

INSTRUCTIONS FOR USE

Mini and Micro Fragments Reconstruction System– GMReis

GENERAL INFORMATION

- 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

Mini and Micro Fragments Reconstruction System - GMReis is intended for fracture fixation, arthrodesis, reconstruction, and osteotomy fixation of the hand and wrist. The use of locking plate/screw systems is suited for treatment of fractures in osteopenic bone.

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:

- Active infection or history of recent infection of bone tissue or of soft parts locations;
- Osteometabolic diseases that cause weakness or reduction of bone mass;
- Insufficient bone mass or of poor quality;
- Inadequate vascularization in the implant placement local that could compromise the adequate blood supply in the place of deployment;
- Patients with previously implants that may compromise the deployment and/or interfere with the product;
- Mental diseases;
- Drugs abuse and alcoholism;
- Fever;
- Allergy and/or sensitivity to metals (pure titanium and titanium aluminum alloy-Vanadium)
- Patients without conditions to follow the medical advice and the health team at any time of their treatment.

PURPOSE OR INTENDED USE OF THE PRODUCT

Mini and Micro Fragments Reconstruction System – GMReis is indicated for treatment of fractures, deformities, osteotomies and pseudarthrosis in the hand and wrist.

The products that compose the system are: plates with locking holes, plates with unlocking holes, plates with combined holes (locking and unlocking on the same plate), cortical screws (versa) and locking screws (Versalock) of variable angles.

The dimensions and sizes of the plates vary according to the surgical needs / fixation possibilities; given the variety of bones for which they are intended. The same applies to screws: smaller diameters for smaller fragments and smaller lengths for smaller bones; and vice versa. Locking screws are used in the plates with locking holes in order to provide angular stability to the plate, ideal for osteoporotic patients in general, and essential for fixation of joint regions, in accordance with the principle of absolute stability and consequent primary consolidation (without callus).

Cortical screws are used in the plates with unlocking holes, with or without dynamic compression, and interfragmentary compression through the pilot hole and sliding hole technique.

The screws, locking and unlocking, have proportional diameters to their regions of implantation; being 1.5 to 2.0 mm in the bones of the hand and 2.4 and 2.7 mm for bones of the wrist. The variety of lengths has the same purpose of suitability to the region of implantation.

The hook plate it is intended to be used for small fragments in a very distal fracture where bigger plates cannot reach without compromising the tendons. It is used in conjunction with the VOLAR FLP Plates only (180-52 / 180-53 / 180-54 / 180-55).

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

Mini and Micro Fragments Reconstruction System – GMReis is indicated for implantation according to techniques and treatments described in the medical literature, such as: interfragmentary compression, internal fixator, bridge plate, neutralization plate and dynamic compression.

The physical principle of Versalock Screws (locking screws) is based on rigid fixation, simulating an internal fixer 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

- Titanium Alloy Ti6Al4V, in accordance with the standard ASTM F136 “Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications”
- Pure Titanium Degree 2, in accordance with the standard ASTM F67 “Standard Specification for Unalloyed Titanium, for Surgical Implant Applications”

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, ie marking laser 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 stowage in individual packaging, where the product is supplied separately with its instruction, the 5 tags of traceability and properly labeled on the back.

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 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), temperature ($\leq 40^{\circ}\text{C}$) and humidity ($\leq 70\% \text{ RH}$).

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.

INSTRUCTION FOR THE CORRECT USE

- 1- Perform the pre-operative clinical planning;
- 2- Perform the pre-operative radiological planning and select the sizes of the implantable components to be used;
- 3- Positioning the patient and performing the incision and access;
- 4- Select the most appropriate implant;
- 5- Reduce the fracture and place the plate; keep it fixed with auxiliary reduction tweezers;
- 6- Position the plate and fix it;
- 7- Perform the fixation of the plate on the bone tissue with screws chosen by the technique selected by the surgeon in charge;

- 8- Perform the radiological evaluation to check the positioning of the plate and the screws;
- 9- Close access.

INDICATION OF TRAINING

Only properly trained, empowered in procedures of osteosyntheses 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 distributed loads on their surface when implanted for stabilization of a particular bone structure, and may rupture until total bone healing occurs.

It is not recommended the modeling of the product, if it's occurs, its mechanical characteristics will be compromised, being able to take the product to failure or break by precocious fatigue.

The use of implants for internal fixation allows the surgeon to fix bone fragments in the correct anatomical position.

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.

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

CRITERIA FOR SIZE SELECTION, SHAPE AND DESIGN ASSOCIATED WITH THE BONE CONSOLIDATION SUCCESS

It is the responsibility of the surgeon in charge of the procedure, the size selection of the implantable component most appropriate for the use, which must be done based on radiological studies pre-operative and the indication of the correct use. The right selection of the implant is extremely important and should take into account the biomechanical aspects, the size and shape of the bone structure to be treated, which corresponds to the size and the model of the implant selected.

	MICRO VERSA SCREW Ø1.5 mm	MINI VERSA SCREW Ø2.0 mm	LOCKING VERSALOCK SCREW Ti T7 Ø2.0 mm	MINI VERSA SCREW TORXDRIVE Ti Ø2.4 mm	MINI VERSA SCREW TORXDRIVE Ti Ø2.7 mm	LOCKING VERSALOCK SCREW Ti T7 Ø2.4 mm	LOCKING VERSALOCK SCREW Ti T7 Ø2.7 mm
BABY FOOT VOLAR VERSALOCK PLATES				✓	✓	✓	✓
VOLAR FLP VERSALOCK PLATES				✓	✓	✓	✓
MINI FRAGMENTS VERSALOCK PLATES				✓	✓	✓	✓
MINI FRAGMENTS VERSALOCK PLATES L				✓	✓	✓	✓

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MINI FRAGMENTS VERSALOCK PLATES T				✓	✓	✓	✓
MINI FRAGMENTS VERSALOCK PLATES Y				✓	✓	✓	✓
MINI FRAGMENTS VERSALOCK HOOK PLATE 2.0 mm		✓	✓				
MICRO VERSA HOOK PLATESS 1.5 mm	✓						

MECHANICAL CONFORMATION

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

Need for Bone Support

In case of the bone failure requires bone support it is the responsibility of the surgeon to define the type and amount of bone graft to be used.

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 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.

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, or metabolic disorders, failure in indication, in surgical technique or lack of cooperation of the patient regarding postoperative recommendations.

It is important to the patient be aware that the implant has a life time of 60 days to the consolidation of the bone regions stabilized with the implants may vary, and the factors that influence this time are: surgical technique, postoperative treatment and biological conditions of each patient.

The physician responsible for the treatment should advise the patient regarding the need for removal and / or replacement of the implants in case of rejection, infection or failure. It is also incumbent upon the physician to advise on the need / feasibility of implant removal after complete consolidation.

Smokers, diabetics, with metabolic disorders and/or making use of anabolic steroids, as well as making use of medication that could impair the consolidation and/or who have other diseases that may lead to a delay consolidation, should take science that the bone consolidation may not occur within the schedule time and that the implants may be loose or broken. If the patient has an accident, he must be advised that the implant can rupture, releasing and/or migrate.

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

It is important to the patient being aware that the failure of the postoperative recommendations may lead to unsuccessful treatment and that the implant can suffer migration, release and/or breaks.

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;

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".

CAUTION ASSOCIATED IN CASE OF FALL OF SOME COMPONENT

In case of fall of any component or suffer any kind of damage, it should be destroyed and disposed of according to the Procedure of 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

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

Pseudo arthrosis;

Delay in bone consolidation;

Failure in surgical technique;

Inappropriate choice of implant;

Early releasing of the load;

The no use of external prostheses, when recommended;

Excessive load or inappropriate activity;

Drugs ingestions that can lead to a delay of the bone consolidation and pseudo arthrosis;

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.

SIDE EFFECTS OR UNDESIRABLE SIDE EFFECTS

- Consolidation delay or pseudo arthrosis, may lead to loosening or fracture of the implant when no consolidation occurs after 60 days of surgery;
- Rupture or loosening of the implants for not following the guidelines of postoperative rehabilitation and/or excessive load during the physiotherapy and/or incorrect positioning of the implant;
- Decrease in bone density;
- Pain, discomfort and abnormal sensations due to the presence of the implant;
- Nerve Injury due to surgical trauma;
- Bone necrosis;
- Vascular changes and other factors inherent to the surgical procedure;

NOTE 1: A second surgery 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.

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 labeling 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.

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.

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

Admissible Combinations with Other Materials

The materials used to manufacture the products are:

- Titanium Alloy Ti6Al4V, in accordance with the standard ASTM F136 “Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications”
- Pure Titanium Degree 2, in accordance with the standard 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 deployed with the specific instruments, by GMReis Brand.

Accessories

None.

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’s product insert 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.

USEFUL INFORMATION TO PREVENT RISKS ARISING OUT OF THE IMPLEMENTATION

Implementation Risk

In spite of the raw materials used for the manufacture of products are biocompatible and normalized according to the rules Pure Titanium - Degrees 2– CPTI – in accordance with the standard ASTM F67 “Standard Specification for Unalloyed Titanium for Surgical Implant Applications” and Titanium Alloy Ti6Al4V in accordance with the standard ASTM F136 “Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications”, 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 care could 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 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, then forward the product for sterilization, by following the recommendations as indicated in the topic "Method of Sterilization".

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 Mini and Micro Fragments Reconstruction System – GMReis 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 Mini and Micro Fragments

Reconstruction System – GMReis in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.”

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 labels of traceability, 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 labeling

The graphic symbols used in labeling 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		Caution
	Keep dry		Keep away from light
	Prescription Only		Manufacturer
	Catalogue Number		Batch Code
	Non-Sterile		

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.

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

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

Revision 03, December 17 2019