

INSTRUCTIONS FOR USE

Versalock Periprosthetic Femur Plates System – GMReis

GENERAL INFORMATION

The Versalock Periprosthetic Femur Plates System is composed of plates, screws and, a cerclage cable and related device.

- Single-use product, do not reuse, even if it is in perfect condition;
- Non-sterile supplied product;
- Sterilize before use, according to recommended sterilization method;
- Prohibited reprocessing.

INDICATIONS FOR USE

The Versalock Periprosthetic Femur Plates System – GMReis is indicated for temporary internal fixation and stabilization of fractures and osteotomies of the femur, including:

- Periprosthetic fractures
- Comminuted fractures
- Supracondylar fractures
- Trochanteric fractures
- Fractures in normal and osteopenic bone
- Non-unions and Malunions

APPLICATIONS

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 recommendations in the Table below should be followed:

Description	Specific site treated
Versalock Proximal Femur Periprosthetic Plate - left/right	Proximal Femur Periprosthetic Fracture
Versalock Distal Femur Periprosthetic Plate - left/right	Periprosthetic Distal Femur Fracture
MIS Versalock Condylar Femur Plate – left/right	
Versalock Trochanteric Periprosthetic Plate - left/right	Used in association with the proximal femur plate to fix the great trochanter.

CONTRAINDICATIONS

Patients with some of the clinical condition described below should not be submitted to procedures in which implants of the Versalock Periprosthetic Femur Plates System are used.

- Active infection or history of recent infection of bone tissue or local soft tissues;
- Osteometabolic diseases that cause weakness or reduction of bone mass;
- Insufficient bone mass or of poor quality;

- Inadequate vascularization at the implant placement local that could compromise the adequate blood supply in the implantation site;
- Mental illnesses;
- Drug abuse and alcoholism;
- Fever;
- Pregnancy;
- Allergy and/or sensitivity to metal, and
- Patients without conditions to follow the medical advice and the health team at any time of their treatment;

The modelling of Versalock Periprosthetic Femur Plates System is not recommended.

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

The Versalock Periprosthetic Femur Plate System is a locking system with variable angle screw fixing, indicated for the stabilization and treatment of femur fractures.

The physical principle is based on rigid fixation, simulating an internal fixator where the screws have a specific thread profile on their head, which when fixed with the appropriate instruments, allows the surgeon to fix with $\pm 15^\circ$ angle in the hole threaded plate, forming an imaginary cone.

TECHNICAL SPECIFICATION OF THE MATERIAL MANUFACTURING

The Versalock Periprosthetic Femur Plate System is manufactured from Ti6Al4V-ELI Titanium Alloy, according to ASTM F136 "Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications" and ASTM F67 "Standard Specification For Unalloyed Titanium, For Surgical Implant Applications", in bar, in the annealed state.

MARKING

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

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

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. 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 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 supplied non-sterile, properly identified by laser marking with the following information:

- Batch of product;
- Product Code;
- Logo of the GMReis Brand;

It is an open system, having as a commercial presentation the packaging of the product in an individual plastic packages, duly labeled on the back, where the components are supplied separately.

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.

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.
- The 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, lubrication (only instruments), and sterilization must be performed by hospital personnel trained in the general procedures involving contaminant removal.
- Instruments must be cleaned prior to lubrication and sterilization.

- All instrument hinged, rotating, and articulating parts must be lubricated prior to sterilization with a water soluble and sterilizable lubricant intended for surgical instruments (Hinge-Free® for example).
- The implants should not be lubricated.

Cleaning Instructions for All 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 of travel.
- 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.
- Use of caustic solutions (caustic soda) will damage the devices.
- Visually inspect each instrument for deterioration such as corrosion and worn components; ensure that the laser markings are legible and verify that all actuating parts move freely. 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, return to the manufacturer.

NOTE 1: 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.

NOTE 2: Visually inspect the instrument after each cleaning step to ensure the instrument is clean. If not clean, repeat the steps until clean.

Manual Cleaning

- Rinse devices in tap water to remove excess soil.
- Submerge device in enzyme solution (Valsure® Enzymatic Cleaner for example) and allow to soak for 2 - 5 minutes.
- Scrub device using a soft bristled brush until all visible soil has been removed. Use of a syringe or water jet is recommended for hard to reach areas.
- Rinse devices in lukewarm tap water for a minimum of 1 minute. Temperatures optimally in the range of 27°C to 44°C [80°F to 110°F], but not to exceed 60°C [140°F].
- Submerge devices in cleaning solution such as Vesta-Syde® and sonicate for 10 minutes
- Thoroughly rinse devices with deionized DI/RO or purified water to remove all detergent residues.
- Dry devices with a clean soft cloth.

Automatic Washer Cleaning (Ultrasonic Washer)

- Rinse devices in deionized DI/RO or tap water to remove excess soil.
- Submerge device in enzyme solution (Valsure® Enzymatic Cleaner for example) and allow to soak for 2 - 5 minutes.

- Rinse devices in lukewarm tap water to remove detergent residuals.
- Place devices in fully extended open position into washer and process through a standard washer instrument cycle (for a minimum of 15 minutes).
- Thoroughly rinse devices with deionized DI or purified water for a minimum of 2 minutes.
- Visually inspect device
- Final rinse on devices with DI or purified water for a minimum of 15 seconds.
- Dry devices with clean soft cloth or clean compressed air.

Automatic Washer/Disinfector Cycle Steps

- Pre Wash, cold tap water, 2 minutes.
- Enzyme wash, hot tap water, 1 minute.
- Detergent wash, Hot tap water (66°C/150°F), 2 minutes.
- Rinse 2x, hot tap water, 15 seconds.
- Purified Water rinse, Hot tap water (66°C/150°F), 10 seconds.
- Hot Air Dry, (116°C/240°F), 7- 30 minutes.

NOTE: GMReis recommend the use of automatic cleaning procedures (washer/disinfectors) when available in the health care services.

INSPECTION, MAINTENANCE, TESTING AND LUBRICATION

- 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.
- Hinged, rotating, or articulating instruments should be lubricated with a water soluble product (e.g. Hinge-Free® or equivalent lubricant) intended for surgical instruments that must be sterilized. Some water-based instrument lubricants contain bacteriostatic agents which are beneficial. To remain effective, the expiration date specified by the manufacturer should be adhered to for both stock and use-dilution concentrations.

STERILIZATION/RESTERILIZATION

All implants and instruments are provided non-sterile and must be cleaned and sterilized before use. Implants and instruments should be autoclave sterilized using the following validated cycle parameters.

The hospital responsible is for sterilization before surgery, through the method he finds more convenient and secure, while respecting the technical norms and current regulations of Ministry of Health. The sterilization procedures as well as the quality and the training of staff involved in this process is sole responsibility of the health service.

GMReis recommends that products must be sterilized by the following method:

STEAM STERILIZATION CYCLES

Type: humid heat

Cycle: gravitational

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 are 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.

PRECAUTIONS

The implants are designed to support distributed loads on their surface when implanted for stabilization of a particular bone structure, and may rupture until total bone healing occurs. The use of implants for internal fixation allows the surgeon to fix bone fragments in the correct anatomical position.

The modeling of all plates included in this system is not recommend, and if it occurs, the mechanical characteristics may be compromised, leading the product to failure or break by precocious fatigue.

The correct choice of implants must be extremely rigorous. The success of bone healing is directly related to the correct choice of characteristics (model, dimension, etc.) of the implant to be used. The size and shape of bone structures are limiting factors in the choice of implants.

Metal implants cannot withstand activity levels and loads equivalent to natural bones. Always follow the instructions for using the product.

Excessive activities and/or trauma may affect the positioning of the implant, which may result in migration, loosening, wear and/or early rupture of the implant, as well as affecting the support bone structure, making the review procedure more difficult and premature.

Implants allow for early patient mobility, but limited to no-load movements until the surgeon confirms bone fracture consolidation through X-rays. 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.

Smoking, diabetic patients, with metabolic disorders and/who use anabolic steroids, or who are using any medication that may compromise consolidation, and/or who have other diseases that

can lead to delayed bone consolidation, should take aware that bone healing may not occur within the 90-day timeframe and that the implants may be loosened or ruptured, and that a second surgery may be necessary to repair side effects. If the patient has an accident, he must be advised that the implant may rupture, loosen and/or migrate.

If bone failure requires bone support, it is the surgeon's responsibility to define the type and quantity of bone graft to be used.

The plates and screws must not visually show any abnormality on their surface, such as scratches, faults, dirt or other defects; if they have any abnormality on their surface, they must be destroyed and discarded, according to the Disposal Procedure.

If any implantable component falls or shows any type of damage, it must be destroyed and discarded, according to the Disposal Procedure.

PATIENT INSTRUCTIONS

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 bones, and that there might be fatigue, breaks or migration of the implant, resulting from abnormal physical activities, trauma or degenerative diseases and other diseases.

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.

The patient should be informed that the implant can be replaced when the surgeon deems it necessary. The patient must be instructed by the surgeon responsible to use adequate external support until the complete fracture consolidation, as well as to restrict physical activities that put the implant at risk or that allow movements in the fracture focus, delaying bone consolidation.

It is important that the patient is aware that the implant has a useful life of 90 (ninety) days, and it should be warned that if bone consolidation does not occur during this period, the implants may suffer loosening, rupture or breakage, especially if they do not follow the post-operative recommendations, there is an excessive load on physiotherapy and/or poor implant positioning, accidents as well as other causes.

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;

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

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;

Ingestion of medications that may affect the success of bone healing;

Patients who have used or are using anabolic steroids;

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

Pseudoarthrosis;

Delay in bone consolidation;

Failure of the surgical technique;

Inappropriate choice of implant;

Early releasing of the load;

The no use of external prostheses, when recommended;

Excessive load or inappropriate activity;

Osteoporosis;

Practice of intense physical activity;

Practice of physical activity prior to the surgeon release;

Exposure to an environment of magnetic resonance, e.g.: examination of MR.

MRI SAFETY INFORMATION

The Versalock Periprosthetic Femur Plates System has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of Versalock Periprosthetic Femur Plates System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

SIDE EFFECTS OR UNDESIRABLE SIDE EFFECTS

The implantable components of the Versalock Periprosthetic Femur Plates System are manufactured with raw materials of recognized biomedical uses. The chemical, metallographic and mechanical requirements of the material standards are used as a criterion to ensure the purity of the product and its biomechanical performance, characterizing it as appropriate to be implanted in the human body. It should be noted, however, that no material for surgical implant is shown to be completely free of adverse reactions in the human body, and that an acceptable level of biological response can be expected when the material is used in appropriate applications. Thus, the product may generate some undesirable side effects due to the biomaterial:

- Sensitivity to metal or allergic reaction to foreign body;
- Pain, discomfort and abnormal sensations due to incorrect use and indication of the implant. It is recommended that the surgeon evaluate the patient possible sensitivity to the use of the biomaterial to be used before implantation.
- Other undesirable side effects related to the surgical procedure and product placement:
 - Consolidation delay or pseudoarthrosis, which may lead to loosening or rupture of the implant when consolidation does not occur 90 days after surgery;
 - Rupture or loosening of the implants for not following the post-operative guidelines for rehabilitation and/or overload during physiotherapy and/or incorrect implant positioning;
 - Shortening of the limb due to fracture compression or bone resorption;
 - Decreased bone density;

- Pain, discomfort and abnormal sensations due to the presence of the implant;
- Nerve injuries due to surgical trauma;
- Bone necrosis; and
- Vascular changes and among others inherent to the surgical procedure.

NOTE 1: Other interventions may be needed to repair the secondary effects;

NOTE 2: Smokers with metabolic disorders have greater difficulties in achieving the bone consolidation, consequently there is a greater chance to occur deformation, rupture or loosening of the implants and does not reach the bone and suffer more progressive degeneracy.

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

Admissible Combinations with Other Materials

The raw materials used to manufacture the products are:

Ti6Al4V-ELI Titanium Alloy, according to ASTM F 136 "Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications" and Ti CP Gr2, according to ASTM F67 "Standard Specification For Unalloyed Titanium, For Surgical Implant Applications".

The materials in question are highly resistant to corrosion of the solution. Despite this, the product cannot be used in conjunction with any product from another manufacturer, or any metallic product with different chemical composition, because this association may generate chemical incompatibilities (producing galvanic corrosion and others), physical, biological and functional, early fatigue and possible risks to the patient.

In the event of any undue combination by the surgeon, he will be responsible for the risks associated with such combination.

The product should only be implanted with GMReis instruments.

USEFUL INFORMATION TO PREVENT RISKS ARISING OUT OF THE IMPLEMENTATION

Implementation Risk

Although the raw material used for the manufacture of products is biocompatible and standardized, the patient may experience sensitivity to the product or allergic reaction. It is known that, even if a raw material presents the chemical requirements, mechanical and microstructural determined by rules (which ensures its purity and biomechanical performance, making it suitable for use as material for the manufacture of implants), there is no material that shows completely free of adverse reactions in the human body.

To prevent others risks of deployment, other precautions may be taken, such as:

- Total aseptic condition;
- Radiologic pre-assessment, intraoperative;
- Follow the instructions for use;
- Proper selection of the type and size of the implant based on pre-operative radiological planning.

Others risks of deployment:

- Failure in the surgical indication,
- Failure in the surgical technique, and/or
- Lack of patient cooperation regarding postoperative recommendations.

Assessment of the implanted product

After implantation, 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 position, or present any non-conformity, it is the responsibility of the surgeon take the more appropriate corrective action.

INSTRUCTIONS IN CASE OF PACKAGING DAMAGE**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 reprocessing

Reprocessing of the product is not allowed, even if it appears to be in perfect condition, as the product may lose its physical and mechanical properties, failing to perform as intended for its intended use, and may put the health of patients and professionals at risk.

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.

INSTRUCTIONS FOR THE CORRECT USE OF THE PRODUCT AND INDICATION OF TRAINING

1. Perform a preoperative radiological and clinical evaluation to select the most appropriate product;
2. Perform the surgical planning;
3. Position the patient and perform the ideal access;
4. Make the implant selection;
5. Reduce the fracture and place the plate; keep it fixed with reduction assist clamps;
6. Attach the corresponding guide to the plate (3.5mm or 5.0mm) and pass the corresponding drill bit, depending on the size (3.5mm or 5.0mm) of the screw;
7. Remove the drill guide and measure the screw length with the depth gauge;
8. Fix the screw using the corresponding wrench;
9. If Gama Cable is used: Place the cable connector into the planned holes and run the cables through the holes, tension them and secure them by crimping the compressor.
10. Remove the reduction clamps;
11. Perform the radiological evaluation to check the positioning of the plate and screws;
12. Perform the closure of surgical incisions in its various planes, the placement of special dressings and the protection of the operated segment with splints, plasters or other type of orthosis.

The time during which this care should be maintained depends on the specific characteristics of each procedure and should be carefully outlined by the surgeon responsible. By the same way, postoperative care and rehabilitation will depend on numerous variables that cannot be

outlined in this document and that are the absolute responsibility of the multidisciplinary team that cares for the patient.

PLATE	COMPATIBLE SCREWS	
	Article #	Description
Versalock Proximal and Distal Femur Periprosthetic Plate	169-18-XXX	Cortical Screw Ø 4.5mm x XXX: 14-110 mm
	327-50-XXX	Versalock Variable Angle Screws Ø 5.0mm x XXX: 20-110 mm
	327-51-XXX	Versalock Variable Angle Cannulated Screw Ø 5.0mm x XXX: 20-110 mm
	327-52-XX	Versalock Variable Angle Periprosthetic Screws Ø 5.0mm x XX: 10-18 mm
	327-XX	Versalock Spacer Screw XX: 1-3 mm
Versalock Trochanteric Periprosthetic Plate	200-35-XX	Cortical Screw Ø 3.5 mm x XX: 10-80 mm
	282-20-02	Trochanteric Plate Fastening Screw
	307-35-XX	Versalock Variable Angle Locking Screw Ø 3.5 mm x XX: 12-90 mm
	327-51-XXX	Versalock Variable Angle Cannulated Screw Ø 5.0mm x XXX: 20-110 mm
	327-PC	Versalock Connector Screw for Gama Cable
MIS Versalock Condylar Femur Plate	327-51-XXX	Versalock Variable Angle Cannulated Screw Ø 5.0mm x XXX: 20-110 mm
	327-52-XX	Versalock Variable Angle Periprosthetic Screws Ø 5.0mm x XX: 10-18 mm
	327-XX	Versalock Spacer Screw XX: 1-3 mm

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 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 medical product must be handled with care, in order to avoid sudden shocks, falls and other risks and/or imperfections that affect the product quality and the user safety.

It must be preserved and stored in its original packaging or in specific surgical boxes until the moment of use, with the proper care of the medical and hospital area, in a clean, dry, ventilated environment protected from sunlight and free of contaminants (acid vapors) at room temperature (25 °C).

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.

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 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 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.

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 GMReis 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, 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 and ASTM F2503-13, as follows:

SYMBOLS	DESCRIPTIONS	SYMBOLS	DESCRIPTIONS
	Manufacturing date		Do not reuse
	Manufactured by		Batch Number
	Expiration date		Caution "See instructions for use"
	Keep dry		Keep away from sunlight
Rx Only	Prescription use only. Notification required by FDA.		Do not use if package is damaged
	Non-sterile		Do not re-sterilize

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>, and can be checked in the search field by trade name, described on the label of the product packaging. 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

A.F.E. nº 1.02.477 - 0

C.N.P.J/M.F 60.040.599/0001-19

I.E: 244.342.283.119

Email: qualidade@gmreis.com.br

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

Geraldo Marins dos Reis Júnior

Technical and Legal Responsible

CREA – SP nº 0682127536

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 01 Aug 3, 2020