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

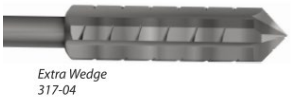
3.1.1. Information necessary for the user to identify the product and its contents

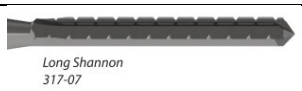
3.1.1.a. Technical Name: Burr, Orthopedic

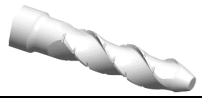
3.1.1.b. Trade Name: Percutaneous Foot Burrs / Arthrodesis Burrs GMReis

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 of Percutaneous Foot Burrs / Arthrodesis Burrs GMReis: Graphics information, Composition and codes.

Percutaneous Foot Burrs			
CODE	**DESCRIPTION**	**IMAGE**	**RAW MATERIAL**
317-01	MIS MICRO BURRS SHANNON SHORT Ø1,9x10.0mm		STAILESS STEEL ASTM F899
317-02	MIS MICRO BURRS SHANNON STRAIGHT Ø2,0x15,0mm		
317-03	MIS MICRO BURRS WEDGE Ø3,1x15.0mm		
317-04	MIS MICRO BURRS EXTRA WEDGE Ø4,1x15,0mm		
317-05	MIS MICRO BURRS CONICAL Ø3.1/Ø1,0x12.0mm		
317-06	MIS MICRO BURRS CONICAL Ø4.1/Ø1,0x12.0mm		
317-07	MIS MICRO BURRS SHANNON LONG Ø2,6x20.0mm		

317-28	MIS MICRO BURRS SHANNON STRAIGHT LONG Ø2,0x20,0mm		

Arthrodesis Burrs GMReis			
CODE	**DESCRIPTION**	**IMAGE**	**RAW MATERIAL**
317-30	ARTHRODESEIS MINI BURRS CYLINDRICAL Ø2.0x8.0mm		STAILESS STEEL ASTM F899
317-31	ARTHRODESEIS MINI BURRS CYLINDRICAL Ø3.0x12.0mm		
317-32	ARTHRODESEIS MINI BURRS CYLINDRICAL Ø4.0x16.0mm		
317-33	ARTHRODESEIS MINI BURRS FLAME Ø4.0x8.0mm		
317-34	ARTHRODESEIS MINI BURRS SPHERIC Ø4.0mm		

3.1.1.d. Identification

The Percutaneous Foot Burrs / Arthrodesis Burrs GMReis are laser marked with batch number, code, GMReis mark.

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

The Percutaneous Foot Burrs / Arthrodesis Burrs GMReis procedure should be used according to specific surgical techniques adopted by a professional duly trained and qualified in percutaneous osteotomy 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.f. 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.g. 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 identification and traceability of the product are ensured through a set of 05 adhesive labels provided on the packaging (see illustrations below), along with the Instructions for Use and the implant, bringing information about the product, such as: name, model, code, batch, product registration and manufacturer identification.

In this way it is possible to reverse the way and achieve the production, raw material, suppliers and other quality control items established in the Gmreis Quality System. Traceability labels shall be affixed to the following locations:

- Label number 1, mandatorily, in the patient's medical records:
- Label number 2, in the report delivered to the patient:
- Label number 3, in the tax documentation that generates the collection to the paying source;
- Label number 4, available for vendor control (distribution history record);
- Label number 5, available for surgeon control.

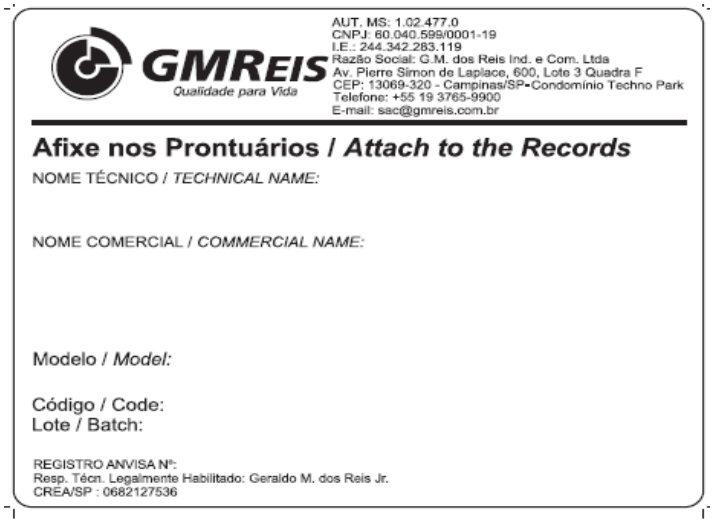


Figure: Traceability label.

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 its original packaging until the time of use in clean, dry, weather-free and ambient temperature. During transport, fall, knock or mechanical damage should be avoided.

Before removing the components of the Percutaneous Foot Burrs / Arthrodesis Burrs GMReis it should be checked that the original packaging remains intact and the shelf life is within the period allowed for use, ensuring its sterility. If the packaging is tampered with, damaged, damaged or shelf life has expired, the product must be unusable and discarded in accordance with the procedure of disuse and disposal.

The components of the Percutaneous Foot Burrs / Arthrodesis Burrs GMReis should only be removed from their original packaging moments before their use, according to medical-hospital procedures that ensure asepsis during handling.

If the packaging is opened and for any reason the product is not used, all components should be discarded and discarded according to the procedure of disuse and disposal.

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 the use and indication of training

The Percutaneous Foot Burrs / Arthrodesis Burrs GMReis procedure should be used according to specific surgical techniques adopted by a professional duly trained and qualified in percutaneous osteotomy procedures.

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.

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

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

The Percutaneous Foot Burrs / Arthrodesis Burrs GMReis procedure should be used according to specific surgical techniques adopted by a professional duly trained and qualified in percutaneous osteotomy procedures.

3.2.b. Contraindications

The Percutaneous Foot Burrs / Arthrodesis Burrs are contraindicated for any procedure other than percutaneous osteotomy.

3.3 Detailed information on the characteristics of all parts, accessories and materials intended for use with the product

If misuse occurs, risks may occur to the patient, the surgical procedure and with room staff, being the responsibility for such improper combination of the surgeon responsible for the surgical procedure.

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 or damaged, all components of the Percutaneous Foot Burrs / Arthrodesis Burrs must be discarded, even if they are in perfect condition. Do not reuse any of the components of the Percutaneous Foot Burrs / Arthrodesis Burrs, as reuse does not guarantee the performance assigned to the product.

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

Packaging opening procedure

Box opening procedure

1- Before removing the product, check that the packaging is not tampered with or damaged, as this may affect the sterility of the product;

2- Check the expiry date and check if the selected model is the one corresponding to the packaging to be opened;
3- When removing the polyolefinic film and the safety seal, open the case and remove the product and;
4- Special care should be taken at the time of opening to ensure aseptic integrity during removal of the implant from its packaging.

Surgical grade paper opening procedure

1. Wear gloves with dry hands;
2. Hold the product firmly;
3. Hold the surgical grade paper with the other hand;
4. To open the packaging pull the surgical grade paper with continuous force;
5. Hold the inner packaging firmly and,
6. With the other hand pull the product.

Procedure for opening the blister

1. Wear dry hands and gloves;
2. Hold the blister firmly;
3. Hold the tongue with your other hand and, to open the package, pull the tongue with continuous force.
4. Hold the corner of the blister firmly and with the other hand pull the tongue from the blister.

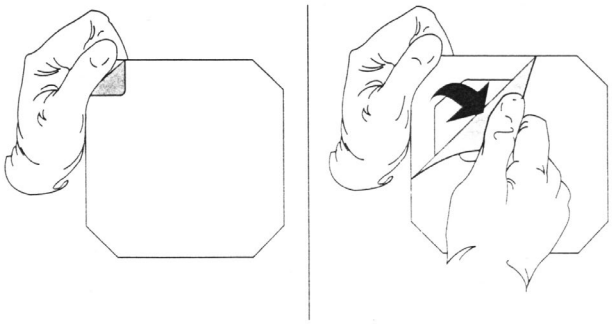


Figure: Blister opening procedure.

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 Percutaneous Foot Burrs / Arthrodesis Burrs GMReis 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.

Restrictions on resterilization and reuse

A single-use (disposable) sterile product should not be re-esterilized and reused, as the performance of the product is not guaranteed for intended use if it is re-esterilized and reused. It is the sole responsibility of the surgeon responsible for the procedure any risk or undesirable effect if re-esterilized or reused the product.

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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Issuue date: 08/31/2022 – Rev. 00

Technical and Legal Responsible Qualified:
Geraldo Marins dos Reis Júnior
CREA - SP N° 0682127536

Revision history
Rev. 00 de 08/31/2022 – Device listing