3. INSTRUCTIONS FOR USE

3.1. General Product Identification Information

Product supplied in sterile form by ethylene oxide (ETO) according to ISO 11135 - "Preview Sterilization of health-care products -- Ethylene oxide -- Requirements for the development, validation and routine control of a sterilization process for medical devices".

Single use product.

Do not reuse.

Product shelf life: 3 years

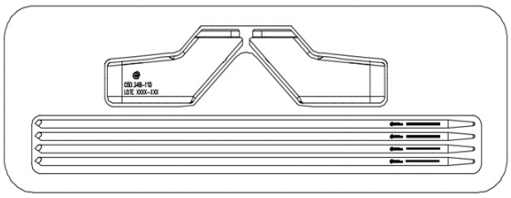
3.1.1. Information necessary for the user to identify the product and its contents

3.1.1.a. Technical Name: Instrumental for Orthopedic Implant

3.1.1.b. Trade Name: Disposable Kit for MIRO procedure

3.1.1.c. Graphic information that allows the visualization of the final product, description, part number and composition of the material.

Table 1. Components ofthe Disposable Kit for MIRO procedure: Graphics information, Composition and codes.

338-700 Disposable Kit for MIRO procedure					
					
COMPONENTS	QUANTITY	PRODUCT DESCRIPTION	DIMENSION	INDICATION OF SPECIFIC USE	RAW MATERIAL
348-110	2	MIRO TIP	46.0x22,0x10.0mm	USED TO GUIDE BONE DRILLING AT EXACT ANGLE	POLYACETAL COPOLYMER ASTM F1855
338-118S	4	GUIDE WIRE Ø2.0x150mm	Ø2.0x150mm	USED TO DRILL BONES AND GIVE STABILITY	STAINLES STEEL F138

3.1.1.d. Description of the physical principle and fundamentals of technology, applied for its operation and its function

The Disposable Kit for MIRO procedure should be used according to specific surgical techniques adopted by a professional duly trained and qualified in lapidusplasty procedures, that is, by a surgeon whose technique to be adopted by him is part of his professional training, thus being the decision of the professional where and how to use them, as well as deciding on the type, shape and dimensions.

3.1.1.e. Product traceability procedure

The surgeon should write down in the medical and patient records the following traceability items of the components used.

- Quantity;
- Product code;
- Lot and
- Manufacturer's name.

The patient should receive his/her medical records with the records of traceability items and other information pertinent to the surgical act described by the surgeon responsible.

3.1.1.f. Presentation form

The product will be marketed in individual form, single use, sterilized by ethylene oxide.

It is an open system, having as a commercial presentation the packaging in blister packs in PETG, thermosealed in Tyvek, and packed in box, duly labeled on the back, where the components are supplied. Accompany the product: 5 traceability labels and a manual of how the user can obtain the *Instructions for Use* of the product, ***through the unprinted format, at no additional cost, including shipping.*** This information is compatible with product labeling.

3.1.1.g.1. Positioning inside the label packaging, Instructions for use, safety seal, sensitive ETO sterilization indicator, and traceability labels.

The Traceability Labels (5 units) will be atached in the patient's medical records, in the report delivered to the patient, in the tax documentation that generates the collection to the paying source, in the control of the supplier (historical distribution record - RHD) and in the control of the responsible surgeon. This traceability label is illustrated below:

Figure: Traceability label.

PORTUGUÊS (PT)	ENGLISH (EN)	ESPAÑOL (ES)	
A Instrução de Uso para este produto está disponível no website www.gmreis.com.br/produtos/IFU, (formato não impresso) e sempre estará de acordo com a última versão vigente, aprovada pela Anvisa	The Instruction for USE (IFU) for this product is available on the website: www.gmreis.com.br/produtos/IFU (printed format) and will always be in accordance with the latest version, approved by Anvisa	La Instrucción de Uso para esto producto está disponible en el sitio web: www.gmreis.com.br/produtos/IFU (formato impreso) y siempre será con arreglo a la última versión en vigor, aprobado por la Anvisa	GMREIS Qualidade para Vida
No campo de busca, procure pelo nº do Registro da Anvisa do Produto ou nome comercial, descrito no rótulo, na embalagem do produto. Para visualização do documento é preciso ter o Adobe Reader. Obtenha gratuitamente no website acima.	In the search field, look for ANVISA registration number or commercial name, described on label in the product packaging. In order to view the document, you must have Adobe Reader, which can be downloaded for free from the website above.	En el campo de búsqueda, busque por el número Registro ANVISA del producto o nombre comercial, descrito en la etiqueta del envase de producto. Para visualizar el documento es necesario tener el Adobe Reader. Reciba gratis en el sitio web arriba.	PT - Guia para acesso das Instruções de Uso GMReis (IFU) EN - GMReis Instructions for Use (IFU) access guide
Caso necessite receber uma versão impressa da IU, sem custo adicional, inclusive de envio, solicite gratuitamente pelo e-mail: sac@gmreis.com.br ou telefone disponível na rotulagem	If you need a printed copy at no extra cost, including shipping, please contact the e-mail: sac@gmreis.com.br or phone number available on labelling	Caso necesite recibir una versión impresa de IFU, sin costo adicional, incluyendo el envío, solicite gratis por el correo electrónico: sac@gmreis.com.br o teléfono disponible en el etiquetad	ES - Guía para acceder a las instrucciones de uso (IFU) IFUGMREIS – Rev.01

Figure: Manual that accompanies the product.

It is the responsibility of the medical team and the hospital (the custodians of the patient's information and medical records) to fix the label on the surgery description sheet or section of the medical records. GMReis recommends that the patient be the custodian of this information, receiving a certificate with the fixation of one of the traceability adhesive labels.

3.1.2. Special storage, handling and/or transportation care and associated risks

The product must be stored, handled and transported in such a way as to prevent any damage or alteration to its characteristics and packaging.

It should be stored in its original packaging until the time of use, with proper care of the medical-hospital area, in a clean, dry, airy environment, protected from sunlight and free of contaminants (acid and organic vapors), and with controls, recommended, temperature (less than or equal 40°C) and humidity (less than or equal 70% RH).

The product must be transported in such a way as to prevent any damage or alteration to its characteristics and packaging.

The medical product should be handled with all care, in order to avoid sudden shocks, falls and other risks and / or imperfections that affect the quality of the same and also the safety of the user.

The handling of the product should be done exclusively by medical-hospital professionals, properly trained, qualified and familiar with the technique and procedures involved.

The effects of vibration, shocks, faulty seating and improper stacking during transport should be avoided.

GM REIS RECOMMENDS SINGLE USE.

If the product is stored, handled and/or transported outside the specific conditions above may pose risks to the procedure and the patient.

3.1.3. Instruction for use

The product should be used according to specific surgical techniques adopted by a properly trained professional and qualified in lapidusplasty procedures. Is the responsibility of the professional responsible for the procedure, the decision of where and how to use the product.

3.1.4. Precautions, restrictions, warnings, special care and clarification on product use, storage, handling and transportation

Products that for some reason were not used during surgery and had the packaging open, or suffered damage and/or falls cannot be reused and/or reprocessed, and must be discarded in the hospital itself according to medical-hospital procedure and/or local legislation or according to the instructions of the Hospital Infection Control Commission - CCIH. If the product has any abnormality in its operation, a new unit must be opened and put into use.

The person responsible for the procedure shall send GMReis the non-conformity product, duly decontaminated, packed with batch, product code and declaration of non-conformity that has occurred.

GM REIS RECOMMENDS SINGLE USE.

The Guide Wires (made of ASTM F138) should not be deployed.

3.2. Indication, purpose or use for which the product is intended

3.2.a. Indication of correct use, purpose or use

The Disposable Kit for Miro procedure is specially designed to assist the surgeon in cases of corrective osteotomies of foot deformities.

3.2.b. Contraindications

The use of the product is contraindicated for any procedure other than for surgical procedures of corrective osteotomies of foot deformities.

GM REIS RECOMMENDS SINGLE USE.

3.6. Characteristics associated with the integrity of the packaging, how to manipulate the product and open the packaging in order to ensure sterility

If any of the packages are tampered with or damaged, all components of the Disposable Kit for MIRO procedure must be discarded, even if they are in perfect condition.

Closure integrity problems can lead to products aseptically packaged, to be contaminated by the entry of microorganisms.

A closure is considered intact when it ensures the product, at least, the same protection that is conferred by the packaging material.

The integrity of the packaging must be preserved during the transport, handling, storage and distribution of the product.

This product will be supplied sterile by ethylene oxide; therefore, it must be kept in its original packaging until the time of its use, according to hospital medical asepsis procedures.

Restrictions and instructions on packaging damage

The product must be unusable and disposed of in accordance with the procedure of disuse and disposal in the following circumstances:

- Safety seal of the tampered packaging;

- Physical damage to any of the packages;
- The illegible label or identification code;
- Expiration date reached.

Disuse and disposal

Before disposal, all components of the Disposable Kit for MIRO procedure must be unused with the aid of moulders, refans, any other instruments or ways, until it is clearly identified that the product is unsuitable for its use, and there is no possibility of it being reused.

After use, the product should be discarded according to the hospital area procedure.

3.8. / 3.9. Additional information about the procedure prior to use of the product

As the product is supplied sterile, there is no need for any preliminary procedure to use such as cleaning, sterilization and decontamination of the product.

3.14. Physician-specific guidance on reporting adverse events and technical complaints

If the product presents adverse events not reported in the instruction of use or has technical complaints about the product, the surgeon should immediately contact the manufacturer through the Customer Service (SAC) of GM Reis, in addition to notifying the competent health authority.

To ensure traceability of the product, the surgeon should proceed according to the "product traceability procedure". Product traceability is ensured through the 5 traceability labels provided inside the package, together with the product, as described in the item "Product Traceability Procedure".

3.17. Customer Complaint

If the medical product presents a specific unpredictable risk, is out of its specifications or is generating any dissatisfaction, notify GM Reis Customer Service (SAC) directly. The product should be forwarded clean and packed in a plastic bag, duly identified and with the description of non-conformity to the following address: **Av. Pierre Simon de Laplace, 600 - Lote 3 - Quadra F - Block 9677 - ZIP Code 13069-320 - Condominium Technopark - Campinas, SP, Brazil or** notify **directly at Tel.: (0XX19) 3283-9020 / Fax.: (0XX19) 3283-9111 / E-mail: sac@gmreis.com.br.**

3.18. Symbology of Labelling

The graphic symbols used in the labeling are in accordance with the NBR ISO 15223 Standard as follows:

SYMBOLS	DESCRIPTIONS	SYMBOLS	DESCRIPTIONS
	Date of manufacture		Single-Use Product *"Do not reuse"*
	Use-by date		Do not re-sterilize
	Do not use if the package is damaged.		Caution, consult accompanying documents *"Attention See Instructions for Use"*

	Manufacturer		Batch code
	Sterilized by ethylene oxide		Keep way from light
	Keep dry		Prescription only

ALERT TO THE CUSTOMER

These Instructions for Use are made available in unprinted format, through the manufacturer's e-mail address: http://www.gmreis.com.br/produtos/IFU. *Always check the correlation of the Version of the Instructions for Use with the version reported on the label.* The instructions for use provided will always be in accordance with the latest version in force. If the user is interested, the Instructions for Use may be made available in printed format at no additional cost. Request for free by e-mail: sac@gmreis.com.br.

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CREA - SP N° 0682127536

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