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".
Product shelf life: 3 years

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

3.1.1.a. Technical Name: Arthroscope

3.1.1.b. Trade Name: Multicutter - Arthroscopic Retrograde Drill

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

Table 1. Commercial models: Graphic Information, Composition, and codes.

CODE	DESCRIPTION	DIMENSION	RAW MATERIAL	APPLICATION
				
312-500	Multicutter - Arthroscopic Retrograde Drill	322 x 36 x 23mm	Stainless Steel AISI 316L F899-20 Stainless Steel AISI 455 302 - ASTM F899 Stainless Steel 455 - ASTM F899 Stainless Steel AISI 420B ASTM F899-20 Polymer ABS ABNT ISO 16061-2021 Silicone ABS ABNT ISO 16061-2021	Multicutter with variable diameter is used in the treatment of knee ligament reconstruction.

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

The Multicutter is used to prepare the femoral and/or tibial canal with variable diameter, in the treatment of knee ligament reconstruction.

3.1.1.e. Product traceability procedure

The surgeon should note the following traceability items for the implanted components in the medical and patient records.

- Amount;
- Product code;
- Batch and
- Manufacturer's name.

The patient should receive his medical record with the records of traceability items and other information relevant to the surgical procedure described by the surgeon in charge.

At the same time, GM Reis keeps in its files the identification of these traceability items associated with the Term of Consignment and Invoice for each surgical event.

3.1.1.f. How Supplied

The model is supplied sterile using ethylene oxide, duly identified, that is, laser marked with its code, batch number and GMReis logo.

Its form of commercial presentation is packaging in double surgical grade paper packaging and packed in a paper box, plasticized, printed, which receives a seal with a Sensitive Indicator of Sterilization by ETO, label and adhesive security seal, constituting the secondary packaging . Finally, the paper box is wrapped in a polyolefin, heat-shrinkable film, constituting the product's tertiary packaging. The product comes with: 5 traceability labels and a manual on how the user can obtain the Instructions for Use of the product, in the non-printed format, at no additional cost, including shipping. This information is compatible with the product labeling. Gm Reis recommends single use.

Description of each packaging level: Primary packaging: Surgical Grade Paper 60 g + 57 g polyester / polypropylene laminated film (tubular structure), minimum width of 80mm.

Secondary packaging: Outer paper box for packaging: After the product is packaged, it is packed in an outer paper box for packaging (Duplex 300G/Triplex 410G).

Tertiary packaging - Polyolefin film.

3.1.1.g.1. Positioning inside the packaging of the labels, Instruction for use, security seal, sensitive ETO sterilization indicator, and traceability labels.

The Traceability Labels (05 units) will be affixed to the patient's clinical record, to the report delivered to the patient, to the tax documentation that generates the charge to the paying source, to the supplier's control (distribution history record - RHD) and to the control of the responsible surgeon are placed inside the quaternary packaging of the product (paper box). This traceability label is illustrated below:

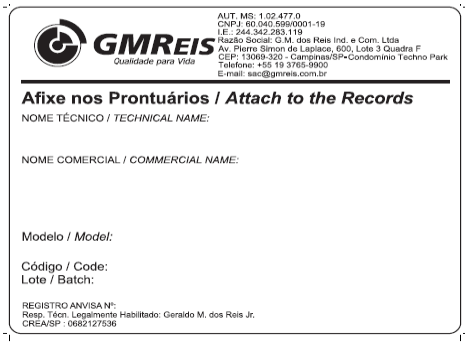

Figure: Traceability label.

PORTUGUÊS (PT)	ENGLISH (EN)	ESPAÑOL (ES)	GMREIS Qualidade para Vida
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	
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 comes with the product.

It is the responsibility of the medical team and the hospital (the depositories of patient information and records) to attach the label to the surgery description sheet or section of the medical record. GMReis recommends that the patient is the depository of this information, receiving a certificate with the attachment of one of the traceability adhesive labels.

3.1.2. Special care for storage, conservation, handling and/or transport and associated risks

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

It must be conserved and stored in its original packaging until the moment of use, with due care in the medical-hospital area, in a clean, dry, airy environment, protected from sunlight and free of contaminating substances (acid and organic vapors), and with recommended controls for temperature (less than or equal to 40°C) and humidity (less than or equal to 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 must be handled with great care, in order to avoid sudden shocks, falls and other risks and/or imperfections that affect its quality and also the safety of the user.

The handling of the product must be done exclusively by professionals in the medical-hospital area, duly trained, qualified and familiar with the technique and procedures involved.

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

The product must be handled with great care, in order to avoid sudden shocks, falls and other risks and/or imperfections that affect its quality and also the safety of the user.
The handling of the product must be done exclusively by professionals in the medical-hospital area, duly trained, qualified and familiar with the technique and procedures involved.
GM REIS RECOMMENDS SINGLE USE.

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

3.1.3. Instruction for use

The Multicutter is used to prepare the femoral and/or tibial canal with variable diameter, in the treatment of knee ligament reconstruction.

3.1.4. Special precautions, restrictions, warnings and cautions

Products that for some reason were not used during the surgical procedure and had their packaging opened, or suffered damage and/or falls cannot be reused and/or reprocessed, and must be discarded in the hospital according to medical-hospital procedure and/or legislation site or according to instructions from the Hospital Infection Control Commission - CCIH. If the product presents any abnormality in its operation, a new unit must be opened and put into use.
The person responsible for the procedure must send the non-compliant product to GMReis, duly decontaminated, packaged with batch, product code and with the declaration of the non-conformity that occurred.
GM REIS RECOMMENDS SINGLE USE.
Stainless steel instruments / components - ASTM F138 must not be implanted.

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

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

The Multicutter – Femoral canal preparation kit is used to prepare the femoral and/or tibial canal with variable diameter, in the treatment of knee ligament reconstruction.

3.2.b. Contraindications

Use of the product is contraindicated for any procedure other than surgical ligament reconstruction procedures.
GM REIS RECOMMENDS SINGLE USE

3.6. Characteristics associated with the integrity of the package, way of handling the product and opening the packages in order to ensure sterility

If any of the packaging is violated or damaged, all components must be discarded, even if they are in perfect condition.

In surgical-grade paper packaging, the integrity of the closure can influence the shelf life of the products packaged in them, since failures in heat sealing constitute entry points for microorganisms, air and/or moisture or even for loss of gaseous mixtures and organic vapors. Therefore, problems with the integrity of the closure can lead to aseptically packaged products being 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 transport, handling, storage and distribution of the product.

This product will be supplied sterile using ethylene oxide, therefore, it must be kept in its original packaging until the time of use, in accordance with hospital medical asepsis procedures.

Restrictions and instructions on packaging damage

The product must be scrapped and disposed of according to the scrapping and disposal procedure under the following circumstances:

- Violated packaging security seal;
- Physical damage to any of the packages;
- The unreadable label or identification code;
- Shelf life is expired.

Disuse and disposal

Before disposal, all components must be destroyed with the help of moulders, twisters, any other instruments or means, until it is clearly identified that the product is unsuitable for use, with no possibility of its being reused. After dismantling, the product must be disposed of in accordance with the hospital area procedure.

3.8. / 3.9. Additional information about the procedure before using the product

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

3.14. Specific guidelines for the physician regarding the reporting of 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. Reclamação do Cliente

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; 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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Rev. 00 06/09/2022 - Notification
Rev. 01 04/17/2023 - Device Listing in USA