INSTRUCTIONS FOR USE

EXPERT – Joint Fixation System

GENERAL INFORMATION

• Single-use product, do not reuse, even if it is in perfect condition;
• Sterile supplied product by EO;
• Prohibited reprocessing.

INDICATIONS FOR USE

The EXPERT – Joint Fixation System is intended as an adjunct in fracture repair involving metaphyseal and periarticular bone fragments where screws are not indicated, and as an adjunct in external and intramedullary fixation systems involving plates and nails, with fracture braces and casting.

The Mini EXPERT, EXPERT Knotless and EXPERT Knotless Dual are intended to provide fixation during the healing process following:

Mini EXPERT
When used for fixation of bone-to-bone, the Mini EXPERT is intended as fixation posts, distribution bridges, or for distributing suture tension over areas of ligament or tendon repair, such as:

- Syndesmotic trauma, such as fixation of dorsal distal radioulnar ligament (DRUL) disruptions;
- Tarsometatarsal (TMT) injury, such as fixation of foot soft tissue separations due to a Lisfranc injury (Midfoot Reconstruction); and
- Carpal Metacarpal (CMC) joint arthroplasty as an adjunct in the healing process of the reconstruction of the ligament at the base of the thumb metacarpal by providing stabilization between the base of the first and second metacarpal when the trapezium has been excised due to osteoarthritis.

EXPERT Knotless and EXPERT Knotless Dual
Syndesmotic trauma, such as fixation of syndesmosis (syndesmosis disruptions) in connection with Weber B and C ankle fractures.

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;

- 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.
- It should not be used in surgical procedures other than those specified.

PURPOSE OR INTENDED USE OF THE PRODUCT

The success of the treatment is directly related to the appropriate surgical technique applied by the surgeon and the correct choice of implants, following their characteristics: model, shape, type, dimensions, etc.
The size and anatomy of the bone structures are the main factors in the definition of the implants to be used.
The recommendations in the Table below should be followed:

Model	Bone Structure
Mini EXPERT	Hand, Wrist and Foot
EXPERT Knotless EXPERT Knotless Dual	Ankle

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

The EXPERT – Joint Fixation System is designed for joint fixation and is used as a biomechanical structure to simulate a support pillar distributing tension in the surgical suture or surgical mesh until the soft tissue heals.

TECHNICAL SPECIFICATION OF THE MATERIAL MANUFACTURING

The EXPERT – Joint Fixation System is manufactured with the following raw materials:
- Plates: are made of Ti6Al4V-ELl Titanium Alloy, according to ASTM F 136 "Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications", in bar, in the annealed state.
- Surgical suture: The surgical suture used for the assembly of the Joint Fixation System is UHMWPE (ultra-high molecular weight polyethylene) braided, non-absorbable, sizes USP 5 (Ø 0.150-0.199mm), USP 2 (Ø 0.600-0.699mm) and USP 2-0 (Ø 0.350-0.399mm).
- Guidewire Ø1.6mm: The guidewire is made of F138 Stainless Steel - Extra Hard as per ASTM F138 "Standard Specification for Wrought 18 Chromium-14Nickel-2.5Molybdenum Stainless Steel Bar and Wire for Surgical Implants".

MARKING

The implantable components are identified by marking laser with the following information:
- Batch of product;
- Product Code;
- Logo of the GMReis brand.

STERILIZATION METHOD

The products are supplied sterile, by ethylene oxide, according to ISO 11135 - "Sterilization of health care products - Ethylene oxide Part 1: Requirements for development, validation and routine control of the sterilization process for medical devices", and must be maintained in its original packaging until the moment of its use.

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 sterile by EO, 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 packaging of the product in an individual plastic envelope, containing an ethylene oxide integrating seal, successively packaged in surgical grade paper and an outer carton for packaging, properly labeled on the reverse.
The product is accompanied by: 5 traceability tags and a manual on how the user can obtain the Instructions for Use of the product, in non-printed form, at no additional cost, including shipping.

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) at room temperature (25 °C).
Exclusively professionals in the hospital area, properly trained, empowered and familiar with the technique and the procedures involved, must do the handling of the product.
Vibrations effects, shocks, defective seating and improper stacking during transportation should be avoided.
Storage outside these conditions may create risk to the procedure, and patient.

PRECAUTIONS

The implants are designed to support distributed loads on their surface when implanted for stabilization of a particular bone structure, and may rupture until total bone healing occurs.
Postoperatively and until healing is complete, fixation provided by this device should be considered as temporary and may not withstand weight bearing or other unsupported stress.
The fixation provided by this device should be protected. The postoperative regiment prescribed by the physician should be strictly followed to avoid adverse stresses applied to the device and bone.
It is not recommended the modeling of the product, if occurs, its mechanical characteristics may be compromised, leading 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.
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".
GMReis do not recommend the modeling or adjustment of the products.
Only properly trained, empowered in orthopedics 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.

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 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;

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.

SIDE EFFECTS OR UNDESIRABLE SIDE EFFECTS

• Pain, discomfort and abnormal sensations due to the presence of the implant;
• Infections, both deep and superficial;
• Allergies and other reactions with implanted materials.

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.

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

Admissible Combinations with Other Materials
- Plates: are made of Ti6Al4V-ELl Titanium Alloy, according to ASTM F 136 "Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications", in bar, in the annealed state.
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- Guidewire Ø1.6mm: The guidewire is made of F138 Stainless Steel - Extra Hard as per ASTM F138 "Standard Specification for Wrought 18 Chromium-14Nickel-2.5Molybdenum Stainless Steel Bar and Wire for Surgical Implants".

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 GMReis instruments.

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, 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. 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.

Additional information about the procedure before using the product
Upon opening the package, check the superficial condition of the product as the deformations, stains, scratches or any other type of superficial alteration or defect. The product packaging must be disposed in accordance with the medical-hospital procedure and/or local law or as instructed by the Hospital Infect Control Commission.

The surgical technique indicated for each procedure is available for access at the following address: https://gmreis.com.br/Produtos/IFU.

MRI SAFETY INFORMATION

The EXPERT – Joint Fixation System has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of EXPERT – Joint Fixation System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury."

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 be clearly identified that the product is inappropriate for your use, ensuring that the product may not be used or improperly reused.

REMOVING AND HANDLING OF IMPLANTS REMOVED FROM PATIENTS FOR ANALYSIS

The implant must not be removed, except in the case of surgical revision.
If the implant should be removed and need to be subjected to analysis, it must be in accordance with ISO 12891-1 "Removal and analysis of surgical implantation - Part 1 - Removal and Handling", following the instructions below:
It is recommended that the implants, and in applicable cases, samples of tissue, are removed in a way that causes minimal damage in both tissue and implant.
It is especially important that functional surfaces, such as surfaces of joints of prostheses and surfaces of fractured implants are protected.
It is also extremely important to list the parties of the fractured implant and other removed components, leaving clear positioning in the deployment place.

The most important part of the implant removal is the prevention of damage that may lead to a scientific examination useless. For an appropriate scientific examination, the implant must be preserved as close as possible of the state, which existed at the time of the patient removal. Consequently, it is important that there be taken care during handling, storage and transport of the implants removed in order to ensure that no damage occurs or changes on the surfaces that will be analyzed.
The same care should be taken with the instruments, which eventually fail during its use.
The implants removed must go through process of cleaning and disinfection, under the responsibility of the health service. Subsequently, must be packaged separately in plastic bags or plastic containers/glass and labelled. The packaging should be designed to minimize the possibility of breakage, damage to surface and possible contamination of the implant by the environment. The labelling of products, which will be forwarded for analysis, should ensure their accurate identification, being that the ISO 12891-1 recommends the use of labels non-removable (that tear in the case of attempted removal).
It is extremely important, for an accurate evaluation failure cause of the product that the X-rays pre, post-operative and the verification of the implant failure are sent together with the material sent for analysis.

SPECIFIC GUIDANCE TO THE PHYSICIAN REGARDING THE REPORTING OF ADVERSE EVENTS

If the product presents adverse events not reported in the instructions for use or there are technical complaints about the product, the physician should immediately contact the manufacturer through the GMReis Customer Service (SAC), in addition to notifying the competent sanitary authority. To ensure the traceability of the product, the physician should continue as the "Procedure for product traceability". The traceability of the product is ensured by the 05 traceability tags, provided within the packaging, along with the instructions for use, as described in the topic "Product Traceability Procedure".

CUSTOMER COMPLAINT

If the medical product presents a risk specific unpredictable, being outside of its specifications or being generated any dissatisfaction, notify directly the GMReis Customer Service (SAC). The product should be sent cleaned and packed in plastic bag, properly identified and with the description of non-compliance to the following address: G. M. dos Reis Indústria e Comércio Ltda - Pierre Simon de Laplace Avenue, no. 600 Lote 3 - Quadra F – Quarteirão 9677 - TECHNOPARK – CEP: 13069-320 – Campinas – SP – BRAZIL or directly notify at Telephone Number:(0xx19)3765-9900/ E-mail: sac@gmreis.com.br.

SYMBOLISM OF LABELLING

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

Symbols	Descriptions	Symbols	Descriptions
	Date of Manufacture		Do Not Re-Use
	Use-By Date		Caution
	Keep dry		Keep away from light
Rx ONLY	Prescription Only		Manufacturer
	Do not re-sterilize	LOT	Batch Code
STERILE EO	Sterile by EO		Do not use if the package is damaged

USER WARNING

These Instructions for Use are available in format that is not printed, through the electronic address of the manufacturer: http://www.gmreis.com.br/produtos/IFU, and can be checked in the search field by trade name, described on the label of the product packaging. The Instructions for use provided will always be in accordance with the current latest version. If there is interest from the user, the Instructions for Use may be available in printed format, without additional cost. Ask for free by e-mail: sac@gmreis.com.br.

Company Name / Manufacturer Name:
GM dos Reis Indústria e Comércio Ltda.
Avenida Pierre Simon de Laplace, no. 600 Lote 3 - Quadra F - Quarteirão 9677
TECHNOPARK – CEP: 13069-320 – Campinas – SP - BRAZIL
A.F.E. n° 1.02.477 - 0
C.N.P.J/M.F 60.040.599/0001-19
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Geraldo Marins dos Reis Júnior
Technical and Legal Responsible
CREA – SP n° 0682127536
GM dos Reis Indústria e Comércio LTDA

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

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