

INSTRUCTIONS FOR USE:

Pedimax II – Pedicular Screw Spinal System

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.
- Conditional for MR: Pedimax II is safe for the patient undergoing Magnetic Resonance (MR), if the following specific conditions are present;
 - Static magnetic fields of 3.0 Tesla, only;
 - Maximum space magnetic field gradient of 4,000 Gauss/cm (40 T/m);
 - Weighted specific absorption rate of all body, as indicated by the MR scanner of 2 W/kg for 15 min of scanning in normal operating mode.
- Pedimax II - Pedicular Screw Spinal System has not been evaluated for RF heating in a 1.5T scanner.

Indications, purpose or intended use of the product

The Pedimax II – Pedicle Screw Spinal System is indicated for posterior, non-cervical fixation in skeletally mature patients. It is intended to be used as an adjunct to fusion using autograft or allograft. The device is indicated for the treatment of the following acute and chronic instabilities or deformities: degenerative disc disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion.

Physical principle and technology fundamentals description, applied to its working and action

Pedimax II – Pedicle Screw Spinal System is composed of polyaxial and monoaxial screws of varying diameters and lengths, rods of varying lengths, crosslink clamp, transversal rods of varying lengths and rod to rod clamps, all implants are top loading and top tightening, and when associated form a system., that is, a biomechanics physical structure with the ability to provide a stabilization in the segment of treaty vertebra, thus enabling the arthrodesis of the segment.

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 and Degree 4, in accordance with the standard ASTM F67 “Standard Specification for Unalloyed Titanium, for Surgical Implant Applications”

Marking

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

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

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 instruction of 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 wheels.

Presentation form of the medical product

The product is supplied non-sterile, properly identified, i.e. marking laser with the following information:

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

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, as shown in the next figure:



Packaging Model

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.

The product sale is restricted to a physician.

Instruction for correct use of the product and indication of training

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- Perform the access and perforate the pedicle in the anatomical angulation;
- 4- Insert the pedicle screws into the perforated pedicle with the radiological control and when necessary insert the hook into the most appropriate anatomical positions;
- 5- Insert the longitudinal element (rods) on the pedicle screws or through connectors;
- 6- Fix the locking elements on the pedicle Screws; If necessary perform the distraction or compression before the final tightening.
- 7- Perform final radiological control and,
- 8- Close access.

Indication of training

Only properly trained, empowered in procedures of column 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.

Precautions

The use of implants for the internal fixation allows the spine surgeon the establishment of the vertebral segments in the closest position of natural anatomy. The implants allow early mobility of patients, but limited to movements without load until the surgeon confirm the bone consolidation through X-rays, which usually occurs in 12 months after surgery. These implants are designed as an assistant to the natural process of bone consolidation, but cannot be used to replace anatomical structures or supporting the body weight in the presence of bone comprehensive.

During recovery, the spine surgeon along with the physiotherapist controls the applied load, increasing this load according to the process of consolidation and the general condition of the patient.

It is very important to perform a careful reduction and a stable fixation for the complete bone healing. The implants used in surgery serve to promote a normal process of bone regeneration. They are not intended to replace the original anatomical structures and nor to sustain permanently mechanical stresses caused by regions that showed no bone consolidation.

The surgeon should instruct the patient about care and physical support appropriate to be used during the period of the implant use.

In the face of a spinal segment with the osseous consolidation completes, the load can be released. If the segment of the column is not with the bone completely, no charge can be given to the implanted system. The load release is the surgeon responsibility, and depends on the bone consolidation.

The implantation of pedicle screw spinal systems should be performed only by experienced spinal surgeons with specific training in the use of this pedicle screw spinal system because this is a technically demanding procedure presenting a risk of serious injury to the patient

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.

Size of the Screws	Regions of Indication
Ø4.5mm	Thoracic Vertebrae
Ø5.5mm	Thoracic Vertebrae and lumbar, and sacrum
Ø6.2mm	Thoracic Vertebrae and lumbar, and sacrum
Ø7.0mm	Thoracic Vertebrae and lumbar, and sacrum
Ø8.0mm	Thoracic Vertebrae and lumbar, and sacrum

Mechanical conformation limit for aptness for use of the product

The products are designed to properly fit into the bone to be treated.

It is only permitted the modeling of implants of the type rods, with the objective of bringing anatomy. If the modeling is required, the surgeon must avoid excessive mechanical, the limit for modeling is the bone anatomy in which it will be used. The rod should not be folded to the contrary, scratched and warped, and once modeled cannot be returned to its original form, which may cause a fracture on the rod and consequent failure in the system function.

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 vertebral column, 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 12 months, until bone consolidation and that should be replaced as soon as the surgeon deems necessary. The patient should be warned that the product could fail (i.e.: break, release and/or migrate), if the bone consolidation does not occur in up to 12 months or in cases of falls and/or accidents of the patient.

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 consolidation delay, 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.

The professional responsible for the surgical procedure should warn the patient that components implanted were designed to provide stability to the vertebral segment treaty and support loads until the arthrodesis at treaty, this period should not exceed 12 months in a healthy individual; experiencing the arthrodesis, the product loses its function, and the bone structures begins to absorb the normal workloads of the patients column. If the arthrodesis does not occur, by some health problem of the patient, the product will be exposed to constant fatigue loads, which could lead it to fail due to lack of bone consolidation, with the need for replacing the same. If the focus is not consolidate in 12 months, is the surgeon responsible for corrective action to be taken.

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;

Conditional to MR (See item "Use Instructions")

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

Patients 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 (see precautions "Instructions of use").

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

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

Removing and handling of implants removed from patients for Analysis

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

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

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

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

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

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

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

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

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

Side effects or undesirable side effects

Consolidation delay or pseudo arthrosis, may lead to loosening or fracture of the implant when no consolidation occur after 12 months 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 osseous 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.

Side effects or undesirable side effects related to conditional for MR

Torsion forces can cause the device to spin on the MR field.

Displacement forces can extract the device from the MR field.

The radio frequency (RF) induces currents that can cause heating of the product implanted in the patient.

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.
- The MR exam is contraindicated for patients with a system of implant **"Conditional for RM"**, if one of the specific conditions presented in the labelling, as well as in item "precautions to take regarding exposure to magnetic fields," is not fulfilled.

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 and Degree 4, 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 equipments, 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 exemple) 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: GM Reis 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 products are non-sterile supplied, with the hospital responsible 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: 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 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 GM Reis to be discarded. Notify your GM Reis 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 and 4 – 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 in 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.

Precautions to take regarding the exposure to magnetic fields

The non-clinical testing in the magnetic resonance environment performed accomplished to evaluate the behavior of the product components Pedimax II – Pedicle Screw Spinal System, under these conditions, demonstrated that the product is Conditional for Magnetic Resonance, providing safe performance in the magnetic resonance exams of the whole body, on the following conditions:

- Static Magnetic Fields of 3.0 Tesla, only;
- Maximum gradient of the spatial magnetic field of 4,000 Gauss/cm (40 T/m);
- Specific pondered absorption rate of the entire body, indicated by the MRI scanner, of 2 W/kg for 15 min of scanning in normal operating mode.

In the conditions described, the product Pedimax II – Pedicular Screw Spinal System presents a maximum increase of temperature of 2.6°C after 15 minutes of continuous scanning.

The artifact generated by the product has approximately 15mm from the product, when use a pulse echo gradient sequence in a resonance system of 3.0 Tesla. It should be emphasized that the quality of MRI image can be compromised if the area of interest is the same area or relatively close to the positioning of the implant.

Pedimax II - Pedicular Screw Spinal System has not been evaluated for RF heating in a 1.5T scanner.

Other Precautions:

The product is safe to be used in a magnetic resonance environment when used within the established specifications.

It is recommended that always verify the procedures information for the magnetic resonance before performing an examination of this type.

The test performed on the product is based on non-clinical testing. The increase in the actual temperature on the patient will depend on factors beyond the SAR (specific absorption rate) and the duration of the administration of radio frequency (RF), which induces currents that can cause heating of the product implanted in the patient.

Therefore, it is recommended to pay attention in particular on the following points:

- Monitor the patients carefully
- Patients with impaired thermoregulation or perception of temperature should not be submitted to magnetic resonance imaging;
- The specific absorption rate (SAR) that will be used should be reduced as much as possible.
- Use a ventilation system helps to reduce the increase in the body temperature.

Specific guidance to the physician regarding the reporting of adverse events

If the product presents adverse events not reported in the instruction of use or there are technical complaints about the product, the physician should immediately contact the manufacturer through the GM Reis Customer Service (SAC), in addition to notifying the competent sanitary authority. To ensure the traceability of the product, the physician should continue as the "Procedure for product traceability". The traceability of the product is ensured by the 05 labels of traceability, provided within the packaging, along with the instruction of 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 GM Reis Customer Service (SAC). The product should be sent cleaned and packed in plastic bag, properly identified and with the description of non-compliance to the following address:

G. M. dos Reis Indústria e Comércio Ltda - Avenida Pierre Simon de Laplace Avenue, no. 600 Lote 3 - Quadra F - Quarteirão 9677 - TECHNOPARK – CEP: 13069-320 – Campinas – SP – BRASIL or directly notify at Telephone Number:(0xx19)3765-9900/ E-mail: sac@gmreis.com.br.

Symbolism of labelling

The graphic symbols used in labelling are in accordance with the ISO 15223 Standard and ASTM F2503-13, as follows:

Symbols	Descriptions	Symbols	Descriptions
	Date of Manufacture		Do Not Re-Use
	Use-By Date		Caution
	Keep dry		Keep away from light
	Prescription Only		Manufacturer
	Catalogue Number		Batch Code
	Non-Sterile		MR Conditional

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 and registration number at Anvisa, described on the label of the product packaging. The Instructions of 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.

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