

INSTRUCTIONS FOR USE

HTA - Headless Titanium Anchors

GENERAL INFORMATION

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

INDICATIONS FOR USE

The GM Reis HTA - Headless Titanium Anchors is intended to be used for suture or tissue fixation in the elbow, shoulder, hand, wrist, foot, and ankle. Specific indications are listed below:

Elbow: Biceps Tendon Reattachment, Ulnar or Radial Collateral Ligament Reconstruction

Shoulder: Rotator Cuff Repair, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clavicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulolabral Reconstruction

Hand/Wrist: Scapholunate Ligament Reconstruction, Repair/Reconstruction of collateral ligaments, Repair of Flexor and Extensor Tendons at the PIP, DIP and MCP joints for all digits, digital tendon transfers, Carpal Ligament Reconstruction and Carpometacarpal joint arthroplasty (basal thumb joint arthroplasty)

Foot/Ankle: Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Metatarsal Ligament Repair, Hallux Valgus reconstruction, digital tendon transfers, Mid-foot reconstruction

PURPOSE OR INTENDED USE OF THE PRODUCT

The success of the treatment is directly related to the appropriate surgical technique applied by the surgeon and the correct choice of implants, following their characteristics: model, shape, type, dimensions, etc.

The size and anatomy of the bone structures are the main factors in the definition of the implants to be used.

It is possible to see below, for each type of suture, the indication of the implantation site.

Diameter (mm)	Implantation site	Model
1,7	Hand	Nano HTA Anchor
2,2	Wrist, Foot	Micro HTA Anchor
2,7	Wrist, Foot	Mini HTA Anchor
3,5	Ankle, Elbow, Shoulder	HTA Anchor
5,0	Ankle, Elbow, Shoulder	Max HTA Anchor

PHYSICAL PRINCIPLE AND TECHNOLOGY FUNDAMENTALS DESCRIPTION, APPLIED TO ITS WORKING AND ACTION

The product enables the fixation of soft tissue to the cancellous bone, promoting its stabilization. For this, an anchor is inserted into the bone, and the surgical suture attached to this anchor are tied to the tissue in order to lead tissue fixation.

TECHNICAL SPECIFICATION OF THE MATERIAL MANUFACTURING

The Suture Anchors GMREIS are manufactured with the following raw materials:

- HTA - Headless Titanium Anchors: made of Ti6Al4V-ELI Titanium Alloy, according to ASTM F 136.
- Inserters: Stainless Steel 316L and 420B, according to ASTM F899; Polyacetal, according to ASTM F1855.

- Needle: made of Stainless Steel 302 or 304, according to ASTM F899.

MARKING

The implantable components are identified by marking laser with the following information:

- Batch of product;
- Product Code;
- Logo of the GMReis brand.

Sterilization Method

The products are supplied sterile, by ethylene oxide, according to ISO 11135 - "Sterilization of health care products - Ethylene oxide Part 1: Requirements for development, validation and routine control of the sterilization process for medical devices" and must be maintained in its original packaging until the moment of its use.

PRODUCT TRACEABILITY PROCEDURE

The Identification and traceability of the product are ensured through a set of 05 adhesive tags contained in the package, along with the instructions for use and the implant, such as: name, model, code, allotment, product registration and manufacturer identification. In this way it is possible to make the reverse path and reach a production, raw material, suppliers, and other quality controls established in the GMReis Quality System

It is a responsibility of the medical and hospital staff (the custodians of patient information and records), the tag fixation on the surgical description sheet or a section of the medical chart. GMReis recommends that the patient receive this information, receiving a certificate stating one of the traceability adhesive tags.

PRESENTATION FORM OF THE MEDICAL PRODUCT

The product is for single use, supplied sterile by ETO, properly identified, presented in 4 levels of packaging.

Primary: blister pack or surgical grade paper, containing an ETO integrating seal;

Secondary: Surgical grade paper;

Tertiary: outer carton for packaging, properly labeled on the reverse.

Finally, the outer carton is wrapped in a thermo-shrinkable polyolefin film constituting the quaternary packaging of the product.

The product is accompanied by 5 traceability tags and a manual on how the user can obtain the Instructions for Use of the product, in non-printed form, at no additional cost, including shipping.

HANDLING, CONSERVATION, STORAGE AND TRANSPORT

The hospital is responsible for the steps of handling, conservation and storage of products from receipt, ensuring that the manufacturer's recommendations are respected to and that the product maintains the original characteristics established.

The product must be preserved, handled and transported in order to prevent any damage or modification to its characteristics and packaging.

The product must be preserved and stored in its original packaging until use, with due care in the medical-hospital area, in a clean, dry, ventilated environment, protected from sunlight and free from contaminating substances (acid and organic vapors), and with controls, recommended, at room temperature.

Exclusively professionals in the hospital area, properly trained, empowered and familiar with the technique and the procedures involved, must do the handling of the product.

Vibrations effects, shocks, defective seating and improper stacking during transportation should be avoided.

Storage outside these conditions may create risk to the procedure, and patient.

INDICATION OF TRAINING

Only properly trained, empowered in in ligament reconstruction may use the product.

Note 1: The surgeon should be aware of all recommendations described in the product "Use Instructions" and other information on the label.

CAUTION/PRECAUTIONS

Load Restrictions

These implants are designed to support physiological loads when implanted for the stabilization of a certain ligament structure and may rupture until full tissue integration/regeneration occurs. Overloads and mechanical manipulation efforts (i.e., torsion, bending, traction, etc.) exerted during implantation compromise its mechanical characteristics, which can lead to early failure of the implant and/or inserter, as well as breakage during implantation.

It is recommended to release the load after the period established by the surgeon for complete recovery of the treated tissue.

The implants are designed as aids to the natural consolidation process but are not intended to replace anatomical structures or support body weight in the presence of incomplete consolidation.

The time during which such care should be maintained depends on the specific characteristics of each procedure and must be carefully delineated by the surgeon in charge. Similarly, postoperative care and rehabilitation will depend on innumerable variables that cannot be delineated in this document, and which are the absolute responsibility of the multidisciplinary team that cares for the patient.

Until full load is released, the patient should follow the surgeon's recommendations.

MECHANICAL CONFORMATION

GMReis do not recommend the modeling or adjustment of the products.

PATIENT INSTRUCTIONS

The patient should be warned about the limits of its initial activities and about their rehabilitation to protect the surgery performed by the surgeon in charge.

Excessive initial activities can affect the positioning of the implantable component or affect the supporting bone and/or ligament structure, making the review procedure more difficult and premature.

The patient should be warned about the risks of surgery, secondary effects, or undesirable side effects and that the reconstruction carried out with the implant will not present the same physical characteristics of the natural tissue, and there may be failures of the implantable component, resulting from abnormal physical activities, trauma or referring to degenerative diseases.

The patient must be instructed by the surgeon in charge to use adequate external support (such as splints or boots), if necessary, for the time stipulated by the surgeon in charge, as well as to restrict physical activities that put the implant at risk or that allow movements at the site of the implant. implantation.

It is important that the patient is aware that the implant has a useful life of 90 (ninety) days and should be warned that if ligament reconstruction does not occur in this period, the implants may loosen, rupture or break, especially if the postoperative recommendations, excessive physical therapy load and/or poor implant positioning, accidents as well as other causes.

The surgeon in charge is responsible to make the postoperative recommendations, accompaniments, clinical evolution and radiological of the patient.

The patient should be informed that, despite of the raw material used for the implant manufacturer is biocompatible, side effects may occur or adverse reactions in more sensitive patients, such as:

- Sensibility to the material;
- Allergic reactions;
- Bone deformity in the place of the implementation;
- Incomplete bone consolidation;

SIDE EFFECTS/ADVERSE EVENTS:

- Pain, discomfort, and abnormal sensations due to the presence of the implant;
- Infections, both deep and superficial;
- Allergies and other reactions with implanted materials.
- Hydrarthrosis (accumulation of fluid in joint cavities);
- Foreign body reactions;
- Titanium only: Shoulder dislocation/subluxation.

NOTE 1: A second surgery may be needed to repair the secondary effects

NOTE 2: Smokers, elderly patients, and who suffer from degenerative disease or metabolic dysfunction, have greater difficulties in achieving tissue integration/regeneration, consequently there are greater chances of rupture or loosening of the implants, and not achieving tissue integration/regeneration.

WARNINGS:

- An internal fixation device must never be reused;
- Do not re-sterilize this device;
- Foreign body sensitivity. Where material sensitivity is suspected, appropriate tests should be made, and sensitivity ruled out prior to implantation.

WARNING REGARDING THE PRODUCT CONDITION WHICH RESTRICT THE USE

The product should not present any visual abnormality in its surface, as risks, failures, dirt or other. The implantable components that exhibit abnormalities in their surface should be destroyed and disposed of according to the procedure of "Destruction and disposal".

FACTORS THAT MAY CAUSE THE IMPLANT TO A POSSIBLE BREACH, LOOSENING, DISPLACEMENT OR HEATING WHICH SHOULD BE INFORMED TO THE PATIENT

The following are the main factors that, alone or in combination, can lead the implantation of a premature failure (breakage, loosening or migration).

Disregard with the postoperative recommendations;

Metabolic disorders;

Diabetes

Smoking

Patients accident (e.g., falls, accidents...);

Failure in surgical technique;

Inappropriate choice of implant;

Failure to use orthosis/immobilization techniques after surgery;

Excessive load or inappropriate activity;

Osteoporosis;

Practice of intense physical activity;

Practice of physical activity prior to the surgeon release;

PROCEDURE FOR DISPOSAL TO ENSURE THE DESTRUCTION OF THE PRODUCT

The implants which for some reason were not used during the surgery and had the package open or suffered damage and/or falls may not be re-used and/or re-sterilized and should be discarded in the hospital as the medical procedure hospital and/or local law or as instructed by the Commission of Hospital Infection Control - CHIC.

The methods and procedures for product disposing should ensure the complete mischaracterization of it, preventing any possibility of reuse. The adulteration of the product is the sole responsibility of the hospital institution, as well as the methods and procedures for disposing used.

It is recommended that they be deformed with molders or twistors until be clearly identified that the product is inappropriate for your use, ensuring that the product may not be used or improperly reused.

REMOVING AND HANDLING OF IMPLANTS REMOVED FROM PATIENTS FOR ANALYSIS

The implant must not be removed, except in the case of surgical revision.

If the implant should be removed and need to be subjected to analysis, it must be in accordance with NBR ISO 12891-1 "Removal and analysis of surgical implantation - Part 1 - Removal and Handling", following the instructions below:

It is recommended that the implants, and in applicable cases, samples of tissue, are removed in a way that causes minimal damage in both tissue and implant.

It is especially important that functional surfaces, such as surfaces of joints of prostheses and surfaces of fractured implants are protected.

It is also extremely important to list the parties of the fractured implant and other removed components, leaving clear positioning in the deployment place.

The most important part of the implant removal is the prevention of damage that may lead to a scientific examination useless. For an appropriate scientific examination, the implant must be preserved as close as possible of the state, which existed at the time of the patient removal. Consequently, it is important that there be taken care during handling, storage and transport of the implants removed in order to ensure that no damage occurs or changes on the surfaces that will be analyzed.

The same care should be taken with the instruments, which eventually fail during its use.

The implants removed must go through process of cleaning and disinfection, under the responsibility of the health service. Subsequently, must be packaged separately in plastic bags or plastic containers/glass and labelled. The packaging should be designed to minimize the possibility of breakage, damage to surface and possible contamination of the implant by the environment. The labelling of products, which will be forwarded for analysis, should ensure their accurate identification, being that the NBR ISO 12891-1 recommends the use of labels non-removable (that tear in the case of attempted removal).

It is extremely important, for an accurate evaluation failure cause of the product that the X-rays pre, post-operative and the verification of the implant failure are sent together with the material sent for analysis.

CONTRAINDICATIONS

The patients, who present some clinical condition described below, should not be subject to the procedure with the use of the product. The contraindications include those listed below, but are not limited to:

- Pregnancy;
- Insufficient bone quality or quantity to receive the product;
- Limitations in blood supply and/or previous infections that may delay recovery;
- Patients in conditions that may compromise implant fixation such as osteoporosis, osteopenia and pathological conditions in soft tissues;
- Patients unable to follow the postoperative recommendations, including those who abuse drugs, tobacco and/or alcohol;
- Patients in inadequate physical conditions to undergo the surgical procedure and;
- Spinal procedures (e.g. This device is not for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic or lumbar spine.);
- Attachment of artificial ligaments or other implants;
- The use of this device may not be suitable for patients with insufficient or immature bone. The physician should carefully assess bone quality before performing orthopedic surgery on patients

who are skeletally immature. The use of this medical device and the placement of hardware or implants must not bridge, disturb or disrupt the growth plate.

DETAILED INFORMATION ON THE CHARACTERISTICS OF ALL PARTS, ACCESSORIES AND MATERIALS DESTINED TO BE USED WITH THE PRODUCT

Admissible Combinations with Other Materials

Combination with other materials is not recommended. The surgeon is entirely responsible for the risks inherent in the combination with other materials.

The product should only be deployed with the specific instruments, by GMReis Brand.

Accessories

None.

USEFUL INFORMATION TO PREVENT RISKS ARISING OUT OF THE IMPLEMENTATION

Implementation Risk

To reduce the risks of implementing the product, the recommendations regarding the indications for use, contraindications and the information described in the "Instruction for Use" must be followed.

Detailed instructions on the use and limitations of the product must be given to the patient.

Preoperative and operating room-related procedures, including knowledge of surgical techniques, proper implant size selection, and proper implant implantation, are important considerations for successful use of this device.

Do not use the product if the date marked on the label has expired or if the packaging is damaged.

Note: The device may break / rupture or become damaged as a result of excessive activity or trauma. This situation may cause the device to fail, requiring a new surgery for removal.

Assessment of the product deployed

After the deployment, in the intra-operative the responsible professional should perform radiological control to verify the correct positioning of the product. The professional responsible must make, and it is his/her responsibility, the clinical and radiological assessments after the surgical procedure, in the frequency stipulated by him, to check the condition of the implant and the bone healing. If the product find itself outside the correct placement, or present any non-compliance, it is the responsibility of the surgeon take the more appropriate corrective action.

THE NECESSARY INSTRUCTIONS IN THE DAMAGE EVENT OF THE PROTECTIVE PACKAGING OF THE STERILITY OF A MEDICAL PRODUCT STERILE, AND, WHERE APPLICABLE, THE INDICATION OF THE APPROPRIATE METHODS AND RESTERILIZATION.

Restrictions and instructions on the damage of the packaging

In the circumstances described below, the product must be unusable and discarded, as the procedure of destruction and disposal:

- The sealing area of the package is violated.
- Any one of the packages present physical damage;
- The label or identification code is unreadable and
- Date of validity is expired.

Restrictions on reuse

It is not allowed any reuse of the product, even if this present to be in perfect condition. The reuse does not guarantee the performance given by GMReis to the product, being free of any responsibility about this act.

Additional information about the procedure before using the product

Upon opening the package, check the superficial condition of the product as the deformations, stains, scratches or any other type of superficial alteration or defect. The product packaging must be disposed in accordance with the medical-hospital procedure and/or local law or as instructed by the Hospital Infect Control Commission.

MRI Safety Information

The HTA - Headless Titanium Anchors has an implantable device made in titanium alloy. This anchor is Conditional for MRI (safe for a patient undergoing a Magnetic Resonance Imaging (MRI) scan), as long as the following specific conditions are present:

 MRI Safety Information A person with the HTA Anchor implant may be safely scanned under the following conditions. Failure to follow these conditions may result in injury.	
Device Name	HTA Anchor
Static Magnetic Field Strength (B0)	3.0T only
Maximum Spatial Field Gradient	30 T/m
Maximum Whole-Body SAR	2 W/kg (Normal Operating Mode)
Scan Duration	2 W/kg whole-body average SAR for 60 minutes of continuous RF (a sequence or back to back series/scan without breaks)
MR Image Artifact	The presence of this implant may produce an image artifact.

Under the defined scanning conditions, the prosthesis is expected to produce a maximum temperature rise of up to 0.6°C after 15 minutes of continuous scanning. In non-clinical testing, the maximum calculated value for the worst-case imaging artifact was 12.8 mm when obtained by image using a gradient echo pulse sequence and a 3 T magnetic resonance system. The generation of artifacts affects images rather than having a physical effect on patients (in other words, they do not threaten patient safety). The contours of metallic objects are no longer sharply outlined, and the surrounding area is blurred, or their signal is altered, which degrades the quality of the images. Initial solutions, such as RF sequence optimization, bring limited corrections to distortions (mainly in-plane distortions), but the arrival of multispectral solutions, namely SEMAC and MAVRIC, considerably improved the quality of the images. The patient card can be seen in "Attachment I" at the end of this IFU.

Specific guidance to the physician regarding the 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 GM Reis Customer Service (SAC), in addition to notifying the competent sanitary authority. To ensure the traceability of the product, the physician should continue as the "Procedure for product traceability". The traceability of the product is ensured by the 05 traceability tags, provided within the packaging, along with the instructions for use, as described in the topic "Product Traceability Procedure".

Customer Complaint

If the medical product presents a risk specific unpredictable, being outside of its specifications or being generated any dissatisfaction, directly notify the GM Reis 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 and ASTM F2503-13, as follows:

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

User Warning

These Instructions for Use are available in format that is not printed, through the electronic address of the manufacturer: <http://www.gmreis.com.br/produtos/IFU>. The Instructions for use provided will always be in accordance with the current latest version. If there is interest from the user, the Instructions for Use may be available in printed format, without additional cost. Ask for free by e-mail: sac@gmreis.com.br.

Company Name / Manufacturer Name:

GM dos Reis Indústria e Comércio Ltda.

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

TECHNOPARK – CEP: 13069-320 – Campinas – SP - BRAZIL

Telephone number: +55 (0XX19) 3765-9900

Geraldo Marins dos Reis Júnior

Technical and Legal Responsible

GM dos Reis Indústria e Comércio LTDA

Caution: Federal (USA) law restricts this device to sale by or on the order of a licensed physician.

Revision: 00 September 30, 2022

Attachment I - Patient Card

Figure 1 - Front of the card

 GMREIS Qualidade para Vida			MRI SAFETY INFORMATION - PATIENT CARD		
Patient					
Followup Physician					
Implanting Physician					
Hospital					
Device Description		Model Number		Serial Number	
Implant Date					
<i>Rev.: 0 (09/2022)</i>					

Figure 2 - Verse of the card

 GMREIS Qualidade para Vida		MRI SAFETY INFORMATION - PATIENT CARD	
<i>This person is implanted with a (device name) implant and can safely undergo an MR exam only under very specific conditions. Scanning under different conditions may result in severe injury of device malfunction.</i> <i>Full MRI safety information is available in the MRI Safety Information section of the Instructions for Use, which can be obtained at www.gmreis.com.br, by calling +55-19-3765-9900 or by scanning the QR code in this card.</i>			
 MR Conditional			

Attachment II - Product Codes

HTA Anchor Inserters



HTA Anchor Codes

PART NUMBER	DESCRIPTION	COMPONENTS X QUANTITY		IMAGE
315-17-01	NANO HTA Ø1,7 x 5,0mm Suture #3-0 Needle 1/2 Circle - 12,7mm	NEEDLE 1/2 CIRCLE 12.7mm (2 un)	SUTURE #3-0 (1un)	
315-22-01-20	MICRO HTA Ø2,2 x 4,0mm Suture #2-0 Needle 3/8 Circle - 17,9mm	NEEDLE 3/8 CIRCLE 17.9mm (2 un)	SUTURE #2-0 (1un)	
315-27-01-20	MINI HTA Ø2,7 x 7,0mm Suture #2-0 Needle 3/8 Circle - 17,9mm	NEEDLE 3/8 CIRCLE 17.9mm (2 un)	SUTURE #2-0 (1un)	
315-35-01-00	HTA Ø3,5 x 10,0mm 2 Sutures #0 Needle 1/2 Circle - 26,5mm	NEEDLE 1/2 CIRCLE 26.5mm (4 un)	SUTURE #0 (2un)	
315-35-01-10	HTA Ø3,5 x 10,0mm Suture #1 Needle 1/2 Circle - 26,5mm	NEEDLE 1/2 CIRCLE 26.5mm (2 un)	SUTURE #1 (1un)	
315-50-01	MAX HTA Ø5,0 x 14,0mm 2 Sutures #2	Without NEEDLE	SUTURE #2 (2un)	
315-50-02	MAX HTA Ø5,0 x 14,0mm 2 Sutures #2 Needle 1/2 Circle - 26,5mm	NEEDLE 1/2 CIRCLE 26.5mm (4 un)	SUTURE #2 (2un)	