manufacturer's e-mail address: http://www.gmreis.com.br/produtos/IFU. *Always check the correlation of the Version of the Instructions for Use with the version reported on the label.* The instructions for use provided will always be in accordance with the latest version in force. If the user is interested, the Instructions for Use may be made available in printed format at no additional cost. Request for free by e-mail: sac@gmreis.com.br.

GM Reis Indústria e Comércio Ltda.
Avenue Pierre Simon de Laplace, n° 600 - Lote 3 - Quadra F - Block 9677
TECHNOPARK - ZIP Code: 13069-320 - Campinas - SP - BRAZIL
Operating Authorization - EGF No 1.02.477 - 0
C.N.P.J/M.F: 60.040.599/0001-19 / I.E: 244,342,283,119
E-mail: gmreis@gmreis.com.br
Phone: (0XX19) 3765-9900 / Fax: (0XX19) 3303-9111
Issue date: 09/06/2022 – Rev. 02

Technical and Legal Responsible Qualified:
Geraldo Marins dos Reis Júnior
CREA - SP N° 0682127536

Revision history
Rev. 00 de 04/13/2013 – Product registration
Rev. 01 de 08/01/2017 – Document padronization
Rev. 02 de 09/06/2022 – Device Listing in USA