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## INSTRUCTIONS FOR USE

### GMReis Fibula Nail System

#### DESCRIPTION

The GMReis Fibula Nail System is a system of locked intramedullary nails for osteosynthesis of fibular fractures. It has multiple lengths and diameters. The arrangement of the holes in the intramedullary nails allows the surgeon to block the implant in different planes. The screws have a specific profile that reduces the risk of skin prominence and have threaded locking in the nail holes.

#### INDICATIONS FOR USE

The GMReis Fibula Nail System is intended for fixation of fractures and osteotomies of the fibula.

#### CONTRAINDICATIONS

The patients who present some clinical conditions 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:

- Active infection or history of recent infection of local bone tissue or soft tissue;
- Local vascular disease, such as severe venous or arterial insufficiency, which may jeopardize the healing of soft tissue or the viability of the affected limb;
- Hypomobility or stiffness of the ipsilateral ankle;
- Drug abuse and alcoholism;
- Allergy and/or hypersensitivity to metals;
- Uncontrolled or medicated mental illness;
- Patients unable to follow the recommendations of their physicians and healthcare team at any stage of their treatment

#### WARNINGS AND PRECAUTIONS

The following are the main factors that, alone or in combination, can lead to early implant failure (breakage, loosening or migration).

- Excessive load or inadequate physical therapy activity;
- Intense physical activity;
- Early release of load;
- Physical activity before the surgeon's approval;
- Failure to follow post-operative recommendations;
- Single-use product, do not reuse, even if it appears to be in perfect condition;
- Product supplied non-sterile;
- Sterilize before use according to the recommended Sterilization Method and,
- Product must not be reprocessed.

#### ADVERSE EFFECTS

- Sensitivity to the material;- Sensitivity to the metal or allergic reaction to a foreign body;
- Pain, discomfort and abnormal sensations due to incorrect use and indication of the implant.
- Malunion of the lateral malleolus, generally caused by insufficient reduction of the fracture or inadequate fixation thereof;
- Delayed consolidation or pseudoarthrosis, which may lead to loosening or fatigue of the implant;
- Loosening or fatigue of the implants, generally due to non-adherence to instructions and/or excessive load in the postoperative period;
- Vascular changes, characterized mainly by residual edema in the operated extremity, generally related to thromboembolic phenomena, such as post-thrombotic syndrome.

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## MRI SAFETY INFORMATION

The GMReis Fibula Nail System has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifacts in the MR environment. The safety of GMReis Fibula Nail System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

## RESTRICTIONS ON REUSE

The reuse and reprocessing of the product is not permitted, even if it appears to be in perfect condition, as the product may lose its physical and mechanical properties, not performing as expected for its intended use, and may put the health of patients and healthcare professionals at risk.

## PACKAGE

The product is supplied non-sterile, duly identified, laser-marked with its code, batch number and GMReis logo. The commercial presentation is packaged in individual surgical-grade paper packaging, duly labeled on the back (as shown in the figure below) where the components are supplied separately. The product is accompanied by 5 traceability labels and a manual showing how the user can obtain the product's Instructions for Use, in non-printed format, at no additional cost, including shipping.



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, lot, 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. Traceability tags shall be fixed to the following locations:

- The tag number 1, obligatorily, in the patient's medical record;
- The tag number 2, in the report delivered to the patient;
- The tag number 3, in the tax documentation that generates the collection to the paying source;
- The tag number 4, available for supplier control (registration distribution history);
- The tag number 5, provided for the control of the doctor.

It is the 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.

## GENERAL INFORMATION – REPROCESSING

Non-sterile Implants (Single-Use) and Instruments:

- Point of Use Preparation for Reprocessing: Remove excess body fluids and tissue from instruments with a disposable, non-shedding wipe. Place devices in a basin of distilled water or in a tray covered with damp towels. Do not allow saline, blood, body fluids, tissue, bone fragments or other organic debris to dry on devices prior to cleaning.
- The cleaning process is the first step in effectively reprocessing devices. Adequate sterilization depends on thoroughness of cleaning.
- Cleaning and sterilization processes in this IFU have been validated and demonstrate that soil and contaminants have been removed leaving the devices effectively free of viable microorganisms.

- It is recommended that all new relevant clinical practice guidelines be followed as per the CDC guidance, "Guideline for Disinfection and Sterilization in Healthcare Facilities".
- It is recommended to rinse the device components with water that meets specifications for AAMI TIR34 "Water for the reprocessing of medical devices" for example, DI/RO water.

Devices are usually supplied in sets and subdivided into trays and cases in which the devices may be arranged by size or in the order needed for a specific surgical procedure and should be used to transportation and storage.

**NOTE:** Any implant that has not been used, but has become soiled, should be handled according to hospital protocols. Refer to implant product inserts for any specific processing, cleaning, and sterilization instructions for that implant.

#### **Devices Preparation:**

- Cleaning, inspection, and sterilization must be performed by hospital personnel trained in the general procedures involving contaminant removal.
- Before use, medical devices must be cleaned to ensure that there is no risk to the patient from the transmission of infectious agents and other residues that could become toxic.

#### **Cleaning Instructions for non-sterile devices:**

- Devices must be cleaned prior to sterilization.
- Disconnect all handles/knobs prior to cleaning.
- Complex instruments, such as those with, cannulas, hinges, retractable features, mated surfaces, and textured surface finishes, require special attention during cleaning. Brush tight tolerance areas with an appropriately sized brush and flush using a water jet or syringe where debris could become trapped.
- Ensure all moving parts of instruments are cleaned at both extents.
- Handle all products with care. Mishandling may lead to damage and possible improper functioning.
- Clean the instruments, trays and inserts using only recommended cleaning solutions.
- Visual inspection must be performed at each cleaning to determine if an instrument is acceptable for use. If an instrument is not acceptable for use, replace it with a new piece.

**NOTE:** The information on concentration, temperature, quality water, exposure time and cycles used in the equipment, follow the instructions for use and labels according to products manufacturer.

#### **Manual Cleaning**

- In a sink the devices must be rinsed in running water to remove excess soil or contaminants.
- Prepare a Prolystica® Steris enzymatic detergent solution according to the label instructions using distilled water at a concentration of 4 mL of detergent per liter of water (4 mL/1L).
- Then, with a brush soaked in the prepared solution, brush the devices
- Wash the devices with running water and repeat the brushing process as many times as necessary.
- Finally, wash the devices with distilled water and dry and protected place.

#### **Preparation of detergent and disinfectant solutions**

- Prepare a solution at a concentration of 4 mL of detergent per liter of water (4 mL/1L) of Prolystica® Steris enzymatic detergent using potable water heated between 35°C and 65°C.
- Prepare another solution at a concentration of 5% neutral detergent according to the label instructions (50 mL of detergent for each liter of water) using potable water heated between 35°C and 65°C.
- Prepare a disinfectant solution at a concentration of 29.6 mL of disinfectant to 3.78 L of water of Vesta Syde SQ disinfectant (K931816) according to label instructions using potable water.

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### Washing

- Pre-rinse the devices in running water to remove excess soil or contaminants.
- Then, immerse the devices in the prepared enzymatic detergent solution for at least 10 minutes.
- After the action time, brush the items with the neutral detergent solution.
- Finally, wash them in running water and drain them on absorbent paper to remove excess water.

### Disinfection

- Immerse the devices in disinfectant solution Vesta Syde SQ disinfectant (K931816) in containers.
- Wait the action time of 10 minutes.
- After that, wash the devices with running potable water.
- With the aid of absorbent paper, dry the devices.

### INSPECTION, MAINTENANCE, TESTING

- Carefully inspect each device to ensure that all visible contamination has been removed. If contamination is noted repeat the cleaning/disinfection process.
- Visually inspect for completeness, damage and/or excessive wear.
- Check the action of moving parts (e.g., hinges, box-locks, connectors, sliding parts, etc.) to ensure smooth operation throughout the intended range of motion.

### STERILIZATION

Implants (non-sterile) and instruments should be autoclave sterilized using the following validated cycle parameters. The hospital is responsible for sterilization before surgery, through the method he finds more convenient and secure, while respecting the technical standards and current sanitary regulations. The sterilization procedures as well as the quality and the training of staff involved in this process is the sole responsibility of the health service. GMReis recommends the following validated cycle:

#### STEAM STERILIZATION CYCLE

Type: moist heat

Cycle: gravity-displacement

Temperature: 121°C (250°F)

Exposure Time: 30 minutes

Minimum Drying Time: 15 – 30 min.

The product must be wrapped with an FDA-cleared wrap.

Additional information regarding sterilization is described in ISO 17665-1- "Sterilization of health care products - Moist heat - Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices".

**NOTE:** Orthopaedic surgical devices generally have a long service life; however, mishandling or inadequate protection can quickly diminish their life expectancy. Devices which no longer perform properly because of long use, mishandling, or improper care should be returned to GMReis to be discarded. Notify your GMReis representative of any instrument problems.

### Symbolism of labeling

The graphic symbols used in labeling are in accordance with the ISO 15223 Standard.

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Table 1 - Description of the information on the packaging label

| Symbol                                                                            | Description           | Symbol                                                                             | Description                        |
|-----------------------------------------------------------------------------------|-----------------------|------------------------------------------------------------------------------------|------------------------------------|
|  | Manufacturing date    | <b>LOT</b>                                                                         | Lot number                         |
|  | Manufactured by       |  | Caution "see instructions for use" |
|  | Expiration date       |  | Keep away from sunlight            |
|  | Keep dry              |  | Do not use if package is damaged   |
| <b>Rx</b> only                                                                    | Prescription use only |  | Do not re-sterilize                |
|  | Non-Sterile           | <b>COD</b>                                                                         | Product catalogue number           |
|  | Do not reuse          | <b>QT</b>                                                                          | Quantity                           |

### 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>. 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](mailto:sac@gmreis.com.br).

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

### 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

C.N.P.J/Tax ID: 60.040.599/0001-19

**Email:** [qualidade@gmreis.com.br](mailto:qualidade@gmreis.com.br)

**Telephone number:** +55 19 3765-9900

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**Table 2 - Product codes**

| CODE      | DESCRIPTION                       | IMAGE                                                                                |
|-----------|-----------------------------------|--------------------------------------------------------------------------------------|
| 302-01US  | Left Fibula Nail 3,0x110mm        |   |
| 302-02US  | Left Fibula Nail 3,0x145mm        |                                                                                      |
| 302-03US  | Left Fibula Nail 3,0x180mm        |                                                                                      |
| 302-04US  | Left Fibula Nail 3,6x110mm        |                                                                                      |
| 302-05US  | Left Fibula Nail 3,6x145mm        |                                                                                      |
| 302-06US  | Left Fibula Nail 3,6x180mm        |                                                                                      |
| 302-07US  | Right Fibula Nail 3,0x110mm       |   |
| 302-08US  | Right Fibula Nail 3,0x145mm       |                                                                                      |
| 302-09US  | Right Fibula Nail 3,0x180mm       |                                                                                      |
| 302-10US  | Right Fibula Nail 3,6x110mm       |                                                                                      |
| 302-11US  | Right Fibula Nail 3,6x145mm       |                                                                                      |
| 302-12US  | Right Fibula Nail 3,6x180mm       |                                                                                      |
| 302-35-08 | Locking Screw T10 Ø3,5mm X 8,0mm  |  |
| 302-35-10 | Locking Screw T10 Ø3,5mm X 10,0mm |                                                                                      |
| 302-35-12 | Locking Screw T10 Ø3,5mm X 12,0mm |                                                                                      |
| 302-35-14 | Locking Screw T10 Ø3,5mm X 14,0mm |                                                                                      |
| 302-35-16 | Locking Screw T10 Ø3,5mm X 16,0mm |                                                                                      |
| 302-35-18 | Locking Screw T10 Ø3,5mm X 18,0mm |                                                                                      |
| 302-35-20 | Locking Screw T10 Ø3,5mm X 20,0mm |                                                                                      |
| 302-35-22 | Locking Screw T10 Ø3,5mm X 22,0mm |                                                                                      |
| 302-35-25 | Locking Screw T10 Ø3,5mm X 25,0mm |                                                                                      |
| 302-35-30 | Locking Screw T10 Ø3,5mm X 30,0mm |                                                                                      |
| 302-35-35 | Locking Screw T10 Ø3,5mm X 35,0mm |                                                                                      |
| 302-35-40 | Locking Screw T10 Ø3,5mm X 40,0mm |                                                                                      |
| 302-35-45 | Locking Screw T10 Ø3,5mm X 45,0mm |                                                                                      |
| 302-35-50 | Locking Screw T10 Ø3,5mm X 50,0mm |                                                                                      |
| 302-35-55 | Locking Screw T10 Ø3,5mm X 55,0mm |                                                                                      |
| 302-35-60 | Locking Screw T10 Ø3,5mm X 60,0mm |                                                                                      |
| 302-35-65 | Locking Screw T10 Ø3,5mm X 65,0mm |                                                                                      |