

## 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 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.

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.

### INDICATIONS FOR USE

The GM Reis Suture Anchors is intended to be used for suture or tissue fixation in the elbow, shoulder, hand, wrist, foot, ankle, knee, and hip. 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)

#### MATRIZ / MAIN OFFICE

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- Foot/Ankle: Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Metatarsal Ligament Repair, Hallux Valgus reconstruction, digital tendon transfers, Mid-foot reconstruction
- Knee: Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair, Iliotibial Band Tenodesis
- Hip: Capsular repair, acetabular labral repair.

## **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.

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## **WARNINGS AND PRECAUTIONS**

- 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.

## **SIDE EFFECTS OR UNDESIRABLE SIDE EFFECTS**

- 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.

## **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. The traceability of the product is ensured by the 05 traceability tags, provided within the packaging, along with the instructions for use.

## **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

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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](mailto: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                  |    | 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 |
|  | Caution. “see instructions for 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

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

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