Instructions for Use
DuoCore Non-Compressive IM Nail

GENERAL INFORMATION
• Single-use product, do not reuse, even if it is in perfect condition;
• Non-sterile or sterile supplied product;
• Non-sterile implants must undergo both cleaning and sterilization prior to use, according to recommended sterilization method
• Prohibited reprocessing.

INDICATIONS FOR USE
The DuoCore Non-Compressive IM Nail are indicated for the treatment of fractures, osteotomies and arthrodesis of the phalanges of the hand and foot, the metacarpals of the hand, the metatarsals of the foot, and for the ulnar styloid. The specific indications by nail diameter are as follows:
• Ø1.9mm and Ø2.5mm: phalanges;
• Ø2.5mm, Ø3.0mm, Ø3.5mm and Ø4.0mm: metacarpus;
• Ø3.0mm, Ø3.5mm, and Ø4.0mm: metatarsus.
• Ø3.5mm, and Ø4.0mm ulnar styloid.

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;
• 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.

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”

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.

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PRESENTATION FORM OF THE MEDICAL PRODUCT

The product is supplied non-sterile or sterile, properly identified, i.e. 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).

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.

SURGICAL TECHNIQUE

1 - Perform radiological and clinical assessment;
2 - Insert the guidewire and verify its position radiologically; if correctly positioned, take measurements using the appropriate measuring device;
3 - Drill to the correct depth using the appropriate drill bit;
4 - Insert the screw using the appropriate screwdriver;
5 - Check screw positioning via radiological imaging; and,
6 - Provide postoperative recommendations to the patient.

INDICATION OF TRAINING

Only properly trained, empowered in this surgical procedures 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 prohibited the modeling of the product, if it’s occurring, its mechanical characteristics will be compromised, being able to take the product to failure or break by precocious fatigue.

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.

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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 consider 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.

MECHANICAL CONFORMATION

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

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.

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 suffering 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 THE PATIENT
The following are the main factors that, alone or in combination, can lead to 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;

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.

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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 the 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, it 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 twisters until are 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”
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.

GENERAL INFORMATION - REPROCESSING
Non-Sterile Implants and Instruments:

• Point of Use Preparation for Reprocessing (ONLY FOR INSTRUMENTS): 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”.
• Final rinse water quality: the final rinse of every cleaning method described in these instructions must be performed with critical water, as defined in ANSI/AAMI ST108 "Water for the processing of medical devices" (water treated to meet the microbial, endotoxin and chemical quality requirements specified for critical water). Utility water (potable tap water) may be used only for the initial and intermediate rinses, where indicated in each step. Tap, potable, distilled, deionized (DI/RO) or "purified" water must not be used for the final rinse unless it meets the critical water specification of ANSI/AAMI ST108.
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: If the implant has been in contact with the patient, body fluids, or tissues, it may NOT be reprocessed and MUST be properly discarded.

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

Cleaning Instructions for non-sterile devices:
• Devices must be cleaned prior to sterilization.
• Disconnect all handles/knobs prior to cleaning.
• Complex instruments, such as those with, cannulas, hinges, retractable features, mated surfaces, and textured surface finishes, require special attention during cleaning. Brush tight tolerance areas with an appropriately sized brush and flush using a water jet or syringe where debris could become trapped.
• Ensure all moving parts of instruments are cleaned at both extents.
• Handle all products with care. Mishandling may lead to damage and possible improper functioning.
• Clean the instruments, trays and inserts using only recommended cleaning solutions.
• 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.
• The instructions for the correct and efficient cleaning, disinfection and sterilization of the devices are provided below. Follow all steps in the sequence presented; do not omit, replace or combine steps with other cleaning methods.

NOTE 1: Use only the cleaning agents, concentrations, temperatures, water quality and exposure times specified in the validated method below.
NOTE 2: Visually inspect the instrument after each cleaning step to ensure the instrument is clean. If not clean, repeat the steps until clean.

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Validated manual cleaning and disinfection method

The method below is the validated cleaning and disinfection method for the non-sterile implants and the compatible instruments. Follow all of its steps in the sequence presented; do not omit, replace or combine steps with other cleaning methods. The final rinse must be performed with critical water (ANSI/AAMI ST108).

Preparation of solutions:

• Enzymatic detergent solution: Prolystica® (Steris) enzymatic detergent at 4 mL per liter of utility water (potable tap water) heated to 35 °C - 65 °C (95 °F - 149 °F), according to the detergent label.

• Neutral detergent solution: neutral detergent at 5% (50 mL per liter) in utility water heated to 35 °C - 65 °C (95 °F - 149 °F), according to the detergent label.

• Disinfectant solution: Vesta-Syde® SQ disinfectant at 29.6 mL per 3.78 L of utility water, according to the disinfectant label.

Steps:

1. Pre-rinse the devices under running utility water to remove gross soil or contaminants.
2. Immerse the devices in the enzymatic detergent solution for at least 10 minutes.
3. After the soak time, brush the devices with a soft-bristled (nylon) brush soaked in the neutral detergent solution.
4. Rinse the devices under running utility water to remove detergent residues (intermediate rinse) and drain them on absorbent paper.
5. Immerse the devices in the disinfectant solution for 10 minutes.
6. Final rinse: rinse the devices under running critical water (ANSI/AAMI ST108) at room temperature for a minimum of [1 minute].
7. Dry the devices with clean, lint-free absorbent paper, in a clean and protected place.

INSPECTION, MAINTENANCE AND TESTING

• Carefully inspect each device to ensure that all visible contamination has been removed. If contamination is noted repeat the cleaning/disinfection process.

• Visually inspect for completeness, damage and/or excessive wear.

• Check the action of moving parts (e.g. hinges, box-locks, connectors, sliding parts, etc.) to ensure smooth operation throughout the intended range of motion.

STERILIZATION

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

STEAM STERILIZATION CYCLES

Type: humid heat
Cycle: gravitational
Temperature: 121°C (250°F)
Exposure Time: 30 minutes
Minimun 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”.

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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.

ETHYLENE OXIDE STERILIZATION - FOR IMPLANTS IN STERILE VERSION
The implants are supplied sterile, the method used is ethylene oxide sterilization, according to ISO 11135, implants must be maintained in its original packaging until the moment of its use.

USEFUL INFORMATION TO PREVENT RISKS ARISING OUT OF THE IMPLEMENTATION
Implantation Risk
In spite of the raw materials used for the manufacture of products are biocompatible and normalized according to 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.

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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.

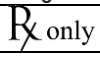
MRI Safety Information
The DuoCore Non-Compressive IM Nail has not been evaluated for safety in the MR environment. It has not been tested for heating or unwanted movement in the MR environment. The safety of DuoCore Non-Compressive IM Nail in the MR environment is unknown. Performing an MR exam on a person who has this medical device may result in injury or device malfunction.

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.

Description of the information on the packaging label - Non-Sterile

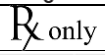
Symbol	Description
	Manufacturing date
	Manufactured by
	Keep dry
	Prescription use only

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GMREIS Qualidade para Vida	**Instructions for Use** **DuoCore Non-Compressive IM Nail**

	Non-Sterile
	Do not reuse
LOT	Lot number
	Caution “see instructions for use”
	Keep away from sunlight
	Do not use it if package is damaged
	Do not re-sterilize
COD	Product catalogue number
QT	Quantity
UDI	Unique Device Identification

Description of the information on the packaging label - Sterile

Symbol	Description
	Manufacturing date
	Manufactured by
	Expiration date
	Keep dry
	Prescription use only
	Sterile - EO
	Do not reuse
LOT	Lot number
	Caution “see instructions for use”
	Keep away from sunlight
	Do not use it if package is damaged
	Do not re-sterilize
COD	Product catalogue number
QT	Quantity
UDI	Unique Device Identification

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:

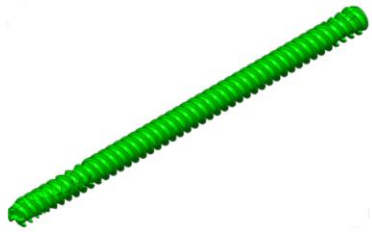
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Geraldo Marins dos Reis Júnior
Technical and Legal Responsible
CREA – SP n° 0682127536

IU DUOCORE EN Revision 00, October 22, 2026

Non-sterile Implants



CODE	DESCRIPTION (Ø X LENGTH)
395-19-12	DuoCore Non-Compressive IM Nail Ø1,9x12,0mm
395-19-14	DuoCore Non-Compressive IM Nail Ø1,9x14,0mm
395-19-16	DuoCore Non-Compressive IM Nail Ø1,9x16,0mm
395-19-18	DuoCore Non-Compressive IM Nail Ø1,9x18,0mm
395-19-20	DuoCore Non-Compressive IM Nail Ø1,9x20,0mm
395-19-22	DuoCore Non-Compressive IM Nail Ø1,9x22,0mm
395-19-24	DuoCore Non-Compressive IM Nail Ø1,9x24,0mm
395-19-26	DuoCore Non-Compressive IM Nail Ø1,9x26,0mm
395-19-28	DuoCore Non-Compressive IM Nail Ø1,9x28,0mm
395-19-30	DuoCore Non-Compressive IM Nail Ø1,9x30,0mm
395-19-32	DuoCore Non-Compressive IM Nail Ø1,9x32,0mm
395-19-34	DuoCore Non-Compressive IM Nail Ø1,9x34,0mm
395-19-36	DuoCore Non-Compressive IM Nail Ø1,9x36,0mm
395-19-38	DuoCore Non-Compressive IM Nail Ø1,9x38,0mm
395-19-40	DuoCore Non-Compressive IM Nail Ø1,9x40,0mm
395-19-42	DuoCore Non-Compressive IM Nail Ø1,9x42,0mm
395-19-44	DuoCore Non-Compressive IM Nail Ø1,9x44,0mm
395-19-46	DuoCore Non-Compressive IM Nail Ø1,9x46,0mm
395-19-48	DuoCore Non-Compressive IM Nail Ø1,9x48,0mm
395-25-12	DuoCore Non-Compressive IM Nail Ø2,5x12,0mm
395-25-14	DuoCore Non-Compressive IM Nail Ø2,5x14,0mm
395-25-16	DuoCore Non-Compressive IM Nail Ø2,5x16,0mm
395-25-18	DuoCore Non-Compressive IM Nail Ø2,5x18,0mm
395-25-20	DuoCore Non-Compressive IM Nail Ø2,5x20,0mm
395-25-22	DuoCore Non-Compressive IM Nail Ø2,5x22,0mm
395-25-24	DuoCore Non-Compressive IM Nail Ø2,5x24,0mm
395-25-26	DuoCore Non-Compressive IM Nail Ø2,5x26,0mm
395-25-28	DuoCore Non-Compressive IM Nail Ø2,5x28,0mm
395-25-30	DuoCore Non-Compressive IM Nail Ø2,5x30,0mm
395-25-32	DuoCore Non-Compressive IM Nail Ø2,5x32,0mm
395-25-34	DuoCore Non-Compressive IM Nail Ø2,5x34,0mm
395-25-36	DuoCore Non-Compressive IM Nail Ø2,5x36,0mm
395-25-38	DuoCore Non-Compressive IM Nail Ø2,5x38,0mm
395-25-40	DuoCore Non-Compressive IM Nail Ø2,5x40,0mm

Instructions for Use
DuoCore Non-Compressive IM Nail

395-25-42	DuoCore Non-Compressive IM Nail Ø2,5x42,0mm
395-25-44	DuoCore Non-Compressive IM Nail Ø2,5x44,0mm
395-25-46	DuoCore Non-Compressive IM Nail Ø2,5x46,0mm
395-25-48	DuoCore Non-Compressive IM Nail Ø2,5x48,0mm
395-25-50	DuoCore Non-Compressive IM Nail Ø2,5x50,0mm
395-25-52	DuoCore Non-Compressive IM Nail Ø2,5x52,0mm
395-25-54	DuoCore Non-Compressive IM Nail Ø2,5x54,0mm
395-25-55	DuoCore Non-Compressive IM Nail Ø2,5x55,0mm
395-25-56	DuoCore Non-Compressive IM Nail Ø2,5x56,0mm
395-25-58	DuoCore Non-Compressive IM Nail Ø2,5x58,0mm
395-25-60	DuoCore Non-Compressive IM Nail Ø2,5x60,0mm
395-30-25	DuoCore Non-Compressive IM Nail Ø3,0x25,0mm
395-30-30	DuoCore Non-Compressive IM Nail Ø3,0x30,0mm
395-30-35	DuoCore Non-Compressive IM Nail Ø3,0x35,0mm
395-30-40	DuoCore Non-Compressive IM Nail Ø3,0x40,0mm
395-30-45	DuoCore Non-Compressive IM Nail Ø3,0x45,0mm
395-30-50	DuoCore Non-Compressive IM Nail Ø3,0x50,0mm
395-30-55	DuoCore Non-Compressive IM Nail Ø3,0x55,0mm
395-30-60	DuoCore Non-Compressive IM Nail Ø3,0x60,0mm
395-30-65	DuoCore Non-Compressive IM Nail Ø3,0x65,0mm
395-30-70	DuoCore Non-Compressive IM Nail Ø3,0x70,0mm
395-35-25	DuoCore Non-Compressive IM Nail Ø3,5x25,0mm
395-35-30	DuoCore Non-Compressive IM Nail Ø3,5x30,0mm
395-35-35	DuoCore Non-Compressive IM Nail Ø3,5x35,0mm
395-35-40	DuoCore Non-Compressive IM Nail Ø3,5x40,0mm
395-35-45	DuoCore Non-Compressive IM Nail Ø3,5x45,0mm
395-35-50	DuoCore Non-Compressive IM Nail Ø3,5x50,0mm
395-35-55	DuoCore Non-Compressive IM Nail Ø3,5x55,0mm
395-35-60	DuoCore Non-Compressive IM Nail Ø3,5x60,0mm
395-35-65	DuoCore Non-Compressive IM Nail Ø3,5x65,0mm
395-35-70	DuoCore Non-Compressive IM Nail Ø3,5x70,0mm
395-40-25	DuoCore Non-Compressive IM Nail Ø4,0x25,0mm
395-40-30	DuoCore Non-Compressive IM Nail Ø4,0x30,0mm
395-40-35	DuoCore Non-Compressive IM Nail Ø4,0x35,0mm
395-40-40	DuoCore Non-Compressive IM Nail Ø4,0x40,0mm
395-40-45	DuoCore Non-Compressive IM Nail Ø4,0x45,0mm
395-40-50	DuoCore Non-Compressive IM Nail Ø4,0x50,0mm
395-40-55	DuoCore Non-Compressive IM Nail Ø4,0x55,0mm
395-40-60	DuoCore Non-Compressive IM Nail Ø4,0x60,0mm
395-40-65	DuoCore Non-Compressive IM Nail Ø4,0x65,0mm
395-40-70	DuoCore Non-Compressive IM Nail Ø4,0x70,0mm
395-40-75	DuoCore Non-Compressive IM Nail Ø4,0x75,0mm
395-40-80	DuoCore Non-Compressive IM Nail Ø4,0x80,0mm

Sterile Implants



CODE	DESCRIPTION (Ø X LENGTH)
395-19-12S	DuoCore Non-Compressive IM Nail Ø1,9x12,0mm
395-19-14S	DuoCore Non-Compressive IM Nail Ø1,9x14,0mm

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Instructions for Use
DuoCore Non-Compressive IM Nail

395-19-16S	DuoCore Non-Compressive IM Nail Ø1,9x16,0mm
395-19-18S	DuoCore Non-Compressive IM Nail Ø1,9x18,0mm
395-19-20S	DuoCore Non-Compressive IM Nail Ø1,9x20,0mm
395-19-22S	DuoCore Non-Compressive IM Nail Ø1,9x22,0mm
395-19-24S	DuoCore Non-Compressive IM Nail Ø1,9x24,0mm
395-19-26S	DuoCore Non-Compressive IM Nail Ø1,9x26,0mm
395-19-28S	DuoCore Non-Compressive IM Nail Ø1,9x28,0mm
395-19-30S	DuoCore Non-Compressive IM Nail Ø1,9x30,0mm
395-19-32S	DuoCore Non-Compressive IM Nail Ø1,9x32,0mm
395-19-34S	DuoCore Non-Compressive IM Nail Ø1,9x34,0mm
395-19-36S	DuoCore Non-Compressive IM Nail Ø1,9x36,0mm
395-19-38S	DuoCore Non-Compressive IM Nail Ø1,9x38,0mm
395-19-40S	DuoCore Non-Compressive IM Nail Ø1,9x40,0mm
395-19-42S	DuoCore Non-Compressive IM Nail Ø1,9x42,0mm
395-19-44S	DuoCore Non-Compressive IM Nail Ø1,9x44,0mm
395-19-46S	DuoCore Non-Compressive IM Nail Ø1,9x46,0mm
395-19-48S	DuoCore Non-Compressive IM Nail Ø1,9x48,0mm
395-25-12S	DuoCore Non-Compressive IM Nail Ø2,5x12,0mm
395-25-14S	DuoCore Non-Compressive IM Nail Ø2,5x14,0mm
395-25-16S	DuoCore Non-Compressive IM Nail Ø2,5x16,0mm
395-25-18S	DuoCore Non-Compressive IM Nail Ø2,5x18,0mm
395-25-20S	DuoCore Non-Compressive IM Nail Ø2,5x20,0mm
395-25-22S	DuoCore Non-Compressive IM Nail Ø2,5x22,0mm
395-25-24S	DuoCore Non-Compressive IM Nail Ø2,5x24,0mm
395-25-26S	DuoCore Non-Compressive IM Nail Ø2,5x26,0mm
395-25-28S	DuoCore Non-Compressive IM Nail Ø2,5x28,0mm
395-25-30S	DuoCore Non-Compressive IM Nail Ø2,5x30,0mm
395-25-32S	DuoCore Non-Compressive IM Nail Ø2,5x32,0mm
395-25-34S	DuoCore Non-Compressive IM Nail Ø2,5x34,0mm
395-25-36S	DuoCore Non-Compressive IM Nail Ø2,5x36,0mm
395-25-38S	DuoCore Non-Compressive IM Nail Ø2,5x38,0mm
395-25-40S	DuoCore Non-Compressive IM Nail Ø2,5x40,0mm
395-25-42S	DuoCore Non-Compressive IM Nail Ø2,5x42,0mm
395-25-44S	DuoCore Non-Compressive IM Nail Ø2,5x44,0mm
395-25-46S	DuoCore Non-Compressive IM Nail Ø2,5x46,0mm
395-25-48S	DuoCore Non-Compressive IM Nail Ø2,5x48,0mm
395-25-50S	DuoCore Non-Compressive IM Nail Ø2,5x50,0mm
395-25-52S	DuoCore Non-Compressive IM Nail Ø2,5x52,0mm
395-25-54S	DuoCore Non-Compressive IM Nail Ø2,5x54,0mm
395-25-55S	DuoCore Non-Compressive IM Nail Ø2,5x55,0mm
395-25-56S	DuoCore Non-Compressive IM Nail Ø2,5x56,0mm
395-25-58S	DuoCore Non-Compressive IM Nail Ø2,5x58,0mm
395-25-60S	DuoCore Non-Compressive IM Nail Ø2,5x60,0mm
395-30-25S	DuoCore Non-Compressive IM Nail Ø3,0x25,0mm
395-30-30S	DuoCore Non-Compressive IM Nail Ø3,0x30,0mm
395-30-35S	DuoCore Non-Compressive IM Nail Ø3,0x35,0mm
395-30-40S	DuoCore Non-Compressive IM Nail Ø3,0x40,0mm
395-30-45S	DuoCore Non-Compressive IM Nail Ø3,0x45,0mm
395-30-50S	DuoCore Non-Compressive IM Nail Ø3,0x50,0mm
395-30-55S	DuoCore Non-Compressive IM Nail Ø3,0x55,0mm
395-30-60S	DuoCore Non-Compressive IM Nail Ø3,0x60,0mm
395-30-65S	DuoCore Non-Compressive IM Nail Ø3,0x65,0mm
395-30-70S	DuoCore Non-Compressive IM Nail Ø3,0x70,0mm
395-35-25S	DuoCore Non-Compressive IM Nail Ø3,5x25,0mm
395-35-30S	DuoCore Non-Compressive IM Nail Ø3,5x30,0mm
395-35-35S	DuoCore Non-Compressive IM Nail Ø3,5x35,0mm
395-35-40S	DuoCore Non-Compressive IM Nail Ø3,5x40,0mm

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Instructions for Use
DuoCore Non-Compressive IM Nail

395-35-45S	DuoCore Non-Compressive IM Nail Ø3,5x45,0mm
395-35-50S	DuoCore Non-Compressive IM Nail Ø3,5x50,0mm
395-35-55S	DuoCore Non-Compressive IM Nail Ø3,5x55,0mm
395-35-60S	DuoCore Non-Compressive IM Nail Ø3,5x60,0mm
395-35-65S	DuoCore Non-Compressive IM Nail Ø3,5x65,0mm
395-35-70S	DuoCore Non-Compressive IM Nail Ø3,5x70,0mm
395-40-25S	DuoCore Non-Compressive IM Nail Ø4,0x25,0mm
395-40-30S	DuoCore Non-Compressive IM Nail Ø4,0x30,0mm
395-40-35S	DuoCore Non-Compressive IM Nail Ø4,0x35,0mm
395-40-40S	DuoCore Non-Compressive IM Nail Ø4,0x40,0mm
395-40-45S	DuoCore Non-Compressive IM Nail Ø4,0x45,0mm
395-40-50S	DuoCore Non-Compressive IM Nail Ø4,0x50,0mm
395-40-55S	DuoCore Non-Compressive IM Nail Ø4,0x55,0mm
395-40-60S	DuoCore Non-Compressive IM Nail Ø4,0x60,0mm
395-40-65S	DuoCore Non-Compressive IM Nail Ø4,0x65,0mm
395-40-70S	DuoCore Non-Compressive IM Nail Ø4,0x70,0mm
395-40-75S	DuoCore Non-Compressive IM Nail Ø4,0x75,0mm
395-40-80S	DuoCore Non-Compressive IM Nail Ø4,0x80,0mm

Instruments

CODE	DESCRIPTION
395-20-01	Guide Wire Ø0,8mm
395-20-02	Cannulated Drill Ø1,8mm
395-20-03	T6 Wrench with Depth Gauge
395-20-T6	T6 Stem
395-20-04	Threaded Nail Extractor Ø2,0mm
395-25-02	Cannulated Drill Ø2,2mm
395-30-01	Guide wire Ø1,0mm
395-30-03	T8 Wrench with Depth Gauge
395-30-04	Threaded Nail Extractor Ø3,0mm
395-35-02	Cannulated Drill Ø2,8mm
395-40-02	Cannulated Drill Ø2,9mm
395-40-T8	T8 Stem
900-395	Disposable Wrench with AO Coupling

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